

cyclopharm

# Macquarie Capital Emerging Leaders Conference

19 June 2024

James McBrayer CEO & Managing Director

ASPIRE. INSPIRE. ILLUMINATE.



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This presentation was approved and authorised for release by James McBryer, Managing Director, CEO and Company Secretary.



# Highlights since Last Year's Macquarie Conference

1

**USFDA Approval** received for Technegas

2

**Technegas Sales in the USA** - Generating Revenues at every installed US clinical site

3

**Regulatory renewals** in existing markets achieved in under the new MDR and renewed MDSAP regimes

4

**"Beyond PE"** studies published, **expanding clinical applications** to include asthma, lung cancer, COPD and Long COVID

5

**Board renewal complete** – skills in place for the next phase of growth

6

**Secured adjacent Sydney manufacturing space**– manufacturing capacity is future-proofed

7

**Fully funded** to deliver USA growth targets – recent \$20m capital raise with additional SPP closing 21 June

8

**US reimbursement awarded** to Technegas last week – accelerating installation



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# Technegas Overview

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# Technegas<sup>®</sup> around the world



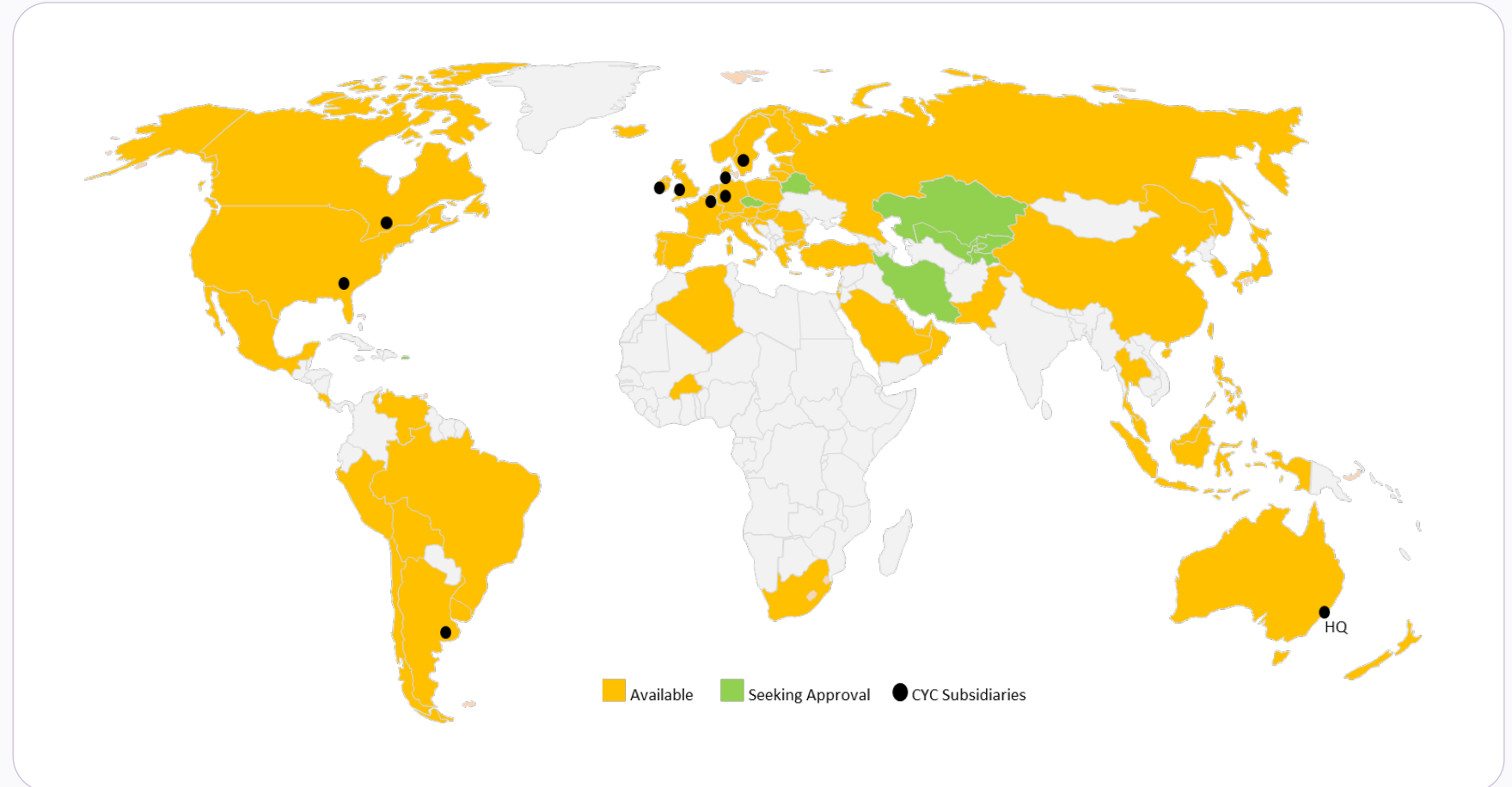
Technegas<sup>®</sup> was introduced clinically **in 1986**



