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Zacks Small-Cap Research

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IR-Med Inc. (OTCQB: IRME)

IRME: IR-Med announces 2nd quarter 2024 financial and operating results. The company is currently focusing on the PressureSafe and DiaSafe products. IR-Med is planning a U.S. national market uplisting in September or October of 2024.

Utilizing a Discounted Cash Flow process containing conservative estimates combined with other valuation methodologies, we believe IRME could be worth **$3.00** per share.

Current Price (8/19/24)	$0.51
Valuation	**$3.00**

OUTLOOK

IR-Med Inc. is a development stage medical device company whose initial device under advanced development is expected to be launched in the 2nd half of 2024 which detects pressure injuries in a non-invasive matter. Pressure Injuries affect over 2.5 million patients annually in the U.S. with the cost to treat and prevent exceeding $2.9 billion. The company has a second major product under development called DiaSafe, which is used to detect diabetic foot ulcers, a treatment market that exceeds $10.0 billion. We expect the company to raise additional capital in 2024. We believe the company will generate significant revenues in 2025.

SUMMARY DATA

52-Week High	**$1.65**
52-Week Low	**$0.51**
One-Year Return (%)	**-50.0**
Beta	**1.5**
Average Daily Volume (sh)	**206**
Shares Outstanding (mil)	**70.7**
Market Capitalization ($mil)	**$36.0**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**43**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Medical Device**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.0 A	$0.0 A	$0.1 E	$0.4 E	$0.5 E
2025					$5.5 E

EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.01 A	-$0.01 A	-$0.01 A	-$0.03 A	-$0.07 A
2023	-$0.02 A	-$0.02 A	-$0.02 E	-$0.01 A	-$0.07 A
2024	-$0.01 A	-$0.01 A	-$0.01 E	-$0.02 E	-$0.05 E
2025					-$0.01 E

Quarterly revenues may not equal annual revenues due to rounding.
Quarterly EPS may not equal annual EPS due to rounding or dilution.

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WHAT'S NEW

2nd Quarter 2024 Financial and Operating Results

The company released its 10-Q filing on August 13, 2024 and the results were largely in line with expectations. The company recorded no revenues in the quarter and research and development expenses decreased to $94,000 from $496,000 in the 2nd quarter of 2023. Gross R&D expenses were $249,000 but that amount was offset by $155,000 in grants received from the Israel innovation authority.

Marketing expenses were $28,000 in the 2nd quarter compared to $162,000 in the prior year period. General and administrative expenses decreased to $236,000 compared to $442,000 in 2nd quarter of 2023. The net loss for the quarter was ($366,000) compared to a loss of ($1.1) million in the prior year period. Net cash used in operations for the quarter was ($372,000).

Cash balances as of June 30, 2024 were $753,000 and net working capital was $422,000. The company has no traditional long-term debt.

The company recently announced that the Israeli innovation authority has recently approved a support plan in the amount of approximately $1.0 million to bring innovative products to market. 50% of this amount is in the form of a grant. $180,000 of that amount was utilized in the 1st quarter of 2024 and $155,000 was recognized in the 2nd quarter (see below).

FDA Listing

On April 9, 2024, the company announced that its PressureSafe decision support device has received U.S. Food and Drug Administration (FDA) listing for the indication of pressure injuries. PressureSafe is classified as a Class I device and is exempt from 510(k) premarket submission.

Ronnie Klein, CTO and Interim CEO stated*, "This regulatory milestone is a major step towards the commercial launch in the U.S. and signifies our commitment to advancing patient care and safety through cutting-edge medical devices. Following our successful usability studies for PressureSafe™ in Israel, we are expanding these studies into the U.S. and expect to commence with a major hospital network in 2024."*

PressureSafe achieved 92% efficacy in the early, non-invasive detection of pressure injuries, regardless of skin color, in a study conducted in Israel with the world's second largest HMO, Clalit. Nearly 1,500 scans were performed on 154 body locations.

In the U.S. alone, 60,000 patients die every year as a direct result of pressure injuries. Patient care cost per pressure injury ranges from $20,900 up to $151,700, for the 2.5 million patients per year who develop pressure injuries. Pressure injuries are one of the five most common harms experienced by patients and the second most common claim for lawsuits after wrongful death.

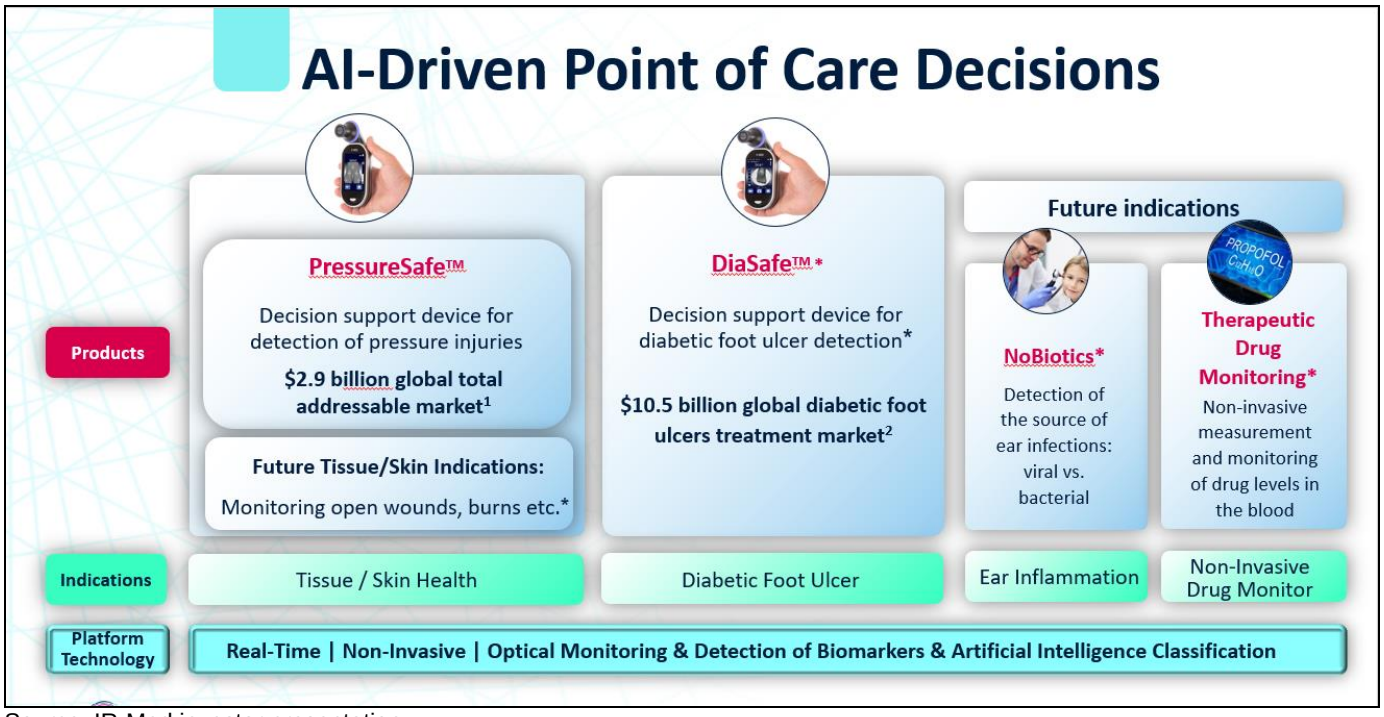
Registration of a device establishment or assignment of a registration number does not necessarily denote approval of the establishment or its products.

