As filed with the Securities and Exchange Commission on May 13, 2025

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

IR-MED, INC.

(Exact name of registrant as specified in its charter)

Nevada	**3845**	**84-4516398**
State or other jurisdiction incorporation or organization	**Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

ZHR Industrial Zone
Rosh Pina, Israel, 1231400
+972-4-655-5054

(Address, including zip code, and telephone number, including area code, of principal executive offices)

Nevada Agency and Transfer Company
50 West Liberty Street, Suite 880
Reno, Nevada 89501

(Address, including zip code, and telephone number, including area code, of agent for service)

with copies to

Oded Har-Even, Esq.
Sullivan and Worcester LLP
1251 Avenue of the Americas, 19th Floor
New York, NY 10020
Tel: (212) 660-3000

Approximate date of proposed sale to public: As soon as practicable on or after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by checkmark 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. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

The information contained in this prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and these securities may not be sold until that registration statement becomes effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED: MAY 13, 2025

IR-MED INC.

80,000,000 shares of Common Stock

This prospectus relates to the resale, from time to time, of up to an aggregate of 80,000,000 shares (the "Shares") of common stock, $0.001 par value per share (the "Common Stock") of IR-Med Inc., a Nevada corporation (the "Company"), to be offered by the selling stockholder, Williamsburg Venture Holdings, LLC ("Selling Stockholder" or "Williamsburg") identified in this prospectus. We are registering the offer and sale of the Shares by the Selling Stockholder to satisfy registration rights we have granted to the Selling Stockholder under an equity purchase agreement (the "Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement"), each dated March 11, 2025.

The Selling Stockholder may sell the Shares of Common Stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the Selling Stockholder may sell its shares of Common Stock in the section titled "Plan of Distribution." The Selling Stockholder has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the Common Stock.

All net proceeds from the sale or other disposition of the shares of Common Stock sold by the Selling Stockholder covered by this prospectus will go to the Selling Stockholder. The Company will not realize any proceeds from sales by the Selling Stockholder.

The Selling Stockholder is an underwriter within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), and any broker-dealers or agents that are involved in selling the Shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the Shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The Selling Stockholder will pay all underwriting discounts and selling commissions relating to the sale of these shares. We have agreed to pay the legal, accounting, printing, and other expenses related to the registration of the sale of the Shares.

Our Common Stock is traded on the OTCQB® Market, or OTCQB, under the symbol "IRME." On May 12, 2025, the last reported sale price of our common stock as reported on the OTCQB was $0.0817 per share.

Investing in our Common Stock involves a high degree of risk. The trading volume in our stock has, been limited.**Before making any investment in our securities, you should read and carefully consider risks described in the "*Risk Factors*" section beginning on page 18 of this prospectus.**

As of the date of this prospectus, the Company had 72,018,144 shares of common stock outstanding of which 28,248,769 shares were held by affiliates. Therefore, the Company's public float is 43,769,375 shares and the number of shares being registered hereunder is approximately 182% of the public float.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act which became law in April 2012 and will be subject to reduced public company reporting requirements. See ***Prospectus Summary—Implications of Being an Emerging Growth Company***" on page 13 of this prospectus.

Prospectus dated _____, 2025

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You should rely only on information contained in this prospectus. We have not authorized anyone to provide you with information that is different from that contained in this prospectus. The selling stockholder is not offering to sell or seeking offers to buy shares of common stock in jurisdictions where offers and sales are not permitted. We are responsible for updating this prospectus to ensure that all material information is included and will update this prospectus to the extent required by law.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. Before investing in our Common Stock, you should carefully read this entire prospectus, especially the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. Unless the context otherwise requires, the terms "IR-Med," "the Company," "we," "us," "our" and similar references in this prospectus refer to IR-Med, Inc. a Nevada corporation.

Overview

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

Our corporate headquarters and research facilities are located at ZHR Industrial Zone, Rosh Pina, Israel.

Business Overview

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

PressureSafe™: Our first product based on this platform, is a handheld device designed to revolutionize the early assessment of pressure injuries, or PIs, affecting the skin and underlying tissue. PIs in the U.S. alone account for $26.8 billion in healthcare spending and result in 60,000 deaths annually. *PressureSafe*™ is expected to contribute to early assessment of PIs, regardless of patient skin tone, which we believe will drive equitable healthcare and help reduce the toll and cost of PIs. We plan to launch PressureSafe™ as a decision support system, or DSS, tool for caregivers in hospitals, nursing homes, and home-care companies. On April 9, 2024, the PressureSafe™ decision support device received FDA listing certification. PressureSafe™ is classified as a Class I device. We are currently working on completing the development of the commercial version of the PressureSafe™ device, with initial sales planned during the second half of 2025, following the listing by the FDA.

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

Our novel technology platform will enable direct assessment of the development of a DFU before it becomes an open wound that may lead to limb amputation. The Israeli Innovation Authority, or IIA, has approved our plan to develop a diabetic foot ulcer device for early assessment of DFU. On January 25, 2024, the IIA approved a program to develop a device for the early assessment of diabetic foot ulcers among diabetic patients, with a project budget of NIS 3,761,978 (approximately US$ 1,030,000) which includes an amount equal to 50% grant of the total budget provided at the time of the grant, disbursed in installments over the course of 13 months, by the project's progress. In consideration for the grant by the IIA, the subsidiary is required to pay royalties at the rate of 3%-5% from the total sales until the repayment date of the full amount of the grant, plus annual interest at the SOFR rate. In addition, the IIA must approve any arrangement whereby the Company seeks to transfer the technology relating to the project, or its development, from Israel. Following the IIA grant we plan to commence a clinical trial in the center of Israel's leading diabetes clinic.

On July 15, 2024, we announced that we received a grant from the IIA in the amount of approximately $500,000, to develop our platform technology for a new indication, a decision support device for the early assessment of diabetic foot ulcers. The grant's 13-month development was finalized, as we achieved the project's milestones. Computer simulations of infrared light reflectance from lesions under the skin surface have been completed.

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

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

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

The global diagnostics market is driven in large by solutions that can be applied in healthcare settings, as these tools will drive decisions regarding specific treatments and the associated outlays. However, despite advances in medical imaging and other diagnostic tools, misdiagnosis remains a common occurrence.

Our initial focus is on the development of decision support system solutions utilizing our proprietary platform for the pre-emptive diagnosis of PIs, and diabetic foot ulcers. Our current business plan focuses on two principal medical devices:

1. *PressureSafe*™, a handheld skin-agnostic optical monitoring device that is being developed to support early assessment of PIs to the skin and underlying tissue, primarily caused by prolonged pressure associated with bed confinement; and

2. *DiaSafe,* a handheld optical monitoring device that is being developed to support early assessment of DFUs in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole of diabetic patients, which sometimes is accompanied by other comorbidities as lower limb neuropathy.

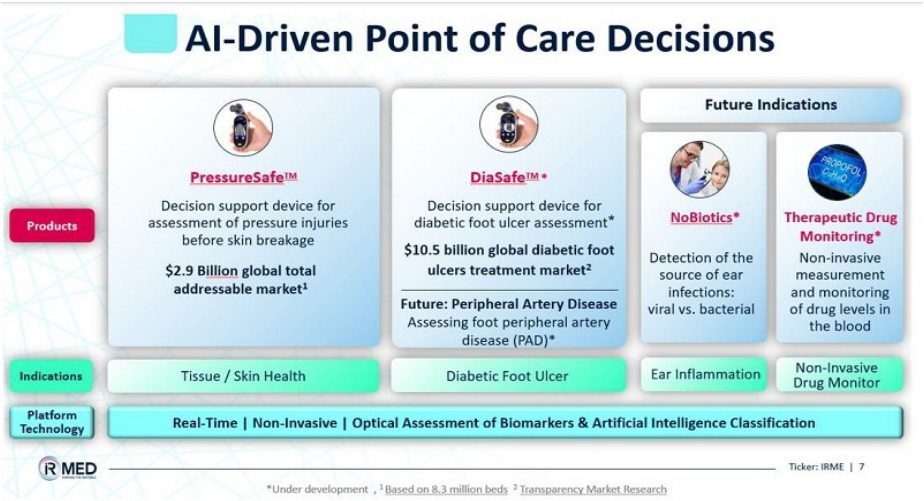

Fig1. IRMED AI-Driven Point of Care Decisions technology platform

Overview of Target Market and Our Solutions

Pressure Injury Market

Populations are aging due to improvements in healthcare. However, there are increased rates of obesity, diabetes and cardiovascular diseases. This combination of an increasingly aging population and such diseases has resulted in more people with decreased mobility needing assistance with activities of daily living. A major morbidity of decreased mobility is development of PIs. PIs develop as a result of a combination of physiologic events and external conditions. Along with localized, oedema, ischemia and reperfusion hindering injury to tissues, impaired lymphatic drainage and mechanical deformation of tissue cells have been shown to contribute to pressure injury.

Compression prevents lymph fluid drainage and leads to deterioration in tissue cell normal activities, which causes increased interstitial fluid and waste build up, contributing to the development of PIs. The time required to develop PIs depends on many factors, including the patient's physiological medical background and the degree of pressure and sheer force placed on the tissue. PIs occur over predictable pressure points where bony protuberances are more likely to compress tissues when the patient is in prolonged contact with hard surfaces. Studies show that the heel area is the second most frequent location for a pressure ulcer, with the most prevalent being the sacrum. The heel accounts for between 23% and 28% of all pressure ulcers.[1]

While the overall number of Hospital Acquired Conditions, or HAC, have decreased by 8%, pressure injuries have resisted improvement efforts and continue to grow by 10% annually. PIs are both costly and deadly. The U.S. Agency for Healthcare Research and Quality, or AHRQ, reports that PIs add $10.2 billion to annual U.S. healthcare costs. Furthermore, these are associated with over 45% of the 63,619 HAC related deaths in the U.S., making it the leading HAC related death.[2]

[1] Smith, S., Ashby, S., Thomas, L. and Williams, F., 2017. Evaluation of a multifactorial approach to reduce the prevalence of pressure injuries in regional Australian acute inpatient care settings. International Wound Journal, 15(1), pp.95-105.

[2] AP News. 2019. *Pressure Ulcers Cost U.S. Healthcare $10.2 Billion and Contribute to Nearly 29,000 Hospital Deaths Each Year.*

(AHRQ, 2019). Source: https://www.ahrq.gov/data/infographics/hac-rates_2019.html; AHRQ National Scorecard on Hospital-Acquired Conditions Final Results for 2014-2017 (PDF, 787 KB).

PIs impose a tremendous healthcare burden. As stated in the National Pressure Injury Advisory Panel fact sheet for 2023, 60,000 patients die every year as a direct result of pressure injuries. Acute care attributable to hospital-acquired PIs reaches $26.8 billion, and 2.5 million patients per year develop a PI. Patient care costs per PI range from $20,900 up to $151,700. PIs are among one of the five most common harms experienced by patients and the second most common claim for lawsuits, after wrongful death. More than 17,000 lawsuits arise due to PIs annually at an average settlement of $250,000. PIs occur across the healthcare industry, including in 10% of acute care patients, 25% of long-term acute care patients, 12% of nursing home patients and 12% of rehabilitation center patients.[3]

The most common method used to detect early PIs is a visual assessment by a professional caregiver focusing on areas at high probability to develop PIs. This skin and tissue visual assessment is subjective, unreliable, untimely (as PIs often occur suddenly without visual cues), and only effective to detect PIs once they are visible. Technology-based methods for detecting and monitoring have been developed, but as far as we know, none have succeeded in providing an effective solution. Pressure injuries, especially HAPIs, are complex, difficult to treat, and at risk for re-occurrence.

Pressure Injuries Background

A pressure injury is caused when skin integrity is broken down by some type of unrelieved pressure, leading to the destruction of normal structure and function. The National Pressure Injury Advisory Panel, or NPIAP, the preeminent U.S. professional organization dedicated to prevention and management of PIs, uses these four criteria to define a PI:

- A pressure injury is localized damage to the skin and underlying soft tissue, usually over a bony prominence.
- The injury can present as intact skin or an open ulcer and may be painful.
- The injury occurs as a result of intense pressure, prolonged pressure, or pressure in combination with shear.
- The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, comorbidities and condition of the soft tissue.

Common places for PIs to develop include the back of the head, shoulders, elbows, buttocks, hips, ankles, and heels.

[3] National Pressure Injury Advisory Panel fact sheet for 2023

The 4 Stages of Pressure Injuries - PI Stage 1

Non-blanchable erythema of intact skin. Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage 1 in Darkly Pigmented Skin: Research indicates that people with darker skin tones are more likely to develop higher stage pressure injuries, possibly because skin assessment protocols are less effective in identifying damage earlier. Pigmentation of the skin may prevent visualizing the reactive hyperemia in the pressure injury.[4]

Currently, PIs are discovered only as they begin to appear on the skin, after they have been festering underneath the skin layers. Nurses regularly assess patients at high risk by evaluating them according to accepted scores (e.g., Braden or Norton Scales). Hospitals can then get the patient onto a different type of mattress that wicks away moisture, changes patient support and reduces pressure and imposes orders for the individual to be turned every few hours, for example. The risk of a PI among acute care patients ranges between 2-40% of patients.

Intrinsic risk factors such as diabetes, malnutrition and smoking also increase the overall risk for pressure injuries. The spinal cord injury patient population is at the highest risk (25-66%) of developing a PI due to the combination of immobility and decreased sensation. A prospective study of spinal cord patients not only found that sacral and ischial PIs were very common (43% and 15%, respectively), as might be expected, but also noted that the second most common location was on the heel (19%).[5]

Nursing home patients have PI prevalence of 11%[6] and are most likely to develop PIs on the sacrum or heels. Nursing home patients were also found to have contractures at a prevalence of 55%. Contractures are caused by decreased elasticity of the tissue surrounding major joints, and the resulting lack of full mobility in the affected extremities significantly increases the risk of PI information.

A significant market is the home healthcare market, which is anticipated to be worth $645 billion by 2025 (CAGR 8.7%).[7] It is estimated that by 2030, seniors aged 65 and over will represent 20% of the U.S. population, and over 19 million seniors are estimated to need homecare services. Homecare companies have a strong incentive to prevent PIs as they are rated and carry part of the cost treating those patients.

According to a survey published in 2000 by UCLA School of Medicine,[8] in a total sample of 3,048 patients, 9.12% had PIs, and of these, 37.4% had more than one PI, and 14% had three or more. Considering the worst PIs for each subject, 40.3% had Stage II and 27% had Stage III or IV injuries.

The Agency for Healthcare Research and Quality (AHRQ) has identified several basic principles for PI prevention: (a) use a validated tool to assess risk such as the Braden Scale and Norton Scale; (b) implement a preventive plan for residents at risk, which should focus on avoiding friction and sheer trauma to at-risk skin regions, as well as an individualized plan to reduce pressure, such as frequent repositioning; and (c) daily inspection of the skin for high-risk residents, as deep tissue damage can occur in as little as two hours. The most common method used to detect early pressure injuries is a visual assessment by a professional caregiver focusing on areas where PIs most frequently develop. This visual assessment is subjective, unreliable, untimely and ineffective as PIs develop under the skin before becoming visible to the naked eye. Technology-based methods for detecting and monitoring PIs have been developed, but none have succeeded in providing an effective solution. These include ulcer assessment based on skin conductivity which has relatively low resolution and is influenced by different topical skin conditions (e.g., moisture, urine or feces). Other system solution methods such as electronic medical record programs, which prompt providers to document results of PI screening every shift or day, are of great importance in diagnosing PIs early and preventing progression. Pads designed to specifically cover pressure points such as the sacrum and heels, as well as foam pads designed to wrap around at-risk body parts, are common products. However, it is important to note that some pads can actually be detrimental; for example, supports with cut-outs can have increased pressure at their edges. Hospital-acquired PI rates are increasing while all other hospital-acquired conditions are decreasing (AHRQ, 2019).

[4] Current Perspectives on Pressure Injuries in Persons with Dark Skin Tones from the National Pressure Injury Advisory Panel, Adv Skin Wound Care. 2023 Sep 1;36(9):470-480. doi: 10.1097/ASW.0000000000000032. Epub 2023 Aug 7. PMID: 37590446.

[5] Delmore, B., Lebovits, S., Suggs, B., Rolnitzky, L. and Ayello, E., 2015. Risk Factors Associated with Heel Pressure Ulcers in Hospitalized Patients. *Journal of Wound, Ostomy & Continence Nursing*, 42(3), pp.242-248.

[6] Palese, A., Zammattio, E., Zuttion, R., Ferrario, B., Ponta, S., Gonella, S. and Comoretto, R., 2020. Avoidable and Unavoidable Pressure Injuries Among Residents Living in Nursing Homes. *Journal of Wound, Ostomy & Continence Nursing*, 47(3), pp.230-235.

[7] Home Healthcare Market will grow at CAGR of 8.7% to hit $645.10 billion by 2025: Adroit Market Research.

[8] Ferrell, B., Josephson, K., Norvid, P. and Alcorn, H., 2000. Pressure Ulcers Among Patients Admitted to Home Care. *Journal of the American Geriatrics Society*, 48(9), pp.1042-1047.

PressureSafe™

Since 2017, we have been designing and developing *PressureSafe™*, a novel device that has the potential to provide a reliable method of monitoring and recording patients, providing additional bio information to healthcare providers as to where and when a pressure injury may occur. The technology platform is designed to record information relating to each patient. The core technologies underlying the *PressureSafe™* device are patent protected (US Patent No. US 10,709,365 and US Patent No. US10,772,541). Our technology platform is based on the fact that tissues of the human body absorb and reflect omitted light in different wave lengths (from the visual light to infra-red light), and the light is reflected and scattered back from different skin layers. During this process, the reflected and scattered light waves through a damaged area changes its properties in comparison to light reflection and scattering from normal healthy tissue. The *PressureSafe™* device is being designed to capture, analyze and identify tissue status to make early PI diagnoses using Spectrographic Analysis, while AI based algorithm is implemented to improve diagnostic accuracy. The *PressureSafe™* device illuminate the skin with a miniature set of LEDs less than a second in order to acquire the tissue fingerprint. The emitted light photons from the device will be absorbed,

scattered, and reflected back. The device will then detect the absorption and reflectance, and by using algorithms, it will process the signals to identify and classify the scanned area.

As all person's skin properties are unique, the diagnosing physician needs to use a device as the *PressureSafe™,* which automatically calibrate the device to the specific patient's skin, a process that takes merely a few seconds and allows personalized diagnosis, improving physician diagnostic process effectiveness, as the *PressureSafe™* device is designed to measure regardless of skin color. Our technology is being developed to enable the assessment of different subepidermal layers by scanning through these skin layers, thus assessing the subepidermal damaged tissue using multi-biomarker approach and assisting with additional information to allow better treatment. Assessing the subepidermal biomarkers has been developed to "raise a flag" to allow the caregivers intervene and prevent their opening ("skin breakage"). The biomarkers that our algorithm uses starts from the early inflammatory process, as soon as local underlying tissue function is disturbed, ischemia and cells begin to be damaged.

PressureSafe™ is a hand-held scanner designed to provide additional information as a DSS, to support the care giver effectively with the main diagnostic ability to identify PIs and to differentiate between deep tissue PIs (before they become visible) and Stage 1 PIs. Deep tissue PIs are serious, deep PIs that form under intact skin, spread in deep tissues and eventually present themselves as full thickness wounds. The *PressureSafe™* is composed of (a) a handheld optic probe device, which utilizes harmless infra-red light that is placed on the skin and has a disposable tip that is changed between patients. The optic probe with its disposable cover is placed on suspected areas for performing measurements; (b) a disposable probe tip component, changed between patients to avoid cross-contamination; (c) a software component containing machine learning algorithm for analyzing the collected data; and (d) software for connectivity and downloading the collected data and measurements results to the EMR/EHR systems used by the medical center or homecare company.

PressureSafe™ is a non-invasive real-time optical monitoring device to support early intervention in PI treatment prior to skin breakage. The device performs a reflectance spectroscopy scan to generate information for the decision maker, while collecting data on epidermal and subepidermal physiological changes together with other bio-signals typical of early formation of PIs in the main three skin layers, thus detecting the appearance of life-risking pressure injuries. *PressureSafe™* is designed to detect changes deep in the skin, regardless of skin tone, by measuring bio markers. As soon as local subcutaneous tissue function is disturbed and cells begin to disintegrate by pressure exerted upon the body area, our scanner is designed to be able to detect this very early inflammatory process and tissue structure changes. The technology will allow patient monitoring and immediate reading in a non-invasive way. It has the potential to help to reduce the number of PIs dramatically through accurate early classification, making it attractive for public and private healthcare systems worldwide.

***PressureSafe*™ Studies**

Our product candidates are in various stages of development and production. The *PressureSafe™* device is in an advanced stage of development and is planned to be our first go-to-market product.

We have completed the development of the first generation *PressureSafe™* prototype in the second quarter of 2022. 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 Maintenance Organization, or HMO, in Israel, to conduct a usability study of *PressureSafe™*.

On July 17, 2023, we published our interim report of usability study performed in Israel in leading medical centers with the following results:*PressureSafe™* demonstrated very high efficacy in noninvasively detecting the presence and absence of PIs below the skin's surface. *PressureSafe™* accurately detected the presence of a PI in 96% of cases. In addition, *PressureSafe™* correctly determined that no wound was present in 91% of cases. The study was conducted at two medical centers owned by Clalit, namely Beit Rivka Hospital and Rabin Medical Center both in Petah Tikva, where 370 *PressureSafe™* scans were performed on 25 patients who had Stage 1 PIs or deep tissue injuries. No device related safety issues were reported in the total of 44 patients evaluated for safety.

On September 26, 2023, we announced that we signed a Clinical Trial Agreement with the Methodist Healthcare System of San Antonio to conduct a useability study titled "Safety and Efficacy of the *PressureSafe™* device for early assessment of Pressure Injury in People with Various Skin Tones, Including Dark Skin Tones." Methodist Healthcare is recognized as the most respected healthcare provider in its region. With a network of 85 hospitals, 9 of which are acute care facilities, Methodist Healthcare employs more than 11,000 people, including 2,700 physicians. Based on our intended protocol, we plan to have 50% of the subjects for the upcoming study to have a dark skin tone, thus producing comparative data on *PressureSafe™'s* accuracy as a decision support device in detecting early-stage PIs in people of darker and lighter skin tones. Early-stage PIs can be more difficult to see on dark skin tones with the current standard of care for the assessment of PIs, which is visual skin inspection.

On February 20, 2024, we reported 92% efficacy for PressureSafe™. Data from the study conducted at two medical centers owned by Clalit, namely Beit Rivka Hospital and Rabin Medical Center, presented at the NPIAP 2024 Annual Conference on February 16 and 17, 2024 in San Antonio, Texas. The 14-day efficacy portion of the single arm, bi-center study evaluated 38 patients at high risk of pressure injury development. A total of 924 scans were conducted on 154 body locations. Nurses conducting the scans were blinded to *PressureSafe™'s* results, which were encrypted. PressureSafe™ detected Stage 1 pressure injuries with 92% sensitivity and 88% specificity. Additional portions of the study evaluated safety, as well as device calibration and validation. Total data from 66 patients was obtained for safety analysis and no safety signals were identified in 1,493 scans. Based on these data, the study concluded that PressureSafe™ is a safe, efficient, and valuable method for early assessment of pressure injuries. On May 22, 2024, we published a poster presentation on our website titled "Near Infra-Red Spectroscopy scanner for early assessment of stage 1 pressure injury and deep tissue injury – clinical study results", which includes data that was presented at the NPIAP 2024 Annual Conference in San Antonio, Texas.

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

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

DiaSafe

We are now in the development stages of Software/Hardware, algorithms and optics to allow early assessment of incipient DFU in the lower limbs, the DiaSafe™. DiaSafe™ is an adjustment to the *PressureSafe™* proven technology allows us to reduce the development period and approach the relevant markets faster. We plan to initiate a

clinical study in Israel, to train the developed algorithm and test patients.

DFU Background

Diabetic foot ulcer are an increasing problem among diabetic patients. Diabetic foot ulcers are one of several serious complications of diabetes progression. Major contributing causes to diabetic foot ulcers are peripheral neuropathy, peripheral arterial disease, and immunosuppression. Up to 15% of patients with diabetes have diabetic foot ulcers, and these ulcers lead to more than 80,000 amputations per year in the United States. The lifetime risk of diabetic foot ulcers for patients with diabetes may reach up to 68 per 1,000 people as reported by some studies. As a diabetic foot ulcer progresses, the patient's risk for amputation increases; in nearly 84% of patients who have a lower limb amputation secondary to diabetes, the amputation is preceded by a diabetic foot ulcer. Peripheral neuropathy secondary to diabetes is an etiologic factor of diabetic foot ulcers and is estimated to affect 5.5 million people in the United States.

These collective findings indicate that diabetic foot ulcers lead to serious disability, serious reduction in patient quality of life, and high financial costs for society. With increased vigilance on risk assessment, diagnosis, and management of diabetic foot ulcers, clinicians can improve patient outcomes and reduce healthcare costs.

There are a few established methods for diagnosing DFU. These methods assess side effects of diabetic related symptoms as Peripheral Artery Disease diabetic neuropathy (mono-filament test tuning fork test), skin temperature, BP, heart rate, skin dryness etc. The suggested DiaSafe™ device measures actual dermal and subdermal changes of injured skin tissue structure caused directly the development of diabetic foot ulcers. The optical platform developed by IR-MED allows direct assessment and measurement of changes in skin structure (including blood flow changes).[9]

- Market Prevalence: The percentage of Americans aged 65 and older diagnosed with diabetes remains high, at 29.2%, or 16.5 million seniors (diagnosed and undiagnosed).

- Diabetic foot ulcers are wounds on the feet that develop in patients with type 1 or type 2 diabetes. About one-third of people with diabetes develop a foot ulcer during their lifetime. Diabetic foot ulcers affect about 18.6 million people worldwide and 1.6 million in the U.S. annually. Treatment of infection in a diabetic ulcer is difficult and expensive. Patients usually need to take long-term medications or become hospitalized for an extended period of time DFU treatment is expensive. On average, the treatment cost for wounds with Wagner grade I in five industrialized countries was $3,096 in 2010. However, if the wound becomes complicated and amputated, the cost will rise to almost $107,900.[10] Average in-hospital costs were $10,827 (range: $702–$82,880) per DFU episode. Primary healed DFUs costs on average $4,830, single minor amputations on average $13,580, multiple minor amputations on average $31,835 and major amputations on average $73,813 per episode.[11]

[9] Tuttolomondo A, Maida C, Pinto A. Diabetic foot syndrome: Immune-inflammatory features as possible cardiovascular markers in diabetes. World J Orthop. 2015 Jan 18;6(1):62-76. doi: 10.5312/wjo.v6.i1.62. PMID: 25621212; PMCID: PMC4303791.

[10] https://journals.lww.com/jaapa/fulltext/2015/05000/pathogenesis_and_management_of_diabetic_foot.6.aspx

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3634178/ Iraj B, Khorvash F, Ebneshahidi A, Askari G. Prevention of diabetic foot ulcer. Int J Prev Med. 2013;4(3):373-376, https://jamanetwork.com/journals/jama/fullarticle/2812203.

[12] https://www.sciencedirect.com/science/article/abs/pii/S0168822717302413.

All the diabetic patients should undergo comprehensive foot exam once a year. The goal of this examination is to determine the risk factors that may result in a foot ulcer and consequently amputation of the affected organ. The physical examination contains observation, palpation of the pulses in the lower extremities, including the posterior tibial and dorsalis pedis pulses. The physical examination also includes neurological tests. At least two neurologic tests are performed and one of the tests should measure the protective sensation in which a 10 g monofilament is used. Vibration sensation using a 128 Hz diapason.

The DiaSafe™ device as the PressureSafe™ device is being designed to capture, analyze and identify tissue status to make early DFU assessment and classification using Spectrographic Analysis, while AI based algorithm is implemented to improve provided diagnostic accuracy. The DiaSafe™ device illuminates the skin with a miniature set of LEDs less than a second in order to acquire the tissue fingerprint. The emitted light photons from the device will be absorbed, scattered and reflected back. The device will then detect the absorption and reflectance, and by using algorithms, it will process the signals to identify and classify the scanned area or DFU.

As all person's skin properties are unique, the diagnosing physician needs to use a device as the DiaSafe™, which automatically calibrate the device to the specific patient's skin, a process that takes merely a few seconds and allows personalized diagnosis, improving physician diagnostic process effectiveness, as the DiaSafe™ device is designed to measure regardless of skin color. Our technology is being developed to enable the assessment of different subepidermal layers by scanning through these skin layers, thus improving the identification of the damage, assessing the subepidermal damaged tissue volume and assisting with additional information to allow better treatment efficacy. Measuring the differences of subepidermal biomarker is being developed to detect early formation of DFUs and to "raise a flag" to allow the caregivers intervene and prevent their appearance. The biomarkers that our algorithm detects start from the early inflammatory process, as soon as local underlying tissue function is disturbed, and cells begin to be damaged.

DiaSafe™ is a hand-held scanner designed to provide additional information as a DSS, to support the care giver effectively with the main diagnostic ability to identify DFUs and to differentiate between DFUs under different skin conditions (before they become visible. The DiaSafe™ is composed of: (a) a handheld optic probe device, which utilizes harmless infra-red light that is placed on the skin and has a disposable tip which is changed between patients. The optic probe with its disposable cover is placed on suspected areas for performing measurements; (b) a disposable probe tip component, changed between patients to avoid cross-contamination; (c) a software component containing machine learning algorithm for analyzing the collected data; and (d) software for connectivity and downloading the collected data and measurements results to the EMR/EHR systems used by the medical center or homecare company.

DiaeSafe™ is a non-invasive real-time optical monitoring device to support early intervention in DFU treatment prior to skin breakage. The device performs a reflectance spectroscopy scan to generate information for the decision maker, while collecting data on epidermal and subepidermal physiological changes together with other bio-signals typical of early formation of PIs in the main three skin layers, thus detecting the appearance of life risking pressure DiaSafe™ is designed to detect changes deep in the skin, regardless of skin tone, by measuring bio markers. As soon as local subcutaneous tissue function is disturbed and cells begin to disintegrate by pressure exerted upon the body area, our scanner is designed to be able to detect this very early inflammatory process and tissue structure changes. The technology will allow patient monitoring and immediate reading in a non-invasive way. It has the potential to help to reduce the number of DFUs dramatically through accurate early classification, making it attractive for public and private healthcare systems worldwide.

Recent Developments

Equity Purchase Agreement and Registration Rights Agreement with Williamsburg

On March 11, 2025, we entered into an Equity Purchase Agreement (the "Purchase Agreement") with Williamsburg, pursuant to which Williamsburg agreed to purchase up to Fifteen Million Dollars ($15,000,000) of our Comon Stock ("Maximum Commitment Amount") by delivering put notices (each, a "Put Notice"). The Purchase Agreement provides that we will sell the shares of Common Stock (the "Put Shares") to Williamsburg pursuant to applicable Put Notices from time to time over a 24-month period (unless otherwise determined therein) in accordance with the terms and conditions the Purchase Agreement, commencing on March 11, 2025, and ending on the earlier of

(i) the date on which the Williamsburg shall have purchased Put Shares pursuant to this Agreement equal to the Maximum Commitment Amount, (ii) March 11, 2027, or (iii) written notice of termination us to Williamsburg (which shall not occur at any time that Williamsburg holds any of the Put Shares) (the "Commitment Period"). Each Put Notice shall state the number of shares of the Common Stock Williamsburg is required to purchase, at such price as determined in accordance with the Purchase Agreement. The per share purchase price for the Put Shares shall be equal to 90% of the market price defined as the average of the two (2) lowest Volume-Weighted Average Price ("VWAP") for the five (5) consecutive trading days immediately preceding the relevant clearing date, as reported by Bloomberg Finance L.P. or other reputable source. Pursuant to the Purchase Agreement, Williamsburg may not acquire at any point, more than 9.99% of our outstanding common stock. Pursuant to the terms of the Purchase Agreement, Williamsburg agreed to accept a Put Notice of up to $500,000 upon a registration statement being declared effective by the SEC.

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

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

Our ability to require Williamsburg to purchase the Shares under the Purchase Agreement is subject to various limitations and conditions, including but not limited to the following:

- The Company shall promptly secure the listing of all Put Shares and Commitment Shares to be issued to Williamsburg hereunder on the Principal Market (subject to official notice of issuance) and shall use commercially reasonable best efforts to maintain, so long as any shares of Common Stock shall be so listed, the listing of all such Put Shares and Commitment Shares from time to time issuable hereunder.

- The Company shall have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company.

- The trading of the Common Stock shall not have been suspended by the SEC, the Principal Market or FINRA, or otherwise halted for any reason, and the Common Stock shall have been approved for listing or quotation on and shall not have been delisted from the Principal Market.

- So long as the Purchase Agreement remains in effect, the Company shall not and will not enter into any other equity line of credit agreement with any other party, without Williamsburg's prior written consent, which consent may be granted or withheld in the Investor's sole and absolute discretion.

- The Registration Statement, and any amendment or supplement thereto, which includes this prospectus covering the Put Shares and the Commitment Shares, shall be and remain effective for the resale and shall not be suspended withdrawn and neither the Company nor Williamsburg shall receive the notice that the SEC has issued or intends to issue a stop order with respect to such Registration Statement or that the SEC otherwise has suspended or withdrawn the effectiveness of such Registration Statement, either temporarily or permanently.

- The number of Put Shares to be purchased by Williamsburg, when aggregated with all other shares of Common Stock beneficially owned by Williamsburg would not exceed 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock.

- The Company's Common Stock must be DWAC eligible and not subject to a "DTC chill."

- Selling Stockholder shall have received an opinion from our outside legal counsel in the form previously agreed to.

There is no guarantee that we will be able to meet the foregoing conditions or any other conditions under the Purchase Agreement or that we will be able to draw down any portion of the amounts available under the Purchase Agreement.

We also entered into the Registration Rights Agreement with Williamsburg, pursuant to which, we have filed a registration statement, which includes this prospectus, with the SEC relating to Williamsburg's resale of any shares of Common Stock it purchased under the Purchase Agreement, including the Commitment Shares we issued to the Selling Stockholder on March 11, 2025. The effectiveness of this Registration Statement is a condition precedent to our ability to sell shares of our Common Stock to Williamsburg under the Purchase Agreement.

If all 80,000,000 shares offered pursuant to this prospectus were sold, they would represent approximately 52% of the total number of shares of our Common Stock outstanding and approximately 65% of the total number of outstanding shares of our Common Stock held by nonaffiliates as of the date of this prospectus. Issuance of the shares in this offering will not affect the rights or privileges of our existing stockholders except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuances. Although the number of shares of our Common Stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any issuances of shares of our Common Stock to the Selling Stockholder.

