

# Polarean Imaging plc

(AIM:POLX)

FDA Approval of XENOVUE™  
(Xenon xenon 129 Hyperpolarized)

Bringing Magnetic Resonance Imaging  
to Pulmonary Medicine

Investor Presentation

February 2023



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# Company Update



# Polarean Imaging: A Novel, Differentiated Diagnostics Company Targeting Areas of High Unmet Medical Need Within Lung Disease with an FDA-Approved Product



1

FDA approved highly innovative product using hyperpolarised  $^{129}\text{Xe}$  to allow MRI of lung ventilation (useful in obstructive diseases e.g., Asthma, COPD, CF and others)

2

Commercialisation plan focusing on leading pulmonary medical centres. Existing research sites provide an enthusiastic clinician base to champion the technology and accelerate adoption

3

Future development supported by existing research imaging alveolar gas exchange; potential for future expansion to higher value diseases (e.g., ILD, long-COVID, PH and others)

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Collaboration opportunity for industry partnerships to improve and streamline pulmonary drug development and to open MRI manufacturers to pulmonary medicine growth

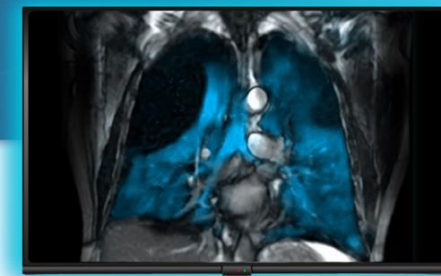
5

Highly experienced management team and board with strong track record of execution of company strategy; **Strong IP position**

CF, Cystic Fibrosis; COPD, Chronic Obstructive Pulmonary Disease; IP, Intellectual Property



# Breaking News: December FDA Decisions on Lead Product



## NDA Approval received Dec 23, 2022

### XENOVIEW™



Supplied as a proprietary blend of  $^{129}\text{Xe}$ , nitrogen, and helium



#### Indication

XENOVIEW, 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.

#### IMPORTANT SAFETY INFORMATION

##### Warnings and Precautions

- Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with XENOVIEW inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVIEW inhalation, and resume oxygen inhalation immediately following the imaging breath hold.
- Risk of Transient Hypoxia: Inhalation of an anoxic gas such as XENOVIEW may cause transient hypoxemia in susceptible patients. Monitor all patients for oxygen desaturation and symptoms of hypoxemia and treat as clinically indicated.

##### Adverse Reactions

- Adverse Reactions in Adult Patients: The adverse reactions (> one patient) in efficacy trials were oropharyngeal pain, headache, and dizziness.
- Adverse Reactions in Pediatric and Adolescent Patients: In published literature in pediatric patients aged 6 to 18, transient adverse reactions were reported: blood oxygen desaturation, heart rate elevation, numbness, tingling, dizziness, and euphoria. In at least one published study of pediatric patients aged 6 to 18 years, transient decrease in SpO2% and transient increase in heart rate was reported following hyperpolarised xenon Xe 129 administration. XENOVIEW is not approved for use in pediatric patients less than 12 years of age.
- Please see full prescribing information at [www.xenoview.net](http://www.xenoview.net)

# Breaking News: December FDA Decisions on Product Accessories

## 510(k) Clearance received Dec 23, 2022

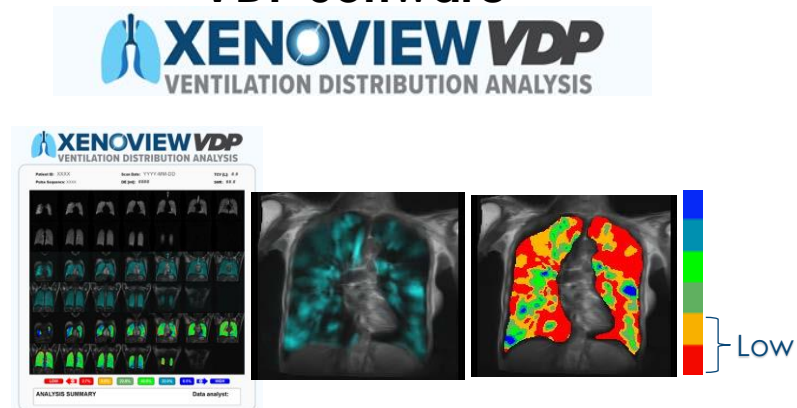
### XENOVIEW 3.0T Chest Coil



#### Indication for Chest Coil

The Polarean XENOVIEW 3.0T Chest Coil is indicated to be used in conjunction with compatible 3.0T MRI scanners and approved Xenon Xe 129 hyperpolarised gas for oral inhalation for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

