



# CYCLOPHARM (CYC)

AGM Presentation  
2018 Financial Year Results

21 May 2019



# Disclaimer

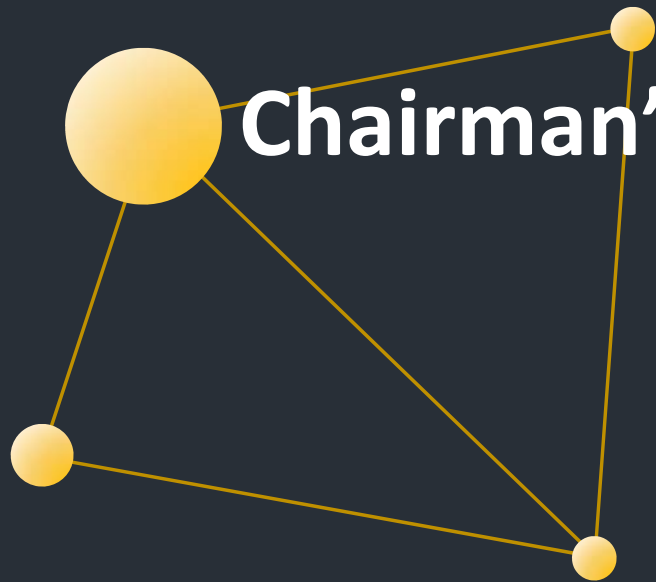
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# Chairman's Address

David Heaney





# Managing Director's Address

James McBrayer



# CYCLOPHARM BUILDING FOR GROWTH



**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

# FY2018 Results Highlights

**Group Sales Revenue**

**\$13.40 million**

**Gross Margin**

\$10.85 million

**Net Loss After Tax**

(\$0.04) million including USFDA investment

**Total Dividend**

1.0 cents per share

**Underlying Technegas EBITDA<sup>1</sup>**

\$1.90 million

**FDA Trial expenses**

(\$2.96) million

**Strong balance sheet<sup>2</sup>**

\$9.19 million of cash reserves as @ 31 Jan 2019

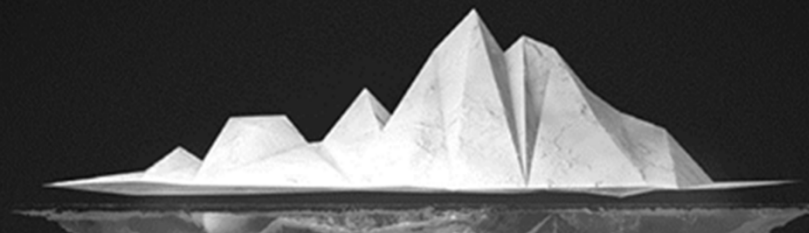
**Guidance Affirmed**

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

# Operating Highlights



• **Technegas is a substantially de-risked commercial proposition with significant upside in the US market**

- Total **global sales of \$104 m** from 2010
- Technegas currently available in **57 countries**
- Over **195,000 patient procedures** in 2018
- Over **4,200,000 patient procedures** since 1986
- **~1,600 Technegas generators** sold globally
- CYC is growing, underlying business is profitable and dividend paying company
- Stable gross margins of greater than 80%
- Around 80% of historical revenue is recurring consumable sales



<b>Share Price (17 May 2019)</b>	<b>\$1.23</b>
<b>Shares on Issue</b>	<b>68.7 million</b>
<b>Market Capitalisation</b>	<b>\$84 million</b>
<b>Cash (30 April 2019)</b>	<b>\$7.14 million</b>