Corporate Information

IR-Med, Inc. was incorporated in the state of Nevada on April 20, 2007, under the name "Monster Motors, Inc." On June 24, 2009, the corporate name was changed to Eco2 Forests, Inc. During September 2012, Eco2 Forests, Inc., accepted a court ordered receiver who authorized a reduction of the authorized shares from 900,000,000 to 500,000,000 and in November 2012 effectuated a 16,000 to 1 stock split. In February 2013, the Company underwent a change of control. On March 25, 2013, Eco2 Forests, Inc., effectuated a 4-to-1 reverse stock split in addition to changing the corporate name to International Display Advertising, Inc. IR-Med, Inc. began operating the business of IR. Med Ltd. An Israeli company, through a reverse acquisition on December 24, 2020 (the "Acquisition"). IR. Med Ltd. (an Israeli company which was founded in 2013) continues as an operating subsidiary of IR-Med, Inc.; IR-Med, Inc. is the sole stockholder of IR. Med Ltd. IR-Med, Inc.'s corporate headquarters and IR. Med Ltd.'s research facilities are located at ZHR Industrial Zone, Rosh Pina, Israel.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- a requirement to provide only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

- reduced disclosure about executive compensation arrangements;

- no non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from the auditor attestation requirement in the assessment of internal control over financial reporting.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we had total annual gross revenues of $1.07 billion or more; (ii) the last day of the year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we had issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934 (the "Exchange Act"), after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (1) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act; (2) scaled executive compensation disclosures; and (3) the requirement to provide only two years of audited financial statements, instead of three years.

THE OFFERING

Issuer:	IR-Med, Inc.
Securities Being Offered by the Selling Stockholder:	Up to 80,000,000 shares of our Common Stock.
Offering Price:	The Selling Stockholder may offer, sell, or distribute all or a portion of the Shares registered hereby either through public or private transactions at prevailing market prices or at negotiated prices. See "Plan of Distribution."
Common stock outstanding before this offering:	72,018,144 shares
Common stock outstanding after the offering:	152,018,144 shares. Assumes that the Selling Stockholder sells all of the Shares offered pursuant to this prospectus.
Terms of the offering:	The Selling Stockholder will determine when and how it sells the Shares offered in this Prospectus as described in "Plan of Distribution."
Use of proceeds:	We will not receive any proceeds from the sale of the Shares by the Selling Stockholder. We have agreed to bear the expenses relating to the registration of the Shares. See "Use of Proceeds."
Risk factors:	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our Common Stock.
Market Information	Our shares of Common Stock are traded on the OTCQB under the symbol "IRME."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus may contain "forward-looking statements" (within the meaning of Section 27A of the Securities Act and Section 21E of the Securities and Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this prospectus, including statements regarding the timing of our clinical trials, our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words or phrases "will likely result", "will be", "will", "are expected to", "will continue to", "is anticipated", "estimate", "project" or similar expressions identify "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical earnings and those presently anticipated or projected. Readers are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date made.

These forward-looking statements include, among other things, statements about:

- the accuracy of our estimates regarding expenses, future revenues, uses of cash, capital requirements and the need for additional financing;
- the initiation, cost, timing, progress and results of our development activities, usability studies, preclinical studies and any clinical trials that we may be required to undertake;
- the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions and/or limitations;
- our plans to research, develop and commercialize our current and future product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize our product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing devices that are or may become available;
- regulatory developments in the United States and other countries;

- the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials;
- the impact of global inflationary pressures;
- our ability to obtain additional financing;
- our use of the proceeds from our securities offerings;
- any restrictions on our ability to use our net operating loss carry-forwards;

- the impact of Israel's multi-front war on our results, including potential economic restrictions imposed on and political and military instability in Israel; and
- our ability to attract and retain key personnel.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time, and it is neither possible for us to predict all risk factors nor address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. Actual results could differ materially from our forward-looking statements due to a number of factors, including the early stage of our product candidates presently under development; our ability to obtain and, if obtained, maintain regulatory approval of our current product candidates and any of our other future product candidates; our need for substantial additional funds in order to continue our operations and the uncertainty of whether we will be able to obtain the funding we need; our future financial performance; our ability to retain or hire key scientific or management personnel; our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; the success of our collaborations with third parties; the size and growth of the potential markets for any of our approved product candidates and the rate and degree of market acceptance of any of our approved product candidates; competition in our industry; regulatory developments in the United States and foreign countries, including the U.S. Food and Drug Administration, or FDA; and the expected impact of new accounting standards.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this prospectus. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled "Risk Factors" and elsewhere in this prospectus could negatively affect our business, operating results, financial condition and stock price. All forward-looking statements included in this document are based on information available to us on the date hereof, and except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this prospectus to conform our statements to actual results or changed expectations.

RISK FACTORS

Investing in our Common Stock involves a high degree of risk. Before investing in our Common Stock, you should carefully consider the risks described below, as well as the other information in this prospectus, Investors should consider carefully the following information about these risks, together with the other information contained in this prospectus, including our consolidated financial statements and the related notes. If any of the following risks actually occur, the business, financial condition or results of operations of the Company could be materially adversely affected, the market price of the Common Stock would likely decline, and investors could lose all or a portion of their investment.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in our Annual Report on Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

- We are a development stage medical device company and have a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve or maintain profitability.
- We will need substantial additional funding to continue our operations, which could result in significant dilution or restrictions on our business activities. We may not be able to raise capital when needed, if at all, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail**.**
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this report. Our audited financial statements on December 31, 2024, were prepared assuming that we will continue as a going concern.
- Medical device development involves a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product.
- The size and future growth in the market for our planned devices under development has not been established with precision and may be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market, our sales growth may be adversely affected.

- Any product candidates we may advance into clinical trials (assuming the FDA so requires) may be subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates, all of which can adversely affect our business
- We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.
- If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market and sell any products we may successfully develop, we may not be able to effectively market and sell any such products and generate product revenue.
- Failure to manage our growth effectively could increase our expenses, decrease our revenue and prevent us from implementing our business strategy.

- Failure to secure or retain coverage or adequate reimbursement for our planned products in development by third-party payors could adversely affect our business, financial condition and operating results.

- If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology, our competitors could develop and commercialize technology similar to ours, and our competitive position could be harmed.

- Our technology development is headquartered in Israel and, therefore, our results may be adversely affected by economic restrictions imposed on, and political and military instability in Israel, including Israel's multi-front war.

Risk Factors

An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this report in evaluating our company and its business before purchasing shares of our company's common stock. Our business, operating results and financial condition could be seriously harmed due to any of the following risks. You could lose all or part of your investment due to any of these risks.

Risks Related to Our Business, Financial Position, Capital Requirements, Managing our Growth and Other Legal Compliance Matters

We are a development stage medical device company and have a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve or maintain profitability.

As a development stage company, we do not currently have revenues to generate cash flows to cover operating expenses. Since our inception, we have incurred operating losses in each year due to costs incurred in connection with research and development activities, marketing and general and administrative expenses associated with our operations. For the years ended December 31, 2024, and 2023, we incurred net losses of approximately $1,899,000 and $4,909,000, respectively. As of December 31, 2024, and 2023, we had an accumulated deficit of $16,738,000 and $14,839,000, respectively.

We expect to incur losses for the foreseeable future as we continue the development of, and seek regulatory clearance and approvals for, our devices in development (for pre-emptive diagnosis of PIs on the skin surface), DiaSafe™ and thereafter, for the *Nobiotics* device (for detecting the ear infections in children). If we fail to generate revenue and eventually become profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or a substantial part of their investment.

We will need substantial additional funding to complete subsequent phases of our medical devices and to operate our business and such funding may not be available or, if it is available, such financing is likely to substantially dilute our existing shareholders.

The discovery, development and commercialization of new medical devices (such as our *PressureSafe*™ and DiaSafe™ devices) entails significant costs. As we are in the early stage of the engineering, electronics, algorithm and mechanical aspects of our devices and prototypes, we still must develop, modify, refine and finalize them. To enable us to accomplish these and other related items and continue to operate our business, we will need to raise substantial additional capital or enter into strategic partnerships to enable us to:

- fund clinical studies and seek regulatory approvals/clearance prior to performing clinical trials (if needed);

- build or access manufacturing and commercialization capabilities;

- develop, test and receive regulatory commercial sale approval to market our products;

- acquire or license additional internal systems and other infrastructure; and

- hire and support additional management, engineering and scientific personnel.

We will need substantial additional funding to continue our operations, which could result in significant dilution or restrictions on our business activities. We may not be able to raise capital when needed, if at all, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

Our operations have consumed substantial amounts of cash since inception. We expect to need substantial additional funding to pursue the clinical development of our drug candidates and launch and commercialize any drug candidates for which we receive regulatory approval.

In 2022 and 2023, we raised aggregate gross proceeds of $3,625,000 and $1,000,000, respectively, from sales of our equity and equity linked securities. On June 4, 2024, and July 4, 2024, we raised aggregate proceeds of $755,000 from sales of our shares of common stock and warrants to purchase shares of common stock.

Nonetheless, we will require additional capital for the further development and commercialization of our three product candidates (which are in various stages of design and development) and may need to raise additional funds sooner if we choose to and are able to expand more rapidly than we currently anticipate. Further, we expect our expenses to increase in connection with our ongoing activities. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to regulatory requirements, product manufacturing, marketing, sales and distribution.

Furthermore, we expect to incur additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our capital needs and/or cause us to spend our cash resources faster than we expect. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

To date, we have financed our operations through a mix of equity investments from private investors, the incurrence of debt, grant funding and technology licensing revenues, and we expect to continue to utilize such means of financing for the foreseeable future. Additional funding from those or other sources may not be available when or in the amounts needed, on acceptable terms, or at all.

If we raise capital through the sale of equity, or securities convertible into equity, it will result in dilution to our then existing stockholders, which could be significant depending on the price at which we may be able to sell our securities.

If we raise additional capital through the incurrence of indebtedness, we may become subject to covenants restricting our business activities, and holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development or commercialization activities.

If we are unable to raise capital when needed on commercially reasonable terms, we could be forced to delay, reduce or eliminate our research and development for our product candidates or any future commercialization efforts or ultimately cease operations. Any of these events could significantly harm our business, financial condition and prospects.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never achieve, we expect to finance our cash needs primarily through public or private equity offerings, debt financings or through the establishment of possible strategic alliances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are not able to secure additional equity funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical studies, development programs or future commercialization initiatives.

In addition, any additional equity funding that we do obtain will dilute the ownership held by our existing security holders. The amount of this dilution may be substantially increased if the trading price of our common stock is lower at the time of any financing. Regardless, the economic dilution to shareholders will be significant if our stock price does not increase significantly, or if the effective price of any sale is below the price paid by a particular shareholder. Any debt financing that we obtain in the future could involve substantial restrictions on activities and creditors could seek a pledge of some or all of our assets. We have not identified potential sources for such financing that we will require, and we do not have commitments from any third parties to provide any future debt financing. If we fail to obtain funding as needed, we may be forced to cease or scale back operations, and our results, financial condition and stock price would be adversely affected.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this prospectus. Our audited financial statements on December 31, 2024, were prepared assuming that we will continue as a going concern.

Primarily as a result of our losses and limited cash balances and cash flows, the report of our independent registered public accounting firm for the fiscal year ended December 31, 2024, contains an explanatory paragraph on our financial statements stating that the Company has suffered recurring losses from operations and has accumulated deficit that raise substantial doubt about the Company's ability to continue as a going concern. While we raised proceeds of $755,000 during the year ended December 31, 2024, by way of private placement offerings to accredited investors, we do not believe our resources will be sufficient to meet our operating and capital needs beyond the second quarter of 2025]. We expect we will require additional capital to fully implement the scope of our proposed business operations, which raises substantial doubt about our ability to continue as a going concern. We will have to continue to rely on equity and debt financing, and/or continued support from our officers and directors. There can be no assurance that financing, whether debt or equity, will be available to us in the amount required at any particular time or for any particular period or, if available, that it can be obtained on favorable terms.

If we are unable to secure additional capital, we may be required to curtail our clinical and research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The accompanying financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our proposed business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment.

Our limited operating history as a development stage company may hinder our ability to successfully meet our objectives.

We were formed in 2013, and since that time our focus has been on our two leading product candidates, which are the*PressureSafe*™ device, DiaSafe™ device. We have limited experience with development stage operations, including manufacturing and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the medical device support systems arena. In addition, the early-stage nature of our development operations can only provide limited operating results upon which investors can evaluate our business and prospects.

Our limited operating history may adversely affect our ability to implement our business strategy and achieve our business goals, which include, among others, the following activities:

- developing our product candidates using unproven technologies;
- undertaking preclinical development and clinical trials as well as formulating and manufacturing products;
- obtaining the human, financial and other resources necessary to develop, test, manufacture, commercialize and market our product candidates;
- engaging collaborators to assist in developing, testing, manufacturing and marketing our product candidates;
- continuing to build and maintain an intellectual property portfolio covering our technology and product candidates;
- achieving acceptance and use by the medical community of our Anticalin platform and drug candidates after they receive regulatory approvals;
- maintaining, growing and managing our internal teams as and to the extent we increase our operations and develop new segments of our business;
- developing and maintaining successful collaboration, strategic and other relationships for the development and commercialization of our product candidates that receive regulatory approvals with existing and new partners; and
- managing our cash flows and any growth we may experience in an environment where costs and expenses relating to clinical studies, regulatory approvals and commercialization continue to increase.

If we are unsuccessful in accomplishing any or all of these objectives, we may not be able to raise capital, expand our business, develop our drug candidates or continue our operations.

We may never achieve profitability.

Because of the numerous risks and uncertainties associated with the development and commercialization of medical device solutions, we are unable to accurately predict the timing or amount of future revenue or expenses or when, or if, we will be able to achieve profitability. We have financed our operations primarily through issuance and sale of equity and equity linked securities. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. We expect to continue to expend substantial financial and other resources on, among other things:

- investments to expand and enhance our platform and technology infrastructure, make improvements to the scalability, availability and security of our platform, and develop new products;
- sales and marketing, including expanding our indirect sales organization and marketing programs;
- planning and conducting clinical trials to obtain regulatory approval/clearance for the commercialization of our products;

- expansion of our operations and infrastructure, both domestically and internationally; and
- general administration, including legal, accounting and other expenses related to being a public company.

If we are unable to successfully commercialize our products or if revenue from any of our products that receives marketing approval is insufficient, we will not achieve profitability. Furthermore, even if we successfully commercialize our products, our planned investments may not result in increased revenue or growth of our business. We may not be able to generate net revenues sufficient to offset our expected cost increases and planned investments in our business and platform. As a result, we may incur significant losses for the foreseeable future, and may not be able to achieve and sustain profitability. If we fail to achieve and sustain profitability, then we may not be able to achieve our business plan, fund our business or continue as a going concern.

Our quarterly results may fluctuate significantly, and period-to-period comparisons of our results may not be meaningful.

Our quarterly results, including the levels of future revenue, if any, our operating expenses and other costs, and our operating margins, may fluctuate significantly in the future, and period-to-period comparisons of our results may not be meaningful. This may be especially true to the extent that we do not successfully establish our business model. Accordingly, the results of any one period should not be relied upon as an indication of our future performance. In addition, our quarterly results may not fully reflect the underlying performance of our business. Factors that may cause fluctuations in our quarterly results include, but are not limited to:

- the timing of regulatory commercial sale approvals for our products in various stages of development;
- the timing of regulatory commercial sale approvals for our products in various stages of development;
- our ability to successfully establish our business model;
- our ability to attract and retain distribution networks, customers and to expand our business;
- enacted or pending legislation effecting the healthcare industry;
- changes in our pricing policies or those of our competitors;
- the timing of our recognition of revenue and the mix of our revenues during the period;
- the amount and timing of operating expenses and other costs related to the maintenance and expansion of our business, infrastructure and operations;
- the amount and timing of operating expenses and other costs related to the development or acquisition of businesses, services, technologies or intellectual property rights;
- the timing and costs associated with legal or regulatory actions;
- changes in the competitive dynamics of our industry, including consolidation among competitors or customers;
- loss of our executive officers or other key employees
- industry conditions and trends that are specific to the vertical markets in which we sell or intend to sell our devices; and
- general economic and market conditions.

Fluctuations in quarterly results may negatively impact the value of our common stock, regardless of whether they impact or reflect the overall performance of our business. If our quarterly results fall below the expectations of investors or any securities analysts who follow our shares, or below any guidance we may provide, the price of our ordinary shares could decline substantially.

Currency exchange rate fluctuations affect our results of operations, as reported in our financial statements.

We incur expenses in U.S. Dollars and in NIS, but our functional currency is the U.S. dollar. However, a significant portion of our headcount related expenses, consisting principally of salaries and related personnel expenses as well as R&D consulting services, leases and certain other operating expenses, are denominated in NIS. This foreign currency exposure gives rise to market risk associated with exchange rate movements of the U.S. dollar against the NIS. Furthermore, we anticipate that a material portion of our expenses will continue to be denominated in NIS.

In addition, increased international sales in the future may result in greater foreign currency denominated sales, increasing our foreign currency risk. If we are not able to successfully hedge against the risks associated with currency fluctuations, our financial condition and results of operations could be adversely affected.

Medical device development involves a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product.

Before the DiaSafe™ and the *Nobiotics* medical devices can be available for commercial sale the United States and in other countries, we must complete all regulatory requirements necessitated by the FDA and foreign health regulatory authorities and demonstrate the performance and safety of our technology. These activities will include performing clinical useability studies. While we currently plan to pursue 510(k) approval which does not require clinical trials, the FDA may require clinical trials in order to approve our product candidates. Clinical Trials are expensive, difficult to design and implement, can take years to complete and are inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Further, the outcomes of completed clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval. We have limited resources to complete the expensive process of medical device development, and clinical trials, putting us at a disadvantage, particularly compared to some of our larger and established competitors, and we may not have sufficient resources to commercialize our products under development in a timely fashion, if ever.

We may experience numerous unforeseen events during or as a result of clinical trials that we may be required to perform that could delay or prevent our ability to receive marketing approval or commercialize our products, including:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- the failure to successfully complete clinical trials testing requirements required by the FDA and foreign health regulatory authorities;

- we may experience delays in reaching agreement (or fail in reaching agreement) on acceptable clinical trial contracts with third parties or acceptable clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among trial sites;

- clinical trials of the technology underlying *PressureSafe*™, DiaSafe™ s devices may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our development programs;

- the number of people with the necessary disorders required for clinical trials may be larger than we anticipate. Enrollment in these clinical trials may be slower than we anticipate. People may drop out of these clinical trials or fail to return for follow-up at a higher rate than we anticipate;

- our third-party contractors conducting the clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- the cost of clinical trials of our products may be greater than we anticipate;

- the supply or quality of our products or other materials necessary to conduct clinical trials of our products may be insufficient or inadequate; and

- delays from our suppliers and manufacturers could impact clinical trial completion and impact future revenue.

If we are required to conduct clinical trials or other testing of our proposed devices under development beyond those that we contemplate or if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- not obtain commercial sale approvals at all;

- be delayed in obtaining commercial sale approvals for our planned products under development in a jurisdiction; or

- be subject to additional testing requirements.

Our development costs will also increase if we experience delays in testing or commercial sale approval from regulatory authorities. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could allow our competitors to bring innovative products to market before we do and impair our ability to successfully commercialize our products.

Changes in the configuration of the technology underlying our devices under development may result in additional costs or delay.

As products are developed towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and configuration, are altered along the way in an effort to optimize processes and results. Any changes we make carry the risk that they will not achieve the intended objectives. Any of these changes could cause our products under development to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered device. Such changes may also require additional testing, regulatory notification or regulatory approval. This could delay the completion of clinical trials, increase costs, delay approval of our future products and jeopardize our ability to commence sales and generate revenue.

We currently have one product that is approved for commercial sale. However, we are unable to predict if our additional products will receive commercial sale approval from regulatory authorities as applicable. If we experience significant delays in doing so, our business will be adversely affected.

We currently have one product that is approved for commercial sale. On April 9, 2024, the *PressureSafe*™ decision support device received an FDA listing certification. *PressureSafe*™ is classified as a Class I device. We are currently working on completing larger scale production of the commercial version of the *PressureSafe*™ device, with initial sales planned during the second half of 2025, following the listing under the FDA. Our ability to generate revenue from our developed products, if any, will depend heavily on their successful development, commercial sale approval, and eventual commercialization. The success of any product that we develop will depend on several factors, including:

- receipt of timely approval from foreign health regulatory authorities (if we seek approval in any jurisdiction outside the United States);
- successful completion of all necessary bench testing, and clinical trials, if necessary;
- our ability to procure and maintain suppliers and manufacturers of the components of the technology underlying *PressureSafe*™ and future versions;
- launching commercial sales of our devices, if approved for commercial sale;
- market acceptance of our devices under development, if approved, by the medical community and third-party payers;
- our ability to obtain extensive coverage and reimbursement for use of our devices;
- the perceived advantages, cost, safety, convenience and accuracy of alternative diagnostic methods;

- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our technology and otherwise protecting our rights in our intellectual property portfolio; and
- maintaining compliance with regulatory requirements, including current good manufacturing practices.

Whether FDA commercial sale approval will be granted for additional products is unpredictable and may depend upon several factors, including the substantial discretion of the regulatory authorities. We may need to perform clinical trials, and the FDA (and as we seek to commercialize in selected international geographies, other foreign regulatory authorities) may require that we conduct additional bench testing, and/or clinical trials, provide additional data, take additional manufacturing steps, or require other conditions, before they let us to market our device. If the FDA or other foreign regulatory authority requires additional clinical trials or data, we would incur increased costs and delays in the access to market, which may require us to expend more resources than we have available.

In cases where we are successful in obtaining commercial sale approval to market one or more of our products, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain commercial sale approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of people we target is not as significant as we estimate or the treatment population is narrowed by competition, physician choice or diagnostic guidelines, we may not generate significant revenue from sales of such products, even if they are available on the market.

Commercial sale approval in the United States by the FDA does not guarantee approval by other regulatory authorities in other countries or jurisdictions or ensure approval for the same conditions of use. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval processes

vary between countries and can involve additional product testing and validation and additional administrative review periods. No product we develop may ever obtain commercial sale approval in the United States or any other jurisdiction, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these approvals promptly or at all, we could experience significant delays or an inability to fully commercialize any product and achieve profitability.

Both before and after a product is commercially released, we will have ongoing responsibilities under U.S. and corresponding foreign regulations, as applicable. We will also be subject to periodic inspections by the FDA and other foreign regulatory authorities as applicable, to determine compliance with U.S. regulatory requirements, such as the Quality System Regulation, or QSR, the medical device reporting, or MDR, the reporting of adverse events and recalls, the regulations regarding notification on changes and other corresponding regulations of other foreign regulatory authorities, as applicable. These inspections can result in observations or reports, warning letters or other similar notices or forms of enforcement action. If the FDA, or any other foreign authority as applicable, concludes that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable health risk, such authority could ban these products, suspend or cancel our marketing authorizations, impose "stop-sale" and "stop-import" orders, refuse to issue export certificates, detain or seize adulterated or misbranded products, order a recall, repair, replacement, correction or refund of such products, or require us to notify health providers and others that the products present unreasonable risks of substantial harm to the public health. Discovery of previously unknown problems with our product's design or manufacture may result in restrictions on use, restrictions placed on us or our suppliers, or withdrawal of an existing commercial sale approval. The FDA or comparable foreign authority may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, assess civil or criminal penalties against our officers, employees or us, or recommend criminal prosecution of our Company. Adverse regulatory action may restrict us from effectively marketing and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our business, financial condition and operating results.

Foreign governmental regulations have become increasingly stringent and more extensive, and we may become subject to even more rigorous regulation by foreign governmental authorities in the future. Penalties for a company's non-compliance with foreign governmental regulation could be severe, including revocation or suspension of a company's business license and civil or criminal sanctions.

Our success depends on our ability to complete development, commercialize and gain market acceptance initially for PressureSafe™ and thereafter for any other device.

Our current business strategy is highly dependent on developing and commercially launching one product initially, our*PressureSafe*™ device and achieving and maintaining market acceptance. We may face challenges convincing physicians, many of whom have extensive experience with competitors' products and established relationships with other companies, to appreciate the benefits of *PressureSafe*™ in a way that is superior to and differentiated from currently available technology or know-how and adopt it for supporting diagnostics for their patients.

Moreover, healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement.

If we are unable to achieve the support of caregivers and healthcare providers or widespread market acceptance for our devices, then our sales potential, strategic objectives and profitability could be negatively impacted, which would adversely affect our business, financial condition and operating results.

We depend on the knowledge and skills of our senior management and our Board of Directors.

We have benefited substantially from the leadership and performance of our senior management. Our success will depend on our ability to retain our current management and recruit additional management personnel. Competition for senior management in our industry is intense, and we cannot guarantee that we will be able to retain our personnel or recruit additional personnel. The loss of the services of certain members of our senior management could prevent or delay the implementation and completion of our strategic objectives or divert management's attention to seeking qualified replacements. In addition, our Board of Directors has determined to limit our operations until such time as sufficient funds that can support our operations have been identified. In December 2024, the company terminated the employment of 4 of its 7 employees.

It may be difficult to enforce a U.S. judgment against us, our officers and directors and the foreign persons named in this registration statement in the United States or in foreign countries, or to assert U.S. securities laws claims in foreign countries or serve process on our officers and directors and these experts.

While we are incorporated in the State of Nevada, currently a majority of our directors and executive officers are not residents of the United States. The majority of our assets are located outside the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws against us or any of these persons in a U.S. or foreign court, or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in foreign countries. Foreign courts may refuse to hear a claim based on a violation of U.S. securities laws on the grounds that foreign countries are not necessary the most appropriate forum in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that foreign law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by foreign countries' law. There is little binding case law in foreign countries addressing the matters described above.

The size and future growth in the market for our planned devices under development has not been established with precision and may be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market, our sales growth may be adversely affected.

Our estimates of the size and future growth in the market for our intended devices under development, including the number of people who may benefit from and be amenable to using our devices for diagnosis, is based on a number of internal and third-party studies, reports and estimates. In addition, our internal estimates are based in large part on current diagnostic patterns by healthcare providers using current generation technology, and our belief is that the incidence of misdiagnosed skin pressure injuries and ear infections in children in the United States and worldwide is increasing. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for our intended products under development, these estimates may not be correct, and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. The actual incidence of these phenomenon, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. As a result, our estimates of the size and future growth in the market for our intended products may prove to be incorrect, it may impair our projected sales growth and have an adverse impact on our business.

Undetected errors or defects in our planned medical devices under development or future versions thereof could harm our reputation, decrease the market acceptance of PressureSafe™ and DiaDafe™.

The technology underlying *PressureSafe*™ and *DiaDafe* may contain undetected errors or defects. Disruptions or other performance problems with devices may delay development, prevent regulatory clearance or harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in the *PressureSafe*™ and *DiaDafe*™ devices or future versions thereof. Material liability claims or other occurrences that harms our reputation or decreases market acceptance of our planned products could harm our business and operating results. This risk exists even if a device is available for commercial sale and manufactured.

Any product candidate we may advance into clinical trials (assuming the FDA so requires) may be subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates, all of which can adversely affect our business.

Before we can market a new medical device, such as our proposed products, we must first receive clearance under Section 510(k) of the FDA. In the 510(k) clearance process, before a device may be marketed in the US, the FDA must determine that such proposed device is "substantially equivalent" to a legally marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed before May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market under an approved pre-market approval, or PMA, and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device.

The 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months but can last longer. Despite the time, effort and cost, a device may not be cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances could harm our business, including our ability to commercialize our product and our shareholders could lose their entire investment. Furthermore, even if we are granted the required regulatory clearances, such clearances may be subject to significant limitations on the indicated uses for the device, which may limit the market for our product.

As noted, on April 9, 2024, the *PressureSafe*™ decision support device received an FDA listing certification. PressureSafe™ is classified as a Class I device. We are currently working on completing larger scale production of the commercial version of the *PressureSafe*™ device, with initial sales planned during the first half of 2025, following the listing under the FDA. However, no assurance can be granted that we will receive 510(K) clearances for our additional products. If the 510(k) clearance is not granted to us, the device testing, clinical trials, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our additional product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets.

Despite the time and expense invested in clinical trials of product candidates, commercial sale approval from applicable regulatory authorities is never guaranteed.

FDA or other regulatory agencies can delay, limit, or deny approval of a product candidate for many reasons, including:

- the FDA or other foreign regulatory authority as applicable may disagree with the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for any indication;
- the FDA may not accept the clinical data from trials which are conducted by individual investigators in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for clearance;
- the FDA may disagree with our interpretation of data from the bench testing or clinical trials;
- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly be changed in a manner rendering our clinical data insufficient for approval.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products or impact our ability to modify our products after clearance on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain clearance for our devices, increase the costs of compliance or restrict our ability to maintain products after clearance. For example, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance. Some of these proposals and reforms could impose additional regulatory requirements upon us that could delay our ability to obtain new clearance, increase the costs of compliance, or restrict our ability to maintain any commercial sale approval we can obtain.

Concerning foreign markets, approval procedures vary among countries and can involve additional product testing and administrative review periods. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, among other things, trade secrets or other intellectual property, and proprietary business information). We must do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result, we manage several third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or to cyber-attacks by malicious third parties. Cyber-attacks are increasing in frequency, sophistication, and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

Significant disruptions of our information technology systems, or those of our third-party vendors or business partners, or security breaches could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information, including, among other things, trade secrets or other intellectual property, and proprietary business information, and could result in financial, legal, business and reputational harm to us. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business. In addition, our liability insurance may not be sufficient in type or amount to cover us against costs of or claims related to security breaches, cyber-attacks, and other related breaches. A cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue, or litigation. See "Item C1. Cybersecurity" for additional information.

We may be subject to numerous and varied privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to laws and regulations covering data privacy and the protection of personal information, including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act.

Other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. The EU and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, for example, effective May 25, 2018, the General Data Protection Regulation, or GDPR, replaced the prior EU Data Protection Directive (95/46) that governed the processing of personal data in the European Union. The GDPR imposes significant obligations on controllers and processors of personal data, including, as compared to the prior directive, higher standards for obtaining consent from individuals to process their personal data, more robust notification requirements to individuals about the processing of their personal data, a strengthened individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data and increased requirements pertaining to health data, and strict rules and restrictions on the transfer of personal data outside of the EU, including to the U.S. The GDPR also imposes additional obligations on, and required contractual provisions to be included in, contracts between companies subject to the GDPR and their third-party processors that relate to the processing of personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data.

Any failure to comply with the requirements of GDPR and applicable national data protection laws of EU member states could lead to regulatory enforcement actions and significant administrative and/or financial penalties against us (including fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher), and could adversely affect our business, financial condition, cash flows and results of operations.

If we or our third-party manufacturers fail to comply with the FDA's Quality System Regulation, or QSR, our manufacturing operations could be interrupted.

In the US, we and our future contract manufacturers are required to comply with the FDA's QSR requirements which cover the methods and documentation of the design, testing, production, quality control, labeling, packaging, storage shipping and distribution of our products. In other foreign countries International Organization for Standardization (ISO) 13485 standard is used to show compliance with the design and manufacturing requirements. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we or our distributors market our products abroad. We continue to monitor our quality management in order to improve our overall level of compliance. Our facilities will be subject to periodic and unannounced inspection by U.S. and other foreign regulatory agencies as applicable to audit compliance with the regulations. If our facilities or those of our suppliers are found to be in violation of applicable laws and regulations, or if we or our suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- recalls, withdrawals, or administrative detention or seizure of our products;
- refusing or delaying requests for 510(k) marketing clearance applications relating to new products or modified products;
- withdrawing the product from the market;
- refusing to provide Certificates for Foreign Government;
- refusing to grant export approval for our products; or
- pursuing cminal prosecution.

Any of these sanctions could impair our ability to produce*PressureSafe*™ or *DiaDafe*™ in a cost-effective and timely manner in order to meet our customers' demands and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

We intend to rely on third parties to conduct clinical trials (if needed). If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical trials programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our clinical trials ourselves. We intend to use Contract Research Organizations, or CROs, to conduct clinical trials that we may be required to conduct and will rely upon medical institutions, clinical investigators and CRO's and consultants to conduct these trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet the expected deadlines, fail to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of these clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for any clinical trials we conduct may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

If our competitors develop tools for the target indications of our product candidates that are approved more quickly, marketed more successfully or demonstrated to be more effective or accurate than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in highly competitive segments of the medical device markets. We face competition from many different sources, including commercial medical device enterprises, academic institutions, government agencies and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established methods, as well as new diagnostic technologies that may be introduced by our competitors. Our competitors may have significantly greater financial, product development, manufacturing and marketing resources than us. Large medical device companies have extensive experience in clinical testing and obtaining regulatory approval for medical devices. We also may compete with these organizations to recruit management, scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including

the development of other medical device technologies and methods of pressure injuries and ear infections diagnostics, may occur in the medical device industries at a rapid pace. Developments by competitors may render our product candidates obsolete or non-competitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market and sell any products we may successfully develop, we may not be able to effectively market and sell any such products and generate product revenue.

The establishment and development of a sales force, either by us or jointly with a third-party distributor, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch. If we, or our development partners, are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may successfully develop, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third parties on acceptable terms, if at all.

If we are not able to develop a strong brand and/ or increase market awareness for our product candidates, then our business, results of operations and financial condition may be adversely affected.

We believe that the success of our product candidates will depend in part on our ability to develop a strong brand identity for our company and products, and to increase the market awareness of our product and their capabilities, once these products are commercially launched. The successful promotion of our brand will depend largely on our continued marketing efforts and our ability to offer high quality AI capabilities with our products and ensure that our technology provides the expected benefits. Our brand promotion and thought leadership activities may not be successful or produce revenue. In addition, independent industry analysts may provide reviews of our products and of competing products and services, which may significantly influence the perception of our products in the marketplace. If these reviews are negative or not as positive as reviews of our competitors' products and services, then our brand may be harmed.

The promotion of our brand also requires us to make substantial expenditures, and we anticipate that this expenditure will increase as our industry becomes more competitive and as we seek to expand into new markets. These higher expenditures may not result in any increased revenue or in revenue that is sufficient to offset the higher expense levels. If we do not successfully maintain and enhance our brand, then our business may not grow, we may see our pricing power reduced relative to competitors and we may lose customers, all of which would adversely affect our business, results of operations and financial condition.

Failure to manage our growth effectively could increase our expenses, decrease our revenue and prevent us from implementing our business strategy.

