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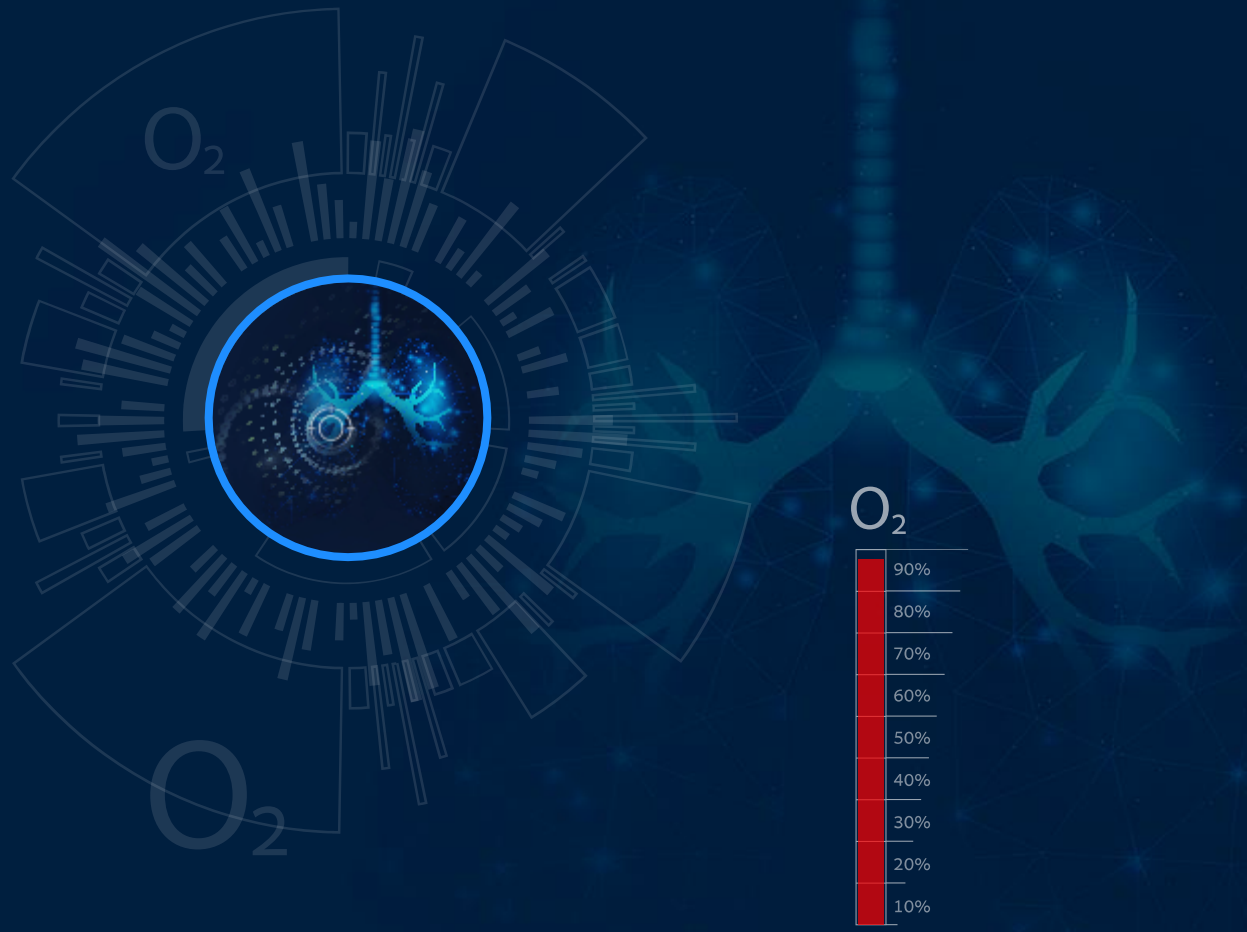
# REVOLUTIONIZING ACUTE RESPIRATORY CARE