# Technegas world's best functional lung ventilation imaging agent



**Easy**  
to prepare and  
administer



**Only need**  
3 to 4 breaths



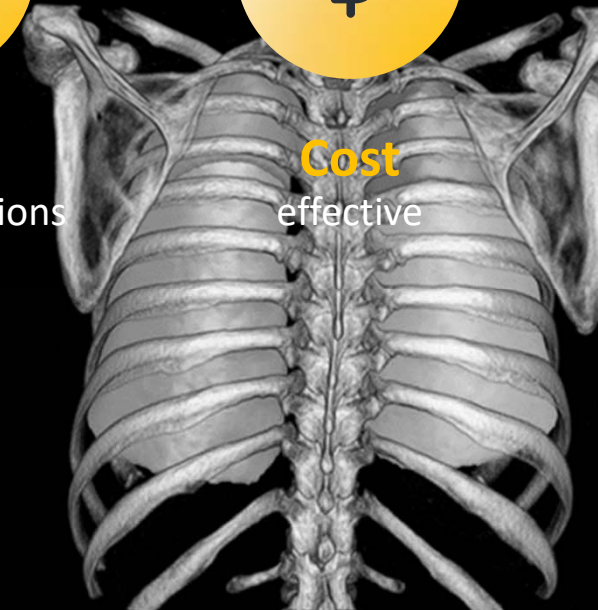
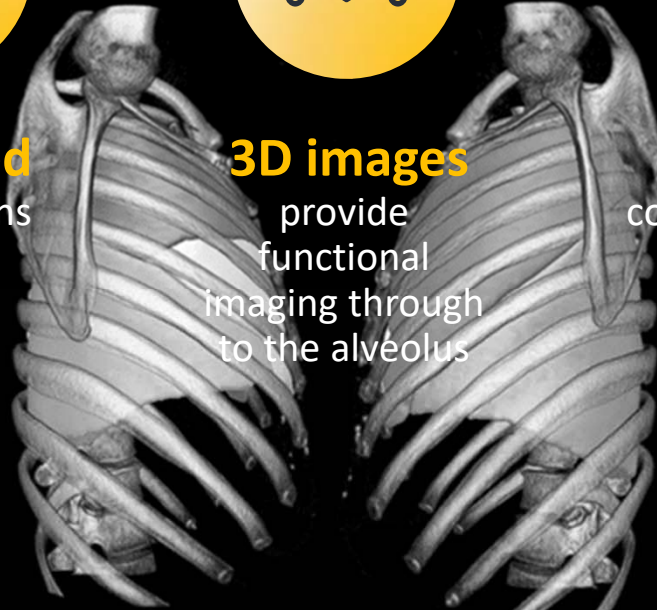
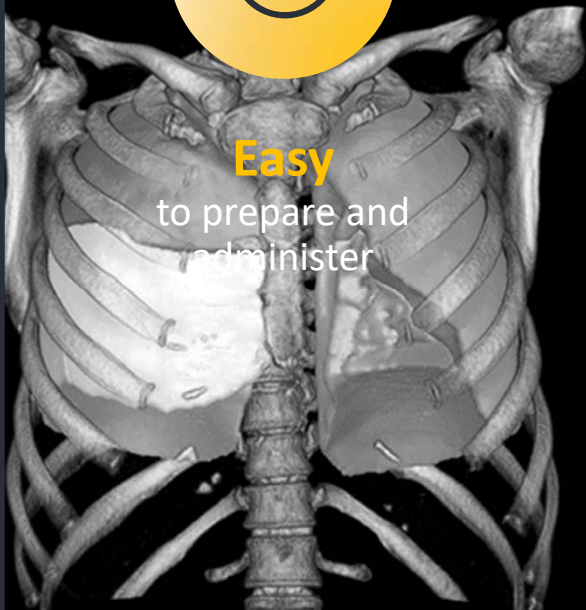
**3D images**  
provide  
functional  
imaging through  
to the alveolus



**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

# Diagnosing Pulmonary Embolism in the USA

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

**Nuclear  
Medicine**  
Predominantly  
Planar Imaging

15%

85%  
CTPA  
radiology

\$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 \$5.85m 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
- 135 Patients enrolled as at 17 May 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. 100 patients enrolled as at 17/05/2019



## 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



# Ultralute Update



- Ultralute™ has the potential to bring significant cost savings in the delivery of pharmaceuticals used in nuclear medicine by extending the useful life of Molybdenum-99 (Mo-99) generators by up to 50%.
- First test sales in 2018,
- Decision taken to register Ultralute™ as a medical device technology within Europe
- Medical Device registration expected to broaden its overall market acceptance and optimise the commercial value of this technology.
- A full commercial launch of Ultralute™ in Europe is expected to commence following registration as a medical device targeted in late 2019.
- Meaningful commercial sales of Ultralute™ within the medical device category in Europe are expected in 2020.

