Filed Pursuant to Rule 424(b)(3)
Registration No. 333-255894

IR-MED, INC.
37,973,724 shares of common stock

This prospectus relates to the offering and resale by the selling stockholders identified herein of up to 37,973,724 shares of common stock, par value $0.001 per share, of IR-Med, Inc. Of the shares being offered, 28,645,395 are presently issued and outstanding. These shares offered are comprised of an aggregate of (i) 18,439,267 shares of common stock issued and sold to qualified investors in private placement offerings (the "2020 Private Placement"), (ii) 9,328,329 shares of common stock issuable upon exercise of common stock purchase warrants issued to the investors on the 2020 Private Placement; (iii) 2,394,404 shares of our common stock issued to former stockholders of IR Med Ltd. in connection with the closing of a share exchange transaction on December 24, 2020 (iv) 4,706,724 shares of common stock held by certain identified officers and directors and (v) 3,105,000 shares of common stock issued to non-management holders of our then outstanding preferred stock, all of which converted on December 24, 2020.

The Selling Shareholders may offer all or part of the shares for resale from time to time through public or private transactions, at $1 per share, which is the fixed price at which the Selling Shareholders may sell their shares until our common stock is quoted on the OTCQX or OTCQB tiers of OTC Markets, at which time the shares may be sold at prevailing market prices or privately negotiated prices. The Company is paying for all registration, listing and qualification fees, printing fees and legal fees.

We will not receive any proceeds from the sale of our common stock by the selling stockholders in the offering described in this prospectus.

Our Common Shares are quoted on OTC Market's "OTC Pink" tier under the ticker symbol "IRME". We intend to apply to have our common stock quoted on the OTCQB-tier of OTC Markets.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should read and carefully consider the risks described in this prospectus under "Risk Factors" beginning on page 11 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 11, 2021

About This Prospectus

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security registered under the registration statement of which this prospectus is a part.

As used in this prospectus, unless the context indicates or otherwise requires, "our Company", "the Company", "IR-Med", "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 that, through a share exchange transaction completed on December 24, 2020, has become our wholly owned subsidiary.

PROSPECTUS SUMMARY

You should read the following summary together with the more detailed information and the financial statements appearing elsewhere in this Prospectus. This Prospectus contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Risk Factors" and elsewhere in this Prospectus. Unless the context indicates or suggests otherwise, references to "we," "our," "us," the "Company," or the "Registrant" refer to IR-Med, Inc., a Nevada corporation.

IR-MED, INC.

We are an innovative development stage medical device company that utilizes Infra-Red light spectroscopy (IR) combined with Artificial Intelligence (AI) technologies to address currently unmet medical needs. Our initial product candidates which are currently in various stages of development are non-invasive, user friendly and designed to address the medical needs of large and growing target patient groups by offering earlier and more accurate detection, reducing healthcare expenses and reducing the widespread reliance on antibiotics, optimizing the delivery of the targeted medical services and, as a result, improving the efficacy and safety of administered treatments.

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

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

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

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

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

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

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. See below "*BUSINESS – Government Regulation and Product Approval*"

Pressure Injuries

PI is a major challenge for care providers throughout the world. Failure to identify and treat is potentially fatal, with an estimated 60,000 mortalities from PI in the US each year[1]. Prevention of PI is a measure of quality in all healthcare settings. There are three main sectors prone to high frequency of PI: hospitals, nursing homes and homecare. IR-Med is developing a user-friendly, non-invasive and real-time optical monitoring device for preemptive detection of PI. The patent protected technology will be utilizing a hand-held scanner for early detection of PI (before it appears on the skin) to help physicians in their decision-making. It will collect and digitize patient results for improved treatment monitoring. Its machine learning algorithms will calculate the probability of developing PI and will suggest an optimized plan for monitoring and management of patient health and PI condition.

Ear Infections

Each year, over 20 million children in the US and Europe are diagnosed with an ear infection[2]. A much larger number are examined by pediatricians and family doctors. Once an infection is detected, doctors are able to immediately diagnose whether the fluid buildup behind the ear drum is of bacterial or viral origin. Consequently, patients either receive no medication apart from pain relief or are prescribed antibiotics which may not help them and may cause short term and/or long term undesirable side effects (especially with toddlers up to two years old) that may have antibiotic resistant bacteria in the ear cavity. We are in preliminary stages of designing and developing an advanced otoscope, known as Nobiotics, to give doctors an immediate indication if there are any effluents accumulated behind the ear drum and its nature (i.e., is it of viral or bacterial origin).

In addition to the above, several other medical applications and opportunities have been identified but are not currently in development.

IR-Med, Inc. is a holding company and the sole stockholder of IR. Med, Ltd., a company formed under the laws of the State of Israel ("IR-Med Ltd."). The corporate headquarters and research facility of IR-Med, Inc. and IR-Med Ltd. are located in Z.H.R Industrial Zone, Rosh Pina, Israel. We currently have no products that have obtained

marketing approval in any jurisdiction, we have not generated revenues since inception and do not expect to do so in the foreseeable future due to the early stage nature of our current product candidates.

Corporate Information

IR-Med, Inc. was incorporated in the state of Nevada on April 20, 2007, under the name "Monster Motors, Inc." On June 24, 2009, the corporate name was changed to Eco2 Forests, Inc. During September 2012, Eco2 Forests, Inc., accepted a court ordered receiver who authorized a reduction of the authorized shares from 900,000,000 to 500,000,000 and in November 2012 effectuated a 16,000 to 1 stock split. In February 2013, the Company underwent a change of control. On March 25, 2013 Eco2 Forests, Inc., effectuated a 4 to 1 reverse stock split in addition to changing the corporate name to International Display Advertising, Inc.

[1] Agency for Healthcare Research and Quality (AHRQ), n.d. *Preventing Pressure Ulcers in Hospital.*

[2] Azarpazhooh, A., Lawrence, H. and Shah, P., 2016. Xylitol for preventing acute otitis media in children up to 12 years of age.*Cochrane Database of Systematic Reviews*,.

According to David Lazar, one of our directors, Custodian Ventures LLC became aware of the Company through its own due diligence. Following such, it appeared to Custodian Ventures LLC that the Company would be a good candidate for an investment and reconstitution. On April 1, 2019, the eighth judicial District Court of Nevada appointed Custodian Ventures, LLC as custodian for IDAD, proper notice having been given to the officers and directors of IDAD. There was no opposition. On April 2, 2019, the Company filed a certificate of revival with the state of Nevada, appointing David Lazar as President, Secretary, Treasurer and Director.

On December 9, 2019, control of the Company was transferred by Custodian Ventures, LLC to certain investors that included Yoram Drucker, one of our directors, by selling to them 9,500,000 shares of Series A Preferred stock (the "Series A Prefered Stock") for a purchase price of $200,000. David Lazar resigned as President, Secretary and Treasurer but remained on the Board of Directors of International Display Advertising, Inc. Concurrently, Mr. Yoram Drucker was appointed to the position of Director and President, Secretary and Treasurer.

On January 29, 2020, the board of directors approved a 1 for 1,000 reverse stock split of our common stock with all fractional shares being rounded up to the next whole share. The reverse stock split was implemented on February 26, 2020.

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

Upon the closing of the Acquisition, IR-Med, Inc. ceased to be a "shell company" under applicable rules of the Securities and Exchange Commission, or the SEC.

In connection with the Acquisition, we held an initial closing on a private placement transaction with certain accredited investors under a securities purchase agreement, for the issuance and sale to such investors of an aggregate of units of our securities, with each unit comprised of (i) two (2) shares of our common stock, par value $0.001 per share and (ii) one (1) common stock purchase warrant to purchase an additional share of common stock, exercisable through December 24, 2023 at an exercise price per share of $0.64 (the "2020 Private Placement"). The 2020 Private Placement was conducted through a series of closings on December 24, 2020 through May 6, 2021 at a purchase price per unit of $0.64 and for aggregate gross proceeds to us of approximately $5,831,000. After deducting placement related expenses, the aggregate net proceeds from the 2020 Private Placement were approximately $5,475,000.

In connection with the Private Placement, we undertook best efforts to file a registration statement with the SEC to register the shares of common stock issued in the Private Placement, the Acquisition and shares of common stock issuable upon exercise of the warrants issued in the 2020 Private Placement for resale. These shares of common stock are covered by the registration statement of which this prospectus forms a part.

On January 20, 2021, IR-Med, Inc. amended and restated its Articles of Incorporation to, among other things, change its name from International Display Advertising, Inc. to "IR-Med, Inc."

Risks Associated with Our Business

Our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in the section entitled "Risk Factors" in this prospectus, as well as the other risks described in the section captioned "Risk Factors."

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We currently have no product revenues and no products approved for commercial sale, and will need to raise additional capital to operate our business.
- 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.
- We are heavily dependent on the success of our lead product candidates (which are in various stages of development), which will require significant additional efforts to develop and may prove not to be viable for commercialization.
- Failure to successfully validate, develop and obtain commercial sale approval for our *PressureSafe* and *Nobiotics*, our current medical devices under development what are designed to scan for, respectively, pressure injuries and mid ear infections in children, could harm our development strategy and operational results.
- The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product candidates from applicable regulatory authorities, we will not be able to market and sell our product candidates in those countries or regions and our business will be substantially harmed.
- We will rely on third parties to conduct clinical trials (if needed). If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain commercial sale approval for our product candidates and our business could be substantially harmed.
- We will need to grow the size of our organization, and we may experience difficulties in managing any growth we may achieve.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market and our business would be harmed.

- The patent protection covering some of our product candidates may be dependent on third parties, who may not effectively maintain that protection.
- If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy.
- 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.
- Our share price is expected to be volatile and may be influenced by numerous factors, some of which are beyond our control.
- We may be exposed to additional risks as a result of "going public" by means of a reverse acquisition transaction with a formerly shell company.

Corporate Information

Solely for purposes of filings with the SEC, the principal contact for IR-Med Inc. shall be at the principal executive office of IR-Med, Ltd., located at Z.H.R Industrial Zone, Rosh Pina, Israel, or under the telephone number +97246555054. Our website address is www.ir-medical.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document.

SUMMARY OF THE OFFERING

Common Stock outstanding Before the Offering	64,601,649 (1)
Common Stock offered by Selling Shareholders	37,973,724
Common Stock Outstanding after the Offering	64,601,649 (2)
Use of Proceeds	We will not receive any of the proceeds from the sale of shares by the Selling Stockholders
OTC Markets Trading Symbol	IRME
Risk Factors	The Common Stock offered hereby involve a high degree of risk and should not be purchased by investors who cannot afford the loss of their entire investment.
Reverse Stock Split	On January 20, 2020, the Board of Directors of the Company approved a 1-for1,000 reverse stock split of the Company's authorized and outstanding common stock, which became effective on February 26, 2020. No fractional shares were issued in connection with the Reverse Stock Split. Any fractional shares resulting from the Reverse Stock Split were rounded up to the nearest whole share.

(1) Excludes 10,000,000 shares of common stock reserved for future issuance under the IR-Med, Inc. 2020 Stock Incentive Plan.
(2) Assumes that none of the warrants for an aggregate of 9,328,329 shares of our common stock issued to the investors in the 2020 Private Placement have been exercised. Excludes 10,000,000 shares of common stock reserved for future issuance under the IR-Med, Inc. 2020 Stock Incentive Plan.

Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties we describe below. The risks and uncertainties described below are those significant risk factors, currently known and specific to us, which we believe are relevant to an investment in our securities. If any of these risks materialize, our business, consolidated results of operations or consolidated financial condition could suffer, the price of our securities could decline substantially and you could lose part or all of your investment. Additional risks and uncertainties not currently known to us or that we now deem immaterial may also harm us and adversely affect your investment in our securities.

Risks Related to Financial Position

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 and general and administrative expenses associated with our operations. For the years ended December 31, 2020 and 2019, we incurred net losses of approximately $752,000 and $248,000, respectively. As of June 30, 2021 and December 31, 2020, we had an accumulated deficit of $3,446,000 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 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.

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.

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. For instance, in connection with the closings of the 2020 Private Placement, we issued an aggregate of 18,439,267 shares of our common stock to investors in that offering as well as warrants exercisable for an additional 9,328,329 shares.

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 drug candidates or any future commercialization efforts. Any of these events could significantly harm our business, financial condition and prospects.

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

Risks Related to Our Business, Industry and Regulatory Process

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 puruse 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 knowhow, 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, and the foreign persons named in this in this registration statement of which this prospectus forms a part are located outside 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.

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 a 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 have 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 OTC Markets Pink Tier, 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 the Selling Shareholders 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 OTC Markets' Pink tier. 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 prospectus, these factors include:

- the product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and medical device industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;

- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

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

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.

We do not have a class of our securities registered under Section 12 of the Exchange Act. Until we do or we become subject to Section 15(d) of the Exchange Act, we will be a "voluntary filer."

We are not currently required under Section 12 or Section 15(d) of the Exchange Act to file periodic reports with the SEC. We expect that we will become subject to the reporting requirements under Section 15(d) of the Exchange Act upon the effectiveness of the registration statement of which this prospectus forms a part. However, until such registration statement becomes effective we are a voluntary filer and we are currently considered a non-reporting issuer under the Exchange Act. Additionally, although we currently anticipate that we will register our common stock under Section 12 of the Exchange Act, until we do so, we are not subject to the SEC's proxy rules, and large holders of our capital stock will not be subject to beneficial ownership reporting requirements under Sections 13 or 16 of the Exchange Act and their related rules. As a result, our stockholders and potential investors may not have available to them as much or as robust information as they may have if and when we become subject to those requirements.

In addition, if we do not register under Section 12 of the Exchange Act, we could again become a voluntary filer and could cease filing annual, quarterly or current reports under the Exchange Act.

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."

Prior to the closing of the Acquisition, we were deemed a "shell company" under applicable SEC rules and regulations 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 promulgated under the Securities Act of 1933, as amended, or the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted (i) until at least 12 months have elapsed from the date of the filing of this Registration Statement was filed with the SEC and (ii) unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and 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 Form 8-K reports. 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 the offering described in this prospectus, 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 after the contractual restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. As of the date of this prospectus, a total of 64,601,651 shares of our common stock are outstanding. Of those shares, only 118,437 are currently freely tradable, without restriction, in the public market. Upon the effectiveness of the registration statement of which this prospectus forms a part, an additional 37,973,724 shares of common stock included in this prospectus which forms a part of this Registration Statement, which number includes 9,328,329 shares issuable upon exercise of warrants issued in the 2020 Private Placement, will be registered for resale under the Securities Act. Such shares will represent approximately 51% of our currently outstanding shares of common stock. 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. As of the date of effectiveness of this registration statement, such shares registered for resale will be freely tradable without restriction, except for 37,973,724 shares of our common stock which will become freely tradable upon the expiration of certain lock-up restrictions applicable to those shares, which prohibit their sale, disposition or other transfer through December 24, 2021 however, in the case of certain former shareholders of IR-Med Ltd, the lock-up restrictions prohibit the sale, disposition or other transfer of approximately 75% of such shareholder's shares.

