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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 333-255894

IR-MED INC.

(Exact name of registrant as specified in its charter)

Nevada	**98-0583166**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)

ZHR Industrial Zone, Rosh Pina, Israel
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **972-4-655-5054**

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

None	**None**
(Title of Class)	Name of Each Exchange on which registered

Securities registered pursuant to Section 12(g) of the Act:
Common Stock. Par value $0.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes☐ No ☒

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

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

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

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

If an emerging growth company, indicate by 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The registrant had 64,601,649 shares of common stock outstanding as of March 31, 2022. The aggregate market value of the common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2021) was $94,868,646, as computed by reference to the closing price of $3.00 of such common stock on the OTC Markets on such date.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2022 Annual Meeting of Stockholders within 120 days after the close of the fiscal year covered by this Form 10-K. Portions of such proxy statement are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this report.

IR-MED INC.
2021 FORM 10-K ANNUAL REPORT
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FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K for the year ended December 31, 2021, or this Annual Report on Form 10-K, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve risks and uncertainties, principally in the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements other than statements of historical fact contained in this Annual Report on Form 10-K, including statements regarding future events, our future financial performance, expectations for growth and revenues, anticipated timing and amounts of milestone and other payments under collaboration agreements, business strategy and plans, objectives of management for future operations, timing and outcome of legal and other proceedings and our ability to finance our operations are forward-looking statements. We have attempted to identify forward-looking statements by terminology including "anticipates," "approach," "believes," "can," "contemplate," "continue," "look forward," "ongoing," "could," "estimates," "expects," "intends," "may," "appears," "suggests," "future," "likely," "goal," "plans," "potential," "possibly," "projects," "predicts," "seek," "should," "target," "would" or "will" and other similar words or expressions or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks and uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements, to differ materially. The description of our Business set forth in Item 1, the Risk Factors set forth in Item 1A and our Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Item 7 as well as other sections in this report, discuss some of the factors that could contribute to these differences. 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, 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 potential impact of the coronavirus disease, or COVID-19, pandemic on our business operations;*

● *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; 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 not possible for us to predict all risk factors, nor can we 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; 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; the expected impact of new accounting standards; and the length and severity of the pandemic relating to SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, which could continue to have an impact on our research, development, supply chain and clinical trials.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this Annual Report on Form 10-K. 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K to conform our statements to actual results or changed expectations.

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "our Company", "the Company", "Pieris", "we", "us" and "our" refer to IR-Med, Inc., a Nevada corporation, and its consolidated subsidiary, IR. Med Ltd., a company organized under the laws of Israel.

PART I

ITEM 1. BUSINESS

Corporate History

General

IR-Med, Inc. was incorporated in the State of Nevada in April 2007 under the name "Monster Motors, Inc." IR-Med, Inc. 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 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.

Business Overview

The Company is a development stage medical device company developing its technology through its fully owned subsidiary. IR-Med Ltd, is looking to utilize Infra-Red light spectroscopy (IR) combined with Artificial Intelligence (AI) technology platform to address currently unmet diagnostic or medical needs. Our initial product candidates which are currently in various stages of development are non-invasive, user friendly and designed to address the medical needs of large and growing target patient groups by offering earlier and more accurate information for detection, which is expected to reduce healthcare expenses and reducing the widespread reliance on antibiotics administration, and other interventional options optimizing the delivery of the targeted medical services and, as a result, improving the efficacy and safety of administered treatments.

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

The global diagnostics market is driven in large part by solutions that can be applied in healthcare settings, as these tools will drive decisions regarding specific

treatments and the associated outlays. However, despite advances in medical imaging and other diagnostic tools, misdiagnosis remains a common occurrence. We believe that offering additional Decision Support Systems (DSS) tools may improve diagnoses and outcomes through the adoption of AI-based decision support tools.

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

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

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

We are currently working on completing the development of first prototype of the*PressureSafe* device, incorporating a more advanced technology platform. We expect to complete the development of the *PressureSafe* prototype in the second quarter of 2022 followed by usability studies

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

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 increasing ageing population and such diseases has resulted in more people needing assistance with activities of daily living due to decreased mobility. A major morbidity of decreased mobility is development of Pressure Injuries (PI). PI develop as a result of a combination of physiologic events and external conditions. Along with localized ischemia and reperfusion injury to tissues, impaired lymphatic drainage and mechanical deformation of tissue cells have been shown to contribute to injury as well.

Compression prevents lymph fluid drainage, and deterioration in tissue cell normal activities, which causes increased interstitial fluid and waste build up and contributes to PI development. The time required to develop a PI is dependent on many factors, including the patient's physiology and the degree of pressure and shear force place on the tissue. PI 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 heel area is the second most frequent location for a pressure ulcer, the most prevalent being the sacrum. The heel accounts for between 23% and 28% of all pressure ulcers[1].

While the number of Hospital Acquired Conditions (HAC) have decreased by 8%[2], pressure injuries have resisted improvement efforts and continue to grow by 10% annually. PI are both costly and deadly. The U.S. Agency for Healthcare Research and Quality (AHRQ) reports that PI add $10.2 billion to annual U.S. Healthcare costs [3]. Furthermore, these are associated with over 45% of the 63,619 HAC related deaths in the U.S., making it the leading contributor to HAC related deaths.

The most common method used to detect early PI is a visual assessment by a professional caregiver focusing on areas where PI most frequently develop. This visual assessment is subjective, unreliable, untimely (PI often occur suddenly without visual cues) ineffective, and can only detect PI once it is visible. Technology-based methods for detecting and monitoring PI have been developed but as far as we know, none have succeeded in providing an effective solution.

PI Background

As of today, PI 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 (Braden, Norton scores), and hospitals can then get the patient onto a different type of mattress that wicks away moisture, reduces pressure and have orders for the individual, for example, to be turned every 2 hours. The risk of a PI in ICU ranges between 18-40% of patients[4].

Intrinsic risk factors such as diabetes, malnutrition, and smoking also increase the overall risk for PI. 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 PI 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 a PI prevalence of 11%[6] and are most likely to develop PI over 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 formation.

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 home care services. The homecare companies have a strong incentive to prevent PI 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 PI and of these 37.4% had more than one PI and 14% had three or more. Considering the worst PI for each subject, 40.3% had Stage II and 27% had Stage III or IV injuries.

[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 Yea.*

[3] Boyko, T., Longaker, M. and Yang, G., 2018. Review of the Current Management of Pressure Ulcers.*Advances in Wound Care*, 7(2), pp.57-67.

[4] Fowler, E., Scott-Williams, S. and McGuire, J., 2008. Practice Recommendations for Preventing Heel Pressure Ulcers.*Ostomy Wound Management*, 54(10), pp.42-57.

[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.
Brandeis, G., Morris, J. and Nash, D., 1990. The Epidemiology and Natural History of Pressure Ulcers in Elderly Nursing Home Residents.*JAMA: The Journal of the American Medical Association*, 264(22), p.2905.

[7] Ferrell, B., Josephson, K., Norvid, P. and Alcorn, H., 2015. Pressure Ulcers Among Patients Admitted To Home Care. *Journal of the American Geriatrics Society*, 48(9), pp.1042-1047.

[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.

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 shear trauma to skin regions at risk as well as an individualized plan to reduce pressure such as frequent repositioning; (c) daily inspection of the skin for high risk residents as deep tissue damage can occur in as little as two hours, there needs to be a daily skin examination. The most common method used to detect early PI is a visual assessment by a professional caregiver focusing on areas where PI most frequently develop. This visual assessment is subjective, unreliable, untimely, as a PI develops under the skin before it becomes visible to the naked eye, and ineffective. Technology-based methods for detecting and monitoring PI have been developed but none have succeeded in providing an effective solution. These include ulcer detection based on skin conductivity which has relatively low resolution and is influenced by different topical skin conditions (moist, urine, 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 PI early and preventing progression. A common product are pads which are designed to specifically cover pressure points such as the sacrum and heels as well as foam pads designed to wrap around body parts at risk. However, it is important to note that some pads can actually be detrimental, i.e. supports with cut-outs can have increased pressure at their edges.

PressureSafe

Over the past six years 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 information to healthcare providers as where and when a PI may occur. The technology platform is designed to record information relating to each patient. The IR based 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 is based on the fact that tissues of the human body absorb and reflect the light that surrounds it in different wave lengths (from the UV through visual light to infra-red light) and the light is reflected and scattered back from inside the body through the skin. During this process the reflected and scattered light through a damaged area changes its properties in comparison to light reflection and scattering from normal healthy tissue. The PressureSafe is being designed to capture, analyze and identify tissue status to make early PI diagnosis using Spectrographic Analysis while AI learning software is planned to improve diagnostic accuracy. The PressureSafe device will illuminate the skin with a miniature LEDs for a few seconds. The emitted light photons from the device will be absorbed, scattered and reflected back. The device will then measure the absorption and reflectance, and using algorithms, will process the signals to identify and diagnose the scanned area.

As every person's skin properties are unique, the diagnosing physician must calibrate the device to the specific patient's skin, a process that takes merely a few seconds and allows personalized diagnosis, improving diagnostic process effectiveness as the PressureSafe device is designed to be indifferent to the skin color. Our technology is being developed to enable the assessment of different subdermal layers by scanning through these skin layers, thus improving the identification of the damage and assessing the subdermal damaged tissue volume, assisting with additional information to allow better treatment efficacy. Measuring the differences of subdermal fluid content and other bio-signals, has been developed to detect early formation of pressure injuries and to "raise a flag" to allow the caregivers intervene and prevent their appearance. The bio-signals that our algorithm detects occur in the early inflammatory process, as soon as local subcutaneous tissue function is disturbed, and cells begin to be damaged.