Technegas<sup>®</sup> generators are available in **65 countries** via a combination of direct and distributor sales models



Over **4.8 million** patient procedures to date





# Technegas® Aerosol for Inhalation

Functional Imaging showing where Oxygen is distributed within the lung

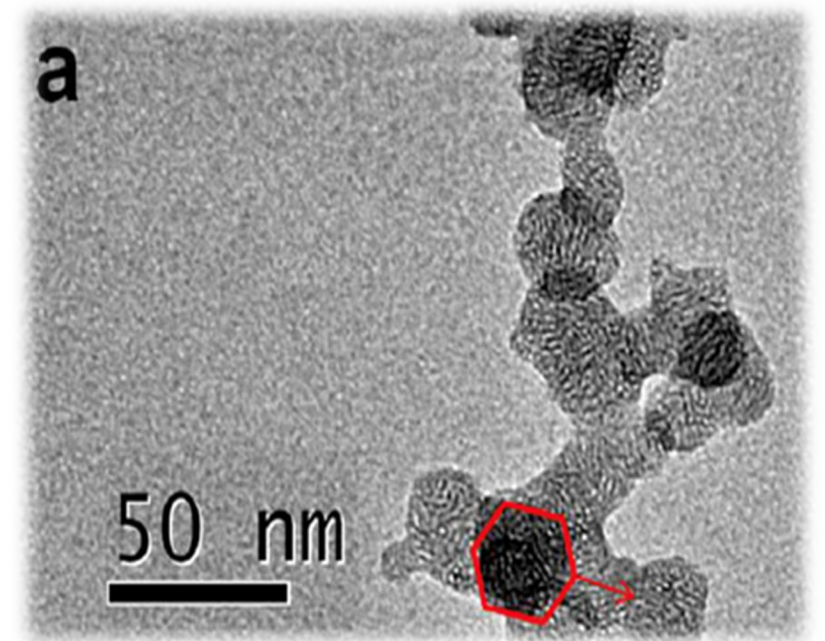
Technegas® is composed of  $^{99m}\text{Tc}$  cores encapsulated within layers of graphite to form individual hexagonal plate-like particles.<sup>1-2</sup>

Technegas is manufactured by heating Technetium-99m in a carbon crucible within an argon environment for a few seconds at 2,750 degrees Celsius.<sup>3</sup>

Its very small particle size allows distribution into the lungs like a gas and deposited in alveoli by diffusion, providing for Planar, SPECT and SPECT/CT ventilation imaging.



Image source:  
Blanc-Béguin et al, 2020



1. Wiebe LI, et al. Current Radiopharmaceuticals 2010; 3(1): 49-59
2. Blanc-Béguin F, et al. Mol Imaging Biol 2020;
3. Lemb M, et al. Eur J Nucl Med 1993; 20(576-579)

# Overview of Technegas®

Unique Drug + Device + Service combination = regulatory barrier to entry

Technegas® comprises the following components

## SYSTEM TECHNEGAS® PLUS SYSTEM



## PER PATIENT CONSUMABLES TECHNEGAS® SYSTEM PACK

Technegas® (Crucible)



Technegas®  
Contacts



Technegas® Patient  
Administration Set  
(PAS)