New Business Focus

During the 1st quarter of 2024 as a result of limited financial resources, the company narrowed its product development program to the development of decision support system solutions using its proprietary platform for the pre-emptive diagnosis of PIs and diabetic foot ulcers. The current business plan focuses on two principal medical devices:

1. PressureSafe - A handheld optical monitoring device that is being developed to support early detection of pressure injuries to the skin and underlying tissue, primarily caused by prolonged pressure associated with bed confinement. PressureSafe will launch also through U.S usability studies in the U.S. (Texas and NYC) in 2024. (see details below)

2. DiaSafe - A handheld optical monitoring device that is being developed to support early detection of diabetic foot ulcers in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole and diabetes. This device is currently under development. (see details below)



Source: IR-Med investor presentation

Nasdaq Uplisting

The company plans to list on the national market (NASDAQ/NYSE) in September or October of 2024. We believe the company is aiming to raise gross proceeds in the range of $6.0 million to $7.0 million.

New Clinical Efficacy Data for Detection of Pressure Injuries

On February 20, 2024, the company announced highly favorable proof of efficacy data for PressureSafe, its decision support device which uses infra-red spectroscopy combined with an AI-based algorithm for the early, non-invasive, and skin color agnostic detection of pressure injuries.

Data from the study was collected at two medical centers owned by Clalit, the world's second largest health maintenance organization and the largest in Israel, Beit Rivka Hospital and Rabin Medical Center. The results were presented at the National Pressure Injury Advisory Panel (NPIAP) 2024 Annual Conference on February 16 and 17, 2024 in San Antonio, Texas. Dr. Gal Maydan of Beit Rivka Hospital Geriatric Rehabilitation Center, and Principal Investigator of the study, presented the data in a poster titled *"Near Infra-Red Spectroscopy for early detection of stage 1 pressure injury and deep tissue injury – clinical study results".*

While the current standard of care for the detection of pressure injuries is visual and tactile clinical evaluation, physiological changes below the skin's surface, including inflammation and interstitial fluids happen before changes on the surface. The objective of the study was to evaluate the sensitivity, specificity, and usability of PressureSafe to detect early-stage pressure injuries Stage 1 / suspected deep

tissue injuries before skin breakage, compared to the current standard of care. PressureSafe detected biomarkers and changes in tissue structures under the skin's surface related to pressure injuries.

The 14-day efficacy portion of the single arm, bi-center study evaluated 38 patients at high risk of pressure injury development. A total of 924 scans were conducted on 154 body locations. Nurses conducting the scans were blinded to PressureSafe's results, which were encrypted. PressureSafe detected Stage 1 / sDTI pressure injuries with 92% sensitivity and 88% specificity. Additional portions of the study evaluated safety, as well as device calibration and validation. Total data from 66 patients was obtained for safety analysis and no significant safety signals were identified in 1,493 scans. Based on this data, the study concluded that PressureSafe is a safe, efficient, and valuable method for early detection of pressure injuries.

Dr. Maydan stated, *"This data demonstrates that PressureSafe, an IR-spectroscopy scanner combined with an AI- based algorithm, provides a very good option for detection of early stage pressure injuries - hence facilitating early treatment that is crucial for prevention of complications. This is especially important in diagnosis of people with darker skin colors, where visual and tactile inspection alone may miss early detection. Our medical staff, including nurses, found the device very easy to use. During the study period the incidence of pressure injuries was reduced by approximately 50% compared to the same period before the study. It is time to integrate advanced technology to augment standard human visual and tactile perception in order to minimize the harmful consequences of pressure injuries. PressureSafe is a device that I can see being used for exactly this purpose."*

Grant Received from Israel Innovation Authority for Development of DiaSafe

On July 15, 2024, the company announced it has received a grant from the Israel Innovation Authority (IIA) in the amount of $500,000 to develop its platform technology for a new decision support device for the early detection of diabetic foot ulcers. The grant's 13-month development timeline is proceeding on schedule with IR-MED having achieved its mid-point milestones. Computer simulations of infrared light reflectance from lesions under the skin surface have been completed, and based on these data, the company is building the DiaSafe device in accordance with the development plan agreed upon with the IIA.

DiaSafe is IR-MED's newest handheld device and is being designed to non-invasively analyze the biomarkers of blood and tissue at the point of care to help doctors and nurses prevent diabetic foot ulcers from developing in their diabetic patients.

The company believes an effective early detection device can reduce healthcare costs, save limbs, and save lives because diabetic foot ulcers are more cost effective to manage in their early stages. Detecting and treating diabetic foot ulcers early can significantly improve quality of life by reducing pain and increasing mobility. In addition, early intervention can reduce the death rates associated with diabetic foot complications.

Diabetic foot ulcers are a major cause of preventable death for people with diabetes, according to an article published in Diabetes Care, the journal of the American Diabetes Association. An estimated 537 million people globally have diabetes, and 19% to 34% of these, or up to 183 million people, will develop a diabetic foot ulcer during their lifetime. Of these, 20%, or up to 37 million people, will require lower-extremity amputation, and 10%, or 18 million people, will die within one year of their first diabetic foot ulcer diagnosis.

IR-MED's DiaSafe(TM) is based on the same platform technology as the Company's lead device, PressureSafe(TM) , a decision support device for the early detection of pressure injuries, which is expected to launch in the U.S. in the second half of 2024.

Ronnie Klein, IR-MED's Chief Technology Officer, stated, "*We are honored to be selected by the IIA for a second grant. This $500,000 covers 50% of our $1 million investment budget for the development of*

DiaSafe(TM) for our second indication in diabetic foot ulcers. Our powerful platform technology has the potential to change treatment paradigms and economics in a large number of multi-billion-dollar indications. We are eager to advance our development pipeline with the addition of DiaSafe(TM) , while PressureSafe(TM) is under usability study in the U.S."

Valuation and Estimates

The global market for Pressure Injury solutions is estimated to be $600 million in the U.S. and $2.9 billion on a global basis. Total global treatment market for diabetic foot ulcers is over $10.0 billion. Once FDA registration is received and commercialization commences for both products, we expect the company's revenues to grow at solid double-digit rates for at least the next 5 years. We expect gross margins to exceed 50% once widespread commercialization occurs.

Our primary valuation tool utilizes a Discounted Cash Flow process. Under the scenario described above, our DCF based valuation target is approximately **$3.00** per share. Our target price may be conservative as it utilizes a high discount rate of 15%.

Our 2024 full year revenue estimate is approximately $0.5 million, and our 2024 EPS estimate is a loss of ($0.05). We expect the first full year of meaningful revenue generation to occur in 2025, which we predict will total approximately $5.5 million. Our 2025 EPS estimate is ($0.01).

KEY INVESTMENT POINTS



Source: IR-Med investor presentation

- IR-Med, Inc. (OTCQB: IRME) is a development stage medical device company that is creating non-invasive devices to detect and measure various biomarkers and molecules in blood and in human tissue in real-time without resorting to invasive procedures.

