



Polarean Imaging plc (AIM:POLX)

Breathtaking Images...

January 2019

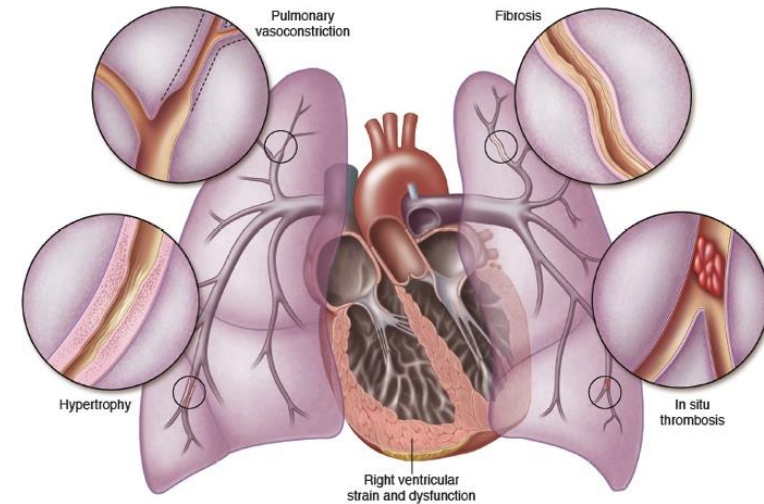
Richard Hullihen - Chief Executive Officer
Richard Morgan - Chairman

Polarean Highlights

- Revenue-generating company
- Visualises polarised Xenon gas via Magnetic Resonance Imaging (MRI)
- We are a drug device combination with a recurring drug revenue line
- Phase 3 clinical trial in process – First Patient Initiated in August 2018
- Market opportunity – >\$500M expected in system sales just to top tier institutions, plus drug sales
- Extensive IP and knowhow
- EIS/VCT qualified (expected to be KIC compliant where applicable)

The Problem

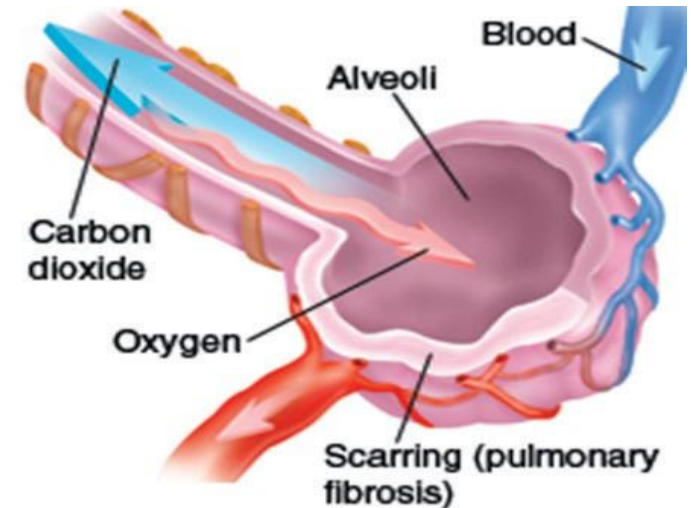
- Pulmonary disease is widespread and growing, affects **40 million Americans**
 - Asthma – 25 million
 - COPD –13 million
 - Cystic Fibrosis (CF), Idiopathic pulmonary fibrosis (IPF), Embolism
- Heavy U.S. economic burden
 - US\$150 billion/year, similar in E.U.
- Higher prevalence in countries with poor air quality and smoking use



Ventilation, Gas Exchange and Microvascular Bloodflow

Pulmonary disease is characterised by specific patterns of impaired:

1. **Ventilation** (airflow into and out of the alveoli)
2. **Gas exchange** through barrier tissue into and out of bloodstream
3. **Microvascular hemodynamics** bloodflow through capillary bed