Corporate Presentation | June 2023



# FORWARD LOOKING-STATEMENTS

This presentation of Inspira™ 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 the acute respiratory distress syndrome device and mechanical ventilator projected market sizes and the potential market sizes of each of its potential future products, its plans to reveal the INSPIRA™ ART100 device at the 2023 ELSO conference, its planned commercial advancement of the INSPIRA™ ART100 device, its expectation of its INSPIRA™ ART500 patent to be granted by the USPTO, the continuing status of its conditional distribution agreements across its three product lines, the potential outcome that INSPIRA™ ART500 can eliminate complications associated with mechanical ventilation, intended uses and potential benefits of its products and technology, its business model, its projected milestone timelines for each of the products, its strategy for market penetration and gaining 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 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 revenue stream that may be realized pursuant to its various distribution agreements, planned milestones for 2023, 2024, and 2025, 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, 2022 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.

# DISCLAIMERS

The INSPIRA™ ART and the ART presented in this presentation are both referring to the INSPIRA™ ART products (as a platform). INSPIRA™ ART500 was previously known as the INSPIRA™ ART. INSPIRA™ ART100 was previously known as the ALICE™.

INSPIRA™ ART or HYLA™ products may either have embedded or integrated INSPIRA™ AI with selective levels or functionality, yet to be decided by the company. These products may also not be embedded or integrated with INSPIRA™ AI and have limited or other types of software.

To-date the Augmented Respiration Technology, INSPIRA™ AI, HYLA™, INSPIRA™ ART100, INSPIRA™ ART500, VORTX and any other Inspira devices, disposables, components or technologies 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.

The HYLA™ is currently in on-going clinical studies as part of the product research and development process.

Timelines and planned or projected milestones 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.

Some or all the clinical studies may be conducted outside of the U.S.

Pilot Study refers to a study that includes a small group of patients to be defined/decided by the company, to be selected according to criteria chosen by those who will design the trial for the purpose of deriving clinical information from a representative population sample size. 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 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 seven years and are subject to the completion of the development and the required regulatory approvals and/or clearances.

$20B Market Size and Total Addressable Market for the INSPIRA™ ART HUB is based on company estimates (slides 4,6,30,31) and internal analysis of various sources including, but not limited to:

1. https://www.ihealthcareanalyst.com/global-acute-respiratory-distress-syndrome-devices-market/
2. https://www.globenewswire.com/en/news-release/2022/09/29/2525390/0/en/Mechanical-Ventilators-Market-Size-to-Hit-USD-19-2-Bn-by-2030.html
3. https://www.ihealthcareanalyst.com/global-acute-respiratory-distress-syndrome-devices-market/
4. https://www.marketdataforecast.com/market-reports/perfusion-systems-market

The statement “Expanding The Extracorporeal Blood Circulation Market to $20B”, refers to the $20B Market Size & Total Addressable Market for the INSPIRA™ ART HUB.

There is no guarantee that the patents or patent families will be granted.

MV = Invasive Mechanical Ventilation
KOLs = Key Opinion Leaders

# **INSPIRA™** END-TO-END SOLUTIONS

inspira™ ART100
AUGMENTED RESPIRATION TECHNOLOGY

## LIFE SUPPORT

Providing cardiac and pulmonary support


inspira™ ART500
AUGMENTED RESPIRATION TECHNOLOGY

## ACUTE RESPIRATORY SUPPORT

Preventing the need for Mechanical Ventilation


## Expanding The Extracorporeal Blood Circulation Market to **$20B***

* based on Company estimates

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**Extracorporeal Blood Circulation** - A procedure in which the patient's blood is circulated outside the body for oxygen enrichment and carbon dioxide removal and then returned to the patient.

# INSPIRA™ ART **HUB**

Augmented Respiration Technology

inspira ART100


HYLA™

Blood Sensor &
Supporting Technologies

INSPIRA™ AI


inspira ART500

# MARKET **SIZE**

**$19.5B**

**Acute respiratory distress syndrome devices**

by 2029[1] at a CAGR of 7.3%

Driven by increasing prevalence of acute lung injury and growing aging population.

INSPIRA™ **ART HUB**

**$20B**

Company Estimate

**$19.2B**

**Mechanical Ventilators**

by 2030[2] at a CAGR of 14.01%

Mechanical ventilation increases risk of infections in the airway as well as lung damage.

