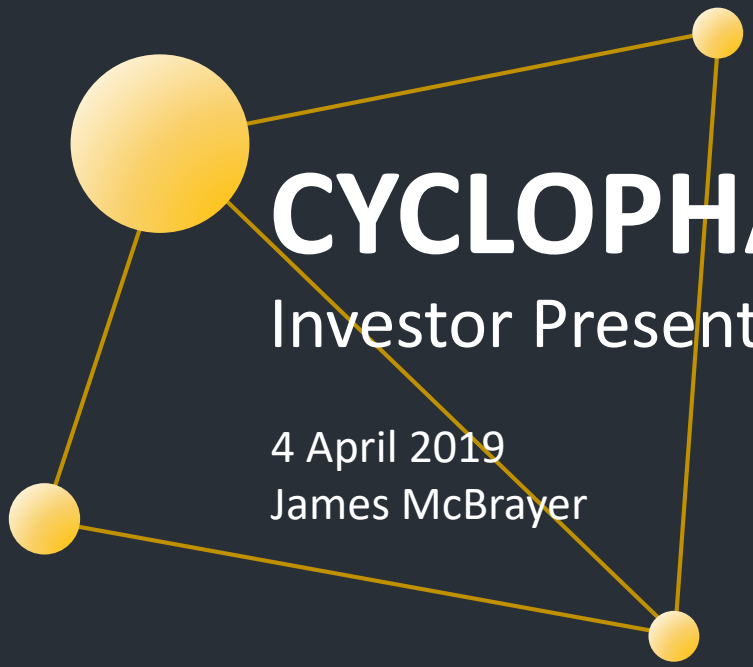
CYCLOPHARM (CYC)

Investor Presentation

4 April 2019

James McBrayer



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CYCLOPHARM OVERVIEW

Profitable & Growing MedTech
underlying business is cash positive and issuing dividends

First in class
Technegas technology generating sales from 57 countries and named as the agent of choice in the Canadian & European EANM Guidelines

Recurring revenue
from high margin consumable sales similar to an annuity model

USFDA approval
set to more than quadruple the existing CYC sales from Pulmonary Embolism (PE)

Optionality
expanding into indications beyond PE could dwarf the near term USA opportunity

Company Overview

Cyclopharm Limited (CYC) is a leading diagnostic lung imaging company

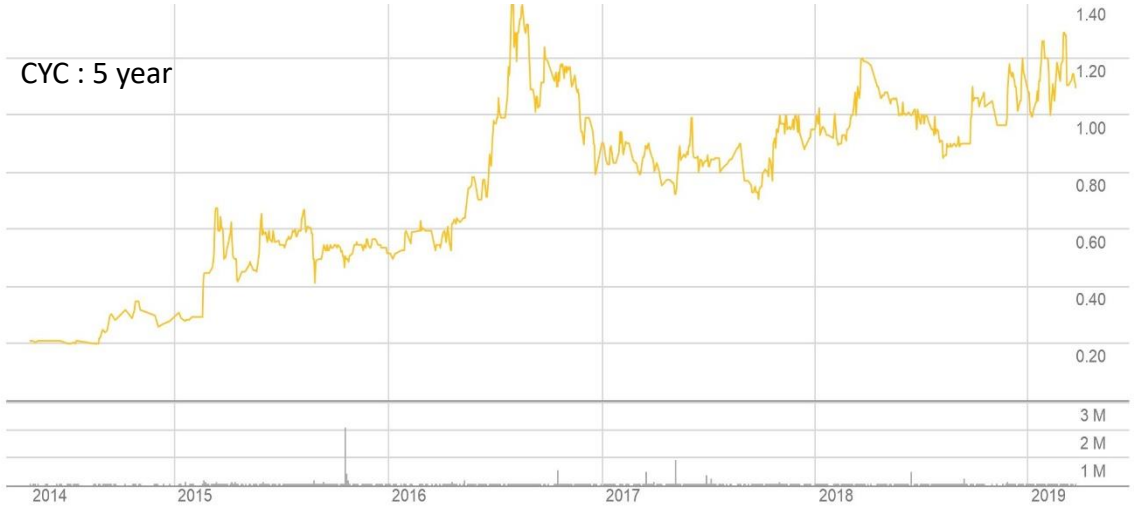
A world leader in functional lung ventilation imaging technology