PressureSafe is a hand-held scanner we are developing to provide additional information as a decision support system (DSS), to support the care giver effectively with the main diagnostic problems of having ability to identify PI and to differentiate between Deep Tissue PI (before it becomes visible) and Stage 1 PI. Deep tissue PI are serious, hospital-acquired deep PIs that form under intact skin, spread in deep tissues and eventually present themselves as full thickness wounds. The PressureSafe will be composed of: (a) a handheld optic probe device, which utilizes harmless infra-red light, that is placed for a few seconds on suspected areas; (b) a disposable probe tip component, changed between patients to avoid cross-contamination; (c) a machine learning software for ulcer development prediction, which creates a data collection and digitalization allowing patient's documentation and treatment monitoring; and (d) for home care use (by health professional), we are planning to develop a probe connected to a tablet or mobile phone, and integrated into a mobile application.

PressureSafe is planned to be a non-invasive real-time optical monitoring device to support early intervention in PI treatment prior to skin breakage.I. We are developing our handheld device to perform a reflectance spectroscopy scan to generate information for the decision maker, while collecting data of subdermal physiological changes together with other bio-signals typical to early formation of PI in the three skin layers, thus detecting the appearance of life risking pressure injuries. PressureSafe will be able to detect changes at a depth of 1-5 mm in the skin, regardless of skin tone, by measuring differences of subdermal fluid content and bio-signals. As soon as local subcutaneous tissue function is disturbed and cells begin to disintegrate by pressure excreted upon by dependent body areas, our scanner is designed to be able to support detecting this as a very early inflammatory process. 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 PI dramatically, through early detection, making it attractive for public and private healthcare systems worldwide.

***PressureSafe* Preliminary Studies and Development Plan**

The *PressureSafe* scanner is now in development and will be released to a larger useability studies during H2 2022.

Our preliminary study began in the first quarter of 2018 at the Rambam Healthcare campus, located in Haifa, Israel and at the Beit Lowenstein Rehabilitation Center, located in Raanana, Israel.

The test readings were obtained both from patients with no Pressure Injuries (PI) and with patients which were diagnosed by the certified doctors. Only a stage 1 PI were included in the study. Higher grades of PI were excluded. Each patient which was included in the study was tested by the PressureSafe scanner to verify or contradict the certified doctors' diagnosis

A total of 76 samples were taken from both medical centers which were composed half of healthy patient tissue and half of PI Stage 1 affected tissue. 38 samples were chosen at random from both groups and were used to train the software to identify Stage 1 pressure injuries. The software uses an artificial intelligence technique to learn from and act on data, this adapting technique enables algorithms to change over time based on new data.

The results demonstrated that the PressureSafe had a 94.7% accuracy in identifying Stage 1 pressure injuries and a 5.3% misclassification rate.

We are currently working on completing the development of prototype, incorporating a more advanced technology platform. Following verification of the 'proof of concept' we believe that the PressureSafe device will be ready for a transition into the next stage: releasing a high-quality device that can be mass produced and introduced to the market in affordable price.

We plan to conduct useability studies in a multi-center study in Israel and the US, to validate the results of the early clinical studies and compare results received by *PressureSafe* device to PI prevention standard of Care (Visual assessment). Clinical useability studies are expected to start in Q2 2022.

Ear Infection Market

Reducing the consumption of antibiotics is a major goal of the health authorities around the world. Doctors all over the world are rushing to keep up with infections that are getting increasingly good at resisting antibiotic treatment, including gonorrhea, tuberculosis, bacterial pneumonia and others.

Antibiotics either kill bacteria or keep them from multiplying. By definition, they work only against bacterial illnesses—and yet, research shows they are often needlessly prescribed for viral illnesses like the flu and common colds. That is a waste of resources and may also contribute to antibiotic resistance. Bacteria is developing better resistance to drugs each time they encounter them. The result is the creation of super bugs that are resistant to that antibiotic.

In 2019 the World Health Organization described antimicrobial resistance—pathogens' ability to evade medical interventions—one of the 10 largest threats to global health[9].

According to the CDC in the US 35,000 people die each year due to antibiotic-resistant infections. A recent study published in the BMJ points to one major propagator of the problem: doctors are incorrectly prescribing antibiotics and up to 43% of U.S. antibiotic prescriptions may be inappropriate.

Studies conducted by the University of Utah[10] showed that in 2016 30% of outpatient oral antibiotic prescriptions may have been inappropriate. For example, 1 in every 5.4 urgent visits, which represents 18.5% of such visits, resulted in an antibiotic prescription. Of these, 37% were for ear infections which turned out to be viral infections.

The health community is already seeing the consequences of these improper prescriptions. In addition to the deaths detailed in the CDC's recent report, an estimated 2.8 million Americans contract and survive antibiotic- resistant infections each year. As illnesses get more and more difficult to treat, patients may suffer longer, and doctors might be forced to turn to increasingly powerful drugs, often with harmful side effects.

The antibiotic taken by children kills bacteria in their body, even the good bacteria, changing gut microbiome with toddlers, possibly leading to other problems, like clostridium difficile (C. difficile infection).

Nearly 70,000 children end up in emergency rooms every year after experiencing adverse reactions to antibiotic drugs, according to the CDC[11]. Most of these incidents were due to an allergy, and most were mild reactions (such as a rash), although some were more serious (such as anaphylaxis). Children under the age of 2 made up the largest share of the ER visits.

There are several long-term problems associated with children's consumption of antibiotics. For example, studies have found that children receiving more rounds of the drugs because of early infections are more likely to be obese as adolescents and adults and the earlier children are exposed to the drugs, the more likely their metabolism is to be affected[12].

Each year in the US, approximately 9 million children, ages 0-17, are reported to have ear infections or otitis media[13]. Of those, 8 million children visited a physician or obtained a prescription drug to treat the condition.

However, the number of children complaining of ear pain and undergoing examination by otoscope is many times these figures and they represent IR-MED's target market.

Medical spending to treat otitis media totals over $2.8 billion, with the average annual expenditure of more than $350 per person. More than one-third of ear infection prescription medications expenditures were paid from out of pocket.

The Global Ear Infection Treatment Market is expected to reach $22.3 billion by 2023, with a CAGR of about 6.6% in the period 2017-2023[14].

The market is being driven by the rise in risk factors, increasing awareness regarding the severity of untreated ear infection, development of healthcare, technological development in diagnostic devices and surgery segment especially the advancements in minimally invasive surgery and so on. Market restraints are the complications of surgery, high cost of treatment and the emergence of bacterial resistance.

[9] Lewis, R., 1995. The Rise of Antibiotic-Resistant Infections. *FDA Consumer magazine*.

[10] Fleming-Dutra, K., Hersh, A., Shapiro, D., Bartoces, M., Enns, E., File, T., Finkelstein, J., Gerber, J., Hyun, D., Linder, J., Lynfield, R., Margolis, D., May, L., Merenstein, D., Metlay, J., Newland, J., Piccirillo, J., Roberts, R., Sanchez, G., Suda, K., Thomas, A., Woo, T., Zetts, R. and Hicks, L., 2016. Prevalence of Inappropriate Antibiotic Prescriptions Among US Ambulatory Care Visits, 2010-2011. *JAMA*, 315(17), pp.1864-1873.

[11] Hirsh, J., 2018. *Antibiotic Side Effects in Children: What Every Parent Should Know*.

[12] Park, A., 2015. *How This Common Drug Can Have Lasting Effects on Kids*.

[13] Soni, a., 2008. *STATISTICAL BRIEF #228: Ear Infections (Otitis Media) in Children (0-17): Use and Expenditures, 200*.

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

Ear Infection Background

An ear infection is an inflammation of the middle ear, usually caused by bacteria or a virus, which occurs together with fluid builds up behind the eardrum. Three out of four children will have at least one ear infection by their third birthday[15]. In fact, ear infections are the most common reason parents bring their child to a doctor.

The presence of middle ear fluid is the key diagnostic marker for the two most common pediatric ear diseases, acute otitis media (AOM) and otitis media with effusion (OME)[16].

AOM, known commonly as an "ear infection" is characterized by the presence of infected fluid in the middle ear and results in symptoms of fever and ear pain.

It is a leading cause of pediatric healthcare visits, and although many cases can resolve without antibiotics, complications may include eardrum perforation, mastoiditis, facial nerve palsy, or meningitis.

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

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

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

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

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

The American Academy of Pediatrics[17] issued guidelines in 2013 that encourage doctors to observe and closely follow these children with ear infections that cannot be definitively diagnosed, especially those between the ages of 6 months to 2 years. If there is no improvement within 48 to 72 hours from when symptoms began, the guidelines recommend doctors start antibiotic therapy. Reducing the consumption of antibiotics is a major goal of the health authorities around the world.