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.

SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

We have made forward-looking statements in this prospectus, including the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include the information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, the effects of future regulation and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words "believe," "expect," "anticipate," "intend," "plan," "estimate" or similar expressions. These statements are only predictions and involve known and unknown risks and uncertainties, including the risks outlined under "Risk Factors" and elsewhere in this prospectus.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We are not under any duty to update any of the forward-looking statements after the date of this prospectus to conform these statements to actual results, unless required by law.

SELLING STOCKHOLDERS

This prospectus relates to the offering and resale by the selling stockholders identified herein of up to 37,973,724 shares of common stock, par value $0.001 per share, of IR-Med, Inc. Of the shares being offered, 28,645,395 are presently issued and outstanding. These shares are comprised of an aggregate of (i) 18,439,267 shares of common stock issued and sold to accredited investors in the "2020 Private Placement", (ii) 9,328,329 shares of common stock issuable upon exercise of common stock purchase warrants issued to the investors on the 2020 Private Placement; (iii) 2,394,404 shares of our common stock issued to former stockholders of IR Med Ltd. in connection with the Acquisition (iv) 4,706,724 shares of common stock held by certain identified officers and directors and (v) 3,105,000 shares of common stock issued to non-management holders of our preferred stock which converted on December 24, 2020.

The selling stockholders identified in the table below may from time to time offer and sell under this prospectus any or all of the shares of common stock described under the column "Shares of Common Stock Being Offered in this Offering" in the table below. The table below has been prepared based upon information furnished to us by the selling stockholders as of the dates represented in the footnotes accompanying the table. The selling stockholders identified below may have sold, transferred or otherwise disposed of some or all of their shares since the date on which the information in the following table is presented in transactions exempt from or not subject to the registration requirements of the Securities Act. Information concerning the selling stockholders may change from time to time and, if necessary, we will amend or supplement this prospectus accordingly and as required.

The following table and footnote disclosure following the table sets forth the name of each selling stockholder, the nature of any position, office or other material relationship, if any, that the selling stockholder has had within the past three years with us or with any of our predecessors or affiliates, and the number of shares of our common stock beneficially owned by the selling stockholder before this offering. The number of shares reflected are those beneficially owned, as determined under applicable rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under applicable SEC rules, beneficial ownership includes any shares of common stock as to which a person has sole or shared voting power or investment power and any shares of common stock which the person has the right to acquire within 60 days through the exercise of any option, warrant or right or through the conversion of any convertible security. Unless otherwise indicated in the footnotes to the table below and subject to community property laws where applicable, we believe, based on information furnished to us, that each of the selling stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

We have assumed that all shares of common stock reflected in the table as being offered in the offering covered by this prospectus will be sold from time to time in this offering. We cannot provide an estimate as to the number of shares of common stock that will be held by the selling stockholders upon termination of the offering covered by this prospectus because the selling stockholders may offer some, all or none of their shares of common stock being offered in the offering.

Name of Selling Shareholder	Shares of Common Stock Owned Prior to Offering	Shares of Common Stock to be Offered for the Selling Shareholder's Account	Shares of Common Stock Owned by the Selling Shareholder After the Offering	Percent of Common Stock to be Owned by the Selling Shareholder After the Offering
Isamar Margareten[1]	1,903,125	1,903,125	—	—
Yochanan Cohen[2]	703,125	703,125	—	—
1632 Equities LLC[3]	937,500	937,500	—	—
Excelsior IDAD Partners LLC[4]	1,171,875	1,171,875	—	—

MZK LLC[5]	937,500	937,500	—	—
Rafael Deutsch[6]	703,125	703,125	—	—
SLA Equities LLC[7]	703,125	703,125	—	—
Moshe Paskesz[8]	1,171,875	1,171,875	—	—
Shlomie Bierman[9]	1,289,064	1,289,064	—	—
Siyata Dishmaya Holdings LLC [10]	1,406,250	1,406,250	—	—
Shlomo Lewenstein[11]	468,750	468,750	—	—
Vineyard Family Holdings LLC[12]	937,500	937,500	—	—
Moshe Eichler[13]	1,171,875	1,171,875		—
Schmuel Horowitz[14]	1,171,875	1,171,875		—
Paul Coulson[15]	5,625,000	5,625,000		—
Third Eye Investors LLC[16]	4,687,500	4,687,500		—
Alelov Capital LLC[17]	2,343,750	2,343,750	—	—
Joseph Schwartz[18]	649,490	649,490	—	—
Sarah Gottdenger	2,573,564	2,573,564	—	—
Yoram Drucker[19]	4,050,000	307,500	3,742,500	5.79%
David Lazar [20]	750,000	750,000	—	—
Bernard Nagelberg	1,800,000	270,000	1,530,000	2.37%
IRDMS LP[21]	2,600,000	990,000	1,610,000	2.49%
Yaacov Safren	4,300,001	345,000	3,955,001	6.12%
Med2BWell Ltd.[22]	8,609,916	1,291,487	7,318,429	11.33%
Liat Electronics Ltd.[23]	3,850,607	577,591	3,273,016	5.07%
Aharon Klein[24]	7,859,110	1,178,867	6,680,243	10.34%
Yaniv Cohen[25]	7,859,136	1,178,870	6,680,266	10.34%
Alexander Blaunshtein	368,940	55,341	313,599	0.49%
Gil Davidson[26]	327,703	49,155	278,548	0.43%
Noam Mordechai Landau	21,500	3,225	18,275	0.03%
Pearl Cohen Zedek Latzer, Baratz	515,226	77,284	437,942	0.69%
Jose Zajac	214,708	214,708	—	—
Falcon Universal Capital S.A. [27]	128,828	128,828	—	—

[1] Includes 634,375 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[2] Includes 234,375 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[3] Includes 312,500 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. Robert Fischman has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Fischman disclaims beneficial ownership with respect to such shares.

[4] Includes 390,625 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. Joel Zupnick has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Zupnick disclaims beneficial ownership with respect to such shares.

[5] Includes 312,500 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. Morris Kaff has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Kaff disclaims beneficial ownership with respect to such shares.

[6] Includes 234,375 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[7] Includes 234,375 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. Samuel Abraham has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Abraham disclaims beneficial ownership with respect to such shares.

[8] Includes 390,625 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[9] Includes 429,688 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[10] Includes 468,750 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. Lipa Lefkowitz has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Lefkowitz disclaims beneficial ownership with respect to such shares.

[11] Includes 156,250 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[12] Includes 312,500 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. Jacob Karmel has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Karmel disclaims beneficial ownership with respect to such shares.

[13] Includes 390,625 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[14] Includes 390,625 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[15] Includes 1,875,000 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[16] Includes 1,562,500 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. Yitzchak Rokonsky has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Rokonsky disclaims beneficial ownership with respect to such shares.

[17] Includes 781,250 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant. Eli Alelov has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Alelov disclaims beneficial ownership with respect to such shares.

[18] Includes 217,391 shares the selling stockholder has the right to acquire through the exercise of a common stock warrant.

[19] Yoram Drucker is a Director of the Company.

[20] David Lazar is a Director of the Company.

[21] David Safren has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities.

[22] Oded Bashan has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Bashan serves as Chairman, interim CEO and a Director of the Company.

[23] David Levy has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities. Mr. Levy serves as a Director of the Company.

[24] Aharon Klein serves as Chief Technology Officer of the Company.

[25] Yaniv Cohen is a Director of the Company.

[26] Nati Ben Zeev disclaims beneficial ownership with respect to such shares, except to the extent of his pecuniary interest therein.

[27] Reuven Moshe has the power to vote or dispose of the securities held of record by the selling stockholder and may be deemed to beneficially own those securities.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issued to the selling stockholders to permit the resale of these shares of common stock by the holders of the shares of common stock from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions, which may involve crosses or block transactions, and may be sold on any national securities exchange or quotation service on which our common stock may be listed or quoted at the time of sale, in the over-the-counter market, or in transactions otherwise than on these exchanges or systems. The selling stockholders will offer their respective shares at a fixed price of $1.00 per share until our shares of common stock are quoted on the OTCQB tier of the OTC Markets Group, Inc. or an exchange, and thereafter sales of the common stock to be registered hereunder could be made at prevailing market prices at the time of the sale, at fixed prices, at negotiated prices, or at varying prices determined at the time of sale. As a result, we cannot know the price at which any of our common stock to be registered hereunder may ultimately be sold by the holders thereof.

The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;

- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(a)(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions, including the requirements of Rule 144(i) applicable to former "shell companies."

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to

whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 5110.

In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and if such short sale shall take place after the date that this registration statement is declared effective by the SEC, the selling stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered pursuant to this registration statement to cover short sales of our common stock made prior to the date the registration statement of which this prospectus forms a part is declared effective by the SEC.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer or agents participating in the distribution of the shares of common stock offered hereby may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act.

Each selling stockholder has informed us that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. Upon us being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker-dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In no event shall any broker-dealer receive fees, commissions and markups, which, in the aggregate, would exceed eight percent (8%).

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with in all respects.

Any selling stockholder may sell some, all or none of the shares of common stock to be registered pursuant to the registration statement of which this prospectus forms a part.

Each selling stockholder and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that each selling stockholder will pay all underwriting discounts and selling commissions, if any, and any legal expenses incurred by it.

USE OF PROCEEDS

We will not receive any proceeds from the sale of our common stock offered by this prospectus. We have agreed to bear the expenses (other than any underwriting discounts or selling commissions or any legal expenses incurred by any selling stockholder) in connection with the registration of the shares of our common stock being offered for resale hereunder by the selling stockholders.

DETERMINATION OF OFFERING PRICE

The selling stockholders will offer their respective shares at a fixed price of $1.00 per share until our shares of common stock are quoted on the OTCQB tier of the OTC Markets Group, Inc. or listed on an exchange, and thereafter the selling stockholders will determine at what price they may sell the shares of common stock offered by this prospectus, and such sales may be made at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices.

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 250,000,000 shares of common stock, par value $0.001. As of October 28, 2021, there are 64,601,649 shares of our common stock issued and outstanding.

Common Stock. Each shareholder of our common stock is entitled to a pro rata share of cash distributions made to shareholders, including dividend payments. The holders of our common stock are entitled to one vote for each share of record on all matters to be voted on by shareholders. There is no cumulative voting with respect to the election of our directors or any other matter. Therefore, the holders of more than 50% of the shares voted for the election of those directors can elect all of the directors. The holders of our common stock are entitled to receive dividends when and if declared by our Board of Directors from funds legally available therefore, cash dividends are at the sole discretion of our Board of Directors. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining available for distribution to them after payment of our liabilities and after provision has been made for each class of stock, if any, having any preference in relation to

our common stock. Holders of shares of our common stock have no conversion, preemptive or other subscription rights, and there are no redemption provisions applicable to our common stock.

Dividend Policy. We have never issued any dividends and do not expect to pay any stock dividend or any cash dividends on our common stock in the foreseeable future. We currently intend to retain our earnings, if any, for use in our business. Any dividends declared on our common stock in the future will be at the discretion of our Board of Directors and subject to any restrictions that may be imposed by our lenders.

Registration Rights

Pursuant to the terms of the subscription agreements for the 2020 Private Placement agreements, we agreed to file with the SEC the registration statement of which this prospectus forms a part, to register for resale all of the 18,439,267 shares of our common stock issued in the 2020 Private Placement, as well as an additional 9,328,329 shares of our common stock issuable upon exercise of warrants issued in the Private Placement.

Dividends

Under NRS 78.288, the directors of a Nevada corporation may authorize, and the corporation may make, distributions (including cash dividends) to stockholders, but no such distribution may be made if, after giving it effect:

- the corporation would not be able to pay its debts as they become due in the usual course of business; or
- the corporation's total assets would be less than the sum of (x) its total liabilities plus (y) the amount that would be needed, if the corporation were to be dissolved at the time of distribution, to satisfy the preferential rights upon dissolution of stockholders whose preferential rights are superior to those receiving the distribution.

The NRS prescribes the timing of the determinations above depending on the nature and timing of payment of the distribution. For cash dividends paid within 120 days after the date of authorization, the determinations above must be made as of the date the dividend is authorized. When making their determination that a distribution is not prohibited by NRS 78.288, directors may consider:

- financial statements prepared on the basis of accounting practices that are reasonable in the circumstances;
- a fair valuation, including, but not limited to, unrealized appreciation and depreciation; and/or
- any other method that is reasonable in the circumstances.

Declaration and payment of any dividend will be subject to the discretion of our Board of Directors. The payment of any future dividends will be at the discretion of our Board of Directors; however, the time and amount of such dividends, if any, will be dependent upon our financial condition, operations, compliance with applicable law, cash requirements and availability, debt repayment obligations, capital expenditure needs and restrictions in our debt instruments, contractual restrictions, business prospects, industry trends, the provisions of Nevada law affecting the payment of distributions and any other factors our Board of Directors may consider relevant. Our ability to pay dividends on our common stock may depend in part on our receipt of cash dividends from our operating subsidiaries, which may be restricted from paying us dividends as a result of the laws of their jurisdiction of organization, agreements of our subsidiaries or covenants under any existing and future outstanding indebtedness we or our subsidiaries incur.

Classified Board of Directors; Removal of Directors for Cause

Pursuant to our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws, our Board of Directors is divided into three classes, with the term of office of the first class to expire at the first annual meeting of stockholders following the initial classification of directors and until their successors are duly elected and qualified, the term of office of the second class to expire at the second annual meeting of stockholders following the initial classification of directors and until their successors are duly elected and qualified, and the term of office of the third class to expire at the third annual meeting of stockholders following the initial classification of directors and until their successors are duly elected and qualified. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire, will be elected for a three-year term of office. All directors elected to our classified Board of Directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. Members of the Board of Directors may only be removed for cause and only by the affirmative vote of at least 80% of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of the Board of Directors. For example, at least two annual meetings will be necessary for stockholders to effect a change in a majority of the members of the Board of Directors.