### VDP Software



#### Indication for VDP Software

XENOVIEW VDP is image processing software that analyses a pulmonary hyperpolarised 129-Xe MR image and a proton chest MR image to provide visualisation and evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

VDP, Ventilation Distribution Percentage



Technology



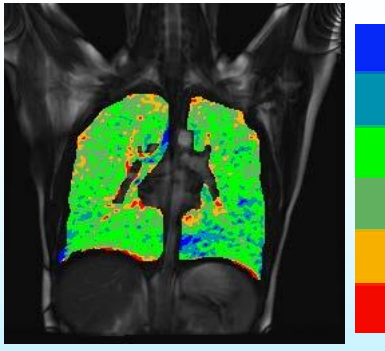
# XENOVUE – Enables Visualization of Lung Ventilation

## Healthy Patient

XENOVUE  
in the lungs



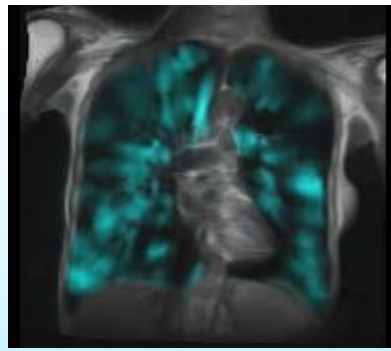
Color map with  
VDP software



Low Ventilation = 8%

## COPD Patient

XENOVUE  
in the lungs



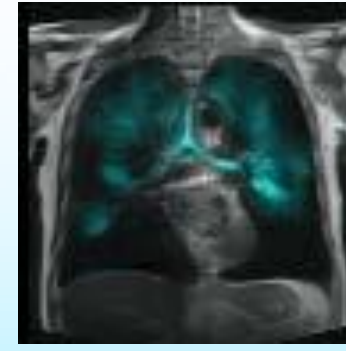
Color map with  
VDP software



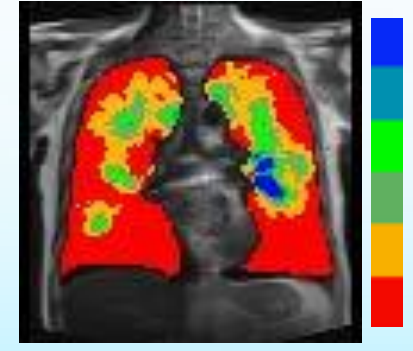
Low Ventilation = 66%

## Asthma Patient

XENOVUE  
in the lungs



Color map with  
VDP software



Low Ventilation = 71%

Duke University Medical Center, unpublished data; used with permission. Polarean Phase III trials.  
COPD, Chronic Obstructive Pulmonary Disease; VDP, Ventilation Distribution Percentage