We expect that our ability to generate revenues and achieve profitability will require substantial growth in our business, which will put a strain on our management and financial resources. To manage this and our anticipated future growth effectively, including as we expand into new clinical areas and geographic regions, we must continue to maintain and enhance our information technology infrastructure, as well as our financial and accounting systems and controls. We also must attract, train and retain a significant number of qualified software and hardware developers and engineers, technical and management personnel, sales and marketing personnel and customer and channel partner support personnel. Failure to effectively manage our rapid growth could lead us to over-invest or under-invest in development and operations, result in weaknesses in our systems or controls, give rise to operational mistakes, losses, loss of productivity or business opportunities and result in loss of employees and reduced productivity of remaining employees. Our growth could require significant capital expenditure and might divert financial resources from other projects such as the development of new products and services. If our management is unable to effectively manage our growth, our expenses might increase more than expected, our revenue could decline or grow more slowly than expected, and we might be unable to implement our business strategy. The quality of our products and services might suffer, which could negatively affect our reputation and harm our ability to retain and attract channel partners or customers.

Failure to secure or retain coverage or adequate reimbursement for our planned products in development by third-party payors could adversely affect our business, financial condition and operating results.

We plan to derive nearly all of our revenue from sales, initially, of our*PressureSafe*™ device under development, in the United States and potentially in selected international geographies and expect to do so for the next several years. We anticipate a substantial portion of the purchase price of our product and disposables will be paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Patients who receive services for their medical conditions and their healthcare providers generally rely on third-party payors to reimburse all or part of the costs associated with their medical treatment and diagnosis, including healthcare providers' services. Coverage and adequate reimbursement from third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, and commercial payors, is critical to new product acceptance. Future sales of our *PressureSafe*™ device initially will be limited unless healthcare providers can rely on third-party payors to pay for all or part of the cost to purchase/lease our devices and then pay for the disposable components. Access to adequate coverage and reimbursement by third-party payors is essential to the market acceptance of our products.

In the United States, a third-party payor's decision to provide coverage for our products does not imply that an adequate reimbursement rate will be obtained. Further, one third-party payor's decision to cover our products does not assure that other payors will also provide coverage for the products or will provide coverage at an adequate reimbursement rate. Healthcare providers may choose not to order a product and/or disposables unless third-party payors pay a substantial portion of the product and disposables. Within and outside the United States, reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans. These third-party payors determine whether to provide coverage and reimbursement for specific products and procedures. Coverage determinations and reimbursement levels of our products are critical to the commercial success of our product, and if we are not able to secure positive coverage determinations and reimbursement levels for our products, our business would be materially adversely affected.

In addition, there may be significant delays in obtaining reimbursement, and coverage may be more limited than the purposes for which the product received commercial sale approval from the FDA or other foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States.

Third-party payors, whether foreign or domestic, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance

systems as well as government-managed systems. If sufficient coverage and reimbursement is not available for any product we develop, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

If we fail to attract and retain key management and R&D personnel, we may be unable to successfully develop or commercialize our product candidates.

In December 2024, the company terminated the employment of 4 of its 7 employees currently the company employee 4 employees . We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our product development and commercialization efforts. As a company with a limited number of personnel, we are highly dependent on the development, regulatory, commercial and financial expertise of the members of our senior management. The loss of such individuals or the services of any of our other senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to the intense competition for qualified personnel among biotechnology, medical device and high-technology and companies, as well as universities and research organizations. If we are not able to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy. During the third quarter of 2024 we recruited a new Chief Executive Officer to lead our business strategy.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other products or technologies that may enhance our products, platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify suitable acquisitions, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology, our competitors could develop and commercialize technology similar to ours, and our competitive position could be harmed.

We rely on a combination of patent and trademark laws in the United States and other countries, trade secret protection, confidentiality agreements and other contractual arrangements with our employees, consultants and others to maintain our competitive position. In particular, our success depends, in part, on our ability to maintain patent protection for our products, technologies and inventions, maintain the confidentiality of our trade secrets and know-how, operate without infringing upon the proprietary rights of others and prevent others from infringing upon our proprietary rights. Despite our efforts to protect our proprietary rights, it is possible that competitors or other unauthorized third parties may obtain, copy, use or disclose our technologies, inventions, processes or improvements. Moreover, other parties may independently develop similar or competing technology, methods, know-how or design around any patents that may be issued to or held by us. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We cannot assure you that our existing or any future patents or other intellectual property rights will not be challenged, invalidated or circumvented, or will otherwise provide us with meaningful protection. If our patents and other intellectual property do not adequately protect our technology, our competitors may be able to offer products similar to ours. Our competitors may also be able to develop similar technology independently or design around any patent(s) granted to us, and we may not be able to detect the unauthorized use of our proprietary technology or take appropriate steps to prevent such use.

Any such activities by our competitors that circumvent our intellectual property protection could subvert our competitive advantage and have an adverse effect on our results of operations.

Furthermore, filing, prosecuting, maintaining and defending patents on our solutions in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Also, it may not be possible to effectively enforce intellectual property rights in some foreign countries at all or to the same extent as in the United States and other countries. Consequently, we may be unable to prevent third parties from using our inventions in all countries, or from selling or importing products made using our inventions in the jurisdictions in which we do not have (or are unable to effectively enforce) patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop, market or otherwise commercialize their own products, and we may be unable to prevent those competitors from importing those infringing products into territories where we have patent protection, but enforcement is not as strong as in the United States.

We may be sued by third parties for alleged infringement of their proprietary rights, which could adversely affect our business, results of operations and financial condition.

There is often litigation between competing companies relying on their respective technologies based on allegations of infringement or other violations of intellectual property rights. Our future success depends, in part, on not infringing the intellectual property rights of others. We may be unaware of the intellectual property rights of others that may cover some or all of our technology. Any such claims or litigation could cause us to incur significant expenses and, if successfully asserted against us, could require that we pay substantial damages or ongoing royalty payments, prevent us from offering some portion of our products, or require that we comply with other unfavorable terms. We may also be obliged to indemnify our customers or channel partners in connection with any such litigation and to obtain licenses or modify our products, which could further exhaust our resources. Patent infringement, trademark infringement, trade secret misappropriation and other intellectual property claims and proceedings brought against us, whether successful or not, could harm our brand, business, results of operations and financial condition. Litigation is inherently uncertain, and any judgment or injunctive relief entered against us, or any adverse settlement could negatively affect our business, results of operations and financial condition. In addition, litigation can involve significant management time and attention and be expensive, regardless of the outcome. During the course of litigation, there may be announcements of the results of hearings

and motions, and other interim developments related to the litigation. If securities analysts or investors regard these announcements as negative, the trading price of our ordinary shares may decline.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and ultimately unsuccessful.

If we attempt enforcement of our patents or other intellectual property rights, we may be subject or party to claims, negotiations or complex, protracted litigation. These claims and any resulting lawsuits, if resolved adversely to us, could subject us to significant liability for damages, impose temporary or permanent injunctions against our solutions or business operations, or invalidate or render unenforceable our intellectual property.

Intellectual property disputes and litigation, regardless of merit, can be costly and disruptive to our business operations by diverting the attention of management and key technical personnel, and by increasing our costs of doing business. Such litigation, regardless of its success, could seriously harm our reputation with our channel partners, business partners, and patients and in the industry at large. Some of our competitors may be able to sustain the costs of complex patent or intellectual property litigation more effectively than we can because they have substantially greater resources. Any of the foregoing could adversely affect our operating results.

Risks Relating to Our Israel Operations

Our technology development personnel are headquartered in Israel and, therefore, our results may be adversely affected by economic restrictions imposed on, and political and military instability in, Israel.

Our technology development headquarters, which houses substantially all of our research and development team, including engineers, machinists, researchers, and clinical and regulatory personnel as well as the facility of our contract manufacturer and final assembly are located in Israel. Our employees, service providers, directors and officers are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could materially and adversely affect our business, financial condition and results of operations and could make it more difficult for us to raise capital. Although we plan to maintain inventory in the United States and Germany, an extended interruption could materially and adversely affect our business, financial condition and results of operations.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas, and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks.

Following the attack by Hamas on Israel's southern border, Hezbollah, a terrorist organization in Lebanon, has also launched missile, rocket, and shooting attacks against Israeli military sites, troops, and Israeli towns in northern Israel. In response to these attacks, the Israeli army has carried out a number of targeted strikes on sites belonging to Hezbollah in southern Lebanon, and in October 2024, the Israeli military initiated a ground operation in Lebanon, primarily near the Israel-Lebanon border. As of the end of November 2024, Israel entered into a ceasefire agreement with Hezbollah, but there are no guarantees as to whether the agreement will hold or whether further hostilities will resume. As of April 4, 2025, the ceasefire that had been in place since January 2025 has ended, and hostilities have resumed.

In April and October 2024, Iran launched missile and unmanned aerial vehicle, or UAV, attacks on Israel. Most of the missiles and UAVs were intercepted by Israel's defense systems, with support from the United States and other countries, including regional allies, preventing significant damage and resulting in no casualties. Despite the successful interceptions, the attacks posed an elevated threat to Israel's security. In response to the Iranian attack in April 2024, Israel conducted targeted military strikes against Iranian military assets in Syria, aiming to degrade Iran's operational capabilities in the region and deliver a strong deterrent message. On April 19, 2024, the air force base in Esfahan, Iran, and the A-T'ala airport in the A-Sweida area of southern Syria were attacked, with these strikes attributed to Israel.

The intensity and duration of Israel's current multi-front war is difficult to predict, as are such war's economic implications on the Company's business and operations and on Israel's economy in general. These events may be intertwined with wider macroeconomic indications of a deterioration of Israel's economic standing, which may have a material adverse effect on the Company and its ability to effectively conduct some of its operations.

Our commercial insurance does not cover losses that may occur as a result of events associated with war and terrorism. It is possible that other terrorist organizations, including Palestinian military organizations in the West Bank, as well as other hostile countries, such as Iran, will join the hostilities. Such hostilities may include terror and missile attacks. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. Any armed conflicts, terrorist activities or political instability in the region could materially and adversely affect our business, financial condition and results of operations.

Our operations and the operations of our contract manufacturer may be disrupted as a result of the obligation of Israeli citizens to perform military service.

Many Israeli citizens are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 45 (or older, for reservists with certain occupations) and may be called to active duty. In connection with the Israeli security cabinet's declaration of war against Hamas and possible hostilities with other organizations, several hundred thousand Israeli military reservists were drafted to perform immediate military service. One of our employees and consultants (and their spouses or partners) in Israel have been called, and additional employees (or their spouses or partners) may be called, for service in the current or future wars or other armed conflicts with Hamas, and such persons may be absent for an extended period of time. As a result, our operations in Israel may be disrupted by such absences, which disruption may materially and adversely affect our business, prospects, financial condition and results of operations.

Our sales may be adversely affected by boycotts of Israel.

Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise, and specifically following the Israel- Hamas war. In addition, there have been increased efforts by activists to cause companies and consumers to boycott Israeli goods based on Israeli government policies. Such actions, particularly if they become more widespread, may adversely impact our ability to sell our products.

Our subsidiary has received Israeli government grants for certain of our research and development activities and we may receive additional grants in the future. The terms of those grants restrict our ability to transfer technologies outside of Israel, and we may be required to pay penalties in such cases or upon the sale of our company.

As of the date of this prospectus, our subsidiary, IR. Med Ltd., received a total of approximately $903,000 from the IIA. We may in the future apply to receive additional grants from the IIA to support our research and development activities. With respect to such grants, we are committed to pay royalties at a rate of 3.0% to 3.5% on sales proceeds up to the total amount of grants received, linked to the U.S. dollar and bearing interest at an annual rate of LIBOR applicable to dollar deposits. Until October 25, 2023, the interest was calculated at a rate based on 12-month LIBOR applicable to U.S. Dollar deposits. However, on October 25, 2023, the IIA published a directive

concerning changes in royalties to address the expiration of the LIBOR. Under such directive, regarding IIA grants approved by the IIA prior to January 1, 2024 but which are outstanding thereafter, as of January 1, 2024 the annual interest is calculated at a rate based on 12-month SOFR, or at an alternative rate published by the Bank of Israel plus 0.71513%; and, for grants approved on or following January 1, 2024, the annual interest shall be the higher of (i) the 12 months SOFR interest rate, plus 1%, or (ii) a fixed annual interest rate of 4%. Even after payment in full of these amounts, we will still be required to comply with the requirements of the Israeli Encouragement of Industrial Research, Development and Technological Innovation Law, 1984, or the R&D Law, and related regulations, with respect to those past grants. When a company develops know-how, technology or products using IIA grants, the terms of these grants and the R&D Law restrict the transfer outside of Israel of such know-how, and of the manufacturing or manufacturing rights of such products, technologies or know-how, without the prior approval of the IIA. Therefore, if aspects of our technologies are deemed to have been developed with IIA funding, the discretionary approval of an IIA committee would be required for any transfer to third parties outside of Israel of know-how or manufacturing or manufacturing rights related to those aspects of such technologies. Furthermore, the IIA may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel or may not grant such approvals at all.

Furthermore, the consideration available to our shareholders in a future transaction involving the transfer outside of Israel of technology or know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA. Any such mergers require IIA approval to avoid penalties.

In addition to the above, any non-Israeli citizen, resident or entity that, among other things, (i) becomes a holder of 5% or more of our share capital or voting rights, (ii) is entitled to appoint one or more of our directors or our chief executive officer or (iii) serves as one of our directors or as our chief executive officer (including holders of 25% or more of the voting power, equity or the right to nominate directors in such direct holder, if applicable) is required to notify the IIA and undertake to comply with the rules and regulations applicable to the grant programs of the IIA, including the restrictions on transfer described above. Such notification will be required in connection with the investment being made by an investor.

Risks Related to this Offering and the Ownership of Our Common Stock

There is not now, and there may never be, an active, liquid and orderly trading market for our common stock, which may make it difficult for you to sell your shares of our common stock.

There is not now, nor has there been, since our inception, an orderly and liquid market for shares of our common stock, and an active trading market for our shares may never develop or be sustained after this offering. As a result, investors in our common stock must bear the economic risk of holding those shares for an indefinite period of time. Our common stock is quoted on the OTCQB-tier of the OTC Markets, an over-the-counter quotation system. An active market for our common stock may never develop or be sustained. If an active market for our common stock does not develop, it may be difficult for you to sell the shares you purchase in this offering without depressing the market price for the shares or at all. Further, an inactive market may also impair our ability to raise capital by selling additional equity in the future and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that our stockholders do not consider to be in their best interests.

Currently, our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 39% of our outstanding voting securities. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices. This concentration of ownership and influence in management and board decision-making could also harm the price of our capital stock by, among other things, discouraging a potential acquirer from seeking to acquire shares of our capital stock (whether by making a tender offer or otherwise) or otherwise attempting to obtain control of our company.

Sale of our common stock by our stockholders could encourage short sales by third parties, which could contribute to the further decline of our stock price.

The significant downward pressure on the price of our common stock caused by the sale of material amounts of common stock could encourage short sales by third parties. Such an event could place further downward pressure on the price of our common stock.

Our common stock has been thinly traded and we cannot predict the extent to which an active trading market will develop.

Our common stock is traded on the OTCQB-tier of OTC Markets. Our common stock is thinly traded when compared to larger more widely known companies. Thinly traded common stock can be more volatile than common stock trading in an active public market. We cannot predict the extent to which an active public market for our common stock will develop or be sustained after this offering.

Our share price is expected to be volatile and may be influenced by numerous factors, some of which are beyond our control.

Market prices for shares of biotechnology and medical device companies such as ours are often volatile, and the quoted price of our common stock is therefore likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the product candidates we seek to pursue and our ability to obtain rights to develop, commercialize and market those candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;

- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;

- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and medical device industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stocks of small-cap biotechnology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition, other biotechnology and medical device companies or our competitors' programs could have positive or negative results that impact their stock prices, and their results or stock fluctuations could have a positive or negative impact on our stock price regardless of whether such impact is direct or not. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

Future capital raises may dilute our existing shareholders' ownership, the value of their equity securities and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities in connection with equity financing, our existing shareholder' percentage ownership may decrease, and these shareholders may experience substantial dilution. If we raise additional funds by issuing debt instruments, these debt instruments could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or products, or to grant licenses on terms that are not favorable to us or could diminish the rights of our shareholders. Furthermore, if we offer to sell our shares of Common Stock in subsequent offerings for the purchase price that is less than the purchase price of shares of Common Stock offered pursuant to this prospectus, this may impact the value of equity securities of the shareholders that are purchasing our shares of Common Stock in the offering pursuant to this prospectus. In addition, the issuance of such additional shares may impact the ability of any investor to sell their shares once such shares are eligible for sale.

The sale of shares of our Common Stock to Williamsburg may cause dilution, and the subsequent resale of the shares of our Common Stock acquired by Williamsburg, or the perception that such resales may occur, could cause the price of our Common Stock to fall.

Under the Purchase Agreement, we may require Williamsburg to purchase up to $15 million of our Common Stock, except that, pursuant to the terms of the Purchase Agreement, we would be unable to sell shares to Williamsburg if such purchase would result in its beneficial ownership of more than 9.99% of our outstanding Common Stock. After Williamsburg has acquired our shares, it may sell all, some, or none of those shares. Therefore, sales to Williamsburg by us could result in substantial dilution to the interests of other holders of our Common Stock. Additionally, the sale of a substantial number of shares of our Common Stock to Williamsburg, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish. Under the Purchase Agreement, Williamsburg's per-share purchase price for our shares will be equal to 90% of the average of the two lowest VWAPs of the Common Stock on the Principal Market during five consecutive Trading Days immediately preceding the Clearing Date associated with the applicable Put Notice during which the purchase price is valued. Depending on market liquidity at the time, resales of these shares may cause the trading price of our Common Stock to fall.

Williamsburg will pay less than the then-prevailing market price for our Common Stock.

We will sell shares of our Common Stock to Williamsburg pursuant to the Purchase Agreement at 90% of the average of the two lowest VWAPs of the Common Stock on the Principal Market during five consecutive Trading Days immediately preceding the Clearing Date associated with the applicable Put Notice during which the purchase price is valued. Williamsburg has a financial incentive to sell our Common Stock immediately upon receiving the shares to realize the profit equal to the difference between the discounted price and the market price. If Williamsburg sells the shares, the market price of our Common Stock could decrease.

The Company's election not to opt out of JOBS Act extended accounting transition period may not make its financial statements easily comparable to other companies.

Pursuant to the JOBS Act, as an emerging growth company, the Company can elect to opt out of the extended transition period for any new or revised accounting standards that may be issued by the PCAOB or the SEC. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the standard for the private company. This may make comparison of the Company's financial statements with any other public company which is not either an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible as possible different or revised standards may be used.

Our common stock is subject to the "penny stock" rules of the SEC and the trading market in the securities is limited, which makes transactions in the stock cumbersome and may reduce the value of an investment in the stock.

Rule 15g-9 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (i) that a broker or dealer approve a person's account for transactions in penny stocks in accordance with the

provisions of Rule 15g-9; and (ii) the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased, provided that any such purchase shall not be effected less than two business days after the broker or dealer sends such written agreement to the investor.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must: (i) obtain financial information, investment experience and investment objectives of the person and (ii) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be reasonably expected to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which: (i) sets forth the basis on which the broker or dealer made the suitability determination; and (ii) in highlight form, confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also must be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. As a result, it may be more difficult to execute trades of our common stock which may have an adverse effect on the liquidity of our common stock and your investment.

If securities or industry analysts do not publish, or cease publishing, research or publish inaccurate or unfavorable research about our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and any trading volume could decline.

Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business, markets or competitors. Securities and industry analysts do not currently, and may never, publish research on us or our business. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively affected. If securities or industry analysts initiate coverage, and one or more of those analysts downgrade our stock or publish inaccurate or unfavorable research about our business or our market, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

"Penny stock" rules may make buying or selling our Common Stock difficult. Limitations upon Broker-Dealers Effecting Transactions in "penny stocks"

Trading in our Common Stock is subject to material limitations as a consequence of regulations which limit the activities of broker-dealers effecting transactions in "penny stocks." Pursuant to Rule 3a51-1 under the Exchange Act, our Common Stock is a "penny stock" because it (i) is not listed on any national securities exchange (ii) has a market price of less than $5.00 per share, and (iii) its issuer (the Company) has net tangible assets less than $2,000,000 (if the issuer has been in business for at least three (3) years) or $5,000,000 (if the issuer has been in business for less than three (3) years).

Rule 15g-9 promulgated under the Exchange Act imposes limitations upon trading activities on "penny stocks", which makes selling our Common Stock more difficult compared to selling securities which are not "penny stocks." Rule 15a-9 restricts the solicitation of sales of "penny stocks" by broker-dealers unless the broker first (i) obtains from the purchaser information concerning his financial situation, investment experience and investment objectives, (ii) reasonably determines that the purchaser has sufficient knowledge and experience in financial matters that the person is capable of evaluating the risks of investing in "penny stocks", and (iii) delivers and receives back from the purchaser a manually signed written statement acknowledging the purchaser's investment experience and financial sophistication.

Rules 15g-2 through 15g-6 promulgated under the Exchange Act require broker-dealers who engage in transactions in "penny stocks" first to provide their customers with a series of disclosures and documents, including (i) a standardized risk disclosure document identifying the risks inherent in investing in "penny stocks", (ii) all compensation received by the broker-dealer in connection with the transaction, (iii) current quotation prices and other relevant market data, and (iv) monthly account statements reflecting the fair market value of the securities.

There can be no assurance that any broker-dealer which initiates quotations for the Common Stock will continue to do so, and the loss of any such broker-dealer likely would have a material adverse effect on the market price of our Common Stock.

FINRA sales practice requirements may also limit a stockholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described below, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our Common Stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

Because our Common Stock is deemed a low-priced "penny stock," it will be cumbersome for brokers and dealers to trade in our Common Stock, making the market for our Common Stock less liquid and negatively affect the price of our stock.

We will be subject to certain provisions of the Exchange Act, commonly referred to as the "penny stock" rules as defined in Rule 3a51-1. A penny stock is generally defined to be any equity security that has a market price less than $5.00 per share, subject to certain exceptions. Since our stock is deemed to be a penny stock, trading is subject to additional sales practice requirements of broker-dealers. These require a broker-dealer to:

- Deliver to the customer, and obtain a written receipt for, a disclosure document;
- Disclose certain price information about the stock;
- Disclose the amount of compensation received by the broker-dealer or any associated person of the broker-dealer;
- Send monthly statements to customers with market and price information about the penny stock; and
- In some circumstances, approve the purchaser's account under certain standards and deliver written statements to the customer with information specified in the rules.

Consequently, penny stock rules and FINRA rules may restrict the ability or willingness of broker-dealers to trade and/or maintain a market in our Common Stock. Also, prospective investors may not want to get involved with the additional administrative requirements, which may have a material adverse effect on the trading of our shares.

We are an "emerging growth company" under the JOBS Act of 2012 and a "smaller reporting company" and, as a result of the reduced disclosure and

governance requirements applicable to emerging growth companies and smaller reporting companies, our Common Stock may be less attractive to investors.

We are an "emerging growth company", as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards.

We will remain an "emerging growth company" until the earlier of (i) the last day of the year following the fifth anniversary of the date of the completion of our initial public offering, (ii) the last day of the year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Common Stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period..

Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including, among other things, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an "emerging growth company" and because we will have an extended transition period for complying with new or revised financial accounting standards, we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected**.**

Since we are traded on OTCQB, an active, liquid trading market for our Common Stock may not develop or be sustained. If and when an active market develops the price of our common stock may be volatile.

Presently, our Common Stock is traded on the OTCQB. There is a very limited trading in our stock and there is no assurance that an active market will develop. In the absence of an active trading market, investors may have difficulty buying and selling or obtaining market quotations, market visibility for shares of our Common Stock may be limited, and a lack of visibility for shares of our Common Stock may have a depressive effect on the market price for shares of our Common Stock. The lack of an active market impairs your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares.

Trading in stocks quoted on OTCQB is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. The securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our Common stock. Moreover, OTCQB is not a stock exchange and is not an established market, and trading of Securities is often more sporadic than the trading of securities listed on a national stock exchange like the NYSE. Accordingly, you may have difficulty reselling any shares of Common Stock.

We may have become exposed to material liabilities that were not discovered before, and have not been discovered since, due to the closing of the Acquisition.

As a result of the Acquisition, we are responsible for any liabilities incurred by IR. Med Ltd. IR. Med Ltd. may have material liabilities that have not been discovered or asserted. We could experience losses as a result of any such undisclosed liabilities that are discovered in the future, which could materially harm our business and financial condition. As a result, our current and future stockholders will bear some, or all, of the risks relating to any such unknown or undisclosed liabilities, if any.

We are exposed to additional risks as a result of "going public" by means of a reverse acquisition transaction.

We are exposed to additional risks because the business of IR. Med Ltd. has become a public company through a "reverse acquisition" transaction, or the Acquisition. There has been increased focus in recent years by government agencies on transactions such as the Acquisition, and we may be subject to increased scrutiny by the SEC or other government agencies and holders of our securities as a result of the completion of that transaction. Further, as a result of our existence as a "shell company" under applicable rules of the SEC prior to the closing of the Acquisition, we are subject to certain restrictions and limitations for certain specified periods of time relating to potential future issuances of our securities and compliance with applicable SEC rules and regulations. Additionally, our "going public" by means of a reverse acquisition transaction may make it more difficult for us to obtain coverage from securities analysts of major brokerage firms following the Acquisition because there may be little incentive to those brokerage firms to recommend the purchase of our common stock. Further, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an initial public offering, or IPO, because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock. The occurrence of any such event could cause our business or stock price to suffer.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act, subject to certain exceptions. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and to obtain attestations of the effectiveness of internal controls by independent auditors. As a private company, IR-Med Operations was not subject to requirements to establish, and did not establish, internal control over financial reporting and disclosure controls and procedures prior to the Acquisition. Our management team and Board of Directors will need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance and accounting staff. Additionally, any of our efforts to improve our internal controls and design, implement and maintain

an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on the tradability of our common stock, which in turn would negatively impact our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

If material weaknesses or deficiencies in our internal controls exist and go undetected or unremedied, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

Shares of our common stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(i) which apply to a former "shell company."

We were previously deemed a "shell company" under applicable SEC rules and regulations, prior to the reverse merger transaction in which we became a public company, because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 of the Securities Act, sales of the securities of a former shell company, such as us, are not permitted unless at the time of a proposed sale, (i) we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act; and (ii) we have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than current reports on Form 8-K. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future. The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time than a non-former shell company could cause the market price of our securities to decline. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned). The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time than a non-former shell company could cause the market price of our securities to decline.

If we issue additional shares of our capital stock in the future, our existing stockholders will be diluted.

Our Amended and Restated Articles of Incorporation authorize the issuance of up to 600,000,000 shares of our common stock. Possible business and financial uses for our authorized capital stock include, without limitation, equity financing, such as future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plan, or other transactions and corporate purposes that our Board of Directors deems are in the interests of our company. Additionally, issuance of shares of our capital stock could have the effect of delaying or preventing changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all; they may have rights, preferences and privileges that are superior to those of our common stock and may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of the date of this report, a total of 72,008,144 shares of our common stock are outstanding. Of those shares, approximately 22,000,000 are currently freely tradable, without restriction, in the public market, and no shares are issuable upon exercise of warrants which are registered for resale under the Securities Act. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

Anti-takeover provisions in our organizational documents could delay or prevent a change of control.

Provisions of our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws may have an anti-takeover effect and may delay, defer or prevent a merger, acquisition, tender offer, takeover attempt or other change of control transaction that a stockholder might consider to be in its interests, including attempts that might result in a premium over the market price for the shares held by our stockholders.

These provisions provide, among other things:

- a classified Board of Directors with staggered three-year terms;
- advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at stockholder meetings;

- certain limitations on convening special stockholder meetings and the prohibition of stockholder action by written consent; and
- directors may only be removed for cause and only by the affirmative vote of the holders of at least eighty percent (80%) of the voting power of all of the then-outstanding shares of our capital stock entitled to vote at an election of directors, voting together as a single class.

These anti-takeover provisions, including those noted above, could make it more difficult for a third party to acquire us, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. See "Description of Securities."

Article XI of our Second Amended and Restated Articles of Incorporation designates the Eighth Judicial District Court of Clark County, Nevada as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders and therefore may limit our shareholders' ability to choose a forum for disputes with us or our directors, officers, employees, or agents.

Article XI of our Second Amended and Restated Articles of Incorporation provides that, to the fullest extent permitted by law, and unless we consent to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Company, (b) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any director or officer of the Company to the Company or the Company's shareholders, (c) any action or proceeding asserting a claim against the Company arising pursuant to any provision of the Nevada Revised Statutes or the Company's amended and restated articles of incorporation or Second Amended and Restated Bylaws (as either might be amended from time to time), or (d) any action or proceeding asserting a claim against the Company governed by the internal affairs doctrine. This exclusive forum provision is not applicable to any action brought under the Securities Act of 1933, as amended or The Securities Exchange Act of 1934, as amended.

We believe the choice-of-forum provision in our Second and Restated Articles of Incorporation provide for the orderly, efficient, and cost-effective resolution of Nevada-law issues affecting us by designating courts located in the State of Nevada (our state of incorporation) as the exclusive forum for cases involving such issues. However, this provision may limit a shareholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or our directors, officers, employees or agents, which may discourage such actions against us and our directors, officers, employees and agents. While there is no Nevada case law addressing the enforceability of this type of provision, Nevada courts have on prior occasion found persuasive authority in Delaware case law in the absence of Nevada statutory or case law specifically addressing an issue of corporate law. The Court of Chancery of the State of Delaware ruled in June 2013 that choice-of-forum provisions of a type similar to those included in our Second Amended and Restated Articles of Incorporation are not facially invalid under corporate law and constitute valid and enforceable contractual forum selection clauses. However, if a court were to find the choice-of-forum provision in our Second Amended and Restated Articles of Incorporation prove inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

The elimination of personal liability of our directors and officers under Nevada law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our Second Amended and Restated Articles of Incorporation and our Amended and Restated Bylaws eliminate to the furthest extent permitted under Nevada law the personal liability of our directors and officers to us, our stockholders and creditors for damages as a result of any act or failure to act in his or her capacity as a director or officer. Furthermore, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws and individual indemnification agreements that we have entered with each of our directors and officers provide that we are obligated to indemnify, subject to certain exceptions, each of our directors or officers to the fullest extent authorized by Nevada law and, subject to certain conditions, to advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures covering the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for such damages, even if such actions might otherwise benefit our stockholders.

We do not intend to pay cash dividends on our capital stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. We currently intend to retain all future earnings to fund the development of our products.

THE SELLING STOCKHOLDER

This prospectus relates to the possible resale of up to 80,000,000 Shares of Common Stock, which may be resold from time to time pursuant to this prospectus by the Selling Stockholder. We are registering the Shares pursuant to the provisions of the Purchase Agreement in order to permit the Selling Stockholder to offer the Shares for resale from time to time.

All expenses incurred with respect to the registration of the Shares will be borne by us, but we will not be obligated to pay any underwriting fees, discounts, commissions or other expenses incurred by the Selling Stockholder in connection with the sale of such Shares.

Neither the Selling Stockholder nor any of its associates or affiliates has held any position, office, or other material relationship with us in the past three years.

The Shares being offered hereby are being registered to permit public secondary trading, and the Selling Stockholder may offer all or part of the Shares for resale from time to time. However, the Selling Stockholder is under no obligation to sell all or any portion of the Shares.

Name of Selling Stockholder	Common Stock Beneficially Owned Prior to this Offering	Common Stock Being Offered	Common Stock Beneficially Owned After this Offering (2)
Williamsburg Venture Holdings, LLC (1)	0	Up to 80,000,000	Up to 9.99%

(1) Ronald Glenn is the Managing Member of Williamsburg Venture Holdings, LLC, and has sole voting control and investment discretion over the securities held by Williamsburg Venture Holdings, LLC. Mr. Glenn disclaims beneficial ownership over the securities listed except to the extent of his pecuniary interest therein. The principal business address of Williamsburg Venture Holdings, LLC is 395 Leonard St, Suite 719, Brooklyn, New York, 11211.

(2) Pursuant to the Purchase Agreement, Williamsburg may not purchase any Shares under the Purchase Agreement if such purchase, when added to the number of Shares already beneficially owned, would cause Williamsburg to be the beneficial owner of more than 9.99% of the Company's Common Stock outstanding on the date of such purchase.

Material Relationships with Selling Stockholder

Other than in connection with the transactions described above, we have not had any material relationships with the Selling Stockholder in the last three (3) years.

DETERMINATION OF OFFERING PRICE

The prices at which the shares of Common Stock covered by this prospectus may actually be sold will be determined by the prevailing public market price for shares of our Common Stock, by negotiations between the Selling Stockholder and buyers of our Common Stock in private transactions, or as otherwise described in "Plan of Distribution."

USE OF PROCEEDS

This prospectus relates to shares of our Common Stock that may be offered and sold from time to time by the Selling Stockholder. We will receive no proceeds from the sale of shares of our Common Stock by the Selling Stockholder under this prospectus. The proceeds from the sales will belong to the Selling Stockholder. However, subject to such limitations as are set forth in the Purchase Agreement, we may receive gross proceeds of up to $15,000,000 assuming that we sell all of our shares of Common Stock that we have the right, but not the obligation, to sell to the Selling Stockholder under the Purchase Agreement.

We intend to use the proceeds that we receive from the purchases under the Purchase Agreement for general corporate purposes and our working capital requirements, including the costs of preparing this prospectus and the registration statement of which it forms a part.

Even if we sell $15,000,000 in Shares to Williamsburg pursuant to the Purchase Agreement, we expect to need to obtain additional financing in the future in order to fully fund all of our planned activities. We may seek additional capital in the private and public equity or debt markets. We are evaluating additional financing opportunities on an ongoing basis and may execute them as appropriate. There is no assurance that we can consummate such a transaction at all or on favorable terms.

PLAN OF DISTRIBUTION

The Selling Stockholder, including its pledgees, assignees and successors-in-interest, may, from time to time, sell any or all of their securities covered hereby on the OTCQB or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholder to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholder may also sell securities under Rule 144 under the Securities Act, if available, rather than under this Prospectus.

Broker-dealers engaged by the Selling Stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholder (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction, a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholder may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholder may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this Prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this Prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholder and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholder will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholder or any other person. We have advised the Selling Stockholder that they should consult with their own legal counsel to ensure compliance with Regulation M. We will make copies of this Prospectus available to the Selling Stockholder and have informed it of the need to deliver a copy of this Prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

MARKET FOR OUR COMMON STOCK AND DIVIDEND POLICY

Our Common Stock has been quoted on the OTCQB under the trading symbol “IRME”. Trading volume in our Common Stock has often been very limited. As a result, the trading price of our Common Stock have been subject to significant fluctuations. There can be no assurance that a liquid market will develop in the foreseeable future.