- The company has two primary products under advanced development called PressureSafe for the detection of pressure injuries and DiaSafe which is used for the detection of diabetic foot ulcers.

- The FDA registration for PressureSafe is relatively straightforward and expedient as the device falls under the 510(k) regulatory process because it is considered a safe decision support device.

- Populations around the world are aging due to improvements in healthcare. When combined with other medical conditions such as obesity, this has resulted in more people needing assistance with activities of daily living due to decreased mobility which can create the development of Pressure Injuries.

- The company targets hospitals, nursing homes, and home healthcare operators for use of the PressureSafe device. The company believes this could be a $600 million revenue opportunity just in

the U.S. alone. The global addressable market could be as high as $2.9 billion. For DiaSafe, the global treatment market value exceeds $10.0 billion.

- The company is also in the early stage of developing an otoscope that distinguishes between bacterial and viral infections as well as a therapeutic drug monitoring device that can detect levels of drugs in patients without the use of blood tests.

- IR-Med is currently a development stage company with no revenues at this time and research & development expenses are estimated to be approximately $1.0 million in 2024 on a net basis after grant money is received.

- IR-Med Ltd is the wholly owned subsidiary of IR-Med Inc., which is a U.S. company. IR-Med Ltd was founded in 2013 and is headquartered in Rosh Pina, Israel.

- We believe IRME stock is worth $**3.00** based on a conservative discounted cash flow (DCF) calculation and a peer multiple comparison.



Source: IR-Med investor presentation

PRODUCT DESCRIPTIONS

PressureSafe

For the past six years, the company has been designing and developing PressureSafe, a novel device that has the potential to provide a reliable method of monitoring and recording patients providing additional information to healthcare providers as to where and when a PI may occur. The technology platform is designed to record information relating to each patient.



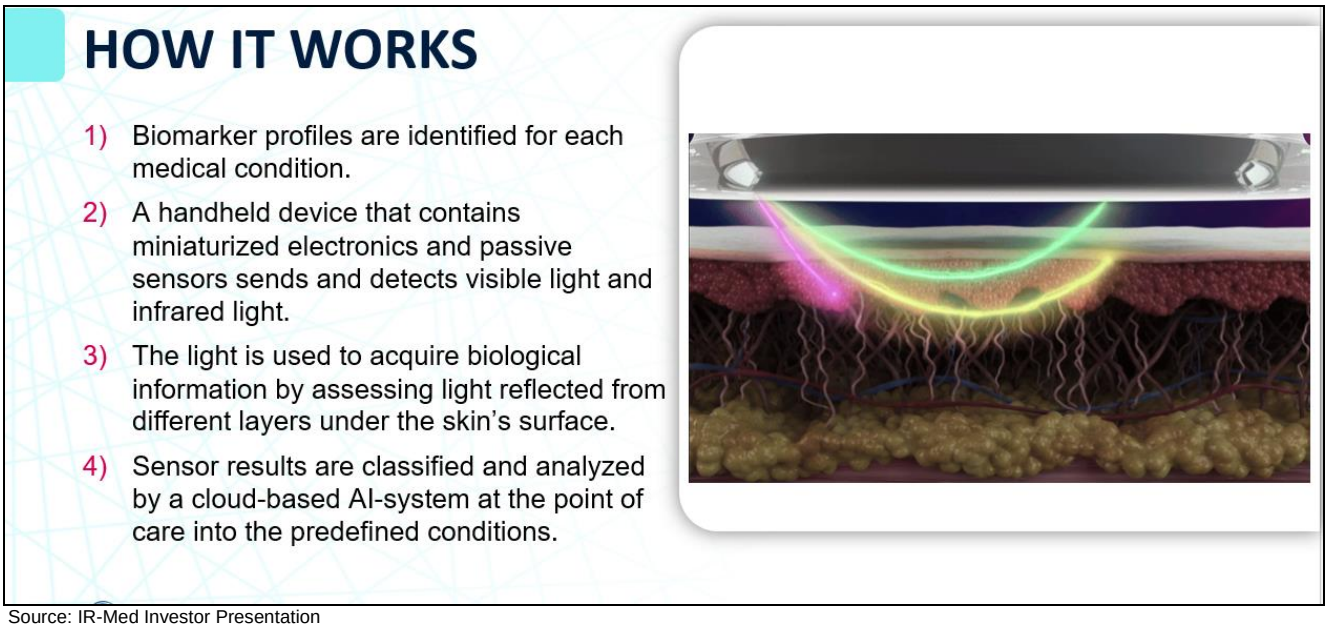
Source: IR-Med Investor Presentation

The technology is based on the fact that tissues of the human body absorb and reflect the light that is illuminating it from the device optic head in different wavelengths (from visual light to infra-red light) and the light is reflected and scattered back from within different depths of skin layers. 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.

PressureSafe is a non-invasive real-time optical monitoring device to support incipient PI detection through skin scans prior to skin breakage. The device performs a reflectance spectroscopy scan to generate information for the decision maker, while collecting data of subdermal physiological changes together with other bio-signals typical to early formation of PI in the three skin layers, which would detect the early appearance of life risking pressure injuries.

PressureSafe is designed to detect changes at the subepidermal layer in the skin, regardless of skin tone, by measuring differences at multi-bio markers. As soon as local subepidermal tissue function is disturbed, cells malfunction and deteriorate in their normal activities leading eventually to disintegration because of pressure excreted upon the skin over boney prominences. IR-Med 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.

The PressureSafe device is being designed to capture, analyze and identify tissue status to make early PI diagnosis using Spectrographic Analysis while AI based learning software is planned to improve the level of accuracy in the readings. The PressureSafe device will illuminate the skin with a miniature set of LEDs for less than a second. The emitted light photons from the device are absorbed, scattered and reflected back. The device will then measure the absorption and reflectance, and using algorithms, will process the signals to identify and provide data of under the skin invisible tissues of the scanned area.



Source: IR-Med Investor Presentation

As every person's skin properties are unique, the device auto calibrates to the specific patient's skin that takes merely a few seconds and allows personalized high accuracy diagnosis, improving diagnostic process effectiveness as the PressureSafe device is designed to be indifferent to the skin color. PressureSafe addresses this healthcare inequality in which people with darker skin tones are often difficult to detect PI. Research has shown that people with darker skin tones suffer PI at rates that are often twice that of those with lighter skin.

The technology is being developed to enable the assessment of different subepidermal layers by scanning through these skin layers which improves the identification of the damage and assessing the subepidermal damaged tissue volume, assisting with additional information to allow better treatment efficacy.

Measuring the differences at multi-biomarkers has been developed to detect early formation of pressure injuries and to "raise a flag" to allow the caregivers to intervene and prevent their appearance. The bio-signals that the algorithm detects occur in the early inflammatory process, as soon as local subcutaneous tissue function is disturbed, and cells begin to be damaged.