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors

Our Second Amended and Restated Bylaws provide that, for nominations to the Board of Directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to our Secretary. For an annual meeting, a stockholder's notice generally must be delivered not less than 90 days nor more than 120 days prior to the first anniversary of the previous year's annual meeting date. For a special meeting, the notice must generally be delivered not earlier than the 90th day prior to the meeting and not later than the later of (i) the 60th day prior to the meeting or (ii) the 10th day following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in the Amended and Restated Bylaws. If it is determined that business was not properly brought before a meeting in accordance with our bylaw provisions, such business will not be conducted at the meeting.

Transfer Agent and Registrar

Our transfer agent and registrar is VStock Transfer, LLC, 18 Lafayette Street, Woodmere, NY, 11598. Their telephone number is (212) 828-8436.

Liability and Indemnification of Directors and Officers

The Nevada Revised Statutes empower us to indemnify our directors and officers against expenses relating to certain actions, suits or proceedings as provided for therein. In order for such indemnification to be available, the applicable director or officer must not have acted in a manner that constituted a breach of his or her fiduciary duties and involved intentional misconduct, fraud or a knowing violation of law and was material to the action, or must have acted in good faith and reasonably believed that his or her conduct was in, or not opposed to, our best interests. In the event of a criminal action, the applicable director or officer must not have had reasonable cause to believe his or her conduct was unlawful.

Under applicable provisions of the Nevada Revised Statutes, our Amended and Restated Articles of Incorporation, Amended and Restated Bylaws or any separate agreement may provide for our payment of expenses incurred by any such director or officer in advance of the final disposition of the applicable action, suit or proceeding, upon

delivery by such director or officer of an undertaking to repay all amounts so advanced if it is ultimately determined that the director or officer is not entitled to be indemnified by us.

Our Amended and Restated Articles of Incorporation provide for indemnification of our directors and officers substantially identical in scope to that permitted under applicable Nevada law. Our Amended and Restated Articles of Incorporation also provide that the expenses of our directors and officers incurred in defending any applicable action, suit or proceeding must be paid by us as they are incurred and in advance of the final disposition of the action, suit or proceeding, provided that the required undertaking by the director or officer is delivered to us.

We have also entered into separate indemnification agreements with each of our current directors and executive officers consistent with Nevada law and in the form approved by our Board of Directors and our stockholders, and we contemplate entering into such indemnification agreements with directors and certain executive officers that may be elected or appointed in the future. Those indemnification agreements require that under the circumstances and to the extent provided for therein, we indemnify such persons to the fullest extent permitted by applicable law against certain expenses incurred by any such person as a result of such person being made a party to certain actions, suits and proceedings by reason of the fact that such person is or was a director, officer, employee or agent of our company, any entity that was a predecessor corporation of our company or any of our affiliates. The rights of each person who is a party to such an indemnification agreement are in addition to any other rights such person may have under applicable Nevada law, our Amended and Restated Articles of Incorporation, our Amended and Restated Bylaws, any other agreement, a vote of our stockholders, a resolution adopted by our Board of Directors or otherwise.

We also maintain a customary insurance policy that indemnifies our directors and officers against various liabilities, including liabilities arising under the Securities Act that may be incurred by any director or officer in his or her capacity as such.

At present, there is no pending litigation or proceeding involving any of our directors or officers for which indemnification is sought, nor are we aware of any threatened litigation that is likely to result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event a claim for indemnification against such liabilities (other than payment by us for expenses incurred or paid by a director, officer or controlling person of ours in successful defense of any action, suit, or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question of whether such indemnification by it is against public policy in the Securities Act and will be governed by the final adjudication of such issue.

BUSINESS

Overview

We are a development stage medical device company utilizing Infra-Red light spectroscopy (IR) combined with Artificial Intelligence (AI) technologies to address currently unmet medical needs. Our initial product candidates which are currently in various stages of development are non-invasive, user friendly and designed to address the medical needs of large and growing target patient groups by offering earlier and more accurate detection, reducing healthcare expenses reducing the widespread reliance on antibiotics, optimizing the delivery of the targeted medical services and, as a result, improving the efficacy and safety of administered treatments.

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

The global diagnostics market is driven in large part by solutions that can be applied in healthcare settings, as these tools will drive decisions regarding specific treatments and the associated outlays. However, despite advances in medical imaging and other diagnostic tools, misdiagnosis and late diagnosis remains a common occurrence. We believe that improved diagnoses and outcomes are achievable through the adoption of AI-based decision support tools.

Our initial focus is on the development of diagnostic supporting solutions utilizing our proprietary platform for the pre-emptive diagnosis of pressure injuries (PI) and mid-ear infections. 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 or nature and thus requiring antibiotic treatment, or of a viral origin.

Our product candidates are in various stages of development and could be commercialized after we obtain the appropriate commercial sale approvals.

PI is a significant challenge to care providers throughout the world. Failure to identify and treat PI is potentially fatal, with an estimated 60,000 mortalities from PI in the United States each year[3]. Prevention of PI is a measure of quality in all healthcare settings. There are three main healthcare setting most prone to high frequency of PI - hospital settings, nursing homes and long term homecare.

A study published in 2019 measured the total cost of acute care attributable to Hospital Acquired Pressure Injury (HAPI) for the entire United States at over $26.8 billion. HAPIs remain a concern with regard to hospital-care quality in addition to representing a major source of economic burden on the U.S. health care system. A single HAPI episode could cost hospitals anywhere from $500 to more than $70,000[4]. Hospitals must invest more in quality improvement of early detection measures and care for PI to avoid higher costs[5]. The problem is critical for nursing homes. Nursing homes pay significant insurance premiums to cover potential lawsuits. At least one PI develops in more than 20% of long-term care residents who have lived in long term care facilities (LTC) for at least two years[6].

[3] Allman RM. Pressure ulcers among the elderly. N Engl J Med. 1989 Mar 30. 320(13):850-3. [Medline].

[4] Padula, W. and Delarmente, B., 2019. The national cost of hospital-acquired pressure injuries in the United States.*International Wound Journal*, 16(3), pp.634-640.

[5] Padula, W. and Delarmente, B., 2019. The national cost of hospital-acquired pressure injuries in the United States.*International Wound Journal*, 16(3), pp.634-640.

[6] Dreyfus, J., Gayle, J., Trueman, P., Delhougne, G. and Siddiqui, A., 2017. Assessment of Risk Factors Associated With Hospital-Acquired Pressure Injuries and Impact on Health Care Utilization and Cost Outcomes in US Hospitals. *American Journal of Medical Quality*, 33(4), pp.348-358.

Lawsuit awards to residents and families of those who developed PI in a facility's care average $250,000 per lawsuit and possibly as high as $312 million[7]. More than 17,000 lawsuits are related to pressure ulcers annually. It is the second most common claim after wrongful death, and greater than falls or emotional distress[8].

Nursing homes need a reliable method of early detection, monitoring, managing patients and recording where and when PI occurs. Reducing numbers of PI cases and having a higher score may also improve reimbursement conditions. In October 2019, a new federal quality plan became effective among U.S. nursing homes based upon patient driven payments (PDPM). Early detection may halt the development of PI and thereby reduce related healthcare costs. Management estimates that the total worldwide addressable market for PressureSafe devices, based on the number of beds in hospitals and nursing facilities and the number of caregivers attending to patients in long term home care, is almost $500 million, with expected annual revenues from disposables potentially worth about $1.8 billion.

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

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

In addition to PI detection devices, we are in preliminary stages of designing and developing an advanced otoscope to support medical personnel with an immediate indication if the mid ear infection is of a viral or bacterial origin. Accurate diagnosis is imperative in order to prevent over administration of antibiotics to toddlers and children up to 5 years of age. Each year, over 20 million children in the U.S. and Europe are diagnosed with mid ear infections[9]. A significantly larger number are examined by pediatricians and family doctors. Once an infection is detected, doctors have no reliable and easy way of determining in real-time whether the fluid buildup behind the ear drum is of bacterial or viral origin. Consequently, patients either receive no medication apart from pain relief or are prescribed antibiotics which may not help them and may cause short term and/or long term undesirable side effects such as development of antibiotic resistance bacteria and undesired changes in little children's micro-biome flora (microorganisms including bacteria, archaea and fungi that naturally live in human body).

Our proprietary advanced optical based otoscope which is in early stage design and development, known as Nobiotics, is designed to facilitate to medical personnel an immediate indication if the infection is of viral or bacterial origin. The Nobiotics device utilizes similar IR-spectrographic analysis technology as used in the PressureSafe device and will use AI to enable the treatment decision to be made "on the spot" (in-situ). The device will be consistent with the major goal of health authorities around the world to reduce the use of antibiotics. In 2019, the World Health Organization[10] called antimicrobial resistance-pathogens' ability to evade medical interventions—one of the ten largest threats to global health. According to a recent Centers for Disease Control and Prevention (CDC) report, in the U.S. alone, 35,000 people die each year due to antibiotic-resistant infections. A new study published in the BMJ showed that as a result of doctors incorrectly prescribing antibiotics, up to 43% of U.S. antibiotic prescriptions may be "inappropriate".

[7] Petrone, K. and Mathis, L., 2017. *Pressure Ulcer Litigation: What is the Wound Center's Liability?*.

[8] Agency for Healthcare Research and Quality (AHRQ), n.d. *Preventing Pressure Ulcers in Hospital.*

[9] Azarpazhooh, A., Lawrence, H. and Shah, P., 2016. Xylitol for preventing acute otitis media in children up to 12 years of age.*Cochrane Database of Systematic Reviews*,.

[10] Ducharme, J., 2019. *Up to 43% of Antibiotic Prescriptions Are Unnecessary or Improperly Written*.

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 disease. 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[11].

While the number of Hospital Acquired Conditions (HAC) have decreased by 8%[12], 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 [13]. 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.

[11] 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.

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

[13] 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.

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[14].

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%)[15].

Nursing home patients have a PI prevalence of 11%[16] 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%)[17]. 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[18], 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.

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.

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

[15] 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.

[16] 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.

[17] 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.

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

PressureSafe

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 patients and recording where and when the PI may occur. 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 cells 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 designed to enable the assessment of different subdermal layers by scanning through these skin layers, 1-5 mm depth, thus not only improving the identification of the damage but also calculating and assessing the subdermal damaged tissue volume and assisting with assessing treatment efficacy. Measuring the differences of subdermal fluid content and bio-signals, is been developed to detect early formation of pressure injuries and to "raise a flag" to allow the caregivers 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 deal 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 mobile phone, and integrated into a mobile application.

PressureSafe is planned to be a non-invasive real-time optical monitoring device for supporting early detection of PI. We are developing our handheld device to perform a reflectance spectroscopy scan to support diagnosis 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 design and development and will be released to a larger useability clinical study.

Our preliminary study began in the first quarter of 2018 in the Rambam Healthcare campus, located in Haifa, Israel and in 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 preliminary prototype (Beta version), 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 clinical useablity studies in a multi-center study in 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 get better and better at evading 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[19].

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[20] 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[21]. 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[22].

Each year in the US, approximately 9 million children, ages 0-17, are reported to have ear infections or otitis media[23]. 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.

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

[20] 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.

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

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

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

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[24].

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.

Ear Infection Background

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

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

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

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

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

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

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.

[2 4] Market Research Future, 2020. *Global Ear Infection Treatment Market: Information By Type (Middle Ear, Outer Ear, Inner Ear), By Pathogen (Bacteria, Virus), By Treatment (Surgery, Medication), By End User (Hospitals, ENT Clinics) and Region (Americas, Europe, Asia-Pacific and the Middle East & Africa) - Forecast till 2027*.

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

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

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[27] 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. The device works on a similar IR-spectrographic analysis method as being developed in the PressureSafe device. The Nobiotics otoscope is based on infrared light reflection and absorption by the effluents behind the ear drum. Reflected (and absorbed infrared light) is compared continuously to the emitted light. Light changes as it penetrated and reflected through different tissues.

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

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 diagnostics, 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 diagnostics, medical devices and medical supplies companies.

[27] 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.

Target large and growing patient populations with significant unmet 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 will utilize a global network of specialists to identify large and growing patient populations with significant unmet 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 arrangement 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 during 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 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 October 2021, we had two 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 $409,000, $61,000 and $495,000 on research and development activities in the years ended December 31, 2020, 2019 and for the six months ended June 30, 2021, 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 making 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. Both these patents were issued in the United States. 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.

We plan to expedite examination for corresponding patent applications for our issued patents (U.S. Patent No. US 10,709,365 and US Patent No. US 10,772,541).

As of the date of this prospectus, 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 agency, 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 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 injures, occur in the medical device industry at a rapid pace.

We expect Nobiotics, if available for sale, to compete with OtoNexus Medical ultrasound otoscope 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 manufacturing requirements contained in the FDA's Quality System Regulation. 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.

Distribution and Revenue Generation

We intend to establish sales and marketing structures and strategic partnerships in the United States 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 has 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 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 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 and sold in packages of up to 50 units.

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 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, 2020, we were paying a monthly rent of 4,273 NIS (approximately, $1,300). On March 15, 2021, the agreement was amended to increase the monthly rental amount to 10,000 NIS per month (approximately $3,115) retroactive to 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 sale. 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 consultant 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.

Clinical Useability Studies

In addition to the above, we plan to conduct clinical useability studies in 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 regulation 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, four employees and one service providers and, on a part-time basis, two employees and seven service providers for a total of 14 employees and service providers. Ten of these individuals are engaged in product research and development and the remainder in 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.

MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our stock is currently quoted on the OTC Markets' "Pink Current Information" tier under the symbol "IRME." Prior to such, our stock was quoted under the symbol "IDAD". We were originally quoted over-the-counter as of September 2009 and are now applying to have our common stock quoted on the OTCQB-tier of OTC Markets. We have 64,601,649 shares of our common stock outstanding as of October, 2021. We implemented a reverse stock split on February 26, 2020 and all the share numbers below reflect such reverse stock split.

The following table sets forth the high and low bid information for each quarter within the two most recent fiscal years, as estimated based on information on OTC Markets. The information reflects prices between dealers, and does not include retail markup, markdown, or commission, and may not represent actual transactions.

Year Ended December 31, 2020

	Bid Prices	
	High	**Low**
First Quarter	$ 14.00	$ 3.00
Second Quarter	$ 6.50	$ 1.26
Third Quarter	$ 5.90	$ 3.27
Fourth Quarter	$ 3.99	$ 1.29
Year Ended December 31, 2019		
First Quarter	$ 6.80	$ 3.90
Second Quarter	$ 33.00	$ 6.50
Third Quarter	$ 33.30	$ 15.00
Fourth Quarter	$ 54.24	$ 12.50

As of October 27, 2021 our common stock closed at $1.90 per share, as quoted on OTC Markets.