Transfer of our Common Stock may also be restricted under the securities or “blue sky” laws of certain states and foreign jurisdictions. Consequently, investors may not be able to liquidate their investments and should be prepared to hold the Common Stock for an indefinite period of time. Over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

The Company does not anticipate that it will declare dividends in the foreseeable future but rather intends to use any future earnings for the development of its business.

As of May 12, 2025, the closing price of our Common Stock was $0.0817 per share and our stock was held of record by approximately 740 holders of record of our Common Stock. The number of record holders does not include an indeterminate number of shareholders whose shares are held by brokers in street name.

THE BUSINESS AND BUSINESS PLAN

General

We were incorporated in the State of Nevada in April 2007 under the name “Monster Motors, Inc.” We began operating the business of IR. Med Ltd., an Israeli company, through a reverse acquisition on December 24, 2020. IR. Med Ltd. (an Israeli company which was founded in 2013) continues to operate as our operating subsidiary, and we are the sole stockholder of IR. Med Ltd.

Our corporate headquarters and research facilities are located at ZHR Industrial Zone, Rosh Pina, Israel.

Business Overview

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

PressureSafe™: Our first product based on this platform, is a handheld device designed to revolutionize the early assessment of pressure injuries, or PIs, affecting the skin and underlying tissue. PIs in the U.S. alone account for $26.8 billion in healthcare spending and result in 60,000 deaths annually. *PressureSafe*™ is expected to contribute to early assessment of PIs, regardless of patient skin tone, which we believe will drive equitable healthcare and help reduce the toll and cost of PIs. We plan to launch PressureSafe™ as a decision support system, or DSS, tool for caregivers in hospitals, nursing homes, and home-care companies. On April 9, 2024, the PressureSafe™ decision support device received FDA listing certification. PressureSafe™ is classified as a Class I device. We are currently working on completing the development of the commercial version of the PressureSafe™ device, with initial sales planned during the second half of 2025, following the listing by the FDA.

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

Our novel technology platform will enable direct assessment of the development of a DFU before it becomes an open wound that may lead to limb amputation. The Israeli Innovation Authority, or IIA, has approved our plan to develop a diabetic foot ulcer device for early assessment of DFU. On January 25, 2024, the IIA approved a program to develop a device for the early assessment of diabetic foot ulcers among diabetic patients, with a project budget of NIS 3,761,978 (approximately US$ 1,030,000) which includes an amount equal to 50% grant of the total budget provided at the time of the grant, disbursed in installments over the course of 13 months, by the project's progress. In consideration for the grant by the IIA, the subsidiary is required to pay royalties at the rate of 3%-5% from the total sales until the repayment date of the full amount of the grant, plus annual interest at the SOFR rate. In addition, the IIA must approve any arrangement whereby the Company seeks to transfer the technology relating to the project, or its development, from Israel. Following the IIA grant we plan to commence a clinical trial in the center of Israel's leading diabetes clinic. On July 15, 2024, we announced that we received a grant from the IIA in the amount of approximately $500,000, to develop our platform technology for a new indication, a decision support device for the early assessment of diabetic foot ulcers. The grant's 13-month development was finalized, as we achieved the project's milestones. Computer simulations of infrared light reflectance from lesions under the skin surface have been completed.

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

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

The global diagnostics market is driven in large by solutions that can be applied in healthcare settings, as these tools will drive decisions regarding specific treatments and the associated outlays. However, despite advances in medical imaging and other diagnostic tools, misdiagnosis remains a common occurrence.

Our initial focus is on the development of decision support system solutions utilizing our proprietary platform for the pre-emptive diagnosis of PIs, and diabetic foot ulcers. Our current business plan focuses on two principal medical devices:

1. *PressureSafe*™, a handheld skin-agnostic optical monitoring device that is being developed to support early assessment of PIs to the skin and underlying tissue, primarily caused by prolonged pressure associated with bed confinement; and

2. *DiaSafe,* a handheld optical monitoring device that is being developed to support early assessment of DFUs in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole of diabetic patients, which sometimes is accompanied by other comorbidities as lower limb neuropathy.

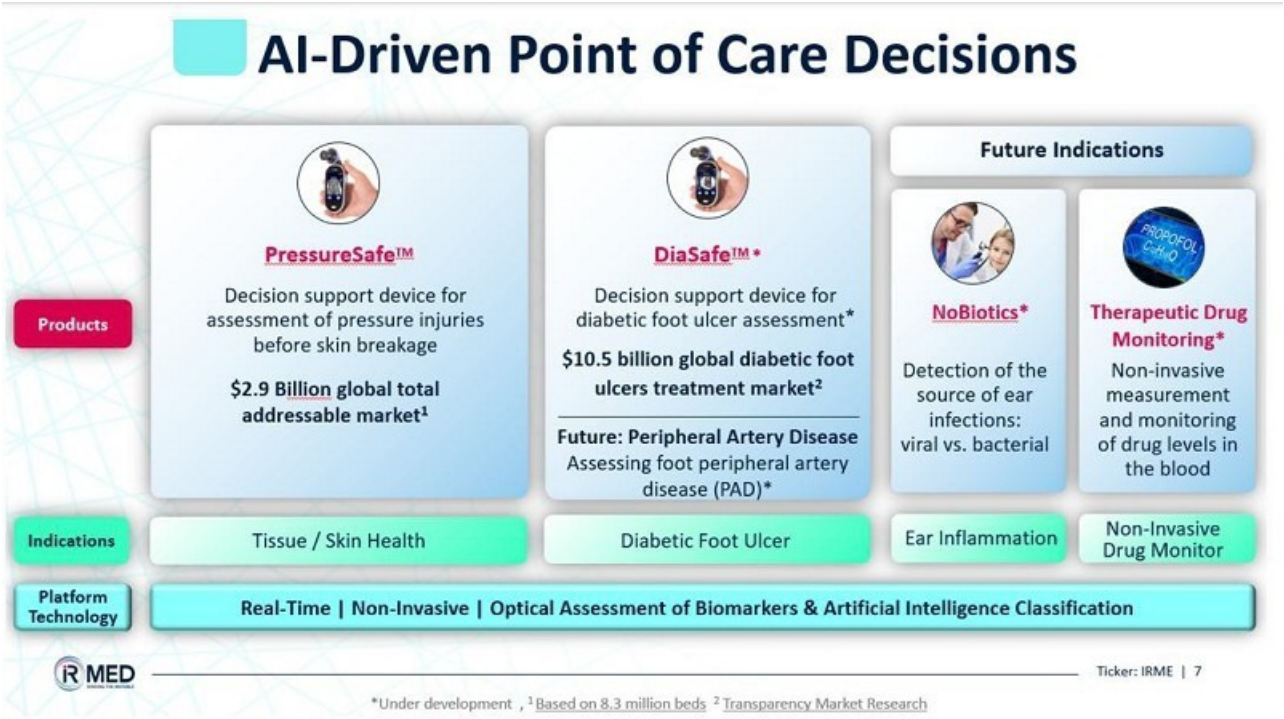

Fig1. IRMED AI-Driven Point of Care Decisions technology platform

Overview of Target Market and Our Solutions

Pressure Injury Market

Populations are aging due to improvements in healthcare. However, there are increased rates of obesity, diabetes and cardiovascular diseases. This combination of an increasingly aging population and such diseases has resulted in more people with decreased mobility needing assistance with activities of daily living. A major morbidity of decreased mobility is development of PIs. PIs develop as a result of a combination of physiologic events and external conditions. Along with localized, oedema, ischemia and reperfusion hindering injury to tissues, impaired lymphatic drainage and mechanical deformation of tissue cells have been shown to contribute to pressure injury.

Compression prevents lymph fluid drainage and leads to deterioration in tissue cell normal activities, which causes increased interstitial fluid and waste build up, contributing to the development of PIs. The time required to develop PIs depends on many factors, including the patient's physiological medical background and the degree of pressure and sheer force placed on the tissue. PIs occur over predictable pressure points where bony protuberances are more likely to compress tissues when the patient is in prolonged contact with hard surfaces. Studies show that the heel area is the second most frequent location for a pressure ulcer, with the most prevalent being the sacrum. The heel accounts for between 23% and 28% of all pressure ulcers.[1]

While the overall number of Hospital Acquired Conditions, or HAC, have decreased by 8%, pressure injuries have resisted improvement efforts and continue to grow by 10% annually. PIs are both costly and deadly. The U.S. Agency for Healthcare Research and Quality, or AHRQ, reports that PIs add $10.2 billion to annual U.S. healthcare costs. Furthermore, these are associated with over 45% of the 63,619 HAC related deaths in the U.S., making it the leading HAC related death.[2]

(AHRQ, 2019). Source: https://www.ahrq.gov/data/infographics/hac-rates_2019.html; AHRQ National Scorecard on Hospital-Acquired Conditions Final Results for 2014-2017 (PDF, 787 KB).

PIs impose a tremendous healthcare burden. As stated in the National Pressure Injury Advisory Panel fact sheet for 2023, 60,000 patients die every year as a direct result of pressure injuries. Acute care attributable to hospital-acquired PIs reaches $26.8 billion, and 2.5 million patients per year develop a PI. Patient care costs per PI range from $20,900 up to $151,700. PIs are among one of the five most common harms experienced by patients and the second most common claim for lawsuits, after wrongful death. More than 17,000 lawsuits arise due to PIs annually at an average settlement of $250,000. PIs occur across the healthcare industry, including in 10% of acute care patients, 25% of long-term acute care patients, 12% of nursing home patients and 12% of rehabilitation center patients.[3]

[1] Smith, S., Ashby, S., Thomas, L. and Williams, F., 2017. Evaluation of a multifactorial approach to reduce the prevalence of pressure injuries in regional Australian acute inpatient care settings. International Wound Journal, 15(1), pp.95-105.

[2] AP News. 2019. *Pressure Ulcers Cost U.S. Healthcare $10.2 Billion and Contribute to Nearly 29,000 Hospital Deaths Each Year.*

[3] National Pressure Injury Advisory Panel fact sheet for 2023

The most common method used to detect early PIs is a visual assessment by a professional caregiver focusing on areas at high probability to develop PIs. This skin and tissue visual assessment is subjective, unreliable, untimely (as PIs often occur suddenly without visual cues), and only effective to detect PIs once they are visible. Technology-based methods for detecting and monitoring have been developed, but as far as we know, none have succeeded in providing an effective solution. Pressure injuries, especially HAPIs, are complex, difficult to treat, and at risk for re-occurrence.

Pressure Injuries Background

A pressure injury is caused when skin integrity is broken down by some type of unrelieved pressure, leading to the destruction of normal structure and function. The National Pressure Injury Advisory Panel, or NPIAP, the preeminent U.S. professional organization dedicated to prevention and management of PIs, uses these four criteria to define a PI:

- A pressure injury is localized damage to the skin and underlying soft tissue, usually over a bony prominence.
- The injury can present as intact skin or an open ulcer and may be painful.
- The injury occurs as a result of intense pressure, prolonged pressure, or pressure in combination with shear.
- The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, comorbidities and condition of the soft tissue.

Common places for PIs to develop include the back of the head, shoulders, elbows, buttocks, hips, ankles, and heels.

The 4 Stages of Pressure Injuries - PI Stage 1

Non-blanchable erythema of intact skin. Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage 1 in Darkly Pigmented Skin: Research indicates that people with darker skin tones are more likely to develop higher stage pressure injuries, possibly because skin assessment protocols are less effective in identifying damage earlier. Pigmentation of the skin may prevent visualizing the reactive hyperemia in the pressure injury.[4]

Currently, PIs are discovered only as they begin to appear on the skin, after they have been festering underneath the skin layers. Nurses regularly assess patients at high risk by evaluating them according to accepted scores (e.g., Braden or Norton Scales). Hospitals can then get the patient onto a different type of mattress that wicks away moisture, changes patient support and reduces pressure and imposes orders for the individual to be turned every few hours, for example. The risk of a PI among acute care patients ranges between 2-40% of patients.

Intrinsic risk factors such as diabetes, malnutrition and smoking also increase the overall risk for pressure injuries. The spinal cord injury patient population is at the highest risk (25-66%) of developing a PI due to the combination of immobility and decreased sensation. A prospective study of spinal cord patients not only found that sacral and ischial PIs were very common (43% and 15%, respectively), as might be expected, but also noted that the second most common location was on the heel (19%).[5]

Nursing home patients have PI prevalence of 11%[6] and are most likely to develop PIs on the sacrum or heels. Nursing home patients were also found to have contractures at a prevalence of 55%. Contractures are caused by decreased elasticity of the tissue surrounding major joints, and the resulting lack of full mobility in the affected extremities significantly increases the risk of PI information.

[4] Current Perspectives on Pressure Injuries in Persons with Dark Skin Tones from the National Pressure Injury Advisory Panel, Adv Skin Wound Care. 2023 Sep 1;36(9):470-480. doi: 10.1097/ASW.0000000000000032. Epub 2023 Aug 7. PMID: 37590446.

[5] Delmore, B., Lebovits, S., Suggs, B., Rolnitzky, L. and Ayello, E., 2015. Risk Factors Associated with Heel Pressure Ulcers in Hospitalized Patients. *Journal of Wound, Ostomy & Continence Nursing*, 42(3), pp.242-248.

[6] Palese, A., Zammattio, E., Zuttion, R., Ferrario, B., Ponta, S., Gonella, S. and Comoretto, R., 2020. Avoidable and Unavoidable Pressure Injuries Among Residents Living in Nursing Homes. *Journal of Wound, Ostomy & Continence Nursing*, 47(3), pp.230-235.

A significant market is the home healthcare market, which is anticipated to be worth $645 billion by 2025 (CAGR 8.7%).[7] It is estimated that by 2030, seniors aged 65 and over will represent 20% of the U.S. population, and over 19 million seniors are estimated to need homecare services. Homecare companies have a strong incentive to prevent PIs as they are rated and carry part of the cost treating those patients.

According to a survey published in 2000 by UCLA School of Medicine,[8] in a total sample of 3,048 patients, 9.12% had PIs, and of these, 37.4% had more than one PI, and 14% had three or more. Considering the worst PIs for each subject, 40.3% had Stage II and 27% had Stage III or IV injuries.

The Agency for Healthcare Research and Quality (AHRQ) has identified several basic principles for PI prevention: (a) use a validated tool to assess risk such as the Braden Scale and Norton Scale; (b) implement a preventive plan for residents at risk, which should focus on avoiding friction and sheer trauma to at-risk skin regions, as well as an individualized plan to reduce pressure, such as frequent repositioning; and (c) daily inspection of the skin for high-risk residents, as deep tissue damage can occur in as little as two hours. The most common method used to detect early pressure injuries is a visual assessment by a professional caregiver focusing on areas where PIs most frequently develop. This visual assessment is subjective, unreliable, untimely and ineffective as PIs develop under the skin before becoming visible to the naked eye. Technology-based methods for detecting and monitoring PIs have been developed, but none have succeeded in providing an effective solution. These include ulcer assessment based on skin conductivity which has relatively low resolution and is influenced by different topical skin conditions (e.g., moisture, urine or feces). Other system solution methods such as electronic medical record programs, which prompt providers to document results of PI screening every shift or day, are of great importance in diagnosing PIs early and preventing progression. Pads designed to specifically cover pressure points such as the sacrum and heels, as well as foam pads designed to wrap around at-risk body parts, are common products. However, it is important to note that some pads can actually be detrimental; for example, supports with cut-outs can have increased pressure at their edges. Hospital-acquired PI rates are increasing while all other hospital-acquired conditions are decreasing (AHRQ, 2019).

PressureSafe™

Since 2017, we have been designing and developing *PressureSafe*™, a novel device that has the potential to provide a reliable method of monitoring and recording patients, providing additional bio information to healthcare providers as to where and when a pressure injury may occur. The technology platform is designed to record information relating to each patient. The core technologies underlying the *PressureSafe*™ device are patent protected (US Patent No. US 10,709,365 and US Patent No. US10,772,541). Our technology platform is based on the fact that tissues of the human body absorb and reflect omitted light in different wave lengths (from the visual light to infra-red light), and the light is reflected and scattered back from different skin layers. During this process, the reflected and scattered light waves through a damaged area changes its properties in comparison to light reflection and scattering from normal healthy tissue. The *PressureSafe*™ device is being designed to capture, analyze and identify

tissue status to make early PI diagnoses using Spectrographic Analysis, while AI based algorithm is implemented to improve diagnostic accuracy. The *PressureSafe™* device illuminate the skin with a miniature set of LEDs less than a second in order to acquire the tissue fingerprint. The emitted light photons from the device will be absorbed, scattered, and reflected back. The device will then detect the absorption and reflectance, and by using algorithms, it will process the signals to identify and classify the scanned area.

As all person's skin properties are unique, the diagnosing physician needs to use a device as the *PressureSafe™*, which automatically calibrate the device to the specific patient's skin, a process that takes merely a few seconds and allows personalized diagnosis, improving physician diagnostic process effectiveness, as the *PressureSafe™* device is designed to measure regardless of skin color. Our technology is being developed to enable the assessment of different subepidermal layers by scanning through these skin layers, thus assessing the subepidermal damaged tissue using multi-biomarker approach and assisting with additional information to allow better treatment. Assessing the subepidermal biomarkers has been developed to "raise a flag" to allow the caregivers intervene and prevent their opening ("skin breakage"). The biomarkers that our algorithm uses starts from the early inflammatory process, as soon as local underlying tissue function is disturbed, ischemia and cells begin to be damaged.

[7] Home Healthcare Market will grow at CAGR of 8.7% to hit $645.10 billion by 2025: Adroit Market Research.

[8] Ferrell, B., Josephson, K., Norvid, P. and Alcorn, H., 2000. Pressure Ulcers Among Patients Admitted to Home Care. *Journal of the American Geriatrics Society*, 48(9), pp.1042-1047.

PressureSafe™ is a hand-held scanner designed to provide additional information as a DSS, to support the care giver effectively with the main diagnostic ability to identify PIs and to differentiate between deep tissue PIs (before they become visible) and Stage 1 PIs. Deep tissue PIs are serious, deep PIs that form under intact skin, spread in deep tissues and eventually present themselves as full thickness wounds. The *PressureSafe™* is composed of (a) a handheld optic probe device, which utilizes harmless infra-red light that is placed on the skin and has a disposable tip that is changed between patients. The optic probe with its disposable cover is placed on suspected areas for performing measurements; (b) a disposable probe tip component, changed between patients to avoid cross-contamination; (c) a software component containing machine learning algorithm for analyzing the collected data; and (d) software for connectivity and downloading the collected data and measurements results to the EMR/EHR systems used by the medical center or homecare company.

PressureSafe™ is a non-invasive real-time optical monitoring device to support early intervention in PI treatment prior to skin breakage. The device performs a reflectance spectroscopy scan to generate information for the decision maker, while collecting data on epidermal and subepidermal physiological changes together with other bio-signals typical of early formation of PIs in the main three skin layers, thus detecting the appearance of life-risking pressure injuries. *PressureSafe™* is designed to detect changes deep in the skin, regardless of skin tone, by measuring bio markers. As soon as local subcutaneous tissue function is disturbed and cells begin to disintegrate by pressure exerted upon the body area, our scanner is designed to be able to detect this very early inflammatory process and tissue structure changes. The technology will allow patient monitoring and immediate reading in a non-invasive way. It has the potential to help to reduce the number of PIs dramatically through accurate early classification, making it attractive for public and private healthcare systems worldwide.

***PressureSafe™* Studies**

Our product candidates are in various stages of development and production. The *PressureSafe™* device is in an advanced stage of development and is planned to be our first go-to-market product.

We have completed the development of the first generation *PressureSafe™* prototype in the second quarter of 2022. 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 Maintenance Organization, or HMO, in Israel, to conduct a usability study of *PressureSafe™*.

On July 17, 2023, we published our interim report of usability study performed in Israel in leading medical centers with the following results:*PressureSafe™* demonstrated very high efficacy in noninvasively detecting the presence and absence of PIs below the skin's surface. *PressureSafe™* accurately detected the presence of a PI in 96% of cases. In addition, *PressureSafe™* correctly determined that no wound was present in 91% of cases. The study was conducted at two medical centers owned by Clalit, namely Beit Rivka Hospital and Rabin Medical Center both in Petah Tikva, where 370 *PressureSafe™* scans were performed on 25 patients who had Stage 1 PIs or deep tissue injuries. No device related safety issues were reported in the total of 44 patients evaluated for safety.

On September 26, 2023, we announced that we signed a Clinical Trial Agreement with the Methodist Healthcare System of San Antonio to conduct a useability study titled "Safety and Efficacy of the *PressureSafe™* device for early assessment of Pressure Injury in People with Various Skin Tones, Including Dark Skin Tones." Methodist Healthcare is recognized as the most respected healthcare provider in its region. With a network of 85 hospitals, 9 of which are acute care facilities, Methodist Healthcare employs more than 11,000 people, including 2,700 physicians. Based on our intended protocol, we plan to have 50% of the subjects for the upcoming study to have a dark skin tone, thus producing comparative data on *PressureSafe™'s* accuracy as a decision support device in detecting early-stage PIs in people of darker and lighter skin tones. Early-stage PIs can be more difficult to see on dark skin tones with the current standard of care for the assessment of PIs, which is visual skin inspection.

On February 20, 2024, we reported 92% efficacy for PressureSafe™. Data from the study conducted at two medical centers owned by Clalit, namely Beit Rivka Hospital and Rabin Medical Center, presented at the NPIAP 2024 Annual Conference on February 16 and 17, 2024 in San Antonio, Texas. The 14-day efficacy portion of the single arm, bi-center study evaluated 38 patients at high risk of pressure injury development. A total of 924 scans were conducted on 154 body locations. Nurses conducting the scans were blinded to *PressureSafe™'s* results, which were encrypted. PressureSafe™ detected Stage 1 pressure injuries with 92% sensitivity and 88% specificity. Additional portions of the study evaluated safety, as well as device calibration and validation. Total data from 66 patients was obtained for safety analysis and no safety signals were identified in 1,493 scans. Based on these data, the study concluded that PressureSafe™ is a safe, efficient, and valuable method for early assessment of pressure injuries. On May 22, 2024, we published a poster presentation on our website titled "Near Infra-Red Spectroscopy scanner for early assessment of stage 1 pressure injury and deep tissue injury – clinical study results", which includes data that was presented at the NPIAP 2024 Annual Conference in San Antonio, Texas.

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

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

DiaSafe

We are now in the development stages of Software/Hardware, algorithms and optics to allow early assessment of incipient DFU in the lower limbs, the DiaSafe™. DiaSafe™ is an adjustment to the *PressureSafe*™ proven technology allows us to reduce the development period and approach the relevant markets faster. We plan to initiate a clinical study in Israel, to train the developed algorithm and test patients.

DFU Background

Diabetic foot ulcer are an increasing problem among diabetic patients. Diabetic foot ulcers are one of several serious complications of diabetes progression. Major contributing causes to diabetic foot ulcers are peripheral neuropathy, peripheral arterial disease, and immunosuppression. Up to 15% of patients with diabetes have diabetic foot ulcers, and these ulcers lead to more than 80,000 amputations per year in the United States. The lifetime risk of diabetic foot ulcers for patients with diabetes may reach up to 68 per 1,000 people as reported by some studies. As a diabetic foot ulcer progresses, the patient's risk for amputation increases; in nearly 84% of patients who have a lower limb amputation secondary to diabetes, the amputation is preceded by a diabetic foot ulcer. Peripheral neuropathy secondary to diabetes is an etiologic factor of diabetic foot ulcers and is estimated to affect 5.5 million people in the United States.

These collective findings indicate that diabetic foot ulcers lead to serious disability, serious reduction in patient quality of life, and high financial costs for society. With increased vigilance on risk assessment, diagnosis, and management of diabetic foot ulcers, clinicians can improve patient outcomes and reduce healthcare costs.

There are a few established methods for diagnosing DFU. These methods assess side effects of diabetic related symptoms as Peripheral Artery Disease diabetic neuropathy (mono-filament test tuning fork test), skin temperature, BP, heart rate, skin dryness etc. The suggested DiaSafe™ device measures actual dermal and subdermal changes of injured skin tissue structure caused directly the development of diabetic foot ulcers. The optical platform developed by IR-MED allows direct assessment and measurement of changes in skin structure (including blood flow changes).[9]

- Market Prevalence: The percentage of Americans aged 65 and older diagnosed with diabetes remains high, at 29.2%, or 16.5 million seniors (diagnosed and undiagnosed).

[9] Tuttolomondo A, Maida C, Pinto A. Diabetic foot syndrome: Immune-inflammatory features as possible cardiovascular markers in diabetes. World J Orthop. 2015 Jan 18;6(1):62-76. doi: 10.5312/wjo.v6.i1.62. PMID: 25621212; PMCID: PMC4303791.
[10] https://journals.lww.com/jaapa/fulltext/2015/05000/pathogenesis_and_management_of_diabetic_foot.6.aspx

- Diabetic foot ulcers are wounds on the feet that develop in patients with type 1 or type 2 diabetes. About one-third of people with diabetes develop a foot ulcer during their lifetime. Diabetic foot ulcers affect about 18.6 million people worldwide and 1.6 million in the U.S. annually. Treatment of infection in a diabetic ulcer is difficult and expensive. Patients usually need to take long-term medications or become hospitalized for an extended period of time DFU treatment is expensive. On average, the treatment cost for wounds with Wagner grade I in five industrialized countries was $3,096 in 2010. However, if the wound becomes complicated and amputated, the cost will rise to almost $107,900.[10] Average in-hospital costs were $10,827 (range: $702–$82,880) per DFU episode. Primary healed DFUs costs on average $4,830, single minor amputations on average $13,580, multiple minor amputations on average $31,835 and major amputations on average $73,813 per episode.[11]

All the diabetic patients should undergo comprehensive foot exam once a year. The goal of this examination is to determine the risk factors that may result in a foot ulcer and consequently amputation of the affected organ. The physical examination contains observation, palpation of the pulses in the lower extremities, including the posterior tibial and dorsalis pedis pulses. The physical examination also includes neurological tests. At least two neurologic tests are performed and one of the tests should measure the protective sensation in which a 10 g monofilament is used. Vibration sensation using a 128 Hz diapason.

DiaSafe

The DiaSafe™ device as the PressureSafe™ device is being designed to capture, analyze and identify tissue status to make early DFU assessment and classification using Spectrographic Analysis, while AI based algorithm is implemented to improve provided diagnostic accuracy. The DiaSafe™ device illuminates the skin with a miniature set of LEDs less than a second in order to acquire the tissue fingerprint. The emitted light photons from the device will be absorbed, scattered and reflected back. The device will then detect the absorption and reflectance, and by using algorithms, it will process the signals to identify and classify the scanned area or DFU.

As all person's skin properties are unique, the diagnosing physician needs to use a device as the DiaSafe™, which automatically calibrate the device to the specific patient's skin, a process that takes merely a few seconds and allows personalized diagnosis, improving physician diagnostic process effectiveness, as the DiaSafe™ device is designed to measure regardless of skin color. Our technology is being developed to enable the assessment of different subepidermal layers by scanning through these skin layers, thus improving the identification of the damage, assessing the subepidermal damaged tissue volume and assisting with additional information to allow better treatment efficacy. Measuring the differences of subepidermal biomarker is being developed to detect early formation of DFUs and to "raise a flag" to allow the caregivers intervene and prevent their appearance. The biomarkers that our algorithm detects start from the early inflammatory process, as soon as local underlying tissue function is disturbed, and cells begin to be damaged.

DiaSafe™ is a hand-held scanner designed to provide additional information as a DSS, to support the care giver effectively with the main diagnostic ability to identify DFUs and to differentiate between DFUs under different skin conditions (before they become visible. The DiaSafe™ is composed of: (a) a handheld optic probe device, which utilizes harmless infra-red light that is placed on the skin and has a disposable tip which is changed between patients. The optic probe with its disposable cover is placed on suspected areas for performing measurements; (b) a disposable probe tip component, changed between patients to avoid cross-contamination; (c) a software component containing machine learning algorithm for analyzing the collected data; and (d) software for connectivity and downloading the collected data and measurements results to the EMR/EHR systems used by the medical center or homecare company.

DiaeSafe™ is a non-invasive real-time optical monitoring device to support early intervention in DFU treatment prior to skin breakage. The device performs a reflectance spectroscopy scan to generate information for the decision maker, while collecting data on epidermal and subepidermal physiological changes together with other bio-signals typical of early formation of PIs in the main three skin layers, thus detecting the appearance of life risking pressure DiaSafe™ is designed to detect changes deep in the skin, regardless of skin tone, by measuring bio markers. As soon as local subcutaneous tissue function is disturbed and cells begin to disintegrate by pressure exerted upon the body area, our scanner is designed to be able to detect this very early inflammatory process and tissue structure changes. The technology will allow patient monitoring and immediate reading in a non-invasive way. It has the potential to help to reduce the number of DFUs dramatically through accurate early classification, making it attractive for public and private healthcare systems worldwide.

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3634178/ Iraj B, Khorvash F, Ebneshahidi A, Askari G. Prevention of diabetic foot ulcer. Int J Prev Med. 2013;4(3):373-376, https://jamanetwork.com/journals/jama/fullarticle/2812203.
[12] https://www.sciencedirect.com/science/article/abs/pii/S0168822717302413.

Our Strategy

Our goal over the next five years is to establish our technology and related products as the gold standard for the targeted sectors. The key elements of our strategy are as follows:

Develop and expand a balanced and diverse pipeline of products and product candidates. Our core platform technologies will include innovative spectrographic analysis tools for diagnostic aid, AI, devices and product candidates in various development and clinical stages. We plan to add products and product candidates to our pipeline by expanding our technologies that are being developed to additional indications and through investing in new technologies, products and product candidates. By maintaining this multi-product approach, we aim to provide a broad and comprehensive product offering, which we believe will result in multiple value inflection events, reduced risks to our potential business associated with a particular product or product candidate and increased return on investment. Furthermore, product candidates that we develop may create attractive collaboration opportunities with pharma, diagnostics, medical devices and medical supplies companies.

Target large and growing patient populations with significant unmet medical needs. PIs and DFUs are medical conditions afflicting large and growing global patient populations, each with significant unmet medical needs such as requiring earlier and more accurate diagnosis, reducing the widespread reliance on antibiotics and optimizing the delivery of medical services, thereby improving the efficacy and safety of treatment.

Maintain a global, diverse network of specialists to accelerate knowledge synergies and innovation. We plan to utilize a global network of specialists to identify large and growing patient populations with significant unmet medical needs, evaluate and prioritize potential technologies, assist in designing development plans and diagnostic protocols and determine potential indications of our platform technologies to our target patient populations in various territories. We believe that maintaining this diverse network of industry specialists will allow us to continue to maximize knowledge and cost synergies, utilize shared commercial infrastructure across products, reduce risks of development and commercialization delays to our overall business and leverage our current and future platform technologies and technologies for additional products and product candidates.

[17] Rosenfeld, R., Schwartz, S., Cannon, C., Roland, P., Simon, G., Kumar, K., Huang, W., Haskell, H. and Robertson, P., 2014. Clinical Practice Guideline. *Otolaryngology-Head and Neck Surgery*, 150(1_suppl), pp. S1-S24.

Establish distribution channels to maximize the commercial potential of our products We plan to seek out collaborative arrangements with major healthcare providers to facilitate market adoption of our product candidates. We believe that such institutions are well-positioned to directly benefit from improvements in accurate diagnosis and the reduction of cost of care associated with the use of our product candidates. We also believe that the marginal cost of our product candidates compared to potential savings will make it economical for healthcare institutions to adopt our products, regardless of whether or not additional costs of purchase of these products will be covered by third-party payors, such as government healthcare programs and commercial insurance companies. Through cooperation with healthcare providers, we aim to develop and prove an economic model beneficial to them. Thereafter, we plan to engage with private insurance plans to develop reimbursement programs encouraging the use of our product candidates. We expect that adoption rates of our products will increase if hospitals and other medical institutions are compensated, in full or in part, for additional costs incurred when purchasing our products.

Disposable unit/Pay Per Use (PPU) business model - Our developing business model will be based on disposable need to be changed per patient examined. This will allow potential customers to pay only per use of the device, with minimal investing in equipment, and have great potential to generate substantial revenues to the company. As we develop large, accumulated databases, we plan to offer software as a service (SAAS) to our customers.

R&D and New Product Development

We believe our strong research and development (R&D) capabilities are one of our principal competitive strengths. Our R&D activities are conducted at our subsidiary's facility in Israel. Our team of employees and sub-contractors is comprised of current and future dedicated research and development employees, system architects, algorithm developer engineers, software engineers, electronics and electro-optics engineers, quality engineers and regulatory and health experts, who are responsible for R&D, development and testing of our technologies and product candidates.

We plan to increase our R&D team as necessary to meet our product development goals and milestones and deliver the products in the right time to market and in the required quality.

Intellectual Property

General

We rely on a combination of patents, trade secrets, non-disclosure agreements and other intellectual property to protect the proprietary technologies that we believe are important to our business. Our success will depend in part on our ability to obtain and maintain patents and other proprietary protection for commercially important inventions and know-how, defend and enforce our patents, maintain our licenses, preserve our trade secrets and operate without infringing valid and enforceable patents and other proprietary rights of third parties. We also rely on continuing technological innovation to develop, strengthen and maintain our proprietary position in the field of diagnostic decision support software devices.

The IR based core technologies underlying the *PressureSafe*™ device are covered by patent issued (US Patent No. US 10,709,365 and US Patent No. US10,772,541) issued on July 14, 2020, and September 15, 2020, respectively. All our patents are marked under "system and method for noninvasive analysis of subcutaneous tissue". Such patents are owned by IR. Med Ltd. and are valid through August 2034.

These patents are based on physical phenomena of light reflection from the surface of the skin. The *PressureSafe*™ device irradiates the surface of tissue with harmless infrared and visual light radiation. The reflected light from the tissue changes its physical properties according to the level of injury in the sub dermal tissue (under the skin). Comparing the reflected light from a healthy tissue and reflected light from a suspected injured tissue allows early assessment of sub dermal PIs.

During 2022, we applied for two new provisional patents in the US. and European Union, one for the *PressureSafe*™ device and one for *Nobiotics*.

During 2023, we applied for two patents in the U.S. protecting different configurations of our devices and new technological developments. We also applied for two design patents covering our unique design of our devices and accessories, and were granted one patent from the Israeli Patent Office supporting the American patents already approved.

During 2024, we applied for three design patents, protecting PressureSafe™ and DiaSafe™ design and our disposable tip cover design in a various stages of approval.

As of the date of this report, a significant portion of our granted U.S. patent applications and pending patent applications in foreign jurisdictions is directed to enhance both the *PressureSafe*™ device and other future applications. However, some of these patent applications may not result in issued patents, and not all issued patents may be maintained in force for their entire term.