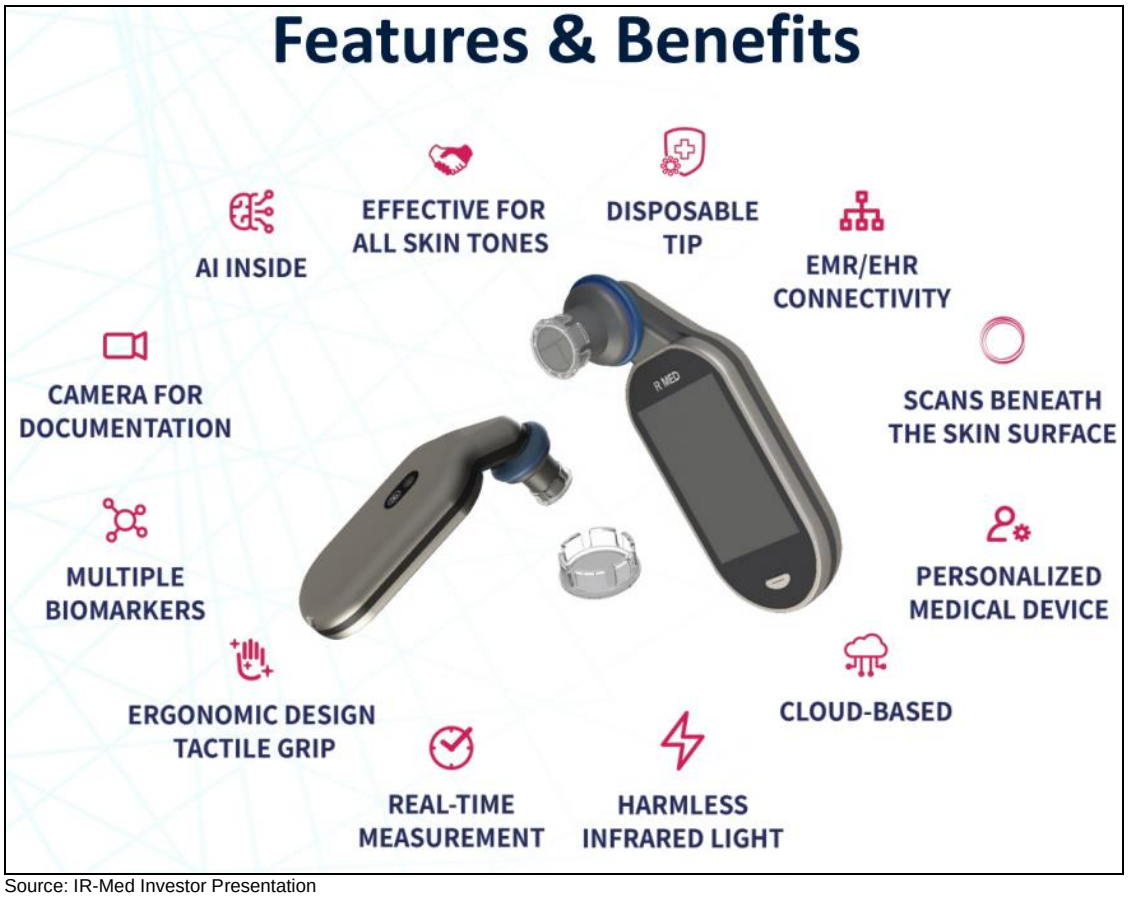
PressureSafe is a hand-held scanner designed to provide additional information as a decision support system (DSS), to support the caregiver effectively with the main diagnostic ability to identify PI and to differentiate between Deep Tissue PI (before it can be seen) and Stage 1 PI. The PressureSafe solution is composed of:

(a) a handheld optic probe device, which utilizes harmless infra-red light, that is placed for less than a second on suspected areas for performing measurements.

(b) a disposable probe tip component, changed between patients to avoid cross-contamination.

(c) a software component containing machine-learning algorithm for analyzing the collected data.

(d) software for connectivity and downloading the collected data and measurements results to the EMR/EHR systems used by the medical center or homecare company as well as to the IR-Med's cloud database.



Source: IR-Med Investor Presentation

The company expects to submit PressureSafe to the EU markets for approval in 2024 and expects approval and commercialization in 2025 in that market. The registration is relatively straightforward and expedient as the device falls under the 510(k) regulatory process because it is considered a safe decision support device. The company expects to begin selling PressureSafe devices through usability studies in 2026.

DiaSafe

The detection of Diabetic Foot Ulcers (DFU) is an important potential use of the PressureSafe technology. Diabetes can affect many parts of the body and is associated with serious complications, such as heart disease, stroke, blindness, kidney failure and lower-limb amputation. Studies suggest that the lifetime risk of developing a DFU is between 19% and 34% of diabetic patients. Infection develops in 50%–60% of ulcers and is a principal cause of damage in diabetic feet. Approximately 20% of moderate or severe diabetic foot infections result in lower extremity amputations.

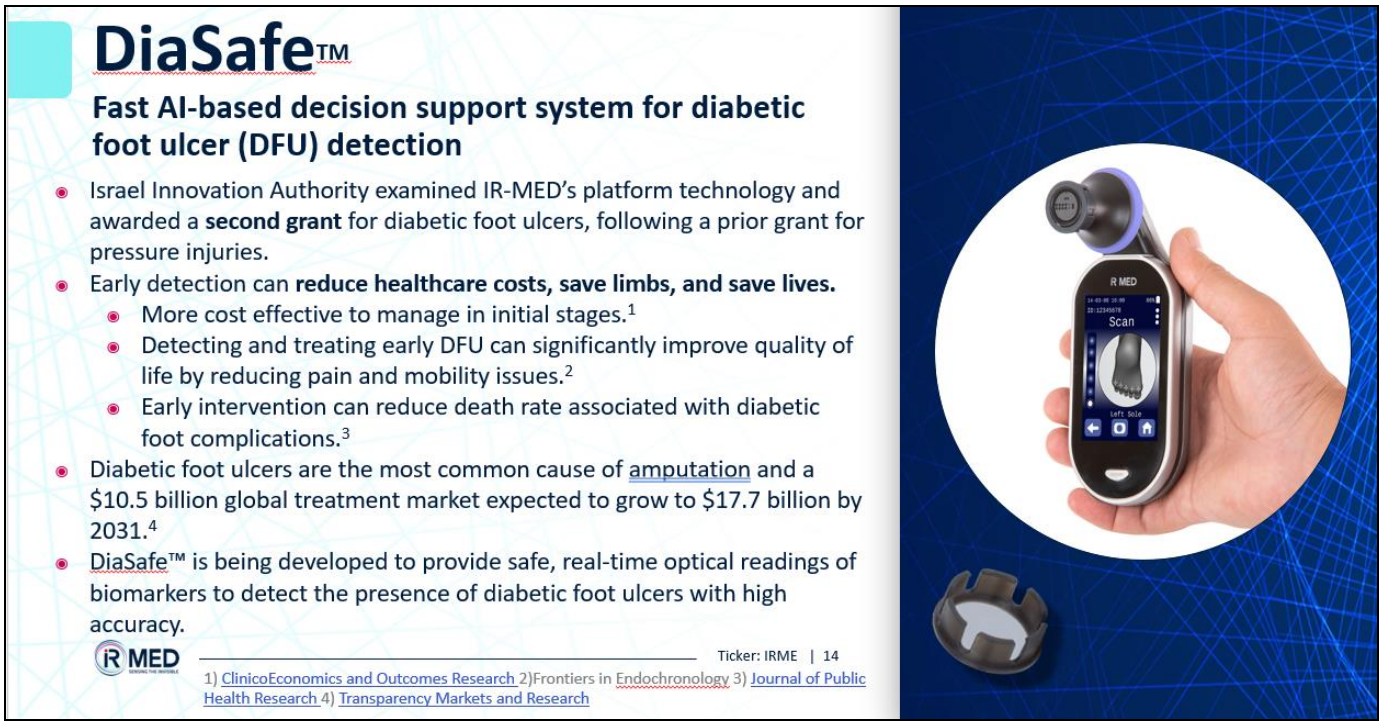
Early detection of DFU is crucial. Signs of redness (which is especially difficult to detect among darker-skin patients), blisters and minor injuries are very important to detect. The company's technology platform for early detection of PIs is being adjusted to detect incipient DFUs. Applying the company's unique AI technology with an appropriate optical design allows different foot measurements and is expected to provide patients and caregivers with an alert of potentially developing DFU in its early stages.

