

# Initiation Report

INSPIRA TECHNOLOGIES LIMITED



## Inspira Technologies Oxy B.H.N. Ltd. – Disrupting the Respiratory Care Market with Innovative Product Portfolio

Inspira Technologies Ltd. (NASDAQ: IINN)

Share Price: \$1.28

Valuation: \$5.81



### Key Statistics

52 Week Range	\$0.98 – \$3.76
Avg. Volume (3 months)	100,608
Shares Outstanding	11.08M
Market Capitalization	\$14.18M
EV/Revenue	n/a
Cash Balance*	\$16.2M
Analyst Coverage	2

\*Cash balance as of September 2022

### Revenue (in \$mm)

Dec - FY	2021A	2022E	2023E
1H	0.00	0.00	0.00
2H	0.00	0.00	0.00
FY	0.00	0.00	0.00

### EPS (in \$)

Dec - FY	2021A	2022E	2023E
1H	(3.11)	(0.33)	(0.63)
2H	(1.09)	(0.74)	(0.85)
FY	(3.20)	(1.07)	(1.48)

### Stock Price Chart



## Investment Highlights

- Innovative Product Pipeline Setting a New Standard of Care** - The company's product pipeline is comprised of innovative and disruptive respiratory support technology that has the potential to improve patient outcomes substantially. The company is developing a novel oxygenation therapy, the INSPIRA™ ART system, designed to rebalance oxygen saturation levels while patients are awake and breathing spontaneously (for patients with acute respiratory failure). The system aims to reduce the need for invasive mechanical ventilation and the potential complications associated with it. The INSPIRA™ ART System is designed in a way to incorporate state-of-the-art technology components that supports multiple benefits, including minimizing medical risks, and reducing the need for perfusionists and operational errors in comparison with currently available extracorporeal blood oxygenation systems. Other products within the company's pipeline include the non-invasive HYLATM Blood Sensor and ALICETM cardio-pulmonary bypass (heart-lung) device. The HYLATM blood sensor aims to contribute to improved hospitalized patient care by providing non-invasive continuous blood measurements in real time of key blood parameters with the intention to alert physicians of signs of changes in a patient's clinical condition, enabling earlier medical response and intervention. The company's innovative product pipeline has the potential to set a new and improved standard of care for millions of patients across the globe while generating long-term value for its multiple stakeholders, including clinicians, hospitals, and investors.
- Multiple Industry Growth Catalysts Propelling the Multi-billion Dollar Market** - There are an estimated 20 million patients annually receiving invasive mechanical ventilation, with 69% of the patients being attributed to acute respiratory failure. In the U.S. alone, 5.7 million patients are admitted to ICUs, with 40% of them being placed on invasive mechanical ventilation ("IMV"). The benefits of the company's solutions and technology over the current standard of care enhance its competitive positioning, allowing it to target a share of the growing \$22.5 billion IMV market and point-of-care blood analyzer market. An increase in the prevalence of respiratory diseases, respiratory comorbidities following COVID-19, and the growing geriatric population are a few of the major catalysts that are expected to propel the market in the coming years.
- Strategic & Exclusive OEM Agreement** – Inspira has signed an exclusive OEM (Original Equipment Manufacturing) agreement with Terumo Cardiovascular, a division of Terumo Corporation, a leading global medical device company. Terumo Corporation operates in over 160 countries and regions around the world, providing patients in a variety of medical settings with over 50,000 products and services. The agreement provides for the manufacture of a flow mechanism that is intended to be integrated into Inspira products for use in the extracorporeal circulation of the blood during the oxygenation process.
- Clinical Study Planned for Q1 of 2023** – Inspira has signed an agreement with Sheba Medical Center, an Israeli hospital ranked 10th in the world, to be the first site for the HYLATM blood sensor's clinical study. Sheba Medical Center is internationally known for its groundbreaking medical research partnering with the MedTech industry to develop diagnostic tools, imaging modalities, drug delivery systems, medical devices, and therapeutic solutions.

## Company Description

Inspira Technologies is a specialty medical device company developing innovative respiratory care solutions as an alternative to invasive mechanical ventilation (IMV) for the treatment of respiratory failure. The company was formerly known as Insense Medical Ltd. and changed its name to Inspira Technologies Oxy B.H.N. Ltd. in July 2020

- **Progressing Towards FDA Submission in 2023** – The Company began the manufacturing process for the ALICE™ CPB (Cardiopulmonary Bypass) device to undergo the Verification and Validation phase prior to its planned 2023 submission to the U.S. Food and Drug Administration (FDA) for 510(k) clearance. If FDA clearance is obtained, the ALICE™ device production line will be extended for Low-Rate Initial Production (LWRIP), which is an important operational stage in developing infrastructure to support serial manufacturing, quality control, and shipping. Additional units are expected to be assembled for the targeted future first deployments of the ALICE™ devices in the U.S. and Israel. The ALICE™ device is being contract manufactured by an end-to-end solution provider that offers New Product Introduction (NPI) services to mass production capabilities for leading medical electronic device companies.
- **Product Market Validation** - Inspira’s disruptive product portfolio has gained a lot of attention in the past year from multiple regional distributors in the U.S.A, Europe, and Israel. The company was also awarded the 2021 Frost & Sullivan Technology Innovation Leadership Award, providing recognition for the development of an innovative and minimally invasive alternative to invasive mechanical ventilation. To date, the company has entered into multiple regional distribution agreements for the potential sale of its INSPIRA™ ART and HYLA™ devices which amount to over \$485 million over a period of up to 7 years, contingent on the completion of product development and successful regulatory approval.
- **Pre-clinical Study Results Supporting Product Capabilities** - The company has completed a phase of animal studies for its INSPIRA™ ART and HYLA™ devices. The company had earlier announced the results of its in-vivo pre-clinical research studies involving the assessment of the INSPIRA™ ART system in a hypoxemic swine model. The results indicated an increase from 85% to 93% in oxygen saturation levels in the carotid artery and an increase from 46% to 72% in the pulmonary artery. It also exhibited a statistically significant decrease in PaCO2 levels. The robust preclinical results are expected to be followed by human clinical studies for both devices.
- **Valuation** – Using a risk-adjusted discounted cash flow model assuming a discount rate of 15%, we have valued the company at \$64.36 million or \$5.81 per share contingent on successful execution by the company.

## Company Overview

Inspira Technologies Oxy B.H.N. Ltd. (NASDAQ: IINN) is a specialty medical device company developing innovative respiratory care solutions as an alternative to invasive mechanical ventilation for the treatment of respiratory failure. Based in Ra'anana, Israel, and incorporated in 2018, the company went public through an IPO in July 2021 and listed its shares on NASDAQ under the tickers IINN and IINN.W. With state-of-the-art respiratory support know-how, Inspira aims to create an all-new standard of care and give patients suffering from respiratory insufficiency or failure a chance to stay awake, experience continuous breathing, and avoid invasive mechanical ventilation-related complications and risks. Respiratory insufficiency is a situation when the lungs cannot perform enough to exchange gasses and support bodily metabolism. The conditions can occur spontaneously and are hard to determine or predict. Main indicators often include the dangerous decrease of oxygen levels in the blood (oxygen saturation). This is often caused by respiratory diseases or infections, such as COPD or Pneumonia, Sepsis, Corona Virus, or acute respiratory distress syndrome (ARDS). A World Health Organisation report dated 2017 estimates that over 400 million people on a global scale suffer from respiratory insufficiency. The Inspira vision is to facilitate the early oxygen saturation elevation and stabilization of conditions to prevent intubation and invasive mechanical ventilation.