The Securities Enforcement and Penny Stock Reform Act of 1990 requires additional disclosure relating to the market for penny stocks in connection with trades in any stock defined as a penny stock. The Commission has adopted regulations that generally define a penny stock to be any equity security that has a market price of less than $5.00 per share, subject to a few exceptions which we do not meet. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated therewith.

The number of holders of record of shares of our common stock is 710.

There have been no cash dividends declared on our common stock. Dividends are declared at the sole discretion of our Board of Directors.

Registration Rights

We entered into subscription agreements with the investors in the Private Placement, pursuant to which we are filing the registration statement of which this prospectus is a part with the SEC to register for resale the 18,439,267 shares of our common stock issued in the 2020 Private Placement and 9,328,329 shares of common stock issuable upon exercise of common stock purchase warrants issued to the investors as part of the 2020 Private Placement.

Lock-Up Agreements

In connection with the Private Placement, the investors therein have executed lock-up agreements providing that, for a period of one year from the date of the Acquisition on December 24, 2020, they will not directly or indirectly sell, offer, contract or grant any option to sell, pledge or otherwise transfer more than 50% of their shareholdings, subject to certain limited exceptions as set forth in the lock-up agreements.

Our directors and executive officers have executed lock-up agreements providing that, for a period of two years from the date of the Acquisition on December 24, 2020, they will not directly or indirectly sell, offer, contract or grant any option to sell, pledge or otherwise transfer more than 75% of their shareholdings, subject to certain limited exceptions as set forth in the lock-up agreements.

SELECTED FINANCIAL DATA

As a smaller reporting company we are not required to provide this information.

MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties as described

under the heading "Forward-Looking Statements" elsewhere in this prospectus. You should review the disclosure under the heading "Risk Factors" in this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

On December 24, 2020 we consummated the Acquisition with IR-Med Ltd. and the former shareholder of IR-Med Ltd. On January 20, 2021, we received approval from FINRA to change our name to IR-Med, Inc. and symbol to IRME.

We are an innovative development stage medical device company focused on leveraging Infra-Red (IR) and Artificial Intelligence (AI) technologies to address currently unmet medical needs. Our initial product candidates which are currently in various stages of development are non-invasive, user friendly and designed to address the medical needs of large and growing patient populations by offering earlier and more accurate diagnosis, reducing the widespread reliance on antibiotics, optimizing the delivery of the targeted medical services, and as a result improving the efficacy and safety of treatment.

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

1. *PressureSafe* — a handheld optical monitoring device that is 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 (Otis Media), a common malady in children, is of a bacterial origin or nature and thus requiring antibiotic treatment, or of a viral origin.

Our product candidates are in various stages of development and will be commercialized after we obtain the appropriate commercial sale approvals.

Since inception, we have devoted nearly all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. For the years ended December 31, 2020 and 2019, we reported net losses of $752 thousands and $248 thousands, respectively. As of December 31, 2020, we had an accumulated deficit of $1,480,000. We expect to continue incurring substantial losses for the next several years as we continue to develop our product candidates. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenues to date, and we do not expect to generate revenues from product sales for at least through the second half of 2022.

The U.S. dollar is the reporting currency for all periods presented. The functional currency for IR-Med Ltd is U.S. dollars. While the majority of the Company's operations are currently conducted in Israel, a significant part of the Company's expenses is denominated and determined in U.S. dollars. The Company's management believes that the U.S. Dollar is the currency of the primary economic environment in which the Company operates and expects to continue to operate in the foreseeable future. Non-Dollar transactions and balances have been remeasured to U.S. Dollars.

IR-Med Inc. is a holding company without operations and the sole stockholder of IR-Med Ltd. The corporate headquarters and research facility of IR-Med Ltd. are located in Rosh Pina, Israel.

Recent Developments

Private Placement

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

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

In connection with the Private Placement, we undertook to file a registration statement with the SEC to register the shares of common stock issued in the Private Placement, the Acquisition and shares of common stock issuable upon exercise of the Warrants for resale. These shares of common stock are covered by the registration statement of which this prospectus forms a part.

Acquisition

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

Upon the closing of the Acquisition, IR-Med, Inc. ceased to be a "shell company" under applicable rules of the Securities and Exchange Commission, or the SEC.

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, section 805 entitled, "Business Combinations," IR-Med Ltd is considered the accounting acquirer in the Acquisition and will account for the transaction as a capital transaction. Consequently, the assets and liabilities and the historical operations that will be reflected in our financial statements will be those of IR-Med Ltd and will be recorded at the historical cost basis of IR-Med Ltd.

Comparison of the Three and Six Months Ended June 30, 2021 to the Three and Six Months Ended June 30, 2020

	For the three months period ended June 30		For the six months period ended June 30	
	2021	2020	2021	2020
	U.S dollars (in thousands)			
Research and development expenses	**391**	**96**	**495**	**146**
Marketing expenses	**593**	**-**	**763**	**-**

General and administrative expenses	**532**	**68**	**690**	**111**
Total operating expenses	**1,516**	**164**	**1,948**	**257**
Financing expenses, net	**6**	**11**	**18**	**2**
Loss for the period	**1,522**	**175**	**1,966**	259

Revenues. We have not recorded any revenues to date.

Research and Development Expenses, Research and development expenses increased from $96,000 and $146,000 for the three and six months ended June 30, 2020 to $391,000 and $495,000 for the corresponding periods in 2021. The increase in each of the three and six month periods resulted primarily from increased use of third party contractors for further research, development activities and recording expenses due to stock based compensation to employees and service providers, primarily with respect to the *PressureSafe* device.

Marketing Expenses -During the six months ended June 30 2021 we started to expend efforts to develop the marketing strategy for*PressureSafe*. In connection therewith, we recorded $593,000 and $763, for the three and six months ended June 2021, respectively which includes non-cash expenses attributable to stock based compensation to employees and service providers.

General and Administrative Expenses. General and administrative expenses increased from $68,000 and $111,000 for the three and six months ended June 30, 2020 to $532,000 and $690,000 for the corresponding periods in 2021. The increase is primarily due to the increased use of outside professionals with respect to ongoing matters associated with the growth of the Company, recruiting employees, patent registration in the U.S., accounting/audit related expenses and recording expenses due to stock based compensation to employees and service providers.

Loss. Loss for the three months and six months ended June 30, 2021 was $1,522,000 and $1,966,000 and is primarily attributable to research and development, marketing activities, general and administrative expenses and recorded of expenses due to stock based compensation to employees and service providers.

Comparison of the Year Ended December 31, 2020 to Year Ended December 31, 2019

Results of Operations

Summary of Results of Operations

	Year Ended	
	December 31, 2020	**December 31, 2019**
Operating Expenses		
Research and Development	**$ 409,000**	**$ 61,000**
General and Administrative	**$ 321,000**	**$ 150,000**
Financing expenses	**$ 22,000**	**$ 37,000**
Loss	**$ 752,000**	**$ 248,000**

Revenues. We have not recorded any revenues to date.

Research and Development Expenses, Research and development expenses increased from $61,000 for the year ended December 31, 2019 to $409,000 in 2020. The increase resulted primarily from increased use third party contractors for further research and development activities, primarily with respect to the PressureSafe device.

General and Administrative Expenses. General and expenses increased from $150,000 for the year ended December 31, 2019 to $321,000 in 2020. The increase primarily due to the increased use of legal professionals with respect to ongoing matters associated with the growth of the Company, patent registration in the U.S. and accounting/audit related expenses.

Loss. Loss for the year ended December 31, 2020 was $752,000 and is primarily attributable to research and development and general and administrative expenses.

Liquidity and Capital Resources

From inception and through the date of the Acquisition, 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 June 30, 2021, we had a total of $4,225,000 in cash resources and approximately $466,000 of liabilities, consisting of $299,000 of current liabilities from operations. In April 2021, we raised an additional $200,000 in gross proceeds of the 2020 Private placement.

IR-Med Ltd. has experienced operating losses since its inception and had a total accumulated deficit of $3,446,000 as of June 30, 2021. IR-Med Ltd. expects to incur additional costs and require additional capital. We have incurred losses in nearly every year since inception and in the year ended December 31, 2020. These losses have resulted in significant cash used in operations. During the fiscal years ended December 31, 2020 and 2019 and for the six months ended June 30, 2021, our cash used in operations was approximately $402,000, $72,000 and $996,000, respectively. We need to continue and amplify our research and development efforts for our product candidates (which are in various stages of development), strengthen our patent portfolio, establish operations processes and pursue FDA clearance and international regulatory approvals As we continue to conduct these activities, we expect the cash needed to fund operations to increase significantly over the next several years.

At the initial closing of the 2020 Private Placement, we entered into a securities purchase agreement with certain accredited investors providing for the issuance and sale to such investors of an aggregate of 7,206,250 shares of our Common Stock and warrants for an additional 3,603,125 shares of our Common Stock, exercisable through December 28, 2023, at a per share exercise price of $0.64. After deducting for offering related expenses, the aggregate net proceeds from the initial closing of the 2020 Private Placement were approximately $2.14 million. Between January and April 2021, we raised an additional $3,525,000 in gross proceeds from the 2020 Private Placement.

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

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements for at least 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.

Our cash is maintained in money market accounts and, to a lesser extent, in CDs at major financial institutions. Due to the current low interest rates available for these instruments, we are earning limited interest income. Our investment portfolio has not been adversely impacted by the problems in the credit markets that have existed over the last several years, but there can be no assurance.

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.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

We have no information required to be disclosed under this Item.

MANAGEMENT

Directors and Executive Officers

The table below sets forth information about our directors and executive officers:

Name	Age	
Oded Bashan	74	Chairman of the Board of Directors
Dr. Rom Eliaz	50	Chief Executive Officer
Sharon Levkoviz	47	Chief Financial Officer
Aharon Klein	56	Chief Technology Officer, Director
Aharon Binur	57	Chief Development Officer
Yaniv Cohen	41	Director
Yoram Drucker	55	Vice President, Business Development, Director

David Lazar [1]	30	Director
Ohad Bashan	49	Director
Ron Mayron [1]	56	Director
David Levy [2]	67	Director of Subsidiary

[1] Member of the Audit Committee.

[2] Mr. Levy is a member of the board of directors of IR-Med Ltd, the Company's subsidiary.

Business Experience

The following is a brief account of the education and business experience of our current directors and executive officers:

Oded Bashan co-founded IR-Med Ltd with Aharon Klein and, since September 2013 has been serving as Chairman of IR-Med Ltd. Upon the effectiveness of the Acquisition, he was appointed to Board of Directors and on January 20, 2021, was appointed as Chairman of the Board and on April 6, 2021 he was appointed Chief Executive Officer on an interim basis following the resignation of Ms. Davidson Mund. Mr. Bashan has over 35 years of experience in managing, building and running technology companies. Founder, CEO & chairman of OTI from 1990 to 2013, a Nasdaq traded global technology leader with more 250 employees, annual sales of $50 Million USD, IP portfolio of over 100 patents and hundreds of millions of users. Previously served (years) as the president of Electro-Galil. He was awarded the Leading Businessman Award in Management, Business and Economics by the Israeli Institute of Public Opinion. Mr. Bashan holds both B.Sc. and M.Sc. in Economics and Business management from the Hebrew University of Jerusalem.

The Board believes that Mr. Bashan's extensive experience in United States public companies, his long standing involvement with IR-Med Ltd. and his knowledge of our product candidates ideally situate him to serve on our Board.

Dr. Rom Eliaz was appointed Chief Executive Officer on June 20, 2021.Prior to his appointment as our Chief Executive Officer, from May 2006 till the present time, Dr. Eliaz was Founder and Managing Director at Elrom Ventures, a consulting firm that specializes in the formation, business development, financing and operational development of biotechnology-based, medical devices, green technology and digital health companies. From June 2017 through October 2018, he served as a Managing Director at aMoon Fund, over $1 Billion fund for investment in late stage or early breakthrough stage companies or concepts. From March 2016 to September 2017, Dr. Eliaz was Head of Merck ventures' Fund and Bio-Incubator in Israel where he co-founded several companies in the incubator. Prior to that time, from May 2012 to March 2016, Dr. Eliaz served as VP of Innovative Branded Products at Teva Pharmaceuticals. From October 2010 to April 2012, he was the CEO of NasVax a publicly traded company listed on the Tel Aviv Stock Exchange. Dr. Eliaz received with honors his PhD in Chemical Engineering and Biotechnology from the Weizmann Institute of Science and Ben-Gurion University (BGU) in Israel, and he holds an MBA from the Harvard Business School and Boston University joint program at BGU.

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

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

The Board believes that Mr. Klein's extensive knowledge of the Company, his long standing involvement with IR-Med Ltd and his knowledge of the core technologies underlying our product candidates ideally situate him to serve on our Board.

Aharon Binur, Mr. Aharon Binur was appointed as Chief Development Officer on April 29, 2021 to lead product development. Mr. Binur is an electronics engineer who graduated from the Technion in Haifa, Israel. He started as an electronics engineer at OTI, and quickly climbed to a development manager at a subsidiary and was later appointed VP of R&D at OTI, and VP of products for a cumulative more than 13 years. Aharon also served as CTO and VP of R&D at Lehavot- advanced fire protection systems, for over 8 years. Aharon has extensive experience in multidisciplinary technological management, including software, hardware and mechanics, development of final systems and products for the client, while maintaining high quality and international standards. Aharon has a unique and creative approach to technology management, including patents registered on his name.

Yaniv Cohen Co-founded IR-Med Ltd as of September 2013 and served as the R&D manager since then and until the Acquisition, whereupon he was appointed to the Board of IR-Med and R&D researcher. Mr. Cohen is an experienced electrical engineer with expertise in the fields of wave propagation and IR Spectroscopy for medical applications. Additionally, Mr. Cohen holds 4 patents in medical devices, co-authored eight articles in scientific journals as well as speaking in conference around the globe. From 2010 to 2013 Mr. Cohen served as R&D manager for PIMS, an Israeli medical device company, focusing on IR imaging and spectral analysis for non-invasive cancer detection and identification. From 2008 to 2009, Mr. Cohen worked for Cisco as a system engineer. Prior to which, from 2006 to 2008 he worked as a service engineer for Intel Israel. Mr. Cohen is a Candidate of Sciences in the doctoral program, Informatics and Computer Engineering in the National Research University Higher School of Economics, School of Electronic Engineering Institute of Electronics and Mathematics (MIEM HSE), Moscow, Russia. Mr. Cohen holds a M.Sc. in Electrical Engineering from Holon Institute of Technology (2007), following which, from 2009 to 2010 he attended the Ben-Gurion University of the Negev, Beer Sheva, Israel where he wrote a thesis in wave prorogation.