1. https://www.ihealthcareanalyst.com/global-acute-respiratory-distress-syndrome-devices-market/
2. https://www.globenewswire.com/en/news-release/2022/09/29/2525390/0/en/Mechanical-Ventilators-Market-Size-to-Hit-USD-19-2-Bn-by-2030.html

# **H2-2023** PLANNED NEWS ALERTS

inspira™ ART100
AUGMENTED RESPIRATION TECHNOLOGY

On track to submit the INSPIRA™ ART100 medical device to the U.S. FDA under the 510(k) pathway

New INSPIRA™ ART100 device to be revealed at the world's largest Extracorporeal Life Support Organization (ELSO) conference

inspira™ ART500
AUGMENTED RESPIRATION TECHNOLOGY

INSPIRA™ ART500 expected to receive additional patent grant by the U.S. Patent and Trademark Office (USPTO)

# INSPIRA™ **CORE TECHNOLOGIES**

## **A**UGMENTED
## **R**ESPIRATION
## **T**ECHNOLOGY


inspira ART500

Specifically designed extracorporeal blood circulation boosts oxygen saturation levels in minutes.

**Patient treated while awake**

NEW TREATMENT CATEGORY

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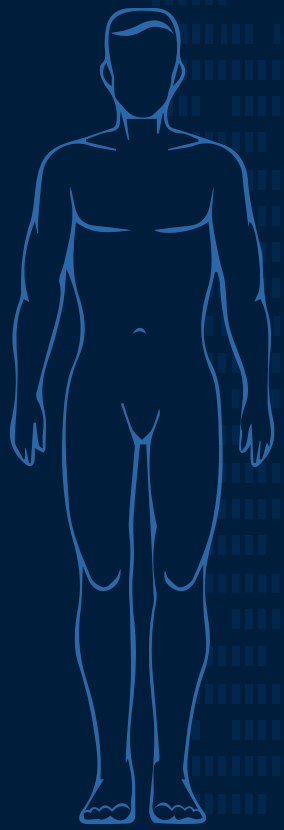
**Extracorporeal Blood Circulation** - A procedure in which the patient's blood is circulated outside the body for oxygen enrichment and carbon dioxide removal and then returned to the patient

Click to watch video

# INSPIRA™ AI **BREAKTHROUGH**

Augmented Respiration Technology

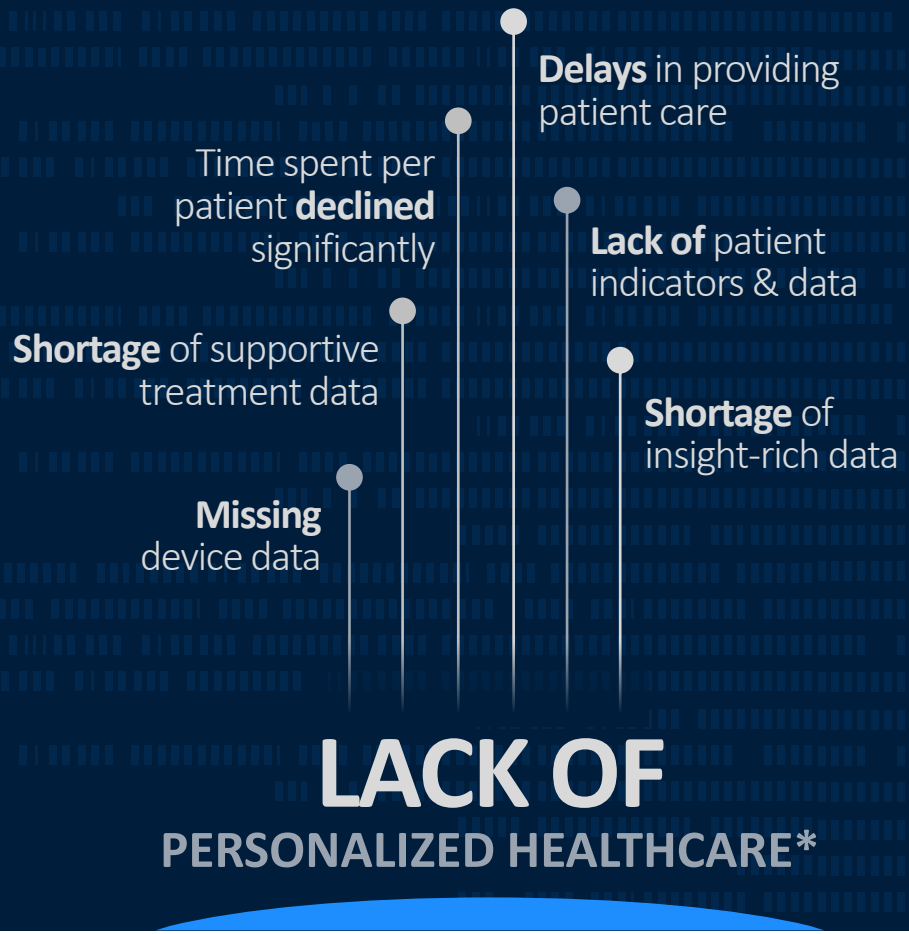
## TARGETING **HYPER-PERSONALIZATION** CARE