Nobiotics

The Nobiotics device is planned to be an otoscope for supporting noninvasive detection of otitis media (ear infection). The device is in initial stages of development as an ear examination device that will give the physician an immediate indication if the infection is from a Viral or Bacterial source and then the physician will make a decision if to prescribe an antibiotic or not (DSS). The device works on a similar IR-spectrographic analysis method as being developed in the PressureSafe device. The Nobiotics otoscope is based on infrared light reflection and absorption by the effluents behind the ear drum. Otoscopes are considered a required device by any physicians performing physical diagnoses. Target customers for the Nobiotics device are general practitioners (GPs), pediatricians and ear nose and throat (ENT) specialists.

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

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

[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.

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 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 potentially 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 ear infections 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, 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 are planning 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 specialists and 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.

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 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 health care 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 product candidates 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 each patient been 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. Especially following the days of a world pandemic of COVID-19, where cross contamination of any kind is forbidden.

R&D and New Product Development

We believe our strong research and development 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 developers engineers, software engineers, electronics and electro-optics engineers, quality engineers and regulatory and health experts, who are responsible for the research design, 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.

As of December 31, 2021, we had six employees and one service provider, on a full-time basis, with an additional seven service providers, on a part time basis, engaged in product research and development at IR-Med Ltd. We spent approximately $1,419,000 and $409,000 on research and development activities in the years ended December 31, 2021 and 2020, respectively.

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 patent 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 detection of sub dermal pressure injuries.

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 and other future applications devices. 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 US, UK and the EU. 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 moisture, a method that it significantly different that the approach contained in the *PressureSafe* device which utilizes real-time optical monitoring device combined with an AI based capabilities for pre-emptive detection of pressure injuries in different settings. In addition, new developments, including the development of other medical device technologies and methods of preventing pressure injuries, occur in the medical device industry at a rapid pace.

We expect Nobiotics, if available for sale, to compete with other otoscopes which is in development or other products in development for the purpose of assisting with assessment of Otitis Media.

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 (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 (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, 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 agreements with a CMO and one or more back-up manufacturers for the commercial production of our product candidates as they near potential approval.

Distribution and Revenue Generation

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

The target market for our PressureSafe device are relevant Health care setting (i.e., hospitals, senior care facilities, etc.). Nursing homes and a growing segment of long terms home care givers. Once we receive the appropriate sales approvals, we expect the marketing will be done with local partners who have the relevant abilities and connections per each territory the company will ask to sell the products at. 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 and so on. Pricing will be determine by the local partner, taking in account all overhead expected costs, regulation requirements and reimbursement methods.

Nobiotics' target users will be pediatricians, family doctors pediatricians and Ear, Nose and Throat (ENT) doctors. The distribution of the Nobiotics is expected to be carried out by companies who are suppling devices and disposables to the target audience.

In both the *PressureSafe* and the *Nobiotics* devices, the revenue stream is expected to be generated mainly from the disposables and PSaaS (*PressureSafe* solution as a service) 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 OEM 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 OEM 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, 2021, we were paying a monthly rent of 12,500 NIS (approximately, $4,000). On November 17, 2021, the agreement was amended to increase the monthly rental amount to 15,000 NIS per month (approximately $4,688) starting from January

2021 to service and support our expanded personnel.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and 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 US, we believe they will need to obtain clearance for commercial sales. Our devices will be subject to ongoing regulation by the FDA in the US 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 Nobiotics that is 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, and 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 working 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 Nobiotics device.

For the PressureSafe and Nobiotics devices, the clearance process may involve three material steps First, we will engage the FDA in a pre-submission conference to ensure that we understand and meet the FDA's requirements, expectations and standards with regard to approval of our product candidates. At this meeting, our team, including our FDA regulatory consultant, will receive FDA comments and guidance regarding our proposed submission during the pre-market notification period for 510(K) clearance (including any suggested modifications to the device description, indications for use or summary of supporting data contained in the notification). Then we will prepare our submission to the FDA accordingly.

The FDA's 510(k) clearance pathway generally takes from three to twelve months from the date the application is completed, but, if additional testing, verifications or other procedures (or even clinical trials) are required, can take significantly longer.

After a medical device receives 510(k) clearance by the FDA, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, requires to re-determine the regulatory path.

The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can, at its discretion, require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance is obtained.

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 rescinding 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 or 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 constate our only products.

Ongoing Regulation by FDA.

For the PressureSafe device we plan to provide enough clinical evidence to comply with the regulatory requirements and to attain both the FDA clearance and CE marking and ensure a scaled-up manufacturing process complying QSR (Quality System Regulation) and ISO 13845:2016 standard. Upon FDA clearance, we will seek to obtain in the U.S. a CPT code for purposes of reimbursement by Medicare and Medicaid.

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 un-cleared, unapproved or "off-label" uses, and other requirements related to advertising and promotional activities;
- Medical device reporting (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 FDCA that may present a risk to health;
- Labelling and Unique Device Identification (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. Inspection may be routine or cause 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.

Useability Studies

In addition to the above, we plan to conduct useability studies in Israel, the U.S. or other countries on products that have not yet been cleared or approved for a particular indication. 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. We may, however, in the future 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 what 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 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 of the Department of Health and Human Services, or OIG, has issued a series of regulations, known as the "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 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 and which 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 the 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 the 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 US market.

Employees & Consultants

We currently engage, on a full-time basis, eight employees and one service providers and, on a part-time basis, two employees and seven service providers for a total of 18 employees and service providers. twelve of these individuals are engaged in product research and development and the remainder in various fields of management, marketing and regulatory consulting.

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.

Legal Proceedings

We are not presently a party to any legal proceedings. We may from time to time be involved in various claims and legal proceedings of a nature we believe are normal and incidental to a medical device business. These matters may include product liability, intellectual property, employment and other general claims. We accrue for contingent liabilities when it is probable that a liability has been incurred and the amount can be reasonably estimated. Regardless of outcome, litigation can have an adverse impact on us because defense and settlement costs, diversion of management resources and other factors.

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 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. As of December 31, 2021, approximately ___% of our global workforce was female and __% of our employees in managerial or supervisory roles were female.

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.

Response to COVID-19

Beginning in March 2020 and continuing through all of 2021, we have supported our employees and government efforts to curb the COVID-19 pandemic through a multifaceted communication, infrastructure and behavior modification and enforcement effort, with the main objective to keep our laboratories in operation while protecting our employees' health and safety:

● Establishing clear and regular COVID-19 policies, safety protocols and weekly updates to all employees;
● Increasing physical distancing in workspaces for employees working onsite by scheduling adjustments and adding work from home flexibility;
● Adjusting attendance policies to encourage those who are sick or are able to perform their work from home to stay home;
● Increasing cleaning protocols across all locations;
● Providing additional personal protective equipment and cleaning supplies;
● Implementing site-specific protocols to address actual and suspected COVID-19 cases and potential exposure;
● Requiring masks to be worn in all locations.

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 (the "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."

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, before making any decision to invest in shares of our common stock. This Annual Report on Form 10-K contains forward-looking statements. If any of the events discussed in the risk factors below occurs, our business, prospects, results of operations, financial condition and cash flows could be materially harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

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 this Annual Report on Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

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, 2021 and 2020, we incurred net losses of approximately $3,716,000 and $752,000, respectively. As of December 31, 2021 and 2020, we had an accumulated deficit of $5,196,000 and $1,480,000, respectively

We expect to incur losses for the foreseeable future as we continue the development of, and seek regulatory clearance and approvals for, initially for our *PressureSafe* device-in-development (for pre-emptive diagnosis of pressure injuries on the skin surface) 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 Nobiotics devices), entail significant costs. As we are in the early stage of the engineering, electronics, algorithm and mechanical aspects of our 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.

We raised gross proceeds to us of $5.831 million under the 2020 Private Placement. Even after giving effect to the Private Placement, we will require additional capital for the further development and commercialization of our two 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 would 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 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 and the Nobiotics 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;
- 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 and 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. which could adversely affect our financial condition and results of operations

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 PressureSafe and/ or 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 or the Nobiotics 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 through 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 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 no products that are approved for commercial sale. If we are unable to successfully develop, receive commercial sale approval from the regulatory authorities as applicable and commercialize initially our PressureSafe device under development, or if we experience significant delays in doing so, our business will be adversely affected.

We currently have no products that are approved for commercial sale. We initially plan to seek commercial sale approval from the regulatory authority (FDA) to commercialize our PressureSafe under development and we may seek approval to commercialize in selected international geographies. 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 FDA clearance of our planned regulatory pathway
- 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 Nobiotics 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 commercial sale approval initially for the PressureSafe device will be granted 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 will let us to market our device. If the FDA or other foreign regulatory authority will require 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 authority 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 country. Approval processes vary between countries and can involve additional product testing and validation and additional administrative review periods. It is possible that no product we develop will 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 in a timely manner 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 the US regulatory requirements, such as, the Quality System Regulation (QSR), the medical device reporting (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 Nobiotics and 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 initially 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.

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.

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 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 Nobiotics.

The technology underlying PressureSafe and Nobiotics 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 PressureSafe and the Nobiotics devices or future versions thereof. A material liability claim or other occurrence 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 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.

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 prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved pre-market approval ("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, our regulatory approval plan is to obtain 510(K) clearance, however no assurance can be granted that we will so succeed. 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 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 authority is never guaranteed.

FDA or and other regulatory agency 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, which 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 are able to obtain.

With respect to 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, proprietary business information and personal information). It is critical that we 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 a number of 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 their 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, proprietary business information and personal information, and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, including the imposition of significant fines, penalties, or other liability for any noncompliance with certain privacy and data security laws. 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.