The Board believes that Mr. Cohen's extensive knowledge of the Company, his long standing involvement with IR-Med Ltd and his extensive knowledge of relevant technologies qualify him to serve on our Board.

Yoram Ducker joined the Board of Directors in December 2019. Mr. Drucker is a serial entrepreneur, founding several companies over the last twenty years and focusing on the Israeli biotech industry. From October 2017 to the present time, Mr. Drucker founded and served as Vice President of Business Development for InnoCan Pharma Ltd., a company traded on the Canadian Stock Exchange (CSE). From September 2016 to April 2020, Mr. Drucker was the CEO and Co-founder of a biotech company,

ViruCure, developing an oncolytic-virus based technology platform. Prior to this, he served as the CEO and Executive Chairman of Cell Source Ltd. From 2011 to 2014. Additionally, Mr. Drucker was a founding member of Brainstorm (BCLI), a company publicly traded on the Nasdaq where he served as COO in 2004 and CEO from 2005 to 2007 and a founding member of Pluristem (NASDAQ: PSTI). Mr. Drucker brings significant expertise in the management, operations, business development and product development in start-ups. He is also involved as a consultant and co-founder of other start-ups in different fields.

The Board believes that Mr. Drucker's extensive experience in a managerial capacity with U.S. public companies brings to our board needed experience is functioning as a U.S. public company.

David Lazar joined the Board in November 2018. Mr. Lazar is a private investor with rich business experience. Mr. Lazar has been a partner at Zenith Partners International since 2013, where he specializes in research and development, sales and marketing. Since February of 2018, Mr. Lazar has been the managing member of Custodian Ventures LLC, where he specializes in assisting distressed public companies. Since March 2018, David has acted as the managing member of Activist Investing LLC, which specializes in active investing in distressed public companies. Mr. Lazar has a diverse knowledge of financial, legal and operations management, public company management, accounting, audit preparation, due diligence reviews and SEC regulations. His expertise includes early-stage company capital restructuring, debt financing, capital introductions, and mergers and acquisitions.

Mr. Lazar was selected to serve as a director due to his knowledge of the capital markets, his judgment in assessing business strategies and accompanying risks, and his expertise with smaller reporting companies.

Ohad Bashan. Mr. Bashan was appointed to the Board of Directors upon the effectiveness of the Acquisition. Mr. Bashan served as a member of the Board of Directors of OTI America, PARX Ltd., ASEC and Digoti Ltd. Mr. Bashan serves as a member of the Board of Directors of Millennium Card's Technology Ltd.. From 1996 to August 1998, he was our business development manager. Mr. Bashan holds a B.A. in business from the College of Business Management, Tel Aviv, with specializations in marketing and finance, and an M.B.A. from Pepperdine University, California. Ohad Bashan is the son of Oded Bashan.

The Board believes that Mr. Bashan's wide ranging international business experience qualify him to serve on our Board.

Ron Mayron. Mr. Mayron was appointed to the Board of Directors upon the effectiveness of the Acquisition. Mr. Mayron has extensive, long-term experience in the pharmaceutical & medical equipment arena and has held various, significant senior management positions, both local and global, within Teva Pharmaceutical Industries Ltd. over the last 21 years. During his career at Teva Mr. Ron Mayron served in various VP positions, his last role was CEO of Teva Israel and VP Israel and Africa from June 2009. Mr. Ron Mayron 's core expertise local and global are Marketing, Sales & Distribution, Merge & Acquisitions, Business Development, Global Operation & supply Chain and Strategic Development. Mr. Ron Mayron serves on several Board of Directors public and private and he holds a B.Sc. – Industrial Engineering & Management, Ben Gurion University and M.B.A from Tel-Aviv University.

As part of his duties as Chairman of an Israeli public company, Wize Pharma Inc. ("Wizw"), Mr. Mayron had signed the 2015 year end and 2016 first quarter financial statements of Wize, after they were approved by Wize's board of Directors and its finance committee **.** The financial statements required an assessment of the value of certain of Wize's assets; namely a certain proposed pharmaceutical product which was in process for FDA approval in the Drug Monograph process (the "fast Lane"). Issues arose in the approval process that indicated that the product would not be suitable to the "fast Lane". This assessment was not reflected in the 2016 first quarter reports. The Israel Securities Authority ("ISA") asserted that the asset valuation was not sufficiently addressed due to the issues which arose with the FDA approval timelines.

The ISA matter was resolved in at the staff level by the ISA approval of the administrative settlement agreement on August 1, 2019 without any formal proceeding being taken. A financial penalty in the amount of NIS 150,000 (approximately $45,000) was imposed upon Mr. Mayron pursuant to the Israeli Securities Law, which was paid in 10 consecutive monthly payments. Furthermore, a conditional financial penalty of NIS 150,000 was imposed also imposed, to be paid provided that he commits a violation of certain specified sections of the Securities Law within nine months of approving the Arrangement. The fine was already paid and the probation period of additional fine has already expired with no additional sanction imposed.

The Board believes that Mr. Mayron's extensive knowledge and experience with public companies qualify him to serve on our Board and on our audit committee.

David Levy. Mr Levy was appointed to the board of directors of our Israel based subsidiary IR-Med Ltd. on February 15, 2015. Mr. Levy has over 40 years' experience in the manufacture of electronic circuits primarily in the defense field. Mr. Levy has served as chief executive officer of Liat Electronics Ltd., a company he co-founded in January 1986 as niche "boutique" developing and manufacturing facility for the most cutting edge industries, and which currently employs 100 employees, that perform manufacturing engineering, new product implementation, and printed circuit board (PCB) assemblies. Our clientele includes a variety of highly sophisticated companies in the medical, defense and security, communication and industrial applications. Mr. Levy received his MBA from Tel Aviv University in 2002.

Term of Office of Directors

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

- the Class I directors are David Lazar and Yaniv Cohen and their terms will expire at the annual meeting of stockholders to be held in 2021;
- the Class II directors are Yoram Drucker, Ohad Bashan and Ron Mayron, and their terms will expire at the annual meeting of stockholders to be held in 2022; and
- the Class III directors are Oded Bashan and Aharon Klein, and their terms will expire at the annual meeting of stockholders to be held in 2023.

Family Relationships

Oded Bashan is the father of Ohad Bashan.

Committees of the Board of Directors

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

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

We currently do not have a nominating or compensation committees or committees performing similar functions nor does our Company have a written nominating or

compensation charter. Our Directors believe that it is not necessary to have such committees, at this time, because the Director(s) can adequately perform the functions of such committees.

Audit Committee

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

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

The members of our audit committee are Ron Mayron and David Lazar. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Capital Market.

Nominations to the Board of Directors

Director candidates are considered based upon various criteria, including without limitation their broad-based business and professional skills and experiences, expertise in or knowledge of the life sciences industry and ability to add perspectives relating to that industry, concern for the long-term interests of our stockholders, diversity, and personal integrity and judgment. Our Board of Directors has a critical role in guiding our strategic direction and overseeing the management of our business, and accordingly, we seek to attract and retain highly qualified directors who have sufficient time to engage in the activities of our Board of Directors and to understand and enhance their knowledge of our industry and business plans.

EXECUTIVE COMPENSATION

The following table summarizes the compensation earned in each of our fiscal years ended December 31, 2020 and 2019 by our named executive officers, which consisted solely of our principal executive officer Mr. Aharon Klein prior to the Acquisition and Ms. Limor Davidson Mund upon the effectiveness of the Acquisition (who has since resigned), as our other executive officers did not earn more than $100,000. The following table includes compensation earned by the parties named therein for services performed for IR-Med Ltd prior to that entity becoming our wholly owned subsidiary upon the completion of the Acquisition on December 24, 2020, as well as compensation earned following the closing of the Acquisition. The following table does not include compensation information for the individuals who served as IR-Med's executive officers prior to the completion of the Acquisition, as all such individuals tendered their resignations from all such positions with us in connection with and effective as of the closing of the Acquisition and no compensation was earned by or paid to any such individuals for their services as officers of IR-Med. We refer to the executive officers listed below as the Named Executive Officers.

Summary Compensation Table

Name and Principal Position	Year (1)	Salary	Bonus ($)	Option Awards ($)(2)	All other compensation ($)	Total
Aharon Klein (3)	2020				$ 70,442	$ 70,442
	2019				$ 17,026	$ 17,026
Limor Davidson Mund (4)	2020	$ 10,937			$ 467	$ 11,404
	2019					

(1) All compensation received by IR-Med Ltd.'s executive officers is paid in NIS. For the purposes of completing this table, with respect to compensation paid during the fiscal year ended December 31, 2020 and 2019, IR-Med converted each NIS denominated amount into U.S. dollars by dividing the NIS amount by the exchange rate effective on the date the fee was incurred.

(2) These amounts represent the aggregate grant date fair value for the option awards granted during the fiscal years presented, determined in accordance with FASB ASC Topic 718. All awards are amortized over the vesting life of the award.
(3) Mr. Klein served as Chief Executive Officer of IR-Med Ltd. from September 2013 through December 23, 2020. Upon the effectiveness of the Acquisition, Mr. Klein was appointed Chief Technology Officer.
(4) Ms. Davidson Mund was appointed as Chief Executive Officer upon the effectiveness of the Acquisition. Ms. Mund resigned from all positions with the Company on April 6, 2021.

Narrative Disclosure to Summary Compensation Table

IR-Med, Ltd.

Aharon Klein. Upon the effectiveness of the Acquisition, IR-Med Ltd. and Mr. Klein entered into an amended and restated consulting agreement replacing a service agreement dated October 1, 2019 between IR-Med Ltd. and the Company (the "Klein Service Agreement"). The Klein Service Agreement provides for a continuous term and may be terminated by either party at any time, provided that if Mr. Klein resigns, he shall provide at least 30 days' prior written notice. Pursuance to this agreement, Mr. Klein's annual fee compensation was increased to $144,000 plus VAT, effective as of the closing of the Acquisition. In addition, Mr. Klein is eligible to receive an automobile allowance of New Israeli Shekel equivalent of approximately $1,525 per month. If Mr. Klein's employment is terminated (i) by us without cause or (ii) by him for any reason, then we must pay Mr. Klein (a) the accrued obligations earned through the date of termination, (b) a lump-sum payment of an amount equal to one month of his base salary at the time of his termination.

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

In consideration of his service on the Board, Mr. Klein was awarded options under our employee stock plan. See below "*Director Compensation*".

Limor Davidson Mund. On December 24, 2020, IR-Med Ltd. and Limor Davidson Mund, the Company's Chief Executive Officer, entered into an employment agreement providing for the employment (the "Limor Employment Agreement") of Ms. Limor Davidson Mund as Chief Executive Officer. Under the Limor Employment Agreement, Ms. Davidson Mund was entitled to an annual salary of the current New Israeli Shekel equivalent of approximately $127,430, payable on monthly basis as well as an automobile allowance of New Israeli Shekel equivalent of approximately $450 per month. Under the Limor Employment Agreement, Ms. Davidson Mund was also entitled to the following: (i) Manager's Insurance under Israeli law for the benefit of Ms. Davidson Mund pursuant to which IR-Med Ltd contributes amounts equal to (a) 8-1/3 percent for severance payments, and 6.5%, or up to 7.5% (including disability insurance) designated for premium payment (and Ms. Davidson Mund contributes an additional 6%) of each monthly salary payment, and (b) 7.5% of Ms. Davidson Mund's salary (with Ms. Davidson Mund contributing an additional 2.5%) to an education fund, a form of deferred compensation program established under Israeli law.

On April 6, 2020, Ms. Davidson Mund resigned from her positions with the Company and IR-Med Ltd. In connection with her resignation, Ms. Davidson Mund was given a severance payment equal to three months' salary (as required under the Limor Employment Agreement) and the Company undertook to issue to her under the Company employee stock option plan options for 75,000 shares of the Company's common stock at a per share price of $0.32 which are exercisable through the fifth anniversary of grant. On December 23, 2020 our Board approved and the shareholders adopted a share based compensation plan ("2020 Incentive Stock Plan") for future grants by us to employees and services providers, including directors. However, as of December 31, 2020, our Board did not approve an appendix to the 2020 Incentive Stock Plan for IR Med Ltd. (the "Israeli Appendix to the 2020 Incentive Stock Plan") in order to obtain favorable tax treatment for grants to Israeli based employees and service providers.

Agreements with Other Executive Officers Entered into on or after the Acquisition

Oded Bashan, Chairman of the Board. On April 8, 2021, Mr. Bashan was appointed Chief Executive Officer on an interim basis. Upon Dr. Eliaz's appointment as Chief Executive Officer on June 20, 2021, resigned from his position as Chief Executive Officer. Mr. Bashan's compensation currently consists of stock options to which he is entitled for his service on the Board as discussed below. See below under "*Director Compensation*"

Dr. Rom Eliaz, On June 22, 2021, Dr. rom Eliaz and IR Med Ltd entered into an employment agreement providing for the employment of Dr. Eliaz as Chief Executive Officer (the "Eliaz Employment Agreement"). Under the Eliaz Employment Agreement, Dr. Eliaz is entitled to an annual salary of the current New Israeli Shekel equivalent of approximately $149,000, payable on monthly basis as well as an automobile allowance of New Israeli Shekel equivalent of approximately $1,900 per month. Under the Eliaz Employment Agreement, Dr. Eliaz also entitled to the following: (i) Manager's Insurance under Israeli law for the benefit of Dr. Rom Eliaz pursuant to which IR-Med Ltd contributes amounts equal to (a) 8-1/3 percent for severance payments, and 6.5%, or up to 7.5% (including disability insurance) designated for premium payment (and Dr. Eliaz contributes an additional 6%) of each monthly salary payment, and (b) 7.5% of his salary (with Dr. Eliaz contributing an additional 2.5%) to an education fund, a form of deferred compensation program established under Israeli law. The Eliaz Employment Agreement provides that his annual salary will be increased to the New Israeli Shekel equivalent of approximately $186,000 upon (i) the successful capital raise by the Company of at least $5.0 million in net proceeds, (ii) the successful completion of a prototype of the *PressureSafe* device, as determined by the Company's board of directors and (iii) receipt by the Company of a letter of intent for the large scale commercial purchase/order of the *PressureSafe* device. If Dr. Eliaz's employment is terminated by us without cause on or prior to December 22, 2021, then we must pay Dr. Eliaz (a) the accrued obligations earned through the date of termination, (b) a lump-sum payment of an amount equal to one month of his base salary at the time of his termination; if such termination occurs after such date, then we must pay to Dr. Eliaz (a) the accrued obligations earned through the date of termination, (b) a lump-sum payment of an amount equal to three months of his base salary at the time of his termination. Under the Eliaz Employment Agreement, Dr. Eliaz was awarded options under the Company's employee stock option plan for 450,000 shares of the Company's common stock at a per share price of $0.32, vesting in six (6) bi-annual instalments of 75,000 shares, beginning the first instalment on the bi-annual period ending December 31, 2021 and thereafter at the end of each subsequent six months, provided that the Executive is then in our employ.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions du ring the term of the agreement and twelve (12) months thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter.

