February 21, 2024

Zacks Small-Cap Research

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IR-Med Inc. (OTCQB: IRME)

IRME: IR-Med announces important safety and efficacy data from recent PressureSafe study. We reaffirm our price target of $3.00 per share.

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 (2/20/24)	$1.40
Valuation	**$3.00**

OUTLOOK

IR-Med Inc. is a development stage medical device company whose initial device under advanced development, expected to be launched in the 1st half of 2024, 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 $11 billion. The company has two other products in the early stage of development. The company targets nursing homes, hospitals and home health care. The company has raised $9.4 million in equity capital over the past two year. We expect the company to generate revenues in 2024.

SUMMARY DATA

52-Week High	**$1.65**
52-Week Low	**$0.40**
One-Year Return (%)	**233.3**
Beta	**1.8**
Average Daily Volume (sh)	**412**
Shares Outstanding (mil)	**69.8**
Market Capitalization ($mil)	**$97.8**
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 2023 Estimate	**N/A**
P/E using 2024 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 E	$0.0 E
2024	$0.1 E	$0.2 E	$0.3 E	$0.5 E	$1.1 E
2025					$17.5 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	-$0.02 E	-$0.08 E
2024	-$0.02 E	-$0.02 E	-$0.02 A	-$0.02 E	-$0.07 E
2025					$0.08 E

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

WHAT'S NEW

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."*

Tzur Di-Cori, IR-MED's CEO, also commented, *"This robust and impressive data from our collaborative study with Clalit comes at an ideal time as we prepare to enter the U.S. market with PressureSafe. We believe the 92% efficacy findings in real-world data settings at two world-class hospitals will be a big factor in driving adoption in the U.S."*

The company plans to start a usability study for PressureSafe in the U.S. in collaboration with Methodist Healthcare of San Antonio in the coming months. This study aims to enroll approximately 50% of patients with darker skin tones in order to produce comparative data for PressureSafe's accuracy as a decision support device in people with lighter and darker skin tones. Published studies show black patients in the U.S. suffer disproportionally from pressure injuries, which are harder to detect visually in darker skin tones.

Other News

- On December 3, 2023, the company announced it has been granted a patent titled “System and method for noninvasive analysis of tissue” from the State of Israel Patent Office. This follows a similar patent granted in the U.S. and other patent applications pending in key markets including the European Union.

  The patent addresses IR-MED’s platform technology, a method for noninvasive analysis of subcutaneous tissue. The method irradiates the surface of the tissue with infrared radiation (IR) in spectral bands that are strongly absorbed or scattered by tissue chromophores like water. The intensity of the radiation in each of the spectral bands emerging from the tissue is measured and then compared by an algorithm that produces data-driven support for the diagnostic assessment of subcutaneous tissue.

- On September 26, 2023, the company announced that it had signed a Clinical Trial Agreement with the Methodist Healthcare System of San Antonio to conduct a useability study titled “Safety and Efficacy of the PressureSafe Device for Early Detection of Pressure Injury in People with Various Skin Tones, Including Dark Skin Tones.

  With a network of 85 hospitals, 9 of which are acute care facilities, Methodist Healthcare employs more than 11,000 people, including 2,700 physicians. Approximately 50% of subjects recruited for the upcoming study will have dark skin tone, which is expected to produce comparative data on PressureSafe’s accuracy as a decision support device in detecting early-stage pressure injuries in people of darker and lighter skin tones. While early-stage pressure injuries can be more difficult to see on dark skin tones, the current standard of care for the detection of pressure injuries is visual skin inspection.

Valuation and Estimates

There are no changes to our revenue and earnings estimates at this time as we await the release of the company’s 4th quarter and full year 2023 results. We are maintaining our price target of **$3.00** per share.

Source: IR-Med investor presentation

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 the blood and in human tissue in real-time without resorting to invasive procedures.

- The company's primary product under advanced development is called PressureSafe and is used to detect Pressure Injuries in a non-invasive manner with high accuracy, regardless of patient skin tone.

- 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.

- The company is also in 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 $2.5 million in 2023.

- 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.

- On October 15, 2023, the company hired a new CEO, Mr. Di-Cori served as the CEO of several well-known companies including Dusmit Ltd., Motorika Ltd., and EZSurgical Ltd Israel, where he also was President of its US-based subsidiary, EZSurgical Inc.