# 2019 Strategic Priorities and Outlook

Strategic Goals & Guidance	Activity	Timeframe
<b>United States FDA Approval &amp; Commercialisation</b>	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
<b>Indication Expansion</b>	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
<b>New Product – Ultralute™</b>	Registration as a medical device technology in Europe	2H 2019
<b>Expand Product &amp; Service Offering</b>	Identify and evaluate business prospects targeting growth, product extension, diversification, improved distribution models, accretion and enhanced returns	Ongoing
	Evaluate other acquisition opportunities	Ongoing
<b>2019 Guidance - Affirmed</b>	Continued underlying solid Technegas sales and underlying earnings growth 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	FY 2019

# 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



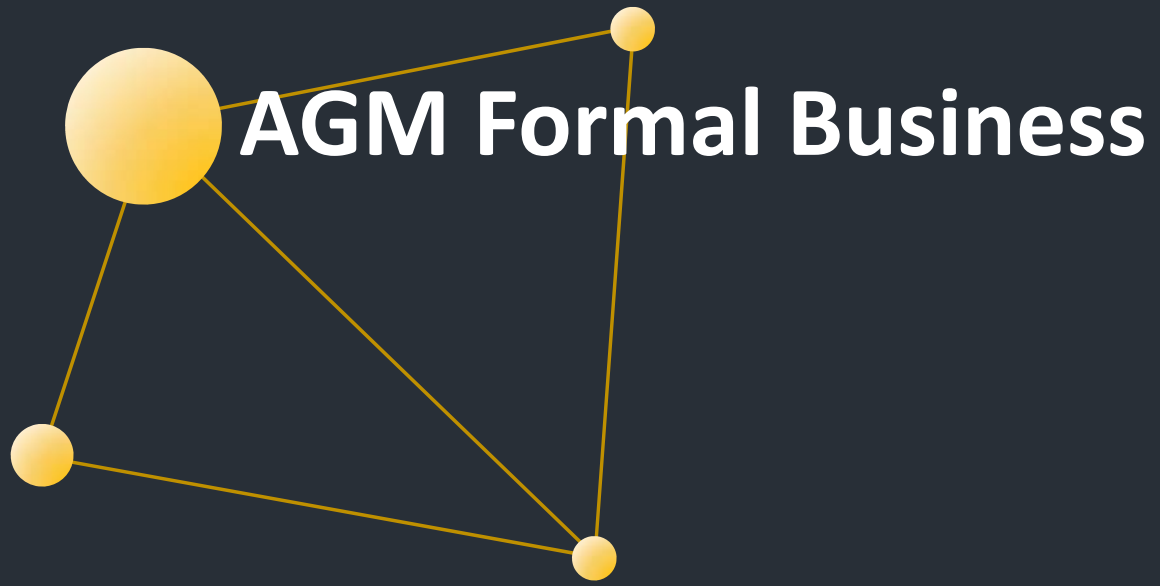
**USFDA approval**  
set to quadruple the size of the existing PE business and further leverage penetration into the CTPA market



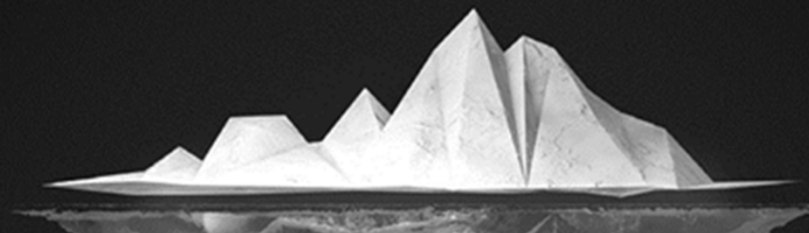
**Optionality**  
into indications beyond PE into chronic respiratory disease management could deliver exponential growth