Competition

We operate in highly competitive segments of the medical device markets. We face competition from many different sources, including commercial medical device enterprises, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large medical device companies have extensive experience in clinical testing and obtaining regulatory approval for medical devices. We also may compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect *PressureSafe*™, if and when commercially available, to compete directly with Bruin's Biometrics Provizio SEM Scanner, which is currently commercially available in the U.S., U.K. and the E.U. As we intend with the *PressureSafe*™ device, the Bruin scanner is marketed to senior care facilities, as well as other health care centers. Bruin's product is based on electro-resistance measurement of the skin's moisture, a method that is significantly different from the approach contained in the *PressureSafe*™ device, which utilizes real-time, multi bio marker, optical monitoring device combined with AI-based capabilities for assessment of PIs in different settings. In addition, new developments, including the development of other medical device technologies and methods of preventing PIs, occur in the medical device industry at a rapid pace.

Diabetic foot ulcer assessment is a process composed of collecting a patient's background data and point of care measurements, such as lower limbs data (pulse quality, level of neuropathy, etc.). The collected information allows rough assessment of a DFU to develop. Since there is no way to measure direct biomarkers associated with DFU, we are developing the technology and a device that will measure direct biomarkers demonstrating development of subdermal DFU.

Manufacturing

We do not own or operate manufacturing facilities. While we plan to depend on third-party contract manufacturers for device manufacturing, we plan to perform the final assembly, quality control and release of finished goods in our facilities.

Manufacturers of our products are required, among other things, to comply with applicable FDA/EMA manufacturing requirements contained in the FDA/EMA's Quality System Regulation, or QSR. The QSR requires manufacturing quality assurance and quality control as well as the corresponding maintenance of records and documentation.

Major changes to the device generally require regulatory approval before being implemented (e.g., adding new indications and additional labeling claims, etc.).

Under FDA Medical Device Reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Discovery of problems with a product after product release may result in restriction on a product or manufacturer, including withdrawal of the product from the market.

We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates if they are approved. We intend to enter into contract manufacturing agreements and one or more back-up manufacturers for the commercial production of our product candidates when they are near potential approval.

Distribution and Revenue Generation

On October 7, 2022, we entered into an exclusive Distribution and License Agreement, or the Distribution Agreement, with PI Prevention Care LLC, a Delaware limited liability company, or the Distributor, pursuant to which the Distributor received exclusive royalty bearing rights to promote, market and sell solely in the United States our *PressureSafe*™ monitoring device.

On June 18, 2024, we provided the Distributor with a notice of the Commercial Launch Date of September 20, 2024. On July 16, 2024, we provided a notice of breach of contract to the Distributor following his lack of response to our Commercial Launch Date notice. Effective as of October 15, 2024, as a result of our notice to the Distributor of the Distributor's material breach of the Agreement following its failure to timely pay the license fee as required, the Agreement was terminated.

We plan to seek out collaborative arrangements with major healthcare providers to facilitate market adoption of our product candidates. We believe that such institutions are well-positioned to directly benefit from improvements in accurate diagnosis and the reduction of cost of care associated with the use of our product candidates. We also believe that the marginal cost of our product candidates compared to potential savings will make it economical for healthcare institutions to adopt our products, regardless of whether or not additional costs of purchase of these products will be covered by third-party payors, such as government healthcare programs and commercial insurance companies. Through cooperation with healthcare providers, we aim to develop and prove an economic model beneficial to them. Thereafter, we plan to engage with private insurance plans to develop reimbursement programs encouraging the use of our product candidates. We expect that adoption rates of our products will increase if hospitals and other medical institutions are compensated, in full or in part, for additional costs incurred when purchasing our products.

We intend to establish sales and marketing structures and strategic partnerships in the United States, U.K. and Europe to support all of our product candidates.

The target market for our *PressureSafe*™ device is relevant healthcare settings (*i.e.*, hospitals, senior care facilities, homecare companies, etc.), nursing homes and a growing segment of long-term homecare givers. Towards that end, in the third quarter of 2022, we began preparations in anticipation of commercialization of *PressureSafe*™ in the United States during 2024, pending regulatory approvals, which have been delayed.

Once we receive the appropriate sales approvals, we expect the marketing will be done with local partners who have the relevant abilities and connections in each territory where the company will ask to sell the products. Since each country has its own specific healthcare system, a local partner (one or more) will be chosen to address the specific market needs in terms of regulation, technical support, etc. Pricing will be determined by the local partner, taking into account all overhead expected costs, regulation requirements and reimbursement methods.

The DiaSafe™ once developed, will be marketed pending our receipt of the appropriate sales approvals. We expect the marketing will be done with local partners who have the relevant abilities and connections per each relevant distribution territory. Since each country has its own specific healthcare system, a local partner (one or more) will be chosen to address the specific market needs in terms of regulations and technical support. Pricing will be determined by the local partner, taking into account all overhead expected costs, regulation requirements and reimbursement methods.

In both the *PressureSafe*™ and the DiaSafe™ devices, the revenue stream is expected to be generated mainly from the disposables and *PressureSafe*™ solution as a service (PSaaS) that are needed for the proper operation of the device, while the device itself likely be given under lease agreements. It is envisioned that the disposable component will be mass produced.

It is expected that market penetration will be achieved through original equipment manufacturing agreements with one of several large medical device companies already selling to the target market. At the current time, we have no commitments from any such distributors or original equipment manufacturing partners.

Facilities

Our subsidiary occupies approximately 130 square meters of facilities located in Rosh Pinna industrial zone, Israel, under an agreement for shared office space and services that expires upon 90 days' notice by either our subsidiary or the landlord. Through December 31, 2024, we recorded liability of 297,000 New Israeli Shekels, or NIS, (approximately $82,000), due to rent and office services.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local levels, as well as other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing.

Government Regulations

Before we can market our product candidates to the public in the U.S., we believe the products will need to obtain clearance for commercial sales. Our devices will be subject to ongoing regulation by the FDA in the U.S. and other federal, state, and local regulatory bodies.

FDA regulations govern, among other things, product design and development, manufacturing, labeling, pre-clinical and clinical trials, post-market adverse event reporting, post-market surveillance, complaint handling, repair or recall of products, product storage, record keeping, pre-market clearance, advertising and promotion and sales and distribution.

Unless an exemption applies, each medical device, such as our*PressureSafe*™and DiaSafe™ that are intended to be commercially distributed in the United States, requires 510(k) clearance from the FDA. Based on the FDA guidance documents that we have reviewed, we expect to be subject to the shorter and more streamlined 510(k) process for *PressureSafe*™, which typically involves less risk of uncertainty and the submission of less supporting documentation, without the costly clinical trials (though of course no prior guarantee can be provided as to such regulatory treatment). Generally, gaining 510(k) clearance for a product depends on demonstrating that the subject product is "substantially equivalent" to a previously cleared 510(k) device.

For the *PressureSafe*™device, we are worked closely with our FDA regulatory consultants to complete our pre-market notification to the FDA for 510(k) clearance and all other necessary design and manufacturing processes. We intend to pursue approximately the same regulatory track for the DiaSafe™ device.

Failure to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies, which may include any of the following sanctions: untitled letters or warning letters, fines, injunctions, consent decrees, civil or criminal penalties, recall or seizure of our current or future products, operating restrictions, partial suspension or total shutdown of production, refusal of or delay in granting 510(k) clearance of new products or modified products or rescission of previously granted 510(k) clearances. Any of these sanctions could result in higher than anticipated costs and have a material adverse effect on our reputation, business and financial condition. See "Risk Factor - Government Regulation," above.

The FDA can delay, limit or deny clearance of our proposed devices for many reasons, including:

- our inability to demonstrate that our product is safe and effective for its intended users;
- our inability to demonstrate that our product is the "substantial equivalent" of a previously cleared device;
- the data from clinical studies that we undertake may be insufficient to support clearance; and
- failure of the manufacturing process or facilities we use to meet applicable requirements.

In addition, the FDA may change its pre-market policies, adopt additional regulations, revise existing regulations or take other actions which may prevent or delay clearance of our devices.

Any delay in or failure to receive or maintain regulatory compliance prior to marketing our devices could prevent us from generating revenue therefrom or achieving profitability.

Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries or other increased scrutiny on us could dissuade some customers from using our proposed product and adversely affect our reputation and the perceived safety and efficacy of our proposed devices. If the FDA requires us to go through a more rigorous examination for our proposed product than we currently expect, such as requiring additional testing further verification or other procedures, we may require substantial additional funding sooner than anticipated and/or our product could be severely delayed. Being subject to an extended period of scrutiny or being required to conduct expensive clinical trials would be particularly harmful to our business because our proposed devices currently constitute our only products.

Ongoing Regulation by FDA.

Placing the *PressureSafe*™device on the market requires in addition:

- Establishment registration and device listing;
- Quality system regulation, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- Labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses, and other requirements related to advertising and promotional activities;
- Medical device reporting, or MDR regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- Corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the 1938 Federal Food, Drug, and Cosmetic Act, or FDCA, that may present a risk to health;
- Labelling and Unique Device Identification, or UDI, regulations; and
- Post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device. (Refer to the section below)

Post-Approval Requirements

Although premarket clinical trials provide important information on a device's safety and effectiveness, it is possible that new safety concerns will emerge once the device is on the market. As a result, the FDA continues to monitor device performance after a device has been approved. FDA officials conduct routine inspections of medical device manufacturing facilities across the United States. Manufactures may be informed of inspections in advance, or the inspections may be unannounced. Inspections may be

routine or caused by a particular problem. The purpose of these inspections is to make sure developers are following good manufacturing practices. Furthermore, the FDA can shut down a manufacturing facility if required standards are not met.

Usability Studies

We have completed the development of the first generation *PressureSafe*™ prototype in the second quarter of 2022. 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, to conduct a usability study of *PressureSafe*™.

In February 2023, our subsidiary IR. Med Ltd. entered into an agreement with Rabin Medical Center in Israel to perform a usability study, as an additional study center to the current study that we have been performing at Beit-Rivka, a large geriatric hospital in Israel. The agreement is to conduct a usability study of our proprietary and patent protected "*PressureSafe*™" device, which we plan to launch as a DSS tool for care givers in hospitals, nursing homes and homecare companies.

On July 17, 2023, we published our interim report of usability study performed in Israel in leading medical centers with the following results:*PressureSafe*™ demonstrated very high efficacy in noninvasively detecting the presence and absence of PIs below the skin's surface. *PressureSafe*™ accurately detected the presence of a PI in 96% of cases. In addition, *PressureSafe*™ correctly determined that no wound was present in 91% of cases. The study was conducted at two medical centers owned by Clalit, namely Beit Rivka Hospital and Rabin Medical Center, both in Petah Tikva, where 370 *PressureSafe*™ scans were performed on 25 patients who had Stage 1 PIs or deep tissue injuries. No device related safety issues were reported in the total of 44 patients evaluated for safety. On February 20, 2024, we reported 92% efficacy for PressureSafe™. Data from the study was presented at the NPIAP 2024 Annual Conference on February 16 and 17, 2024 in San Antonio, Texas. The 14-day efficacy portion of the single arm, bi-center study evaluated 38 patients at high risk of pressure injury development. A total of 924 scans were conducted on 154 body locations. Nurses conducting the scans were blinded to *PressureSafe*™*'s* results, which were encrypted. PressureSafe™ detected Stage 1 pressure injuries with 92% sensitivity and 88% specificity. Additional portions of the study evaluated safety, as well as device calibration and validation. Total data from 66 patients was obtained for safety analysis and no safety signals were identified in 1,493 scans. Based on these data, the study concluded that PressureSafe™ is a safe, efficient, and valuable method for early assessment of pressure injuries. On May 22, 2024, we published a poster presentation on our website titled "Near Infra-Red Spectroscopy scanner for early assessment of stage 1 pressure injury and deep tissue injury – clinical study results", which includes data that was presented at the NPIAP 2024 Annual Conference in San Antonio, Texas.

On September 26, 2023, we announced that we signed a Clinical Trial Agreement with the Methodist Healthcare System of San Antonio to conduct a useability study titled "Safety and Efficacy of the *PressureSafe*™ Device for Early Assessment of Pressure Injury in People with Various Skin Tones, Including Dark Skin Tones." On September 10, 2024, we announced the start of a usability study PressureSafe™, at San Antonio, Texas based Methodist Healthcare. The study, titled "Safety and Efficacy of the PressureSafe™ Device for Early Assessment of Pressure Injury in People with Various Skin Tones, Including Dark Skin Tones," has received approval from Methodist Healthcare and has commenced patient enrollment and monitoring.

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

In March 2025, we announced that our clinical and executive team had the privilege of demonstrating PressureSafe™ at the National Pressure Injury Advisory Panel (NPIAP) 2025 Conference, the leading U.S. conference for pressure injuries, held during the last week of February 2025. During the conference, our booth drew significant interest from key opinion leaders, healthcare practitioners, scientists, and commercial partners, which reinforced the industry's enthusiasm for our innovative technology. Two principal investigators presented compelling results from key studies. The first study, conducted at Clalit Medical Centers in Israel, included final results from Beit Rivka Hospital and Rabin Medical Center, both part of Clalit, the world's second-largest Health Maintenance Organization (HMO). This study assessed PressureSafe™'s Infrared Spectroscopy Scanner (IRSS) for evaluating Stage 1 pressure injuries (PI) and suspected deep tissue injuries (sDTI). Findings from 924 scans revealed a sensitivity of 89% and specificity of 90%, with no device-related adverse events across 1,475 scans. The device improved the assessment of pressure injuries before skin breakage, reduced reliance on subjective visual assessment, and contributed to a measurable reduction in pressure injuries. The second study, focused on diverse skin tones, was conducted in two Methodist hospitals in Texas to evaluate the effectiveness of Near-Infrared (NIR) Spectroscopy in addressing pigmentation-related challenges. Ongoing Phase 1 data from 294 scans demonstrated a 90% sensitivity rate, establishing PressureSafe™'s reliability across diverse populations. By using the IRSS with a multi-biomarker approach to assess underlying tissue, the device provides a reliable quantitative method to assist healthcare professionals in clinical assessments

In addition, we plan to conduct usability studies in the U.S. or other countries on the*PressureSafe*™ and on the DiaSafe™. Additional regulations govern the approval, initiation, conduct, documentation and reporting of clinical studies to regulatory agencies in the countries or regions in which they are conducted. Such investigational use is generally also regulated by local and institutional requirements and policies which usually include review by an ethics committee or institutional review board, or IRB. Failure to comply with all regulations governing such studies could subject the company to significant enforcement actions and sanctions, including halting of the study, seizure of investigational devices or data, sanctions against investigators, civil or criminal penalties and other actions. Without the data from one or more clinical studies, it may not be possible for us to secure the data necessary to support certain regulatory submissions, to secure reimbursement or demonstrate other requirements. We cannot assure that access to clinical investigators, sites and subjects, documentation and data will be available on the terms and timeframes necessary.

Reimbursement

Our current go-to-market strategy does not contemplate or rely upon governmental or third-party payor reimbursement. However, in the future we plan to seek reimbursement for product candidates as a means to expand the adoption of products and broaden our customer base.

To the extent that we adopt a market strategy which is in whole or in part reliant on third-party reimbursement, commercial sales of our future products will depend in part on the availability of reimbursement from such third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Each third-party payor may have its own policy regarding which products it will cover, the conditions under which it will cover such products, and how much it will pay for such products. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved devices. Further, healthcare policy and payment reform models and medical cost containment models are being considered and/or adopted in the United States and other countries. Legislative and/or administrative reforms to applicable reimbursement systems may significantly reduce reimbursement for the services in which our products are used or result in the denial of coverage for such services outright. As a result, third-party reimbursement adequate to enable us to realize an appropriate return on our investment in research and product development may not be available for our products.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (*e.g.,* the

Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments.

Anti-Kickback Statutes in the United States

The U.S. federal anti-kickback statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of a good or service, for which payment may be made in whole or in part under a U.S. federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that, if any one purpose of an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under U.S. federal healthcare programs, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other U.S. federal healthcare programs. The reach of the federal anti-kickback statute was broadened by the Affordable Care Act (ACA), which, among other things, amends the intent requirement of the federal anti-kickback statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. The ACA further provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act or the Civil Monetary Penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The U.S. federal anti-kickback statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General (OIG) of the Department of Health and Human Services, has issued a series of regulations, known as "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the anti-kickback statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG or the U.S. Department of Justice.

Many states have adopted laws similar to the U.S. federal anti-kickback statute. Some of these state prohibitions are broader than the U.S. federal statute and apply to the referral of patients and recommendations for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. Government officials have focused certain enforcement efforts on marketing of healthcare items and services, among other activities, and have brought cases against individuals or entities with sales personnel who allegedly offered unlawful inducements to potential or existing physician users in an attempt to procure their business.

U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, including private payors, or making false statements relating to healthcare matters. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information, can impose civil or criminal liability for violations of its provisions.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH and its implementing regulations, imposes certain requirements relating to privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"— independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

International Regulation

The European Commission is the legislative body responsible for the EU MDR (Medical Device Regulation) with which manufacturers selling medical products in the European Union and the European Economic Area, or EEA, must comply. The European Union has adopted regulations of design, manufacture, labeling, clinical studies, post-market clinical follow-up, post-market surveillance and vigilance for medical devices. Devices that comply with the requirements of a relevant EU MDR will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable regulations and, accordingly, can be marketed throughout the European Union and EEA, after being certified by a Notified Body. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states.

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical trials and commercial sales and distribution of any product candidates. The approval process varies from country to country, and the time may be longer or shorter than that required for bringing the product to the U.S. market.

Employees & Consultants

As of April 4, 2025, we had 3 employees on a full-time basis, with one employee and one service provider on a part-time basis, engaged in product research and development at IR. Med Ltd.

During February 2024, as a result of financial difficulties, we notified 10 of our 11 employees, including our then-Chief Executive Officer, of the termination of their employment. The effective termination dates vary based on contractual notice periods, which range between March 22, 2024, and April 22, 2024. During March 2024 following the approval of the IIA plan, we canceled the termination notice of two employees.

Israeli labor laws govern the length of the workday, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination of employment, equal opportunity and anti-discrimination laws and other conditions of employment. Subject to specified exceptions, Israeli law generally requires severance pay upon the retirement, death or dismissal of an employee, and requires us and our employees to make payments to the National Insurance Institute, which is similar to the U.S. Social Security Administration. Our employees have defined benefit pension plans that comply with the applicable Israeli legal requirements. Our employees are not represented by a labor union. We consider our relationship with our employees to be good. To date, we have not experienced any work stoppages.

Corporate Values and Ethics

We strongly believe that our success depends on all of our employees identifying with our company's purpose and understanding how their work contributes to the Company's overall strategy. To this end, we engaged in an inclusive all-company process to develop our company purpose, vision, mission and values.

Our corporate culture and values, along with our employees are our most valuable. These values, are:

- Passion,
- Integrity,
- Excellence,
- Responsibility,
- Innovation, and
- Spirit of Collaboration.

These values form part of our goal setting and review process to ensure accountability to these values at all levels. In order to further ensure that we live our values, and our culture stays unique and strong, our Board of Directors and executive management team put significant focus on our human capital resources.

We utilize a variety of channels to facilitate open and direct communication, including: (i) monthly all-hands staff meetings, (ii) regular open learning forums to promote peer learning or town hall meetings with executives; (iii) regular ongoing update communications; and (iv) employee surveys beyond the annual engagement survey referenced above on an as-needed basis.

Employee Compensation and Benefits

Our compensation programs are designed to align the compensation of our employees with the Company's performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance. Specifically:

- We provide employee base salaries that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location.
- To foster a stronger sense of ownership and align the interests of employees with those of our shareholders, we offer both a stock option program and employee stock purchase program to eligible employees under our broad-based equity incentive plans.
- Annual increases and incentive compensation are based on merit, which is communicated to employees at the time of hiring and documented through our talent management process as part of our annual review procedures and upon internal transfer and/or promotion.

Diversity and Inclusion

Ingrained in our culture is the philosophy that each individual offers diverse perspectives, backgrounds and experiences that create great outcomes when we are united as a team. We respect our people and embrace our differences. We welcome everyone and value the ideas generated by our collective uniqueness. We aspire that all of our teammates reach their full potential, and we encourage them to be confident in their differences.

Employee Development and Training

We invest significant resources in developing and retaining the talent needed to achieve our business goals. To support our employees in reaching their full potential, we offer internal and promote external learning and development opportunities. Education assistance is offered to financially support employees who seek to expand their knowledge and skill base.

Corporate and Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports are available free of charge though our website (*http://www.irmedical.com*) as soon as practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission, or SEC. Except as otherwise stated in these documents, the information contained on our website or available by hyperlink from our website is not incorporated by reference into this report or any other documents we file, with or furnish to, the SEC.

Our common stock is listed and traded on the over-the-counter market OTCQB under the symbol "IRME."

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following section contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws and is subject to the safe-harbor created by such Act and laws. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of such terms, or other variations thereon or comparable terminology. The statements herein and their implications are merely predictions and therefore inherently subject to known and unknown risks, uncertainties, assumptions and other factors that may cause actual results, performance levels of activity, or our achievements, or industry results to be materially different from those contemplated by the forward-looking statements. Except as required by law, we undertake no obligation to release publicly the result of any revision to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Further information on potential factors that could affect our business is described under the heading "Risk Factors" in Part I, Item 1A, of our 2024 Annual Report on Form 10-K for the fiscal year ended December 31, 2024 as filed with the SEC, on April 4, 2025. See also "Cautionary Note Regarding Forward-Looking Statements".

Results of Operation

Revenues

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

Research and Development Expenses

The process of researching and developing our products is lengthy, unpredictable and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our product candidates. We are unable, with any certainty, to estimate either the costs or the timelines in which those expenses will be incurred. Our current development plans focus on the development of our *PressureSafe™ and DiaSafe™* 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 are comprised of:

- internal recurring costs, such as personnel-related costs (salaries, employee benefits, equity compensation and other costs), materials and supplies, facilities and maintenance costs attributable to research and development functions; and

- fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing, related testing and clinical trial activities.

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 of the impact of exchange rates derived from re-measurement of monetary balance sheet items denominated in non-dollar currencies. Other financial expenses include bank's fees and interest on stockholders' loans.

Comparison of the Year Ended December 31, 2024, to the Year Ended December 31, 2023.

Our financial results for the year ended December 31, 2024, are summarized as follows in comparison to the year ended December 31, 2023:

	Year Ended	
	December 31, 2024	**December 31, 2023**
	U.S. dollars (in thousands)	
Operating Expenses:		
Research and Development		
Expenses incurred	**1,178**	2,061
Less- government grants	**(468)**	-
Research and development expenses, net	**710**	2,061
Marketing	**220**	822
General and Administrative	**1,011**	2,028
Total operating loss	**1,941**	4,911
Other income	**(48)**	-
Financing expenses (income), net	**6**	(2)
Loss for the year	**1,899**	4,909

Revenues. We have not recorded any revenues to date.

Research and Development Expenses. Research and development expenses decreased from $2,061,000 for the year ended December 31, 2023, to $710,000 for the year ended December 31, 2024. The decrease resulted primarily from a decrease in the use of third-party contractors for further research and development activities due to the completion of the development of the *PressureSafe*™ device and the measures we implemented to cut our costs in response to our cash flow situation, a reduction in payroll expenses, proceeds of a grant from the IIA, and a reduction in non-cash expenses recorded relating to stock-based compensation to employees.

Marketing Expenses. Marketing expenses decreased from $822,000 for the year ended December 31, 2023, to $220,000 in the year ended December 31, 2024. The decrease resulted primarily from the reduction in professional services, and a reduction in non-cash expenses attributable to stock-based compensation granted to employees and service providers.

General and Administrative Expenses. General and administrative expenses decreased from $2,028,000 for the year ended December 31, 2023, to $1,011,000 in the year ended December 31, 2024. The decrease resulted primarily from a decrease in non-cash expenses attributable to stock-based compensation to our directors, officers and service providers, a reduction in payroll expenses, and a reduction in fees for professional services following the cost-cutting measures we undertook as a response to our current cash flow limitations.

Loss. Loss for the year ended December 31, 2024, was $1,899,000 compared to $4,909,000 for the year ended December 31, 2023, and is primarily attributable to the decrease in use of third-party contractors for further research and development activities due to the completion of the development of the *PressureSafe*™ device, proceeds of a grant from the IIA, a decrease in non-cash expenses attributable to stock-based compensation to our directors, officers and service providers and a reduction in payroll expenses and in fees paid for professional services following the cost-cutting measures in response to our current cash flow limitations.

Liquidity and Capital Resources

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

From inception, we have funded our operations from a combination of loans and sales of equity instruments. In 2022 and 2023, we raised aggregate gross proceeds of $3,625,000 and $1,000,000, respectively, from sales of our equity and equity linked securities. In addition, on June 4 and July 4, 2024, we received aggregate

proceeds of $755,000 from the sales of our common stock and warrants to purchase shares of common stock in a private placement offering.

As of December 31, 2024, we had a total of $129,000 in cash resources and approximately $545,000 of liabilities, consisting of $388,000 of current liabilities from operations.

The following table provides a summary of operating, investing, and financing cash flows for the years ended December 31, 2024, and 2023 respectively (in thousands):

	Year ended	
	December 31, 2024	December 31, 2023
	US Dollars (In thousands)	
Net cash used in operating activities	**(1,386)**	(3,232)
Net cash used in investment activities	**-**	(2)
Net cash provided by financing activities	**750**	1,000

We have experienced operating losses since the Company's inception and had a total accumulated deficit of $16,738,000 as of December 31, 2024. We expect to incur additional costs and require additional capital. We have incurred losses in nearly every year since inception and for the year ended December 31, 2024. These losses have resulted in significant cash used in operations. During the years ended December 31, 2024, and 2023, our cash used in operations was approximately $1,386,000 and $3,232,000, respectively. We need to continue and intensify our research and development efforts for our product candidates (which are in various stages of development), strengthen our patent portfolio, establish operations processes and pursue FDA clearance and international regulatory approvals. As we continue to conduct these activities, we expect the cash needed to fund operations to increase significantly over the next several years.

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.

In addition, on June 12, 2023, we raised aggregate proceeds of $1,000,000 from sales of our shares of common stock and warrants to purchase shares of common stock.

On June 4, 2024, we entered into a securities purchase agreement with certain, pursuant to which we agreed to issue and sell, in a private placement offering, 715,000 shares of our common stock, at a per share price of $1.00 and warrants to purchase up to an additional 1,144,000 shares of common stock. The warrants are exercisable beginning on the six (6) month anniversary of their issuance, have a term of five years from the initial exercise date and entitle the holders to purchase up to 1,144,000 shares of common stock. The warrants have an exercise price of $1.00 per share and contain a one-time dilution protection in the event the Company sells securities at a price less than the then exercise price in effect in a public offering in conjunction with a listing on a national securities exchange. The offering closed on June 7, 2024 and we received aggregate proceeds of $715,000.

On July 4, 2024, we entered into securities purchase agreements with a certain investor, pursuant to which it agreed to issue and sell, in a private placement offering, 40,000 shares of its common stock, at a per share price of $1.00 and warrants to purchase up to an additional 64,000 shares of common stock. The offering closed on July 10, 2024, and we received aggregate proceeds of $40,000. This transaction was part of the securities purchase agreements that were closed on June 7, 2024.

On March 11, 2025, we entered into an Equity Purchase Agreement with Williamsburg, pursuant to which the Investor agreed to invest up to Fifteen Million Dollars ($15,000,000) over a 24-month period (unless otherwise determined therein) in accordance with the terms and conditions of an Equity Purchase Agreement, dated as of March 11, 2025, by and between us and the Investor, or the Equity Purchase Agreement. In connection with the Equity Purchase Agreement, the parties also entered into a Registration Rights Agreement, or the Registration Rights Agreement, pursuant to which we agreed to register with the SEC our common stock issuable under the Equity Purchase Agreement. Pursuant to the terms of the Equity Purchase Agreement, the Investor agreed to accept a put notice of up to $500,000 upon a registration statement being declared effective by the SEC.

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

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

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

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements through the second quarter of 2025. Our requirements for additional capital during this period will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our development and engineering efforts to develop the *PressureSafe*™ and DiaSafe™ devices, clinical studies (to the extent necessary), preliminary testing activities and other related activities;
- the cost, timing and outcomes of regulatory related efforts for commercial sales approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

For the year ended December 31, 2024, and as of the date of this report, we assessed our financial condition and concluded that based on our current and projected cash resources and commitments, as well as other factors mentioned above, there is a substantial doubt about our ability to continue as a going concern. We are planning to raise additional capital to continue our operations, as well as to explore additional avenues to increase revenues and reduce expenditures. We cannot be sure that future funding will be available to us on acceptable terms, or at all. Due to 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.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Accounting for share-based compensation

We recognize all employee and nonemployee stock-based compensation as a cost in the consolidated financial statements. For awards with a graded vesting schedule, we use the graded vesting attribution approach to recognize compensation cost over the vesting period.

We estimated grant date fair value using the Black-Scholes-Merton option-pricing model.

Smaller Reporting Company Status

Currently, we qualify as a smaller reporting company.

As a smaller reporting company, we are eligible and have taken advantage of certain exemptions from various reporting requirements that are not available to public reporting companies that do not qualify for this classification, including, but not limited to:

● An opportunity for reduced disclosure obligations regarding executive compensation in our periodic and annual reports, including without limitation exemption from the requirement to provide a compensation discussion and analysis describing compensation practices and procedures,

● An opportunity for reduced financial statement disclosure in registration statements and in annual reports on Form 10-K, which only requires two years of audited financial statements rather than the three years of audited financial statements that are required for other public companies,

● An opportunity for reduced audit and other compliance expenses as we are not subject to the requirement to obtain an auditor's report on internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002, and

● An opportunity to utilize the non-accelerated filer time-line requirements beginning with our annual report for the year ending December 31, 2024, and quarterly filings thereafter.

For as long as we continue to be a smaller reporting company, we expect that we will take advantage of both the reduced internal control audit requirements and the disclosure obligations available to us as a result of this classification.

JOBS Act Transition Period

Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies which may make comparison of our financials to those of other public companies more difficult.

MANAGEMENT

Directors, Executive Officers and Advisors

The Company's directors hold office until the next annual general meeting of the stockholders or until their successors are elected and qualified. The Company's officers are appointed by its board of directors and hold office until the earlier of their death, retirement, resignation, or removal.

The following table sets forth the names and ages of the members of the board of directors and the executive officers and the positions held by each as of May 12, 2025.

Name	Age	Positions
Ran Ziskind	56	Chief Executive Officer
Oded Bashan	78	Chairperson of the Board of Directors

Aharon Klein	64	Chief Technology Officer, Director
Sharon Levkoviz	51	Chief Financial Officer
Aharon Binur	61	Chief Development Officer
Yaniv Cohen	45	Director
Ohad Bashan	54	Director
Ron Mayron	61	Director
Yechiel Even	76	Director

The Company is authorized to have at least one director but no more than five. Each of the Company's directors serves for a term of one year or until a successor is elected and qualified. Set forth below is a brief description of the background and business experience of our executive officers and directors.

Ran Ziskind, was appointed to act as Chief Executive Officer on September 1, 2024. Mr. Ziskind was co-founder and CEO of Galatea Ltd., a groundbreaking startup in diamond manufacturing from 2004 to 2023. Under his leadership, Galatea developed a pioneering electro-optics technology that became the industry gold standard, driving significant innovations in the field. His role encompassed a broad range of responsibilities, including spearheading research and development, managing intellectual property with a global patent portfolio, defining product specifications, and leading the company through challenging global conditions, including the 2007-2008 financial crisis, ultimately resulting in its acquisition by Sarin Technologies, the world's leading company in the field. Prior to this, Mr. Ziskind was an engineer at Lithotech Ltd., where he contributed to the development of medical technologies, and at Eurika Ltd., where he worked on various engineering projects. Mr. Ziskind has dual degrees in mechanical engineering and management from Tzur University.

Oded Bashan, co-founded IR. Med Ltd. with Aharon Klein and, since September 2013 has been serving as Chairman of IR. Med Ltd. Upon the effectiveness of our acquisition in December 2020 of IR. Med Ltd. (the "Acquisition"), he was appointed to Board of Directors and on January 20, 2021, was appointed as Chairman of the Board, and on April 6, 2021, he was appointed Chief Executive Officer on an interim basis following the resignation of Ms. Davidson Mund. Mr. Bashan has over 35 years of experience in managing, building and running technology companies. He was Founder, CEO & chairman of OTI Ltd. from 1990 to 2013, a Nasdaq traded global technology leader with more than 250 employees. Since January 2013, together with his son Mr. Ohad Bashan, they have been managing several private companies engaged in biotech. Previously, Mr. Bashan served as the president of Electro-Galil form 1984 to1990. He was awarded the Leading Businessman Award in Management, Business and Economics by the Israeli Institute of Public Opinion. Mr. Bashan holds both B.Sc. and M.Sc. in Economics and Business management from the Hebrew University of Jerusalem.

Aharon Klein, co-founded IR. Med Ltd. in September 2013 and has served as a director of the Company since. He also served as the Company's Chief Operating Officer from September 2013 until December 2020, as well as the Company's Interim Chief Executive Officer from February 2024 to September 2024. Since December 2020, Mr. Klein serves as the Company's Chief Technology Officer. Mr. Klein is a medical device and biotech expert, with a strong clinical background. Prior to founding the Company, from 2004 to 2007 Mr. Klein co-founded and served as Chief Executive Officer of Fertiligent, a start-up company focused on innovative fertility treatments, which was acquired by a United Kingdom based investment group in 2008. From 2008 to 2013, immediately prior to co-founding of the Company, he founded a medical device company developing infrared based diagnostic tools for diagnosing colon cancer without the need for biopsies (optical biopsies). Mr. Klein graduated from the Faculty of Engineering in the Technion - Israel Institute of Technology. Mr. Klein is experienced in initiating and running medical device start-up companies, including development, clinical trials and regulatory affairs.

Sharon Levkoviz, was appointed to Chief Financial Officer upon the effectiveness of the Acquisition. Mr. Levkoviz served from 2011-2021 in Achdut Israel Ltd., an Israeli company providing accounting and economic consulting services, as regional manager. Prior to that period, Mr. Levkoviz served as a Chief Controller at OTI, Nasdaq traded company, from 2005 through 2011. Mr. Levkoviz received his CPA from Ramat Gan College and a B.A. in Business Administration from Rupin College in Israel. In addition, Mr. Levkoviz served 10 years as a chairman of finance and human resource committee at Ohalo College. He also served five years as a director at the development company of Katzrin and eight years as a member of Katzrin plenum.