- Designed to continuously learn the patient and devices in real-time
- Decision-supportive data
- Aims to provide physicians with monitoring and predictive analytics
- Targeted to identify and monitor health issues or risks
- Intends to alert the need for attention or intervention

# SHORTAGE OF **REAL-TIME** PATIENT TREATMENT

Impacts quality of patient diagnosis and level of care




Can mean a significant difference in patient recovery…

*https://sambanova.ai/blog/hyperpersonalized-AI-to-improve-patient-care-and-reduce-costs/

# INSPIRA™ AI **PERSONALIZING TREATMENT**

## DATA COLLECTION

### Patient & Data Sources

Health Indicators, EMR, Patient Personal Data


### HYLA™

Blood Sensor & Supporting Technologies

### INSPIRA™ ART500

Augmented Respiration Technology

## ADAPTIVE ANALYTICS

- Collects data and generates simulations & augmented data models
- Analyzes and identifies patterns, anomalies, trends to generate insights and prediction-based analytics
- Query analytics to obtain more information or confirmation about certain aspects of patient health or device performance

# PROJECTED MILESTONE TIMELINE

Targeting additional strategic & distribution agreements

| PRODUCT | H1-2023 | H2-2023 | H1-2024 | H2-2024 | 2025 |
|---|---|---|---|---|---|
|  INSPIRA™ ART500 | **Cannula Patent Approval** Achieved | **INSPIRA™ ART Patent Approvals** | | **FiH (First in Human)** Clinical Study may be outside of U.S.A | **Pilot Clinical Study** may be outside of U.S.A Or **FDA IDE** (Investigational Device Exemption) |
|  HYLA™ Blood Sensor | **Clinical Study Start** (Data Collection Analysis) Sheba Medical Center Up to 100 patients In-Process | **Clinical Study Results** (Data Collection Analysis) | **FDA Submission 510 (k)** | **FDA Clearance** | **1st Market Penetration** |
|  INSPIRA™ ART100 | | **FDA Submission 510 (k)** | **FDA Clearance** | **1st Market Penetration** **HYLA™ Compatible** | **Additional Sites** |

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This timeline is representative of the Company's current expectations and is subject to change. There is no guarantee of any FDA clearance or success of any trial. In addition, there is inherent risk and variability in the overall regulatory process. Approval by the FDA may not be granted. While the Company anticipates potential market penetration in the future, there is no guarantee of success and such market penetration may never occur.

# INSPIRA™ **PATENT PORTFOLIO**

## THREE PATENT FAMILIES

### FAMILY #1

INS-001 A Cannula Fixation Device

**Granted in Israel 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**

# MANAGEMENT **TEAM**

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

Executive Chairman

Urologic surgeon, inventor & entrepreneur.
Multiple well-known industry exits

**Dagi Ben-Noon, BSc**

Co-Founder, Director & CEO

Co-founded Nano Dimension
Nasdaq: NNMD

**Joe Hayon, MBA**

Co-Founder, Director & President

M&A experience & track record Elscint Technologies

Arazim Integrated Technologies

**Avi Shabtay**

COO

New technology development & delivery track record

**Dr. Dekel Stavi, MD**

Medical Director

Senior Intensive Care physician at
Tel Aviv Sourasky Medical Center.
Chairman of the Israeli ECMO Society

**Dr. Adi Rizansky Nir, PhD**

CMO

Extensive experience in clinical strategy implementation

**Dr. 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

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# CHAIRMAN **OF THE BOARD**

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

Urologic surgeon, inventor, entrepreneur & venture capital VC

Vast experience in leading high growth, publicly traded medical companies.

