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Investor Presentation

NASDAQ: \$IINN, \$IINNW

February 2023

Inspira

# Forward looking-Statements

This presentation of InspiraTM Technologies Oxy B.H.N. Ltd. ("Inspira Technologies" or the "Company") contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act and other securities law. Words such as "expects," "intends," "plans," "believes," "seeks," "estimates," and similar expressions or variations of such words are intended to identify forward-looking statements. For example, the Company is using forward-looking statements when it discusses its intention to revolutionize acute respiratory care, intended uses and potential benefits of its products and technology, its business model, the potential market growth in the industry, its strategy for gaining market penetration and market share, its go-to market strategy, potential strategic collaborations with third parties, its reimbursement strategy, its regulatory strategy, market potential for its products, commercialization of its products, the potential to use its products together with mechanical ventilation, the regulatory approval process of its product candidates and the potential submission of approvals with such regulators, the benefits and uses of its product candidates for intended patient populations, lines of therapy, the timing, and design, of its clinical studies and expected timing of regulatory approvals, the potential amounts that may be realized pursuant to its various distribution agreements and planned milestones for 2023, and its future growth. The presentation also contains estimates with respect to the Company's health economics model. Forward-looking statements are not historical facts, and are based upon management's current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management's expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed or indicated by the forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward-looking statements. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in the Company's annual report on Form 20-F for the fiscal year ended December 31, 2021 filed with the U.S. Securities and Exchange Commission (the "SEC"), which is available on the SEC's website, www.sec.govForward-looking statements speak only as of the date the statements are made. The Company assumes no obligation to update forward-looking statements to reflect actual results, subsequent events or circumstances, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws as well as subsequent filings with the SEC. If the Company does update one or more forward-looking statements, no inference should be drawn that the Company will make additional updates with respect thereto or with respect to other forward-looking statements.

### **Acute Respiratory Failure**

Invasive Mechanical Ventilation (IMV)

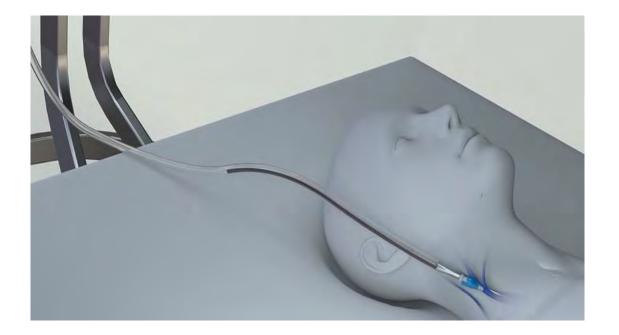
... is this your

ONLY CHOICE?



### Creating a New Class of Respiratory Care

### **INSPIRA™ ART** System



# Your right to choose

between intubation and coma (IMV) or being awake & breathing spontaneously with the **INSPIRA™ ART** 

\*The INSPIRA ART and the ART presented in this presentation are both referring to the INSPIRA ART. IMV = Invasive Mechanical Ventilation.



To-date the INSPIRA<sup>™</sup> ART System is still in development and has not been tested or used on humans and has not been cleared or approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

# **Creating Early Revenue Opportunities**

### **HYLA<sup>™</sup>** Blood Sensor



A non-invasive optical blood sensor being developed using machine learning based algorithms to measure blood parameters during extracorporeal procedures

- o Clinical Study in Q1-2023
- FDA Submission 510(k) H1-2024

### **ALICE<sup>™</sup>** Device



An extracorporeal blood circulation device designed to provide cardiac and pulmonary support

• FDA Submission 510(k) H2-2023

Potential Deployment H1-2024

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To-date the HYLA<sup>™</sup> and ALICE<sup>™</sup> are still in development and have not been tested or used on humans and have not been cleared or approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

# Leading the Industry



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# Inspira Achievements

https://inspira-technologies.com/news/



Inspira<sup>™</sup> Technologies Granted Patent by U.S. Patent Office for the INSPIRA<sup>™</sup> ART System's Convertible Dual Lumen Cannula Device and Method of Use

Inspira<sup>™</sup> Technologies Signs Strategic OEM Agreement with Terumo

14 December 2022

Inspira<sup>™</sup> Technologies Signs Agreement to Conduct Clinical Study of HYLA<sup>™</sup> Blood Sensor

23 November

Inspira™ Technologies Reports Third Quarter 2022 Financial Results

2022

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20 December 2022

27 December

2022

Inspira<sup>™</sup> Technologies Begins Manufacturing of the ALICE<sup>™</sup> CPB Device, Ahead of Planned 2023 FDA Submission

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Cardiovascular

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22 November 2022

Inspira<sup>™</sup> Technologies Signs a Strategic Agreement in Europe to potentially provide \$26.1 Million for Deployment of 1,364 HYLA™ Blood Sensors

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# A Growing Market



### **Acute Respiratory Failure Trends**

#### Global Market Expected to Grow

(Based on invasive mechanical ventilation market)

Growing geriatric population



Increase in the prevalence of respiratory diseases



Respiratory comorbidities following COVID-19

1. "Respiratory Care Devices Market by Product". Report by "Research and Market", June 2020. ID: 5129035

2. Forum of International Respiratory Societies. The Global Impact of Respiratory Disease – Second Edition. Sheffield, European Respiratory Society, 2017.