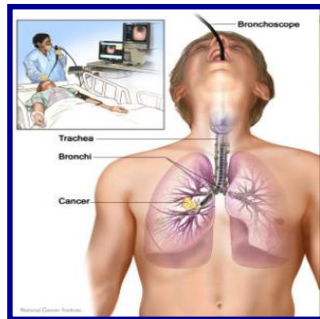
Improving Diagnosis in Pulmonary Disease

- Current methods to diagnose and monitor lung disease are invasive and sub-optimal

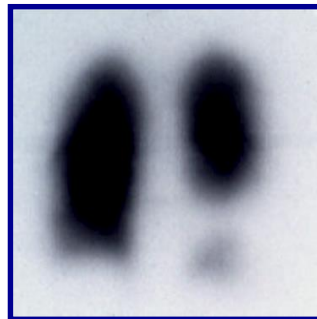
Spirometry



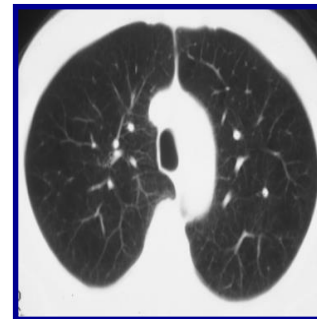
Bronchoscopy



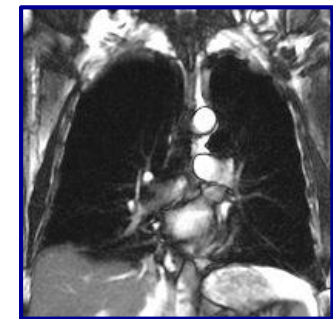
Scintigraphy



X-ray, CT



MRI



- Polarean's technology is superior being quantitative, image-based, and cost-effective

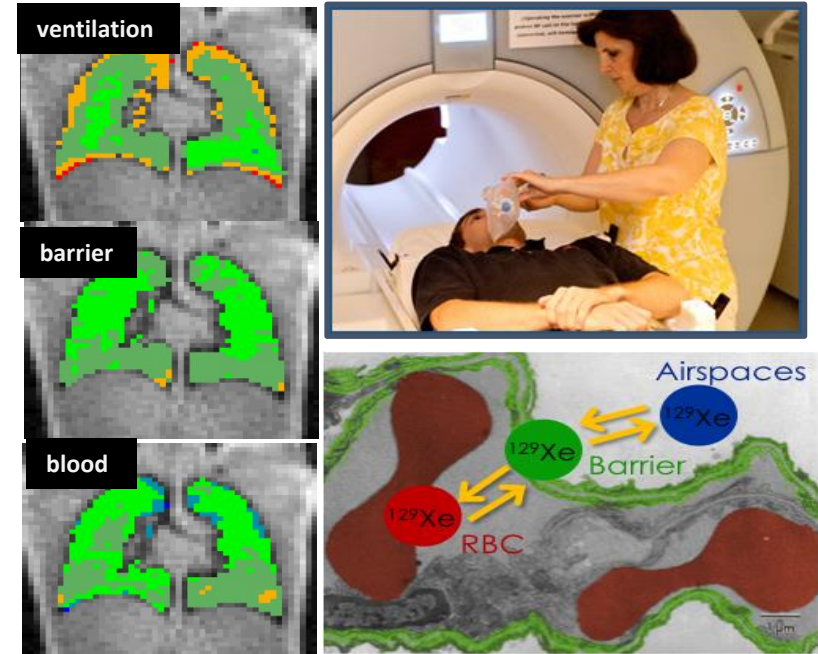
Our Technology – Hyperpolarised Xenon¹²⁹ MRI (HPX MRI)

A Faster, Simpler, Safer Test:

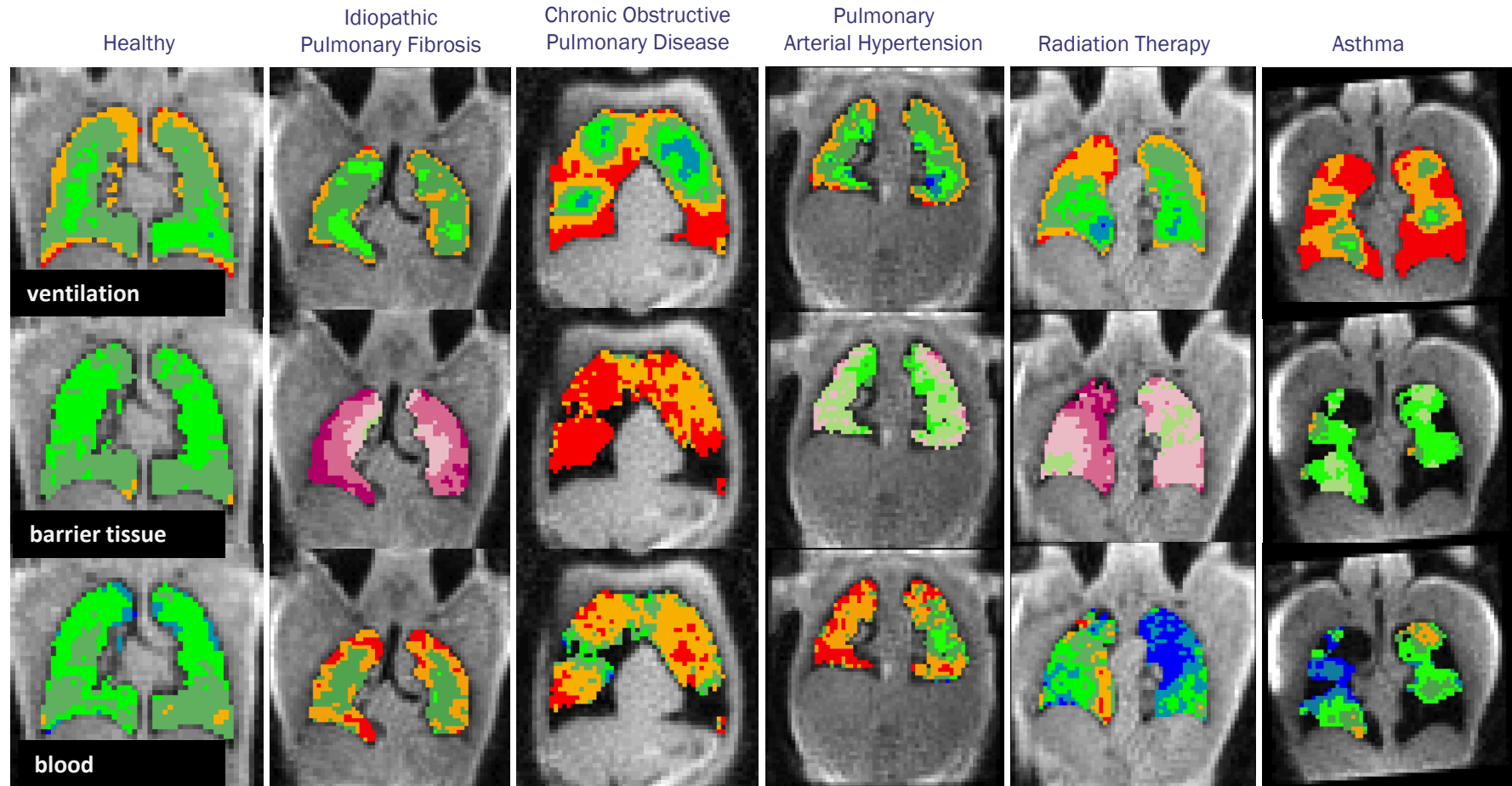
- Brief exam requiring a few, short breath-holds
- Easy to administer, not effort-dependent
- Non-invasive, no radiation, repeatable

Comprehensive information:

- Quantifiable 3D maps of ventilation and gas exchange
- Quantitative measures of cardiopulmonary dynamics to identify pre- and post-capillary Pulmonary Hypertension