IN ADDITION TO  
THE SYSTEM PACK  
Nose Clips



## SUPPORT

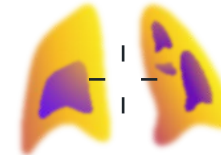
Training



Engineering  
Support



Image  
Analysis



- USFDA Drug-Device Combination product
- Razor - Razorblade Model business model
- Per-patient consumables drive an annuity-like revenue stream
- All Technegas components are manufactured / assembled by Cyclopharm



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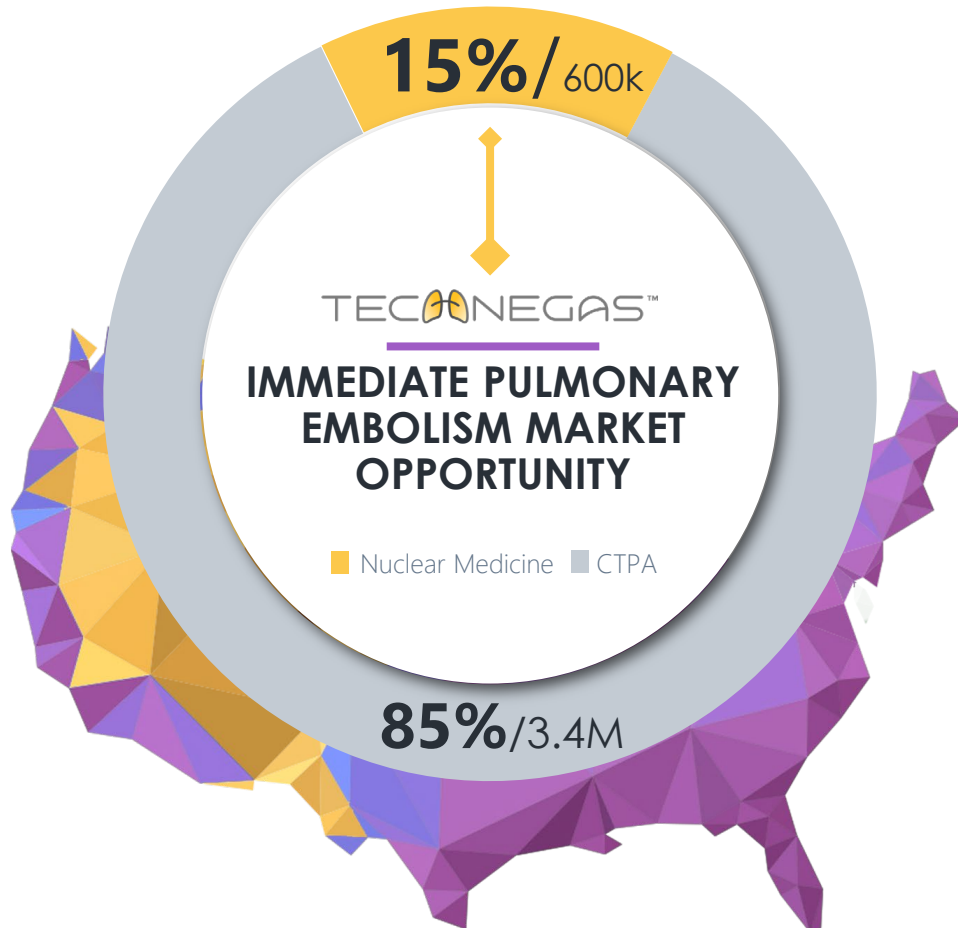
# Technegas USA Opportunity

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# Overview of the US market opportunity

600K Nuclear Medicine Ventilation Procedures p.a. in the USA\* for PE



- 1 Estimated **4,000,000 pulmonary embolism procedures** in the USA p/a (15% Nuclear Medicine / 85% CTPA)
- 2 ~600,000 (15%) Nuclear Medicine procedures represents an initial **US\$90m** addressable market
- 3 Initial target for Technegas® ~**480,000 patient** procedures
- 4 Technegas® expected to **displace Xe133 followed by DTPA** as the standard of care nuclear medicine diagnostic product in the US
- 5 3D SPECT imaging using Technegas® is proven to be **clinically superior and safer than CTPA\*\***
- 6 Cyclopharm's target is to **double the existing nuclear medicine PE market** in the US, which is dominated by CTPA, from **15% to 30%**
- 7 US entry expected to drive our **Beyond PE** strategy to use Technegas® for additional disease states (asthma, long-Covid etc.) which are exponentially larger than the existing markets