The novel technology platform will enable direct assessment of the development of a DFU before it becomes an open wound that may lead to a limb amputation. The Israeli Innovation Authority, or IIA, has approved a plan to develop a diabetic foot ulcer device for early detection of DFU .On January 25, 2024,

the Israel Innovation Authority approved a program to develop a device for the early detection of diabetic foot ulcers among diabetic patients, with a project budget of NIS 3,761,978 (approximately $1,030,000) which includes an amount equal to 50% grant of the total budget provided at the time of the grant, disbursed in installments over the course of 13 months, in accordance with the project's progress.

In consideration for the grant by the IIA, the subsidiary is required to pay royalties at the rate of 3%-5% from the total sales until the repayment date of the full amount of the grant, plus annual interest at the SOFR rate. In addition, the IIA must approve any arrangement whereby the Company seeks to transfer the technology relating to the project, or its development, from Israel.

This is a handheld optical monitoring device that is being developed to support early detection of diabetic foot ulcers (DFU) in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole and diabetes. The Israel Innovation Authority examined IR-MED's platform technology and recently awarded a second grant for diabetic foot ulcers, following a prior grant for pressure injuries.



Source: IR-Med Investor Presentation

Early detection of diabetic foot ulcers can reduce healthcare costs, save limbs, and save lives. It is far more cost effective to manage these ulcers in early initial stages. Detecting and treating early DFU can significantly improve quality of life by reducing pain and mobility issues in patients and early intervention can also reduce the death rate associated with diabetic foot complications.

Diabetic foot ulcers are the most common cause of amputation and is a $10.5 billion global treatment market expected to grow to $17.7 billion by 2031. DiaSafe is being developed to provide safe, real-time optical readings of biomarkers to detect the presence of diabetic foot ulcers with high accuracy.

PRODUCT IN THE PIPELINE

NoBiotics

The NoBiotics device is planned to be an otoscope for supporting noninvasive detection of otitis media (ear infection). An otoscope is a medical device which is used to look into the ears. The device is in initial stages of development as an ear examination device that will give the physician an immediate indication if the infection is from a viral or bacterial source and then the physician will make a decision if to prescribe an antibiotic or not.



Source: IR-Med Investor Presentation

The device works on a similar IR-spectrographic analysis method as being developed in the PressureSafe device. The Nobiotics otoscope is based on infrared light reflection and absorption by the effluents behind the ear drum. Otoscopes are considered a required device by any physician performing physical diagnoses. Target customers for the Nobiotics device are general practitioners, pediatricians and ear nose and throat specialists.

Although no specific timelines have been provided for approval and commercialization of this device, key developments are expected in 2026.

Non-Invasive Pharmaceutical Measurement Device

IR-MED is developing a real-time, noninvasive optical monitor to determine a chosen drug blood concentration. The monitor includes a set of sensors which are topically attached to the patient's skin during scanning and a display.

With approval from the Israel Ministry of Health and IRB, the first human study was completed at the Rambam Healthcare Campus in Israel. The IR-MED non-invasive real-time monitor of blood Propofol was used to monitor a group of 40 women who underwent gynecological procedures under Propofol sedation. The results of the study confirmed the ability to follow Propofol blood concentration changes noninvasively, in real-time and in a repeatable manner. The time frame for development and potential partnering for this product will likely occur in 2027.

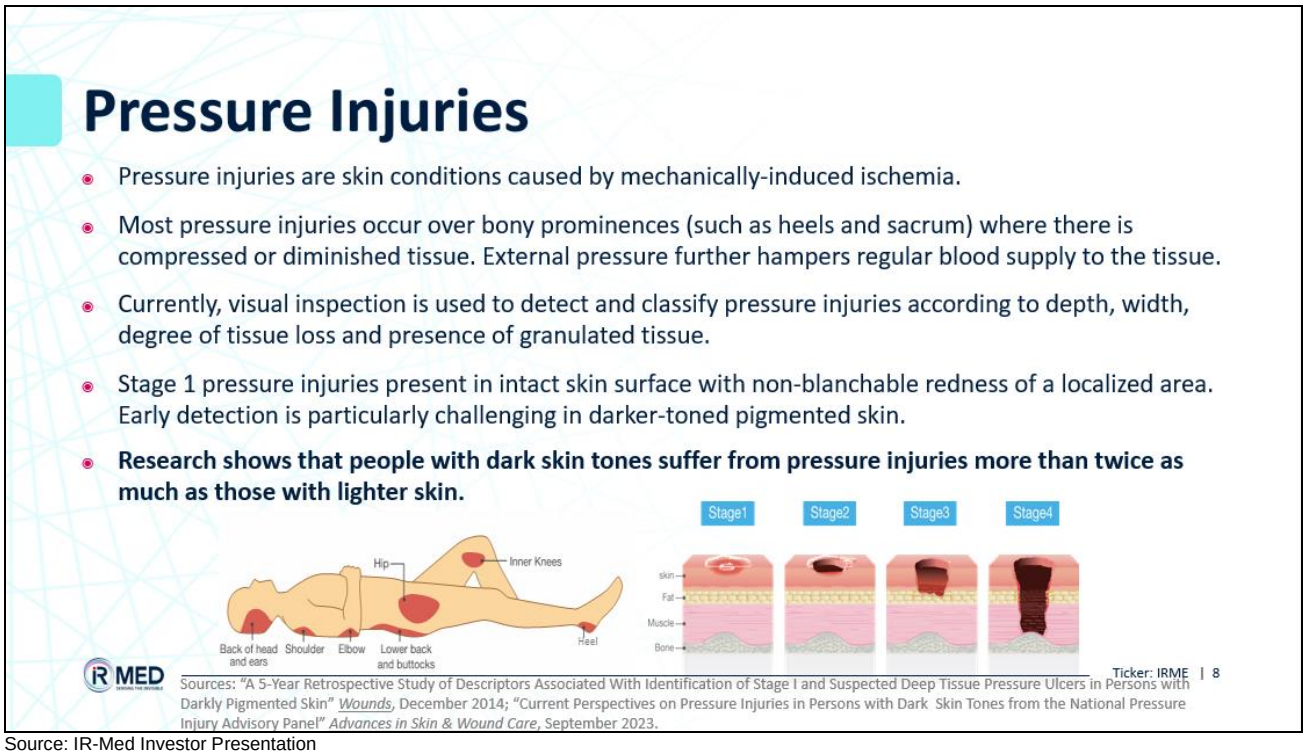
INDUSTRY & ADDRESSABLE MARKET

Pressure Injury Market

Populations around the world are aging due to improvements in healthcare. However, there are increased rates of obesity, diabetes, and cardiovascular diseases. This combination of an increasing aging population and such diseases has resulted in more people needing assistance with activities of daily living due to decreased mobility. A major injury of decreased mobility is the development of Pressure Injuries. PIs develop as a result of a combination of physiologic events and external conditions. 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 buildup 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 placed on the tissue. Pressure Injuries occur over predictable pressure points where bony protuberances are more likely to compress tissues when the patient is in prolonged contact with hard surfaces. Studies show that the heel area is the second most frequent location for a pressure ulcer, the most prevalent being the sacrum. The heel area accounts for between 23% and 28% of all pressure ulcers.