# The Respiratory Gap



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# Invasive Mechanical Ventilation Puts Patients at Risk <sup>1-3</sup>



### Invasive Intubation & Induced Coma

### **Potential Risks & Complications**

- Ventilator-induced lung injury (VILI)
- Ventilator-associated pneumonia (VAP)
- Ventilator-induced diaphragmatic dysfunction
- Muscular atrophy

### **High Cost of Treatment**

- Prolonged Ventilation & ICU stay
- Requires weaning process
- Extended rehabilitation period
- Patient re-admissions

- 1. Am J Respir Crit Care Med Vol. 196, P3-4, 2017. ATS Patient Education Series © 2017 American Thoracic Society
- 2. Diling Wu et al. Frontiers in pharmacology MINI REVIEW published: 09 May 2019. doi: 10.3389/fphar.2019.00482
- 3. Kalil AC, Metersky ML, Klompas M, et al. Management of Adults With Hospital-acquired and Ventilator-associated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society. Clin Infect Dis. 2016;63:e61-e111.



INSPIRA To-date the not been clea

To-date the INSPIRA<sup>™</sup> ART System, ALICE<sup>™</sup> Device and HYLA<sup>™</sup> Blood Sensor have not been tested or used on humans and have not been cleared or approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

### **INSPIRA™** ART System - Overview



#### A new class of acute respiratory care

Breakthrough Augmented Respiration Technology, designed to reduce the need for Invasive Mechanical Ventilation (IMV)

#### **Initial Target Population**

~633,000 acute respiratory failure patients in the U.S. each year<sup>1</sup>. The respiratory care market size is estimated to reach approximately \$27.6 Bn by 2026<sup>2</sup>

#### **Targeted Benefits**

- Designed to assist the compromised lung, by oxygenating a reduced volume of blood to boost patient saturation levels within minutes
- Aims for patient to be awake & spontaneously breathing
- No need for intubation, induced coma and weaning
- Potential to reduce risks, complications and high costs
- Designed for larger patient populations in and beyond ICU settings

Etiologies: ARDS, Pneumonia, Sepsis, COPD and acute Asthma patients

1. Kempker, Jordan A. MD, MSc et al. "The Epidemiology of Respiratory Failure in the United States 2002–2017: A Serial Cross-Sectional Study". Critical Care Explorations: June 2020 - Volume 2 - Issue 6 - p e0128

2. https://www.marketsandmarkets.com/Market-Reports/respiratory-care-368.html?gclid=CjwKCAiA\_vKeBhAdEiwAFb\_nrWoX-X7YUxRCJH1JpuEvdQ7AZYbIJ-E-XJIaS6GeJgg3LXYEg9yxKBoCGBkQAvD\_BwE

The INSPIRA ART and the ART presented in this presentation are both referring to the INSPIRA ART



To-date the INSPIRA<sup>™</sup> ART System, ALICE<sup>™</sup> Device and HYLA<sup>™</sup> Blood Sensor have not been tested or used on humans and have not been cleared or approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

### HYLA<sup>™</sup> Blood Sensor- Overview

#### Non-invasive blood measurement

A non-invasive optical blood sensor being developed using machine learning based algorithms to measure blood parameters, intended to provide continuous blood parameter measurements in real-time during extracorporeal procedures

#### Expected Regulatory Pathway - FDA 510(k)

#### **Annual Market Size**

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**~1.2m** applicable procedures annually: Acute Respiratory Failure (VV-ECMO), VA ECMO and Heart Surgery<sup>1</sup>



#### Key features (Incl. next generation)

- Continuous & real-time measurements
- o Measurements: SO<sub>2</sub>, Hb, HCT, PCO<sub>2</sub>, PO<sub>2</sub>, Temperature
- Potentially alerting physicians of sudden changes in a patient's key blood parameters, enabling prompt medical intervention
- Potentially alerting perfusionists of sudden changes in oxygenator performance (i.e., blood clotting, gas supply failure, system function and blood recirculation)
- Intuitive user-centric software and display
- A stand-alone or integrated device

1. Based on internal market assumptions and calculations

To-date the INSPIRA<sup>™</sup> ART System, ALICE<sup>™</sup> Device and HYLA<sup>™</sup> Blood Sensor have not been tested or used on humans and have not been cleared or approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