Aharon Binur, was appointed as Chief Development Officer on April 29, 2021, to lead product development. Mr. Binur is an electronics engineer who graduated from the Technion in Haifa, Israel. He was an electronics engineer at OTI from November 1999 through February 2001 and became a development manager at a subsidiary of OTI in March 2001 and held several other positions at OTI through April 2013. Mr. Binur also served as CTO (August 2009 through November 2014) and VP of R&D (March 2017 through April 2021) at Lehavot, an advanced fire protection system company. Mr. Binur has extensive experience in multidisciplinary technological management, including software, hardware and mechanics, development of final systems and products for clients, while maintaining high quality and international standards. Mr. Binur has a unique and creative approach to technology management, including patents registered in his name.

Yaniv Cohen, co-founded IR. Med Ltd. in September 2013 and has served as the R&D manager since then. Following the completion of the of IR. Med Ltd. by our company (the "Acquisition"), he was appointed to the Board. Mr. Cohen is an experienced electrical engineer with expertise in the fields of wave propagation and IR Spectroscopy for medical applications. Additionally, Mr. Cohen holds four patents in medical devices, has co-authored eight articles in scientific journals, and has spoken in conferences around the globe. From 2010 to 2013, Mr. Cohen served as R&D manager for PIMS, an Israeli medical device company, focusing on IR imaging and spectral analysis for non-invasive cancer assessment and identification. From 2008 to 2009, Mr. Cohen worked for Cisco as a system engineer. From 2006 to 2008, he worked as a service engineer for Intel Israel. Mr. Cohen is a Candidate of Sciences in the doctoral program, Informatics and Computer Engineering in the National Research University Higher School of Economics, School of Electronic Engineering Institute of Electronics and Mathematics (MIEM HSE) in Moscow, Russia. Mr. Cohen holds a M.Sc. in Electrical Engineering from Holon Institute of Technology (2007). From 2009 to 2010, he attended the Ben-Gurion University of the Negev, Beer Sheva, Israel where he wrote a thesis in wave prorogation.

Ohad Bashan, joined the Board upon the completion of the Acquisition. Mr. Bashan is an entrepreneur, innovator and executive with a proven track record of more than 25 years of building, leading and running technology companies from startup to NASDAQ trade. He is an experienced director, after having served on the boards of private and publicly traded companies in the U.S., Israel, China, Poland and France. From 1998 to 2013, Mr. Bashan held several senior positions at OTI, which was acquired by Nyax Ltd. From 2013 to the present, Mr. Bashan has run a management services business. Mr. Bashan holds a B.A. in business from the College of Business Management, Tel Aviv, with specializations in marketing and finance, and an M.B.A. from Pepperdine University, California.

Ron Mayron, joined the Board upon the completion of the Acquisition. Mr. Mayron has extensive experience in the pharmaceutical and medical equipment industries and has held various, significant senior management positions, both local and global, within Teva Pharmaceutical Industries Ltd. ("Teva") over the last 21 years. During his career at Teva, Mr. Mayron served in various VP positions. Most recently he was CEO of Teva Israel and VP Israel and Africa from June 2009 until September 2013. Mr. Mayron's core expertise is in marketing, sales and distribution, mergers and acquisitions, business development, global operation and supply chain and strategic development.

Mr. Mayron currently serves on the board of directors of Innocan Pharma Corporation (CSE: INNO), Nurexone Biologic Inc. (TSX: NRX), IceCure Medical Ltd. (NASDAQ: ICCM), BioLight Life Sciences Ltd. (TASE: BOLT), Entera Bio (NASDAQ: ENTX) and Kadimastem Ltd. (TASE: KDST). Mr. Mayron holds a B.Sc. in Industrial Engineering & Management from Ben Gurion University and M.B.A from Tel-Aviv University.

Yechiel Even, age 76, is a senior economic consultant, Israeli business executive, and former Israeli Air Force officer with over 35 years of experience in economic consulting, strategic advisory, and investment banking. Mr. Even currently serves as Chairman of the Board and founding partner of Giza Singer Even Ltd., Israel's leading economic consulting and investment banking firm, a position he has held since 2004. In this role, he leads complex consulting engagements across sectors including infrastructure, technology, real estate, and government privatization, and oversees the firm's strategic development and operations. From 1991 to 2004, Mr. Even served as Founder and Partner at Singer & Even Ltd., where he advised on high-profile infrastructure and BOT projects such as Road 6 and national desalination initiatives, and supported companies in capital raising, valuation, and due diligence processes. Mr. Even has provided expert consulting on large-scale real estate developments, high-tech company valuations, and financial structuring for both private entities and government corporations. He has also delivered expert opinions in legal and regulatory proceedings, particularly in the areas of antitrust, commerce, and industry. Mr. Even holds an M.B.A. with a specialization in Finance (1987) and a B.A. in Economics and Business Administration (1985), both from Bar-Ilan University.

Family Relationships

Oded Bashan is the father of Ohad Bashan.

Director Independence

Our Board of Directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based on this review, our Board of Directors has determined that Ron Mayron and Yechiel Even are "independent directors" as defined in Nasdaq Listing Rules and Rule 10A-3 promulgated under the Exchange Act.

Corporate Governance

We strongly believe that our success depends on all of our employees identifying with our company's purpose and understanding how their work contributes to the Company's overall strategy. To this end, we engaged in an inclusive all-company process to develop our company purpose, vision, mission and values.

Our corporate culture and values, along with our employees are our most valuable. These values, are:

- Passion,
- Integrity,
- Excellence,
- Responsibility,
- Innovation, and
- Spirit of Collaboration

These values form part of our goal setting and review process to ensure accountability to these values at all levels. In order to further ensure that we live our values, and our culture stays unique and strong, our Board of Directors and executive management team put significant focus on our human capital resources.

We utilize a variety of channels to facilitate open and direct communication, including: (i) monthly all-hands staff meetings, (ii) regular open learning forums to promote peer learning or town hall meetings with executives; (iii) regular ongoing update communications; and (iv) employee surveys beyond the annual engagement survey referenced above on an as-needed basis.

Term of Office of Directors

We currently have authorized six directors. In accordance with our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, our Board of Directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders commencing with the meeting in 2021, the successors to the directors whose terms then expire will be elected to serve until the third annual meeting following the election. Our directors are divided among the three classes as follows:

- Class I directors are Yechiel Even and Yaniv Cohen, and their term will expire at the annual meeting of stockholders to be held in 2025;
- Class II directors are Ohad Bashan and Ron Mayron, and their terms will expire at the annual meeting of stockholders to be held in 2026; and
- Class III directors are Oded Bashan and Aharon Klein, and their terms should have expired at the annual meeting of stockholders to be held in 2024. As we did not hold the annual meeting of stockholders in 2024, the Class III directors will be subject to reelection in our annual meeting of stockholders to be held in 2025.

On March 27, 2025, Ms. Avital Rosenberg notified us of her resignation from the Board, effective immediately. The resignation of Ms. Rosenberg as a director was not related to any disagreement with the Company on any matter relating to the Company's operations, policies or practices.

Committees of the Board of Directors

Our Board of Directors has established an audit committee which operates under a charter that has been approved by our board.

Our Board of Directors has determined that all of the members of our audit committee are independent as defined under the rules of the Nasdaq Capital Market. In addition, all members of the audit committee meet the independence requirements contemplated by Rule 10A-3 under the Exchange Act. We currently do not have a board member that qualifies as an "audit committee financial expert" as defined in Item 407(D)(5) of Regulation S-K.

We currently do not have a nominating or compensation committees or committees performing similar functions, nor does our Company have a written nominating or compensation charter. Our directors believe that it is not necessary to have such committees at this time because the director(s) can adequately perform the functions of such committees.

Audit Committee

Our audit committee is comprised of Mr. Ron Mayron and Mr. Yechiel Even , who are independent directors . Mr. Mayron is the Chairman of the Audit Committee and is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K. The Audit Committee's main function is to oversee our accounting and financial

reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements;
- reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board any changes to such investment policy;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

EXECUTIVE COMPENSATION

The following table summarizes the compensation earned in each of our fiscal years that ended December 31, 2024 and 2023 by our named executive officers, which consists of our chief executive officer and our two next most highly compensated executive officers who earned more than $100,000 during the fiscal year ended December 31, 2024 and 2023 and were serving as executive officers as of such date and our former chief executive officers. We refer to the executive officers listed below as the Named Executive Officers.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($) (1)	All other compensation ($) (2)	Total ($)
Ran, Ziskind	2024	8,219		60,021	1,527	69,767
Chief Executive Officer (3)	2023	-		-	-	-
Oded Bashan,	2024	-		-	-	-
Executive Chairman	2023	-		273,728	-	273,728
Aharon Klein,	2024	105,886		-	16,438	122,324
Chief Technology Officer and former Interim Chief Executive Officer	2023	90,657		-	10,417	101,074
Aharon Binur	2024	87,168		37,345	39,343	163,856
Chief Development Officer (4)	2023	114,558		92,268	45,845	252,671
Mr. Tzur Di Cori,	2024	39,425		-	18,219	57,644
former Chief Executive Officer (5)	2023	31,135		48,031	14,811	93,977

1. In accordance with SEC rules, the amounts in this column reflect the fair value on the grant date of the option awards granted to the named executive, calculated in accordance with ASC Topic 718. Stock options were valued using the Black-Scholes model. The grant-date fair value does not necessarily reflect the value of shares which may be received in the future with respect to these awards. The grant-date fair value of the stock options in this column is a non-cash expense for us that reflects the fair value of the stock options on the grant date and therefore does not affect our cash balance. The fair value of the stock options will likely vary from the actual value the holder receives because the actual value depends on the number of options exercised and the market price of our Common Stock on the date of exercise. For a discussion of the assumptions made in the valuation of the stock options, see Note 9.C to the Annual Report on Form 10-K for the year ended December 31, 2024.
2. For 2023 and 2022, represents the compensation as described under the caption "All Other Compensation" below.
3. Mr. Ziskind was appointed Chief Executive Officer on September 1, 2024.
4. Mr. Klein served as Interim Chief Executive Officer from February 28, 2024 to September 1, 2024.
5. Mr. Tzur Di-Cori was appointed Chief Executive Officer on October 15, 2023, and on February 22, 2024, the Board of Directors terminated his employment.

There are no arrangements for officers, employees or advisors that would result from a change-in-control.

All Other Compensation

The following table provides information regarding each component of compensation for fiscal years 2024 and 2023 included in the "All Other Compensation" column in the "Summary Compensation Table" above. Represents amounts paid in New Israeli Shekels (NIS) and converted at average exchange rates for the year.

Name	Year	Automobile and Related Expenses $ (1)	Social Benefits $ (2)	Total $
Ran Ziskind	2024	-	1,527	1,527

	2023	-	-	-
Aharon Klein	2024	16,438	-	16,438
	2023	10,417	-	10,417
Aharon Binur	2024	15373	23,970	39,343
	2023	15,805	30,040	45,845
Tzur Di Cori	2024	7,849	10,370	18,219
	2023	5,755	9,056	14,811

1. Represents a leased automobile expense.

2. These are comprised of contributions by us to savings, health, severance, pension, disability and insurance plans generally provided in Israel, including health, education, managerial insurance funds, and redeemed vacation pay. This amount represents Israeli severance fund payments, managerial insurance funds, disability insurance, supplemental education fund contribution and social securities. See discussion below under "Narrative Disclosure to Summary Compensation Table."

Outstanding Equity Awards on December 31, 2024

The following table sets forth information concerning equity awards held by each of our Named Executive Officers as of December 31, 2024.

Name	Grant Date	Number of Securities Underlying Options (#) Exercisable	Number of Securities Underlying Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Ran Ziskind	August 21,2024	-	1,400,00	0.58	*
Oded Bashan	June 20,2021	240,000	-	0.32	*
Oded Bashan	December 30, 2022	1,200,000	-	0.58	*
Aharon Klein	June 20,2021	240,000	-	0.32	*
Aharon Binur	June 20,2021	225,000	75,000	0.32	*
Aharon Binur	November 14, 2022	225,000	75,000	0.58	*

* Options expiration date is ten (10) years from vesting

Narrative Disclosure to Summary Compensation Table

Our Board follows the following processes and procedures for the consideration and determination of executive and director compensation:

In establishing compensation amounts for executives, we seek to provide compensation that is competitive in light of current market conditions and industry practices. Accordingly, we will generally review market data, which is comprised of proxy-disclosed data from peer companies and information from nationally recognized published surveys for the biopharmaceutical industry, adjusted for size. The market data helps the committee gain perspective on the compensation levels and practices at the peer companies and to assess the relative competitiveness of the compensation paid to our executives. The market data thus guides us in its efforts to set executive compensation levels and program targets at competitive levels for comparable roles in the marketplace. We then consider other factors, such as the importance of each executive officer's role to the Company, individual expertise, experience, performance, retention concerns and relevant compensation trends in the marketplace, in making its final compensation determinations.

Elements of Compensation

In addition to each officer's base salary, our executive officer compensation program consists of a cash incentive bonus plan and discretionary stock option awards in addition to customary benefits. The amounts of compensation awarded for each element of the Company's compensation program (*i.e.*, base salary, bonuses and stock options) are reviewed in connection with the Company's performance.

Base Salary

Annual base salaries compensate our executive officers for fulfilling the requirements of their respective positions and provide them with a level of cash income predictability and stability with respect to a portion of their total compensation. We believe that the level of an executive officer's base salary should reflect the executive's performance, experience and breadth of responsibilities, our understanding of salaries for similar positions within our industry and any other factors relevant to that particular job.

Base salaries are typically negotiated at the outset of an executive's employment. Salary levels are considered annually as part of our performance review process, but also in cases including promotion or other changes in the job responsibilities of an executive officer. For named executive officers, initial base salaries generally are established in connection with negotiation of an offer of employment and employment agreement. Increases in base salary have several elements. In addition to promotion and increased responsibilities, merit and Company-wide general increases are also taken into consideration.

Stock-Based Awards

Historically, we have generally granted stock options to our employees, including our named executive officers, in connection with their initial employment with us. We also have historically granted stock options on an annual basis as part of annual performance reviews of our employees.

Our equity award program is the primary vehicle for offering long-term incentives to our executives. We do not have any equity ownership guidelines for our executives, which is consistent with other pre-commercial biotechnology companies that use stock options as the long-term incentive vehicle. Further, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, the vesting feature of our equity awards contributes to executive retention by providing an incentive for our executives to remain in our employment during the vesting period. We expect that our Board will continue to use annual equity awards to compensate our executive officers. We may also make additional discretionary grants, typically in connection with the promotion of an employee, to reward an employee, for retention purposes or in other circumstances as the Board deems appropriate.

Employment and Severance Arrangements

We consider it essential to the best interests of our stockholders to foster the continuous employment of our key management personnel. In this regard, we recognize that the possibility of a change in control may exist and that the uncertainty and questions that it may raise among management could result in the departure or distraction of management personnel to the detriment of the Company and our stockholders. In order to reinforce and encourage the continued attention and dedication of certain key members of management, we have entered into written employment agreements with certain of our named executive officers that, while at-will, contain certain change in control and severance provisions.

Employment Agreements

Oded Bashan. On June 27, 2022, our subsidiary IR. Med Ltd. and Bashanti Ltd., a company that is owned by Oded Bashan, entered into consulting agreement. The Agreement provides for a continuous term and may be terminated by either party at any time with at least 12 months prior written notice. Pursuant to this agreement, Mr. Bashan's annual fee compensation is $144,000 plus value added tax (VAT). On October 26, 2022, Mr. Bashan agreed to defer payment of his fee pending a capital raise. On December 12, 2022, Mr. Bashan was awarded options under the Company's employee stock option plan for 1,200,000 shares of the Company's common stock at a per share price of $0.58, of which 600,000 were vested upon grant and the balance vest on December 30, 2023, subject to his continued service. The options are exercisable through the tenth anniversary of grant.

Aharon Klein. On October 31, 2024, our Board of Directors approved a reduction of Mr. Aharon Klein's compensation in light of our current cash position, which was agreed upon with Mr. Klein. Under the amended terms of Mr. Klein's service provider agreement, he will receive monthly payments of NIS 16,000, plus NIS 5,000 for car expenses totaling a monthly compensation of NIS 21,000 starting from October 2024 onwards. The current reduction amends an amendment to the consulting agreement with Mr. Aharon Klein, which we entered into on July 7, 2024 (the "Klein Amendment"). The Klein Amendment amended the original consulting agreement executed by and between us and Mr. Klein, dated October 1, 2019, as amended on December 24, 2020. Effective June 1, 2024, the Klein Amendment provides for a monthly compensation in the amount of NIS 30,000 and an additional NIS 5,000 for car expenses. All other terms related to Mr. Klein overall compensation and equity-based awards remain unchanged. If Mr. Klein's employment is terminated (i) by us without cause or (ii) by him for any, then we must pay Mr. Klein (a) the accrued obligations earned through the date of termination and (b) a lump-sum payment of an amount equal to one month of his base salary at the time of his termination.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions during the term of the agreement and 12 months thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter. Mr. Klein also agreed to assign certain intellectual property rights to IR. Med Ltd.

On December 25, 2024, due to the company's financial situation, the company and Mr. Klein decided to terminate the consulting agreement between the parties until further notice. Mr. Klein continues to serve as a director of the Company.

Aharon Binur. On March 2, 2021, IR. Med Ltd. and Aharon Binur entered into an employment agreement pursuant to which Mr. Binur oversees the development of our product candidates which are in various stages of development. Under the agreement with Mr. Binur, he is paid an annual salary of the current New Israeli Shekel equivalent of approximately $120,170, payable on monthly basis. IR. Med Ltd. is authorized to terminate the employment agreement for any reason subject to payment of two months' salary. Under the terms of the employment agreement with him, Mr. Binur also receives Manager's Insurance under Israeli law for his to which IR. Med Ltd. contributes amounts equal to (a) 8-1/3 percent for severance payments, and 6.5%, or up to 7.5% (including disability insurance) designated for premium payment (and Mr. Binur contributes an additional 6%) of each monthly salary and (b) 7.5% of his salary (with Mr. Binur contributing an additional 2.5%) to an education fund, a form of deferred compensation program established under Israeli law. Mr. Binur is also provided with a leased automobile.

On June 20, 2021, Mr. Binur was awarded 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 $0.32, of which 15,000 were vested upon grant and the balance vest at the end of each calendar quarter at the rate of 15,000 shares per quarter, beginning with the quarter ended September 31, 2021, subject to his continued employment. The options are exercisable through the tenth anniversary of grant.

On November 14, 2022, Mr. Binur was awarded 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, vesting at the end of each calendar quarter at the rate of 25,000 shares per quarter, beginning with the quarter ended December 31, 2022, subject to his continued employment. The options are exercisable through the tenth anniversary of grant.

On May 1, 2024, with the consent of the parties, Mr. Binur's salary was updated to 23,600 NIS (approximately $6,466) per month, and the notice termination period was shortened from two months to one month.

On October 1, 2024, with the consent of the parties, Mr. Binur's salary was updated to 16,000 NIS (approximately $4,384) per month.

On February 3, 2025, the parties agreed that for the months of January and February 2025, Mr. Binur's salary would be 8,500 NIS (approximately $2,295) and 10,000 NIS (approximately $2,700), respectively

On March 1st ,2025 the company and Mr. Binur agreed to amend the monthly salary to 30,000 NIS (approximately $8,100)

Tzur Di-Cori. On October 15, 2023, Mr. Di-Cori was appointed to serve as the Company's Chief Executive Officer. In conjunction with his appointment, the Company and Mr. Di-Cori entered into an employment agreement, pursuant to which he was subject to standard confidentiality, intellectual property assignment and non-compete provisions. In addition, in consideration of his service, Mr. Di-Cori received a monthly gross salary of NIS 45,000 ($11,842 approximately) and options to purchase 1,000,000 shares of the Company's common stock at an exercise price of $0.58 per share, subject to and in accordance with the terms and conditions of the Company's 2020 Incentive Stock Plan. On February 22, 2024, as a result of financial difficulties, the Company notified Mr. Di-Cori, of the termination of his employment.

Ran Ziskind. On September 1, 2024 Mr. Ziskind was appointed as Chief Executive Officer. In conjunction with his appointment, the Company and Mr. Ziskind entered into an employment agreement (the "Employment Agreement"), pursuant to which he will be subject to standard confidentiality, intellectual property assignment and non-compete provisions. In addition, in consideration for his service, Mr. Ziskind will receive a monthly gross salary of NIS 6,000 until the Company raises at least $4,000,000 in funding, and following such potential capital raise, his compensation will be increased to NIS 45,000 per month, as well as will be entitled to NIS 10,000 for car expenses. Under the Employment Agreement, Mr. Ziskind will also receive 1,400,000 restricted shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), at an exercise price of $0.58 per share (the "Shares"). The Shares will vest over a four-year period commencing on the grant date such that (i) 350,000 of the Shares will become fully vested and exercisable on the first anniversary elapsed from the grant date and (ii) the balance will vest in six (6) bi-annual installments of 175,000 Shares, subject to Mr. Ziskind's continued employment.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Except as described below, there has not been, nor is there currently proposed, any transaction to which we are or were a party in which the amount involved exceeds the lesser of $120,000 and 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers, holders of more than 5% of any class of our voting securities or any of their respective affiliates or immediate family members, had, or will have, a direct or indirect material interest.

In 2015, our subsidiary IR. Med Ltd. received a loan from certain of the former IR-Med stockholders to fund its continuing operations. This loan bore interest at an annual rate ranging in 2024 and 2023, from 5.18%-2.9% annually. The aggregate loan amount was repayable only upon the approval of IR Med's board of directors and when the Company's profits reach an amount of $500,000, and upon such terms and such installments as shall be determined by the Company's board of directors.

In 2017, our subsidiary IR. Med Ltd. received a loan from certain of the former IR-Med stockholder to fund its continuing operations. This loan bears interest at an annual rate ranging from 2.9%-5.18% annually in 2023 and 2024. The aggregate loan amount was repayable only upon the occurrence of an investment round greater than $500,000.

In March 2020, IR. Med Ltd. and the lenders agreed to amend and restate the terms of the above referenced loans, or the Amended Loan Agreement, pursuant to which the lender waived all rights to convert their respective outstanding loan amounts, and the repayment date was set to December 31, 2023, or such later date to be agreed between IR. Med Ltd. and the lender. On March 1, 2024, the lenders agreed to extent the repayment date to December 31, 2025.

On July 4, 2024, the Company and one of the lenders agreed to repay US$3 thousand from the total loans amount.

As of December 31, 2024, the carrying amounts of these loans were $35 thousand.

On March 6, 2018, certain of IR. Med Ltd.'s shareholders advanced to it a convertible bridge loan in the principal amount of NIS 379,000 ($104,000), hereinafter, the 2018 CLA, bearing a per annum interest rate of 3% compounded and accrued annually and, originally payable on December 31, 2018, or a later date agreed to by the then holders of 80% of the outstanding shares of IR. Med Ltd. Under the terms of the 2018 CLA, the loan is convertible by the holders under certain specified circumstances and is automatically convertible upon other terms. In an Exit event (as deveined in the 2018 CLA), the loan is repayable at 200% the outstanding amount or converted, at the option of the majority lenders. In March 2020, the Company and the lenders agreed to amend and restate the 2018 CLA ("the Amended CLA"). According to the Amended CLA, the lenders waived any and all rights to convert their respective outstanding loan amounts, and the repayment date was set to December 31, 2023, or such later date to be agreed by IR. Med Ltd. and the lenders. On March 1, 2024, the lenders agreed to extent the repayment date to December 31, 2025. In addition, in case of an Exit event, as described in the Amended CLA, the loan and all accrued interest will be fully repaid immediately following the Exit event.

On July 4, 2024, the Company and one of the lenders agreed to repay US$2 thousand from the total loan amount.

As of December 31, 2024, and 2023, the carrying amounts of the loans were $122,000 and $123,000, respectively.

For the years ended December 31, 2024, and 2023, the Company paid to two directors an aggregate consideration of $170 thousand and US$161 thousand, respectively, in respect of research and development services.

For the years ended December 31, 2024, and 2023 the Company paid to one shareholder of the Company and his relative an aggregate consideration of $5 thousand and $150 thousand, respectively in respect consulting services.

For the years ended December 31, 2024, and 2023, the Company paid to three of the Parent Company non-employee directors an aggregate consideration of US$32 thousand and US$36 thousand, respectively ,with respect of their services. For the year ended December 31, 2024, the Company paid to four of its officers, salary and related expenses that totaled to $252 thousand. For the year ended December 31, 2023, the Company paid to four of its officers, salary and related expenses totaled to $439 thousand, respectively, in respect thereof.

For the year ended December 31, 2024, the Company recorded a liability on amount of $82 thousand and for the year ended 2023, the Company paid a yearly amount of US$80 thousand to an entity in which two directors of the Company are stakeholders in the entity, for rent and office services

Following the adoption of the 2020 incentive stock plan, or the Plan, by the Company on December 23, 2020, and the adoption of the sub plan, or the Israeli Appendix, on April 29, 2021, the Company granted during the years 2024 and 2023 to its directors, officers, and shareholder 1,715,500 and 1,636,000 options to purchase shares of Common Stock respectively.

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

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of May 12, 2025 for (a) the executive officers named in the Summary Compensation Table of this annual report, (b) each of our directors, (c) all of our current directors and executive officers as a group and (d) each stockholder known by us to own beneficially more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Under the rules of the SEC, a stockholder is deemed to be a beneficial owner of any security of which that stockholder has the right to acquire beneficial ownership in 60 days of May 12, 2025. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based on 72,018,144 shares of common stock outstanding on May 12, 2025.

Name and Address of Beneficial Owner	Number of Shares beneficially owned	Percentage Beneficially owned
5% or more shareholders		
Yaakov Safren	5,550,060(1)	7.5%
Paul Coulson	5,625,000(2)	7.61%
Yoram Drucker	4,862,471(3)	6.87%
Third Eye Investors LLC	4,687,500(4)	6.37%

Isamar Margareten	8,727,907(5)	11.47%
Liat Electronics Ltd.	3,850,607	5.35%
Officers and Directors		
Oded Bashan	10,049,916(6)	13.68%
Aharon Klein	8,099,110(7)	11.21%
Yaniv Cohen	8,099,136(8)	11.21%
Ron Mayron	400,000	*
Yechiel Even	0	*
Ohad Bashan	240,000(9)	*
Aharon Binur	530,000(9)	*
Ran Ziskind	257,500(10)	*
Sharon Levkoviz	390,921(9)	*
Officers and Directors as a Group (9 persons)	**28,066,583**	**37.08%**

* less than 1%

(1) Includes 2,006,119 shares issuable upon the exercise of stock options.

(2) Includes 1,875,000 shares issuable under a currently exercisable common stock warrant.

(3) Includes 812,471 shares issuable upon the exercise of stock options.

(4) Yitzchak Rokonsky, of Third Eye Investors LLC, or Third Eye, has sole voting and dispositive power over shares held by Third Eye. Includes 1,562,500 shares issuable under a currently exercisable common stock warrant.

(5) Includes 4,043,466 shares issuable under a currently exercisable common stock warrant.

(6) Represents (i) 8,609,916 shares owned by Med2Bwell Ltd., or Med2Bwell, of which Mr. Bashan has sole voting and dispositive power and (ii) 1,440,000 shares of common stock issuable upon the exercise of stock options.

(7) Includes 240,000 shares issuable upon the exercise of stock options

(8) Includes 240,000 shares issuable upon the exercise of stock options.

(9) Represents shares of common stock issuable upon the exercise of stock options.

(10) Includes 75,500 shares issuable upon the exercise of stock options and 112,000 shares issuable under a currently exercisable common stock warrant.

DESCRIPTION OF SECURITIES

As of May 12, 2025, we had one class of securities registered under Section 12(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): Common Stock, $0.001 par value per share ("Common Stock"). Each of our securities registered under Section 12(g) of the Exchange Act are quoted on the OTC Market tier, QB.

General

As of the date of this registration statement, our authorized capital stock consists of 600,000,000 shares of Common Stock. As of May 12, 2025, there were 72,018,144 shares of our common stock outstanding.

In addition, as of the date of this registration statement, we had issued and outstanding:

- options to purchase 14,922,175 shares of our Common Stock, at a weighted average exercise price of $0.44 per share; and
- warrants to purchase 12,538,259 shares of our Common Stock, at a weighted average exercise price of $0.89 per share.

The following summary description of our capital stock is based on the provisions of our certificate of incorporation and bylaws, the applicable provisions of applicable law, including the provision of Chapters 78 and 92A of the Nevada Revised Statutes or NRS.

Common Stock

Each share of Common Stock entitles the holder to one vote on all matters submitted to a vote of the stockholders including the election of directors. Except as otherwise required by law the holders of our Common Stock possess all voting power. According to our bylaws, when a quorum is present or represented at any meeting, the vote of the holders of a majority of the stock having voting power present in person or represented by proxy shall be sufficient to elect members of the Board of Directors or to decide any question brought before such meeting, unless the question is one upon which by express provision of the statutes or of the Certificate of Incorporation, a different vote is required in which case such express provision shall govern and control the decision of such question.. Our bylaws provide that stockholders holding at least a majority of the shares entitled to vote, represented in person or by proxy, constitute a quorum at the meeting of our stockholders. Our bylaws also provide that any action which may be taken by the vote of the stockholders at a meeting may be taken without a meeting if authorized by the written consent of stockholders holding at least a majority of the voting power, unless the provisions of the statutes or of the Articles of Incorporation require a greater proportion of voting power to authorize such action in which case such greater proportion of written consents shall be required.

Our certificate of incorporation and bylaws do not provide for cumulative voting in the election of directors. Because the holders of our common stock do not have cumulative voting rights and directors are generally to be elected by a majority of the votes casts with respect to the directors at any meeting of our stockholders for the election of directors, holders of more than fifty percent, and in some cases less than 50%, of the issued and outstanding shares of our common stock can elect all of our directors.

Provisions of our Restated Certificate of Incorporation and Restated Bylaws

Classified board of directors. Our restated certificate of incorporation and restated bylaws provide that our board of directors is classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations. Our restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Amendment of Bylaws. Our bylaws provide that our board of directors may amend our bylaws by a majority vote of our board of directors including any bylaws

adopted by our stockholders, but our stockholders may from time to time specify particular provisions of these bylaws, which must not be amended by our board of directors. Our current bylaws were adopted by our board of directors. Therefore, our board of directors can amend our bylaws to make changes to the provisions relating to the quorum requirement and votes requirements to the extent permitted by Nevada Law.

Dividend Rights. The holders of our common stock are entitled to receive such dividends as may be declared by our board of directors out of funds legally available for dividends. Our board of directors is not obligated to declare a dividend. Any future dividends will be subject to the discretion of our board of directors and will depend upon, among other things, future earnings, the operating and financial condition of our company, its capital requirements, general business conditions and other pertinent factors. We do not anticipate that dividends will be paid in the foreseeable future.

Miscellaneous Rights and Provisions. In the event of our liquidation or dissolution, whether voluntary or involuntary, each share of our common stock is entitled to share ratably in any assets available for distribution to holders of our common stock after satisfaction of all liabilities.

Our common stock is not convertible or redeemable and has no preemptive, subscription or conversion rights. There are no conversions, redemption, sinking fund or similar provisions regarding our common stock.

Our common stock, after the fixed consideration thereof has been paid or performed, are not subject to assessment, and the holders of our common stock are not individually liable for the debts and liabilities of our company.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer Company located at 18 Lafayette Pl, Woodmere, NY 11598.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following discussion is a summary of the U.S. federal income tax considerations generally applicable to the ownership and disposition of our Common Stock. This summary is based upon U.S. federal income tax law as of the date of this prospectus, which is subject to change or differing interpretations, possibly with retroactive effect. This summary does not discuss all aspects of U.S. federal income taxation that may be important to particular investors in light of their individual circumstances, including investors subject to special tax rules (e.g., financial institutions, insurance companies, broker-dealers, tax-exempt organizations (including private foundations), taxpayers that have elected mark-to-market accounting, S corporations, regulated investment companies, real estate investment trusts, passive foreign investment companies, controlled foreign corporations, investors that will hold Common Stock as part of a straddle, hedge, conversion, or other integrated transaction for U.S. federal income tax purposes, or investors that have a functional currency other than the U.S. dollar), all of whom may be subject to tax rules that differ materially from those summarized below. In addition, this summary does not discuss other U.S. federal tax consequences (e.g., estate or gift tax), any state, local, or non-U.S. tax considerations or the Medicare tax or alternative minimum tax. In addition, this summary is limited to investors that will hold our securities as "capital assets" (generally, property held for investment) under the Code. No ruling from the Internal Revenue Service, (the "IRS") has been or will be sought regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain a position contrary to any of the tax aspects set forth below.

For purposes of this summary, a "U.S. Holder" is a beneficial holder of securities who or that, for U.S. federal income tax purposes is:

- an individual who is a United States citizen or resident of the United States;
- a corporation or other entity treated as a corporation for United States federal income tax purposes created in, or organized under the law of, the United States or any state or political subdivision thereof;
- an estate the income of which is includible in gross income for United States federal income tax purposes regardless of its source; or
- a trust (A) the administration of which is subject to the primary supervision of a United States court and which has one or more United States persons (within the meaning of the Code) who have the authority to control all substantial decisions of the trust or (B) that has in effect a valid election under applicable Treasury regulations to be treated as a United States person.

A "non-U.S. Holder" is a beneficial holder of securities that is neither a U.S. Holder nor a partnership for U.S. federal income tax purposes.

If a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our securities, the tax treatment of a partner, member or other beneficial owner in such partnership will generally depend upon the status of the partner, member or other beneficial owner, the activities of the partnership and certain determinations made at the partner, member or other beneficial owner level. If you are a partner, member or other beneficial owner of a partnership holding our securities, you are urged to consult your tax advisor regarding the tax consequences of the ownership and disposition of our securities.

THIS DISCUSSION MATERIAL OF U.S. FEDERAL INCOME TAX CONSIDERATIONS IS FOR GENERAL INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE HOLDERS SHOULD CONSULT THEIR TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF OWNING AND DISPOSING OF OUR SECURITIES, AS WELL AS THE APPLICATION OF ANY, STATE, LOCAL AND NON-U.S. INCOME, ESTATE AND OTHER TAX CONSIDERATIONS.

U.S. Holders

Taxation of Distributions

We have not paid cash dividends on our capital stock, and we do not anticipate paying any dividends on our Common Stock in the foreseeable future. However, if we do pay distributions to U.S. Holders of shares of our Common Stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. Holder's adjusted tax basis in our Common Stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the Common Stock and will be treated as described under "U.S. Holders—Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock" below.