Yoram Drucker, Vice President, Business Development and Director. On May 5th, 2021, IR-Med Ltd. and Mr. Yoram Drucker entered into an amended and restated employment agreement replacing a consulting agreement dated January 1, 2020 between IR-Med, Inc. and himself (the "Drucker Employment Agreement). The Drucker Employment Agreement provides for a term effective through December 31, 2022, with an automatic renewal for a period of one (1) year and may be terminated by either party at any time, provided a notice is provided at least 30 days prior. Pursuant to the Drucker Employment Agreement, Mr. Drucker's annual salary compensation is the current New Israeli Shekel equivalent of $47,404, with retroactive effect as of January 1, 2021. Mr. Drucker is entitled to options to purchase up to 572,471 shares of our common stock under the 2020 Stock Incentive Plan at a per share exercise price of $0.32, which options can be issued only following the adoption by the Board of the of the Israeli Appendix to the 2020 Incentive Stock Plan and its submission to the Israel Tax Authorities.

In addition, if a Material Event (as defined in the Drucker Employment Agreement) occurs later than four-years following the closing of the Acquisition, Mr. Drucker is entitled to bonus compensation of: (a) $50,000 bonus and (b) grant to purchase 150,000 shares of Common Stock at an exercise price equal to 10% discount on the closing price of the Company's publicly traded Common Stock on the trading day preceding the effectiveness of a Material Event. Furthermore, Mr. Drucker is eligible to receive a return of out-of-pocket expenses. Under the Drucker Employment Agreement, Mr. Drucker also receives the following: (i) Manager's Insurance under Israeli law for the benefit of Mr. Drucker, pursuant to which IR-Med Ltd contributes amounts equal to (a) 8-1/3% for severance payments, and 6.5%, or up to 7.5% (including disability insurance) designated for premium payment (and Mr. Drucker contributes an additional 6%) of each monthly salary payment.

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

In consideration of his service on the Board, Mr. Drucker was awarded options under our employee stock plan. See below "*Director Compensation*"

Sharon Levkoviz, Chief Financial Officer. Sharon Levkoviz provided financial services to IR-Med Ltd. prior to and following the Acquisition. Upon the effectiveness

of the Acquisition, Mr. Levkoviz was appointed Chief Financial Officer. On March 1, 2021, IR-Med, Ltd. and Sharon Levkoviz entered into an employment agreement pursuant to which Mr. Levkoviz provides chief financial services to IR Med and to the Company. Under the agreement with Mr. Levkoviz, he is paid an annual salary of the current New Israeli Shekel equivalent of approximately $64,000, payable on monthly basis. IR-Med Ltd. is authorized to terminate the employment agreement for any reason subject to payment of two months' salary. Under the terms of the employment agreement with him, Mr. Levkoviz also receives Manager's Insurance under Israeli law for his to which IR-Med Ltd contributes amounts equal to (a) 8-1/3 percent for severance payments, and 6.5%, or up to 7.5% (including disability insurance) designated for premium payment (and Mr. Levkoviz contributes an additional 6%) of each monthly salary and (b) 7.5% of his salary (with Mr. Levkoviz contributing an additional 2.5%) to an education fund, a form of deferred compensation program established under Israeli law. Mr. Levkoviz is also provided with a leased automobile. Mr. Levkoviz was awarded options under the Company's employee stock option plan for 390,921 shares of the Company's common stock at a per share price of $0.32, of which 113,030 were vested upon grant and the balance vest at the end of each calendar quarter at the rate of 23,158 shares per quarter, beginning with the quarter ending September 30, 2021 and are exercisable through the tenth anniversary of grant, subject to his continued employment with the Company.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions during the term of the agreement and twelve (12) months thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter.

Aharon Binur, Chief Development Officer. On March 2, 2021, IR-Med, Ltd. and Aharon Binur entered into an employment agreement pursuant to which Mr. Binur oversees the development of our product candidates which are in various stages of development. Under the agreement with Mr. Binur, he is paid an annual salary of the current New Israeli Shekel equivalent of approximately $128,040, payable on monthly basis. IR-Med Ltd. is authorized to terminate the employment agreement for any reason subject to payment of two months' salary. Under the terms of the employment agreement with him, Mr. Binur also receives Manager's Insurance under Israeli law for his to which IR-Med Ltd contributes amounts equal to (a) 8-1/3 percent for severance payments, and 6.5%, or up to 7.5% (including disability insurance) designated for premium payment (and Mr. Binur contributes an additional 6%) of each monthly salary and (b) 7.5% of his salary (with Mr. Binur contributing an additional 2.5%) to an education fund, a form of deferred compensation program established under Israeli law. Mr. Binur is also provided with a leased automobile. On June 20, 2021, Mr. Binur was awarded options under the Company's employee stock option plan for 300,000 shares of the Company's common stock at a per share price of $0.32, of which 15,000 were vested upon grant and the balance vest at the end of each calendar quarter at the rate of 15,000 shares per quarter, beginning with the quarter ended September 31, 2021, subject to his continued employment. The options are exercisable through the tenth anniversary of grant.

The agreement contains (i) customary confidentiality obligations which are not limited by the term of the agreement, (ii) certain non-compete provisions during the term of the agreement and twelve (12) months thereafter and (iii) certain non-solicitation provisions during the term of the agreement and for one year thereafter.

Description of 2020 Incentive Stock Plan

In December 2020, our Board of Directors and stockholders adopted the 2020 Incentive Stock Plan (the "2020 Incentive Stock Plan"). The Plan is intended to encourage ownership of common stock by our employees and directors and certain of our consultants, including employees of IR-Med Ltd, in order to attract and retain such people, to induce them to work for the benefit of us and to provide additional incentive for them to promote our success. As of December 31, 2020 no equity awards were granted.

Types of Awards. The Plan provides for the granting of incentive stock options, non-qualified stock options, stock grants and other stock-based awards, including restricted stock units.

- *Incentive and Non-qualified Stock Options.* The plan administrator determines the exercise price of each stock option. The exercise price of a non-qualified stock option may not be less than the fair market value of our common stock on the date of grant. The exercise price of an incentive stock option may not be less than the fair market value of our common stock on the date of grant if the recipient holds 10% or less of the combined voting power of our securities, or 110% of the fair market value of a share of our common stock on the date of grant otherwise.

- *Stock Grants*. The plan administrator may grant stock, including restricted stock, to any participant, which purchase price, if any, may not be less than the par value of shares of our common stock. The stock grant will be subject to the conditions and restrictions determined by the administrator. The recipient of a stock grant shall have the rights of a stockholder with respect to the shares of stock as of the grant date.

- *Stock-Based Awards*. The administrator of the Plan may grant other stock-based awards, including stock appreciation rights, phantom stock awards and restricted stock units, with terms approved by the administrator, including restrictions related to the awards. The holder of a stock-based award shall not have the rights of a stockholder until shares of our common stock are issued pursuant to such award.

Plan Administration. Our Board is currently the administrator of the Plan, except to the extent it delegates its authority to a committee, in which case the committee shall be the administrator. The administrator has the authority to determine the recipients of the awards, the terms of awards, including exercise and purchase price, the number of shares subject to awards, the vesting schedule applicable to awards, the form of consideration, if any, payable upon exercise or settlement of an award and the terms of award agreements for use under the Plan. In addition, the administrator may amend any term or condition of any outstanding award including, without limitation, to reduce or increase the exercise price or purchase price, accelerate the vesting schedule or extend the expiration date, provided that no such amendment shall impair the rights of a participant without such participant's consent.

Eligibility. The administrator will determine the participants in the Plan from among our employees, directors and consultants.

Termination of Service. Unless otherwise provided by the administrator or in an award agreement, upon a termination of a participant's service, all unvested options then held by the participant will terminate and all other unvested awards will be forfeited.

Transferability. Awards under the Plan may not be transferred except by will or by the laws of descent and distribution, unless otherwise provided by our board in its discretion and set forth in the applicable agreement, provided that no award may be transferred for value.

Adjustment. In the event of a stock dividend, stock split, recapitalization or reorganization or other change in change in capital structure, the administrator will make appropriate adjustments to the number and kind of shares of stock or securities subject to awards.

Corporate Transaction. Upon a merger, consolidation or sale of all or substantially all of our assets, the administrator, or the board of directors of any corporation assuming our obligations, may, in its sole discretion, take any one or more of the following actions pursuant to our plan, as to some or all outstanding awards:

- provide that outstanding options will be assumed or substituted for shares of the successor corporation or consideration payable with respect to our outstanding stock in connection with the corporate transaction;

- provide that the outstanding options must be exercised within a certain number of days, either to the extent the options are then exercisable, or at the administrator's discretion, any such options being made partially or fully exercisable;

- terminate outstanding options in exchange for payment of an amount equal to the difference between (a) the consideration payable upon consummation of the corporate transaction to a holder of the number of shares into which such option would have been exercisable to the extent then exercisable (or, in the administrator's discretion, any such options being made partially or fully exercisable) and (b) the aggregate exercise price of those options;

- provide that outstanding awards will be assumed or substituted for shares of the successor corporation, become realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the corporate transaction; and

- terminate outstanding stock grants in exchange for payment of any amount equal to the consideration payable upon consummation of the corporate transaction to a holder of the same number of shares comprising the stock grant, to the extent the stock grant is no longer subject to any forfeiture or repurchase rights (or, at the administrator's discretion, all forfeiture and repurchase rights being waived upon the corporate transaction).

Amendment and Termination. The Plan will terminate in December 2030 or at an earlier date by vote of the stockholders or our Board of Directors; provided, however, that any such earlier termination shall not affect any awards granted under the Plan prior to the date of such termination. The Plan may be amended by our Board of Directors, except that our Board of Directors may not alter the terms of the Plan if it would adversely affect a participant's rights under an outstanding stock right without the participant's consent. Stockholder approval will be required for any amendment to the Plan to the extent such approval is required by law, include the Internal Revenue Code or applicable stock exchange requirements.

On June 20, 2021, the Board approved a resolution to increase the shares of common available under the Plan from 7,000,000 to 10,000,000 shares and, on July 22, 2021, the holders of a majority of our voting stock approved such increase.

Director Compensation

Effective upon the closing of the Acquisition on December 24, 2020, our board appointed Oded Bashan, Aharon Klein, Ohad Bashan, Ron Mayron and, Yaniv Cohen to the board of directors. Messrs. Yoram Drucker and David Lazar continue to serve on the board. Following the closing of the Acquisition, the directors appointed Oded Bashan as the Chairman of the Board.

Non-Employee directors, who are currently comprised of Oded Bashan, Ohad Bashan, Ron Mayron and David Lazar, are compensated by an annual cash fee of $5,000 payable on a biannual basis (every June 1 and December 1) and an additional fee of $1,000 per Board meeting and $300 per consent or telephonic Board meeting. In addition, audit committee members receive an $500 per audit committee meeting.

In addition, as of January 20, 2021 each director is entitled to receive under the 2020 Incentive Plan options to purchase 240,000 shares of our common stock at a per share exercise price of $0.32. The option have different vesting periods through December 31, 2022. The options were granted on June 20, 2021, following the submission to the Israeli Tax Authorities of the Israeli Appendix to the 2020 Incentive Stock Plan.

Each of Messrs. Drucker, Mayron and Lazar were issued 240,000 options, of which 120,000 were vested upon issuance and the balance vest at the end of each calendar quarter at the rate of 20,000 shares per quarter, beginning with the quarter ending September 30, 2021. The options are exercisable through the tenth anniversary of grant.

Each of Messrs. Oded Bashan, Ohad Bashan, Klein and Cohen were issued 240,000 options, of which 160,000 vested immediately upon issuance and the balance vest at the end of each calendar quarter at the rate of 20,000 shares per quarter, beginning with the quarter ended September 30, 2021. The options are exercisable through the tenth anniversary of grant

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the number of shares of our common stock beneficially owned as of October 27, 2021, by (i) each of our current directors and named executive officers, (ii) all executive officers and directors as a group, and (iii) each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock. We have determined beneficial ownership in accordance with applicable rules of the SEC, which generally provide that beneficial ownership includes voting or investment power with respect to securities. Except as indicated by the footnotes to the table below, we believe, based on the information furnished to us, that the persons named in the table have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

The information set forth in the table below is based on 64,601,651 shares of our common stock issued and outstanding as of October 27, 2021. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants or other convertible securities held by that person that are currently exercisable or will be exercisable within 60 days after October 27, 2021. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as otherwise noted in the footnotes below, the address for each person listed in the table below, solely for purposes of filings with the SEC, is c/o IR-Med, Inc. ZHR Industrial Zone, Rosh Pina Israel.

Name and Address of Beneficial Owner	Number of Shares beneficially owned	Percentage Beneficially owned
5% or more shareholders		
Yaakov Safren[(1)]	5,706,119	8.64%
Paul Coulson[(2)]	5,625,000	8.46%
Third Eye Investors LLC[(3)]	4,687,500	6.92%
Officers and Directors		
Oded Bashan[(4)]	8,789,916	13.57%
Aharon Klein[(5)]	8,039,110	12.40%
Yaniv Cohen[(6)]	8,039,136	12.40%
Yoram Drucker[(7)]	4,762,471	7.30%
David Lazar[(8)]	890,000	1.37%
Ron Mayron[(9)]	140,0000	*
Ohad Bashan[(9)]	180,000	*
Rom Eliaz[(10)]	—	*
Aharon Binur[(11)]	30,000	*

Sharon Levkoviz[12]	136,188	*
David Levy [13]	3,850,607	5.96%
Officers and Directors as a Group (11 persons)	34,857,428	52.39%

* less than 1%

[1] Comprised of (i) 4,300,000 shares common stock and (ii) 1,406,119 shares of common stock issuable upon the exercise of vested stock options issued in consideration of consulting services provided to the Company.