Recurring consumables , service and capital equipment revenue streams

A profitable and growing company with a history of dividend payments

Lead nuclear medicine product Technegas generates sales from 57 countries with significant opportunity to expand into USA with USFDA approval expected in 2020

Opportunity to broaden Technegas applications beyond pulmonary embolism diagnosis into exponentially larger addressable markets such as COPD and Asthma



Share Price (3 April 2019)	$1.10
Shares on Issue	68.7 million
Market Capitalisation	$75 million
Cash (31 Jan 2019)	$9.19 million

Technegas USFDA Phase 3 clinical trial underway

Special Protocol Assessment (SPA)

–advanced finding from the USFDA has been received that de-risks potential issues when filing our NDA

Interim 40 patient read

– results submitted with a face-to-face meeting on 11 October 2018 at USFDA Headquarters

240 patient “all-comers” Protocol

– wide cross section of diseases

– 122 patients imaged as at 1/04/2019

USFDA approval

– 505(b)2 NDA submission - 2H 2019

– expected approval – 2020

FY2018 Results Highlights

Group Sales Revenue	**$13.40 million**
Gross Margin	$10.85 million
Net Loss After Tax	($0.04) million including USFDA investment
Interim Dividend	1.0 cents per share
Underlying Technegas EBITDA[1]	$1.90 million
FDA Trial expenses	($2.96) million
Strong balance sheet[2]	$9.19 million of cash reserves as @ 31 Jan 2019
Guidance Affirmed	The Board expects continuing modest growth in underlying Technegas volumes from existing markets for FY19

Note 1: Underlying Results represent results from the division excluding R&D tax incentive, reversal of contingent consideration, FDA expenses, Pilot Clinical Trial expenses and net expenses for Germany
Note 2: Cash reserves as at 31 December 2018 was $5.85 million

Technegas
world's best functional lung ventilation imaging agent

Patient inhales Technegas: carbon particles labeled with Tc99m.

Clinician can visualize functional ventilation using Technegas through to the alveolus: the site of gas exchange