\* Revenue and patient volume projections based on internal company analysis

\*\*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) 2.a

# US Economic Model

## Placement Model to Expedite Consumable Demand

- **US\$7k** one-off installation and training fee
- **US\$7k p.a.** technology fee, includes servicing
- **Annuity Revenue**  
Per patient fee for consumables (sold in 50 patient units)
- **US\$70k** revenue per system per annum expected from larger sites<sup>1</sup>
- **>15 yrs** average life per system
- **Targeting 2,000** of the 8,000 US nuclear medicine departments
- **System Placement model** supports rapid uptake by US customers by removing the initial capital outlay to drive implementation of the technology
- Initial focus on **clinical trial** and **high-volume sites** for the greatest clinical impact and greater repeat demand for consumables
- **Modest cost base** for US roll-out - ~US\$6.5m operating costs per annum by 2025
- High consumable annuity gross **margins** expected at **greater than 80%**
- **\$180m USD** market for diagnosing PE. Beyond PE applications to significantly grow the global market

1. Calculation based on expected demand and market price for competing products (e.g. Xe133).

# Broad Indication for use approved by USFDA

Potential applications across the entire field of respiratory medicine

Technegas (kit for the preparation of technetium Tc99m labeled carbon inhalation aerosol) for oral inhalation use – NDA 022335

## -----USFDA APPROVED INDICATIONS AND USAGE-----

TECHNEGAS, when used with sodium pertechnetate Tc 99m in the Technegas Plus System, provides technetium Tc 99m-labeled carbon inhalation aerosol (Technegas Aerosol), a radioactive diagnostic agent for use in adults and pediatric patients aged 6 years and older for:

- visualization of pulmonary ventilation
- evaluation of pulmonary embolism when paired with perfusion imaging

# Beyond PE: Blue Sky





## Indication Expansion – The Importance, Urgency & Opportunity Beyond PE



- 1 Lung Disease in 2019 accounted for **6 million deaths** worldwide (**12%** of all deaths)
- 2 COPD and Lower Respiratory Infections and Lung Cancer will be the **3<sup>rd</sup>, 4<sup>th</sup> and 6<sup>th</sup> largest causes of death** by 2030.
- 3 “Over and underdiagnosis of Lung Disease has a **huge economic impact**. COPD misdiagnosis revealed that the under or over diagnosis and prevalence of this disease was 56.7–81.4% and 29.0–65.0%, respectively leading to **55.4% squandering of treatment costs<sup>2</sup>**”
- 4 Misdiagnosis can be **fatal**
- 5 **Exponential Growth Potential** for Technegas

1. World Health Organisation - The top 10 causes of death 2019 (who.int)

2. Munir, M., Setiawan, H., Awaludin, R. *et al.* Aerosolised micro and nanoparticle: formulation and delivery method for lung imaging. *Clin Transl Imaging* (2022). <https://doi.org/10.1007/s40336-022-00527-3>



# Beyond PE applications

## Already underway

>US\$1.1bn global market size\*



Diagnosis and follow-up of **Pulmonary Embolism**<sup>1</sup> and **Pulmonary Hypertension**<sup>2, 15, 16,18, 22</sup>



Preoperative assessment of homogeneous **Endoscopic Lung Volume Reduction (ELVR)** candidates<sup>3,17,</sup>



Preoperative assessment of **lung resection** candidates with borderline pulmonary reserve<sup>4,5,6,20</sup>



Planning **radiation therapy** to target tumors while preserving functional lung zones<sup>6-7</sup>



Advanced approach to phenotyping **chronic airways diseases such as asthma and COPD** and identifying patient likely to respond to treatment<sup>8-10</sup>



Use of alternate isotopes to make Galligas™ for **PET Molecular Imaging**<sup>14, 15</sup>

\*Including PE applications. On a long-term basis. See Slide 15 'Horizon 3' for further details.

1. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596
2. Ohira H, et al. J Nucl Cardiol 2015;22(1): 141-157
3. Hsu K, et al. J Bronchology Interv Pulmonol 2018; 25(1): 48-53
4. Mortensen J, Berg RMG. Semin Nucl Med 2019; 49(1): 16-21
5. Wechalekar K, et al. Semin Nucl Med 2019; 49(1): 22-30
6. Elojimy S, et al. AJR Am J Roentgenol 2016; 207(6): 1307-1315
7. Eslick EM, et al. Semin Nucl Med 2019; 49(1): 31-36
8. Farrow C, King GG. Semin Nucl Med 2019; 49(1): 11-15
9. Jögi J, et al. Int J Chron Obstruct Pulmon Dis 2014; 10: 25-30
10. Bajc M, et al.. Int J Chron Obstruct Pulm Dis 2017; 12: 1579-1587
11. Verger A, et al. Eur J Nucl Med Mol Imaging 2020; 47(11): 2709-2710
12. Baloul A, et al, Eur J Nuc Med Mol Imaging 2021; 48(8):2525-2530
13. Bajc M, et al. Clin Med Insights 2021; Vol 14 1-4
14. Blanc-Beguín F, et al, Mol Img Bio 2021, 23:62-69
15. Currie G, J Nuc Med Tech 2021; 49:313-319
16. Ozguven, S, et al; Mol Imag Rad Therapy; 2021; 30:28-33
17. Tee, et al; Intrevent Pulmonology; 2021, DOI 10.1159/000515336
18. Le Roux, et al, J Nuc Med July 2022, 63 (7) 1070-1074
19. Berhouse, et al, Respiratory Research 2022; 23: 296
20. Ridiadia, et al, ATS Abstract; doi.org/10.1164/ajrccm-conference.2022.205.1\_MeetingAbstracts.A2554
21. Venegas C, et al, ATS Abstract; doi.org/10.1164/ajrccm-conference.2022.205.1
22. Le Roux, et al; Clinical Nuclear Medicine, 27 Oct 2022; doi: 10.1097/RLU.0000000000004426

# Beyond Pulmonary Embolism CYC Initiatives

7 Cyclopharm sponsored Beyond PE clinical trials – US approval expected to drive clinician led studies

1

**Hunter Medical Research Institute (Newcastle, AU):** Diagnosis and response to therapy in severe asthma and COPD<sup>1</sup>  
100 Patient Study \* 100% Recruited \* **Study Published**<sup>6</sup>, (See following slide)

2

**Woolcock Institute (Sydney, AU):** Diagnosis and response therapy in mild to moderate COPD<sup>3</sup>  
25 Patient / 75 Scan Protocol \* 88% Completed

3

**CHUM (Montreal, CA):** Early detection of COPD in asymptomatic smokers<sup>4</sup>  
30 Patient Study \* 100% Recruited \* Analysis complete \* Paper submitted for publication

4

**Dalhousie (Halifax, CA):** Post-lung transplant patients  
30 Patient Study \* 30% Recruited

5

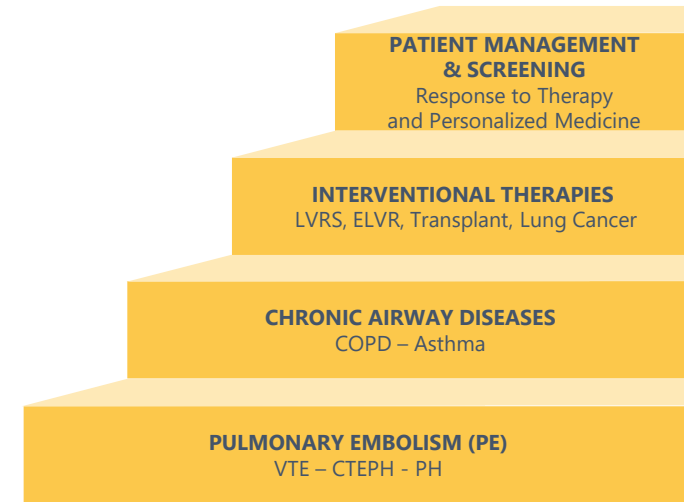
**McMaster University Firestone Institute (Hamilton, CA):** Ventilation in lung cancer patients pre and post lung resection<sup>2</sup>; 100% Recruited \* **Study Published** bridging research initiatives with clinical applications using Technegas .