# 2019 AGM Formal Business



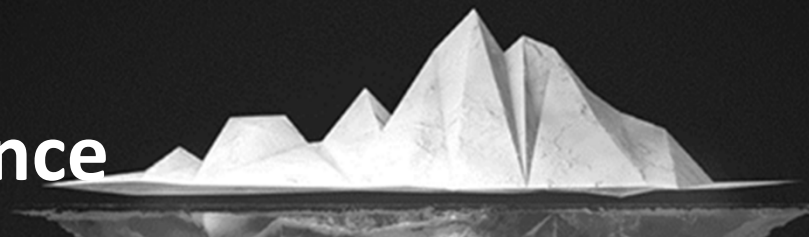
Resolution	Business	For *	Against	Abstain	Proxy's Discretion	Excluded
1	Remuneration report	28,764,048	31,617	1,854,369	13,211,332	12,185,066
2	Re-election of Tom McDonald	42,835,100	-	-	13,211,332	-
3	Removal of Nexia Sydney Audit & Assurance as Auditor	42,792,280	2,460	40,360	13,211,332	-
4	Appointment of Nexia Sydney Audit Pty Ltd as Auditor	42,794,740	-	40,360	13,211,332	-
5	Approval for share buy-back	42,813,061	22,039	-	13,211,332	-
6	Issue of shares to Managing Director	40,962,919	39,180	1,833,001	13,211,332	-
7	Issue of options to Managing Director	40,963,506	38,593	1,833,001	13,211,332	-
8	Increase in the Maximum Aggregate Annual Remuneration of Non-Executive Directors	28,759,211	57,822	1,833,001	13,211,332	12,185,066

\*Includes Open Useable Proxies that have instructed the Chairman to vote on their behalf and have voted in favour of the resolution.

# Appendix

- FY18 Results
- Technegas Clinical Information

# Group Underlying Performance



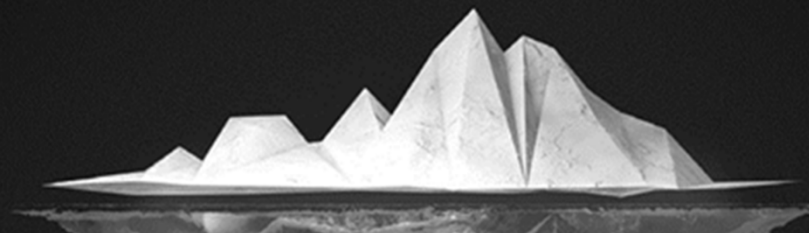
## Solid Underlying Financial Results

Year ended 31 December (\$000's)	2018	2017
<b>Consolidated sales</b>	<b>13,404</b>	<b>13,189</b>
Gross margin	10,855	10,740
<i>Gross margin % sales</i>	<i>81.0%</i>	<i>81.4%</i>
<b>Consolidated EBITDA</b>	<b>655</b>	<b>1,043</b>
Add back:		
<i>CPET / Ultralute™ division EBITDA</i>	335	457
<i>Reversal of contingent consideration</i>	(314)	-
<i>Unrealised gain on forward exchange contract</i>	(275)	-
<i>Expenses net of writebacks for Germany</i>	410	677
<i>FDA expenses and other pilot trial expenses</i>	3,216	2,855
<i>R&amp;D Tax Incentive</i>	(2,122)	(2,391)
<b>Technegas Underlying EBITDA</b>	<b>1,905</b>	<b>2,641</b>

During the year, CYC continued to implement its strategic priorities, which are to:

1. Accelerate the path to regulatory approval to sell Technegas into the world's largest and new highly prospective US market;
2. Pursue sales of Technegas in new applications: Chronic Obstructive Pulmonary Disease ("COPD") and Asthma which are significantly larger markets than the Pulmonary Embolism market where CYC traditionally operates;
3. Identifying, developing and commercialising complementary innovative technology such as Ultralute™; and
4. Leveraging our core global regulatory strengths, fiscal discipline, strong balance sheet and well-developed expertise in nuclear medicine and pulmonary healthcare to seek out complementary technologies and businesses.

# Group Balance Sheet



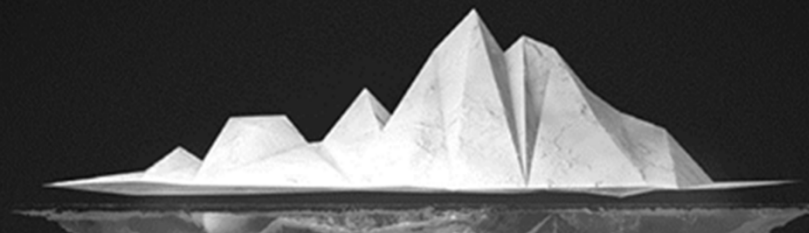
## Financial Foundation to Leverage Growth Strategy

Year ended 31 December (\$000's)	2018	2017
Cash	5,855	8,690
Other current assets	9,600	8,139
Non-current Assets	8,082	6,548
<b>Total Assets</b>	<b>23,537</b>	<b>23,377</b>
Current Liabilities	5,219	5,212
Non-current Liabilities	1,302	916
<b>Total Liabilities</b>	<b>6,521</b>	<b>6,128</b>
<b>Net Assets</b>	<b>17,016</b>	<b>17,249</b>

