

Polarean Imaging Ltd.

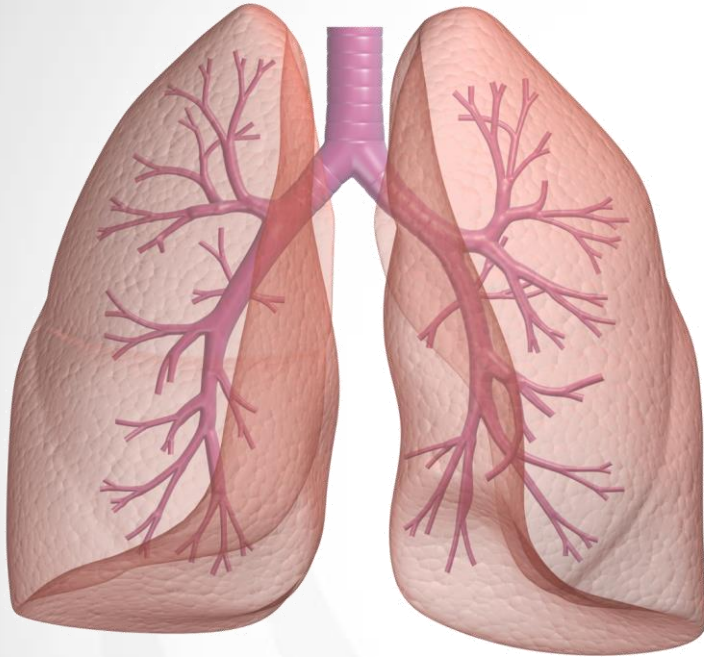
Addressing the unmet needs for non-invasive, quantitative, image-based diagnosis in the \$150B annual *USA pulmonary medicine* market

Richard Hullahen Chief Executive Officer
Richard Morgan Chairman

Polarean Key Highlights

- Revenue generating company
- Visualises polarised Xenon gas via Magnetic Resonance Imaging (MRI)
- Sells drug/device systems, RF coils, and Xenon drug
- Phase III asset with clear regulatory pathway to clinical market
- Major market opportunity
- Extensive IP and knowhow
- EIS/VCT qualified

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

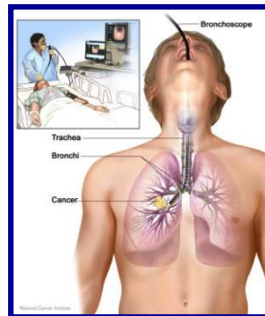
Improving Diagnosis in Pulmonary Disease