Co-founded Vidamed Inc., acquired by Medtronic Inc. (NYSE: MDT).

Co-founded Medinol, partnered with Boston Scientific (NYSE: BSX).

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# FIRST QUARTER 2023 **FINANCIAL RESULTS**

**$11.5M**

**in cash, cash equivalents and deposits as of March 31, 2023**

## COMPANY WELL FINANCED FOR

**INSPIRA™ ART100**
FDA Clearance

On-going **HYLA™**
Research Clinical Study

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# APPENDICES


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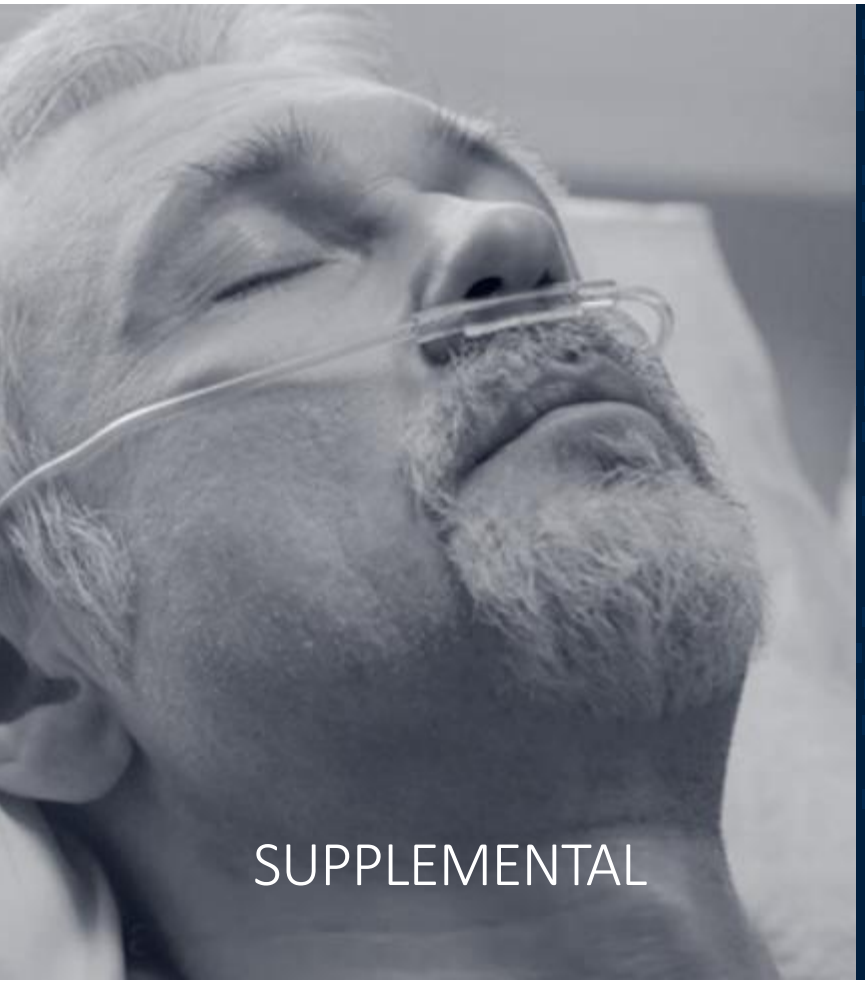