6

**McMaster University Firestone Institute (Hamilton, CA):** COVID-19 Related Lung Ventilation and Perfusion Injury<sup>5</sup>  
100% Recruited \* Abstract presented at the American Thoracic Society May 2023 with paper to follow.

7

**PRONOSPECT (France):** 665 Patient multicentre trial designed to Predict the Risk of Venous Thromboembolism (VTE) Recurrence in Patients With Pulmonary Embolism (PE). Patients will be imaged with nuclear medicine regardless if initially diagnosed with CTPA or nuclear medicine<sup>8</sup>. Recruitment commenced.



1. ACTRN12617001275358 - Can functional lung ventilation imaging identify treatable traits in obstructive airway disease?  
2. <https://clinicaltrials.gov/ct2/show/NCT04191174?term=technegas&draw=2&rank=3>  
3. [http://investor.cyclopharm.com/site/PDF/1561\\_0/BetterDefiningAirwaysDiseaseWithTechnegas](http://investor.cyclopharm.com/site/PDF/1561_0/BetterDefiningAirwaysDiseaseWithTechnegas)  
4. <https://ichgcp.net/clinical-trials-registry/NCT03728712>

5. <https://clinicaltrials.gov/ct2/show/NCT04549636>  
6. <https://pubmed.ncbi.nlm.nih.gov/38151119/>  
7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10206636/>  
8. <https://classic.clinicaltrials.gov/ct2/show/NCT06372730>



# “Ventilation Heterogeneity Is a Treatable Trait in Severe Asthma<sup>1</sup>”

1. Gibson PG, et al. Ventilation Heterogeneity Is a Treatable Trait in Severe Asthma. J Allergy Clin Immunol Pract. 2024 Apr;12(4):929-935.e4. doi: 10.1016/j.jaip.2023.12.030. Epub 2023 Dec 25. PMID: 38151119
2. <https://www.newcastle.edu.au/newsroom/featured/new-use-for-a-lung-scanning-test-to-benefit-severe-asthma-patients>

“Because of its sensitivity in the ‘silent zone’ of the lung – the notoriously difficult to see small airways that are 2mm – 4mm in diameter – **this test helps us see if the drugs we are giving patients for severe asthma are working.**”

“There are four different types of drugs given to severe asthma sufferers so this will help **ensure patients are being prescribed the correct drug.**”

The (Technegas) imaging procedure is “safe, fast and cost-effective way of ensuring **personalised treatments** were working.”

“Previously, we have had to rely on symptoms surveys from patients. This test provides very accurate, **objective and detailed information** to support patient accounts of their symptoms.”

**Professor Peter Gibson<sup>2</sup>**

Technegas - Applications in Patient Management and Response to Therapy



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# Understanding the Opportunity

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# Total value creation opportunity

Exponential Growth Opportunity Over The Next Decade

## Pulmonary Embolism:

	Timeline	USA PE Market Share	Market size
1 <b>Horizon 1</b> – Full displacement of existing nuclear medicine tests for PE	0 - 5 years	15%	US\$90m
2 <b>Horizon 2</b> – Commence converting CTPA exams to Technegas	0 - 8 years	30%	US\$180m*

## Beyond Pulmonary Embolism:

	Timeline Global	Market size
3 <b>Horizon 3</b> – Expanding Beyond PE Globally into new indications such as asthma and chronic obstructive pulmonary disease	> 8 years	US\$900m
<b>Total long term revenue opportunity</b>		<b>&gt;US\$1.1bn</b>

\*Assumes Combined Nuclear Medicine and CTPA Market



# WHAT THE GUIDELINES SAY ABOUT TECHNEGAS® :



Endorsed by the guidelines from the European<sup>1-2</sup> and the Canadian<sup>3</sup> Associations of Nuclear Medicine (EANM & CANM)