Benefits of using Technegas

Easy
to prepare and administer

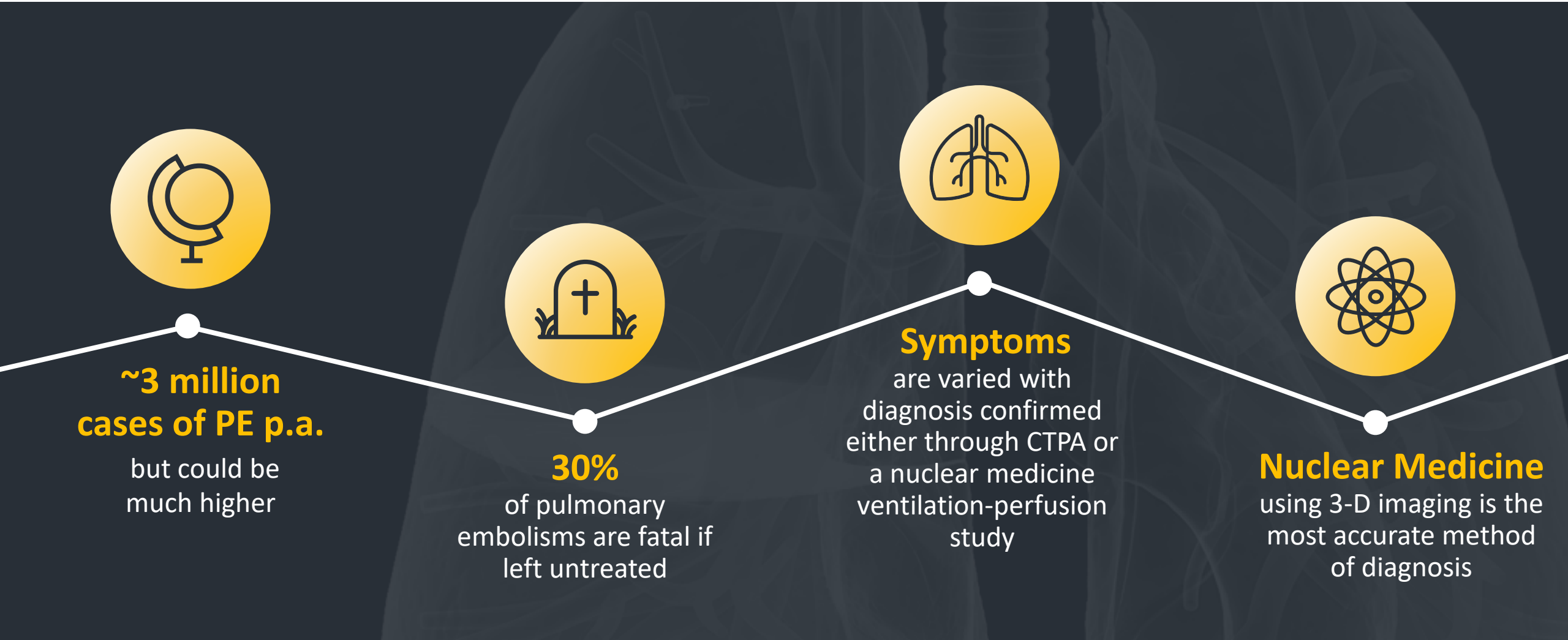
Only need
3 to 4 breaths

3D images
provide functional imaging through to the alveolus

No
contraindications

Cost
effective

Pulmonary Embolism



~3 million cases of PE p.a.

but could be much higher

30%

of pulmonary embolisms are fatal if left untreated

Symptoms

are varied with diagnosis confirmed either through CTPA or a nuclear medicine ventilation-perfusion study

Nuclear Medicine

using 3-D imaging is the most accurate method of diagnosis

Superior to competitive nuclear medicine products

Technegas

- Easy
- 3 to 4 breaths
- 3D images
- No contraindications
- Cost-effective

Xenon - 133

True radioactive gas
inhaled with full face mask

Constant inhale -exhale breathing
for 15 mins

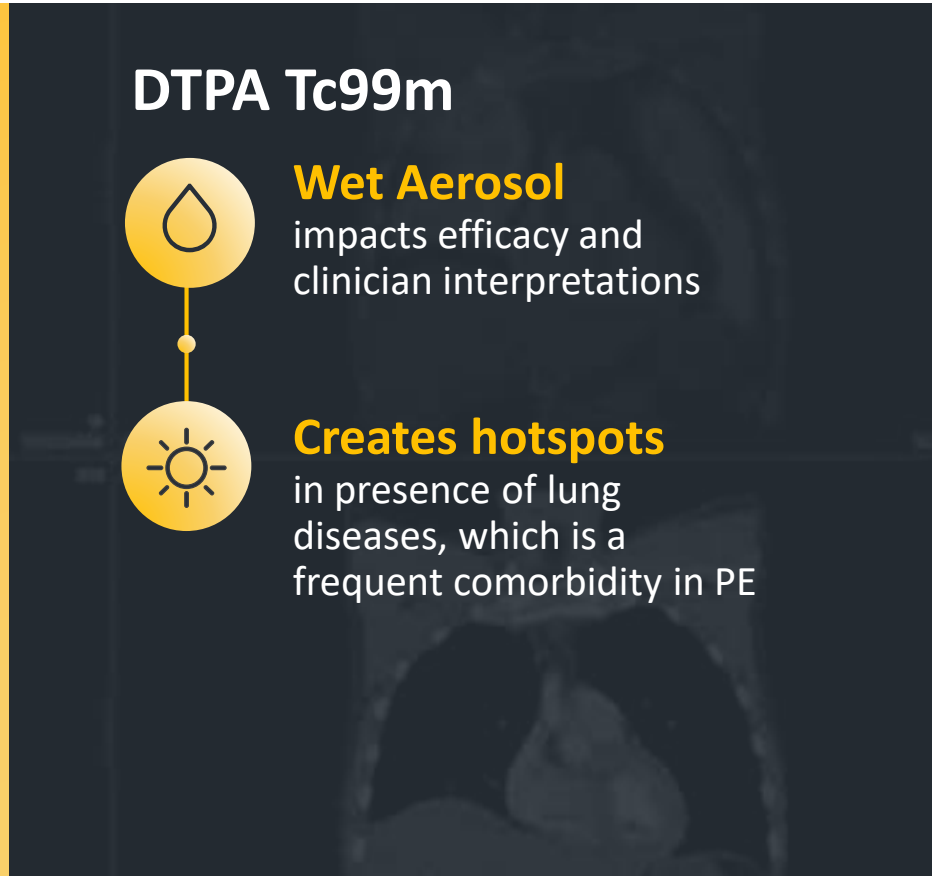
No 3D images
limited to planar imaging resulting in inferior clinical outcomes