Dividends we pay to a U.S. Holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. Holder will generally constitute "qualified dividends" that will be subject to tax at the maximum tax rate accorded to long-term capital gains.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock

U.S. Holder will recognize gain or loss on the sale, taxable exchange or other taxable disposition of our Common Stock. Any such gain or loss will be capital gain or loss, and

will be long-term capital gain or loss if the U.S. Holder's holding period for the Common Stock so disposed of exceeds one year. The amount of gain or loss recognized will generally be equal to the difference between (1) the sum of the amount of cash and the fair market value of any property received in such disposition and (2) the U.S. Holder's adjusted tax basis in its Common Stock so disposed of. A U.S. Holder's adjusted tax basis in its Common Stock will generally equal the U.S. Holder's acquisition cost less any prior distributions treated as a return of capital. The deductibility of capital losses is subject to limitations.

Redemption of Common Stock

In the event that a U.S. Holder's Common Stock is redeemed by us, including pursuant to an open market transaction, the treatment of the transaction for U.S. federal income tax purposes will depend on whether the redemption qualifies as sale of the Common Stock under Section 302 of the Code. If the redemption qualifies as a sale of Common Stock under the tests described below, the tax consequences to the U.S. Holder will be the same as described under "U.S. Holders—Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock" above. If the redemption does not qualify as a sale of Common Stock, the U.S. Holder will be treated as receiving a corporate distribution, the tax consequences of which are described above under "U.S. Holders—Taxation of Distributions." Whether the redemption qualifies for sale treatment will depend primarily on the total number of shares of our stock treated as held by the U.S. Holder both before and after the redemption. The redemption of Common Stock will generally be treated as a sale of the Common Stock (rather than as a corporate distribution) if the redemption (1) is "substantially disproportionate" with respect to the U.S. Holder, (2) results in a "complete termination" of the U.S. Holder's interest in us or (3) is "not essentially equivalent to a dividend" with respect to the U.S. Holder. These tests are explained more fully below.

In determining whether any of the foregoing tests are satisfied, a U.S. Holder takes into account not only stock actually owned by the U.S. Holder, but also shares of our stock that are constructively owned by it. A U.S. Holder may constructively own, in addition to stock owned directly, stock owned by certain related individuals and entities in which the U.S. Holder has an interest or that have an interest in such U.S. Holder. A redemption of a U.S. Holder's stock will be substantially disproportionate with respect to the U.S. Holder if the percentage of our outstanding voting stock actually and constructively owned by the U.S. Holder immediately following the redemption of Common Stock is, among other requirements, less than 80% of the percentage of our outstanding voting stock actually and constructively owned by the U.S. Holder immediately before the redemption. There will be a complete termination of a U.S. Holder's interest if either (1) all of the shares of our stock actually and constructively owned by the U.S. Holder are redeemed or (2) all of the shares of our stock actually owned by the U.S. Holder are redeemed and the U.S. Holder is eligible to waive, and effectively waives in accordance with specific rules, the attribution of stock owned by certain family members and the U.S. Holder does not constructively own any other stock. The redemption of the Common Stock will not be essentially equivalent to a dividend if the redemption results in a "meaningful reduction" of the U.S. Holder's proportionate interest in us. Whether the redemption will result in a meaningful reduction in a U.S. Holder's proportionate interest in us will depend on the particular facts and circumstances. The IRS has indicated in a published ruling that even a small reduction in the proportionate interest of a small minority stockholder in a publicly held corporation who exercises no control over corporate affairs may constitute such a "meaningful reduction." A U.S. Holder is urged to consult its tax advisors as to the tax consequences of a redemption, including the application of the constructive ownership rules described above.

If none of the foregoing tests is satisfied, the redemption will be treated as a corporate distribution, the tax consequences of which are described under "U.S. Holders—Taxation of Distributions," above. After the application of those rules, any remaining tax basis of the U.S. Holder in the redeemed Common Stock should be added to the U.S. Holder's adjusted tax basis in its remaining stock, or, if it has none, to the U.S. Holder's adjusted tax basis in its warrants or possibly in other stock constructively owned by it.

Non-U.S. Holders

Taxation of Distributions

In general, any distributions (including constructive distributions) we make to a non-U.S. Holder of shares of our Common Stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the non-U.S. Holder's conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such non-U.S. Holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E, as applicable). In the case of any constructive dividend, it is possible that this tax would be withheld from any amount owed to a non-U.S. Holder by the applicable withholding agent, including cash distributions on other property or other property subsequently paid or credited to such holder. Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the non-U.S. Holder's adjusted tax basis in its shares of our Common Stock and, to the extent such distribution exceeds the non-U.S. Holder's adjusted tax basis, as gain realized from the sale or other disposition of the Common Stock, which will be treated as described under "Non-U.S. Holders—Gain on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock" below. In addition, if we determine that we are classified as a "United States real property holding corporation" (see "Non-U.S. Holders—Gain on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock" below), we will withhold 15% of any distribution that exceeds our current and accumulated earnings and profits.

Dividends we pay to a non-U.S. Holder that are effectively connected with such non-U.S. Holder's conduct of a trade or business within the United States (or if a tax treaty applies are attributable to a U.S. permanent establishment or fixed base maintained by the non-U.S. Holder) will generally not be subject to U.S. withholding tax, provided such non-U.S. Holder complies with certain certification and disclosure requirements (usually by providing an IRS Form W-8ECI). Instead, such dividends will generally be subject to U.S. federal income tax, net of certain deductions, at the same graduated individual or corporate rates applicable to U.S. Holders. If the non-U.S. Holder is a corporation, dividends that are effectively connected income may also be subject to a "branch profits tax" at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

Gain on Sale, Exchange or Other Taxable Disposition of Common Stock

A non-U.S. Holder will generally not be subject to U.S. federal income or withholding tax in respect of gain recognized on a sale, taxable exchange or other taxable disposition of our Common Stock unless:

- the gain is effectively connected with the conduct of a trade or business by the non-U.S. Holder within the United States (and, if an applicable tax treaty so requires, is attributable to a U.S. permanent establishment or fixed base maintained by the non-U.S. Holder);
- the non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met; or
- we are or have been a "United States real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the non-U.S. Holder held our Common Stock, and, in the case where shares of our Common Stock are regularly traded on an established securities market, the non-U.S. Holder has owned, directly or constructively, more than 5% of our Common Stock at any time within the shorter of the five-year period preceding the disposition or such non-U.S. Holder's holding period for the shares of our Common Stock. There can be no assurance that our Common Stock will be treated as regularly traded on an established securities market for this purpose.

Gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates. Any gains described in the first bullet point above of a non-U.S. Holder that is a foreign corporation may also be subject to an additional "branch profits tax" at a 30% rate (or lower applicable treaty rate). Gain described in the second bullet point above will generally be subject to a flat 30% U.S. federal income tax. Non-U.S. Holders are urged to consult their tax advisors regarding possible eligibility for benefits under income tax treaties.

If the third bullet point above applies to a non-U.S. Holder, gain recognized by such holder on the sale, exchange or other disposition of our Common Stock will be subject to tax at generally applicable U.S. federal income tax rates. In addition, a buyer of our Common Stock from such holder may be required to withhold U.S. income tax at a rate of 15% of the amount realized upon such disposition. We will be classified as a United States real property holding corporation if the fair market value of our "United States real property interests" equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests plus our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes. We do not believe we currently are or will become a United States real property holding corporation, however there can be no assurance in this regard. Non-U.S. Holders are urged to consult their tax advisors regarding the application of these rules.

Redemption of Common Stock

The characterization for U.S. federal income tax purposes of the redemption of a non-U.S. Holder's Common Stock will generally correspond to the U.S. federal income tax characterization of such a redemption of a U.S. Holder's Common Stock, as described under "U.S. Holders—Redemption of Common Stock" above, and the consequences of the redemption to the non-U.S. Holder will be as described above under "Non-U.S. Holders—Taxation of Distributions" and "Non-U.S. Holders—Gain on Sale, Exchange or Other Taxable Disposition of Common Stock," as applicable.

Foreign Account Tax Compliance Act

Sections 1471 through 1474 of the Code and the Treasury Regulations and administrative guidance promulgated thereunder (commonly referred as the "Foreign Account Tax Compliance Act" or "FATCA") generally impose withholding at a rate of 30% in certain circumstances on dividends in respect of, and the gross proceeds of dispositions of, our securities which are held by or through certain foreign financial institutions (including investment funds), unless any such institution (1) enters into, and complies with, an agreement with the IRS to report, on an annual basis, information with respect to interests in, and accounts maintained by, the institution that are owned by certain U.S. persons and by certain non-U.S. entities that are wholly or partially owned by U.S. persons and to withhold on certain payments, or (2) if required under an intergovernmental agreement between the United States and an applicable foreign country, reports such information to its local tax authority, which will exchange such information with the U.S. authorities. Under proposed Treasury Regulations promulgated by the Treasury Department on December 13, 2018, which state that taxpayers may rely on the proposed Treasury Regulations until final Treasury Regulations are issued, this withholding tax will not apply to the gross proceeds from the sale or disposition of our securities. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Accordingly, the entity through which our securities are held will affect the determination of whether such withholding is required. Similarly, dividends in respect of our securities held by an investor that is a non-financial non-U.S. entity that does not qualify under certain exceptions will generally be subject to withholding at a rate of 30%, unless such entity either (1) certifies to us or the applicable withholding agent that such entity does not have any "substantial United States owners" or (2) provides certain information regarding the entity's "substantial United States owners," which will in turn be provided to the U.S. Department of Treasury. Prospective investors should consult their tax advisors regarding the possible implications of FATCA on their investment in our securities.

LEGAL MATTERS

The validity of the shares of common stock offered in this prospectus is being passed upon for us by Sullivan and Worcester LLP, New York, New York.

EXPERTS

The consolidated financial statements of IR-Med Inc. as of December 31, 2024 and 2023 and for each of the years in the two-year period ended December 31, 2024, have been included herein in reliance upon the report of Somekh Chaikin, a member firm of KPMG International, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The audit report covering the December 31, 2024 consolidated financial statements contains an explanatory paragraph that states that the Company's recurring losses from operations and accumulated deficit raise substantial doubt about the entity's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information requirements of the Exchange Act and we therefore file periodic reports, proxy statements and other information with the SEC relating to our business, financial statements and other matters. The reports, proxy statements and other information we file may be inspected and copied at prescribed rates at the SEC's Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the SEC. The address of the SEC's website is http://www.sec.gov.

This prospectus constitutes part of a registration statement on Form S-1 filed under the Securities Act with respect to the shares of common stock covered hereby. As permitted by the SEC's rules, this prospectus omits some of the information, exhibits and undertakings included in the registration statement. You may read and copy the information omitted from this prospectus but contained in the registration statement, as well as the periodic reports and other information we file with the SEC, at the public reference room and web site of the SEC referred to above. You may also access our filings with the SEC on our web site is located at https://www.ir-medical.com/. The information contained on our web site is not part of this prospectus.

IR-Med, INC. and subsidiary

Consolidated Financial Statements
December 31, 2024

IR-Med, Inc.

Consolidated Financial Statements as of December 31, 2024

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Somekh Chaikin
KPMG Millennium Tower
17 Ha'arba'a Street, PO Box 609
Tel Aviv 61006, Israel
+972 3 684 8000

Report of Independent Registered Public Accounting Firm
To the Stockholders and the Board of Directors of IR Med, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of IR-Med, Inc. and subsidiary (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, changes in stockholders' equity (deficit) and cash flows for each of the years in the two-year period ended December 31, 2024, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1b to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1b. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Somekh Chaikin
Somekh Chaikin
Member Firm of KPMG International

We have served as the Company's auditor since 2020.

Tel Aviv, Israel

April 4, 2025

KPMG Somekh Chaikin, an Israeli partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee.

IR-Med, Inc.

Consolidated Balance Sheets as of December 31

	Note	2024	2023
		US Dollars (In thousands)	
Assets			
Current assets			
Cash and cash equivalents	3	**129**	767

Accounts receivable	4	**76**	81
Total current assets		**205**	848
Non-current assets			
Long term restricted deposits	10	**11**	11
Right of use assets	6	**-**	84
Property and equipment, net	5	**35**	56
Total non-current assets		**46**	151
Total assets		**251**	999
Liabilities and stockholders' equity (deficit)			
Current liabilities			
Trade and other payables	7	**388**	473
Stockholders' loans	8	**157**	-
Total current liabilities		**545**	473
Non-current liabilities			
Stockholders' loans	8	-	161
Total non-current liabilities		**-**	161
Total liabilities		**545**	634
Contingent liabilities and commitments	10		
Stockholders' equity (deficit)	9		
Common stock, par value $0.001 per share, 600,000,000 shares authorized: 71,008,144 and 69,931,056 issued and outstanding as of December 31, 2024 and 2023, respectively		**70**	69
Additional paid-in capital		**16,374**	15,135
Accumulated deficit		**(16,738)**	(14,839)
Total stockholders' equity (deficit)		**(294)**	365
Total liabilities and stockholders' equity		**251**	999

The accompanying notes are an integral part of the consolidated financial statements.

IR-Med, Inc.

Consolidated Statements of Operations

	Note	For the year ended December 31, 2024	For the year ended December 31, 2023
		US Dollars (In thousands)	
Research and development expenses			
Expenses incurred	11	**1,178**	2,061
Less- government grants		**(468)**	-
Research and development expenses, net		**710**	2,061
Marketing expenses	12	**220**	822
General and administrative expenses	13	**1,011**	2,028
Total operating loss		**1,941**	4,911
Other income		**(48)**	-
Financial expenses (income), net	14	**6**	(2)
Loss for the year		**1,899**	4,909
Loss per share	15		
Basic and dilutive loss per common stock (in U.S. dollars)		**(0.03)**	(0.07)

The accompanying notes are an integral part of the consolidated financial statements.

Consolidated Statement of Changes in Stockholders' Equity (Deficit)

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total
	Number of Shares	US dollars (In Thousands)			
Balance as of January 1, 2024	**69,931,056**	**69**	**15,135**	**(14,839)**	**365**
Stock-based compensation	**322,088**	*****	**485**	—	**485**
Private placement of common stock and warrants	**755,000**	**1**	**754**	—	**755**
Loss for the year	—	—	—	**(1,899)**	**(1,899)**
Balance as of December 31, 2024	**71,008,144**	**70**	**16,374**	**(16,738)**	**(294)**
Balance as of January 1, 2023	68,808,970	68	12,454	(9,930)	2,592
Stock-based compensation	122,086	*	1,682		1,682
Private placement of common stock and warrants	1,000,000	1	999		1,000
Loss for the year				(4,909)	(4,909)
Balance as of December 31, 2023	69,931,056	69	15,135	(14,839)	365

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

The accompanying notes are an integral part of the consolidated financial statements.

Consolidated Statements of Cash Flows

	For the year ended December 31, 2024	For the year ended December 31, 2023
	US Dollars (In thousands)	
Cash flows from operating activities		
Loss for the year	**(1,899)**	(4,909)
Adjustments to reconcile loss for the year to net cash used in operating activities:		
Stock based compensation	**485**	1,682
Depreciation	**21**	17
Financial expenses (income), net	**2**	(3)
Decrease (increase) in accounts receivable	**6**	(25)
(Decrease) increase in trade and other payables	**(1)**	6
Net cash used in operating activities	**(1,386)**	(3,232)
Cash flows from investing activities		
Purchase of property and equipment	—	(2)
Net cash used in investing activities	—	(2)
Cash flows from financing activities		
Repayment of shareholder loan	**(5)**	—
Proceeds from private placement of common stock and warrants	**755**	1,000
Net cash provided by financing activities	**750**	1,000
Effect of exchange rate changes on cash	**(2)**	(1)
Net decrease in cash and cash equivalents	**(638)**	(2,235)
Cash and cash equivalents as at the beginning of the year	**767**	3,002
Cash and cash equivalents as at the end of the year	**129**	767

The accompanying notes are an integral part of the consolidated financial statements.

Notes to the Consolidated Financial Statements

Note 1 - General

A. Description of Business

IR-Med, Inc. (OTC QB: IRME, hereinafter: the "Parent Company") was incorporated in Nevada in 2007. IR-Med, Inc. was previously named International Display Advertising, Inc. and changed its name to IR-Med, Inc. in January 2021.

The registered office of IR-Med, Inc. and the corporate headquarters and research facility of IR. Med, Ltd. (the "Subsidiary") are located in Rosh Pina, Israel. The Parent Company and the Subsidiary are at times collectively referred to as the "Company".

On April 9, 2024, the Company's first device, the PressureSafe™, decision support system, received a U.S. Food and Drug Administration (FDA) listing certification. *PressureSafe*™ is classified as a Class I device , decision support system. Following the listing certification of the *PressureSafe*™ device, the Company has started usability studies and the preparations for the commercial launch of its first device, the *PressureSafe*™. The Company is developing its technology through its Subsidiary and is utilizing Infra-Red-light spectroscopy (IR) combined with an Artificial Intelligence (AI) technology platform to develop non-invasive devices for various medical indications, by assessing various biomarkers and molecules in the blood and in human tissue in real-time. The second product candidate, DiaSafe™ which is currently under development is a non-invasive, user friendly devise which is designed to address the medical needs of large and growing target patient groups by offering assessment of Diabetic Foot Ulcer ("DFU") before skin breakage, which is expected to reduce healthcare expenses and better patient care.

B. Going Concern

The Company is starting preparations for the commercial launch of its first device the "PressureSafe™" and does not expect to generate significant revenue until such time as the Company will start the commercialization of the PressureSafe™ and shall complete the design and development of its other product candidates. During the year ended December 31, 2024, the Company incurred losses of US$1,899 thousand and had a negative cash flow from operating activities of US$ 1,386 thousand. The accumulated deficit as of December 31, 2024, is US$16,738 thousand.

Based on the current expected level of operating expenditures, the Company's cash resources as of December 31, 2024 will be sufficient to meet its operating and capital needs through the second quarter of 2025 and shall not be sufficient for a period of at least 12 months from the issuance of these consolidated financial statements. Management's plans regarding these matters include continued development and marketing the company's products, as well as seeking additional financing arrangements. Although management continues to pursue these plans, in the event financing is not obtained, the Company may pursue additional cost cutting measures or may be required to delay, reduce the scope of, or eliminate any of its development programs, these events could have a material adverse effect on its business. These factors raise significant doubt about the Company ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Note 1 - General (Cont'd)

C. Iron Swords war impact

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of horrific terrorist attacks on civilian and military targets. Following the attack, Israel's security cabinet declared Iron Swords War ("war") and commenced a military campaign in Gaza against Hamas. Since the commencement of these events, there have been additional active hostilities, including a campaign focused in southern Lebanon against Hezbollah, an air campaign against the Houthi movement in Yemen and multiple airstrikes in Iran, in response to Iranian missile attacks. In October 2024, Israel began ground operations against Hezbollah in Lebanon culminating in a 60-day cease fire agreed to between Israel and Lebanon on November 27, 2024. On January 19, 2025, a temporary ceasefire between Israel and Hamas went into effect, the result of which is uncertain. On January 27, 2025, the ceasefire between Israel and Lebanon was extended to February 18, 2025. While ceasefire agreements have been reached, there is no guarantee that the parties will continue to comply with the terms of the agreements and, accordingly, it is possible that these hostilities will resume with little to no warning and that additional terrorist organizations and, possibly, countries will actively join the hostilities. Such clashes may escalate in the future into greater regional conflict.

The Company did not experience significant changes in its activities from the continuation of the war during the reporting period. However, the Company's management continues to believe that the general conditions have brought further difficulties in management's efforts to seek additional financing arrangements.

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

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

Note 2 - Summary of Significant Accounting Policies

A. Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S GAAP) assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, substantial doubt about the Company's ability to continue as a going concern exists.

Note 2 - Summary of Significant Accounting Policies (Cont'd)

B. Functional Currency

The Company finances its operations in U.S. dollars. While the majority of the Company's operations are currently conducted in Israel, a significant part of the Company's expenses is denominated and determined in U.S. dollars. Future revenues are expected to be earned in US dollars. The Company's management believes that the U.S. Dollar is the currency of the primary economic environment in which the Company operates and expects to continue to operate in the foreseeable future. Thus, the functional and reporting currency of the Company is the U.S. Dollar.

The Company's transactions and balances denominated in U.S. dollars are presented at their original amounts. Non-Dollar transactions and balances have been re-measured to U.S. Dollars in accordance with Accounting Standards Codification (ASC) 830, "Foreign Currency Matters", of the Financial Accounting Standards Board ("FASB"). All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statements of operations as financial income or expenses, as appropriate.

C. Principles of Consolidation

The consolidated financial statements include the accounts of the Parent Company and its wholly owned Subsidiary, IR. Med, Ltd. Intercompany transactions and balances have been eliminated in consolidation.

D. Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant items subject to such estimates and assumptions including fair value of share-based compensation and legal claims. Actual results could differ from those estimates.

E. Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents are stated at their carrying values, which approximates their fair values.

F. Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and accumulated impairment losses, if any. Maintenance and repair expenses are charged to operation as incurred. Depreciation is calculated on the straight-line method based on the estimated useful lives of the assets and commences once the assets are ready for their intended use. The cost of property and equipment include expenditure that is attributable to the acquisition of the assets.

Note 2 - Summary of Significant Accounting Policies (Cont'd)

Annual rates at depreciation are as follows:

	%
Computers and electronics equipment	10-33
Laboratory equipment	15
Furniture and equipment	15
Leasehold improvements	10

G. Research and Development Expenses

Research and development expenses are expensed as incurred. Those expenses include payments to third party consultants, expenses related to conducting clinical and pre-clinical trials, salaries and related personnel expenses.

H. Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, accounts receivables, trade and other accounts payable and stockholders' loans do not significantly vary from their fair values. Amounts from related parties' approximate fair value because of their short-term nature.

Fair value for the measurement of financial assets and liabilities is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The Company utilizes a valuation hierarchy for disclosure of the inputs for fair value measurement. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1 inputs are unadjusted quoted prices in active markets for identical assets or liabilities.

Note 2 - Summary of Significant Accounting Policies (Cont'd)

H. Fair Value of Financial Instruments (cont'd)

- Level 2 inputs are quoted prices for identical or similar assets or liabilities in less active markets or model derived valuations in which significant inputs are observable for the asset or liability, either directly or indirectly through market corroboration.

- Level 3 inputs are unobservable inputs based on the Company's assumptions used to measure assets and liabilities at fair value.

By distinguishing between inputs that are observable in the marketplace, and therefore more objective, and those that are unobservable and therefore more subjective, the hierarchy is designed to indicate the relative reliability of the fair value measurements. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

I. Warrants

The Company assesses whether warrants issued require accounting as derivatives. The Company determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with FASB ASC Topic 815, Derivatives and Hedging. As such the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders' equity

J. Commitments and Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigations, fines and penalties and other sources are recognized when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated.

K. Accounting for Share-Based Compensation

Stock Option Plan

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

The Company estimates grant date fair value using the Black-Scholes-Merton option-pricing model.

L. Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company records valuation allowances to reduce deferred income tax assets to the amount that is more likely than not to be realized.

Note 2 - Summary of Significant Accounting Policies (Cont'd)

L. Income taxes (cont'd)

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company accounts for interest and penalties related to an underpayment of income taxes as a component of income tax expense.

M. Concentrations of credit risks

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. Cash and cash equivalents are held in commercial banks in the U.S. and in Israel. Management believes that the financial institution that holds the Company investments have high credit ratings. The Company has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

N. Employee benefits

Pension

The Company's liability for severance pay for its Israeli employees is calculated pursuant to Israeli severance pay law based on the most recent salary of the employee multiplied by the number of years of employment, as of the balance sheet date. Those employees are entitled to one month's salary for each year of employment or a portion thereof.

The Company has a defined deposit plan in respect of the Company's obligation to pay the benefit component of provident funds as well as in respect of its employees to whom section 14 of the Dismissal Compensation Law applies. pursuant to the terms of Section 14 of the Israeli Severance Pay Law, 1963, according to which the current deposits in the pension fund and/or with the insurance company exempt the Company from any additional obligation to these employees for whom the said depository payments are made. During the years ended December 31, 2024, and 2023, the Company paid for severance pay for its Israeli employees amounts of NIS 263 thousand (approximately US$71 thousand) and NIS 415 thousand (approximately US$113 thousand), respectively.

Short-term benefits

Short-term employee benefit obligations are measured on an undiscounted basis and are expensed as the related service is provided or upon the actual absence of the employee when the benefit is not accumulated (such as maternity leave).

The employee benefits are classified, for measurement purposes, as short-term benefits or as other long-term benefits depending on when the Company expects the benefits to be wholly settled.

O. Governments grants

The Company records grants received from the Israel Innovation Authority (the "IIA", formerly known as the Office of the Chief Scientist of the Israeli Ministry of Industry and Trade) as a liability, if it is probable that the Company will have to repay the grants received. If it is not probable that the grants will be repaid, the Company records the grants as a reduction to research and development expenses.

Note 2 - Summary of Significant Accounting Policies (Cont'd)

P. Leases

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.

Operating leases are included in ROU assets and trade and other payables in the consolidated balance sheet.

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.

The subsidiary occupies approximately 130 square meters of facilities, under an agreement for shared office space and services that expires upon 90 days' notice by either the Subsidiary or the landlord (See also note 18-B4).

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 assumed 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.

Note 2 - Summary of Significant Accounting Policies (Cont'd)

P. Leases (Cont'd)

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).

The Company uses the long-lived assets impairment guidance in Accounting Standards Codification ("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 leases of motor vehicles 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.

Q. Stockholders' loans

Stockholders' loans with terms that were amended after the reporting date are considered in determining the classification of debt at the reporting date. Due to agreements reached in 2024 between the stockholders and the Company regarding the repayment date of the loan (see note 8), the stockholders' loans at December 31, 2023 were classified as non- current liabilities.

Notes to the Consolidated Financial Statements

R. New Accounting Pronouncements

Recently Adopted Accounting Standards

Segment Reporting: In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. It requires incremental disclosures related to an entity's reportable segments, including (i) significant segment expense categories and amounts for each reportable segment that are provided to the chief operating decision maker ("CODM"), (ii) an aggregate amount and description of other segment items included in each reported measure, (iii) all annual disclosures about a reportable segment's profit or loss and assets required by Topic 280 to be disclosed in interim periods, (iv) the title and position of the individual or the name of the group identified as the CODM and (v) an explanation of how the CODM uses the reported measures of segment profit or loss to assess performance and allocate resources to the segment. The standard improves transparency by providing disaggregated expense information about an entity's reportable segments. The standard does not change the definition of a segment, the method for determining segments or the criteria for aggregating operating segments into reportable segments. This guidance is effective for annual reporting periods beginning after December 15, 2023, and interim reporting periods beginning after December 15, 2024. The Company adopted this guidance retrospectively, providing the additional disclosures as required. See note 17 for more information.

Accounting Standards Not Yet Adopted

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

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

Notes to the Consolidated Financial Statements

Note 3 - Cash and Cash Equivalents

	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Cash - NIS	**26**	68
Cash - US dollars	**103**	699
	129	767

Note 4 - Accounts Receivable

	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Prepaid expenses	**22**	30
Government institutions	**22**	40
Grant Receivable	**29**	—
Related parties	**3**	11
	76	81

Note 5 – Property and Equipment, net

	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Computers and electronics' equipment	**45**	45
Laboratory equipment	**19**	19
Furniture and equipment	**10**	10
Leasehold improvement	**19**	19

	93	93
Less – accumulated depreciation	**(58)**	(37)
	35	56
Annual depreciation expenses	**21**	17

Note 6 - Leases

As of December 31 ,2024, the Company has no lease contracts for motor vehicles used in its operation. Leases of motor vehicles generally have lease terms of three years and are all classified as operating leases. The contracts expired on various dates during 2024. The Company continues to use some of the vehicles after their initial lease terms without any minimum period commitment.

The above operating leases were included in "Right-of-use assets" on the Company's Consolidated Balance Sheets as of December 31, 2023, and represented the Company's right to use the underlying asset for the lease term. The Company's obligations to pay lease payments were included as "Lease liability" on the Company's Consolidated Balance Sheets as of December 31, 2023. Based on the present value of the lease payments for the remaining lease term of the Company's existing lease agreements, the Company recognized operating right-of-use assets and operating lease liabilities of approximately US$170 thousand on January 1, 2022.The Company uses its incremental borrowing yearly rate of 5.8% based on the information available at the commencement date to determine the present value of the lease payments.

During the years ended December 31, 2024, and 2023, the Company recognized expenses of US$121 thousand and US$111 thousand from leases of motor vehicles, respectively. (including a decrease in right-of-use assets of US$84 thousand and US$71 thousand, respectively).

Note 7 - Trade and Other Payables

	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Trade payables	**58**	62
Accrued expenses	**188**	160
Payroll and related accruals	**28**	98
Advance from customer	—	50
Lease liability	—	39
Related Parties	**114**	64
	388	473

Note 8 - Stockholders' Loans

A. The 2015 loans

In 2015, certain of the Company's stockholders granted loans to the Company to finance its ongoing operation (hereinafter: the "2015 Loans"). These loans bear interest at an annual rate ranging in 2024 and 2023 from 5.18% to 2.9%. Under the original loan terms, the aggregate loan amount is payable to the lenders by the Company only upon the approval of the Company's board of directors that the Company's profits reached an amount of US$500 thousand and upon such terms and in such installments as shall be determined by the Company's board of directors.

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

On July 4, 2024 the Company and one of the lenders agreed to repay US$3 thousand from the total loan amount.

As of December 31, 2024, and 2023, the carrying amounts of the 2015 Loans were US$31 thousand and US$ 34 thousand, respectively.

B. The 2017 loans

In 2017, one of the Company's stockholders provided the Company with a loan to finance its ongoing operation (hereinafter: the "2017 Loan"). This loan bears interest at annual rate ranging in 2024 and 2023 from 5.18% to 2.9% annually. Under the original loan terms, the aggregate loan amount was repayable by the Company upon the closing of an investment in the Company with proceeds greater than US$500 thousand.

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

As of December 31, 2024, and 2023, the carrying amounts of the 2017 Loan were US$4 thousand.

Note 8 - Stockholders' Loans (cont'd)

C. Convertible Loan

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

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

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

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

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

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

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

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

On July 4, 2024, the Company and one lender agreed to repay US$2 thousand from the total loan amount.

Financing expenses recorded in respect of the loans during 2024 and 2023 were US$3 thousand .

As of December 31, 2024, and 2023, the carrying amounts of the loans were US$122 thousand and US$ 123 thousand, respectively.

Note 9 - Stockholders' Equity

A. Common Stock

As of December 31, 2024, the Company has 71,008,144 shares of Common Stock issued and outstanding.

Each share of IR-Med, Inc.´s common stock entitles its holder to one vote, and all shares rank equally as to voting and other matters.

Dividends may be declared and paid on the common stock from funds legally available therefor, if, as and when determined by the Board of Directors.

B. Financing round

(I) During the first four months of 2021, the Company raised in the aggregate $3,525,000 net of issuance cost of $223,000. According to the agreements, the Company shall issue to the Investors 5,507,813 units of its securities (hereinafter: "Unit" and collectively the "Units") at a price per Unit of $0.64. Each Unit is comprised of two shares of IR-Med, Inc.'s common stock and one warrant to purchase an additional share of IR-Med, Inc.'s common stock, exercisable for a three-year period from the date of issuance at a per share exercise price of $0.64, subject to certain limited adjustments.

(II) Between April 2022 through July 2022, the Company 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 the Company common stock and warrants for an additional 4,119,321 shares of the Company common stock, exercisable through 2024, at a per share exercise price of $1.10, subject to certain limited adjustments. The aggregate gross proceeds from the private placement were approximately $3,625,000.

(III) On June 12, 2023, the Company entered into a subscription agreement with one investor pursuant to which the Company issued 1,000,000 shares of its common stock at a per share price of $1.00 and warrants to purchase up to an additional 1,000,000 shares of common stock at a per share exercise price of $1.40. The warrants expire on the third anniversary from the date of issuance of the warrants to the holder subject to certain limited adjustments. The aggregate proceeds from the private placement were approximately $1,000,000.

(VI) On June 4, 2024 and July 4, 2024, the Company entered into Securities Purchase Agreements (the "Purchase Agreement") with certain investors (the "Investors"), pursuant to which it agreed to issue and sell, in a private placement offering (the "2024 Private Placement"), 755,000 shares of the Company's Common Stock, at a per share price of $1.00 and warrants to purchase up to an additional 1,208,000 shares of Common Stock at a per share exercise price of $1.00 (subject to a one time dilution protection adjustment). The 2024 Private Placement closed on June 7, 2024 and July 10, 2024, respectively, and the Company received aggregate proceeds of $755,000.

Note 9 - Stockholders' Equity (cont'd)

C. Share-based compensation

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 Parent Company. on April 29, 2021, the Company adopted a sub plan (the "Israeli appendix"). On September 27, 2023, the Company's Board approved a further amendment to the 2020 Incentive Stock Plan to increase the number of shares authorized for issuance of awards under the 2020 Incentive Stock Plan from 16,000,000 shares to an aggregate of 17,500,000 shares of common stock. The holders of a majority of the Company's voting stock approved such an increase.

As of December 31, 2024, the Company awarded to its employees and service providers options to purchase up to 15,072,175 shares of common stock, of which options for 7,535,675 shares were at an exercise price of US$0.32 per share, options for 7,281,000 shares were at an exercise price of US$0.58 per share, options for 255,500 shares were at an exercise price of US$0.01 per share . As of December 31, 2024, options for 13,125,925 shares were vested with weighted average of exercise price of US$ 0.42, and the remaining balance has a vesting period ranging betweenone to five years. The options are exercisable for periods ranging between three to 10 years from the vesting date.

Options awarded:

	2024		2023	
	Weighted average of exercise price	*Number of options*	*Weighted average of exercise price*	*Number of options*
Outstanding as of the beginning of the year	$ 0.42	**15,544,175**	$ 0.4	13,943,842
Granted	$ 0.55	**1,715,500**	$ 0.58	2,467,000
Forfeited	$ 0.39	**(1,500,000)**	$ 0.32	(866,667)
Expired	$ 0.28	**(687,500)**		-
Outstanding as of the end of year	$ 0.42	**15,072,175**	$ 0.42	15,544,175

On June 12, 2022, the Company entered into a consulting agreement for professional services. As part of this agreement, the Company granted the consultant 2,272 shares at par value per month. As of December 31, 2024, the Company granted the consultant 43,174 shares at par value.

On August 15, 2022, the Company entered into a consulting agreement for professional services. As part of this agreement, the Company granted the consultant 88,000 shares at par value.

Note 9 - Stockholders' Equity (cont'd)

C. Share-based compensation (cont'd)

On June 1, 2023, the Company entered into a consulting agreement for professional services. As part of this agreement, the Company will grant the consultant 176,000 shares at par value in four tranches. As of December 31, 2024, the Company granted the consultant 176,000 shares at par value.