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

Spirometry



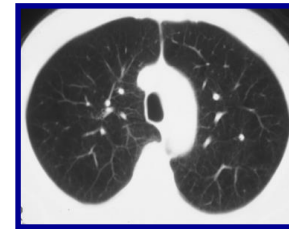
Bronchoscopy



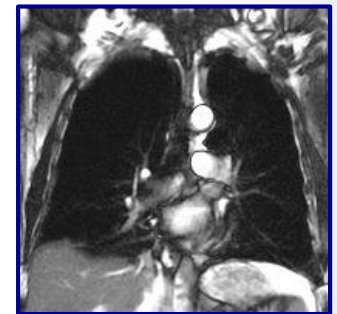
Scintigraphy



X-ray, CT



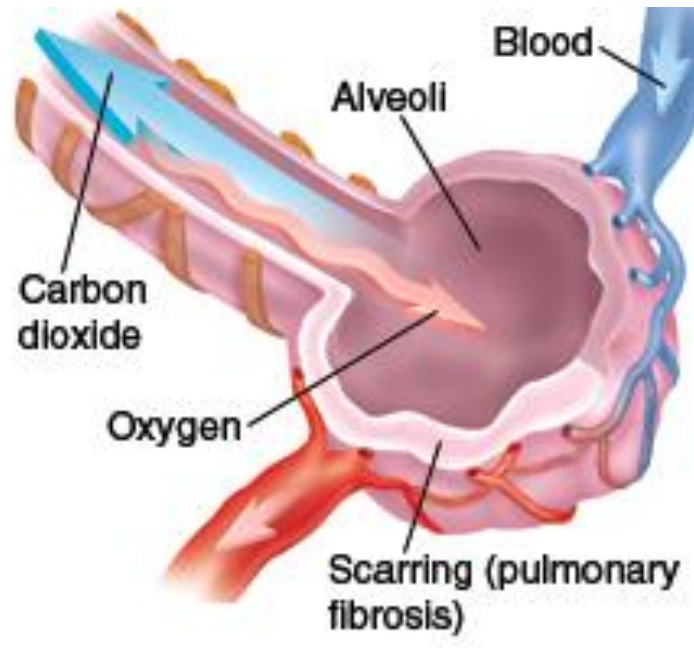
MRI



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

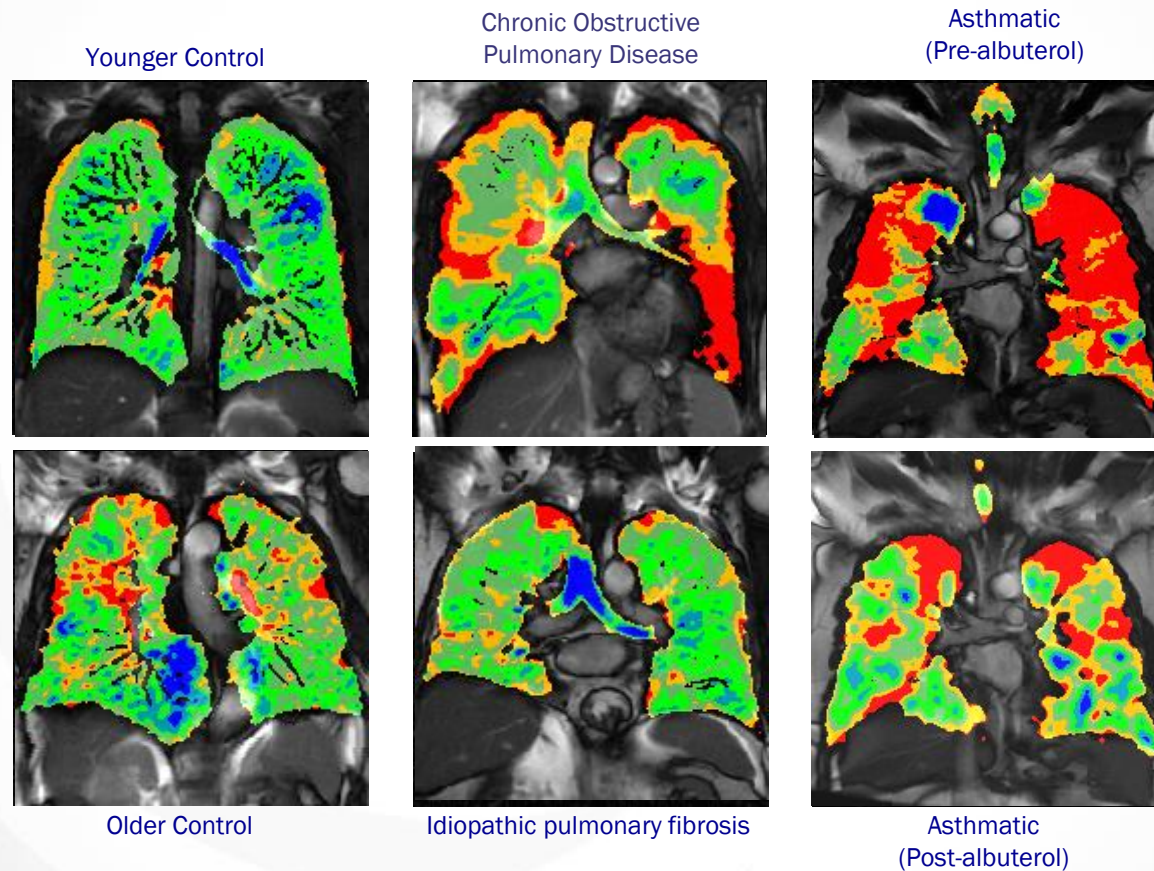
Ventilation and Gas Exchange

- Lung disease is characterised by **specific patterns** of impaired:
 - **ventilation** (oxygen flow into the alveoli, CO₂ out)
 - **gas exchange** (through the lung membranes into and out of the bloodstream)