Polarean Technology is Broadly Applicable



- In addition to ventilation, key information is also available from barrier tissue and blood

Products and Workflow

- Polarean's products are “add-ons” compatible with existing MRI systems from GE, Siemens, Philips etc



In TEN SECONDS we get:

- 3 dimensional multi-slice data
 - Direct ventilation image
 - Barrier tissue signal
 - Arterial blood signal

Markets

- There is a global installed base of >35,000 clinical MRI systems (and 3,500 preclinical ones)
- Market opportunity – >\$500M expected in system sales just to top tier institutions, plus drug sales
- Polarean's Xenon imaging procedure increases hospital MRI systems “asset utilisation” and profitability (“new products for radiology”)

Business Model – Single Customer

System selling price including RF coils	US\$475,000	Scales with hospitals
Gross margin: 60%	US\$285,000	
Price paid to Polarean per dose Xenon	US\$240	Scales with patients
Gross margin: 70%	US\$170	
Service contract per annum	US\$40,000	Scales with systems
Gross margin: 50%	US \$20,000	
Applications software per annum	US\$50,000	Scales with new applications and sites
Gross margin: 90%	US\$45,000	

Company Update – November 2018

- Delivered new systems:
 - University of Illinois, Cincinnati Children's Hospital, University of Virginia, Duke University, University of Missouri
- Received latest order from SickKids Hospital, Toronto for system upgrade
- Nanocluster patent issued
- Pulmonary Vascular Disease (PVD) provisional patent filed
- New Enhanced License LOI with Duke University signed
- Completion of Pilot Study prior to Phase III trials
- **Phase III Clinical Trial on schedule for completion of enrollment in Q2'2019**

Clinical Trial Update

- Phase III Clinical Trial first patient enrolled August 23, 2018
- 80 patient non-inferiority trial versus $^{133}\text{Xenon}$ Scintigraphy in two indications:
 - 32 subjects lung lobe resection
 - 48 subjects lung transplant
- Two trials sites at Polarean's closest and biggest collaborators:
 - Duke University
 - University of Virginia
- Subjects enrolled in both pathways, data collection is underway
- Readouts to be done in “batch” mode
- Trials proceeding and scheduled for completion of enrolment in Q2'2019