While the number of Hospital Acquired Conditions (HAC) has decreased by 8%, pressure injuries have resisted improvement efforts and continue to grow by 10% annually. PI can be both costly and dangerous. The U.S. Agency for Healthcare Research and Quality (AHRQ) reports that PI add $10.2 billion to annual U.S. Healthcare costs. Furthermore, these are associated with over 45% of the 63,619 HAC related deaths in the U.S., making it the leading contributor to HAC related deaths. There are over 6,000 hospitals operating in the U.S. currently.



Source: IR-Med Investor Presentation

The most common method used to detect early PI is a visual assessment by a professional caregiver focusing on areas where PI most frequently develops. This visual assessment is subjective, unreliable, untimely (PI often occurs 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 none have apparently succeeded in providing an effective solution.

As of today, PI's 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. 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%).



Source: IR-Med Investor Presentation

Nursing home patients have a PI prevalence of 11% 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. There are currently roughly 15,600 nursing homes in the U.S. with approximately 1.7 million beds.

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

According to a survey published in 2000 by UCLA School of Medicine 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.

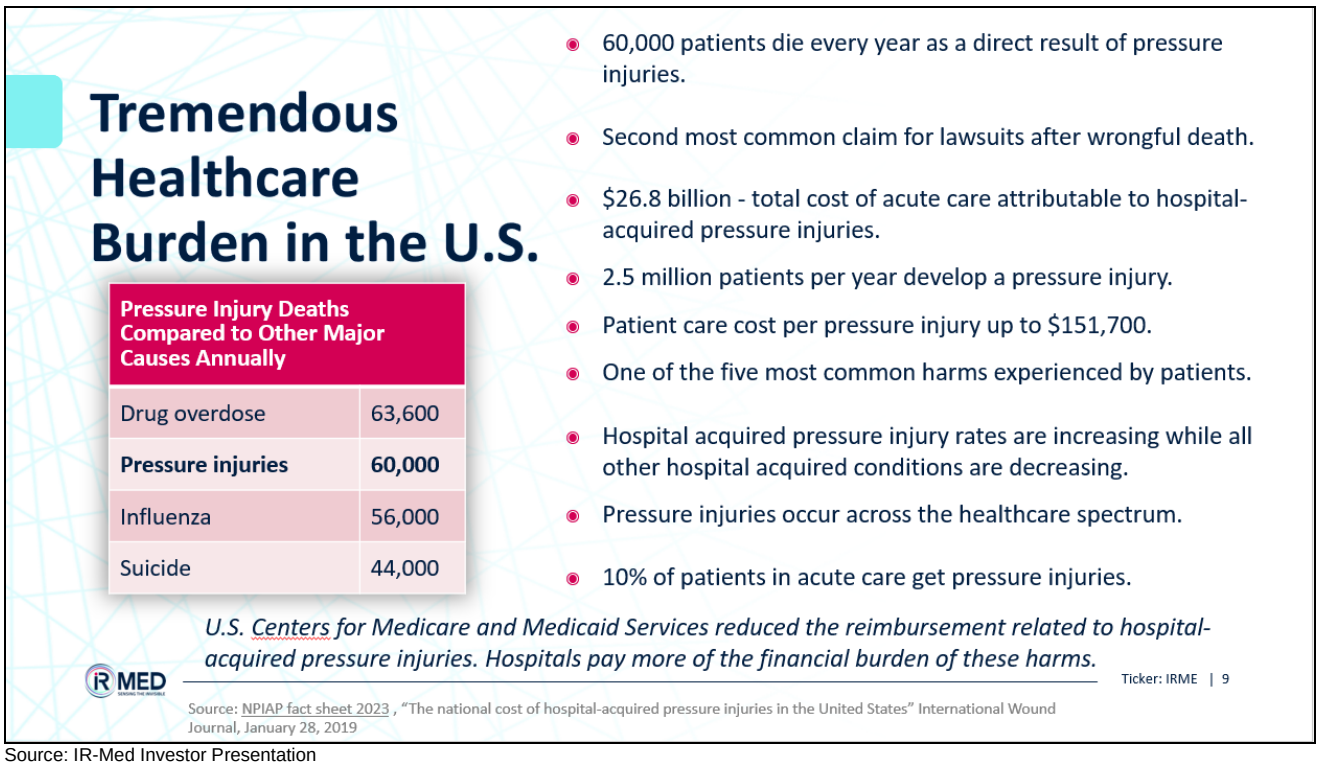
The Agency for Healthcare Research and Quality (AHRQ) has identified several basic principles for PI prevention:

(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

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 solution is 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 because supports with cut-outs can have increased pressure at their edges.

An estimated 60,000 patients die annually from pressure injuries and an estimated 2.5 million develop a pressure injury to some degree. Patient care costs per injury range from $20,900 to $151,700. Hospital acquired pressure injuries are increasing while most other hospital acquired injuries are decreasing which led to a situation where PI now represent the 2nd largest source of lawsuit claims after wrongful death which is #1. Pressure injuries occur across the healthcare universe with 25% occurring long-term acute care patients, 10% in short-term acute care patients, 12% in nursing homes, and 12% in rehabilitation centers.



Source: IR-Med Investor Presentation

The global addressable market is estimated at $2.9 billion. The global number of beds at hospitals, nursing homes, and home care is estimated to be 17.3 million beds which is comprised of 2.6 million beds in the U.S., 5.2 million beds in the E.U., and 9.5 million in other countries around the world. Of these beds, 8.2 million could be relevant or susceptible to pressure injuries. Potential revenue sources that could be relevant to the company would include the sale of the PressureSafe unit at $4,000 to one out of every 25 beds. Those beds would need an estimated 96 consumable tests per year.

About 5% of patients with diabetes mellitus develop foot ulcers, and approximately 1% end up with an amputation. The lifetime risk of a person with diabetes developing a foot ulcer ranges between 19% to 34%. These ulcers are the leading cause of non-traumatic amputations in the U.S. and are responsible for more hospital admissions than any other diabetic complication.

RISKS

- IR-Med is a development stage medical device company with a history of significant operating losses. Losses may continue to be incurred, and profitability may never be achieved.

- The company will likely need substantial additional funding to continue operations which could result in significant dilution to shareholders or restrictions on business operations. The debt and equity markets may not be available to the company when needed.