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

OVERVIEW

Source: IR-Med investor presentation

IR-Med, Inc. (IRME) is a development stage medical device company that is creating a technology platform for non-invasive devices to be used as a decision support system tool (DSS) for various medical indications by detecting and measuring various biomarkers and molecules in blood and human tissue in real-time without resorting to invasive procedures.

The initial product under advanced development is called PressureSafe, which is a handheld optical monitoring device that is being developed to support early detection of pressure injuries (PI) to the skin and underlying tissue, which is primarily caused by prolonged pressure associated with bed confinement. Acute care pressure injuries have an annual cost of $26.8 billion, with $22 billion of that coming from Medicare patients.

This device has high accuracy regardless of skin tone and is personally calibrated to each patient's skin. The skin-device-interphase personalized medical device allows high accuracy readings from the human body in a non-invasive method, that may provide a caregiver the optimal decision support-system in their decision processes. The company plans to launch the device as a decision support system (DSS) tool for care givers in hospitals, nursing homes and home-care companies.

The company is also in the preliminary stage of research and development of an innovative otoscope called Nobiotics. An otoscope is a medical device which is used to look into the ears. This device would 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.

The company's technology platform utilizes artificial intelligence (AI) in its working device and skin scanning process. Basic AI includes machine learning, where a machine uses algorithms to parse data, learn from it, and then make a probability prediction about a given occurrence. The machine algorithm is "trained" using large amounts of data and allows high accuracy relevant options for the caregiver to decide upon.

The company's initial focus is on the development of Decision Support Systems (DSS) solutions utilizing their proprietary platform for the pre-emptive diagnosis of pressure injuries (PI) and of mid-ear infections detection. Three principal medical devices are in various stages of development:

> PressureSafe — This is a handheld optical monitoring device that is being developed to support early detection of pressure injuries to the skin and underlying tissue. These PIs are, primarily caused by prolonged pressure associated with bed confinement. The PressureSafe device is in an advanced stage of development and is planned to be the company's first go-to-market product.
>
> NoBiotics – This is an innovative otoscope that is being designed to support physicians with an immediate indication as to whether mid-ear infection (otitis media) is of a bacterial origin and requires antibiotic treatment, or of a viral origin and does not require antibiotic treatment. NoBiotics is in the initial stage of research and development.

Non-Invasive Pharmaceutical Measurement Device – The company is developing a real-time, noninvasive optical monitor to determine drug blood concentration. The monitor includes a set of sensors which are topically attached to the patient's skin during patient assessment at the point of care.

In February 2022, the company uplisted from the Pink Sheets to the OTCQB market tier. It is the company's goal to uplist to the national market at some point in the future.

As of September 30, 2023, the company had $1.5 million in cash on the balance sheet and working capital of $1.0 million. There was no traditional long-term debt as of that date.

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.