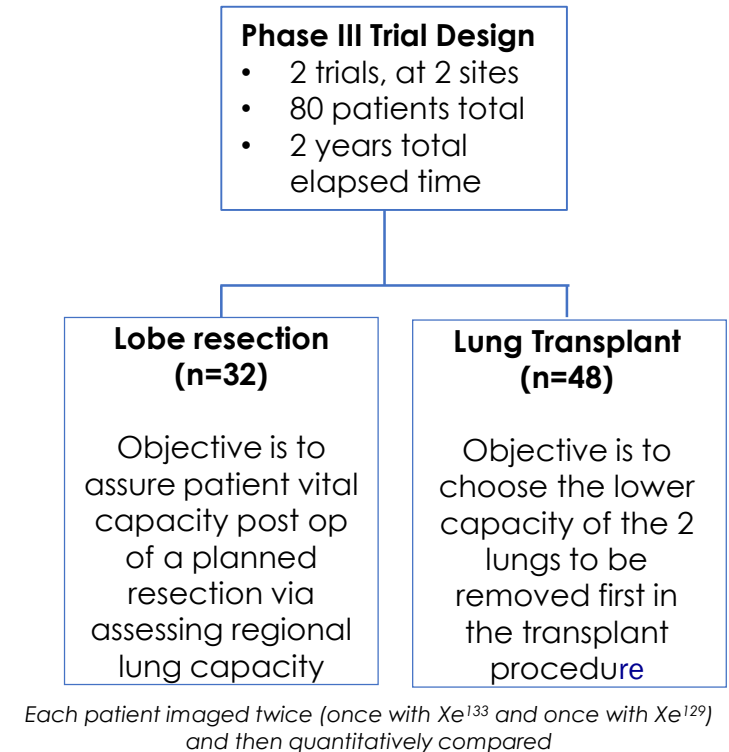
Regulatory Path and Clinical Trials

FDA

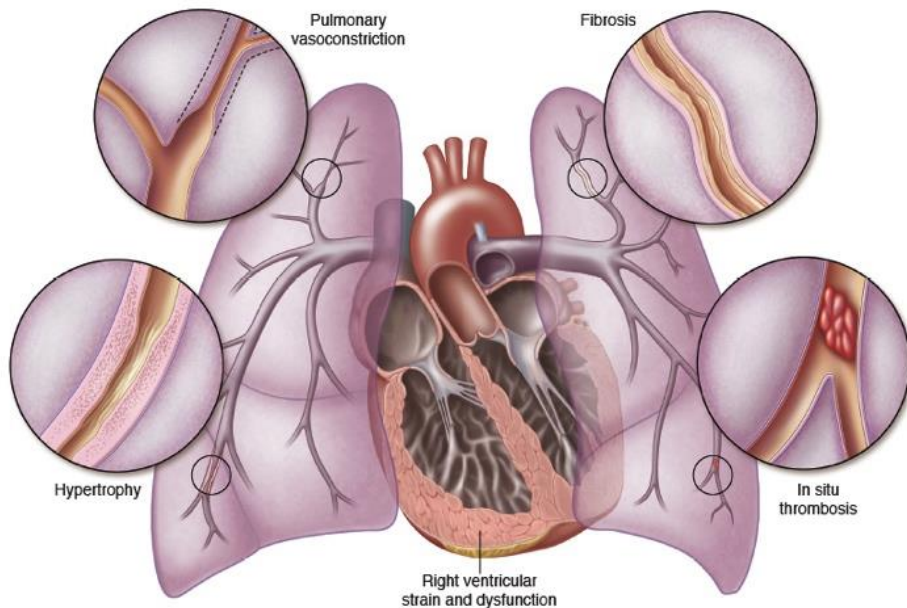
- Xenon is well understood by the FDA
- FDA agreed trial design and comparator technology
- Non-inferior end point versus ^{133}Xe gamma camera scan

Pilot Study

- Tested the Phase III trial design and analytical methods in ten patients (representative of the trial population)
- Further validation the trial design should accurately reflect the comparative values of ^{129}Xe MRI versus ^{133}Xe scintigraphy



Significant Burden of Pulmonary Hypertension (PH) and Pulmonary Vascular Disease (PVD)



- A group of disorders that cause high blood pressure in the lungs (PH)
- c.200,000 hospitalizations occur annually in the United States due to PH with c.15,000 deaths/year¹
- Heavy U.S. economic burden: \$100k/year for Group 1 patients
 - Prevalence increased 25% over 2 decades²
- Challenging to diagnose and monitor when heart and lung disease also present
 - These more common forms of “dirty PH” represent 30% of cases
- Better tests are needed to make an early diagnosis

¹ American Thoracic Society ([link](#))

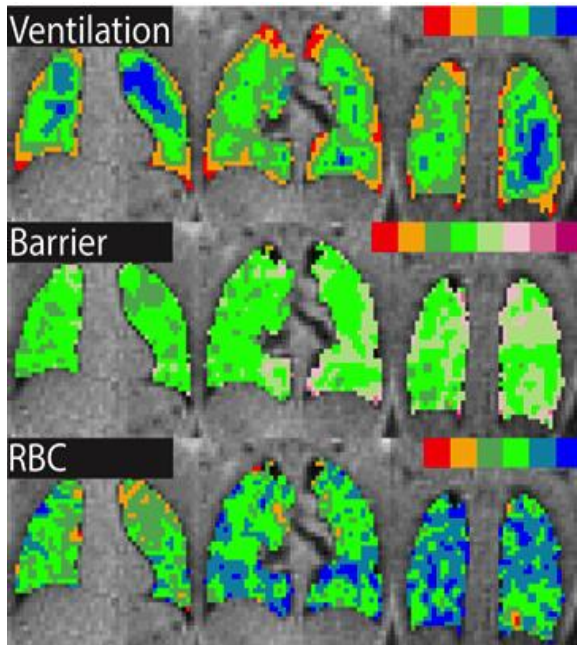
² Circ Cardiovasc Qual Outcomes. 2018;11:e003973.