[2] Includes 1,875,000 shares Mr. Coulson has the right to acquire through the exercise of a common stock warrant.

[3] Includes1,562,500 shares Third Eye Investors LLC has the right to acquire through the exercise of a common stock warrant.

[4] Comprised of (i) 8,609,916 shares of common stock held by and through Med2Bwell Ltd. and (ii) 180,000 shares of common stock issuable upon the exercise of employee stock options exercisable through September 30, 2021. Does not include an additional 60,000 shares of common stock issuable upon exercise of stock options exercisable through June30, 2022.

[5] Comprised of (i) 7,859,110 shares of common stock and (ii) 180,000 shares of common stock issuable upon the exercise of employee stock options exercisable through September 30, 2021. Does not include an additional 60,000 shares of common stock issuable upon exercise of stock options exercisable through June 30, 2022.

[6] Comprised of (i) 7,859,136 shares of common stock and (ii) 180,000 shares of common stock issuable upon the exercise of employee stock options exercisable through September 30, 2021. Does not include an additional 60,000 shares of common stock issuable upon exercise of stock options exercisable through June 30, 2022.

[7] Comprised of (i) 4,050,000 shares of common stock and (ii) 712,471 shares of common stock issuable upon the exercise of employee stock options exercisable through September 30, 2021. Does not include an additional 100,000 shares of common stock issuable upon exercise of stock options exercisable through December 31, 2022.

[8] Comprised of (i) 750,000 shares of common stock and (ii) 140,000 shares of common stock issuable upon the exercise of employee stock options exercisable through September 30, 2021. Does not include an additional 100,000 shares of common stock issuable upon exercise of stock options exercisable through December 31, 2022.

[9] Represents shares of common stock issuable upon the exercise of employee stock options exercisable through September 30, 2021. Does not include an additional 60,000 shares of common stock issuable upon exercise of stock options exercisable through June 30, 2022.

[10] Does not include 450,000 shares of common stock issuable upon warrants which vest at the rate of 75,000 shares per each bi-annual period beginning December 31, 2021.

[11] Represents shares of common stock issuable upon the exercise of employee stock options exercisable through September 30, 2021. Does not include an additional 270,000 shares of common stock issuable upon exercise of stock options exercisable through March 31, 2026

[12] Represents shares of common stock issuable upon the exercise of employee stock options exercisable through September 30, 2021. Does not include an additional 254,733 shares of common stock issuable upon exercise of stock options exercisable through June 30, 2024

[13] Represents shares of common stock held through Liat Electronics, Ltd. Mr. Levy is a director on the board of directors of our wholly owned subsidiary IR-Med Ltd.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Except as set out below, as of December 31, 2020, there have been no transactions, or currently proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of the following persons had or will have a direct or indirect material interest:

- any director or executive officer of our company;
- any person who beneficially owns, directly or indirectly, shares carrying more than 5% of the voting rights attached to our outstanding shares of common stock;
- any promoters and control persons; and
- any member of the immediate family (including spouse, parents, children, siblings and in laws) of any of the foregoing persons.

In 2015, our subsidiary IR-Med, Ltd received a loan from certain of the former IR-Med stockholders to fund its continuing operations. This loan bore interest at an annual rate ranging in 2020 and 2019, from 2.56%-2.62% annually. The aggregate loan amount was repayable only upon the approval of IR Med's board of directors and when the Company's profits reach an amount of NIS 1,500,000 (approximately $467,000 as of December 31, 2020) and upon such terms and such installments as shall be determined by the Company's board of directors.

In 2017, our subsidiary IR Med, Ltd received a loan from certain of the former IR-Med stockholder to fund its continuing operations. This loan bear interest at an annual rate ranging in 2020 and 2019, from 2.56%-2.62% annually. The aggregate loan amount was repayable only upon the occurrence of an investment round greater than $500,000.

In March, 2020, the Company and the lenders agreed to amend and restate the terms of the above referenced loans ("the Amended loan agreement") pursuant to which the lender waived all rights to convert their respective outstanding loan amounts, and the repayment date was set to December 31, 2023, or such later date to be agreed between the Company and the lender. As of December 31, 2020 and 2019 the carrying amounts of these loans were $38,000 and $31,000.

On March 6, 2018, some of the Company's shareholders advanced to our subsidiary IR-Med Ltd, a convertible bridge loan in the principal amount of NIS 379,000 ($113,000) (hereinafter, the "2018 CLA"), bearing a per annum interest rate of 3% compounded and accrued annually and, originally payable on December 31, 2018, or a later date agreed to by the then holders of 80% of the outstanding shares of IR Med. Under the terms of the 2018 CLA, the loan is convertible by the holders under certain specified circumstances and is automatically convertible upon other terms. In an Exit event (as deveined in the 2018 CLA), the loan is repayable at 200% the outstanding amount or converted, at the option of the majority lenders. In March, 2020, the Company and the lenders agreed to amend and restate the 2018 CLA ("the Amended CLA"). According to the Amended CLA, the lenders waived any and all rights to convert their respective outstanding loan amounts, and the repayment date was set to December 31, 2023, or such later date to be agreed by IR Med and the lenders. 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. As of December 31, 2020 and 2019, the carrying amounts of the loans were $128,000 and $116,000, respectively. The Company classified the 2018 CLA as a long term liability on its balance sheets.

In the course of 2020 and 2019, IR-Med Ltd paid to two of our directors an aggregate of $93,000 and $25,000, respectively, in respect of research and development services.

In the course of 2020 and 2019, IR-Med Ltd. paid $15,000 and $20,000, respectively, to an entity controlled by two of our directors in respect of rent and office services for our premises.

Upon the effectiveness of the Acquisition, the 10,000,000 shares of Series A Preferred Stock then outstanding were converted into 15,000,000 common stock. Of these, our directors Yoram Drucker and David Lazar and our shareholder Yaacov Safren, were issued 4,050,000, 750,000 and 4,300,001, respectively, of common stock upon conversion of the 2,700,000, 500,000 and 2,866,667 shares Series A Preferred Stock, respectively, then held by them.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Article VIII of our Second Amended and Restated Articles of Incorporation provides that, to the fullest extent permitted by law, no director or officer shall be personally liable to the corporation or its shareholders for damages for breach of any duty owed to the corporation or its shareholders.

Article IX of our Second Amended and Restated Articles of Incorporation provides that, to the fullest extent permitted by the General Corporation Law of the State of Nevada we will indemnify our officers and directors from and against any and all expenses, liabilities, or other matters.

Article V of our Bylaws further addresses indemnification of our directors and officers and allows us to indemnify our directors in the event they meet certain criteria in terms of acting in good faith and in an official capacity within the scope of their duties, when such conduct leads them to be involved in a legal action.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

AVAILABLE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the resale of shares of our common stock by the Selling Shareholders. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us, our common stock and the Selling Shareholders, reference is made to the registration statement and the exhibits filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and in each instance we refer you to the copy of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, NE, Washington, DC 20549, and copies of all or any part of the registration statement may be obtained from that office upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

Upon effectiveness of this registration statement, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, we will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

LEGAL MATTERS

The validity of the common stock being offered by this prospectus is being passed upon by Aboudi Legal Group PLLC.

EXPERTS

The consolidated financial statements of IR-Med Inc. as of December 31, 2020 and 2019 and for each of the years in the two-year period ended December 31, 2020, have been included herein in reliance upon the report of Somekh Chaikin, a member firm of KPMG International independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

Aboudi Legal Group PLLC serves as our legal counsel in connection with this offering. Mr. Aboudi holds options to purchase 350,000 shares of our Common stock at an exercise price per share of $0.32.

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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. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, 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.

Somekh Chaikin
Member Firm of KPMG International

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

Tel Aviv, Israel
May 7, 2021

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

Consolidated Balance Sheets as of December 31

	Note	December 31 2020	December 31 2019
		US Dollars (In thousands)	
Assets			
Current assets			
Cash and cash equivalents	4	**1,866**	235
Accounts receivable	5	**218**	13
Total current assets		**2,084**	248
Non-current assets			
Property and equipment, net	6	**6**	7
Total non-current assets		**6**	7
Total assets		**2,090**	255
Liabilities and stockholders' equity (deficit)			
Current liabilities			
Trade and other payables	7	**523**	189
Total current liabilities		**523**	189
Non-current liabilities			
Stockholders' loans	8	**166**	147
Total non-current liabilities		**166**	147
Total liabilities		**689**	336
Contingent Liabilities and Commitments	11		
Stockholders' equity (deficit)	10		
Common Stock, par value $0.001 per share, 250,000,000 shares authorized: 53,586,023 and 30,185,183 issued and outstanding as of December 31, 2020 and 2019, respectively		**54**	*29
Capital reserve		**24**	24
Additional paid-in capital		**2,803**	*594
Accumulated deficit		**(1,480)**	(728)

Total Stockholders' equity (deficit)		**1,401**	(81)
Total liabilities and stockholders' equity (deficit)		**2,090**	255

(*) Share capital was retroactively adjusted using the exchange ratio established pursuant to the Stock Exchange Agreement to reflect the capital of the legal entity (the Parent Company), see also Note 10A.

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

Consolidated Statements of Operations

	Note	For the year ended December 31, 2020	For the year ended December 31, 2019
		US Dollars (In thousands)	
Research and development expenses	12	**409**	61
General and administrative expenses	13	**321**	150
Total operating loss		**730**	211
Financial expenses	14	**22**	37
Loss for the year		**752**	248
Loss per share			
Basic and dilutive loss per common stock (in dollars)	15	**(0.02)**	*(0.01)

(*) Share capital was retroactively adjusted using the exchange ratio established pursuant to the Stock Exchange Agreement to reflect the capital of the legal entity (the Parent Company), see also Note 10A.

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

Consolidated Statement of Changes in Stockholders' Equity (Deficit)

	Common Stock		Capital Reserve	Additional paid-in Capital	Accumulated deficit	Total
	Number of shares	US dollars (In thousands)				
Balance as of January 1, 2020	**30,185,183**	**29**	**24**	**594**	**(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**	**24**	**2,803**	**(1,480)**	**1,401**
Balance as of January 1, 2019	*28,896,912	*29	4	*248	(480)	(199)
Effect of early adoption of ASU 2018-07 (***)	-	-	-	14	-	14
Issuance of common stock, net	*1,288,271	**	-	300	-	300
Capital reserve for transaction with related parties	-	-	20	-	-	20
Loss for the year	-	-	-	-	(248)	(248)
Liability reclassified to equity (see note 9A)	-	-	-	32	-	32
Balance as of December 31, 2019	*30,185,183	*29	24	*594	(728)	(81)

(*) Adjusted to reflect the share capital of the combined entity, see also Note 10A.
(**) Represents an amount less than US$ 1 thousand.
(***) See Note 2(J) and Note 9 for the adoption of ASU 2018-07

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

Consolidated Statements of Cash Flows

	For the year ended December 31, 2020	For the year ended December 31, 2019
	US Dollars (In thousands)	
Cash flows from operating activities		
Loss for the year	**(752)**	(248)
Adjustments to reconcile loss for the year to net cash used inoperating activities:		
Depreciation	**1**	2
Compensation related to warrants issued to service providers	**25**	-
Capital reserve from transaction with related parties	**-**	20
Increase in accrued interest and exchange rates on Stockholders' loans	**20**	37
Increase in accounts receivable	**(16)**	(7)
Increase in trade and other payables	**320**	124
Net cash used in operating activities	**(402)**	(72)
Cash flows from financing activities		
Proceeds from issuance of common stock, net	**81**	300
Proceeds from private placement of common stock and warrants, net	**1,955**	-
Net cash provided by financing activities	**2,036**	300
Effect of exchange rate changes on cash	**(3)**	(5)
Net increase (decrease) in cash and cash equivalents	**1,631**	223
Cash and cash equivalents as at the beginning of the year	**235**	12
Cash and cash equivalents as at the end of the year	**1,866**	235
Non-cash financing Activities:		
Increase in other receivable from shares issuance	**189**	-

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

Notes to the Consolidated Financial Statements

Note 1 - General

A. Description of Business

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

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

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

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, 2020, the Company has incurred losses of US$ 752 thousand and had a negative cash flow from operating activities of US$ 402 thousand. The accumulated deficit as of December 31, 2020 is US$ 1,480 thousand.

Management's plans regarding these matters include continued development and marketing of its products, as well as seeking additional financing arrangements. Although management continues to pursue these plans, there is no assurance that the Company will be successful in raising the needed capital from revenues or financing on commercially acceptable terms. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Between January 2021 and April 2021, the Company raised additional gross proceeds of approximately $3,525 thousand from the 2020 Private Placement.

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. 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. Actual results could differ from those estimates.

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.

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

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:

	%
Computers and software	10-33
Furniture and equipment	15

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, patents, salaries and related personnel expenses and travel 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.

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.

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

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.

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 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.

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. 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 2020	December 31 2019
	US Dollars (In thousands)	
Cash - NIS	**16**	25
Cash - US dollars	**1,850**	210
	1,866	235

Note 5 - Accounts Receivable

	December 31 2020	December 31 2019
	US Dollars (In thousands)	
Funds in trust	**189**	-
Prepaid expenses	**4**	-
Government institutions	**22**	9
Related parties	**3**	3
Other	**-**	1
	218	13

Note 6 – Property and Equipment, Net

	December 31 2020	December 31 2019
	US Dollars (In thousands)	
Computers and software	**1**	1
Furniture and equipment	**10**	10
	11	11
Less - accumulated depreciation	**(5)**	(4)
	6	7

Note 7 - Trade and Other Payables

	December 31 2020	December 31 2019
	US Dollars (In thousands)	
Trade payables	**25**	35
Accrued expenses	**462**	136
Payroll and related	**19**	2
Government institution	**-**	1
Related Parties	**17**	14
Other	**-**	1
	523	189

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 2020 and 2019 from 2.56% 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, 2020, and 2019, the carrying amounts of the 2015 Loans were US$35 thousand and US$ 28 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 2020 and 2019, from 2.56% 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.

Note 8 - Stockholders' Loans (Cont'd)

In March 2020, the Company and the lender agreed to amend the terms of the 2017 Loan and the repayment date was set to December 31, 2023.