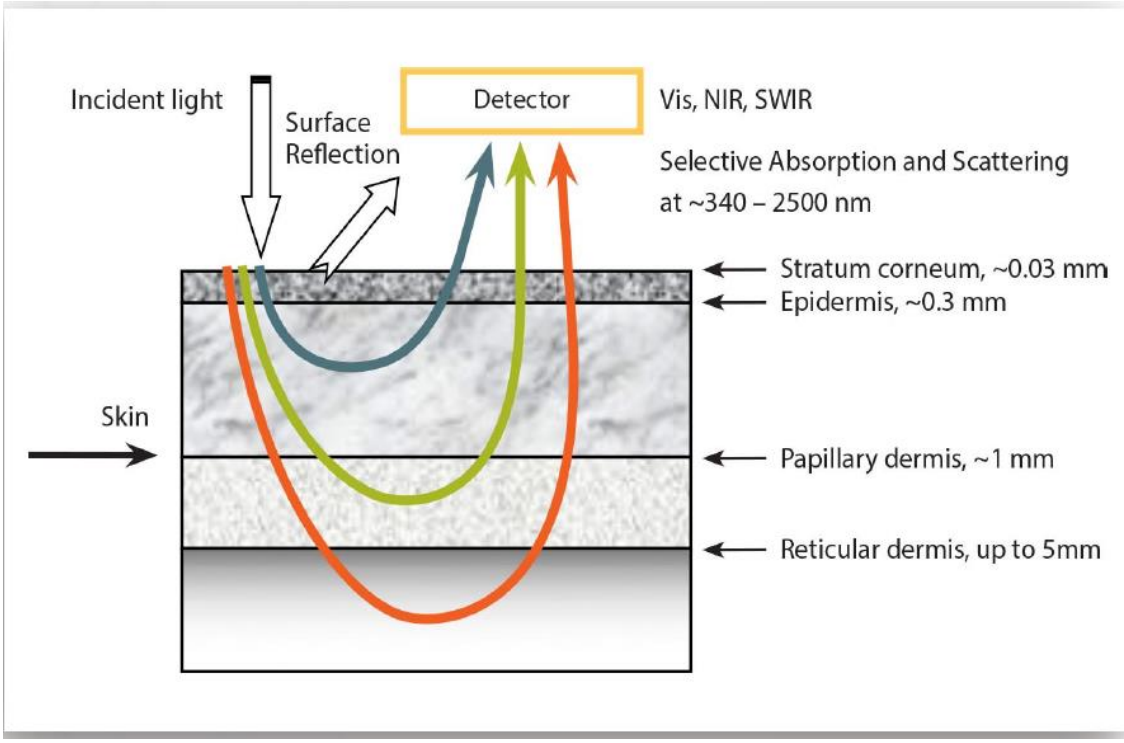
Source: IR-Med Investor Presentation

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 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, cells malfunction and deteriorate in its 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 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 diagnosing physician must calibrate the device 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 the 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 subdermal layers by scanning through these skin layers which improves the identification of the damage and assessing the subdermal damaged tissue volume, assisting with additional information to allow better treatment efficacy.

Measuring the differences of subdermal fluid content and other bio-signals, has been developed to detect early formation of pressure injuries and to “raise a flag” to allow the caregivers 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 has completed the development of the first generation PressureSafe prototype in the 2nd quarter of 2022. In June 2022, IR-Med entered into a study agreement with Beit Rivka, a large geriatric hospital in Israel associated with Clalit, the largest HMO in Israel (and 2nd largest in the world), to conduct a usability study of PressureSafe. In August 2022, the company entered into an agreement with an Israeli boutique industrial design company specializing in the design of medical devices and diagnostic products for the design of the PressureSafe device in its advanced configuration. This incorporates preliminary results from a usability study currently being performed in Israel, including feedback from healthcare professionals. In February 2023, the company entered into an agreement with Rabin Medical Center in Tel-Aviv, Israel to perform a usability study, as an additional study center to the current study that is being performed at Beit-Rivka, a large geriatrics hospital in Israel.

The timeline for commercialization of the PressureSafe device is an FDA registration in the 4th quarter of 2023 with an FDA response also expected in the 4th quarter of 2023. The company also plans to complete a usability study in the 1st quarter of 2024 with commercial launch of the device in the 1st half of 2024. 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.

In the 3rd quarter of 2022, the company began preparations in anticipation of commercialization of PressureSafe in the U.S. pending regulatory approvals. A distribution agreement was entered into with PI Prevention Care LLC, a newly formed entity focused on marketing to the senior care facility, hospital and homecare markets. This distributor, which received exclusive rights for PressureSafe distribution across the U.S., includes personnel who have many years' experience in addressing and responding to the needs of these types of organizations. Under the terms of the agreement, in order to maintain product exclusivity, the distributor is obligated to comply with minimum purchase requirements of the device and accompanying disposables. The selling price of the device to the distributor is expected to approximately $4,000 and the selling price of the disposable tip is estimated at $2.25 per use.

On July 17, 2023, the company announced topline interim results from the clinical study of PressureSafe which showed promising results. PressureSafe demonstrated very high efficacy in noninvasively detecting the presence and absence of pressure injuries below the skin's surface. Sensitivity was 96% indicating the device accurately detected the presence of a pressure injury in 96% of cases. Specificity was 91% which shows the device determined no wound was present in 91% of cases.

The study was conducted at two medical centers owned by Clalit, the world's 2nd largest health maintenance organization (HMO) and the largest in the country of Israel. The facilities were Beit Rivka Hospital and Rabin Medical Center both in Petah Tikva, where 370 PressureSafe scans were performed on 25 patients who had Stage 1 pressure injuries or deep tissue injuries. No device related safety issues were reported in the total of 44 patients evaluated for safety.

Executive Chairman and Interim CEO Oded Bashan stated, *"We believe PressureSafe can become the new standard of care in the detection of pressure injuries, and we are very pleased to share this data as we plan to file for U.S. FDA approval and subsequent market launch following regulatory clearance. We believe that the healthcare economics benefits PressureSafe offers combined with the improvement in patient outcomes is a powerful combination for rapid market adoption."*

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 physicians 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 2024.