We may be subject to numerous and varying 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 Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA.

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 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 (fines of up to Euro 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 covers the methods and documentation of the design, testing, production, quality control, labeling, packaging, storage shipping and distribution of our products. In other foreign countries ISO 13485 standard is used (but not limited), 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 criminal prosecution.

Any of these sanctions could impair our ability to produce PressureSafe or Nobiotics 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 (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 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.

We do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates, and must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or jointly with a development partner, 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 these expenditures 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 expenditures 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, if approved for commercial sale, 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, or 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.

The continuing prevalence of the COVID-19 pandemic may adversely affect our operations and our capital raising efforts.

In late 2019, a novel strain of Coronavirus, also known as COVID-19, was reported in Wuhan, China. While initially the outbreak was largely concentrated in China, it has now spread globally. Many countries around the world, have significant governmental measures implemented to control the spread of the virus, including temporary closure of businesses, severe restrictions on travel and the movement of people, limited access to nursey homes, hospitals and other medical institutes and other material limitations on the conduct of business. These measures have resulted in work stoppages and other disruptions. Our research and development activities, sales and marketing efforts, as well as our ability to perform clinical trials (if needed) depend, in part, on attendance at in-person meetings, industry conferences and other events, facility visiting, and as a result some of our sales and marketing activities have been halted.

The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, the continued spread of the coronavirus globally, could have a material adverse impact on our operations and workforce, including our marketing and sales activities and ability to raise additional capital, and our ability to perform clinical trials, which in turn could have a material adverse impact on our business, financial condition and results of operation.

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.

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.

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 obligated 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 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 attention and energies 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 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.

Recent political uprisings, social unrest and violence in various countries in the Middle East and North Africa, including Israel's neighbors Egypt and Syria, are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and these countries and has raised concerns regarding security in the region and the potential for armed conflict. Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Any losses or damages incurred by us could have a material adverse effect on our business. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among parties hostile to Israel in areas that neighbor Israel, such as the Syrian government, Hamas in Gaza and Hezbollah in Lebanon. 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, in the event of a military conflict, may be called to active duty. In response to terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be additional military reserve duty call-ups in the future in connection with this conflict or otherwise. Some of our employees, consultants and employees of the manufacturer of our products, are required to perform annual military reserve duty in Israel and may be called to active duty at any time under emergency circumstances. Our operations and the operations of our manufacturer could be disrupted by such call-ups.

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. 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.

Our subsidiary, IR-Med Ltd., received a total of $327,000 from the Israel Innovation Authority (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 dollar and bearing interest at an annual rate of LIBOR applicable to dollar deposits. 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 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 51% 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 a 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 report, 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.

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 has to 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 have to 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.

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. 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 (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 authorizes the issuance of up to 250,000,000 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, issuances 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. Shares of our common stock representing 51% of our currently outstanding shares will become freely tradable upon the effectiveness of the registration statement of which this prospectus forms a part.

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 64,601,649 shares of our common stock are outstanding. Of those shares, approximately 27 million are currently freely tradable, without restriction, in the public market 9,328,329 shares 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 provide 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 be 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 provide 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 provide 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 to cover 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real property. We occupy approximately 130 square meters of facilities located in Rosh Pina 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, 2021, we were paying a monthly rent of 12,500 NIS (approximately, $4,000). On November 17, 2021, the agreement was amended to increase the monthly rental amount to 15,000 NIS per month (approximately $4,688) starting from January 2022 to service and support our expanded personnel. See also "Related Transactions"

We believe that our facilities are generally in good condition and suitable to carry on our business. We also believe that, if required, suitable alternative or additional space will be available to us on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

We are not involved in any pending legal proceedings that we anticipate would result in a material adverse effect on our business or operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is currently quoted on the OTCQB-tier of OTC Markets under the symbol "IRME." We started being quoted on the OTCQB-tier of OTC Markets on February 1, 2022. As of March 31, 2022, we had 64,601,649 shares of our common stock outstanding. Any over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions

As of March 29, 2022, there were 710 active holders of record of our common stock, and the last reported sale price of our common stock on the OTCQB-tier of OTC Markets on March 28, 2022 was $3.60.

Dividend Policy

To date, we have paid no dividends on our common stock and do not expect to pay cash dividends in the foreseeable future. We plan to retain all earnings to provide funds for the operations of our company. In the future, our Board of Directors will decide whether to declare and pay dividends based upon our earnings, financial condition, capital requirements, and other factors that our Board of Directors may consider relevant. We are not under any contractual restriction as to present or future ability to pay dividends.

Unregistered Sales of Equity Securities

None

Issuer Purchases of Equity Securities

None

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the fiscal years ended December 31, 2021 and December 31, 2020 and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2021, as compared to the fiscal year ended December 31, 2020. This discussion should be read in conjunction with our consolidated financial statements for the fiscal years ended December 31, 2021 and December 31, 2020 and related notes included elsewhere in this Annual Report on Form 10-K. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains numerous forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Item 1A. Risk Factors."

The full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. We have made estimates of the impact of COVID-19 within our financial statements, and although there is currently no major impact, there may be changes to those estimates in future periods. Actual results may differ from these estimates.

Corporate Overview

We are a development stage medical device company developing a proprietary technology platform that utilizes Infra-Red light spectroscopy (IR) combined with Artificial Intelligence (AI) technology platform to address currently unmet diagnostic or medical needs. Our initial product candidates, which are currently in various stages of development, are designed to be non-invasive, user friendly and designed to address the medical needs of large and growing target patient groups by offering earlier and more accurate information for diagnostic detection, which is expected to reduce healthcare expenses and reducing the widespread reliance on antibiotics administration, and other interventional options and optimizing the delivery of the targeted medical services, thereby improving the efficacy and safety of administered treatments.

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

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

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

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

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

Our product candidates are in various stages of development. We are currently working on completing the development of the prototype of the*PressureSafe* device, incorporating a more advanced technology platform. We expect to complete the development of the *PressureSafe* prototype in the second quarter of 2022. The*Nobiotics* device is planned to be an otoscope for supporting noninvasive detection of otitis media (ear infection). The device is in initial stages of development as an ear examination device.

Our product candidates may be commercialized only after we obtain the requisite clearance from the FDA. We intend to pursue the simpler 510(k) clearance for *PressureSafe* but the FDA may require a more extensive pre- market approval process, which may require, among other things, clinical trials.

Key Financial Terms and Metrics

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

Revenues

We have not generated any revenues from product sales to date and we do not expect to generate revenues from product sales for the foreseeable future.

Research and Development Expenses

The process of researching and developing our product candidates is lengthy, unpredictable, and subject to many risks. We expect to continue incurring substantial expenses 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 *Nobiotics* diagnostic devices. The design and development of these devices will consume a large proportion of our current, as well as projected, resources.

Our research and development costs include costs are comprised of:

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

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

Marketing

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

General and Administrative Expenses

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

Financial Expenses

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

Comparison of the Year Ended December 31, 2021 to the Year Ended December 31, 2020.

Our financial results for the year ended December 31, 2021 are summarized as follows in comparison to the year ended December 31, 2020:

	Year Ended	
	December 31, 2021	**December 31, 2020**
Operating Expenses		
Research and Development	**$ 1,419,000**	**$** 409,000
Marketing	**888,000**	—
General and Administrative	$ **1,368.000**	**$** 321,000
Financing expenses	$ **41,000**	**$** 22,000
Loss for the year	$ **3,716,000**	**$** 752,000

Revenues. We have not recorded any revenues to date.

Research and Development Expenses, Research and development expenses increased from $409,00 for the year ended December 31, 2020 to $1,419,000 in 2021. The increase resulted primarily from the recruitment of employees, increased use of third-party contractors for further research and development activities and the recording of non-cash expenses resulting from stock based compensation to employees and service providers that was awarded in June 2021.

Marketing Expenses -During the year ended December 2021, we started to expand efforts to develop the marketing strategy for*PressureSafe*. In connection therewith, we recorded $888,000 in marketing expenses, which includes non-cash expenses attributable to stock based compensation to employees and service providers that was awarded in June 2021, recruitment of employees and use of professional services.

General and Administrative Expenses. General and expenses increased from $321,000 for the year ended December 31, 2020 to $1,368,000 in 2021. The increase is primarily due to the increased resulted primarily from recruitment of new employees, patent registration in the U.S. accounting/audit related expenses and the recording of non-cash expenses due to stock based compensation to employees and service providers awarded in June 2021.

Loss. Loss for the year ended December 31, 2021 was $3,716,000 and is primarily attributable to research and development and general and administrative expenses.

Liquidity and Capital Resources

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

From inception, we have funded our operations from a combination of loans and sales of equity instruments. Between December 24, 2020 and April 10, 2021, we raised aggregate gross proceeds in the approximate amount of $5.83 million.

As of December, 2021, we had a total of $2,815,000 in cash resources and approximately $572,000 of liabilities, consisting of $395,000 of current liabilities from operations.

