# Revolutionising Pulmonary Medicine

Polarean Imaging plc. AIM: POLX May 2024 POLAREAN

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### At a Glance

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POLAREAN

#### Revolutionising pulmonary medicine through direct visualisation of lung function



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### **Polarean Senior Management Team**

### **PLAREAN**

#### Successful, experienced healthcare professionals

		Selected Prior Company Attiliations	
Christopher von Jako, PhD Chief Executive Officer	<ul> <li>Joined in June 2023</li> <li>30+ years of global executive leadership experience in MedTech with a primary focus on capital image guidance equipment</li> <li>Led organisations in early-stage, expansion, and turnaround environments with five entities resulting in M&amp;A</li> </ul>	ST. JUDE MEDICAL' <b>NeuroTherm Medtronic</b>	
Charles Osborne Chief Financial Officer	<ul> <li>Joined in 2019</li> <li>30+ years of global life sciences experience, 20+ years as CFO</li> <li>Extensive public company, corporate partnering, and M&amp;A experience</li> </ul>	innocrin SCYNEXIS	
Alex Dusek Chief Commercial Officer	<ul> <li>Joined in 2019</li> <li>25+ years of global executive commercial leadership in Pharma, Biotech, and MedTech</li> <li>Led global pulmonary pharma product launches</li> </ul>	Boehringer Ingelheim	
<b>Bastiaan Driehuys, PhD</b> Chief Scientific Officer & Founder	<ul> <li>Joined in 2012</li> <li>A Polarean founder and technology founder with over 100 peer-reviewed articles on hyperpolarised gases and holds over 30 patents in this area</li> <li>Professor in the Department of Radiology at Duke University Health System</li> </ul>	GE Healthcare Amersham Health	

### **Investment Highlights**

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### Significant unmet clinical need in improved lung disease diagnosis

#### Pioneering Functional Imaging Platform

Proprietary, noninvasive, radiation-free technology with an attractive per patient consumable revenue model

#### Massive Label Expansion Market

\$3B+ U.S. TAM\* opportunity in interstitial lung disease (ILD) and pulmonary vascular disease

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### Large Market with Unmet Clinical Need

\$2B+ U.S. total addressable market\* (TAM) opportunity in obstructive lung disease

### **Industry Partnerships**

Pharma and MedTech represent a multi-faceted growth avenue

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### **Our Vision - Optimise Lung Health**

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### Prevent avoidable loss by illuminating hidden disease

- The Challenge
  - Why is the patient short of breath?
  - Current pulmonary functional modalities cannot "see" or quantify disease in the "silent zone," yielding them antiquated, unreliable, and insensitive

### • The Solution

- Only technology that can illuminate hidden disease in the "silent zone," allowing clinicians potentially to rectify and/or continuously monitor the patient
- Xenon MRI visualizes and quantifies pulmonary function in the whole lung, enabling precise treatment tailored to each patient's needs and timing to prevent avoidable loss



The Lung Airway Network is divided into 23 generations, with each splitting into two smaller airways

### Introduce the Power and Safety of MRI to the Lung POLAREAN

### MRI's under utilisation in lung imaging until now

- Limitations with traditional (proton) lung MRI
  - Low proton density (87% of lungs are air)
  - Multiple air/tissue interfaces
  - Long acquisition times and cardiac and lung motion
- Benefits of Xenon MRI
  - Utilises a radiation-free, diagnostic pharmaceutical agent to illuminate function
  - Visualises and quantifies lung ventilation and gas exchange\* in the patient's own thoracic cavity



Inhaled polarised noble gas (xenon), mimicking oxygen's path, uniquely visualises lung airway in one 10-second breath hold.

### **Our Solution: Xenon MRI Technology**

### POLAREAN

#### Game-changing drug-device imaging product with per patient consumable

Polarean offers the Gas, Production and QA Devices, and Single-use Dose Bags to administer XENOVIEW™

#### Hospital Hyperpolarisation Lab



#### **XENOVIEW Indication**

Prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarised contrast agent indicated for use with MRI for evaluation of lung ventilation in adults and paediatric patients aged 12 years and older.

XENOVIEW has not been evaluated for use with lung perfusion imaging.

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### The Value – See More

### **POLAREAN**

### Xenon MRI is uniquely suited to more precisely characterise multiple diseases



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### Large Unmet Need in Chronic Lung Diseases POLAREAN

### Why is a patient short of breath?



#### **Pulmonary Vascular Disease\***

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### **Pulmonary Xenon Functional MRI platform**

Unlocks \$5B+ U.S. TAM<sup>+</sup> in quantitative ventilation & gas exchange\* visualisation



#### **Pulmonary Vascular Disease\***

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### **Decades Without Advancement in Pulmonary Function Testing**

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### Standard of care for pulmonary function testing falls short with blunt tools