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 2025.

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.

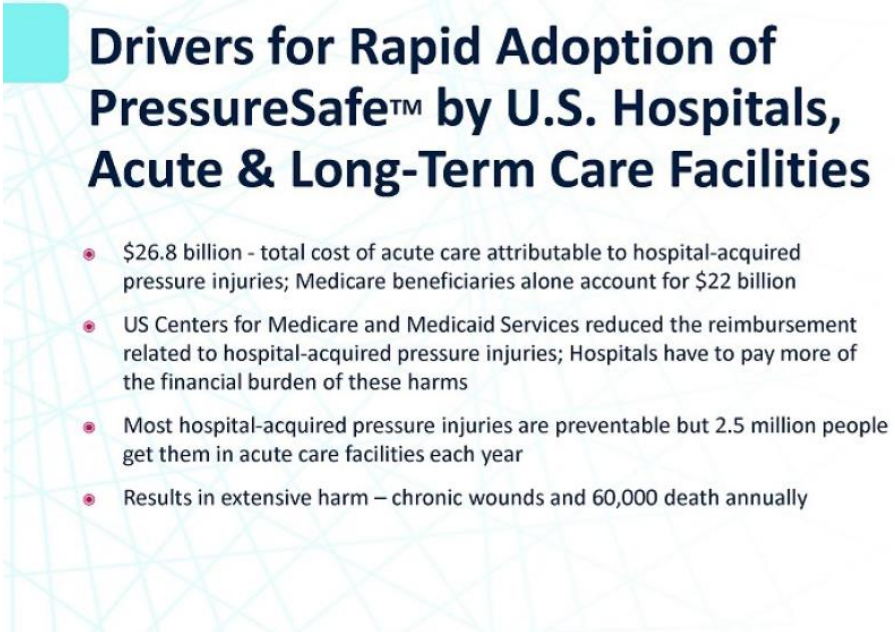
Compression prevents lymph fluid drainage, and deterioration in tissue cell normal activities, which causes increased interstitial fluid and waste buildup and contributes to PI development. The time required to develop a PI is dependent on many factors, including the patient's physiology and the degree 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.

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 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%).



Pressure Injury Deaths Compared to Other Major Causes Annually	
Drug overdose	63,600
Pressure injuries	**60,000**
Influenza	56,000
Suicide	44,000

"Hospitals should invest more in quality improvement of early detection and care for pressure injury to avoid higher costs." Peer-reviewed study recommendation

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.

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.

Ear Infection Market

An ear infection is an inflammation of the middle ear, usually caused by bacteria or a virus, which occurs together with fluid buildup behind the eardrum. Three out of four children will have at least one ear infection by their 3rd birthday. Ear infections are the most common reason parents bring their child to a doctor. The global market for treating ear infections is estimated at $11.7 billion with 20 million children visiting their doctor annually for ear infection issues.

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). 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 be resolved 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 evident symptoms, making diagnosis more difficult, it can be associated with speech delay, sleep disruption, poor school performance, balance issues, and a higher likelihood of developing future 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 a 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.

NoBiotics Unmet Need:

- When diagnosing pediatric Acute Otitis Media, physicians currently do not have tools that allow them to distinguish between bacterial and viral infections of the middle-ear
- Access to this information could improve treatment and avoid unnecessary prescription and use of antibiotics
- Children under 6 years of age are the largest consumers of antibiotics*
- Over-usage of antibiotics leads to antibiotic-resistant bacteria**

Source: IR-Med Investor Presentation

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 as well 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, the child 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 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 health authorities around the world.

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

TZUR DI-CORI
Chief Executive Officer

During 20+ years of success in the medical device industry, Mr. Di-Cori has demonstrated exceptional leadership skills in start-ups and publicly-traded companies. Mr. Di-Cori served as the CEO of several well-known companies including Dusmit Ltd., Motorika Ltd., and EZSurgical Ltd Israel, where he also was President of its US-based subsidiary, EZSurgical Inc. At LifeWatch Technologies Ltd, Mr. Di-Cori served as President, leading the company to $130 million in annual sales in the Medical Telemonitoring Solutions sector. Mr. Di-Cori's educational background includes a B.A in Practical Engineering in Electronic & Computers from Singalovski College Tel Aviv, and an MBA from the University of Derby.