The following table provides a summary of operating, investing, and financing cash flows for the years ended December 31, 2021 and 2020 respectively (in thousands):

	Year Ended	
	December 31, 2021	**December 31, 2020**
Net cash used in operating activities	**(2,482)**	(402)
Net cash used in investment activities	**(61)**	-
Net cash provided by Financing Activities	**3,491**	2,036

We have experienced operating losses since its inception and had a total accumulated deficit of $5,196,000 as of December 31, 2021. 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, 2021. These losses have resulted in significant cash used in operations. During the years ended December 31, 2021 and 2020, our cash used in operations was approximately $2,482,000, and $402,000, 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 that we undertook between December 2020 and April 2021,we entered into a securities purchase agreement with certain accredited investors providing for the issuance and sale to such investors of an aggregate of 18,221,876 shares of our Common Stock and warrants for an additional 9,110,938 shares of our Common Stock, exercisable through December 24, 2023, at a per share exercise price of $0.64. After deducting for offering related expenses, the aggregate net proceeds from the initial closing of the 2020 Private Placement were approximately $5,446,000.

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

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

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

We cannot be sure that future funding will be available to us on acceptable terms, or at all. Due to often volatile nature of the financial markets, equity and debt financing may be difficult to obtain.

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

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

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

Until December 31, 2018, the Company accounted for equity-based compensation to non-employees in accordance with ASC 505-50, Equity – Equity-based Payments to Non-employees ("ASC 505-50"), with respect to options and warrants issued to non-employees. All transactions with nonemployees in which goods or services are

received in exchange for equity-based instruments are accounted for based on the fair value of the consideration received or the fair value of the equity-based instruments issued, whichever is more reliably measurable.

In June 2018, the FASB issued ASU 2018-07 "Improvement to Nonemployee Share-Based Payments Accounting." This guidance simplifies the accounting for non-employee share-based payment transactions. The amendments specify that ASC 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company adopted the provisions of this update as of January 1, 2019.

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, 2021 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by Item 8 is included following the "Index to Financial Statements" on page F-1 contained in this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of December 31, 2021, we conducted an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, regarding the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"). The term "disclosure controls and procedures" means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods and that such disclosure controls and procedures were effective to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management, under the supervision of and with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting and disclosure controls and procedures as of December 31, 2021. In making this assessment, management used the updated criteria set forth in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at reasonable assurance level due to a material weakness in internal control over financial reporting, as further described below.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The limitation of our internal control over financial reporting was due to the applied risk-based approach which is indicative of many small companies with limited number of staff in corporate functions implying:

(i) Lack of information technology controls to maintain appropriate access rights and backup procedures; and

(ii) Insufficient segregation of duties with control objectives

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

Remediation Plan

In January 2022, we have implemented a risk management, resource planning and internal control system, which are all intended to strengthen our overall control environment. Management has taken additional steps to address the causes of the above weaknesses and to improve our internal control over financial reporting, including the re-design of our accounting processes and control procedures and the identification of gaps in our skills base and the expertise of our staff as required to meet the financial reporting requirements of a public company. In particular, during the first quarter of fiscal year 2022, we retained qualified independent third-party personnel, to conduct a comprehensive review of our internal controls and formalization of our review and approval processes in order. The appointed qualified independent third party assessed the Company's risk management framework to manage enterprise risk. The appointed qualified independent third party designed a remediation plan which. The risk based approach identified by the Company reflects the awareness of an acceptable level of risk to manage the Company, considering the strategy, resources and regulatory environment.

This measure led to an overarching remediation plan and program brief to be followed by a detailed action plan for each major risk selected. Subsequently, it is expected to lead to an improvement in our internal controls which will enable us to expedite our month-end close process, thereby facilitating the timely preparation of financial reports and to strengthen our segregation of duties at the Company.

We are committed to maintaining a strong internal control environment, and believe that these remediation efforts will represent significant improvements in our control environment. Our management will continue to monitor and evaluate the relevance of our risk-based approach and the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements, as necessary and as funds allow.

Changes in Internal Control Over Financial Reporting

Except for the material weakness, during the quarter ended December 31, 2021, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated herein by reference to our definitive Proxy Statement (the "2022 Proxy Statement") for our 2022 annual meeting of stockholders, which will be filed with the SEC not later than 120 days subsequent to December 31, 2021.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our 2022 Proxy Statement for the 2022 annual meeting of stockholders, which will be filed with the SEC not later than 120 days subsequent to December 31, 2021.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our 2022 Proxy Statement for the 2022 annual meeting of stockholders, which will be filed with the SEC not later than 120 days subsequent to December 31, 2021.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our 2022 Proxy Statement for the 2022 annual meeting of stockholders, which will be filed with the SEC not later than 120 days subsequent to December 31, 2021.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will is incorporate by reference to our 2022 Proxy Statement for the 2022 annual meeting of stockholders, which will be filed with the SEC not later than 120 days subsequent to December 31, 2021.

Our Board of Directors has appointed Somekh Chaikin, Tel Aviv, Israel, ID 1057, a member firm of KPMG as our independent registered public accounting firm for the fiscal year ended December 31, 2021.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a)

c. Financial Statements

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

d. Financial Statement Schedules

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable or are not required or because the information is otherwise included herein.

e. Exhibits required by Regulation S-K

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)
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)

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	Description of Registered Securities
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 December 24, 2020 between IR. Med Ltd and Aharon Klein (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.10@	Employment Agreement dated as of April 1, 2021 IR. Med. Ltd and Yoram Drucker (incorporated by reference to Exhibit 10.10 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 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)
10.12@	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)
10.13@	Settlement and Termination Agreement dated as of April 7, 2021 between IR. Med Ltd and Limor Davidson Mund (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.14@	Consulting Agreement dated November 19, 2019 between IR. Med Ltd and Yaniv Cohen (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 filed with the SEC on May 7, 2021)
10.15@	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)
10.16	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)
10.17	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)
10.18@	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)
10.19@	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)
10.20@	Employment Agreement dated as of June 22, 2021 between Dr. Rom Eliaz and IR-Med Ltd. (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@	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)
10.22	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)
21.1	List of Subsidiaries (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)
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer (Principal Executive Officer), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

@ Management Contract or Compensatory Plan Arrangement

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)

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IR-MED INC.

By: */s/ Rom Eliaz*
Rom Eliaz
Chief Executive Officer (Principal Executive Officer)
Date: March 31, 2022

By: */s/ Sharon Levkoviz*
Sharon Levkoviz
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)
Date: March 31, 2022

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Oded Bashan Oded Bashan	Chairman of the Board	March 31, 2022
/s/ Rom Eliaz Rom Eliaz	Chief Executive Officer (Principal Executive Officer)	March 31, 2022
/s/ Sharon Levkoviz	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2022
/s/ Aharon Klein Aharon Klein	Chief Technology Officer, Director	March 31, 2022
/s/ Yoram Drucker Yoram Drucker	Director	March 31, 2022
/s/ David Lazar David Lazar	Director	March 31, 2022
/s/ Ohad Bashan Ohad Bashan	Director	March 31, 2022
/s/ Ron Mayron Ron Mayron	Director	March 31, 2022
/s/Yaniv Cohen Yaniv Cohen	Director	March 31, 2022

IR-Med, INC.
and subsidiary

Consolidated Financial Statements
December 31, 2021

IR-MED INC.
CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2021

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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, 2021 and 2020, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

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. 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
March 31, 2022

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	December 31 2021	December 31 2020
		US Dollars (In thousands)	
Assets			
Current assets			
Cash and cash equivalents	4	**2,815**	1,866
Accounts receivable	5	**67**	218
Total current assets		**2,882**	2,084
Non-current assets			
Long term deposits	11	**30**	-
Property and equipment, net	6	**31**	6
Total non-current assets		**61**	6
Total assets		**2,943**	2,090
Liabilities and stockholders' equity			

Current liabilities			
Trade and other payables	7	**395**	523
Non-current liabilities			
Stockholders' loans	8	**177**	166
Total liabilities		**572**	689
Contingent Liabilities and Commitments	11		
Stockholders' equity	10		
Common Stock, par value $0.001 per share, 250,000,000 shares authorized: 64,601,649 and 53,586,023 issued and outstanding as of December 31, 2021 and 2020, respectively		**64**	54
Additional paid-in capital		**7,503**	2,827
Accumulated deficit		**(5,196)**	(1,480)
Total Stockholders' equity		**2,371**	1,401
Total liabilities and stockholders' equity		**2,943**	2,090

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, 2021	For the year ended December 31, 2020
		US Dollars (In thousands)	
Research and development expenses	12	**1,419**	409
Marketing expenses	13	**888**	-
General and administrative expenses	14	**1,368**	321
Total operating loss		**3,675**	730
Financial expenses	15	**41**	22
Loss for the year		**3,716**	752
Loss per share			
Basic and dilutive loss per common stock (in dollars)	16	**(0.06)**	(0.02)

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

IR-Med Inc.