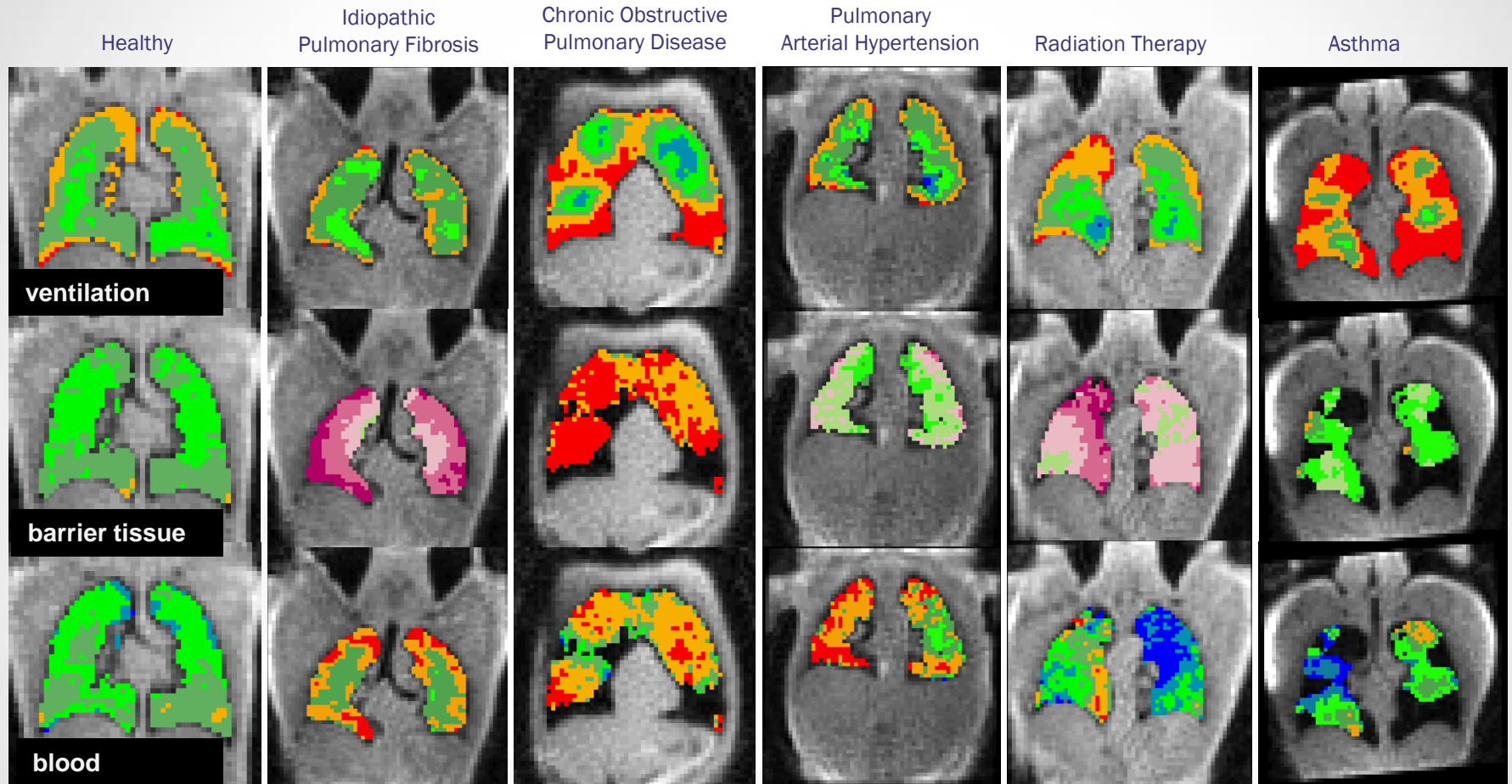
Ventilation Issues

- Polarean technology shows ventilation *differences*



- These images and this information are only possible with Polarean's technology

Polarean Technology is Broadly Applicable



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

Products and Markets

- Polarean's products are “add-ons” compatible with existing MRI systems from GE, Siemens, Philips etc
- There is a global installed base of >35,000 clinical MRI systems (and 3,500 preclinical ones)
- Polarean's Xenon imaging procedure increases hospital MRI systems “asset utilisation” and profitability (“new products for radiology”)



Our Drug
Proprietary Xenon¹²⁹ blend



Polariser
Uses laser technology, cryogenics, and magnetic fields to excite Xenon spins