ODED BASHAN
Chairman

Mr. Bashan is an entrepreneur, innovator and executive with over 35 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, IP portfolio of over 100 patents and hundreds of millions of users. Prior to founding OTI, he served as the president of Electro-Galil. Mr. Bashan 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.

RONNIE KLEIN
Co-Founder and CTO

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.

INSIDER TRADING AND OWNERSHIP

Officers and directors of the company own approximately 43.7% of outstanding shares.

Name and Address of Beneficial Owner	Number of Shares beneficially owned	Percentage Beneficially owned
5% or more shareholders		
Yaakov Safren	5,706,120(1)	8.13%
Paul Coulson	5,625,000(2)	7.96%
Third Eye Investors LLC	4,687,500(3)	6.66%
Isamar Margareten	8,721,307(4)	11.97%
Officers and Directors		
Oded Bashan	9,449,916(5)	13.57%
Aharon Klein	8,099,110(6)	11.73%
Yaniv Cohen	8,099,136(7)	11.73%
Yoram Drucker	4,862,471(8)	6.98%
Ron Mayron	260,000(9)	*
Inna Martin	30,000(9)	*
Ohad Bashan	240,000(9)	*
Moshe Gerber	—	*
Aharon Binur	130,000(9)	*
Sharon Levkoviz	251,978(9)	*
Officers and Directors as a Group (10 persons)	31,422,611	43.73%

Source: IR-Med SEC filings

VALUATION

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. Once FDA registration is received and commercialization commences, we expect the company's revenues to grow at solid double-digit rates for at least for 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 2023 full year EPS estimate is ($0.08) and for 2024, the EPS estimate is ($0.07). We expect the first full year of meaningful revenue generation to occur in 2025, which we predict will be approximately $17.5 million. We forecast 2026 revenues of $34.9 million.

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.

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 2024 and 2025.

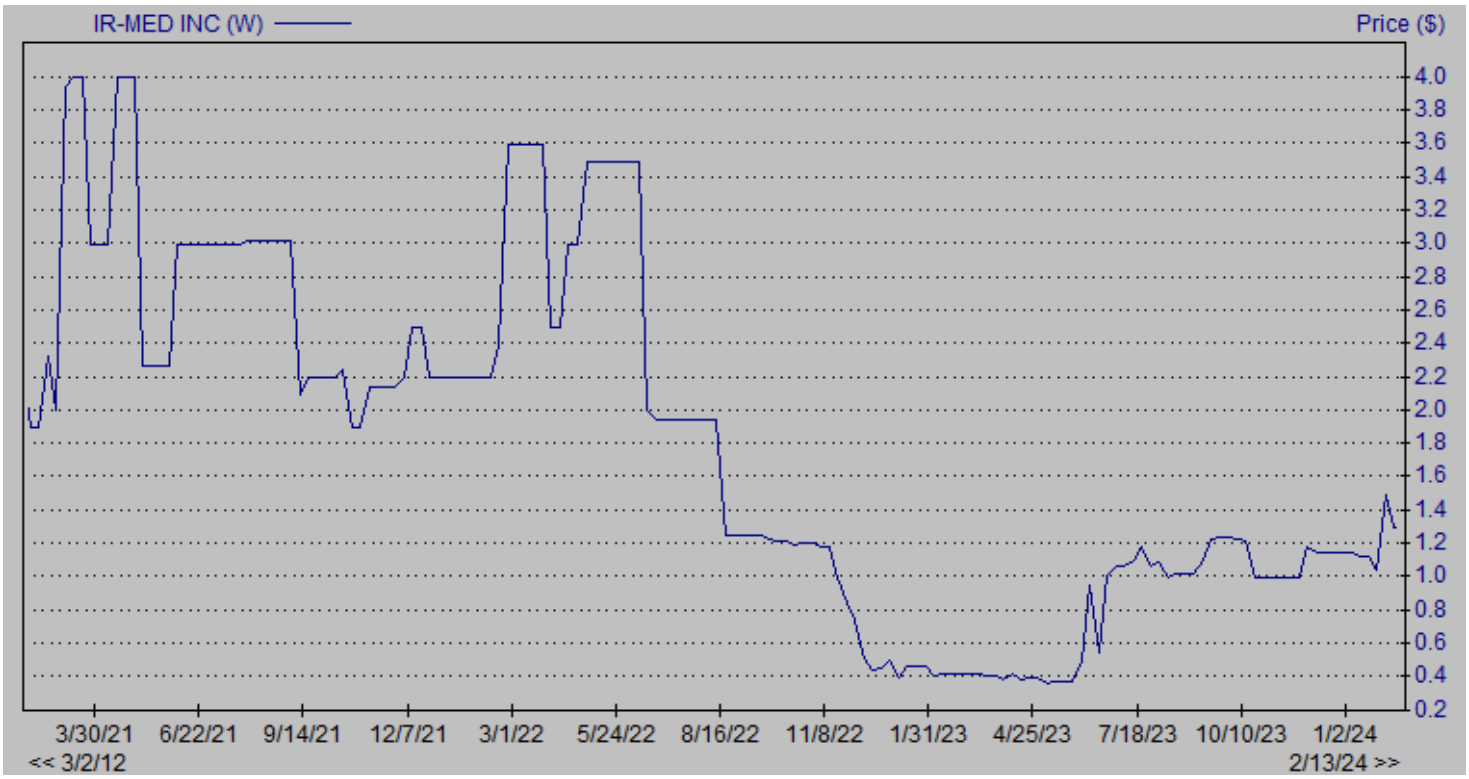
IR-Med has the potential to grow both revenues and earnings at very robust double-digit growth rates starting in 2024 if it is able to execute on the commercialization of its PressureSafe device. The company's current stock price does not likely reflect that potential level of profitable growth going forward and we believe the stock to be significantly undervalued at this time.