1. Bajc M, et al. Eur J Nucl Med Mol Imaging 2019; [Epub ahead of print]: <https://link.springer.com/content/pdf/10.1007%2Fs00259-019-04450-0.pdf>
2. Bajc M, et al. Eur J Nucl Med Mol Imaging 2009; 36(8): 1356-70; [https://eanm.org/publications/guidelines/gl\\_pulm\\_embolism\\_part1.pdf](https://eanm.org/publications/guidelines/gl_pulm_embolism_part1.pdf)
3. Leblanc M, et al. CANM 2018; [https://canm-acmn.ca/resources/Documents/Guidelines\\_Resource/MasterDocument\\_Final\\_Nov\\_21\\_incl-Exec-Sum\\_ver3\\_Dec.%202012\\_.pdf](https://canm-acmn.ca/resources/Documents/Guidelines_Resource/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%202012_.pdf) 2.a

“ Using 99m-Tc-Technegas is according to clinical experience **better than the best aerosols** ”

“ Technegas® **facilitates interpretation**, particularly in 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 ”

Technegas is the nuclear medicine agent of choice in established markets

# Compelling US Clinical Support

## SNMMI Technegas Press Release – USA Catching up with the R.O.W.

### FDA Approves Widely Used Imaging Agent for Respiratory Disease

September 29, 2023

**Reston, VA**—The U.S. Food and Drug Administration (FDA) has approved the imaging agent Technegas for use in ventilation–perfusion studies to diagnose pulmonary embolism and other respiratory pathologies. A carbon-based nanoparticle developed in Australia nearly 40 years ago, Technegas has been recognized as a standard for ventilation studies and is widely used in clinics around the world.

Benefits of Technegas include high diagnostic accuracy, low radiation burden to patients, and easy administration. It offers advantages for scanning of COVID-19 patients, as the procedure is quick and the apparatus is single use, without recirculation. In 2021, SNMMI urged FDA to begin a fast-track review of the agent.

“We applaud the FDA for the long-awaited approval of Technegas,” said SNMMI president Helen Nadel, MD, FRCPC, FSNMMI. “Technegas will offer advantages in diagnostic accuracy, workflow, and patient comfort for departments that adopt the technology and will have a large impact on those undergoing imaging for pulmonary disease.”

Pulmonary embolism affects approximately 900,000 Americans per year, and more than 34 million Americans live with chronic lung disease, according to the American Lung Association.

Technegas is manufactured by Cyclomedica and is currently distributed to 54 countries worldwide.

- “Recognised standard for ventilation studies”
- “Diagnostic Accuracy”
- “Improved workflow”
- “Patient Comfort”
- “Large impact on those undergoing imaging for pulmonary disease”



# Technegas Launch

SNMMI –Annual Conference

**8-11 June 2024**



A Great Week for CYC!

- **First annual** conference since USFDA approval
- **US Reimbursement Announced** triggering further implementations
- **SNMMI Sponsored Session:** *“Lung Scintigraphy in the Current Era”*
- **Technegas Symposium:** *“Nuclear Pulmonology. Technegas Here Now and the Future”*

# CYCLOPHARM INVESTMENT CASE



## Profitable and Growing MedTech

Underlying business (ex-USA) is cash positive



## First in Class

Established Gold Standard

Proprietary product sales to 65 countries with over 4.8 million patient procedures to date

Clinical Agent of Choice referenced by name in multiple clinical guidelines



## USFDA Approval Granted

Set to quadruple the size of the existing PE business, based on significant existing demand

Further leverage penetration into the CTPA market

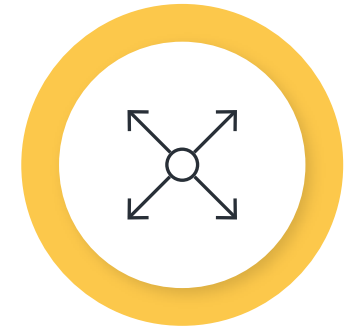
Reimbursement Granted from 1 July 2024



## Recurring Revenue

From single patient consumables

Similar to an annuity model



## Technegas Product expansion

Indications Beyond PE into chronic respiratory disease management in large markets such as asthma, COPD and lung cancer could deliver exponential growth