### HYLA™ Blood Sensor



### INSPIRA™ ART System



### ALICE™ Device



*Inspira Technologies is a medical device company developing innovative respiratory care solutions as an alternative to invasive mechanical ventilation for the treatment of respiratory failure*

Exhibit 1: Product Portfolio. Source: Company Presentation

The company's lead product is the augmented respiration technology system (INSPIRA™ ART), a minimally invasive early-stage extracorporeal blood oxygenation system designed to utilize proprietary technology to rebalance oxygen saturation levels to potentially reduce the need for invasive mechanical ventilation and prevent its associated risks and costs. Inspira is actively working to establish collaborations with strategic partners, targeting (to date) approximately half a billion dollars in pre-conditional distribution agreements. Inspira has also signed an exclusive OEM (Original Equipment Manufacturing) agreement with Terumo Cardiovascular, a division of Terumo Corporation, a leading global medical device company. Terumo Corporation is a well-known global medical device company that operates in over 160 countries and provides a wide range of products and services to patients in various medical settings. The agreement provides for the manufacture of a flow mechanism that is intended to be integrated into Inspira products for use in the extracorporeal circulation of the blood during the oxygenation process. The company plans an FDA pre-submission for the INSPIRA™ ART system during H2 2023.

The company's second product is its HYLA™ blood sensor, a non-invasive optical blood sensor designed to perform real-time and continuous measurements of key blood parameters in patients.

Inspira is also developing a CPB (Cardiopulmonary Bypass) or heart-lung bypass device, ALICE™, which is designed to provide life support as well as to facilitate blood oxygenation and circulation for up to 6 hours of cardiac surgery. It is expected to be the first system created to integrate with the company’s non-invasive HYLATM blood sensor technology, designed to conduct continuous blood measurements in real-time, potentially alerting physicians of changes in an individual’s clinical condition. Inspira has recently signed an agreement with Sheba Medical Center, a 10th-ranked hospital in the world, to be the first site for the HYLATM blood sensor’s clinical study. Sheba Medical Center is internationally known for its ground-breaking medical research, integrating basic research, translational research, and clinical studies across a broad spectrum of medical disciplines.

The company actively seeks out strategic partnerships and globally ranked health centers to achieve endorsements and clinical adoption for deployment across regions. Inspira’s main targets are ICUs, medical units, emergency medical services, as well as small and rural hospitals.

## Respiratory Failure and Lack of Effective Treatment Options

Acute respiratory failure is a serious condition of a deteriorating lung’s ability to oxygenate the arterial blood and prevent carbon dioxide retention, which is crucial for optimal organ functioning. Failure of the gas exchanging and ventilatory process leads to life-threatening conditions such as hypoxemia (type 1 respiratory failure) or alveolar hypoventilation and hypercapnia (type 2 respiratory failure). In 2017, in the United States, there were an estimated 3,213,030 hospital discharges with a diagnosis code of respiratory failure.<sup>1</sup> Acute respiratory failure encompasses a heterogeneous spectrum of conditions and causes, such as chronic obstructive pulmonary disease (COPD), Covid-19, and acute respiratory distress syndrome (ARDS). Treatment is directed toward the underlying cause but is often accompanied by oxygen therapy providing necessary oxygenation and ventilation support.

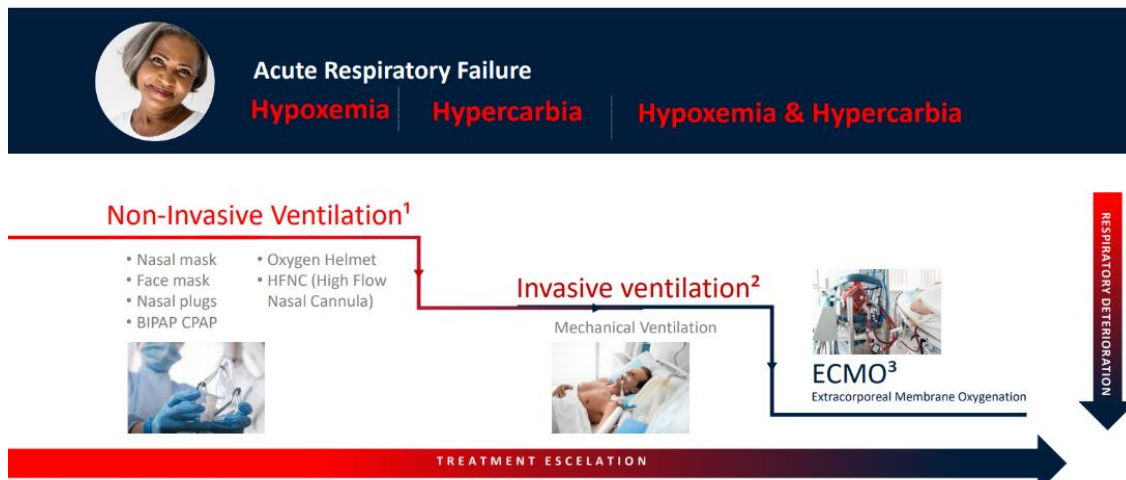


Exhibit 2: Acute Respiratory Failure Treatment Paradigm. Source: Company Presentation

<sup>1</sup> Kempker et al., Crit Care Explor. 2020

Based on the severity of the respiratory deterioration, the treatment for the underlying cause is supported by either non-invasive ventilation (NIV), invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO). Both invasive and non-invasive mechanical ventilation represents the common procedural code among patients with respiratory failure, while the ECMO procedure is often a last resort, being administered to less than 1% of patients with respiratory failure. Use of both IMV and NIV has steadily increased in the past two decades (2002-2017), exhibited by an 83% increase in incidence from 249 to 455 cases per 100,000 adult discharges being diagnosed with respiratory failure and requiring an accompanying mechanical ventilation procedure.<sup>1</sup> Mechanical ventilation is one of the common procedures used in intensive care units, with more than half of the patients in the ICU being ventilated in the first 24 hours after ICU admission; individuals who have acute respiratory failure, compromised lung function, difficulty in breathing, or failure to protect their airway.<sup>2</sup> Even though MV remains one of the vital medical interventions, it is also accompanied by the risk of significant and life-threatening complications such as ventilator-induced lung injury (VILI), bronchopleural fistula, ventilator-associated pneumonia (VAP), pneumothorax, and tracheomalacia. Furthermore, endotracheal tube intubation, a common invasive medical ventilation route, has been associated with laryngeal injury leading to laryngeal inflammation, edema, paralysis, and laryngotracheal stenosis. Mechanical ventilation-induced complications have been found to worsen the overall mortality and morbidity and can prolong the duration of mechanical ventilation resulting in an increased stay in the hospital and treatment costs. The in-hospital mortality rate for patients requiring intubation is as high as 44.3% and 48.4% in cases of pneumonia and acute respiratory distress syndrome (ARDS), respectively.<sup>3</sup> A study conducted in patients (n=3588) after cardiac surgery found that 11.57% of patients (n=415) requiring prolonged mechanical ventilation represented most of the post-operative mortality that was associated with complications that were not directly linked to surgery or a history of heart disease.<sup>4</sup>

The prevalent use and need for mechanical ventilation among patients with respiratory failure are evident but are accompanied by a set of drawbacks requiring continuous circumspection even after the treatment is administered. There is clearly an unmet need for much safer alternatives that can potentially reduce complications and improve prognosis and survival outcomes.