### **ALICE™** Device - Overview

### An extracorporeal blood circulation device designed to provide cardiac and pulmonary support

Expected Regulatory Pathway - FDA 510(k)

#### **Annual Market Size**

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- o **\$673m** Market Size by 2026<sup>1</sup>
- o **15,000-20,000** Procedures (U.S.)<sup>2</sup>
- **337** Hospitals in the U.S.<sup>3</sup>
  with extracorporeal experience



#### **Key Features**

- Intuitive user-centric software and display
- o Ergonomic device configuration
- Enabling in-hospital patient transfer with integrated lithium batteries provide up to 240 minutes of operating time when fully charged
- o Portable and light weight

#### **Next Generation - Key features**

- o Compatible with Inspira's HYLA blood sensor
- o Allowing integration of additional new sensors

1. https://www.emergenresearch.com/industry-report/extracorporeal-membrane-oxygenation-machine-market \*, Elso website.

2. ELSO Registry Dashboard. Data included patients from North America, Europe, Asia Pacific, Latin America, SWAAC

3. https://www.elso.org/Registry/SupportDocuments/CenterIDList.aspx

To-date the INSPIRA<sup>™</sup> ART System, ALICE<sup>™</sup> Device and HYLA<sup>™</sup> Blood Sensor have not been tested or used on humans and have not been cleared or approved by the U.S. Food and Drug Administration (FDA) or any other regulatory authority.

# Go-To-Market Strategy









#### Industry Endorsements



### **Planned Clinical Studies**

- Razor-Blade business model (System + Disposable Kits)
- ~\$480m in pre-conditional distribution agreements

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- Strategic OEM agreements
- Collaboration, Sheba Medical Center (Ranked in Top-10)
- World renowned KOLs continue to join our Scientific Advisory Board

- o HYLA, Q1-2023 (Data Collection Analysis)
- o INSPIRA ART, H2-2024 (First in Human)
- o INSPIRA ART, 2025 (Pilot Study)

KOLs = Key Opinion Leaders. There is no guarantee as to the success of any trial. In addition, there is inherent risk and variability in the overall regulatory process. Approval or clearance by the FDA may not be granted, or the FDA may require different study parameters from those that are intended to be included in the submission. While the Company

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intends to execute on strategic distribution agreements, there is no guarantee any sales will occur pursuant to those existing agreements, and agreements that may be executed in the future. The pre-conditional distribution agreements are for a period of up to 7-year and subject to completion of development, and the required regulatory approvals or clearances.

# **Planned Product Milestone Timeline**

H1-2023	H2-2023	H1-2024	H2-2024	2025
<b>Clinical Study Start</b> (Data Collection Analysis) Sheba Medical Center Up to 100 patients	<b>Clinical Study Results</b> (Data Collection Analysis)	<b>V&amp;V</b> Verification & Validation Testing	FDA Clearance	1 <sup>st</sup> Market Penetration
		FDA Submission 510 (k)		1 <sup>st</sup> Sales Order



	V&V Verification & Validation Testing	FDA Submission 510 (k)	FDA Clearance	1 <sup>st</sup> Market Penetration 1 <sup>st</sup> Sales Order	Additional Sites & Sales Order
J				<b>HYLA</b> Compatible	



Cannula Patent Approval	FDA Pre-Submission	V&V Verification & Validation Testing	<b>FiH</b> (First in Human) Clinical Study may be outside of U.S.A	Pilot Clinical Studymay be outside ofU.S.A orFDA IDE(Investigational DeviceExemption)
	Pre-clinical chronic model investigation			
	INSPIRA ART Patent Results	Pre-clinical study		

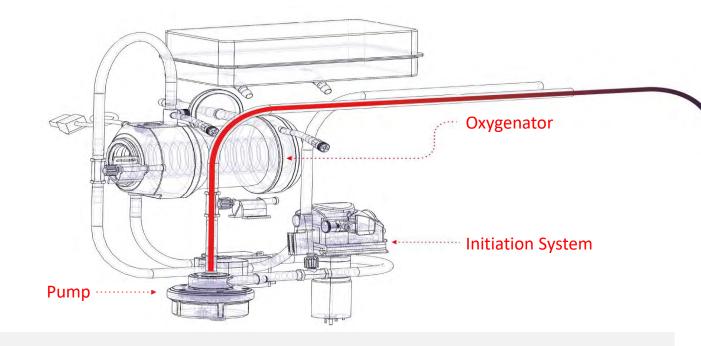
Timelines are subject to change. There is no guarantee as to the success of any trial or regulatory approval or clearance. In addition, there is inherent risk and variability in the overall regulatory process. Approval or clearance by the FDA may not be granted or the FDA may require different parameters from those that are intended to be included in the submissions. The estimated date/time of FDA clearance or approval may be subject to change and subject to approval or clearance of products by the FDA (Food & Drug Administration).