SUPPLEMENTAL

# THE RESPIRATORY GAP

MECHANICAL VENTILATION

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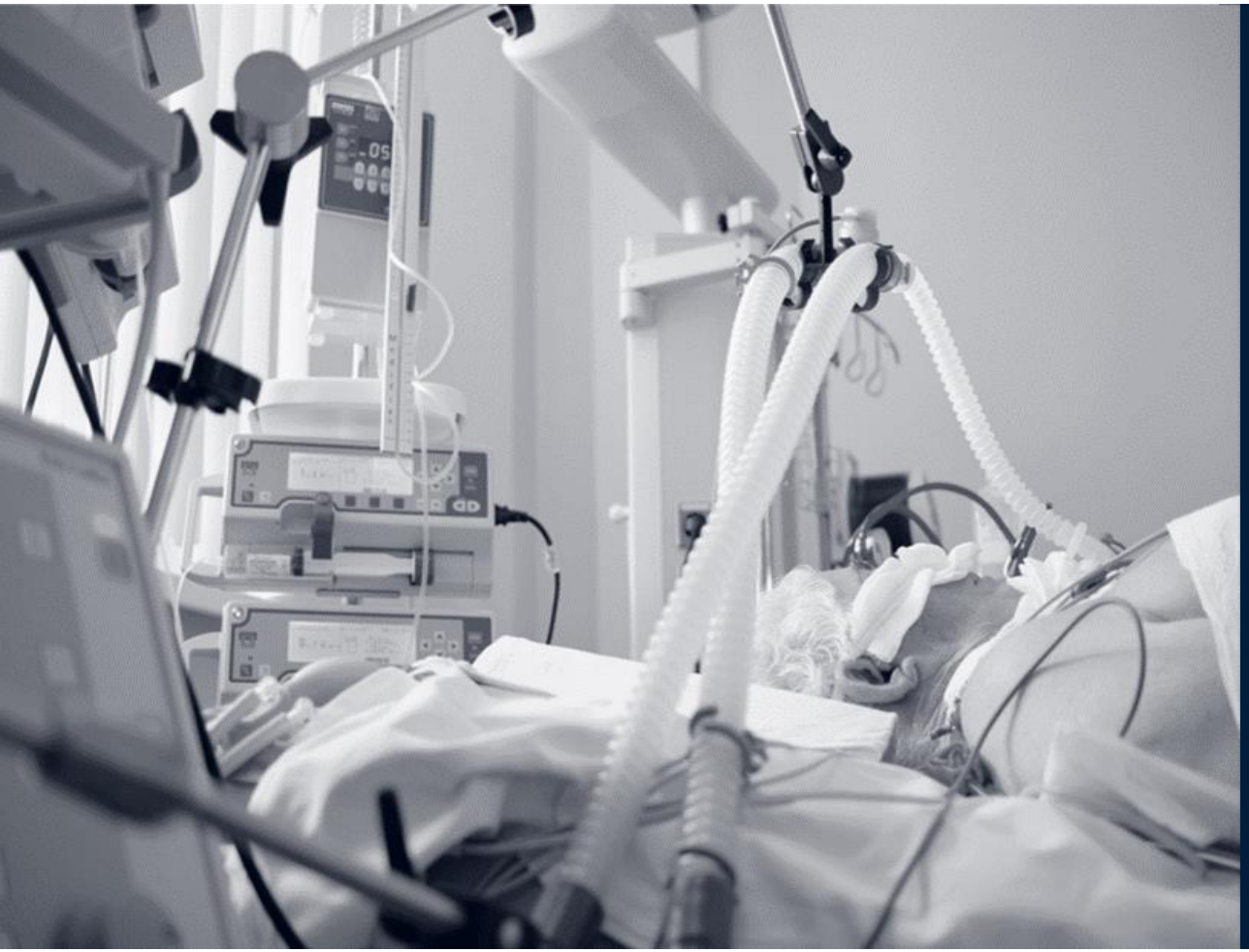

# 20M

PATIENTS EACH YEAR ON MECHANICAL VENTILATION*

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

# MECHANICAL VENTILATION – THE CURRENT STANDARD

A SLIDING

**50%**

MORTALITY RATE

- Intubation & coma
- No real-time patient data monitoring
- High risks of bacterial infections
- High risks of pulmonary edema & lung damage
- High risk of collapsed lung
- Risk of vocal cord paralysis
- Heart & blood flow changes (less oxygen gets to your blood)
- Risk of not being able to wean patient off ventilator
- Prolonging the dying process
- Liquid nutrition, usually through a tube that goes through your nose and into your stomach
- Mostly limited to ICUs

https://my.clevelandclinic.org/health/treatments/15368-mechanical-ventilation https://www.intechopen.com/chapters/59759#:~:text=Prolonged%20intubation%20is%20the%20major,)%20or%20bilateral%20%5B6%5D.
The use of mechanical ventilation in patients with idiopathic pulmonary fibrosis in the United States: A nationwide retrospective cohort analysis - ScienceDirect