## The INSPIRA™ ART System

Inspira's Augmented Respiration Technology (ART) aims to disrupt and redefine the standard of care for patients with respiratory failure across the globe. The INSPIRA™ ART System is designed to provide a much safer and more effective alternative to currently marketed invasive mechanical ventilation devices. The INSPIRA™ ART System utilizes extracorporeal direct blood oxygenation in small volumes of blood of up to 1.5 to 2 litres per minute to elevate and stabilize deteriorating oxygen saturation levels within minutes while the patient is awake and spontaneously breathing both in ICUs and prospectively in other treatment environments (general medical wards or ambulatory settings). The INSPIRA™ ART System targets patients who continue to deteriorate

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<sup>2</sup> The American Association for The Surgery of Trauma. [www.aast.org/resources-detail/mechanical-ventilation-in-intensive-care-unit](http://www.aast.org/resources-detail/mechanical-ventilation-in-intensive-care-unit)

<sup>3</sup> Shebl et al., Respiratory Failure, 2022

<sup>4</sup> Maria et al., Respiratory Care May 2018

while being treated with non-invasive ventilation treatment, reducing their need for intubation and invasive mechanical ventilation and avoiding related complications, including VILI (Ventilator-induced lung injury), VIDD (Ventilator-induced diaphragmatic dysfunction) and VAP (Ventilator-associated pneumonia).

### About INSPIRA™ ART

- Extracorporeal approach**  
A first-in-class system specifically designed to provide continuous low-flow venous-venous extracorporeal respiratory support  
Cannula is designed to draw blood at a rate of 1-2L per minute<sup>1</sup>

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- Rapid oxygenation improvement & CO2 removal**  
O2 saturation level is raised in minutes<sup>2</sup>

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- Low flow utilization**  
Designed to reduce clotting and hemolysis

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- Compact & portable**  
Designed for ICUs, general medical wards & ambulatory settings



Exhibit 3: INSPIRA™ ART System. Source: Company Presentation

*INSPIRA™ ART is a minimally invasive early-stage extracorporeal blood oxygenation system that utilizes proprietary technology to rebalance oxygen saturation levels to potentially reduce the need for invasive mechanical ventilation and prevent associated risks and costs of IMV*

The system is being designed in a way to provide long-term respiratory care (longer than 6 hours) that provides assisted extracorporeal circulation and physiologic gas exchange. The INSPIRA™ ART System includes several primary components, including the control unit, dual lumen cannula, pump, initiation system, and disposable respiratory support unit. The proprietary components working together are intended to allow multiple innovative features to potentially magnify the company’s competitive positioning in the respiratory care market. The technology potentially reduces the risk of hemolysis, a single insertion point of a dual-lumen cannula can potentially lower the risk of multiple infections and bleeding, and the whole system reduces the need for a perfusionist.

<i>Blood protection</i>		
<b>INSPIRA ART’s designed features</b>	<b>Hemolysis reduction</b>	<b>Thrombosis reduction</b>
A unique (Low) flow-velocity ratio maintained throughout blood passage in disposable set	V	V
A low-volume oxygenator		V
Pump head design for low flow	V	V
Short dual lumen cannula design	V	
Entire disposable set is coated with anticoagulants		V

*The INSPIRA™ ART system technology leverages innovative designs which appears to have several competitive advantages*

Exhibit 4: INSPIRA™ ART’s Proprietary Hemo-protective Flow Technology Features. Source: Company Presentation

The innovative technology and the unique intervention modalities offered by the INSPIRA™ ART System have the potential to overcome shortcomings posed by invasive mechanical ventilation and FDA-approved treatments with a much more reasonable treatment cost. The INSPIRA™ ART System focuses on allowing the simplicity of administration with minimal invasiveness and no induced coma. The simplicity of the procedure and the innovative features of the technology are expected to reduce IMV-associated complication and mortality rates, shorten the treatment time with up to a 50% reduction in hospital days, which includes eliminating the requirement of IMV weaning, and target to be administered in ICU and non-ICU settings. In addition to reducing the need for invasive mechanical ventilation, the INSPIRA™ ART System may potentially also complement the IMV treatment modality shortening the invasive mechanical ventilation duration and reducing the risk of life-threatening complications such as VILI, VID, and VAP. The company has filed multiple patents with international coverage providing broad protection to its INSPIRA™ ART System. The patent application covers a cannula fixation device, dual lumen cannula, and extracorporeal oxygenation system for partial/low flow rates, their respective methods of use, and intent of use. Already the Israeli Patent Office (ILPO) has granted a patent for a key safety component securing neck cannula from moving or dislodging.

### Non-Clinical Study Design and Results

The company has concluded multiple pre-clinical studies examining the feasibility of direct blood oxygenation to prevent the need for IMV. The studies were performed in a swine model evaluating the use of the INSPIRA™ ART System and its ability to increase oxygen gas exchange during medically induced respiratory failure.

The study included placing large-white X landrace swine species (which resembles the anatomy, size scale, and other characteristics of adult humans) into a medically induced state of hypoxemia, reducing the oxygen saturation to between 80%-85%, thus mimicking the state of respiratory failure of compromised sick lungs. The INSPIRA™ ART System treatment was administered to the swine through the right jugular veins. Blood oxygenation and CO2 removal were assessed in 20 consecutive observations at a flow rate of just 1 litre/min.

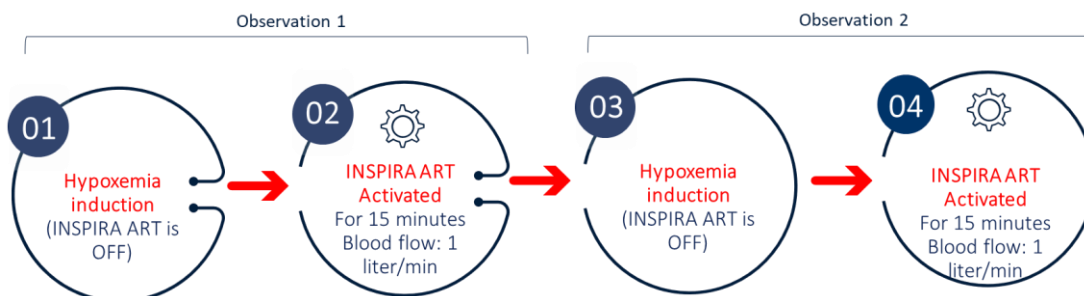


Exhibit 5: Pre-clinical Study Design. Source: Company Presentation

*Pre-clinical studies indicate that Inspira's ART technology facilitates blood oxygenation and CO2 removal, reducing the burden on the lungs*

The treatment administered with the INSPIRA™ ART System immediately elevated and stabilized the blood oxygen saturation levels. This underlying effect was noted in multiple observations proving consistency and repeatability using the System. Pre-clinical studies conducted in LAHAV CRO in Israel show that the System, in the hypoxemic swine model,



increased carotid artery oxygen saturation from 85% to 93% and increased pulmonary artery oxygen saturation from 46% to 72% with the blood pressure unaffected. The System also exhibited a significant decrease in PaCO<sub>2</sub>, demonstrating that the System facilitates blood oxygenation and CO<sub>2</sub> removal, reducing the burden on the lungs. Furthermore, the structure of the proprietary dual-lumen cannula after the removal did not display any signs of damage, and there were no indications of blood clots or fatigue.