Consolidated Statement of Changes in Stockholders' Equity

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total
	Number of shares	US dollars (In Thousand)			
Balance as of January 1, 2021	**53,586,023**	**54**	**2,827**	**(1,480)**	**1,401**
Stock-based compensation	**-**	**-**	**1,384**	**-**	**1,384**
Private placement of common stock and warrants, net	**11,015,626**	**10**	**3,292**	**-**	**3,302**
Loss for the year	**-**	**-**	**-**	**(3,716)**	**(3,716)**
Balance as of December 31, 2021	**64,601,649**	**64**	**7,503**	**(5,196)**	**2,371**
Balance as of January 1, 2020	30,185,183	29	618	(728)	(81)
Issuance of common stock, net	343,536	1	80	-	81
Exercise of warrants	515,226	1	73	-	74
Private placement of common stock and warrants, net	22,542,078	23	2,056	-	2,079
Loss for the year	-	-	-	(752)	(752)

Balance as of December 31, 2020	53,586,023	54	2,827	(1,480)	1,401

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

Consolidated Statements of Cash Flows

	For the year ended December 31, 2021	For the year ended December 31, 2020
	US Dollars (In thousands)	
Cash flows from operating activities		
Loss for the year	**(3,716)**	(752)
Adjustments to reconcile loss for the year to net cash used in operating activities:		
Stock based compensation	**1,339**	-
Depreciation	**5**	1
Compensation related to warrants issued to service providers	**-**	25
Financial expenses	**11**	20
increase in accounts receivable	**(38)**	(16)
Increase (decrease) in trade and other payables	**(83)**	320
Net cash used in operating activities	**(2,482)**	(402)
Cash flows from investing activities		
Purchase of property and equipment	**(31)**	-
Increase in long term deposit	**(30)**	-
Net cash used in investing activities	**(61)**	-
Cash flows from financing activities		
Proceeds from issuance of common stock, net	**-**	81
Proceeds from private placement of common stock and warrants, net	**3,491**	1,955
Net cash provided by financing activities	**3,491**	2,036
Effect of exchange rate changes on cash	**1**	(3)
Net increase in cash and cash equivalents	**949**	1,631
Cash and cash equivalents as at the beginning of the year	**1,866**	235
Cash and cash equivalents as at the end of the year	**2,815**	1,866
Non-cash financing Activities:		
Increase in other receivable from shares issuance	**-**	189
Decrease in trade and other payables from grant of options	**45**	-

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

On December 24, 2020 IR-Med Inc. entered into a stock exchange agreement (hereinafter: the “Stock Exchange Agreement” or the “Reverse Acquisition”) with an Israeli company, IR. Med Ltd. (hereinafter: the “Company” or the “Subsidiary”) which was founded in May 2013. The Parent Company and its Subsidiary are referred in these consolidated financial statements as the “Group”. According to the Stock Exchange Agreement, IR. Med Ltd. became a wholly owned subsidiary of IR-Med, Inc. pursuant to a share exchange transaction among IR Med, Inc., IR. Med Ltd. and the former shareholders of IR. Med Ltd. For further information on the Reverse Acquisition. See also Note 3 - Reverse Acquisition.

The registered office of IR-Med, Inc. and the corporate headquarters and research facility of IR. Med Ltd. are located in Rosh Pina, Israel.

The Company is a development stage medical device company developing its technology through its fully owned subsidiary. IR-Med Ltd, is looking to utilize

Infra-Red light spectroscopy (IR) combined with Artificial Intelligence (AI) technology platform to address currently unmet diagnostic or medical needs. The Group's initial product candidates which are currently in various stages of development are non-invasive, user friendly and designed to address the medical needs of large and growing target patient groups by offering earlier and more accurate information for detection, which is expected to reduce healthcare expenses and reducing the widespread reliance on antibiotics administration, and other interventional options optimizing the delivery of the targeted medical services and, as a result, improving the efficacy and safety of administered treatments.

B. The Company is in its development stage and does not expect to generate significant revenue until such time as the Company shall have completed the design and development of its initial product candidate and obtained the requisite approvals to market the product. During the year ended December 31, 2021, the Company incurred losses of US$ 3,716 thousand and had a negative cash flow from operating activities of US$ 2,482 thousand. The accumulated deficit as of December 31, 2021 is US$ 5,196 thousand.

Management's plans regarding these matters include continued development and marketing of its products, as well as seeking additional financing arrangements. The Company believes that its cash resources are sufficient for the operations of the next 12 months. Although management continues to pursue these plans, there is no assurance that the Company will be successful in raising the needed capital from revenues or financing on commercially acceptable terms. If the Company is unable to raise capital when needed on commercially reasonable terms, it could be forced to delay, reduce, or eliminate its research and development for its product candidates or any future commercialization efforts. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 1 – General (Cont'd)

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

Note 2 - Summary of Significant Accounting Policies

A. Basis of Presentation

The financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP")

B. Functional Currency

The Group finances its operations in U.S. dollars. While the majority of the Group's operations are currently conducted in Israel, a significant part of the Group's expenses is denominated and determined in U.S. dollars Future revenues are expected to be earned in US dollars. The Group'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 Group is the U.S. Dollar.

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

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

E. Cash and Cash Equivalents

The Group 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.

Annual rates at depreciation are as follows:

	%
Computer's equipment	33
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 Group 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.

● 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.

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

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

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. 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.

J. Accounting for Share-Based Compensation

Until December 31, 2018, the Company accounted for equity-based compensation to non-employees in accordance with ASC 505-50, Equity – Equity-based Payments to Non-employees ("ASC 505-50"), with respect to warrants issued to non-employees. All transactions with nonemployees in which goods or services are received in exchange for equity-based instruments are accounted for based on the fair value of the consideration received or the fair value of the equity-based instruments issued, whichever is more reliably measurable.

In June 2018, the FASB issued ASU 2018-07 "Improvement to Nonemployee Share-Based Payments Accounting." This guidance simplifies the accounting for non-employee share-based payment transactions. The amendments specify that ASC 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company adopted the provisions of this update as of January 1, 2019.

Stock Option Plan

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

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

K. 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

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

K. Income taxes (Cont'd)

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 Group records valuation allowances to reduce deferred income tax assets to the amount that is more likely than not to be realized.

The Group 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 records interest related to unrecognized tax benefits in interest expense and penalties in selling, general, and administrative expenses.

L. Concentrations of credit risks

Financial instruments that potentially subject the Group 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 Group investments have high credit ratings. The Group has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

M. Employee benefits

Pension

The Group 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 some of its employees to whom section 14 of the Dismissal Compensation Law applies.

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 Group expects the benefits to be wholly settled.

N. Government 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. Royalties paid to the IIA are recognized as a reduction of the above-mentioned liability. In instances where a liability was not recorded, the payment of the royalties is recorded as cost of sales

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

O. New standards not yet adopted

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842)." This ASU requires that lessees recognize assets and liabilities on the balance sheet for the rights and obligations created by all leases with terms of more than 12 months. ASU No. 2016-02 also will require disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative information. This ASU is effective for quarterly and annual periods, beginning after December 15, 2021 with earlier adoption permitted. The expected impact on the Company's Balance Sheet on the date of initial recognition will be an increase in right of use assets and financial liabilities of approximately $150 thousand. The impact on the Statement of Operations is not expected to be material.

2021-04 are effective for annual reporting periods beginning after December 15, 2021, and interim reporting periods within those annual periods, with early adoption permitted. The ASU is applied prospectively to modifications or exchanges occurring on or after the effective date of the amendments. The Company does not expect the adoption to have a material effect on its consolidated financial statements.

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance, which requires business entities (except for not for-profit entities and employee benefit plans) to disclose information about certain government assistance they receive. The Topic 832 disclosure requirements include: (i) the nature of the transactions and the related accounting policy used; (ii) the line items on the balance sheet and income statement that are affected and the amounts applicable to each financial statement line item; and (iii) significant terms and conditions of the transactions. The ASU is effective for the Company for fiscal years beginning after December 15, 2021. The ASU will be applied to government assistance received on or after the effective date.

Note 3 – Reverse Acquisition

On December 24, 2020, IR-Med Inc., IR. Med Ltd. and the former shareholders of IR. Med Ltd. entered into the Stock Exchange Agreement. Pursuant to the Stock Exchange Agreement, the former shareholders of IR. Med Ltd. contributed all of their equity interests in IR. Med Ltd. in exchange for 31,043,945 shares of the IR-Med Inc.'s common stock, which resulted in IR. Med Ltd. becoming a wholly owned subsidiary of IR-Med Inc. (the "Reverse Acquisition"). Upon the closing of the Reverse Acquisition, the former shareholders of IR. Med Ltd. collectively owned approximately 58% of IR-Med Inc.'s outstanding shares of the common stock, par value $0.001 per share (the "Common Stock") including the issuance of shares of the December 2020 private placement.

In accordance with FASB, ASC Section 805 "Business Combinations," Prior to the business combination with IR. Med Ltd., IR-Med, Inc. did not meet the definition of a business as it was a non-operating company. As a result, the Reverse Acquisition has been accounted for as a reverse recapitalization, as the former shareholders of IR. Med Ltd controlled immediately following the Acquisition a majority of the outstanding voting shares of IR-Med, Inc, the principal officers of IR-Med Ltd. have assumed the senior management positions at IR-Med, Inc. Accordingly, IR. Med Ltd. is the acquirer for financial reporting purposes and IR-Med, Inc. is the acquired company. Consequently, the assets and liabilities and the operations reflected in the historical financial statements prior to the Acquisition are those of IR-Med Ltd. and are recorded at the historical cost basis of IR- Med Ltd., and the consolidated financial statements after completion of the Reverse Acquisition include the assets and liabilities and results of operations of the combined company.

Note 3 – Reverse Acquisition (Cont'd)

Share capital and loss per share prior to the closing of the Reverse Acquisition has been retroactively adjusted to reflect the legal capital of IR-Med Inc.

Following the Reverse Acquisition, in January 2021, IR-Med Inc. filed an amended and restated certificate of incorporation where, it changed its corporate name to "IR-Med Inc.".