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# **INSPIRA™** ART100

## OVERVIEW


## LIFE SUPPORT

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

inspira™ ART100
AUGMENTED RESPIRATION TECHNOLOGY

# ABOUT **INSPIRA™ ART100**

## WHAT IS THE INSPIRA™ ART100?

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

## HOW DOES IT WORK?

In order to replace the entire heart-lung function, the INSPIRA™ ART100 circulates the entire output of a patient's blood (5-7 liters per minute) in a procedure that enriches the blood with oxygen and removes carbon dioxide. The blood is then returned to the patient to provide oxygen to the patient’s tissues and organs.

## WHERE IS IT USED?

Suitable for a wide range of extracorporeal treatments in the ICU and during heart surgery.


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# INSPIRA™ ART100

## COMPETITIVE ADVANTAGE

### USER FOCUS

- Intuitive user-centric software and display
- Ergonomic device configuration
- Troubleshooting

### PATIENT FOCUS

- Enabling in-hospital patient transfer with integrated lithium batteries provide up to 240 minutes of operating time when fully charged
- Portable and light weight

### NEXT GENERATION - KEY FEATURES

- Compatible with Inspira's HYLA™ blood sensor intended to provide continuous blood parameter measurements in real-time during extracorporeal procedures
- Allowing integration of additional new sensors
- Integrated with INSPIRA™ AI

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# **HYLA™** BLOOD SENSOR

## OVERVIEW


## BLOOD DETECTION & MEASUREMENT

A non-invasive optical blood sensor to measure blood parameters continuously and in real-time during extracorporeal blood circulation procedures

# ABOUT **HYLA™ BLOOD SENSOR**

## WHAT IS THE HYLA™ BLOOD SENSOR?

A non-invasive optical blood sensor being developed using INSPIRA™ AI to measure blood parameters, intended to provide continuous blood parameter measurements in real-time during extracorporeal procedures.

## HOW DOES IT WORK?

The optical blood sensor takes continuous measurements of the blood as it flows through the extracorporeal tube.
The data is processed utilizing INSPIRA™ AI to provide continuous readings in real-time that are displayed on the system monitor.
INSPIRA™ AI displays alerts of projected trending changes in the patient's condition to allow early medical intervention.

## WHERE IS IT USED?

Suitable for a wide range of extracorporeal treatments in the ICU and during heart surgery.


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# HYLA™ BLOOD SENSOR

## COMPETITIVE ADVANTAGE

### USER FOCUS

- Easy clip-on sensor mounted onto the blood tube
- INSPIRA™ AI provides continuous information of key blood parameter in real time
- INSPIRA™ AI alerts of trending changes in the patient's condition to allow early medical intervention
- Intuitive user-centric software and display
- Stand-alone

### PATIENT FOCUS

- Non-invasive blood sensor
- No direct contact with the blood
- Reduces the need for blood sampling


### NEXT GENERATION - KEY FEATURES

- Compatible with the INSPIRA™ART to provide continuous blood parameter measurements and alerts of trending changes in the patient's condition in real-time during extracorporeal procedures
- Integrated device

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# **INSPIRA™** PATHWAY TO MARKET