Exhibit 6: Pre-clinical Studies Results. Source: Company Presentation

Inspira plans to schedule an FDA Pre-Submission in the second half of 2023, allowing the company formal feedback and providing more clarity on the potential pathway for the FDA approval of its INSPIRA™ ART System device. The System is expected to be categorized as a Class II medical device, and given the uniqueness of the device, we believe there is potentially no predicate for proving substantial equivalence. We expect a De-Novo or Premarket Approval (PMA) pathway, which might require the need for further clinical studies.

### Product Validation and Sale Agreements

The company has entered into multiple sales and distribution agreements, exhibiting the market's strong confidence in the unique technology. The five summary distribution agreements executed by Inspira target over \$400 million in sales of INSPIRA™ ART Systems and disposable units across major geographies, including the U.S., Europe, and Israel. The agreements are for a period of up to seven years and are subject to the completion of product development and necessary regulatory approval. Of the five agreements signed to date, the agreement with the U.S.-based Glo-Med Networks is valued at \$212 million. As per the agreement, Glo-Med has committed to

purchase a minimum of 2,121 INSPIRA™ ART systems and 131,413 disposable units in return for territorial exclusivity across the six states in the country (Texas, New Jersey, New York, Florida, North Carolina, and South Carolina). Another major strategic agreement with Europe’s Innovimed and WAAS group is valued at \$108 and \$66 million, respectively. Innovimed Sp. z o.o and WAAS group are leading distributors of state-of-the-art medical devices and solutions in major European countries. Both companies have committed to purchase 2,592 ART devices and 94,400 disposable units combined for deployment in ICUs and medical centers across Spain, Portugal, Poland, the Czech Republic, and Slovakia. Additional agreements have been signed for the HYLA™ Blood Sensor.

*Inspira has entered into multiple sales and distribution agreements, exhibiting the market’s strong confidence in the unique technology*

### Market Opportunity and Competitive Overview

As per the WHO estimates, over 400 million people are affected by respiratory insufficiency globally, and approximately 20 million people are admitted to ICUs requiring mechanical ventilation. Acute respiratory failure (ARF) accounts for 69% of people requiring MV. In the United States, in 2017, there were an estimated 1,146,195 discharges with a diagnosis of respiratory failure and procedural code for mechanical ventilation with an average length of stay of 10.5 days and a hospital discharge cost of \$158,443.<sup>1</sup> Based on over a million patients, the company estimates the initial potential market size in the U.S. at 633,000 patients per year. The INSPIRA™ ART System technology aims to potentially replace or complement mechanical ventilation devices in the U.S., which is valued at \$5.9 billion in 2021 and forecasted to grow at a CAGR of 14.01% from 2022 to 2030 to reach \$19.2 billion.<sup>5</sup>



Exhibit 7: Global Mechanical Ventilators Market Size (\$ billion). Source: Precedence Research

*The company estimates that the INSPIRA™ ART system has a potential U.S. addressable market of \$1.3 billion, based on a targeted patient treatment cost of at least \$1,250 for each disposable respiratory support and a system unit cost of \$22,500*

The company estimates the unit cost of the system at approximately \$22,500, and the disposable respiratory support unit cost is estimated at \$1,250. Based on the company’s initial U.S. target population size and the cost estimates, the potential initial addressable for the U.S. is valued at approximately \$1,300 million (system and disposable sales). The company estimates that

<sup>5</sup> Precedence Research, <https://www.precedenceresearch.com/mechanical-ventilators-market>

approximately 25,000 INSPIRA™ ART systems will be required in order to treat the initial U.S. target market of 633,000 patients per year.

## Multiple Trends Propelling the Market in the Coming Years

### U.S. Market is Expected to Grow Steadily – A stable growth is expected

(Based on invasive mechanical ventilation market – Inspira’s patient population target market)

The global mechanical ventilators market size was valued at \$7.24 billion in 2020 and is expected to record a CAGR of 4.9% from 2022 to 2028.

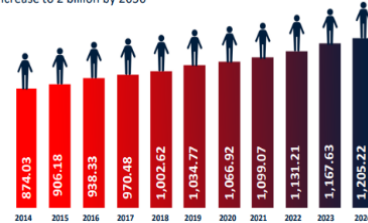
Source: WHO, U.S. CDC, FDA, Investor Presentations, Primary Interviews, Grand View Research



### Growing geriatric population

According to estimates published by the WHO, the global population aged 60 years and above is expected to increase to 2 billion by 2050

Source: United Nations, Grand Research



### Increase in the prevalence of respiratory diseases

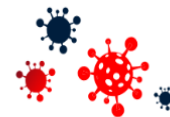
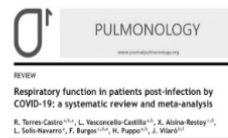
One of the key driving factors for invasive mechanical ventilation is the rising prevalence of respiratory diseases, which is expected to have a significant impact on the market.



Grand View Research Invasive Mechanical Ventilation Market Analysis and Segment Forecast to 2028

### Respiratory comorbidities following COVID-19

"Post-infection COVID-19 patients showed impaired lung function; the most important of the pulmonary function tests affected was the diffusion capacity".



U. Torres-Castro et al. "Respiratory function in patients post-infection by COVID-19: a systematic review and meta-analysis". Pulmonary, Volume 27, Issue 4, Pages 281-302 (July-August 2021)

Exhibit 8: Industry Growth Catalysts. Source: Company Presentation

The mechanical ventilation market is currently populated with legacy players, which represent the company’s primary competitors in this space. The market has displayed very little innovation, despite intense competition by players to maintain and grow market share. The INSPIRA™ ART System aims to penetrate the respiratory support system market by providing a new category of respiratory care designed to reduce the need for invasive mechanical ventilation, potentially disrupting the current IMV market. We believe the cost-effective and potentially much better respiratory care offered by the System provides Inspira with a substantial competitive advantage in the IMV technology landscape. The market is currently occupied by other players in MV technology, such as Hamilton Medical, which aims to create a competitive positioning in portable MV with the HAMILTON-C6, HAMILTON-MR1, and HAMILTON-T1 MILITARY. MOVES® SLC™ by Thornhill Medical is also an integrated life support system that was recently approved by the Army Aviation and Missile Research, Development and Engineering Center (AMRDEC) for the fleet-wide U.S. Army Airworthiness Release (AWR) as a Patient Movement Item (PMI). Non-Invasive Ventilation players such as COMEN with their V1 and V3 specializing in transportable intensive care and the Dräger’s Savina® 300 NIV (Non-Invasive Ventilation). In the COPD NIV space is Konsung with its Electronic ventilator DM28-25SA-BP, Electronic ventilator DM28-20A-WP, and electronic ventilator DM28-20C-G; Heinen and Löwenstein’s prisma30ST; Air Liquide Medical Systems’ Vendom and O-Two Medical Technologies’ CAREvent®. Other potential competitors include Boston Scientific Corporation, ResMed Inc., Masimo Corporation, Beckton, Dickinson, and Company.