Note 4 - Cash and Cash Equivalents

	December 31 2021	December 31 2020
	US Dollars (In thousands)	
Cash - NIS	**59**	16
Cash - US dollars	**2,756**	1,850
	2,815	1,866

Note 5 - Accounts Receivable

	December 31 2021	December 31 2020
	US Dollars (In thousands)	
Funds in trust	**-**	189
Prepaid expenses	**1**	4
Government institutions	**63**	22
Related parties	**3**	3
	67	218

Note 6 – Property and Equipment, net

	December 31 2021	December 31 2020
	US Dollars (In thousands)	
Computer's equipment	**32**	1
Furniture and equipment	**6**	10
Leasehold improvement	**3**	-
	41	11
Less – accumulated depreciation	**(10)**	(5)
	31	6

Note 7 - Trade and Other Payables

	December 31 2021	December 31 2020
	US Dollars (In thousands)	
Trade payables	**58**	25
Accrued expenses	**140**	462
Payroll and related	**129**	19
Related Parties	**65**	17
Other	**3**	-
	395	523

Note 8 - Stockholders' Loans

A. In 2015, certain of the Company's stockholders advanced loans to the Company to finance its ongoing operation (hereinafter: the "2015 Loans"). These loans bear interest at annual rate ranging in 2021 and 2020 from 2.45% to 2.62%. 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$ 0.5 million and upon such terms and in such installments as shall be determined by the Company's board of directors.

As of December 31, 2021, and 2020, the carrying amounts of the 2015 Loans were US$7 thousand and US$ 35 thousand, respectively.

In 2017, one of the Company's shareholders provided the Company with a loan to finance its ongoing operation (hereinafter: the "2017 Loan"). This loan bears interest at annual rate ranging in 2021 and 2020, from 2.45% to 2.62% annually. Under the original loan terms, the aggregate loan amount are 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 set toDecember 31, 2023.

As of December 31, 2021, and 2020, the carrying amounts of the 2017 Loan were US$4 thousand and US$3.5 thousand, respectively.

B. Convertible Loan

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

In accordance with 2018 CLA, the loan bears interest at a rate per annum equal to three percent (3%) compounded and accrued annually, and was originally repayable on December 31, 2018, or later date as determined by the shareholders representing more than 80% of 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**.**

Note 8 - Stockholders' Loans (Cont'd)

B. Convertible Loan (Cont'd)

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.

Financing expenses recorded in respect of the loan during 2021 and 2020 were US$5 thousand and US$5 thousand, respectively.

As of December 31, 2021 and 2020, the carrying amounts of the loans were US$136 thousand and US$ 128 thousand, respectively.

Note 9 – Warrants

A. In December 2015, the Company issued a warrant (hereinafter: the "2015 Warrant") to one of its service providers. Under the 2015 Warrant, the service provider was originally entitled to purchase such number of the Company's ordinary shares equivalent to the outcome of US$ 24 thousand divided by a price per share in the immediate Company's financing round greater than US$250 thousand, plus 25% discount on the price per share, in consideration of an exercise price of NIS0.01 per share, all as described in the 2015 Warrant Agreement. Following the financing round that took place at the end of 2019, the total number of shares exercisable under the 2015 Warrant approximates to 16 thousand ordinary shares of the Company. As a result the Company reclassified the warrant to equity.

B. In addition to the above, during 2014, the Company issued a warrant ("the 2014 Warrant") to one of its service providers, according to which, the service provider is entitled to purchase 6,894 of the Company's ordinary shares in consideration of an exercise price of NIS 0.001 per share, all as described in the 2014 Warrant agreement.

The warrants will no longer be exercisable and be terminated upon the consummation of an M&A transaction of the Company, subject to and in accordance with the definitions in each of the warrant agreements.

Note 9 – Warrants (Cont'd)

During May 2020, the Company and the above warrants holder, entered into a new warrant agreement ("the New Warrant"), according to which the 2014 Warrant and the 2015 Warrant will be cancelled and replaced by a new warrant to purchase up to approximately 60 thousand ordinary shares of the Company in consideration of an exercise price of NIS 0.01 per share, all as described in the New Warrant agreement. Following this agreement, the Company recorded additional general and administrative expenses of $25 thousands.

Prior to the Reverse Acquisition, on December 24, 2020, the above referenced Warrants were exercised at par value into59,910 shares of the Company's ordinary shares.

Per the Guidance provided in ASU 2018-07 as issued by the FASB, the Company classified the warrant as equity.

C. The November 2020 Private Placement includes issuance of additional warrants to investors. For more details, see also Note 10B.

Note 10 - Stockholders' Equity

A. Common Stock

The Parent Company has authorized 250,000,000 shares of Common Stock. As of December 31, 2020, there were 53,586,023 shares of Common Stock issued and outstanding. As a result of the Reverse Acquisition, the equity structure of IR. Med Ltd. was retroactively adjusted using the exchange ratio established pursuant to the Stock Exchange Agreement to reflect the capital of the legal entity (the Parent Company). The retroactively adjusted number of shares as of December 31, 2019 was equivalent to 30,185,183 shares of Common Stock of IR-Med Inc.

As of December 31, 2021, the company has 64,601,649 shares of Common Stock issued and outstanding.

Each share of IR-Med Inc.´s common stock is entitled 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 rounds

(i) During July 2020, the Company entered into two investment agreements according to which the Company issued 39,946 Ordinary shares for a total consideration of USD 81 thousand.

(ii) On July 16, 2020, the Parent Company entered into a private placement agreement (hereinafter the "July 2020 Private Placement Agreement") with an investor (hereinafter: the "Investor") for aggregate consideration of $50,000. Under the terms of the July 2020 Private Placement Agreement, the Parent Company issued to the Investor 217,391 units of its securities at a price per Unit of $0.23. Each Unit was comprised of one share 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.

(iii) In connection with the Reverse Acquisition, the Parent Company entered into private placement agreements (hereinafter: the "November 2020 Private Placement") with existing and new investors (hereinafter the "Investors") for aggregate consideration of $2,144,908, net of issuance cost of $161,092. Under the November 2020 Private Placement Agreement, subject to the closing of the Reverse Acquisition, the Parent Company undertook to issue to the Investors 3,603,125 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.

Note 10 - Stockholders' Equity (Cont'd)

B. Financing rounds (Cont'd)

Following the closing of the Reverse Acquisition, on December 24, 2020, the Parent Company issued the Investors 7,206,250 Common Stock and warrants for an additional 3,603,125 shares (hereinafter the "November 2020 Private Placement Warrant").

(v) During the first four months of 2021, the Company raised in the aggregate an additional $3,525,000 in gross proceeds. 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.

C. Share-based compensation

On December 23, 2020 the Group'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.

As of December 31, 2021, the Parent Company awarded to its employees and service providers options to purchase up to 8,402,843 shares of Common Stock, of which options for 7,642,843 shares were at an exercise price of US$0.32 per share, options for 480,000 shares were at an exercise price of 0.01 per share and options for 280,000 shares were are an exercise price of $0.64 per share. Of the options granted, options for 6,069,579 shares were vested upon grant and the remaining balance has a vesting period ranging between one to five years. The options are exercisable for periods ranging betweenthree to ten years from the vesting date. The

grant was approved following the adoption of the 2020 incentive stock plan (hereinafter the "Plan") by the Parent Company on December 23, 2020 and the adoption of the sub plan (the "Israeli appendix") on April 29, 2021. The Group recorded in the statement of operations a non-cash expense of $1,339 thousands during the year ended December 31, 2021. The stock-based compensation expenses for the year ended December 31, 2021 were recognized in the statements of operations as follows; $250 thousands were recorded as research and development expenses, $470 thousands were recorded as marketing expenses and $619 thousands were recorded as general and administrative expenses.

The following table sets forth information about the weighted-average fair value of options granted to employees and service providers during the year period ended December 31, 2021, using the Black- Scholes-Merton option-pricing model and the weighted-average assumptions used for such grants:

	For the year ended December 31, 2021
Dividend yields (see (a) below)	0.0%
Share price (in U.S. dollar) (see (b) below)	0.26
Expected volatility (see (c) below)	82.77%-142.57%
Risk-free interest rates (see (d) below)	0.18%-1.7%
Expected life (in years)	1.5-14.79

Note 10 - Stockholders' Equity (Cont'd)

C. Share-based compensation (Cont'd)

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

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

c. As the Company is at its early stage of operation, there is not sufficient historical volatility for the expected term of the stock options. Therefore, the Group uses an average historical share price volatility based on an analysis of reported data for a peer group of comparable publicly traded companies which were selected based upon industry similarities.

d. The Group determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.

Note 11 - 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 LIBOR rate.

In addition, the IIA may stipulate any arrangement whereby the Company will be able to transfer the technology or development from Israel.

As of December 31, 2021, 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 $356 thousand (including interest in the amount of $29 thousand).

For the years ending December 31, 2021 and 2020 no additional IIA grants were obtained.

B. Vehicle Leases

The Company has lease contracts for five motor vehicles used in its operations in Israel. Motor vehicle leases generally have lease terms of three years and require a deposit amount of three-monthly lease payment. As of December 31, 2021, the Company deposited an aggregate of NIS 54,157 (approximately US 17,000$) in respect of the vehicle leases.

C. Long term deposits

During 2021 the Company received a bank credit line in the amount of NIS40,000 (Approximately US$ 13,000) and pledged a security in the same amount.