Requires special rooms
to contain radioactive gas in the event of a release

DTPA Tc99m

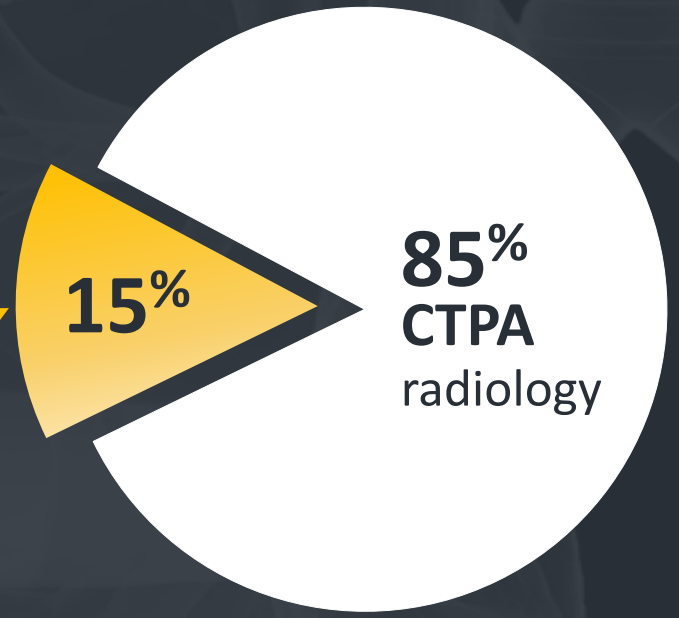
Wet Aerosol
impacts efficacy and clinician interpretations

Creates hotspots
in presence of lung diseases, which is a frequent comorbidity in PE



Diagnosing Pulmonary Embolism in the USA

USA = 4 million studies p.a.
to rule out PE



Nuclear Medicine
Predominantly Planar Imaging

$90m USD
nuclear medicine ventilation imaging market (Planar)

OPPORTUNITY TO DISPLACE CTPA:

High radiation burden
CTPA delivers at least 27 times more radiation to the breast as compared to V/Q SPECT

Contraindications
CTPA should not be performed with pregnancy, renal impairment, contrast media allergy, diabetes

AKI
Acute Kidney Injury occurs in up to 13% of CTPA cases

Lower Clinical Sensitivity
Planar = 67%
CTPA = 82%
SPECT = 93%

Technegas
FDA Clinical Trial Process and Design

Study Specifics

- Non-inferiority structural ventilation study comparing Xe133 vs. Technegas
- Special Protocol Assessment Granted
- Total estimated trial cost $7.5 million USD with $5.5m USD spent to date
- Assumes 240 patient study at up to 10 clinical sites
- CYC completed a preliminary 40 patient trial submitted to the FDA
- 122 Patients enrolled as at 1 April 2019
- Face to Face meeting with the FDA on 11 October 2018 – constructive guidance provided relating to an alternative 505(b)2 New Drug Application Pathway and a variation to the existing trial expected to expedite patient enrolment approved

Timeline

1H 2018

Finalise Trial Site Recruitment

1H 2018

Submit Preliminary Trial Results for FDA Review

2H 2019

Submit NDA

2020

Commence US Commercialisation

Building from a strong & well established foundation

Near term opportunities providing significant growth potential beyond PE toward patient management

USA Market

nuclear medicine ventilation imaging market to diagnose PE equal to $90m USD with reimbursement already in place

Targeting USA CTPA PE market

opportunity to convert CTPA to nuclear medicine imaging by shifting market to SPECT imaging

Half billion

combined sufferers of Asthma and Chronic Obstructive Pulmonary Disease globally.