## INSPIRA ART Respiratory Support System's Potential Benefits




		
<p><b>The patient's perspective</b></p> <ul style="list-style-type: none"> <li>• Immediate oxygen saturation elevation</li> <li>• No need for induced coma</li> <li>• Decreased work of breathing - Improving compliance to High Flow Nasal Cannula</li> <li>• Patient can communicate their symptoms and needs to the medical team</li> <li>• Avoiding some forms of complications associated with MV</li> </ul>	<p><b>The clinician's perspective</b></p> <ul style="list-style-type: none"> <li>• Clinicians would be able to offer an alternative to mechanical ventilation</li> <li>• Minimal learning curve</li> <li>• Self priming system, can potentially minimize the need for perfusionist</li> <li>• Self priming system results in less human errors</li> <li>• Designed for use in ICUs, general wards &amp; ambulatory settings</li> </ul>	<p><b>The hospital perspective</b></p> <ul style="list-style-type: none"> <li>• Reduced costs and staff burden associated with MV complications</li> <li>• Increased patient throughput</li> <li>• New level of acute respiratory care available outside of ICUs</li> <li>• Reduction of patient load in ICU</li> <li>• Reduced staffing - No need for perfusionists</li> <li>• No need for surgical access team</li> </ul>

Exhibit 9: Potential Benefits to Multiple Stakeholders. Source: Company Presentation

There is a clear treatment gap between non-invasive ventilation and invasive mechanical ventilation that needs to be filled, and this is where Inspira comes in. The INSPIRA™ ART System technology concentrates on fulfilling an unmet need for patients who are deteriorating on non-invasive ventilation and require much more effective but safer treatment options than invasive mechanical ventilation, which is essentially life support and, therefore, should be a last resort. We believe the INSPIRA™ ART System has the potential to fulfill this need and has demonstrated its effectiveness in recent pre-clinical studies. The INSPIRA™ ART System has the potential to penetrate and widen the breadth of the present respiratory care market, providing multiple benefits to patients, clinicians, and hospitals. The company has also laid down targets for its reimbursement strategy and insurance coverage when treated with the INSPIRA™ ART System and intends to pursue reimbursement under specified Medicare severity-diagnosis-related groups or MS-DRG.

### HYLA™ Blood Sensor

HYLA™ is a non-invasive optical blood sensor designed by Inspira to perform continuous and real-time measurements of key blood parameters in patients. The non-invasive HYLA™ blood sensor is being developed together with a team of cyber-warfare specialists who formerly served in the Israeli Defence Forces' elite cyber-attack special forces. The sensor is designed to perform continuous measurements of key blood parameters in real time. The HYLA™ blood sensor is non-invasive, in contrast to the frequent invasive blood tests that are performed today to identify the changes in the medical condition of the patients. The sensor is intended to measure multiple key indicators like partial oxygen and carbon dioxide levels, with the intention to alert physicians of signs of changes in a patient's clinical condition, enabling earlier medical response and intervention.

The HYLA™ non-invasive blood sensor is attached to the outer walls of a tube that has blood flowing through it. The sensor functions on optical technology and machine-learning-based algorithms that are being developed for the INSPIRA™ ART System. Like the INSPIRA™ ART System, the HYLA™ blood sensor is designed to minimize the need for invasive medical procedures with the intention of reducing risks, complications, and costs.



Exhibit 10: HYLATM Blood Sensor. Source: Company Website

*Based on optical technology and machine learning (ML) algorithm, the HYLATM non-invasive blood sensor provides rapid, real-time, and continuous vital blood monitoring*

Currently, blood-gas analyzers only reflect the patient's clinical condition at the exact moment the sample is drawn, meaning that, by the time the result is received, the blood-gas parameters no longer reflect the patient's actual condition. This problem is further magnified if the patient's condition is critical, and waiting for the diagnosis could prove to be deleterious. By continuously monitoring the patient's blood-gas parameters in real-time, the HYLATM blood sensor could potentially support the medical team during various extracorporeal blood treatment procedures such as ECMO (Extracorporeal Membrane Oxygenation), Heart-Lung Surgery, etc. The HYLATM blood sensor has broad potential application, benefiting patients undergoing extracorporeal blood treatment procedures by providing continuous in-line monitoring of the patient's blood parameters and allowing the medical team to react quickly to changes. Further, for critical and emergency cases, targeted patient populations can potentially include those suffering from acute respiratory failure, cardiac failure, or pneumonia, as well as patients undergoing open-heart surgery.

In September 2022, Inspira announced the completion of an animal study that was conducted at Lahav Contract Research Organization (C.R.O) by leading intensive care unit and respiratory specialists who are members of Inspira's Scientific Advisory Board. During the animal study, the HYLATM blood sensor performed measurements of blood parameters, with results being compared to numerous blood samples taken and analyzed using a routine blood gas analyzer, which is considered the standard of care used by hospitals today. The animal study was performed following prior successful ex-vivo data obtained with the HYLATM blood sensor in the company's laboratory. The completion of the animal study is an additional important step toward initiating human studies using the HYLATM blood sensor at Sheba Medical Center, which Inspira plans to commence in Q1 of 2023.

Inspira has signed an agreement with Sheba Medical Center, a 10th-ranked hospital in the world, to be the first site for the HYLATM blood sensor's clinical study. Sheba Medical Center is a renowned institution known for its pioneering work in medical research, encompassing a wide range of medical disciplines. Over the years, the center has worked closely with the MedTech industry to develop a range of medical innovations, including therapeutic solutions, diagnostic tools, imaging techniques, drug delivery systems, and medical devices.

## Product Validation and Sale Agreements

Since the announcement of the HYLA™ Blood Sensor, Inspira has signed strategic agreements in both the US and European markets to deploy its HYLA™ Blood Sensors. In July 2022, Inspira signed an exclusive summary distribution agreement with the U.S.-based Glo-Med Networks (“Glo-Med”) for the distribution of the HYLA™ blood sensor device and disposable units across six states in the United States (Texas, New Jersey, New York, Florida, North Carolina, and South Carolina). The agreement has an initial term of 3 years, subject to the completion of product development and regulatory approvals. The parties will collaborate on the marketing and deployment of the HYLA™ blood sensor. Pursuant to the agreement, and in order to maintain exclusivity in the territory, Glo-Med has committed to purchase a minimum order of 3,889 HYLA™ blood sensors and 264,873 disposable units for deployment at hospitals and medical centers, targeting a total value of \$59 million.