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

- The company currently has no products that are commercially available for sale. If the company is unable to successfully develop, receive approval from regulatory authorities, and commercialize initially the PressureSafe device under development, the business will be adversely affected.

- Any product candidates that are advanced into clinical trials (assuming the FDA so requires) may be subject to extensive regulation, which can be costly and time consuming.

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

- The company's technology development is headquartered in Israel and results may be adversely affected by economic restrictions imposed on the business or by political and military instability in Israel.

MANAGEMENT

ODED BASHAN
Chairman

Mr. Bashan has over 40 years of experience in managing, building and running technology companies. He is the founder & CEO of OTI, a NASDAQ traded global technology leader with more than 250 employees, annual sales of $50 million, an IP portfolio of over 100 patents and hundreds of millions of users.

RONNIE KLEIN
Co-Founder, CTO, and Interim CEO

Mr. Klein is a biochemical engineer from the Technion, Israeli institute of Technology and an experienced entrepreneur with a history of turning good ideas into commercialized products in the medical device field and pharmaceuticals. He has experience in medical devices development, market development and fund raising, and has submitted 14 patents.

AHARON BINUR
Chief Development Officer

Mr. Aharon Binur has been appointed CDO, Chief Development Officer, of R&D to lead product development at IR-MED. Aharon 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 time of more than 13 years. Aharon also served as CTO and VP of R&D at Lehavot, an advanced fire protection systems company 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.

SHARON LEVKOVIZ
Chief Financial Officer

Mr. Levkoviz was appointed Chief Financial Officer upon the effectiveness of the acquisition. Mr. Levkoviz served from 2011-2021 at Achdut Israel Ltd., an Israeli company providing accounting and economic consulting services, as a regional manager. Prior to that period, Mr. Levkoviz served as a Chief Controller at OTI, a global Nasdaq traded company from 2005 through 2011. Mr. Levkoviz received his CPA from Ramat Gan College and an executive BA 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 5 years as a director at the development company of Katzrin.

DR. YANIV COHEN
Co-Founder & CSO

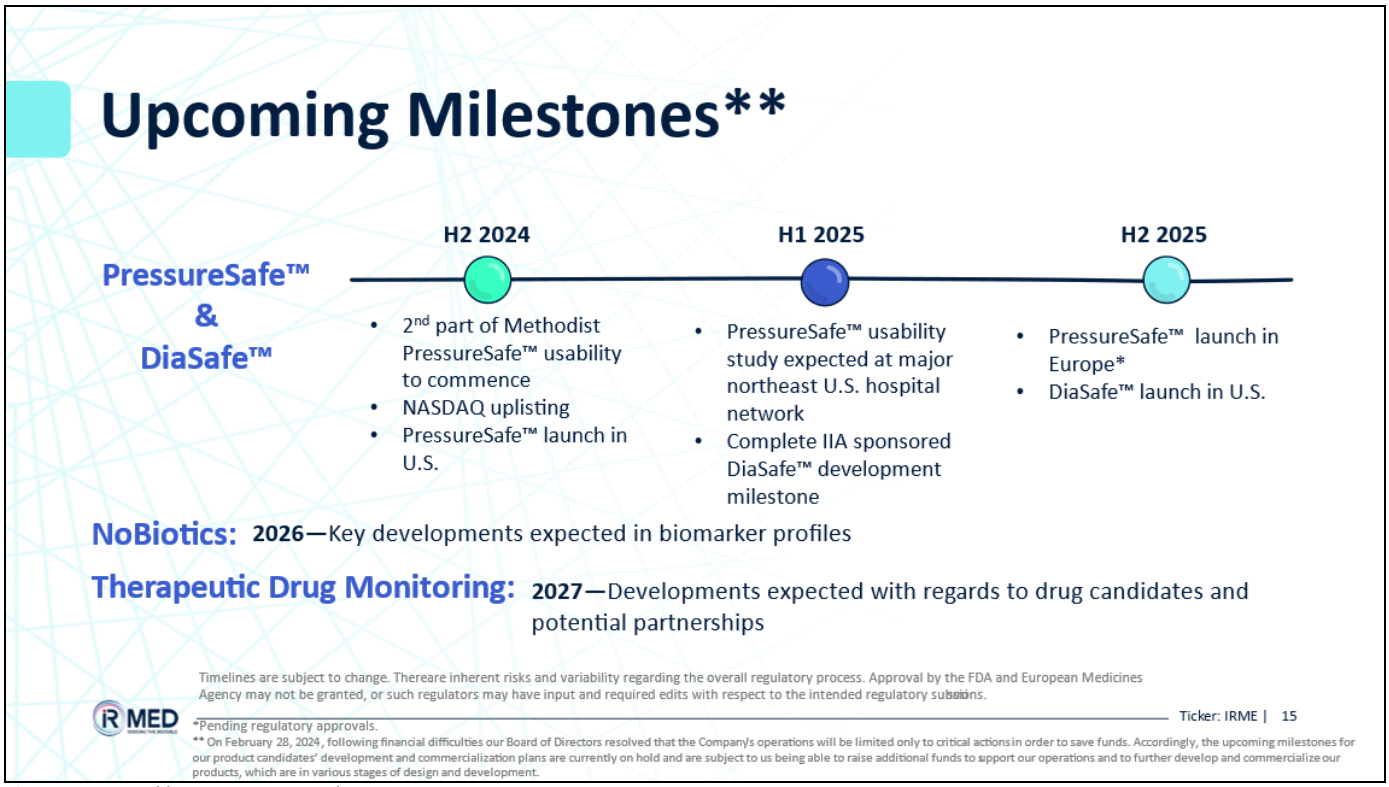
Dr. Yaniv Cohen, PhD MSc, co-founder of IR-Med, is a skilled scientist and entrepreneur, with years of experience leading R&D development for medical devices companies. His fields of expertise include electro-optics, infrared spectroscopy and medical devices using infrared light. He has successfully led the development of medical devices from early concept to commercial product. His current research at Prof. Avigdor Scherz's lab at the Weizmann Institute of Science is focused on the launch of Immune Photo Activated Cancer Therapy treatment for solid tumors. Previous work experience includes Cisco and Tokyo Electron Israel.

SUMMARY

We believe IR-Meds transformative medical device testing technology products will provide substantial opportunities for profitable revenue growth over a mid-to-long term time frame. The Pressure Injury detection market could exceed $2.9 billion in revenue opportunities in coming years and even small market share gains in that area would generate substantial revenues for the company. Detection of Diabetic Foot Ulcers can help reduce the costs of DFU treatment which exceeds $10.0 billion at this time.

In addition, the company's other two devices under development have the potential to address unmet medical needs and may generate profitable revenues over the long-term after approval and commercialization in 2026 and 2028.

IR-Med has the potential to grow both revenues and earnings at very robust double-digit growth rates starting in 2025 if it is able to execute on the commercialization of its PressureSafe and DiaSafe devices. The company's current stock price does not likely reflect that potential level of profitable growth in the future, and we believe the stock to be significantly undervalued at this time.