# Lung Disease Provides Large Global Market Opportunity



Chronic Lung Disease  
in the U.S. affects nearly  
**37 million people**

The economic impact  
of asthma and  
COPD in the U.S.  
**>\$125 billion/yr**



**> 5 million**  
Lung Diagnostic  
Procedures Annually  
in the U.S.



Long-COVID globally  
estimated to affect  
**>100 million**

**XENOVIEW™**  
(xenon Xe 129 hyperpolarized) for oral inhalation



COPD is the  
**3<sup>rd</sup> leading**  
**cause of death**  
worldwide



Global MRI system  
market  
**US\$4.8 billion**



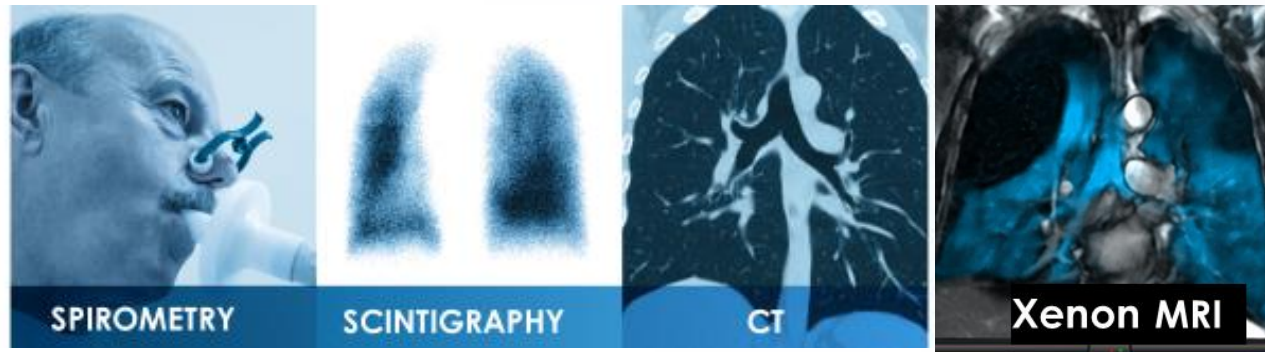
CF, ILD, BOS, and PH  
are the most common  
diseases that lead to  
**lung transplant**



In the U.S.  
**1/4 of all ER visits**  
are related to asthma



# Hyperpolarised Xenon MRI Comparison



Functional Measure?	YES	YES	NO	YES
Regional Visualisation?	NO	YES	YES	YES
Radiation-Free Procedure?	YES	NO	NO	YES
Patient Effort Independence?	NO	YES	YES	YES
# of Annual US Procedures	~15M	~250K	~10M	

## Benefits



Provides direct measure of regional lung ventilation



Spatially distributes to image the smallest airways



Avoids radiation exposure to patient



Non-invasive approach (10-15 second breath hold)

# Commercialisation





# US Commercial Launch – Core 2023 Initiatives



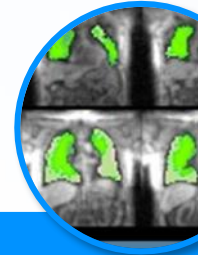
## Convert US Research Base

- Enable Handful of Sites to Use Clinical Gas
- Shortens Capital Equipment Review Cycles



## Secure Reimbursement

- Pre-existing MRI CPT Codes
- Upside payments Drug and Image Processing



## Drive Clinical Scans and Gas Sales

- Pulmonologists, Surgeons, and Radiologists are Key Targets
- Multiple Clinical Applications Exist For Ventilation Imaging

## Expand System Footprint

- Pre-existing MRI compatibility
- ROI for Hospital Purchaser is Strengthened with Successful Reimbursement Coverage

CPT, Current Procedural Terminology; ROI, Return on Investment

# Convert Existing Research Sites to Clinical-Grade System



## Existing Users Are our Strongest Champions



Dr. Jason Woods  
Director of Research, Division of Pulmonary Medicine  
at Cincinnati Children's Hospital Medical Center

IT, Information Technology

## WAVE 1



## WAVE 2



## Enabling Sites for Clinical Use

- Print approved labeling on all drug supplies and prepare for shipment
- Application for state licenses to distribute gas has begun
- On-site service team to upgrade system to newly approved specs
- Hospital loads XENOVUE imaging protocol into their IT system to integrate scheduling, imaging and billing in electronic medical records

24 month target =  
9 conversions



# Pricing and Reimbursement: Utilise Immediate Reimbursement and Expand Coverage

## Hyperpolarisation Lab

Polarean Sells Capital Equipment, Cylinder and Dose Bags to Hospital

Xenon Gas Blend  
Multi-dose Cylinder



**Xe Gas Blend**  
(TBD est.) \$~ 40-60K per cylinder  
~125 scans: Cost: ~\$300-475/dose

Dose  
Production



Dose  
Measurement



**Capital Equipment**  
Cost: ~\$530,000  
for each system

XENOVIEW  
Active Dose



**Dose Delivery  
Bags**  
Cost: \$75/bag

## MRI Suite

Polarean Sells Coil to Hospital

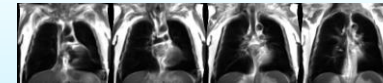
Xenon Dosing



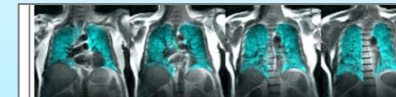
**Xenon-specific Chest coil**  
Cost: ~\$75,000