In November 2022, Inspira announced that it signed another such agreement with Innovimed Sp. z o.o (“Innovimed”), a company specializing in the commercialization of medical products in Europe, the Middle East, and Africa. The agreement has an initial term of 5 years, subject to the completion of product development and the receipt of regulatory approvals. Innovimed has committed to purchase a minimum order of 1,364 HYLA™ Blood Sensors and 128,511 disposable units for deployment in hospital units and operating theatres in Poland, the Czech Republic, and Slovakia, targeting a total value of \$26.1 million. To date, Inspira has HYLA™ distribution agreements in the US and Europe, amounting to a total value of \$85.1 million. Increased collaboration and interest validate the company’s development efforts and its HYLA™ Blood Sensor technology.

## Market Opportunity and Competitive Overview

Arterial blood gas analysis is necessary to monitor and assess the blood gas exchange among critically ill patients and during major surgeries. Instantaneous and point-of-care blood gas monitoring has been the need of the hour to overcome the obstacles associated with intermittent blood gas analysis under laboratory testing. Instantaneous blood gas monitoring could hold the key to providing rapid, efficient time-sensitive care, avoiding complications, and can potentially improve patient outcomes. The use of continuous in-line blood gas monitoring results in more accurate blood gas management during a cardiopulmonary bypass and results in an improvement in a number of post-operative outcomes variables.<sup>6</sup> The company is targeting the \$2.5 billion point-of-care blood gas analyzer market with the potential to improve outcomes for patients in ICUs, as well as patients undergoing ECMO, ECLS, or cardiopulmonary bypass procedures. The blood gas analyzer market growth catalysts include a growing geriatric population, increasing incidence of blood-related disorders, increasing incidence of respiratory diseases, and growing number of patients being treated in ICUs and NICUs. The HYLA™ blood sensor, upon approval, can potentially compete with a number of blood gas monitoring devices, including LivaNova’s B-Capta™ Blood-Gas Monitoring, Terumo CDI500, Siemens Healthineers’ RAPIDPoint 500e blood gas analyzer, and Spectrum Medical’s Quantum. Other potential competitors with a range

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<sup>6</sup> Trowbridge et al., J Extra Corpor Technol. 2000 Sep

of BGA product portfolios and point-of-care testing include Instrumental Laboratory, Radiometer Medical, Abbott Laboratories, and Roche Diagnostics.

## ALICE™ Cardiopulmonary Bypass (CPB) Device

The ALICE™ CPB (Cardiopulmonary Bypass) or heart-lung bypass device is designed to facilitate blood oxygenation and circulation for up to 6 hours or less of cardiac surgery. It is expected to be the first system to be integrated with the company's non-invasive HYLA™ blood sensor technology, which conducts continuous blood measurements in real-time, potentially minimizing the need to collect blood samples from patients and assisting physicians in monitoring an individual's clinical condition.

*The ALICE™ CPB (Cardiopulmonary Bypass) or heart-lung bypass device is designed to facilitate blood oxygenation and circulation for up to 6 hours of cardiac surgery*

Cardiopulmonary bypass (CPB) is a technique in which a machine temporarily takes over the function of the heart and lungs during surgery, maintaining the circulation of blood and oxygen to the body. The CPB pump itself is often referred to as a heart-lung machine or "the pump." The current CPB technology mechanically circulates and oxygenates blood for the body while bypassing the heart and lungs. It uses a heart-lung machine to maintain circulation to other body organs and tissues while the surgeon works in a bloodless surgical field. CPB is not benign, and there are a number of associated risks. As a consequence, CPB is only used during the several hours a cardiac surgery may take. In a CPB process, the patient is administered heparin to prevent clotting, and protamine sulfate is given after to reverse the effects of heparin. A CPB device that could continuously monitor the blood could be helpful in potentially detecting abnormalities instantaneously, which could help the medical professional to take the required action quickly.



Exhibit 11: ALICE™ CPB Device. Source: Company Website

The ALICE™ device is built to be compatible with several of Inspira Technologies' developed features and capabilities. This device is to be fully integrable with the HYLA™ Blood Sensor for continuous blood monitoring and includes a large touchscreen with a colorful graphic representation that increases the visibility, scope, and functionality of the data displayed. The device is lightweight with a small form factor, which makes it extremely portable. Despite being lightweight, it is designed to be highly durable, being built with an aerospace-grade aluminium structure. The device will be equipped with long battery life, making it distinctly suitable for patient mobility within hospitals.

Prior to its anticipated 2023 submission to the U.S. Food and Drug Administration (FDA) for 510(k) approval, the company has started manufacturing the ALICE™ CPB device for it to go through the Verification and Validation phase. The ALICE™ device production line will be expanded for Low-Rate Initial Production (LWRIP), a crucial operational phase in creating infrastructure to support serial manufacturing, quality control, and delivery, if FDA clearance is received. For the planned future first deployments of the ALICE™ devices in the U.S. and Israel, more units are anticipated to be built. The ALICE™ device is being contract manufactured by an end-to-end solution provider that offers New Product Introduction (NPI) services to mass production capabilities for leading medical electronic device companies. This includes full turn-key manufacturing, full system integration, including PCB (Printed Circuit Board) manufacturing, assembly services, testing, and packaging in facilities that meet Good Manufacturing Practices (GMP) compliance.

### **Market Opportunity and Competitive Overview**

The global cardiopulmonary device market is valued at \$2.8 billion annually; with the rising incidence of cardiopulmonary diseases, rising awareness of cardiopulmonary devices, and growing cases of complex cardiac surgeries, the market is poised to grow manifold in the next few decades.<sup>7</sup> Over the next five years, the global cardiopulmonary device market is expected to grow at a CAGR of 5%. The favorable regulatory policies just during the onset of the Covid-19 pandemic have played a key role in boosting the market. To offer cardiopulmonary and advanced circulatory support products and therapies to benefit Covid-19 virus-infected patients, the FDA, in April 2020, permitted manufacturers of cardiopulmonary bypass devices to modify the product indications for use to include ECMO therapy for greater than six hours, without prior submission of a premarket notification to FDA. The favorable regulatory policy change resulted in increased sales of cardiopulmonary and advanced circulatory support products. Benefiting from the policy, in October 2020, Abiomed received FDA 510(k) clearance for a cardiopulmonary bypass system called the Abiomed Breathe OXY-1 System.

The global heart-lung space was valued at approximately \$300 million in 2020, set to grow at a CAGR of 6.9% to reach \$700 million by 2031. The market is driven by increased R&D investments, collaborations between healthcare professionals and governments as well as the promotion of high-tech surgeries. This gives a large space to the ALICE™ system to work with and exploit. The ALICE™ CPB device is expected to be the first device to be integrated with the company's non-invasive HYLATM Blood Sensor for continuous blood monitoring in real-time. The LivaNova Cardiopulmonary's S5™ Heart-lung Machine, Medtronic Century Heart-lung machine, and Maquet HL heart-lung machine are some of the most widely used CPB devices and have been used in more than 12 million patients to date. Other major competitors in the industry are Terumo Corporation, Braile Biomedica, Tianjin Medical, and Senko Medical Instrument Manufacturing Company. The most recent development in the Cardiopulmonary Bypass (CBP) equipment was in August 2021, when FDA awarded the breakthrough privileges to Abiomed's Impella ECP expandable percutaneous heart pump.