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GLEEN MAY DE ADDRESSED TO GEO. TIEMANN & CO., 67 CRATHAN STREET, N.Y. 0% to the Manufacture of Prediction G. W. BROWN, M. D., HOX 405, ROCKFORD, LLA	<b>Spirometry</b> Developed in 1846 15m US procedures/yr.	<b>DLCO</b> Developed in 1954 1m Total US procedures/yr.	<b>Scintigraphy</b> Developed in 1964 200k Total US procedures/yr.	<b>CT Scan</b> <b>Developed in 1971</b> 10m Total US procedures/yr.	Xenon MRI Ventilation FDA Approv December 2022
Lung Disease States?	<ul><li>✓ Obstructive Lung</li><li>✓ Restrictive Lung</li></ul>	<ul> <li>✓ Obstructive Lung</li> <li>✓ Restrictive Lung</li> <li>✓ Pulmonary Vascular</li> </ul>	<ul><li>✓ Obstructive Lung</li><li>✓ Pulmonary Vascular</li></ul>	<ul> <li>✓ Obstructive Lung</li> <li>✓ Restrictive Lung</li> <li>✓ Pulmonary Vascular</li> </ul>	<ul> <li>✓ Obstructive Lung</li> <li>✓ Restrictive Lung</li> <li>✓ Pulmonary Vascular</li> </ul>
Functional Measure?	YES, Global Only	YES, Global Only	YES	NO	YES
Not based on Ref. Equations?	NO	NO	YES	YES	YES
Regional Visualisation?	NO	NO	YES	YES, 3D (Structure Only)	YES, 3D
Radiation-free Procedure?	YES	YES	NO	NO	YES
Patient Effort Independence?	NO (Variability)	NO (Variability)	YES	YES	YES
Other Limitations?	Insensitive to the "Silent Zone"	Insensitive to the Interstitial Membrane	Low Resolution	Insensitive to the "Silent Zone"	Current Footprint

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### **Delayed Diagnosis:** Losses Extend Beyond Time, Cost, and Health

**ONLY comprehensive solution to provide the full picture in one 10-second exam** 

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Structure (Large Airways)	Bronchoscopy	X-ray CT	Traditional MRI	Polarean Xenon MRI
Whole Lung Function	Stethoscope Spirometry	FeNO N <sub>2</sub> W	Ashout	Defect         1%         2.6±1.8%           Low         25%         17.5±8.7%           High         10%         16.7±3.3%           CV         0.55         0.37±0.04
Regional Small Airway Ventilation	<sup>133</sup> Xe Scintigraphy	CT Parametric Modelin	g	11、14、14、14、143 143 143 143 143 143 113 143 143 143 143
Gas Exchange*	MIGET	DLCO	CPET	
Pulmonary-Vascular Hemodynamics*	ECG	Right Heart Catheterisatio	n	
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### **Clinician and Industry Validation**

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"This is the cutting edge of lung imaging technology. We're in the middle of the renaissance medically in the lung. And imaging of gas exchange is one of the most exciting future technologies as it allows us to visualise and quantify the gas ... it is a completely a new level of precision determining **thromboembolic and** cardiovascular disease abnormalities"



"The Polarean technology will be critical in informing and/or changing our treatment decisions. We will use it to detect and quantify airway obstruction **difficult Asthma cases** and guide chronic bronchodilator, steroid, and biological **therapeutic decision-making**.





Dr. Erik Hysinger

"I am a big fan of this technology! There's a real opportunity to understand lung physiology and mechanics, and **early detection** of lung disease"

"XENOVIEW<sup>™</sup> is a muchneeded clinical test that fills the current clinical gaps for the diagnosis and management of pulmonary diseases. One of the largest is **dyspnea on exertion.** It is one of the most common causes for referrals to pulmonary clinics."



Dr. Tony Huang
U
DukeHealth

"Long-COVID represents a major challenge to diagnose. This can uncover hidden damage not seen by CT scans. There are now important questions to answer, such as, how many patients with long-Covid will have abnormal scans, the significance of the abnormality we've detected, the cause of the abnormality, and its longer-term consequences. Once we understand the mechanisms driving these symptoms, we will be better placed to develop more effective treatments."



"A remarkable feature is the technology signifies lung tissue that is at risk of **progression in ILD.** It usually takes 100s of patients over a year to demonstrate a change. You can see that **within 3 months** in an individual patient and see response to treatment. For early-stage drug trials, there is a huge advantage to see whether an individual drug has potential in an individual population. Instead of \$500m on a stage 3 clinical trial, a **Pharma Companies** can spend a few million."