Image Acquisition

**MRI Chest Code (2a)**  
Anatomical Proton Scan



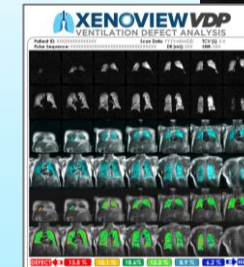
**Xe MRI ICD-10-PCS Code (2b)**



## Image Analysis Lab

Polarean Sells Software to Hospital

Image Analysis



**XENOVIEW VDP Software**  
Cost: ~\$50-60k

## Reimbursement

- Hospital to use drug codes for administered dose
- New Tech APC Code Application in March; CMS payment for APC Expected in 2H 2023
- Prior to APC code approval, hospital to apply for reimbursement based on individually calculated hospital costs

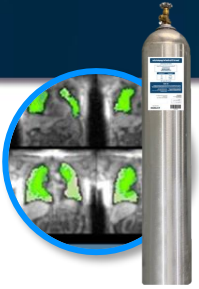
- Hospital to Existing procedure codes for CHEST MRI reimbursable immediately

- Hospital to use existing processing codes for MRI Quantitative analysis and radiologist interpretation

Third-party reimbursement is affected by many factors. This information is presented for informational purposes only. Polarean Imaging plc does not promise or guarantee coverage, levels of reimbursement, or payment.

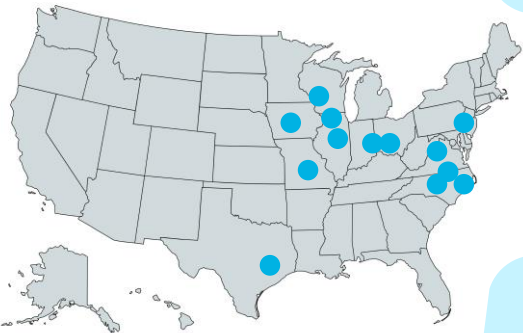
APC, Ambulatory Payment Classification; CMS, Centers for Medicare and Medicaid Services

# Drive Gas Sales in Converted Sites



1

**Pulmonary Reps**  
**Drive Demand** via  
Scan prescriptions  
from Pulmonologists  
and Surgeons



1-on-1 detailing  
to potential  
prescribing MDs,  
conference  
exhibits and  
speaker programs

2

**Medical Science Liaisons**  
**Scientific Exchange**  
amongst key  
opinions leaders  
including response to  
research inquiries



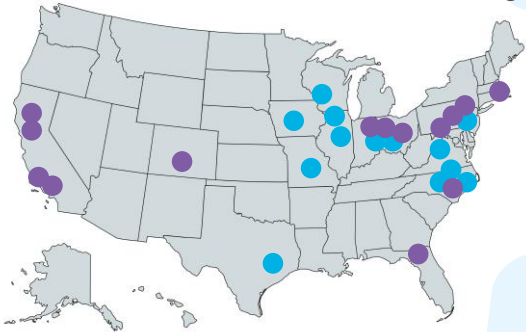
Peer-to-peer  
interactions,  
symposia, webinars,  
and professional  
meetings



**24 month target =  
75-100 cylinders**



# Expand System Footprint to New Sites



1

## Capital Equipment Reps Sell Systems

through presentations to  
radiology departments and  
hospital finance committees



Project Manage  
Successful VAC  
Assessment,  
Purchase, and  
Installation into  
New Site

2

## Marketing Team Increase Interest

via  
promotional print and  
digital media channels



Increase interest  
and awareness of  
the technology  
through  
congresses, web  
and social media  
communications



24 month target =  
15-20 systems

VAC, Value Analysis Committee

Future Growth





# 5 Year Utilisation Growth Pathway

Chronic lung disease affects nearly 37 million people in the US and costs >US\$125 Billion