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<sup>7</sup> MediTech Insights, <https://meditechinsights.com/cardiopulmonary-devices-market/>



## Management Overview

Inspira Technologies is led by an experienced team with deep expertise and extensive experience in product design, manufacturing, marketing, and commercializing in the medical technology industry. The management also has vast specialization in the fields of blood oxygenation and ECMO, and strives to develop a cost-effective, less-invasive respiratory support system as an alternative to mechanical ventilation used today to save the lives of patients with acute respiratory failure.

- **Dagi Ben Noon - Chief Executive Officer, Director & Co-Founder**

Dagi Ben Noon holds the position of Chief Executive Officer and is the Co-founder of Inspira Technologies. Dagi brings over 15 years of experience in product development, from idea inception to design specification, manufacturing, and commercial launch. Prior to founding Inspira Technologies, he co-founded Nano Dimension Ltd. (Nasdaq: NNDM) and served as the company's Chief Operating Officer and Director from July 2012 to October 2017. Dagi received a Bachelor of Science in Mechanical Engineering from the Ben-Gurion University of Negev.

- **Joe Hayon - President, Director & Co-Founder**

Joe Hayon is the Co-founder, President, and Director at Inspira Technologies. He has over twenty years of experience in finance, fundraising, and M&A and has been part of senior leadership teams in the medical and defense industries. Prior to joining Inspira, he served as Treasurer and Cost Accountant at Sanmina Ltd. (formerly Elscint), as Chief Financial Officer at the Arazim Group, and as Chief Information Officer and Controller (FP&A) at Plasan Sasa Ltd. Joe received his MBA from Ono Academic College, Israel,

- **Prof. Benad Goldwasser, MD, MBA - Chairman of the Board of Directors**

Prof. Benad Goldwasser chairs the board of directors at Inspira Technologies. Prof. Goldwasser is a urologic surgeon, inventor, entrepreneur, and venture capitalist with extensive leadership experience in high-growth, publicly-traded medical device companies. He co-founded Vidamed Inc., which was acquired by Medtronic Inc. (NYSE: MDT), and co-founded Medinol Ltd. in partnership with Boston Scientific (NYSE: BSX). He has served as a Chairman of Medigus Ltd (Nasdaq and TASE: MDGS), Chairman of Save Foods, Inc. (OTC: SAFO), Chairman of ScoutCam Inc. (OTC: SCTC), as well as a Director at Innoventric Ltd. In 2016 Prof. Goldwasser launched a venture capital fund partnered with Shanghai Alliance Investment Ltd (SAIL), a Shanghai Government investment company.

- **Avi Shabtay - Chief Operations Officer & VP, R&D**

Avi Shabtay holds the position of Chief Operations Officer and is Vice President of R&D at Inspira Technologies. Avi has over 25 years of experience managing high-tech

companies, particularly in their R&D and operations departments. Avi's expertise lies in engineering, testing, quality management, regulatory compliance, risk management, and production across an entire product's life cycle from concept to production. Prior to joining Inspira, Avi served as VP of R&D at Nano Dimension Ltd. (Nasdaq: NNDM).

- **Daniella Yeheskely-Hayon, Ph.D. - Chief Technology Officer**

Daniella holds the position of Chief Technology Officer at Inspira Technologies. Daniella has extensive experience in the fields of blood oxygenation and ECMO. Prior to joining Inspira, Daniella served as Director of R&D and COO at O2Cure Ltd. Daniella specializes in the development of long-term oxygenators and respiratory-assist devices for hospitals. Daniella holds a Ph.D. from the Technion and has authored 18 peer-reviewed publications.

- **Yafit Tehila - Chief Financial Officer**

Yafit holds the position of Chief Financial Officer at Inspira Technologies. Yafit is an experienced financial professional and accountant, and brings with her over 13 years of vast financial experience, working across various domains in PwC, Migdal Capital Markets, and Nano Dimension Ltd. (Nasdaq: NNDM). Yafit holds a B.A. in Economics, Accounting, and Business Administration from Tel-Aviv University.

## Financial Positioning and Major Milestones

As of September 2022, the company reported a cash and cash equivalents and cash deposits balance of \$16.2 million. The total short and long-term debt at the end of Q3 2022 is \$1.4 million. During the first half of 2022, the company reported an operating cash burn of \$1.96 million and an operating loss of \$11.6 million for the nine months ended September 2022. Based on the current cash balance and burn rate, we believe the company’s balance sheet strength reflects its ability to support its operational and research activities through 2023. The company is expected to commence and complete clinical studies for its HYLA™ blood sensor in 2023, with a planned FDA submission in 2023/2024. For the ALICE™ device, the company is planning a FDA submission during the second half of 2023 and can potentially reach commercialization in 2024. We expect a financing round potentially during 2024, supporting the company’s commercialization efforts.





















Distribution Agreements	Strategic Collaborations	New Technology & Product Reveals	Clinical Studies	FDA Submissions
 Signed Agreement in U.S. for future deployment* of INSPIRA™ ART Systems	 Leading World Renowned Hospital	 ALICE™ CPB Device	 Commencement of HYLA™ Study	 ALICE™ CPB (Heart-Lung) Device
 Signed Agreement in IL for future deployment* of INSPIRA™ ART Systems	 Manufacturing Agreement	 HYLA™ Blood Sensor	 Results of HYLA™ Study	 INSPIRA™ ART System (2023/2024)
 Signed Agreement in U.S for future deployment* of HYLA™ Blood Sensors	 Licensing Agreement	 New Tech Device	 Commencement of New Product Study	 Inspira DL Cannula (2023/2024)
 New Region	 HYLA™ Blood Sensor	 INSPIRA™ ART System	 Results of New Product Study	 Inspira Disposable Kit