#### MedTech Partners

J MEDICAL CENTER





Ingelheim

MERCK

Pharma Sponsored Trials

Roche





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Dr. Fergus Gleeson

UNIVERSITY OF

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### **5-fold Growth Strategy**

### **PLAREAN**

### Generating value and paving the path for success in 2024 and beyond



### **Commercialisation Strategy**

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#### A three-pronged approach in market development phase



#### **Convert Research Base**

- Our Strongest Champions
- Enable handful of sites to begin utilising clinical gas

#### **Drive Utilisation**

- Pulmonologists, surgeons, and radiologists are Key Targets
- Multiple Clinical Applications exist for our beachhead in ventilation imaging
- Future growth magnified through utilisation

#### Target Top-100 U.S. Pulmonary Hospitals

- Build credibility with early influencers / publishers
- Leverage early success with research base customers
- Pre-existing MRI compatibility
- Promote updated ROI with new reimbursement codes

### **Clinical Utility for Quantitative Ventilation**



- Asthma / COPD phenotyping
- BPD acinar airway morphometry
- Cystic Fibrosis
- Post-Transplant Rejection

- CF when spirometry is misleading
- Rule out masquerading disease
- Severe asthma biologic optimisation
- Endobronchial Valve Placement
- Functional Avoidance Rad Therapy
- Surgical Resection Planning

## **High Value Ventilation Applications**

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### **Positive Procedure Economics**

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### A combination of existing codes and a new code for Xenon MRI procedure



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### Strong Economic/Clinical Incentive to Drive Adoption **P**©LAREAN

**Attractive reimbursement - 3 scans/week yields positive cash** 



### **Planned FDA Label Expansion\***

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### Focused on high-value market expansion products

- Gas Exchange
  - De-risked product label expansion by leveraging current product and research
    - ✓ Significant unmet clinical need
    - ✓ Product safety profile
    - ✓ FDA Feedback from Type B meeting
    - ✓ Regulatory process experience
    - ✓ Secured hospital reimbursement
    - Gas exchange science has been researched for 10+ years with numerous publications
    - ✓ Proof-of-concept study with 142 subjects †

- Lowering on-label age (12 yo to 6 yo)
  - Benefits to children and providers
    - ✓ No radiation, facilitates longitudinal imaging
    - Simpler and less reliant on individual effort than spirometry
    - ✓ No reference equations
    - Visualisation of their lungs to monitor progress and aid compliance
    - Quantifies alveolar simplification in early childhood development through adolescence
    - ✓ Gas exchange provides a functional measure of membrane conductance and RBC transfer

## Clinical Utility in Gas Exchange\* Applications



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### **Development of Key Industry Partnerships**

#### <u>Pharma</u>

#### **XENOVIEW MRI can Accelerate Drug Development** and Save Pharmaceutical companies Time and Money

- 58% of Respiratory Drug Trials Fail at the Final Stage of Development Thomas DW, et al. Clinical development success rates 2006-2015. Biotechnology Innovation Organization, Washington DC. June 2016.
- Lung is the #1 most expensive clinical trial category https://aspe.hhs.gov/reports/examination-clinical-trial-costs-barriers-drug-development-0
  - \$985M average Research and Development costs for a novel drug https://jamanetwork.com/journals/jama/article-abstract/2762311
- Multiple Academic Trials are Ongoing Exploring Xenon MRI as a measure of Drug Effectiveness in several therapeutic applications:
  - Asthma, COPD, Cystic Fibrosis, ILD, Pulmonary Hypertension
- XENOVIEW MRI can facilitate respiratory drug development
  - Less variability in the measure leads to lower sample sizes required to observe the treatment effect
  - It allows the visualisation and quantification of lung function not visible using other technologies to aid in early product characterisation and differentiation

### <u>MedTech</u>

XENOVIEW MRI Message is Amplified Through Shared Value Proposition in Philips Radiology Customers



### **Software**

XENOVIEW Imaging Platform to be Strengthened with VIDA Expertise and Creation of Harmonised Multisite Trial Network



### **Financial Overview**

### **Near-term Strategic Focus and Milestones**

- Drive Commercial Traction
  - Commercial Team Expansion
  - Engage Additional Key Opinion Leaders
- Extend labeling of minimum age to 6 yo
- Finalise Gas Exchange Trial Plan
- Product Enhancements
- Generate Additional Clinical Data
- Advance Partnerships



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# **Thank You!**

#### Enquiries :

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### Optimise lung health and prevent avoidable loss by illuminating hidden disease









POLAREAN

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### **Board of Directors** (excluding management)



#### Industry leaders with extensive industry and leadership experience

				Selected Prior Amiliations	
R	Ken West	Non-Executive Chairman	Former Polarean CEO, serial entrepreneur	POLAREAN EMBR	<b>BIOLEX</b>
<u>E</u>	Bill Blair	Non-Executive Director	Non-Executive Director and Chairman of the Audit Committee, North East Finance	THERAPEUTICS	Bene
	Dan Brague	Non-Executive Director	Former CEO of Curium North America		Mallinckrodt Pharmaceuticals
	Juergen Laucht	Non-Executive Director	Former Managing Director of NUKEM Isotopes	NU Isotop	KEM Des
	Cyrille Petit	Non-Executive Director	Chief Corporate Development Officer and Head of Strategic Initiatives, Bracco Group	SmithNephew	Goldman Sachs
	Marcie Ruddy, MD	Non-Executive Director	Chief Medical Officer, Tectonic Therapeutic	REGENERON	2 Alnylam
9	Frank Schulkes	Non-Executive Director	Chief Financial Officer, Distalmotion	e convatec	GE Healthcare

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