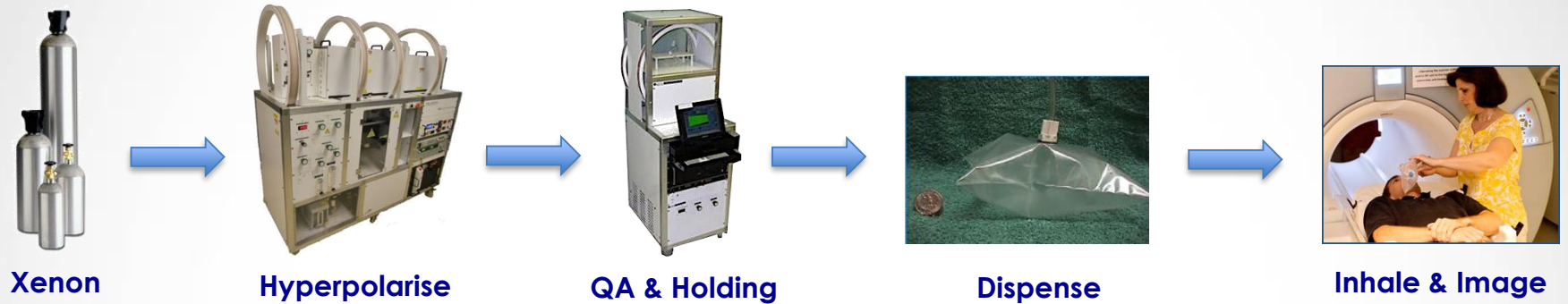


Quality Assessment (QA) Station
Used to certify and document the polarization process, per patient batch



Torso Xenon RF coil
Multi element array RF coil for thoracic imaging in MR

Polarean Technology Clinical Workflow



- In **TEN SECONDS** we get:
- 3 dimensional multi-slice data
 - Direct Ventilation image
 - Barrier tissue signal
 - Arterial Blood signal

Mature Technology in Pre-Clinical Use

Substantial investment of over US\$50 million in R&D by strategic and financial investors, including:

- GE
- Amersham
- Amphion Innovations

15 Xenon polarisers in use in US and Europe, including:

- Duke University
- University of Virginia
- Oxford University
- Cincinnati Children's Hospital (joint on SBIR grant)

Agreed FDA protocol for Phase 3 clinical trial

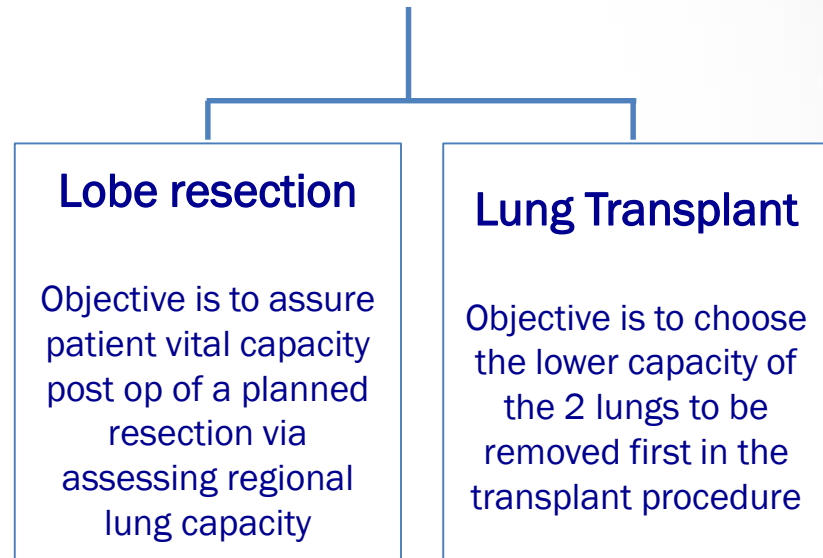
Regulatory Path and Clinical Trials

FDA

- Xenon is well understood by the FDA
- FDA agreed trial design and predicate technology
- Non-inferior end point versus Xenon¹³³ gamma camera scan

Trial Design

- 2 trials, at 2 sites
- 80 patients total
- 2 years



Each patient imaged twice (once with Xe¹³³ and once with Xe¹²⁹) and then quantitatively compared

Predicate Comparator for Clinical Trial: Xe¹³³ Gamma Camera scan

1



Patient is placed in detector, breathes in Xe¹³³, and holds breath for 15s

2

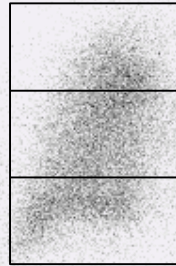


Image acquired

3

	Right Lung %	Left Lung %
Upper Zone	16.4	16.3
Middle Zone	23.2	19.1
Lower Zone	14.1	10.9
Total Lung	53.7	46.3

Total of 100%

Translated into quantification

- Xe¹²⁹ measures will be quantifiably compared to Xe¹³³

Intellectual Property

Intellectual Property – an IP portfolio based on 29 patents which cover four broad areas and extend into 2034:

- **Imaging methods** – cover the imaging of a subject who has inhaled a hyperpolarised noble gas used as a contrast agent. Newly licensed technology from Duke University extends patent protection through the late 2020's
- **Hyperpolarisation equipment** – cover multiple preferred mechanical design elements of hyperpolarised equipment
- **Hyperpolarisation methods** – cover methods by which noble gases are polarized and methods by which the resulting polarised gas is isolated and delivered to human subjects. These expire in the early 2020's
- **RF coil and electronics patents** – relate to the use of cryogenics to improve performance of RF coils in magnetic resonance, and associated electronics

Additional Opportunities

- **Other Clinical Applications**

- Beyond pulmonary gas exchange academic research is progressing in several other clinical applications:
 - Neuro imaging
 - Nephrology, Radiation Therapy planning

- **Other Geographic Markets**

- UK, EU
- Rest of Europe
- Asia

- **Pharma R&D Opportunity**

- More than 100 new respiratory drugs are in development
- Polarean in touch with a number of pharmaceutical companies

- **Image-Guided Therapeutics**

- The fast-growing field of interventional pulmonology (stents, valves, ablative therapies) should benefit from Polarean technology

Investment Considerations

- Addresses unmet needs of US\$150B market
- Upside multiples in both markets and applications
- Drug device product with strong follow-on drug sales
- Revenue generating company
- Clear regulatory pathway
- Experienced management team

Key Risks

- **Regulatory pathway risk**
 - As with all drug-device companies the Company has no guarantee Polarean's technology will be approved by the regulator.
- **Developmental risk**
 - The clinical trial outcome is not pre-determined and there is no guarantee the technology will meet the Phase III trial primary endpoints.
- **Financing risk**
 - Should the Company not raise funds or there are delays in the clinical trial timeline the Company may need to seek further financing.
- **Competition**
 - The healthcare sector is highly competitive containing potential competitors with larger resources.
- **Xenon gas supply**
 - The technology relies on consistent supply of Xenon gas. Polarean has both strategic investment from a ¹²⁹Xe supplier, and a signed LOI with one of the world's largest gas blenders.

Directors and Senior Management Team

Richard C.E. Morgan, Chairman, Founder and Executive Director of Amphion Innovations plc. Richard has played an active role in the development of over 35 life science companies, including MediSense, Celgene, Vortech, Kromek and Motif Bio. Prior to founding Amphion, he spent time at Wolfensohn and spent 15 years with Schroders plc where he was a member of the board and head of the Schroder Strategy Group. He graduated with a B. Engineering First Class Honors from the University of Auckland and in 1982 completed the Advanced Management Program at the Harvard Business School.

Richard Hullihen, CEO, BSEE, MBA 30 years in medical imaging with GEC-Picker International, and Marconi Medical systems creating their CT and MR businesses before moving to start m2m imaging with Amphion Innovations. Broad experience in medical imaging technology management, engineering, sales and marketing, manufacturing, and business development, in the US and internationally. CEO of m2m imaging since its formation.

Bastiaan Driehuys, PhD, CTO and Founder, 25 years experience in the field, both academically and commercially, currently also Professor of Radiology, Medical Physics, and Biomedical Engineering at Duke. Doctorate in Atomic Physics from Princeton.

Ken West, COO, BSCE, MBA, 30 year senior executive in both Fortune 500 scale companies, and medical startups in RTP. Broadly experienced in management, capital raising, contracting, and strategic partnerships. Has started and sold small businesses to large players in healthcare market.

Bob Bertoldi, Non – Executive Director, CFO of Amphion Innovations plc and serves as a director of three other Amphion Partner Companies: WellGen, Inc., Axxess International Inc., and DataTern, Inc. Began career at KPMG and is a member of the American Institute of Certified Public Accountants (AICPA) and New York State Society of Certified Public Accountants (NYSSCPA).

Directors and Senior Management Team

Juergen Laucht, Non-Executive Director, over 40 years of business experience in the chemical engineering industry and since 2011, the Managing Director of NUKEM Isotopes. Previously held positions at Siemens and at Reactor Brennelement Union, both in Germany. Has a degree in Chemical Engineering from the Technical University of Darmstadt, Germany.

Dr Jonathan Allis, Non-Executive Director, joined the board in September 2017. Founding CEO of Blue Earth Diagnostics. Prior to this role, Jonathan was the General Manager for PET at GE Healthcare Life Sciences, and had global responsibility for GE Healthcare's PET agent and PET synthesis platforms business. Undergraduate degree in physics from the University of Cape Town and a doctorate in biochemistry from the University of Oxford.

William Patrick CFO (non-board), BS, CPA, 25 years in corporate finance, in both public global multinationals, including GEC-Picker, and privately held and venture backed technology based businesses. Skilled in manufacturing businesses, international operations, and business finance.

Prestigious Installed Base



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