Est. US Prevalent Patient Population  
~ 42M

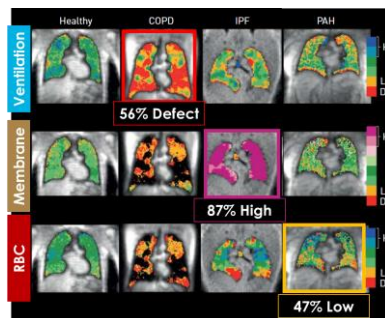
## Ventilation

- > Lung Surgical Planning
- > Cystic Fibrosis
- > Asthma
- > COPD

Est. US Prevalent Patient Population  
~ +12M

## Gas Exchange

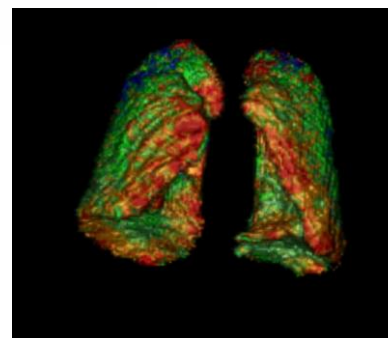
- > ILD
- > Long-COVID



Est. US Prevalent Patient Population  
~ +5M

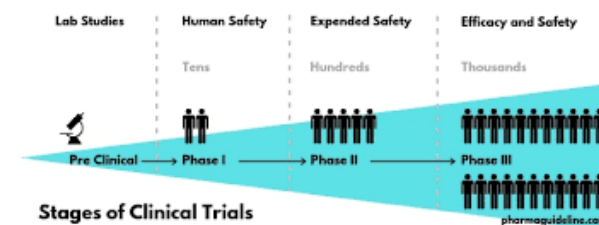
## Hemodynamics

- > Unexplained Dyspnea
- > Pulmonary Hypertension

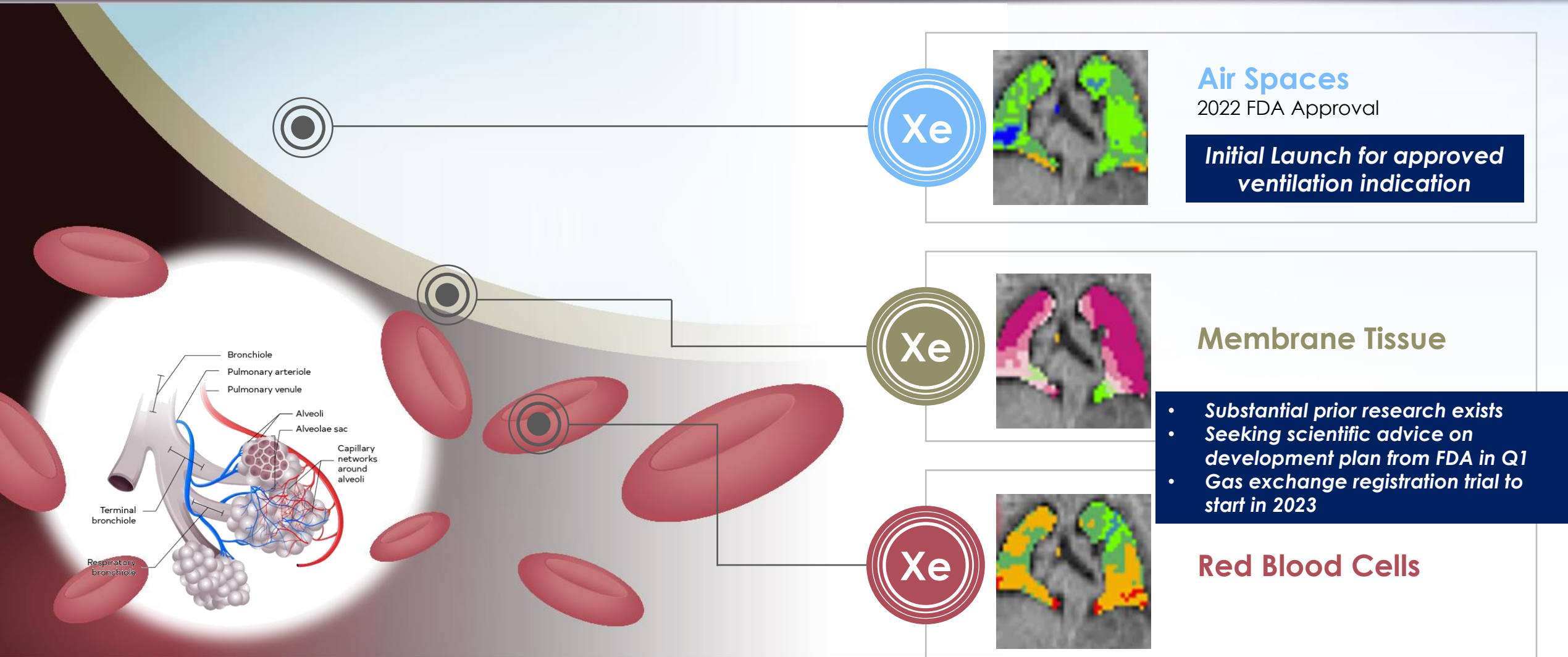


## Industry Partners

- > Pharma Drug Development
- > MRI manufacturer collaborations
- > Ex-US expansion