Trials underway

Clinical Study Strategy Beyond PE Underway

Hunter Medical Research Institute

100 patient trial targeting phenotyping and response to therapy in severe asthma. 99 patients enrolled as at 1/04/2019

Woolcock Institute

100 patient trial to commence 2Q 2019 targeting the diagnosis of mild to moderate COPD and response to therapy

Other clinical trials initiated

Lung Volume Reduction, assessment of Lung Transplant patients and early detection of COPD and response to therapy

Protocol development underway

Clinical trial to determine the effectiveness of early detection of COPD in asymptomatic smokers

2019 Strategic Priorities and Outlook

Strategic Goals & Guidance	Activity	Timeframe
United States FDA Approval & Commercialisation	Continue patient recruitment	Ongoing
	Finalise clinical trial sites (Mayo and Univ of Utah)	1H 2019
	Finalise paediatric plan and submit to USFDA	1H 2019
	Complete internal development of pharmaceutical and device manufacturing requirements to comply with USFDA requirements	1H 2019
	Submit New Drug Application to the USFDA	2H 2019
	Initiate USA Commercialisation Plan	1H 2019
Indication Expansion	Continue UoN-HMRI-JHH clinical trial	Ongoing
	Commence new pilot trials in Canada and Australia	1H 2019
	Commence COPD trial Woolcock Institute	1H 2019
	Expand clinical marketing	Ongoing
New Product – Ultralute™	Registration as a medical device technology in Europe	2H 2019
Expand Product & Service Offering	Identify and evaluate business prospects targeting growth, product extension, diversification, improved distribution models, accretion and enhanced returns	Ongoing
	Evaluate other acquisition opportunities	Ongoing
2019 Guidance - Affirmed	Continued underlying solid Technegas sales and underlying earnings growth	FY 2019
	Expenditure of approximately AUD $3.4 million on FDA approval process and regulatory / operational readiness for US launch	
	Finalise operational and regulatory readiness for USFDA launch	
	Ongoing investment in trials to support expanded use of Technegas supported by AusIndustry R&D grants	

CYCLOPHARM BUSINESS CASE

Profitable & Growing MedTech
underlying business is cash positive and issuing dividends

First in class
proprietary product sales to 57 countries with 4 million studies to date

Recurring revenue
from consumables similar to an annuity model

USFDA approval
set to quadruple the size of the existing PE business and further leverage penetration into the CTPA market

Optionality
into indications beyond PE into chronic respiratory disease management could deliver exponential growth

Clinical Information

Technegas is the preferred ventilation agent

Endorsed by the guidelines from the European[5] and the Canadian[6] Associations of Nuclear Medicine (EANM & CANM)

- “Using 99m-Tc-Technegas is according to clinical experience better than the best aerosols”
- “Technegas is preferred to DTPA in patients with COPD”
- “For ventilation, 99m-Tc Technegas is the best-aerosol particularly in patients with COPD”
- “Liquid aerosols are inferior for SPECT and should not be used unless Technegas is not available”
- “The best widely available agent for ventilation is 99m-Tc-Technegas”
- “Because of the very small particle size, this agent is distributed in the lungs almost like a gas and deposited in alveoli by diffusion, where they remain stable, thus providing the best possible images for ventilation SPECT”
- “Another advantage is that only a few breaths are sufficient to achieve an adequate amount of activity in the lungs, reducing time and personnel exposure to radiation”
- “Technegas is considered the agent of choice in the COPD population as there is less central airway deposition, better peripheral penetration, and it does not wash out as quickly as traditional aerosols”

5. Bajc M, et al. Eur J Nucl Med Mol Imaging 2009; 36(8): 1356-70
6. Leblanc M, et al. CANM 2018; https://canm-acmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%2012_.pdf

Diagnosing Pulmonary Embolism with V/Q SPECT

Primary imaging procedure
when
PE is suspected[7]

Excellent diagnostic performance[8]
Sensitivity 93.0%
Specificity 93.3%
NPV 96.1%

Detects PE
at subsegmental level[3]

Non-invasive
Aids patient comfort and compliance[9], even in COPD patients[10]

COMPARED TO CTPA:

Less radiation burden
V/Q SPECT delivers 27 times less radiation to the breast as compared to CTPA[11]

Minimal exclusion criteria
V/Q SPECT can be performed in case of pregnancy[11-12], renal impairment[13], contrast media allergy[13] and diabetes[3]

Higher clinical sensitivity
V/Q SPECT has a higher sensitivity to diagnose PE compared to CTPA (93% vs 82% respectively)[8].

3. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596
7. Waxman AD, et al. J Nucl Med 2017; 58: 13N-15N
8. Hess S, et al. Semin Thromb Hemost 2016; 42(8): 833-845
9. Sánchez-Crespo A, et al. Nucl Med Commun 2008; 29(2): 173-177
10. Nasr A, et al. ECPRM 2017; 4(3): 85-91
11. Isidoro J, et al. Phys Med 2017; 41: 93-96
12. Bajc et al. Eur J Nucl Mol Imaging 2015; 42: 1325-1330
13. Miles S, et al. Chest 2009; 136: 1546-1553

Hybrid V/Q SPECT/CT

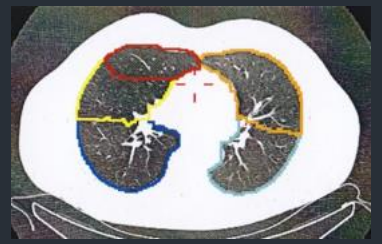
V/Q SPECT provides **functional** information on ventilation and perfusion of the lungs[14-15]

Low-dose CT provides **anatomical** information such as fissures delineation[16]

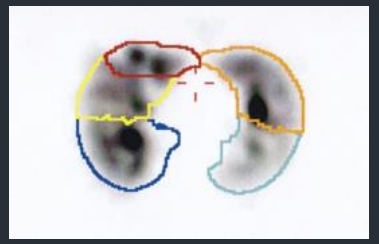
Combination of functional and anatomical information allow for objective results through **quantitative software**[15-16]

Ventilation SPECT

Low-dose CT



Fused SPECT/CT



Lobar distribution of ventilation

		RIGHT				LEFT		
		RUL	RML	RLL	Total	LUL	LLL	Total
Counts	kcts	27% 254	11% 103	28% 261	66% 617	24% 227	10% 95	34% 321
Volume	ml	24% 1256	9% 456	25% 1321	57% 3033	26% 1364	17% 914	43% 2278

Percentages, volumes and counts of individual lobes
(Images and 3D quantification provided by MMI)

IMPROVES DIAGNOSTIC CAPABILITIES AND OFFERS ANATOMICALLY-BASED QUANTIFICATION OF LOBAR CONTRIBUTION FOR INTERVENTIONAL THERAPIES

14. Reinartz P, et al. J Nucl Med 2004; 45: 1501-1508
15. King GG, et al. Semin Nucl Med 2010; 40(6): 467-473
16. Provost K, et al J Nucl Med Technol 2017; 45(3): 185-192

Beyond PE applications of V/Q SPECT/CT

Diagnosis and follow-up of **Pulmonary Embolism**[3] and **Chronic thromboembolic pulmonary hypertension (CTEPH)**[17]

Preoperative assessment of **Endoscopic Lung Volume Reduction (ELVR)** candidates[18]

Preoperative assessment of **lung resection candidates with** borderline pulmonary reserve[19-21]

Planning **radiation therapy** to target tumors while preserving functional lung zones[21-22]

Advanced approach to phenotyping **chronic airways diseases such as asthma and COPD** and identifying patient likely to respond to treatment[4,23-24]

3. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596
4. Farrow C, King GG. Semin Nucl Med 2019; 49(1): 11-15
17. Ohira H, et al. J Nucl Cardiol 2015;22(1): 141-157
18. Hsu K, et al. J Bronchology Interv Pulmonol 2018; 25(1): 48-53
19. Mortensen J, Berg RMG. Semin Nucl Med 2019; 49(1): 16-21
20. Wechalekar K, et al. Semin Nucl Med 2019; 49(1): 22-30
21. Elojeimy S, et al. AJR Am J Roentgenol 2016; 207(6): 1307-1315
22. Eslick EM, et al. Semin Nucl Med 2019; 49(1): 31-36
23. Jögi J, et al. Int J Chron Obstruct Pulmon Dis 2014; 10: 25-30
24. Bajc M, et al.. Int J Chron Obstruct Pulm Dis 2017; 12: 1579-1587

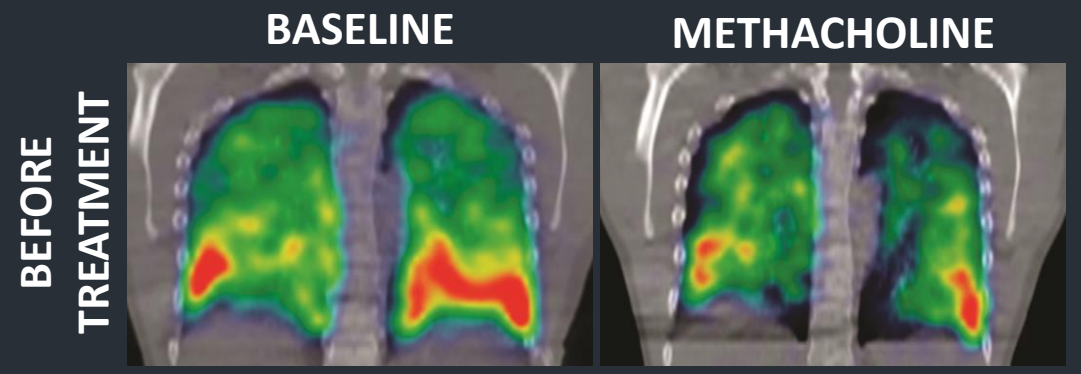
Treatment response in asthma patient

Case 1

CLINICAL HISTORY
Male patient of 25 years old with life-long asthma

REFERRAL
Evaluation of asthma treatment efficacy

PROTOCOL
Ventilation SPECT/CT imaging at baseline and after methacholine challenge before and after asthma treatment



Bronchoconstriction after methacholine challenge worsened ventilation function and increased ventilation heterogeneity. This was predicted by baseline peripheral ventilation heterogeneity

After treatment, ventilation improved and is more homogeneous on ventilation SPECT imaging, at baseline and also after methacholine-induced bronchoconstriction

Images and data were kindly provided by the Woolcock Institute of Medical Research

VENTILATION SPECT/CT TO MONITORE TREATMENT RESPONSE IN PATIENTS WITH LIFELONG ASTHMA

Planning lung volume reduction surgery

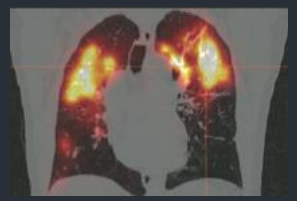
Case 2

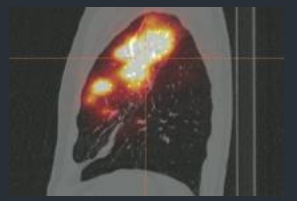
CLINICAL HISTORY
Male patient of 64 years old with emphysema

REFERRAL
Assessment of lung ventilation function before planning endoscopic lung volume reduction

PROTOCOL
VQ SPECT/CT imaging with Technegas as ventilation agent

Images and data were kindly provided by Macquarie Medical Imaging


CORONAL FUSION


SAGITTAL FUSION


UPPER LOBES TRANSVERSE FUSION


LOWER LOBES TRANSVERSE FUSION

The ventilation SPECT/CT scan reveals the function of the lower lobes is severely affected. The left oblique fissure is intact so the left lower lobe should be a good target lobe for endobronchial valves insertion.

Assessment for collateral ventilation was confirmed using CHARTIS assessment tool during the procedure.

Decision: 3 valves were inserted into the left lower lobe.