# **TOTAL** ADDRESSABLE MARKET

INSPIRA™
ART500

**~$18B**

Company Estimate

INSPIRA™
ART100

**~$0.9B**

by 2030[1] at a CAGR of 5.75%


HYLA™
& Supporting
Technologies

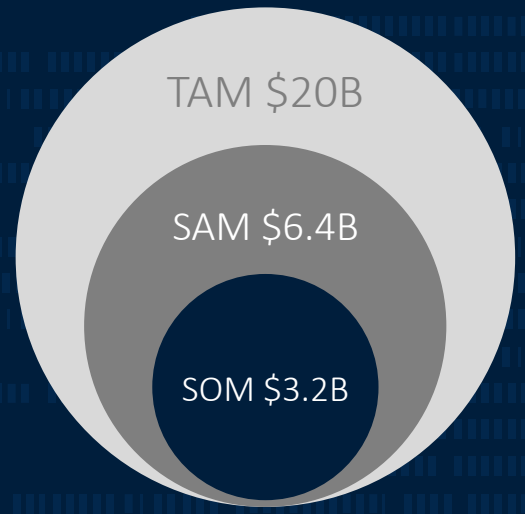
**~$1.1B**

Company Estimate



1. https://www.verifiedmarketresearch.com/product/extracorporeal-membrane-oxygenation-machine-market/

# **INSPIRA™** MARKET OPPORTUNITY


**SOM Company Estimates**

Primary markets: North America & Europe

TAM- Total addressable market
SAM- Serviceable Available Market
SOM- Serviceable Obtainable Market

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* All data is based on internal company estimates and are non-binding and subject to change

# **INSPIRA™** REIMBURSEMENT STRATEGY

Inspira plans to utilize existing CPT Codes

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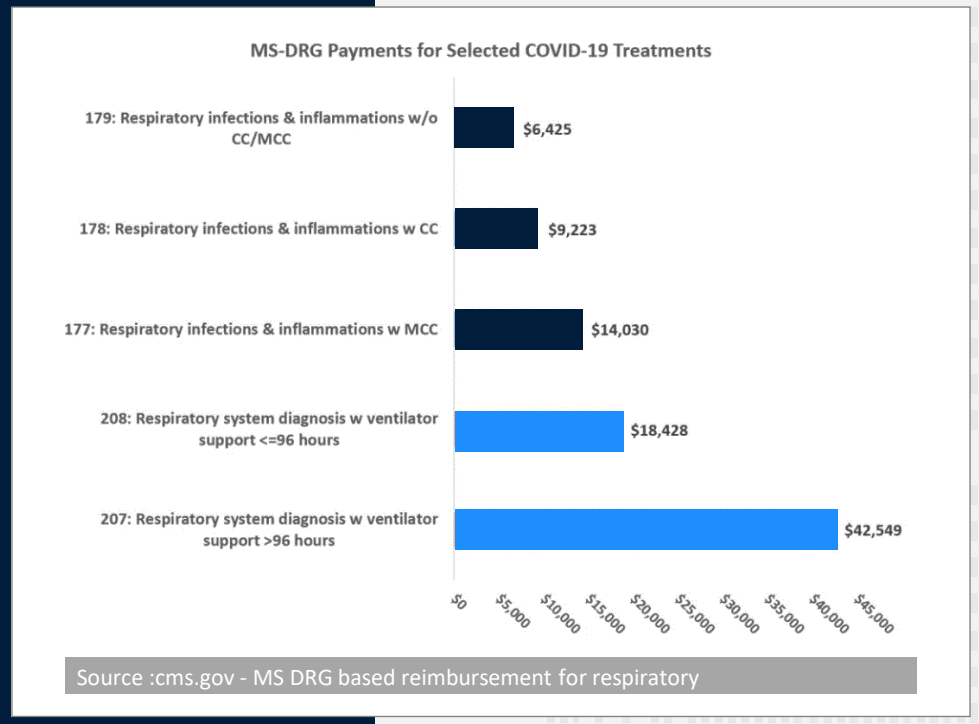
- Expected to eliminate complications associated with MV
- Aimed to reduce length of stay & re-admissions
- Designed to reduced costs & operational expenses
- Designed to reduce hospital & staff burden



# STRONG **BOARD OF DIRECTORS**

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

**Tal Parnes**
Director

**Lior Amit**
Director

**Limor Rozen**
Director

# SCIENTIFIC ADVISORY BOARD

**World-Renowned Key Opinion Leaders**

**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`

KOLS = Key Opinion Leaders

# SCIENTIFIC ADVISORY BOARD

**World-Renowned Key Opinion Leaders**

## 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 Medical ICU & Pulmonology Institute, leads the hospital's nationwide research of COPD

## Dr. Orit 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 Research

# THANK YOU!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