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There is no guarantee that the patents or patent families will be granted. Potentially some or all the clinical studies may be conducted outside of the U.S.A. Pilot Study refers to study that includes a small group of patients to be defined/decided by the company Copyright © 2018-2023 Inspira Tech

# **Inspira Patent Portfolio**

# 3 Patent Families

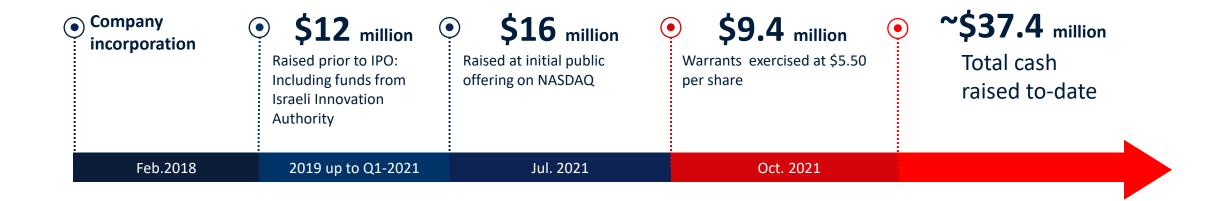


Family #1. INS-001 A Cannula Fixation Device – Granted in IL November 2022, Filed in U.S. September 2022

Family #2 INS-002 Dual Lumen Cannula and Methods of Use – Granted January 2023 in U.S.

Family #3 INS-003 Extracorporeal Oxygenation System for Low Flow Rates and Methods of Use – Filed in U.S. September 2022

### Inspira Cash Management



### \$16.2 million, Cash on hand as of Sep 30, 2022

**~\$0.9** million, average monthly burn-rate (Mar 31 to Sep 30, 2022)

### **Experienced Leadership Team**



**Prof. Benad Goldwasser, MD, MBA** Chairman

Multiple well-known industry exits



Dagi Ben-Noon, BSc Co-Founder, Director & CEO

Co-founder of Nano Dimension Nasdaq: NNMD



Joe Hayon, MBA Co-Founder, Director & President

#### M&A experience & track record

- Elscint Technologies
- Arazim Advanced Technologies



**Dr. Dekel Stavi, MD** Medical Director

Chairman of the Israel ECMO Society. Cardiac Surgeon at Sheba Medical Center



Avi Shabtay, BSc

25 yrs of Startup Development Experience



Daniella Yeheskely-Hayon, PhD CTO

Renowned Expert in the Field of Artificial Lung Development



Yafit Tehila, CPA CFO & Legal

Financial management experience in multiple public companies

### Scientific Advisory Board - Several World-Renowned KOLs



**Prof. Daniel Brodie** Intensivist & ECMO Advisor

President-elect of the Extracorporeal Life Support Organization (ELSO). Chairman of the Executive Committee of the International ECMO Network (ECMONet)



**Prof. Eddy Fan** Intensivist & ECMO Advisor

Medical director of the extracorporeal life support program at the Toronto General Hospital. Intensivist at the University Health Network/Mount Sinai Hospital



Dr. Stephan Ledot Intensivist & ECMO Advisor

World-renowned expert in critical care, ECMO, anesthesia and echocardiography. Fellowships in ECMO at the NHS, UK and cardiothoracic anesthesia at Harefield Hospital`



Dr. Yigal Kasif, MD ECMO Advisor

Former Chairman of the Israel ECMO Society. Director of ECMO program at Sheba Medical Center. Surgeon, Specializing in Adult Cardiac Surgery, Heart Transplantation and Assist Devices.

### Scientific Advisory Board - Several World-Renowned KOLs



**Prof. Eli Gabbay** Respiratory Disease Specialist

Professor of Respiratory Medicine, University of Notre Dame (Australia) Medical School & The University of Western Australia Medical School.



Dr. Avraham Abutbul Intensivist

Senior physician at Hadassah Medical Center's ICU & Pulmonology Institute, leads the hospital's nationwide research in COPD.



Dr. Yael Lichter Intensivist

Director of the ICU at Tel Aviv Sourasky Medical Center, Treasurer of the Israeli ECMO Society.



**Dr. Yorit Cohen Jacob** Veterinary Surgeon

Specialist in laboratory animal medicine, consults in pre-clinical research, GMP regulations.



**Dr. Sharon Marx** Physical Organic Chemistry

Department Head at the Israel Institute for Biological

US Public Relations Dave Gentry RedChip Companies Inc. 1-800-RED-CHIP (733-2447) or 407-491-4498 <u>IINN@redchip.com</u>

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