During the year, CYC continued to implement its strategic priorities, which are to:

- Low debt & cash on hand – provides balance sheet and funding flexibility
- Funding used toward USFDA clinical trial enrolment and New Drug Application submission
- Strong financial position supports ongoing investment in R&D and expansion into new markets and indications

# Group Cash Position



## Cash Position Funding Growth

<b>Year ended 31 December (\$000's)</b>	<b>2018</b>	<b>2017</b>
Operating Activities	(1,107)	(682)
Investing Activities	(1,403)	(1,136)
Financing Activities	(353)	5,828
Net (Decrease ) / Increase in Cash	(2,863)	4,010
Opening Cash	8,690	4,591
Foreign Exchange	28	89
<b>Closing Cash @ 31 December (\$000's)</b>	<b>5,855</b>	<b>8,690</b>
<b>Closing Cash @ 30 April 2019 (\$000's)</b>	<b>7,137</b>	

- Capital Raising \$6.59 m June 2017 with 90% Shareholder Participation
- Benefited from expanded R&D tax Incentive Program resulting in Other Income of \$2.12 million



TECONNEGAS™

FUNCTIONAL LUNG IMAGING

Clinical Information



# Technegas is the preferred ventilation agent

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



"Technegas is according to clinical experience better than the best aerosol"

"Technegas is preferred to DTPA in patients with COPD"

"In COPD, 99m-Tc Technegas is the best-aerosol particularly in patients with COPD"

"Traditional aerosols are inferior for SPECT and should not be used unless Technegas is not available"

"The most 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 for a long time thus providing the best possible images for ventilation SPECT"

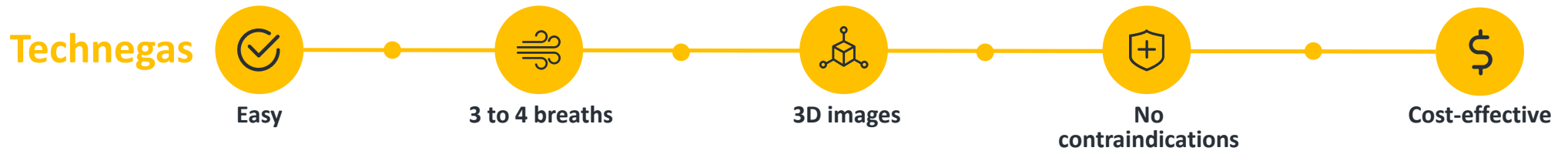
"Another advantage is that only a few breaths are sufficient to achieve an adequate amount of activity in the lungs, reducing time and personnel exposure to radiation"

"Technegas is considered the agent of choice in the COPD population as the result of 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](https://canm-acmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%2012_.pdf)