PROJECTED INCOME STATEMENT

Income Statement	Dec-21	Dec-22	Dec-23	Dec-24	Dec-25
Net Sales	**0**	**0**	**0**	**1,100,000**	**17,250,000**
Growth	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*1468.2%*
Cost of Goods Sold	**0**	**0**	**0**	**495,000**	**5,325,000**
%	*N/A*	*N/A*	*N/A*	*45.0%*	*30.9%*
Depreciation & Amort	**0**	**0**	**0**	**0**	**0**
Gross Profit	**0**	**0**	**0**	**605,000**	**11,925,000**
Margin	*N/A*	*N/A*	*N/A*	*55.0%*	*69.1%*
Sales & Marketing Expenses	**888,000**	**759,000**	**1,017,100**	**1,450,334**	**1,812,917**
% of sales	*N/A*	*N/A*	*N/A*	*131.8%*	*10.5%*
General & Administrative Expenses	**1,368,000**	**2,118,000**	**2,008,300**	**1,975,043**	**1,678,787**
% of sales	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*179.5%*	*9.7%*
Research & Development	**1,419,000**	**1,885,000**	**2,179,700**	**2,277,235**	**2,220,304**
% of sales	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*207.0%*	*12.9%*
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)**	**(5,205,100)**	**(5,097,613)**	**6,212,991**
Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-463.4%*	*36.0%*
EBITDA	**(3,675,000)**	**(4,762,000)**	**(5,205,100)**	**(5,097,613)**	**6,212,991**
Margin	*N/A*	*N/A*	*N/A*	*-463.4%*	*36.0%*
Other Expenses/(Income)	**35,000**	**(34,000)**	**(1,000)**	**(8,000)**	**12,541**
%	*N/A*	*N/A*	*N/A*	*-0.7%*	*0.1%*
EBIT	**(3,710,000)**	**(4,728,000)**	**(5,204,100)**	**(5,089,613)**	**6,200,450**
%	*N/A*	*N/A*	*N/A*	*-462.7%*	*35.9%*
Total Interest Exp (net)	**6,000**	**6,000**	**0**	**0**	**0**
%	*N/A*	*N/A*	*N/A*	*0.0%*	*0.0%*
Net Profit Before Tax	**(3,716,000)**	**(4,734,000)**	**(5,204,100)**	**(5,089,613)**	**6,200,450**
%	*N/A*	*N/A*	*N/A*	*-462.7%*	*35.9%*
Income Tax	**0**	**0**	**0**	**0**	**930,068**
% 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)**	**(5,204,100)**	**(5,089,613)**	**5,270,383**
%	*N/A*	*N/A*	*N/A*	*-462.7%*	*30.6%*
Non-recurring income (expense)					
Average Diluted Shares Outstanding	63,110,764	67,577,734	68,833,011	68,829,424	68,829,424
Reported FD EPS					
Zacks Cash EPS	**(0.06)**	**(0.07)**	**(0.08)**	**(0.07)**	**0.08**
Zacks EPS	**(0.06)**	**(0.07)**	**(0.08)**	**(0.07)**	**0.08**

Source: Zacks analyst

HISTORICAL STOCK PRICE



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