Exhibit 12: Planned Milestones (2022-2023). Source: Company Presentation

Year-end 31 Dec. (in \$000's)	2020A	2021A	2022E	2023E	2024E
<b>INCOME STATEMENT</b>					
Revenue	\$0	\$0	\$0	\$0	\$6,296
Gross Profit	\$0	\$0	\$0	\$0	\$3,778
EBITDA	(\$6,117)	(\$13,214)	(\$15,959)	(\$18,009)	(\$9,760)
Depreciation & Amortization	(\$203)	(\$218)	(\$294)	(\$396)	(\$459)
EBIT	(\$6,320)	(\$13,432)	(\$16,253)	(\$18,405)	(\$10,219)
Interest Income/Expense	(\$959)	(\$3,523)	\$4,487	(\$96)	(\$107)
Profit Before Tax (PBT)	(\$7,228)	(\$16,955)	(\$11,766)	(\$18,500)	(\$10,325)
Profit After Tax (PAT)	(\$7,228)	(\$16,955)	(\$11,766)	(\$18,500)	(\$10,325)
Basic Shares Outstanding	1,968	5,306	10,868	12,498	17,498
EPS	(\$3.7)	(\$3.2)	(\$1.1)	(\$1.5)	(\$0.6)
<b>BALANCE SHEET</b>					
Cash and cash equivalents	\$496	\$23,749	\$8,550	\$3,005	\$7,203
Other current assets	\$188	\$759	\$5,256	\$1,509	\$3,400
Total current assets	\$684	\$24,508	\$13,806	\$4,515	\$10,603
Non-current assets	\$303	\$1,362	\$1,231	\$1,136	\$1,306
<b>Total Assets</b>	<b>\$987</b>	<b>\$25,870</b>	<b>\$15,038</b>	<b>\$5,650</b>	<b>\$11,909</b>
Short-term borrowing	\$180	\$281	\$309	\$309	\$309
Other current liabilities	\$771	\$4,033	\$942	\$1,662	\$2,737
Total current liabilities	\$951	\$4,314	\$1,251	\$1,971	\$3,046
Long-term borrowing	\$95	\$900	\$787	\$987	\$1,302
Other non-current liabilities	\$1,645	\$302	\$293	\$293	\$293
Total liabilities	\$2,691	\$5,516	\$2,331	\$3,251	\$4,641
Total Equity	(\$1,704)	\$20,354	\$12,707	\$2,399	\$7,268
<b>Total Liabilities &amp; Equity</b>	<b>\$987</b>	<b>\$25,870</b>	<b>\$15,038</b>	<b>\$5,650</b>	<b>\$11,909</b>

Exhibit 13: Income Statement Snapshot. Source: Diamond Equity Research

## Valuation

We have valued Inspira Technologies using risk-adjusted DCF as our preferred methodology. Our assumptions include a 75% probability of success for the INSPIRA™ ART and HYLA™ Blood Sensor and 85% for the ALICE™ System. We have assumed a system unit cost and disposable kit cost based on cues from company filings and the cost of competitive products. Our revenue assumptions are primarily based on the company's ability to actualize its strategic agreements. Our model incorporates expansion in gross margins in the initial years from 55%-60% to approximately 70% as the company scales with the addition of new customers and distributors.

Device	System Unit Cost	Disposable Kit Cost
INSPIRA™ ART System	\$22,500	\$1,250
HYLA™ Blood Sensor	\$5,000	\$150
ALICE™ Device	\$15,000	\$1,500

Exhibit 14: System Unit Cost and Disposable Kit Cost Assumption. Source: Diamond Equity Research

We have discounted the cash flows assuming a 15% discount rate yielding a value of \$64.36 million or \$5.81 per share contingent on successful execution by the company. We will further adjust our assumptions as the company progresses toward planned clinical studies and commercialization.

Device	Targeted Treatment	Prob. of Success	Pathway	Commercialization Year
Inspira™ ART System	ARF	75%	De-Novo or PMA	H1 - 2025
HYLA™ Blood Sensor	POC ABG testing	75%	De-Novo or PMA	H2 - 2024
ALICE™ Device	Heart-Lung Bypass	85%	Class II 510(k)	H1 - 2024

		Approaches (in \$' 000s)	Value	Weight	Wtd. Value
Calculated Equity Value (\$'000s)		DCF	\$64,141	90%	\$57,727
Enterprise Value	\$49,334	GPCM	\$66,304	10%	\$6,630
- Debt and Preferred Stock	\$1,409	GTM	-	0%	\$0.00
+ Cash	\$16,216	<b>Wtd Avg. Equity Value (USD)</b>			<b>\$64,357</b>
Net Debt	\$14,807	<b>No of Diluted Shares Outstanding (in 000's)</b>			<b>11,079</b>
Equity Value	\$64,141	<b>Intrinsic Value Per Share</b>			<b>\$5.81</b>

Company Name	Ticker	Price	Currency	Country	Mkt. Cap.#	P/B*	P/R&D*
Medtronic plc	MDT	\$80.86	USD	IE	\$107,558	2.10x	39.98x
Beckton, Dickinson, and Co.	BDX	\$259.34	USD	US	\$73,722	2.90x	58.51x
Boston Scientific Corporation	BSX	\$46.33	USD	US	\$66,359	3.80x	50.66x
ResMed, Inc.	RMD	\$208.89	USD	US	\$30,686	8.90x	119.49x
Terumo Corporation	TRUMY	\$27.42	USD	JP	\$20,417	2.50x	57.04x
Getinge AB (publ)	GNGBY	\$21.08	USD	SE	\$5,742	2.10x	47.70x
LivaNova PLC	LIVN	\$56.35	USD	GB	\$3,016	2.60x	19.46x
Nipro Corporation	NPRRF	\$8.50	USD	JP	\$1,386	0.80x	10.71x
<b>Median</b>						<b>2.55x</b>	<b>49.18x</b>
<b>Mean</b>						<b>3.21x</b>	<b>50.44x</b>

Exhibit 15: Valuation Snapshot. Source: Diamond Equity Research  
(#Market Cap in \$mm, \*Both P/B and P/R&D are trailing multiples)

## Risks Profile

- **Clinical Development Risks:** The success of the company heavily relies on the success of the Inspira technology trials. It is also important to note that these tests are expensive, time-consuming, and difficult to plan and implement, all with the risk of an uncertain outcome. Inspira products are based on novel technologies, which make it difficult to predict the cost, timing, and results of product candidates. Some products, such as the HYLA™ blood sensor, have not yet reached human trials, having recently passed animal studies.
- **Financial/Dilution Risks:** Inspira has a limited operating history, has not achieved profitability yet, and might never achieve or sustain profitability. Additional rounds of financing run the risk of dilution and unfavourable terms. There is also the risk of concentrating scarce resources on a tech product candidate that fails to yield returns and fails to capitalize on a profitable product.
- **Regulatory Risks:** Any disruptions in the FDA or other authorities, domestic or foreign, could impact development and commercialization. FDA and other regulatory processes are lengthy, costly, uncertain, and time-consuming. Serious defects or other adverse observations might emerge after final approval leading to discontinuation of the product, losing approval on all products, or if discovered after marketing approval, it could lead to the loss of marketing authorizations on their other product candidates. Besides regulatory approvals for product candidates, there are the regulatory requirements required for continued marketing.
- **Intellectual Property Risks:** Medical Technology companies rely on intellectual property, and the patents need to be protected. This bears the risks of possible lawsuits filed against the firm for infringement by the firm to protect their own IP rights, potential hurdles along the patent filing channels, and the processes these IP products entail in different jurisdictions.
- **Strategic/Competitive Risk:** Growth depends on the product candidates' success in commercialization, discovery, and development. Failure to do so would significantly hinder growth. Furthermore, competitive products could diminish or eliminate commercialization potential. With a company that solely deals with technology and technology-based patents, there comes a risk of a new and more efficient technology emerging from the competition. Reliance on third parties for trials, manufacturing, and development also poses a significant risk. Lastly, even if product candidates receive regulatory approval, the possibility of failing in market acceptance poses a risk to successful commercialization.

*These risk factors are not comprehensive for full risk factors, please review Inspira Technologies Oxy B.H.N. Ltd.'s relevant SEC filings with risk factors.*

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