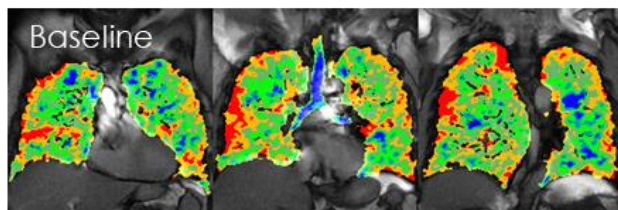


# Pipeline: Ability to Image Xenon in 3 separate compartments represents Broad Opportunity to Revolutionise Pulmonary and Cardiopulmonary Diagnostics

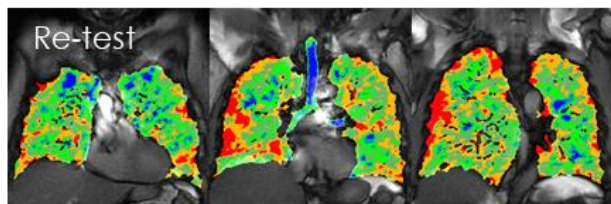


# Pharma Collaboration Opportunity – Enhance Drug Development By Using A Precise, Quantitative, Visual Measure

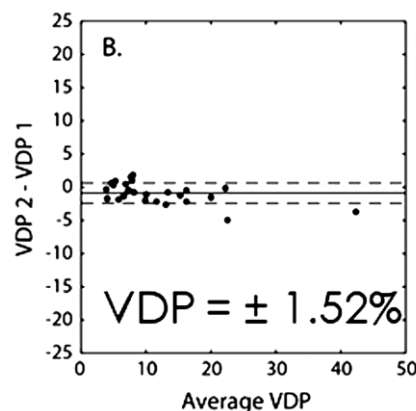
## Repeat Scan



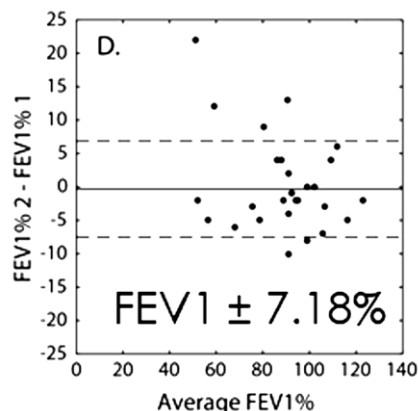
VDP = 10.2%, low = 29.5%, high = 9.5%, CV = 0.50



VDP = 10.9%, low = 27.2%, high = 9.1%, CV = 0.49



## Repeat Spirometry



## XENOVIEW offers Pharma the Potential to:

- Reduce Trial Size
- Reduce Development Costs
- Reduce Time to Market
- Visualise Treatment Response
  - May Differentiate Product From Competitors = increased market share
  - May Increase Patient Adherence to Therapy = increased revenue per patient start

Diagnostic	Minimum Treatment Difference to Detect	Alpha	Power	Standard Deviation	Numbers of subjects needed
Xe MRI VDP	2%	0.05	90%	1.52	24
Spirometry FEV <sub>1</sub>	2%	0.05	90%	7.18	542

CV, Coefficient of Variation; FEV<sub>1</sub>, Forced Expiratory Volume in 1 second; VDP, Ventilation Defect Percentage.



# Broad IP Portfolio and Data Exclusivity Post US Launch

## The Group's competitive protections strategy includes:

- Patents that proceed from current time to 2035 and potentially beyond, including those covering the following:
  - imaging methods and RF coil designs
  - hyperpolarisation methods
- 5-year regulatory exclusivity was granted for a New Chemical Entity ("NCE").
  - Verified as included in the FDA Orange Book in January
- Additional developments underway.

RF, Radiofrequency

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CF, Cystic Fibrosis; COPD, Chronic Obstructive Pulmonary Disease; IP, Intellectual Property

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