What Do Clinicians Need to Better Diagnose and Monitor PH/PVD?

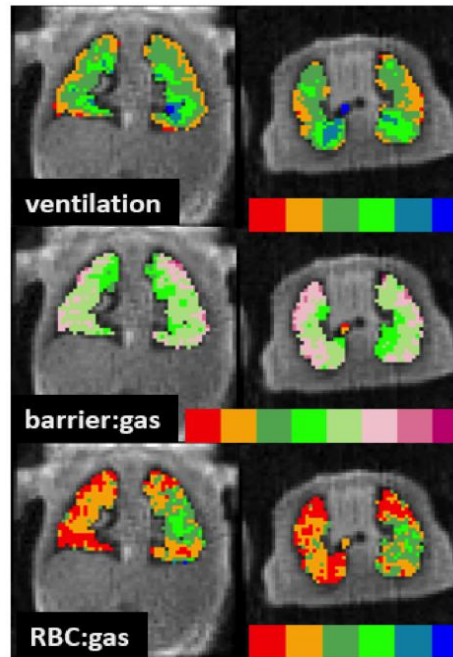
- Diagnose or rule out PVD, even when heart or lung disease are present
- “One stop shopping” including heart and lung function
- Non-invasive, repeat assessment of therapy response
- Xenon MRI could address **all** of these limitations by providing:
 - Quantifiable 3D maps of ventilation and gas exchange
 - Quantitative measures of cardiopulmonary dynamics to identify pre- and post-capillary PH

HPX MRI – Detects Impaired Gas Exchange and Altered Hemodynamics

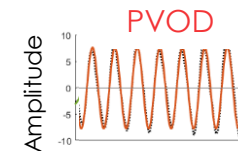
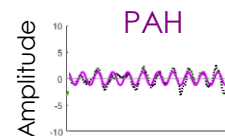
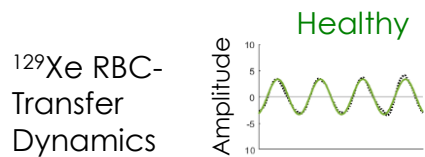
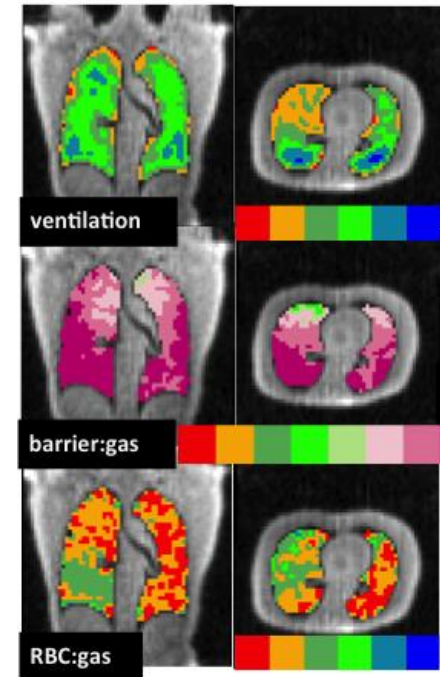
Age-Matched Control



Pulmonary Arterial Hypertension



Pulmonary Venous Occlusive Disease



PVD Partnering and Intellectual Property Status

- Partnered with Duke University
- Duke has licensed Polarean its IP for ^{129}Xe gas exchange MRI
 - US11866552, US14535990, US9625550B2, and pending applications
- Duke has filed IP for cardiopulmonary dynamics (PH)
 - Filed 5/18/2018
- Expanded license letter of intent signed with Duke

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