# Superior to competitive nuclear medicine products



## 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

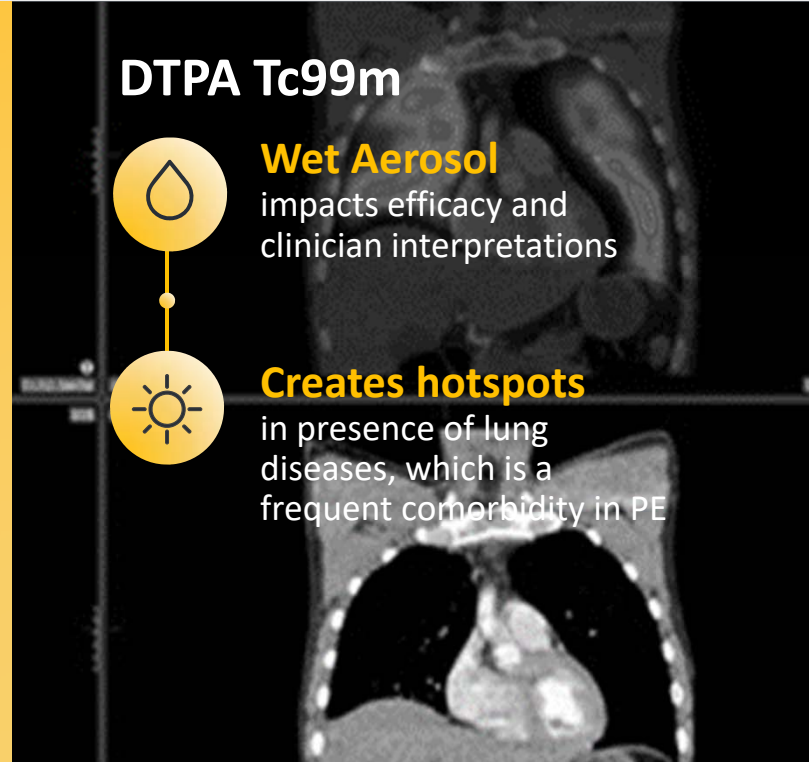
## DTPA Tc99m



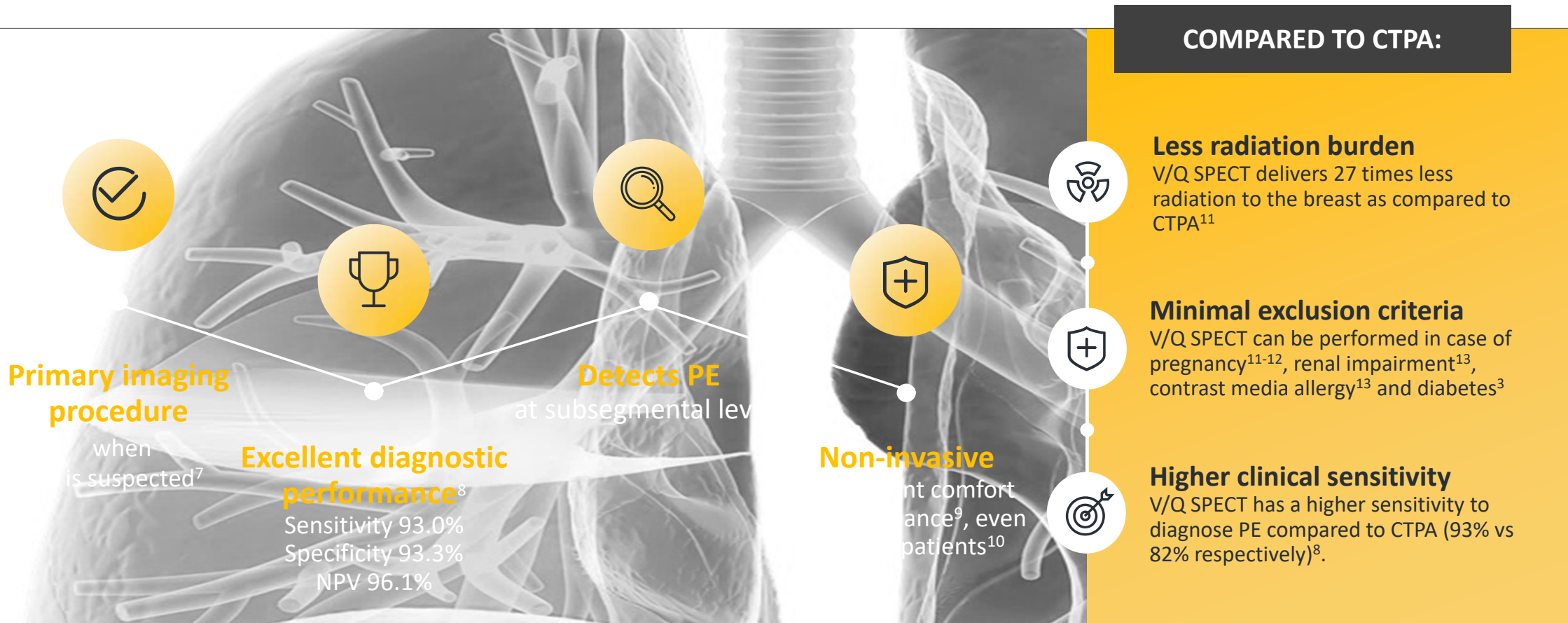
**Wet Aerosol** impacts efficacy and clinician interpretations



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



# Diagnosing Pulmonary Embolism with V/Q SPECT



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

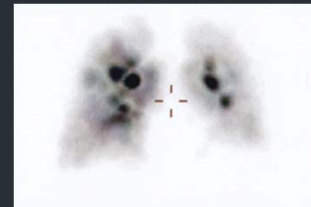
**V/Q SPECT** provides **functional** information on ventilation and perfusion of the lungs<sup>14-15</sup>