Note 12 - Research and Development Expenses

	For the year ended December 31 2021	For the year ended December 31 2020
	US Dollars (In thousands)	
Salaries and related expenses	**300**	-
Subcontractors	**747**	393
Materials	**76**	-
Other expenses	**46**	16
Stock based compensation expenses	**250**	-
Total research and development expenses	**1,419**	409

Note 13 – Marketing Expenses

	For the year ended December 31 2021	For the year ended December 31 2020
	US Dollars (In thousands)	
Salaries and related expenses	**106**	-
Professional expenses	**307**	-
Other expenses	**5**	-
Stock based compensation expenses	**470**	-
Total marketing expenses	**888**	-

Note 14 - General and Administrative Expenses

	For the year ended December 31 2021	For the year ended December 31 2020
	US Dollars (In thousands)	
Salaries and related expenses	**283**	15
Professional expenses	**341**	283
Rent and Maintenance	**51**	18
Depreciation	**5**	1
Other expenses	**69**	4
Stock based compensation expenses	**619**	-
Total general and administrative expenses	**1,368**	321

Note 15 - Financial Expenses

	For the year ended December 31 2021	For the year ended December 31 2020
	US Dollars (In thousands)	
Interest expenses on loans	**5**	9
Exchange rate loss	**35**	12
Other	**1**	1
Total financial expenses	**41**	22

Note 16- Loss per share

The calculation of basic and diluted losses per share for the year ended on December 31, 2021 and 2020 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 year ended on December 31, 2020 is adjusted to reflect the new equity structure resulting from the Reverse Acquisition, calculated as follows:

	For the year ended December 31 2021	For the year ended December 31 2020
Loss attributable to shareholders ($ in thousands)	**(3,716)**	(752)
Weighted average number of ordinary shares:		
Balance at beginning of year	**53,586,023**	29,688,988
Effect of shares issued during the year	**9,524,741**	343,510
Weighted-average shares – basic and dilutive as at end of year	**63,110,764**	30,032,498
Basic and dilutive loss per share ($)	**(0.06)**	(0.02)

As of December 31, 2021, total number of16,008,567 options and warrants which granted by the Group's board of directors and not included in the loss per share computation because all such securities have an anti-dilutive effect for the year.

Note 17 – Income Taxes

A. Corporate tax rate

a) The tax rates relevant to the Parent company in Nevada for the years 2020-2021 was 21%.

Current taxes for the reported periods are calculated according to the enacted tax rates presented above.

The tax rates relevant to the Subsidiary in Israel for the years 2020-2021 was23%.

b) Tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959 (the "Investments Law");

During January 2011, an amendment to the Israeli Investments Law (the "Amendment") became effective. The Amendment's provisions apply to Preferred Income derived or accrued in 2011 and thereafter by a Preferred Company, per the definition of these terms in the Amendment.

The amendment provides a uniform and reduced tax rate for all the Company'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 Company is 7.5%, subject to terms as defined within the law.

Note 17 – Income Taxes (Cont'd)

B. Deferred tax assets

The following is a summary of the significant components of deferred tax assets:

	December 31 2021	December 31 2020
	US Dollars (In thousands)	
Operating loss carry forward	**677**	252
Research and development costs	**218**	69
Employee benefits	**6**	
Gross total deferred tax assets	**901**	321
Valuation allowance for deferred tax assets	**(901)**	(321)
Net deferred tax assets	**-**	-

C. Net operating losses carry forward

As of December 31, 2021, and 2020, the Company had incurred carry forward losses for tax purposes in the amount of US$2,960 thousand and US$ 1,096 thousand, respectively.

As of December 31, 2021, and 2020, the Company has provided full valuation allowance of US$901 thousand and US$ 321 thousand against the gross deferred tax asset in respect of net operating carry forward losses 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.

D. Tax assessment

As of December 31, 2021, the Company has tax assessments that are considered as final due to lapse of statute of limitation period, through tax year 2016. The Parent Company has not been assessed for tax purposes since its inception.

Note 17 – Income Taxes (Cont'd)

E. Reconciliation of the statutory tax expense (benefit) to actual tax expense

Reconciliation between the theoretical tax expense, assuming all income is taxed at the statutory tax rate applicable to income of the Company and the actual tax expense as reported in the statements of operations is as follows:

	For the year ended December 31 2021	For the year ended December 31 2020
	US Dollars (In thousands)	
Loss before taxes as reported in the statements of operations	**(3,716)**	(752)
Statutory tax rate	**21%**	21%
Theoretical tax benefit on the above amount at the Israeli statutory tax rate	**(780)**	(158)
Additional tax (tax savings) in respect of:		
Excess tax benefit - share based compensation	**308**	-
Change in valuation allowance	**580**	173
Differences in tax rates between statutory tax and income tax of the Subsidiary*	**(77)**	(15)
Other	**(31)**	-
Actual taxes on income	**-**	-

(*)The Subsidiary operates in Israel in a tax jurisdiction with corporate tax rate of23%.

Note 18- Related Parties Balances and Transactions

The Group's related parties are seven directors, three officers, one shareholder and two entities controlled by three of the Company's shareholders.

A. Balances with related parties

	December 31 2021	December 31 2020
	US Dollars (In thousands)	
Assets		
Other receivables	**3**	3
Liabilities		
Payables	**26**	46
Accrued expenses	**27**	-
Payroll and related	**12**	-
Stockholders' loans	**177**	166

Note 18- Related Parties Balances and Transactions (Cont'd)

B. Transactions with related parties

	For the year ended December 31 2021	For the year ended December 31 2020
	US Dollars (In thousands)	
Subcontractors and professional expenses (1)	**341**	93
Salaries and related expenses (2)	**374**	-
stock based compensation (3)	**794**	-
Rent and Maintenance (4)	**51**	15
Interest expenses	**5**	9

(1) For the years ended December 31, 2021 and 2020, the Company paid to two directors and one shareholder of the Parent Company an aggregate consideration of US$227 thousand and US$93 thousand, respectively, in respect of research and development services.

On September 1, 2020 the Parent Company entered into consulting agreement with one of its shareholders. For the year ended December 31, 2021 the Company paid to the shareholder an aggregate consideration of US$60 thousand, in respect of such consulting services.

For the year ended December 31, 2021, the Company paid to four of the Parent Company non-employee directors an aggregate consideration of US$54 thousand, in respect of their services.

(2) During 2021, the Company entered into an employment agreements with one of the Parent Company's directors and three of its officers. For the year ended December 31 2021, salary and related expenses totaled to US$374 thousand, in respect thereof.

(3) Following the adoption of the 2020 incentive stock plan (hereinafter the "Plan") by the Parent Company on December 23, 2020, and the adoption of the sub plan (the "Israeli appendix") on April 29, 2021, the Parent Company granted to its directors, officers and shareholder 4,423,960 options to purchase shares of Common Stock (See also note 10-C).

(4) On February 2020 the Company entered into an office rental agreement with an entity controlled by two of the Company's directors, retroactive to January 1, 2020. For the years ended December 31, 2021 and 2020, the Company paid US$51 thousand and US$15 thousand, respectively, in respect thereof.

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 30, 2022, IR-Med, Inc. ("IR-Med," "we," "us" or the "Company") 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 the Company's 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 Annual Report on Form 10-K, our authorized capital stock consists of 250,000,000 shares of Common Stock. As of March30, 2022, there were 64,601.658 shares of our common stock outstanding.

In addition, as of the date of this Annual Report on Form 10-K, we had issued and outstanding:

- options to purchase 8,402,843 shares of our Common Stock, at a weighted average exercise price of $0.32 per share; and
- warrants to purchase 9,328,329 shares of our Common Stock, at a weighted average exercise price of $0.64 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 Delaware 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 at18 Lafayette Pl, Woodmere, NY 11598,.

Exhibit 31.1

IR-Med, Inc.
Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Rom Eliaz, certify that:

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

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

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

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

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

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

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

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

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

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

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

By: */s/ Rom Eliaz*
Rom Eliaz, Chief Executive Officer

Date: March 31, 2022

Exhibit 31.2

IR-Med, Inc.
Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Sharon Levkoviz, certify that:

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

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

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

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

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

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

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

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

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

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

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

By: */s/ Sharon Levkoviz*
Sharon Levkoviz, Chief Financial Officer

Date: March 31, 2022

Exhibit 32.1

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

I, Rom Eliaz, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the annual report of IR-Med, Inc. on Form 10-K for the year ended December 31, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such annual report on Form 10-K fairly presents in all material respects the financial condition and results of operations of IR-Med, Inc. as of and for the year ended December 31, 2021. This written statement is being furnished to the Securities and Exchange Commission as an exhibit accompanying such annual report and shall not be deemed filed pursuant to the Securities Exchange Act of 1934.

By: */s/ Rom Eliaz*
Rom Eliaz, Chief Executive Officer

Date: March 31, 2022

Exhibit 32.2

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

I, Sharon Levkoviz, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the annual report of IR-Med, Inc. on Form 10-K for the year ended December 31, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such annual report on Form 10-K fairly presents in all material respects the financial condition and results of operations of IR-Med, Inc. as of and for the year ended December 31, 2021. This written statement is being furnished to the Securities and Exchange Commission as an exhibit accompanying such annual report and shall not be deemed filed pursuant to the Securities Exchange Act of 1934.

By: */s/ Sharon Levkoviz*
Sharon Levkoviz, Chief Financial Officer

Date: March 31, 2022