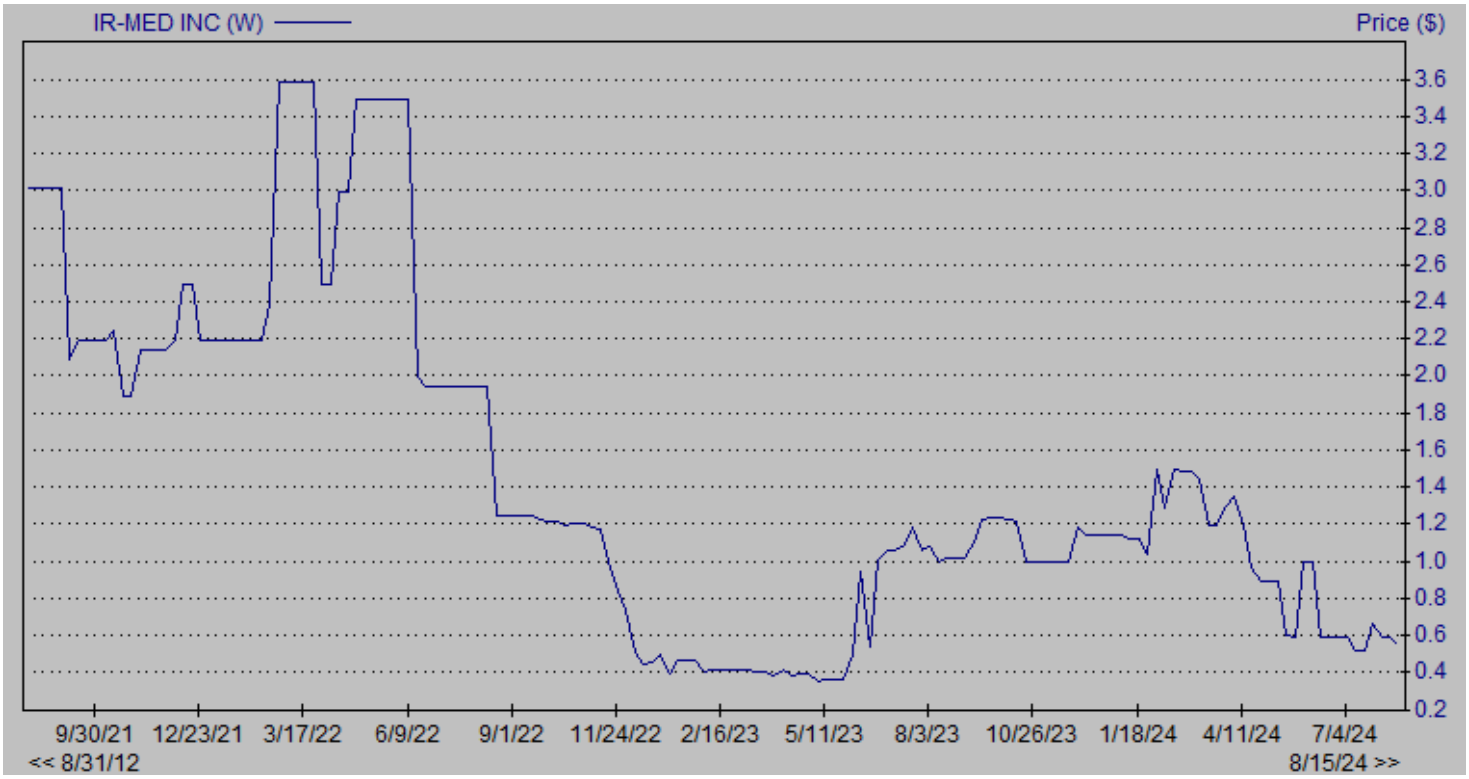
Source: IR-Med investor presentation

PROJECTED INCOME STATEMENT

Income Statement	Dec-21	Dec-22	Dec-23	Dec-24	Dec-25
Net Sales	**0**	**0**	**0**	**500,000**	**5,500,000**
Growth	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*1000.0%*
Cost of Goods Sold	**0**	**0**	**0**	**405,000**	**2,250,000**
%	*N/A*	*N/A*	*N/A*	*81.0%*	*40.9%*
Depreciation & Amort	**0**	**0**	**0**	**0**	**0**
Gross Profit	**0**	**0**	**0**	**95,000**	**3,250,000**
Margin	*N/A*	*N/A*	*N/A*	*19.0%*	*59.1%*
Sales & Marketing Expenses	**888,000**	**759,000**	**822,000**	**780,900**	**858,990**
% of sales	*N/A*	*N/A*	*N/A*	*156.2%*	*15.6%*
General & Administrative Expenses	**1,368,000**	**2,118,000**	**2,028,000**	**1,419,600**	**1,206,660**
% of sales	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*283.9%*	*21.9%*
Research & Development	**1,419,000**	**1,885,000**	**2,061,000**	**1,044,000**	**2,000,000**
% of sales	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*208.8%*	*36.4%*
Amortization	**0**	**0**	**0**	**0**	**0**
% of sales	*N/A*	*N/A*	*N/A*	*0.0%*	*0.0%*
Operating Income	**(3,675,000)**	**(4,762,000)**	**(4,911,000)**	**(3,149,500)**	**(815,650)**
Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-629.9%*	*-14.8%*
EBITDA	**(3,675,000)**	**(4,762,000)**	**(4,911,000)**	**(3,149,500)**	**(815,650)**
Margin	*N/A*	*N/A*	*N/A*	*-629.9%*	*-14.8%*
Other Expenses/(Income)	**35,000**	**(34,000)**	**(2,000)**	**3,000**	**2,800**
%	*N/A*	*N/A*	*N/A*	*0.6%*	*0.1%*
EBIT	**(3,710,000)**	**(4,728,000)**	**(4,909,000)**	**(3,152,500)**	**(818,450)**
%	*N/A*	*N/A*	*N/A*	*-630.5%*	*-14.9%*
Total Interest Exp (net)	**6,000**	**6,000**	**0**	**0**	**15,295**
%	*N/A*	*N/A*	*N/A*	*0.0%*	*0.3%*
Net Profit Before Tax	**(3,716,000)**	**(4,734,000)**	**(4,909,000)**	**(3,152,500)**	**(833,745)**
%	*N/A*	*N/A*	*N/A*	*-630.5%*	*-15.2%*
Income Tax	**0**	**0**	**0**	**0**	**(125,062)**
% Effective Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*
% Cash Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*
Minority Interests	**0**	**0**	**0**	**0**	**0**
Net Profit	**(3,716,000)**	**(4,734,000)**	**(4,909,000)**	**(3,152,500)**	**(708,683)**
%	*N/A*	*N/A*	*N/A*	*-630.5%*	*-12.9%*
Non-recurring income (expense)					
Average Diluted Shares Outstanding	63,110,764	67,577,734	69,404,351	69,931,056	69,931,056
Reported FD EPS					
Zacks Cash EPS	**(0.06)**	**(0.07)**	**(0.07)**	**(0.05)**	**(0.01)**
Zacks EPS	**(0.06)**	**(0.07)**	**(0.07)**	**(0.05)**	**(0.01)**

Source: Zacks analyst

HISTORICAL STOCK PRICE


IR-MED INC (W)
Price ($)
3.6
3.4
3.2
3.0
2.8
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
9/30/21
12/23/21
3/17/22
6/9/22
9/1/22
11/24/22
2/16/23
5/11/23
8/3/23
10/26/23
1/18/24
4/11/24
7/4/24
<< 8/31/12
8/15/24 >>

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