As of December 31, 2020, and 2019, the carrying amounts of the 2017 Loan were US$ 3.5 thousand and US$ 3 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**.**

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 2020 and 2019 were US$ 5 thousand and US$4 thousand, respectively.

As of December 31, 2020 and 2019, the carrying amounts of the loans were US$128 thousand and US$ 116 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 NIS 0.01 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.

   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 into 59,910 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 (Deficit)

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.

Note 10 - Stockholders' Equity (Deficit) (Cont'd)

A. Common Stock (Cont'd)

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 October and December 2019, IR. Med Ltd. signed investment agreements according to which the Company issued 149,799 shares of common stock for a total consideration of approximately USD 300 thousand.

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

(iii) On July 16, 2020, the Parent Company signed a private placement agreement (hereinafter: the "July 2020 Private Placement Agreement") with an investor (hereinafter: the "Investor") in a total consideration of $50,000. According to the July 2020 Private Placement Agreement, the Parent Company shall issue to the Investor 217,391 units of its securities (hereinafter: "Unit" and collectively the "Units") at a price per Unit of $0.23. Each Unit is 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.

(iv) In connection with the Reverse Acquisition, the Parent Company signed another private placement agreement (hereinafter: the "November 2020 Private Placement") with existing and new investors (hereinafter: the "Investors") in a total consideration of $2,144,908, net of issuance cost of $161,092. According to the November 2020 Private Placement Agreement, subject to the closing of the Reverse Acquisition, the Parent Company shall 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.

Following the closing of the Reverse Acquisition, on December 24, 2020, the Parent Company had issued the Investors 7,206,250 common stock at a par value of $0.001 per share and 3,603,125 warrants (hereinafter: the "November 2020 Private Placement Warrant").

(v) As of April, 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.

Note 10 - Stockholders' Equity (Deficit) (Cont'd)

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, 2020 no equity awards were granted by the Parent Company.

Accordingly, no expense was recorded in 2020 and 2019.

Note 11 - Contingent Liabilities and Commitments

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, 2020 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 $355 thousand (including interest in the amount of $28 thousand).

For the years ending December 31, 2020 and 2019 no additional IIA grants were obtained.

Note 12 - Research and Development Expenses

	For the year ended December 31 2020	For the year ended December 31 2019
	US Dollars (In thousands)	
Clinical trials	-	9
Subcontractors	393	48

Other expenses	**16**	4
Total research and development expenses	**409**	61

Notes to the Consolidated Financial Statements

Note 13 - General and Administrative Expenses

	For the year ended December 31 2020	For the year ended December 31 2019
	US Dollars (In thousands)	
Salaries and related expenses	**15**	-
Professional expenses	**283**	125
Rent and Maintenance	**18**	22
Depreciation	**1**	2
Other expenses	**4**	1
Total general and administrative expenses	**321**	150

Note 14 - Financial Expenses

	For the year ended December 31 2020	For the year ended December 31 2019
	US Dollars (In thousands)	
Other	**1**	-
Warrants revaluation	**-**	20
Interest expenses on loans	**9**	4
Exchange rate loss	**12**	13
Total financial expenses	**22**	37

Notes to the Consolidated Financial Statements

Note 15 - Loss per share

The calculation of basic and diluted losses per share for the years ended on December 31, 2020 and 2019 was based on the losses attributable to the Company's ordinary stockholders for the period divided by a weighted average number of ordinary shares outstanding, adjusted to reflect the new equity structure resulting from the Reverse Acquisition, calculated as follows:

	For the year ended December 31 2020	For the year ended December 31 *2019
Loss attributable to shareholders ($ in thousands)	**(752)**	(248)
Weighted average number of ordinary shares:		
Balance at beginning of year	**29,688,988**	28,896,912
Effect of shares issued during the period	**343,510**	10,736
Weighted-average shares - basic as at end of year	**30,032,498**	28,907,648
Effect of dilutive share	**-**	-
Weighted-average shares - dilutive as at end of year	**30,032,498**	28,907,648
Basic and dilutive loss per share ($)	**(0.02)**	(0.01)

As of December 31, 2020, total number of warrants which granted by the Group's board of directors and not included in the loss per share computation is 4,170,516.

(*) Share capital was retroactively adjusted using the exchange ratio established pursuant to the Stock Exchange Agreement to reflect the capital of the legal entity (the Parent Company), see also Note 10A.

Note 16 - Income Taxes

A. Corporate tax rate

a) The tax rates relevant to the Parent company in Nevada for the years 2019-2020 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 2019-2020 was 23%.

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 16 - Income Taxes (Cont'd)

B. Deferred tax assets

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

	December 31 2020	December 31 2019
	US Dollars (In thousands)	
Operating loss carry forward	**252**	148
Research and development costs	**69**	16
Gross total deferred tax assets	**321**	164
Valuation allowance for deferred tax assets	**(321)**	(164)
Net deferred tax assets	**-**	-

C. Net operating losses carry forward

As of December 31, 2020, and 2019, the Company had incurred carry forward losses for tax purposes in the amount of US$ 1,096 thousand and US$ 644 thousand, respectively.

As of December 31, 2020, and 2019, the Company has provided full valuation allowance of US$ 321 thousand and US$ 164 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, 2020, the Company have tax assessments that are considered as final due to lapse of statute of limitation period, through tax year 2014. The Parent Company has not been assessed for tax purposes since its inception.

Note 16 - 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 2020	For the year ended December 31 2019
	US Dollars (In thousands)	
Loss before taxes as reported in the statements of operations	**(752)**	(248)
Statutory tax rate	**21%**	21%
Theoretical tax benefit on the above amount at the Israeli statutory tax rate	**(158)**	(52)
Additional tax (tax savings) in respect of:		

Differences in tax rates between statutory tax and income tax of the Subsidiary*	**(15)**	(10)
Current year tax losses and benefits for which deferred taxes were not created.	**173**	62
Actual taxes on income	**-**	-

(*) The Subsidiary operates in Israel in a tax jurisdiction with corporate tax rate of 23%.

Notes to the Consolidated Financial Statements

Note 17- Related Parties Balances and Transactions

A. Balances with related parties

	December 31 2020	**December 31 2019**
	US Dollars (In thousands)	
Assets		
Other receivables	**3**	3
Liabilities		
Payables	**46**	35
Stockholders' loans	**166**	147

B. Transactions with related parties

	For the year ended December 31 2020	**For the year ended December 31 2019**
	US Dollars (In thousands)	
R&D Subcontractors	**93**	25
Rent and Maintenance[(1)]	**15**	20
Interest expenses	**9**	4

(1) During 2019 the Company used an office facility and received office services from a related party for no consideration. The Company recorded a capital reserve for transaction for with related parties in respect of the benefit received.

IR-Med, Inc.
and subsidiary

Interim Condensed Consolidated Financial Statements

As of June 30, 2021

(Unaudited)

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IR-Med Inc.

Interim Unaudited Condensed Consolidated Balance Sheets

	June 30 2021	December 31 2020
	U.S dollars (in thousands)	
Assets		
Current assets		
Cash and cash equivalents	**4,225**	1,866
Short term restricted deposit	**12**	-
Accounts receivable	**92**	218
Total current assets	**4,329**	2,084
Non- current assets		
Property plant and equipment, net	**16**	6
Total assets	**4,345**	2,090
Liabilities and Stockholders' equity		
Current liabilities		
Trade and other payables	**299**	523
Non-current liabilities		
Stockholders' loans	**167**	166
Total non-current liabilities	**167**	166
Total liabilities	**466**	689
Stockholders' Equity		
Common Stock, par value $0.001 per share, 250,000,000, shares authorized as of June 30, 2021 and December 31, 2020; 64,601,649 and 53,586,023 shares issued as of June 30, 2021 and December 31, 2020, respectively	**64**	54
Additional paid-in capital	**7,261**	2,827
Accumulated deficit	**(3,446)**	(1,480)
Total Stockholders' equity	**3,879**	1,401
Total liabilities and Stockholders' equity	**4,345**	2,090

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

IR-Med Inc.

Interim Unaudited Condensed Consolidated Statements of Operations

	For the three months period ended June 30		For the six months period ended June 30	
	2021	2020	2021	2020
	U.S dollars (in thousands)			
Research and development expenses	**391**	96	**495**	146
Marketing expenses	**593**	-	**763**	-
General and administrative expenses	**532**	68	**690**	111
Total operating loss	**1,516**	164	**1,948**	257
Financial expenses, net	**6**	11	**18**	2
Loss for the period	**1,522**	175	**1,966**	259
Basic and dilutive loss per common stock (in dollars)	(0.02)	*(0.005)	(0.03)	*(0.01)

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

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

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

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of shares	Amount			
		U.S dollars (in thousands)			
For the six months period ended June 30, 2021					
Balance as of January 1, 2021	**53,586,023**	**54**	**2,827**	**(1,480)**	**1,401**
Private placement of common stock and warrants, net	**11,015,626**	**10**	**3,367**	-	**3,377**
Stock-based compensation	-	-	**1,067**	-	**1,067**
Loss for the period	-	-	-	**(1,966)**	(1,966)
Balance as of June 30, 2021	**64,601,649**	**64**	**7,261**	**(3,446)**	**3,879**

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' deficit
	Number of shares	Amount			
		U.S dollars (in thousands)			
For the six-months period ended June 30, 2020					
Balance as of January 1, 2020	*30,185,183	*29	*618	(728)	*(81)
Loss for the period	-	-	-	(259)	(259)
Balance as of June 30, 2020	*30,185,183	*29	*618	(987)	*(340)

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

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

Interim Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total stockholders' equity
	Number of shares	Amount			
		U.S dollars (in thousands)			
For the three months period ended June 30, 2021					
Balance as of April 1, 2021	**63,976,649**	**64**	**6,011**	**(1,924)**	**4,151**
Private placement of common stock and warrants, net	**625,000**	*	**183**	**-**	**183**
Stock-based compensation	**-**	**-**	**1,067**	**-**	**1,067**
Loss for the period	**-**	**-**	**-**	**(1,522)**	**(1,522)**
Balance as of June 30, 2021	**64,601,649**	**64**	**7,261**	**(3,446)**	**3,879**

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

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total stockholders' deficit
	Number of shares	Amount			
		U.S dollars (in thousands)			
For the three-months period ended June 30, 2020					
Balance as of April 1, 2020	*30,185,183	*29	*618	(812)	*(165)
Loss for the period	**-**	**-**	**-**	(175)	(175)
Balance as of June 30, 2020	*30,185,183	*29	*618	(987)	*(340)

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

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

Interim Unaudited Condensed Consolidated Statements of Cash Flows

	For the six-months period ended	
	June 30 2021	June 30 2020
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	**(1,966)**	(259)
Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	**1,067**	-
Depreciation	**2**	1
Compensation related to warrants issued to service providers	**-**	25
Increase in accrued interest and exchange rates on stockholders' loans	**1**	2
Decrease (increase) in accounts receivable	**125**	(1)
Increase (decrease) in trade and other payables	**(225)**	49
Net cash used in operating activities	**(996)**	(183)
Cash flows from investing activities		
Purchase of property and equipment	**(12)**	-
Investment in restricted deposit	**(12)**	-
Net cash used in investing activities	**(24)**	-
Cash flows from financing activities		
Proceeds from private placement of common stock and warrants, net (see also Note 1.B)	**3,377**	-
Net cash provided by financing activities	**3,377**	**-**
Effect of exchange rate changes on cash	**2**	(1)
Net increase (decrease) in cash and cash equivalents	**2,359**	(184)
Cash and cash equivalents as at the beginning of the period	**1,866**	235
Cash and cash equivalents as at the end of the period	**4,225**	51

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

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 1 – General

A. Description of Business

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

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

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

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

B. - The Group is in its development stage and does not expect to generate significant revenue until such time as the Group shall have completed the design and development of its initial product candidate and obtained the requisite approvals to market the product. During the six-month period ended June 30, 2021, the Group incurred losses of US$ 1,966 thousand and had negative cash flows from operating activities of US$ 996 thousand. The accumulated losses as of June 30, 2021 is US$ 3,446 thousand.

Management's plans regarding these matters include continued development and marketing of its products, as well as seeking additional financing arrangements. Although management continues to pursue these plans, there is no assurance that the Group will be successful in raising the needed capital from revenues or financing on commercially acceptable terms. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Between January 2021 and April 2021, the Company raised in the aggregate $3,377,655 net of issuance cost of $147,345. According to the subscription agreements, the Group issued to the Investors 5,507,813 units of its securities (hereinafter: "Unit" and collectively the "Units") at a price per Unit of $0.64. Each Unit is comprised of two shares of IR-Med Inc.'s common stock and one warrant to purchase an additional share of IR-Med Inc.'s common stock, exercisable for a three years period from the date of issuance at a per share exercise price of $0.64, subject to certain limited adjustments.

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 - Interim Unaudited Financial Information

The accompanying unaudited financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements and therefore should be read in conjunction with the Company's Annual Report on for the year ended December 31, 2020.

In the opinion of management, all adjustments considered necessary for a fair statement, consisting of normal recurring adjustments, have been included. Operating results for the six months period ended June 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

Use of Estimates:

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

Note 3 - Significant Accounting Policies

These interim unaudited condensed consolidated financial statements have been prepared according to the same accounting policies as those discussed in the Company's Annual Report for the year ended December 31, 2020, excluding the following:

Stock Option Plan

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

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

Note 4 – Stock options plan

On June 20, 2021, the Parent Company awarded 7,534,843 and 180,000 options to purchase the Parent Company's common stock to the Company's employees and service providers, respectively, at an exercise price of US$ 0.32 and 0.01 per option respectively. 5,729,579 of these options from the total awarded options were vested upon grant and the vesting period of the rest of options ranges between 1-5 years and period expires between 3-10 years from the vesting date. The grant was approved following the adoption of the 2020 incentive stock plan (hereinafter: the "Plan") by the Board of Directors of 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 an expense of US$ 1,022,569 during the six-month and three-month periods ended June 30, 2021. The stock-based compensation expenses were recognized in the statements of operations as follows; US$ 179 thousands were recorded as research and development expenses, US$ 470 thousands were recorded as marketing expenses and US$ 373 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 six month period ended June 30, 2021, using the Black Scholes-Merton option-pricing model and the weighted-average assumptions used for such grants:

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

A. The Group used 0% as its expected dividend yield.

B. The Parent-Company common stocks are listed on the Over the Counter ("OTC"). However, the Group considers its share price as it is traded on OTC, as not to 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 a low number of transactions of the Parent Company's 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 unit of common stock and Warrants at a per unit exercise 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.