VENTILATION RELATIVE UPTAKE [%]		
	Right	*Left*
UPPER	45 %	36 %
MIDDLE	12 %	N/A
LOWER	**3 %**	**4 %**
TOTAL	60 %	40 %

Lobar 3D quantification provided by Hermes

VENTILATION SPECT/CT AS A TOOL TO ASSIST IN PREDICTING FUNCTIONAL LUNG VENTILATION PRIOR TO LUNG VOLUME REDUCTION

Clinical Research

2018

Ongoing studies

- **FDA clinical trial phase 3 (Multiple sites, USA)**
  The United States FDA (USFDA) phase 3 clinical trial is a non-inferiority structural ventilation study comparing Technegas with Xenon-133 in a total of 240 patients.[19]

- **Hunter Medical Research Institute (Newcastle, Australia):**
  100 patients with chronic airways diseases will undergo V/Q SPECT imaging with a low-dose CT scan to illustrate detailed images of airspaces and blood vessels in the lungs. 30 patients will have a follow-up image taken to provide important insights into early treatment response.[20]

25. NCT03054870 – A comparison of Technegas and Xenon-133 planar lung imaging in subjects referred for ventilation scintigraphy
26. ACTRN12617001275358 - Can functional lung ventilation imaging identify treatable traits in obstructive airway disease?

Clinical Research

2018 2019

Upcoming studies

- **Woolcock Institute - Sydney, Australia:**
  Ventilation SPECT as a clinical tool to determine disease characterization and treatment response in 84 patients with asthma and COPD
- **The Centre hospitalier de l'Université de Montréal (CHUM) Montreal, Canada:**
  Quantitative ventilation lung SPECT/CT scan with Technegas to assess early small airway disease in smokers
- **Dalhousie University - Halifax, Canada:**
  Using Technegas SPECT and quantification lung imaging in patients with small airways disease post lung transplant and post hematopoietic stem cell transplant
- **Macquarie University - Sydney, Australia:**
  Procedure evaluation for ELVR with endobronchial valves targeting lower lobes in severe COPD patients
- **Macquarie University - Sydney, Australia:**
  Measurement of small airway function for bronchial thermoplasty procedure (Sydney)

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1. Fawdry RM, et al. Initial experience with Technegas – a new ventilation agent. Australas Radiol 1988; 32(2): 232-238
2. Senden TJ, et al. The physical and chemical nature of Technegas. J Nucl Med 1997; 38: 1327-1333
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4. Farrow C, King GG. SPECT Ventilation imaging in asthma. Semin Nucl Med 2019; 49(1): 11-15
5. Bajc M, et al. Eur J Nucl Med Mol Imaging 2009; 36(8): 1356-70
6. Leblanc M, et al. CANM 2018; https://canm-acmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%2012_.pdf
7. Waxman AD, et al. Appropriate use criteria for Ventilation-Perfusion imaging in pulmonary embolism: summary and excerpts: J Nucl Med 2017; 58: 13N-15N
8. Hess S, et al. State-of-the-art imaging in pulmonary embolism: Ventilation/perfusion single-photon emission computed tomography versus computed tomography angiography – Controversies, results, and recommendations from a systematic review. Semin Thromb Hemost 2016; 42(8): 833-845
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11. Isidoro J, et al. Radiation dose comparison between V/P-SPECT and CT-angiography in the diagnosis of pulmonary embolism. Phys Med 2017; 41: 93-96
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13. Miles S, et al. A comparison of single-photon emission CT lung scintigraphy and CT pulmonary angiography for the diagnosis of pulmonary embolism. Chest 2009; 136: 1546-1553
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15. King GG, et al. V/Q SPECT: utility for investigation of pulmonary physiology. Semin Nucl Med 2010; 40(6): 467-473
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23. Jögi J, et al. The added value of hybrid ventilation/perfusion SPECT/CT in patients with stable COPD or apparently healthy smokers. Cancer-suspected CT findings in the lungs are common when hybrid imaging is used. Int J Chron Obstruct Pulmon Dis 2014; 10: 25-30
24. Bajc M, et al. Identifying the heterogeneity of chronic obstructive pulmonary disease by V/P SPECT: a new tool for improving the diagnosis of parenchymal defects and grading the severity of small airways disease. Int J Chron Obstruct Pulm Dis 2017; 12: 1579-1587
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