**Low-dose CT** provides **anatomical** information such as fissures delineation<sup>16</sup>

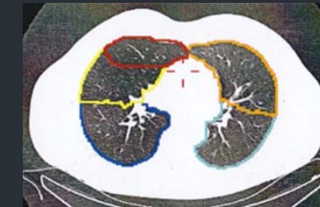
Combination of functional and anatomical information allow for objective results through **quantitative software**<sup>15-16</sup>



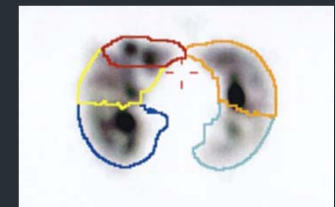
Ventilation SPECT



Low-dose CT



Fused SPECT/CT



Lobar distribution of ventilation

	RIGHT				LEFT		
	RUL	RML	RLL	Total	LUL	LLL	Total
Counts	27%	11%	28%	66%	24%	10%	34%
kcts	254	103	261	617	227	95	321
Volume	24%	9%	25%	57%	26%	17%	43%
ml	1256	456	1321	3033	1364	914	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**<sup>3</sup> and **Chronic thromboembolic pulmonary hypertension (CTEPH)**<sup>17</sup>



Preoperative assessment of **Endoscopic Lung Volume Reduction (ELVR)** candidates<sup>18</sup>



Preoperative assessment of **lung resection** candidates with borderline pulmonary reserve<sup>19-21</sup>



Planning **radiation therapy** to target tumors while preserving functional lung zones<sup>21-22</sup>



Advanced approach to phenotyping **chronic airways diseases such as asthma and COPD** and identifying patient likely to respond to treatment<sup>4,23-24</sup>

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

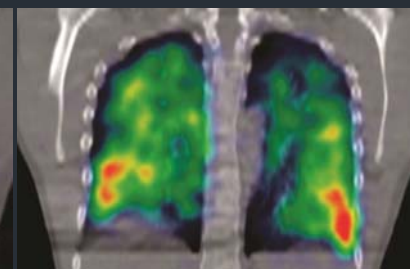
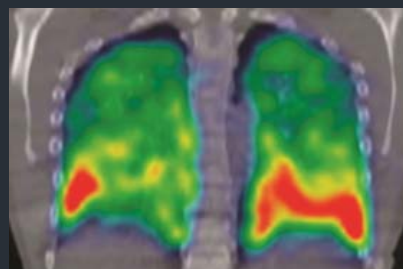
*Images and data were kindly provided by the Woolcock Institute of Medical Research*



### BASELINE

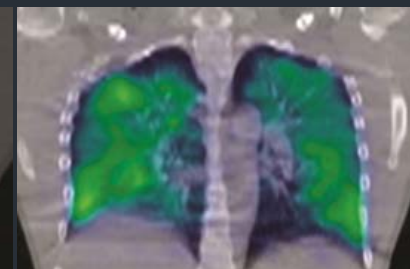
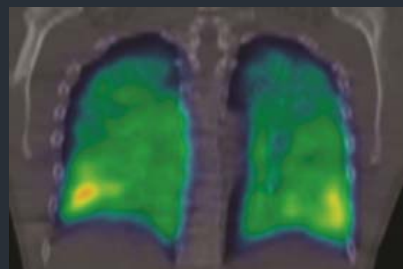
### METHACHOLINE

BEFORE  
TREATMENT



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

AFTER  
TREATMENT



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

**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

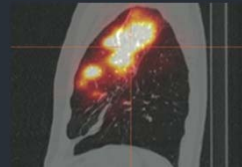
### PROTOCOL

VQ SPECT/CT imaging with Technegas as ventilation agent

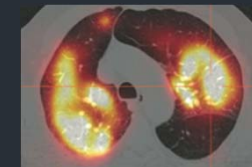
*Images and data were kindly provided by Macquarie Medical Imaging*



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.<sup>19</sup>

- **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 airspace and blood vessels in the lungs. 30 patients will have a follow-up image taken to provide important insights into early treatment response.<sup>20</sup>

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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26. ACTRN12617001275358 - Can functional lung ventilation imaging identify treatable traits in obstructive airway disease?