On October 8, 2024, the Company entered into a consulting agreement for professional services. As part of this agreement, the Company granted the consultant 225,000 shares at par value.

The Company recorded in the statement of operations a non-cash expense of US$485 thousands and US$1,682 thousands during the years ended December 31, 2024, and 2023, respectively. As of December 31, 2024, there was US$ 356 thousand unrecognized compensation cost related to non-vested employees and consultants options. The cost is expected to be recognized over a period of four years.

The stock-based compensation expenses for the years ended December 31, 2024, and 2023 were recognized in the statements of operations as follows;

	Year ended December 31	
	2024	2023
	US Dollars (In thousands)	
Research and development expenses	**43**	158
Marketing expenses	**215**	659
General and administrative expenses	**227**	865
	485	1,682

The Company will not be allowed to claim as an expense for tax purposes the amounts charged as stock-based compensation expenses.

The following table sets forth information about the weighted-average fair value of options granted to employees and service providers during the years ended December 31, 2024 and 2023, using the Black-Scholes-Merton option-pricing model and the weighted-average assumptions used for such grants:

Note 9 - Stockholders' Equity (cont'd)

C. Share-based compensation (cont'd)

	For the years ended	
	December 31 2024	December 31 2023
Dividend yields (see (I) below)	0.0%	0.0%
Share price (in U.S. dollar) (see (II) below)	0.52	0.58
Expected volatility (see (III) below)	45%-52%	84%-99%
Risk-free interest rates (see (IV) below)	3.72%-4.24%	4.16%-4.39%
Expected life (in years) (see (V) below)	5-10	5-10

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

II. The Company's common stock is quoted on the OTCQB. However, the Company considers its share price as it is traded on OTCQB to not be an appropriate representation of fair value, since it is not traded on an active market. The Company determined that the market is inactive due to low level of activity of the Company's common stock, stale or non-current price quotes and price quotes that vary substantially either over time or among market makers. Consequently, the price of the Company's common stock has been determined based on private placement equity offerings conducted in June and July 2024 and June 2023 consisting of units comprised of shares of common stock and warrants, at a per unit purchase price of $1.00. In order to evaluate the price per share, the warrant value has been deducted from the total unit price.

III. As the Company is at its early stage of operation, there is not sufficient historical volatility for the expected term of the stock options. Therefore, the 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.

IV. 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.

V. The expected life of the granted options was determined based on the estimated behavior of the grantees; since most of the grantees are executives, the Company assumed that the large majority of the options will be exercised prior to their expiration.

Note 10 - Contingent Liabilities and Commitments

A. Israel Innovation Authority

The Company operates within the framework of the Incubators Program (Directive No. 8.3 of the Ministry of Economy) ("The program"). As part of this plan, 60% of the approved program budget was financed by the IIA and 40% by the shareholders. In return for the participation of the IIA, the Company is required to pay royalties at the rate of 3.5% - 3% of the sales of the developed products linked to the dollar until the repayment date of the full amount of the grants, plus annual interest at the SOFR rate. In addition, the IIA may stipulate any arrangement whereby the Company will be able to transfer the technology or development from Israel.

On January 25, 2024, the Israel Innovation Authority (the "IIA") approved a program to develop a device for the early assessment of diabetic foot ulcers among diabetic patients, with a project budget of NIS 3,761,978 (approximately US$ 1,030,000) which includes an amount equal to 50% grant of the total budget provided at the time of the grant, disbursed in installments over the course of 13 months, in accordance with the project's progress. In consideration for the grant by the IIA, the Subsidiary is required to pay royalties at the rate of 3%-5% from the total sales until the repayment date of the full amount of the grant, plus annual interest at the SOFR rate. In addition, the IIA must approve any arrangement whereby the Subsidiary seeks to transfer the technology relating to the project, or its development, from Israel.

As of December 31, 2024, the Company's maximum possible future royalties commitment, subject to future sales of such products and based on grants received from the IIA and not yet repaid, is approximately $761 thousand (including interest in the amount of approximately $32 thousand).

For the years ending December 31, 2024, and 2023, IIA grants that were obtained are $439 thousand and $0 ,respectively.

B. Long term deposits

During 2021 the Company received a bank credit line in the amount of NIS 40,711 (approximately US$11,000) and pledged a security in the same amount.

C. Legal claims

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

The Company records a provision in its financial statements to the extent that it concludes that a contingent liability is probable, and the amount thereof is reasonably estimable. Based upon the status of the case described above, management's assessments of the likelihood of damages, and the advice of counsel, no provisions have been made regarding the matter disclosed in this note. Litigation outcomes and contingencies are unpredictable, and excessive verdicts can occur.

Note 11 - Research and Development Expenses

	For the years ended	
	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Salaries and related expenses	**489**	778
Subcontractors	**499**	947
Materials	**1**	55
Stock based compensation expenses	**43**	158
Other expenses	**146**	123
Total research and development expenses	**1,178**	2,061

Note 12 - Marketing Expenses

	For the years ended	
	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Salaries and related expenses	**3**	—
Professional expenses	**2**	153
Other expenses	**—**	10
Stock based compensation expenses	**215**	659
Total marketing expenses	**220**	822

Note 13 - General and Administrative Expenses

	For the years ended	
	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Salaries and related expenses	**86**	242
Professional expenses	**504**	683
Rent and Maintenance	**115**	94
Depreciation	**21**	17
Other expenses	**58**	127
Stock based compensation expenses	**227**	865
Total general and administrative expenses	**1,011**	2,028

Note 14 - Financial Expenses

	For the years ended	
	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Interest (income) expenses, net	**3**	(20)
Exchange rate loss	**2**	17
Other	**1**	1
Total financial expenses (income), net	**6**	(2)

Note 15 - Loss Per Share

The calculation of basic and diluted losses per share for the year ended on December 31, 2024, and 2023 was based on the losses attributable to the Company's ordinary stockholders for the year divided by a weighted average number of ordinary shares outstanding. The calculation of basic and diluted losses per share for the years ended on December 31, 2024, and 2023 are as follows:

	For the years ended	
	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Loss attributable to shareholders ($ in thousands)	**(1,899)**	(4,909)

Weighted average number of ordinary shares:		
Balance at beginning of year	**69,931,056**	68,808,970
Effect of shares issued during the year	**543,206**	595,381
Weighted-average shares – basic and dilutive as at end of year	**70,474,262**	69,404,351
Basic and dilutive loss per share ($)	**(0.03)**	(0.07)

As of December 31, 2024, and 2023, options and warrants which were granted by the Company's board of directors were not included in the loss per share computation because all such securities have an anti-dilutive effect for the year. Such securities totaled to 27,610,434 and 29,774,434, respectively.

Note 16 – Income Taxes

A. Corporate income tax rate

a) The income tax rates relevant to the Parent company in Nevada for the years 2024 and 2023 was 21%.

The tax rates relevant to the Subsidiary for the years 2024 and 2023 was 23%.

Current taxes for the reported periods are calculated according to the enacted tax rates presented above.

b) Tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959 (the "Investments Law").

The Israeli Investments Law applies to Preferred Income derived or accrued in 2011 and thereafter by a Preferred Company.

Note 16 – Income Taxes (Cont'd)

The law provides a uniform and reduced income tax rate for all the Subsidiary's income entitled to the benefits ("Preferred Income"). Starting from tax year 2017, the tax rate on Preferred Income for a company operating in the same area as the Subsidiary is 7.5%, subject to terms as defined within the Investments law.

B. Deferred tax assets

The following is a summary of the significant components of deferred tax assets:

	December 31 2024	**December 31 2023**
	US Dollars (In thousands)	
Operating loss carryforwards	**2,182**	1,678
Research and development costs capitalized for tax purposes	**161**	423
Payroll and related payables	**1**	7
Lease liability	**—**	9
Total deferred tax assets	**2,344**	2,117
Right of use asset- deferred tax liability	**—**	(19)
Total deferred tax assets, net	**2,344**	2,098
Valuation allowance for deferred tax assets	**(2,344)**	(2,098)
Deferred tax assets, net of valuation allowance	**—**	—

As of December 31, 2024, and 2023, the Company has provided full valuation allowance of US$2,344 thousand and US$ 2,098 thousand against its deferred tax assets given that it is not more likely than not that it will generate sufficient income for tax purposes to utilize the available deferred tax assets in the foreseeable future.

C. Accounting for uncertainty in income taxes

For the years ended December 31, 2024 and 2023, the Company did not have any significant unrecognized tax benefits. In addition, the Company does not expect that the amount of unrecognized tax benefits will change significantly within the next 12 months.

The Company accounts for interest and penalties related to an underpayment of income taxes as a component of income tax expense. For the years ended December 31, 2024 and 2023, no interest and penalties related to income taxes have been accrued.

D. Operating losses carry forwards and valuation allowance

As of December 31, 2024, and 2023, the Company had operating loss carryforwards in the amount of US$ 10,235 thousand and US$ 7,668 thousand, respectively. The Company and its Subsidiary can reduce future taxable income with no limitation to the period of use.

Note 16 – Income Taxes (Cont'd)

E. Composition of loss from continuing operations before income taxes:

	For the year ended December 31 2024	For the year ended December 31 2023
	US Dollars (In thousands)	
Loss from continuing operations before income taxes:		
US	**282**	346
Israel	**1,617**	4,563
	1,899	4,909

F. Income tax assessment

As of December 31, 2024, the Subsidiary has tax assessments that are considered as final in Israel due to lapse of statute of limitation period, through tax year 2019. The Parent Company has not been assessed for income tax purposes in the U.S. since its inception and is open to examination by the IRS from the tax year 2020.

Note 16 – Income Taxes (Cont'd)

G. Reconciliation of the statutory income tax expense (benefit) to actual income tax expense

Reconciliation between the theoretical income tax expense, assuming all income is taxed at the federal statutory income tax rate applicable to income of the Parent Company and the actual income tax expense as reported in the statements of operations is as follows:

	For the years ended December 31 2024	December 31 2023
	US Dollars (In thousands)	
Loss before income taxes as reported in the statements of operations	**(1,899)**	(4,909)
Statutory tax rate	**21%**	21%
Theoretical income tax benefit on the above amount at the US federal statutory income tax rate	**(399)**	(1,031)
Additional tax (tax savings) in respect of:		
Nondeductible expenses	113	389
Differences in tax rates between statutory tax and income tax of the Subsidiary*	(33)	(91)
Change in valuation allowance	246	644
Effect of currency exchange differences	60	87
Other	13	2
Actual taxes on income	—	—

(*) The Subsidiary operates in Israel in a tax jurisdiction with a corporate income tax rate of 23%.

H. Roll forward of valuation allowance

	US Dollars (In thousands)
Balance on January 1, 2023	1,454
Change in valuation allowances - Income tax expense	644
Balance on December 31, 2023	2,098
Change in valuation allowances - Income tax expense	246
Balance on December 31, 2024	2,344

Note 17 – Segment Information

This segment structure reflects the financial information and reports used by the Company's management, specifically its CODM, to make decisions regarding the Company's business, including resource allocations and performance assessments, as well as the current operating focus in compliance with ASC 280, Segment Reporting.

The Company reports segment information based on the management approach, which designates the internal reporting used by the CODM, the Company's Chief Executive Officer and Chairman of the Board, for making decisions and assessing performance as the source of the Company's reportable segments.

The Company has one operating and reportable segment, *PressureSafe™ & DFU* device activity. The *PressureSafe™ & DFU* device utilizes Infra-Red-light spectroscopy (IR) combined with an Artificial Intelligence (AI) technology platform to develop non-invasive devices for various medical indications, by detecting and measuring various biomarkers and molecules in the blood and in human tissue in real-time.
To date, the Company has not generated revenue. The Company expects to continue to incur significant expenses and operating losses as its product matures for distribution.

The accounting policies of the Company segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance of its operations based on net loss excluding non-cash items (depreciation and stock-based compensation).

As such, the CODM uses cash forecast model in deciding how to invest into the *PressureSafe™ & DFU* segment. Such models are reviewed to assess the entity-wide operating results and performance. Net loss (excluding non-cash items) is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment along with cash forecast model.

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

The following table presents information about the Company's single reportable segment by significant expenses categories regularly reviewed by the CODM for the year ended December 31, 2024 and 2023:

	For the year ended December 31, 2024	For the year ended December 31, 2023
	US Dollars (In thousands)	
Research and development expenses		
Salaries and related expenses	**489**	778
Subcontractors	**464**	794
Materials	**1**	55
Usability study	**33**	153
Other expenses	**148**	123
Less- government grants	**(468)**	—
Research and development expenses, net	**667**	1,903
Marketing expenses	**5**	163
General and administrative expenses		
Salaries and related expenses	**86**	242
Professional expenses	**504**	683
Rent and Maintenance	**115**	94
Other expenses	**58**	127
Total General and administrative expenses	**763**	1,146
Other income	**(48)**	—
Financial expenses (income), net	**6**	(2)
Segment net loss	**1,393**	3,210
Reconciliation of profit or loss adjustments and reconciling items		
Depreciation	**21**	17
Stock-based compensation	**485**	1,682
Net loss	**1,899**	4,909

Notes to the Consolidated Financial Statements

Note 18 - Related Parties Balances and Transactions

The Company's related parties are seven directors, four officers, one shareholder and two entities controlled by three of the Company's shareholders.

A. Balances with related parties

	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Assets		
Other receivables	**3**	11
Liabilities		
Payables	**19**	22
Accrued expenses	**88**	31
Payroll and related	**7**	14
Stockholders' loans	**157**	161

B. Transactions with related parties

	For the years ended	
	December 31 2024	December 31 2023
	US Dollars (In thousands)	
Subcontractors and professional expenses (1)	207	347
Salaries and related expenses (2)	252	439
Stock based compensation (3)	279	1,459
Rent and Maintenance (4)	82	80
Interest expenses, see note 8	4	5

(1) For the years ended December 31, 2024, and 2023, the Company paid to two directors of the Parent Company an aggregate consideration of US$170 thousand and US$161 thousand, respectively, in respect of research and development services.

For the years ended December 31, 2024, and 2023, the Company paid to one shareholder of the Parent Company and his relative an aggregate consideration of

Note 18 - Related Parties Balances and Transactions (Cont'd)

B. Transactions with related parties (cont'd)

US$5 thousand and US$150 thousand, respectively in respect to consulting services.

For the years ended December 31, 2024, and 2023, the Company paid to the Parent Company non-employee directors an aggregate consideration of US$32 thousand and US$36 thousand, respectively ,with respect of their services.

(2) For the year ended December 31, 2024, and 2023 the Company paid to four of its officers, salary and related expenses totaled to US$252 thousand and US$439 thousand, respectively.

(3) Following the adoption of the 2020 Incentive Stock Plan by the Parent Company on December 23, 2020, and the adoption of the sub plan (the "Israeli appendix") on April 29, 2021, the Parent Company granted during the year 2024 to its officer and director 1,715,500 options to purchase shares of Common Stock (See also note 9-C).

The Parent Company granted during the year 2023 to its officers and shareholder and his relative 1,636,000 options to purchase shares of Common Stock (See also note 9-C).

(4) For the year ended December 31, 2024, the Company recorded a liability on amount of $2 thousand and for the year ended 2023, the Company paid a yearly amount of US$80 thousand to an entity in which two directors of the Company are stakeholders in the entity, for rent and office services.

C On July 7, 2024, the Company entered into an Amendment to the Consulting Agreement with Mr. Aharon Klein, its Interim Chief Executive Officer and Chief Technology Officer and (the "Klein Amendment"). The Klein Amendment amends the original consulting agreement executed by and between the Company and Mr. Klein, dated October 1, 2019, as amended on December 24, 2020. Effective June 1, 2024, the Klein Amendment provides for a monthly compensation in the amount of NIS 30,000 and an additional NIS 5,000 for car expenses. All other terms related to Mr. Klein overall compensation and equity-based awards remain unchanged. On October 31, 2024, the Board approved a reduction in the monthly payments made to Mr. Klein, in light of the Company's current cash position, which was agreed upon with Mr. Klein. Under the amended terms of Mr. Klein's service provider agreement, he will receive monthly payments of NIS 16,000, instead of NIS, 30,000, plus NIS 5,000 for car expenses totaling a monthly compensation of NIS 21,000 starting from October 2024 onwards.

On July 7, 2024, the Company entered into an Amendment to the Consulting Agreement with Dr. Yaniv Cohen, Chief Scientific Officer of the Company (the "Cohen Amendment"). The Cohen Amendment amends the original consulting agreement executed by and between the Company and Dr. Cohen, dated November 1, 2019, and provides for monthly consideration of NIS 15,000, commencing as of June 1, 2024. On October 31, 2024, the Board of Directors approved the reduction in the monthly payments made to Dr. Cohen, pursuant to his service provider agreement, from his current rate of NIS 15,000 to NIS 8,000, commencing in October 2024.

On December 25, 2024, in light of the Company's cash position, the Company terminated the consulting agreements with Aharon Klien and Yaniv Cohen.

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

Note 19 – Subsequent Events

1. In January 2025, in light of the Company's cash position, the Company and its two officers agreed to reduce their salaries for the months of January and February 2025. According to this agreement, their salaries will range between NIS 6,000 (approximately $1,644) and NIS 10,000 (approximately $2,740) per month.

2. On February 16, 2025, the Company obtained a short-term loan of NIS 140,000 (approximately $38,000) from Bank Hapoalim. The loan bears an annual interest rate of 9% and is repayable in two equal installments on April 30, 2025, and May 31, 2025. In March 2025, the Company repaid the loan.

3. On march 11 ,2025 the Company entered into an Equity Purchase Agreement with Williamsburg Venture Holdings, LLC, a Nevada limited liability company ("Investor"), pursuant to which the Investor agreed to invest up to Fifteen Million Dollars ($15,000,000) over a 24-month period (unless otherwise determined therein) in accordance with the terms and conditions of an Equity Purchase Agreement, dated as of March 11, 2025, by and between the Company and the Investor (the "Equity Purchase Agreement"). In connection with the Equity Purchase Agreement, the parties also entered into a Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which the Company agreed to register with the Securities and Exchange Commission (the "SEC") the Company's common stock issuable under the Equity Purchase Agreement. Pursuant to the terms of the Equity Purchase Agreement, the Investor agreed to accept a put notice of up to $ 500,000 upon a registration statement being declared effective by the SEC.

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

4. Effective March 26, 2025, IR-Med, Inc. (the "Company") entered into a Note Purchase Agreement (the "Purchase Agreement") with Mr. Ran Ziskind, Mr. Yaniv Cohen, and Mr. Oded Bashan for an aggregate amount of $31,200. Pursuant to the Purchase Agreement, the Company issued unsecured convertible promissory notes (the "Notes") to Mr. Ziskind, Mr. Cohen, and Mr. Bashan in the principal amount of $ 10,400 for each Note. The Notes bear simple interest at a rate of9% per annum and mature on the earlier of (i) March 26, 2026, or (ii) upon the completion by the Company of an equity or debt financing generating gross proceeds of at least $100,000. The Notes are convertible, at the election of the holder, on the maturity date into shares of the Company's common stock at a price per share equal to 85% of the closing price of the common stock on the applicable trading market as of the maturity date. The Notes are subject to customary events of default, upon which the outstanding principal and accrued interest may become immediately due and payable. The Company may not prepay the principal amount without the consent of a majority of the holders of all outstanding Notes, though accrued interest may be paid at any time.

5. On March 31, 2025, the Company's board of directors decided to approve the extension of the expiration date of3,636,634 warrants until June 30, 2025. This extension is subject to the approval of the warrants holders.

80,000,000 shares of Common Stock

IR-MED, INC.

COMMON STOCK

PROSPECTUS

May 13, 2025

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other expenses of Issuance and Distribution

The following table sets forth the Company's expenses in connection with this registration statement. All of the listed expenses are estimates, other than the filing fees payable to the Securities and Exchange Commission.

SEC registration fee	$	967.59
Accounting fees and expenses	$	3,000
Legal fees and expense	$	25,000
Miscellaneous	$	200
Total	$	29,167.59

Item 14. Indemnification of Directors and Officers

Our Amended and Restated Articles of Incorporation and our Amended and Restated Bylaws provide that each person who was or is made a party or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was one of our directors or officers or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, whether the basis of such action, suit or proceeding is alleged action in an official capacity as a director, officer or trustee or in any other capacity while serving as a director, officer or trustee, shall be indemnified and held harmless by us to the fullest extent authorized by the Nevada Revised Statutes, or NRS, against all expense, liability and loss (including attorneys' fees and amounts paid in settlement) reasonably incurred or suffered by such.

NRS 78.7502 permits a corporation to indemnify any director or officer of the corporation against expenses (including attorneys' fees) and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person (i) is not liable pursuant to NRS 78.138 and (ii) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the conduct was unlawful. In a derivative action (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or the suit if such person (i) is not liable pursuant to NRS 78.138 and (ii) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought or some other court of competent jurisdiction determines that such person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

Our Amended and Restated Articles of Incorporation provide that the liability of our directors and officers shall be eliminated or limited to the fullest extent permitted by the NRS. NRS 78.138(7) provides that, subject to limited statutory exceptions and unless the articles of incorporation or an amendment thereto (in each case filed on or after October 1, 2003) provide for greater individual liability, a director or officer is not individually liable to a corporation or its stockholders or creditors for any damages as a result of any act or failure to act in his or her capacity as a director or officer unless it is proven that: (i) the act or failure to act constituted a breach of his or her fiduciary duties as a director or officer, and (ii) the breach of those duties involved intentional misconduct, fraud or a knowing violation of law.

Item 15. Recent Sales of Unregistered Securities

Over the past three years, we have issued and sold the following securities without registration under the Securities Act:

Between December 24, 2020 and April 20, 2021, we issued to certain accredited investors an aggregate of 9,110,938 units of our securities, with each Unit comprised of (i) two (2) shares of our common stock and (ii) one common stock purchase warrant to purchase an additional share of our common stock at a per share exercise price of $0.64, for aggregate gross proceeds to us of approximately $5.83 million. After deducting for placement related expenses, the aggregate net proceeds from the Private Placement were approximately $5.53 million. The issuance and sale of all such shares has not been registered under the Securities Act, and such shares were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act as a transaction by an issuer not involving any public offering.

Between April 2022 through July 2022, the Company 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 the Company Common Stock and warrants for an additional 4,119,321 shares of the Company Common Stock, exercisable through 2024, at a per share exercise price of $1.10. subject to certain limited adjustments. The aggregate gross proceeds from the private placement were approximately $3,625,000.

On June 12, 2023, we entered into a subscription agreement with one investor pursuant to which we issued 1,000,000 shares of its common stock at a per share price of $1.00 and warrants to purchase up to an additional 1,000,000 shares of common stock at a per share exercise price of $1.40 and expire on the third anniversary from the date of issuance of the warrant to the holder. We are entitled to accelerate 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 shall equal or exceed 75,000 shares, in each case for the preceding forty (40) consecutive trading days. We received aggregate proceeds of $1,000,000 from this financing.

On June 4, 2024, we entered into a securities purchase agreement with certain, pursuant to which we agreed to issue and sell, in a private placement offering, 715,000 shares of our common stock, at a per share price of $1.00 and warrants to purchase up to an additional 1,144,000 shares of common stock. The warrants are exercisable beginning on the six (6) month anniversary of their issuance, have a term of five years from the initial exercise date and entitle the holders to purchase up to 1,144,000 shares of common stock. The warrants have an exercise price of $1.00 per share and contain a one-time dilution protection in the event the Company sells securities at a price less than the then exercise price in effect in a public offering in conjunction with a listing on a national securities exchange. The offering closed on June 7, 2024 and we received aggregate proceeds of $715,000.

On July 4, 2024, we entered into securities purchase agreements with a certain investor, pursuant to which it agreed to issue and sell, in a private placement offering, 40,000 shares of its common stock, at a per share price of $1.00 and warrants to purchase up to an additional 64,000 shares of common stock. The offering closed on July 10, 2024, and we received aggregate

proceeds of $40,000. This transaction was part of the securities purchase agreements that were closed on June 7, 2024.

The above issuances did not involve any underwriters, underwriting discounts or commissions, or any public offering and we believe is exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(2) thereof and/or Regulation D promulgated thereunder.

EXHIBITS

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description of Exhibit
2.1	Stock Exchange Agreement dated as of December 24, 2021, by and among IR-Med, Inc., IR. Med Ltd. and the former stockholders of IR. Med Ltd. (incorporated by reference to Exhibit 2.1 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
3.1	Amended and Restated Articles of Incorporation of IR-Med, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
3.2	Certificate of Amendment filed with the Secretary of State for the State of Nevada on June 6, 2024 (incorporated by reference to Exhibit 3.1 to report on Form 8-K filed with the SEC on June 10, 2024)
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form 10-Q filed with the SEC on August 14, 2023)
3.4	Amendment to Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.4 to the Registrant's Amendment No. 3 to the Registration Statement on Form S-1 filed with the SEC on October 28, 2021)
4.1	Specimen of Stock Certificate (incorporated by reference to Exhibit 2.1 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
4.2	Form of June 2023 Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 10-Q filed with the SEC on August 14, 2023)

4.3	Form of June 2024 Warrant (incorporated by reference to Exhibit 4.1 to report on Form 8-K filed with the SEC on June 10, 2024)
5.1**	Legal Opinion of Sullivan & Worcester LLP
10.1	Convertible Bridge Loan Agreement dated March 6, 2018, among IR. Med Ltd. and the Lenders scheduled therein (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.2	Amendment to the Convertible Bridge Loan Agreement referred in Exhibit 10.3 dated as of March 31, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.3	Second Amendment to the Convertible Bridge Loan Agreement referred in Exhibit 10.3 dated as of July 20, 2020 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.4@	Loan Agreement between Yaniv Cohen and IR. Med Ltd. dated January 2015 (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.5@	Loan Agreement between Aharon Klein and IR. Med Ltd. dated January 2015 (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.6	Clarification to the agreements referred to Exhibits 10.4 and 10.5 (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.7@	Form of Letter Engagement with Non-Employee Directors (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.8@	Form of Letter Agreement with Employee Director (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.9@	Amended and Restated Consulting Agreement dated as of July 7, 2024, between IR. Med Ltd. and Aharon Klein (incorporated by reference to Exhibit 10.1 to the report on Form 8-K filed with the SEC on July 11, 2024)
10.10@	Employment Agreement dated as of January 2021 between IR. Med Ltd. and Sharon Levkoviz (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.11@	Employment Agreement dated as of December 24, 2020, between IR. Med Ltd. Limor Davidson Mund (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.12@	Amended and Restated Consulting Agreement dated as of July 7, 2024, between IR. Med Ltd. and Yaniv Cohen (incorporated by reference to Exhibit 10.1 to the report on Form 8-K filed with the SEC on July 11, 2024)
10.13@	Employment Agreement dated as March 2, 2021, between IR. Med Ltd. and Aharon Binur (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.14	Form of Securities Purchase Agreement, dated December 24, 2021, by and among IR-Med, Inc. and the Purchasers (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.15	Form of Common Stock Purchase Warrants (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)

10.16	Form of Purchase Agreement, dated June 4, 2024, among the Company and the Investors (incorporated by reference to Exhibit 10.1 to report on Form 8-K filed with the SEC on June 10, 2024)
10.17@	2020 Incentive Stock Plan (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.18@	Form of Stock Option Award Agreement under the 2020 Incentive Stock Plan (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.19@	Lease Agreement dated between IR. Med Ltd. and Algaennovation Ltd. dated as of February 1, 2020 [English Language Translation] (incorporated by reference to Exhibit 10.20 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 filed with the SEC on August 26, 2021)
10.20	Amendment to Lease Agreement [English Language Translation] (incorporated by reference to Exhibit 10.20 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 filed with the SEC on August 26, 2021)
10.21@	Employment agreement between IR.Med Ltd. and Ran Ziskind dated as of August 22, 2024 (incorporated by reference as Exhibit 10.1 to the report on Form 8-K filed on August 28, 2024)
10.22	Distribution and License Agreement dated as of October 7, 2022, between IR.Med Ltd. and PI Prevention Care LLC (incorporated by reference as Exhibit 10.1 to the quarterly report on Form 10-Q for the quarter ended September 30, 2023 filed on November 14, 2022)
10.23	Termination and Settlement Agreement, dated as of May 22, 2023, by and among IR-Med, Inc., IR. Med Ltd. and Moshe Gerber (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on May 24, 2023)
10.24	Form of 2023 Subscription Agreement (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 10-Q filed with the SEC on August 14, 2023)
10.25	Form on Warrant Extension dated December 20, 2023, signed between the Company and certain warrant holders.
10.26	Amendment and Extension to 2015 Loan Agreement between the Company and Aharon Klein, dated March 1, 2024 (incorporated by reference to Exhibit 10.26 of our annual report on Form 10-K filed on April 4, 2025).
10.27	Amendment and Extension to 2015 Loan Agreement between the Company and Yaniv Cohan, dated March 1, 2024 (incorporated by reference to Exhibit 10.27 of our annual report on Form 10-K filed on April 4, 2025).
10.28	Amendment and Extension to 2017 Loan Agreement between the Company and Yaniv Cohan, dated March 1, 2024 (incorporated by reference to Exhibit 10.28 of our annual report on Form 10-K filed on April 4, 2025).
10.29	Amendment and Extension to Convertible Bridge Loan between the Company and certain investors, dated March 1, 2024 (incorporated by reference to Exhibit 10.29 of our annual report on Form 10-K filed on April 4, 2025).
10.30	Equity Purchase Agreement, dated March 11 2025 by and between IR-Med, Inc. and Williamsburg Venture Holdings, LLC (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on March 14, 2025).
10.31	Registration Rights Agreement, dated March 11, 2025, by and between IR-Med, Inc. and Williamsburg Venture Holdings, LLC (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on March 14, 2025).
10.32	Form of Note Purchase Agreement, dated March 26, 2025, between the Company and certain shareholders (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on April 1, 2025).
10.33	Form of Convertible Loan Agreement, dated March 26, 2025, between the Company and certain shareholders (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on April 1, 2025).
23.1*	Consent of KPMG
23.2**	Consent of Sullivan and Worcester LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on the signature page of this Registration Statement)
107*	Filing Fee Table
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document

101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

@ Management Contract or Compensatory Plan Arrangement.
* filed herewith.
** to be filed by amendment.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, on this 13th day of May 2025.

IR-MED, INC.

/s/ Ran Ziskand
Ran Ziskand
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Ran Ziskand and Sharon Levkoviz, and each of them, his true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstituting, for him and in his name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date

/s/ Oded Bashan Oded Bashan	Chairman of the Board	May 13, 2025
/s/ Ran Ziskind Ran Ziskind	Chief Executive Officer (Principal Executive Officer)	May 13, 2025
/s/ Aharon Klein Aharon Klein	Director	May 13, 2025
/s/ Sharon Levkoviz Sharon Levkoviz	Chief Financial Officer (Principal Financial and Accounting Officer)	May 13, 2025
/s/ Ohad Bashan Ohad Bashan	Director	May 13, 2025
/s/ Ron Mayron Ron Mayron	Director	May 13, 2025
/s/ Yaniv Cohen Yaniv Cohen	Director	May 13, 2025
/s/ Yechiel Even Yechiel Even	Director	May 13, 2025

Exhibit 23.1

Somekh Chaikin
17 Ha'arba'a Street, PO Box 609
KPMG Millennium Tower
Tel Aviv 6100601, Israel
+972 3 684 8000

Consent of Independent Registered Public Accounting Firm

We consent to the use of our report dated April 4, 2025, with respect to the consolidated financial statements of IR-Med Inc., included herein and to the reference to our firm under the heading "Experts" in the prospectus.

/s/ Somekh Chaikin
Somekh Chaikin

Member Firm of KPMG International

Tel Aviv, Israel
May 13, 2025

Exhibit 107

Calculation of Filing Fee Tables
FORM S-1
(Form Type)
IR-MED INC.
(Exact Name of Registrant as Specified in its Charter)
Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered (1)	Proposed Maximum Offering Price Per Unit (2)	Maximum Aggregate Offering Price (2)	Fee Rate	Amount of Registration Fee (2)
Securities to Be Registered								
Fees to Be Paid	Equity	Shares of Common Stock, $0.001 par value per share	Other	80,000,000 (3)	$ 0.079	$ 6,320,000	$ 0.00015310	$ 967.59
				Total Offering Amounts		$ 6,320,000		$ 967.59
				Total Fees Previously Paid				$ 0
				Total Fee Offsets				$ 967.59(4)
				Net Fee Due				$ 0

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended (the "Securities Act"), this Registration Statement shall also cover any additional shares of common stock, par value $0.001 per share ("Common Stock"), of the registrant that become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without receipt of consideration.

(2) In accordance with Rule 457(c), based on the average of the high ($0.079) and low ($0.079) prices of the Common Stock on the OTCQB® Market on May 9, 2025.

(3) Represents 80,000,000 shares that may be sold by the selling stockholder named herein, including 79,000,000 shares that we may sell to the selling stockholder under an equity purchase agreement (the "Equity Purchase Agreement") and 1,000,000 commitment shares we agreed to issue to the selling stockholder as consideration for its irrevocable commitment to purchase shares of our common stock under the Equity Purchase Agreement.

(4) A registration fee of $2,439.54 was previously paid with respect to securities registered under the Registrant's registration statement on Form S-1 filed on June 24, 2024 (No. 333-280446) (the "**Prior Registration Statement**"), pertaining to the registration of securities of the Registrant, which remained unutilized and subsequently withdrawn on May 2, 2025, and therefore, available for future registration fees pursuant to Rule 457(p) under the Securities Act. As the total filing fee required for this Registration Statement is $967.59, taking into consideration the available offset of $2,439.54 from the Prior Registration Statement, $0 is currently due for this Registration Statement.

Table 2: Fee Offset Claims and Sources

	Registrant or Filer Name	Form or Filing Type	File Number	Initial Filing Date	Filing Date	Fee Offset Claimed	Security Title Associated with Fee Offset Claimed	Amount of Registration Fee	Unsold Securities Associated with Fee Offset Claimed	Unsold Aggregate Offering Amount Associated with Fee Offset Claimed	Fee Paid with Fee Offset Source
Rule 457(b) and 0-11(a)(2)											
Fee Offset Claims											
Fee Offset Sources											
Rule 457(p)											
Fee Offset Claims	IR-Med Inc.	S-1	333-280446	June 24, 2024			Units Each Unit Consisting of One Share of Common Stock and One Warrant to Purchase One Share of Common Stock	$ 2,439.54	Withdrawal of Prior Registration Statement	$ 16,528,000	
Fee Offset Sources	IR-Med Inc.	S-1	333-280446		June 24, 2024						$ 967.59