Market Development already underway



# Questions







# Presentation Attachments

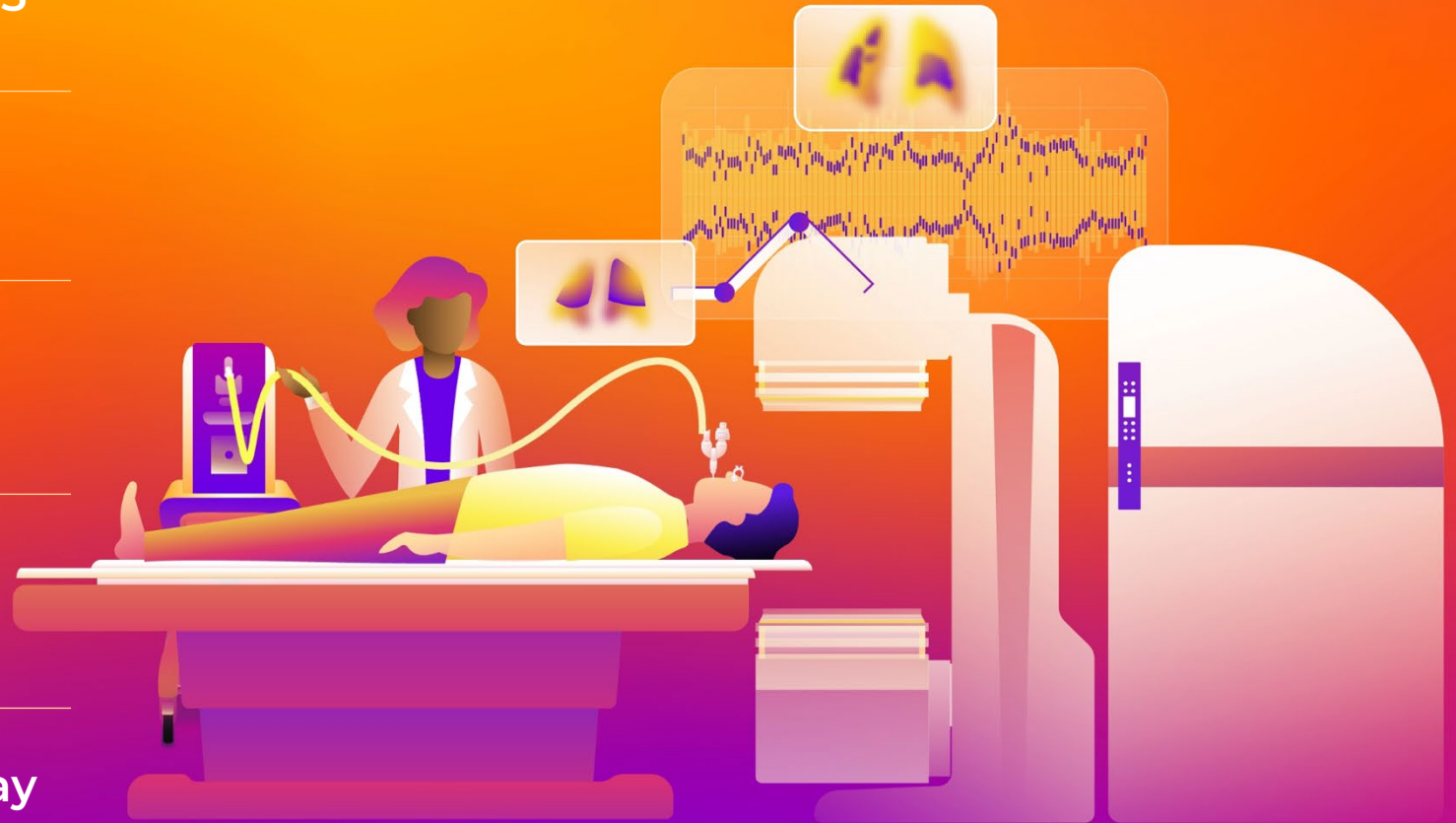
01 Cyclopharm Financials – FY 2023

02 Canada Case Study

03 USA Pipeline

04 Competitive Product Comparison

05 USA Commercialisation Pathway



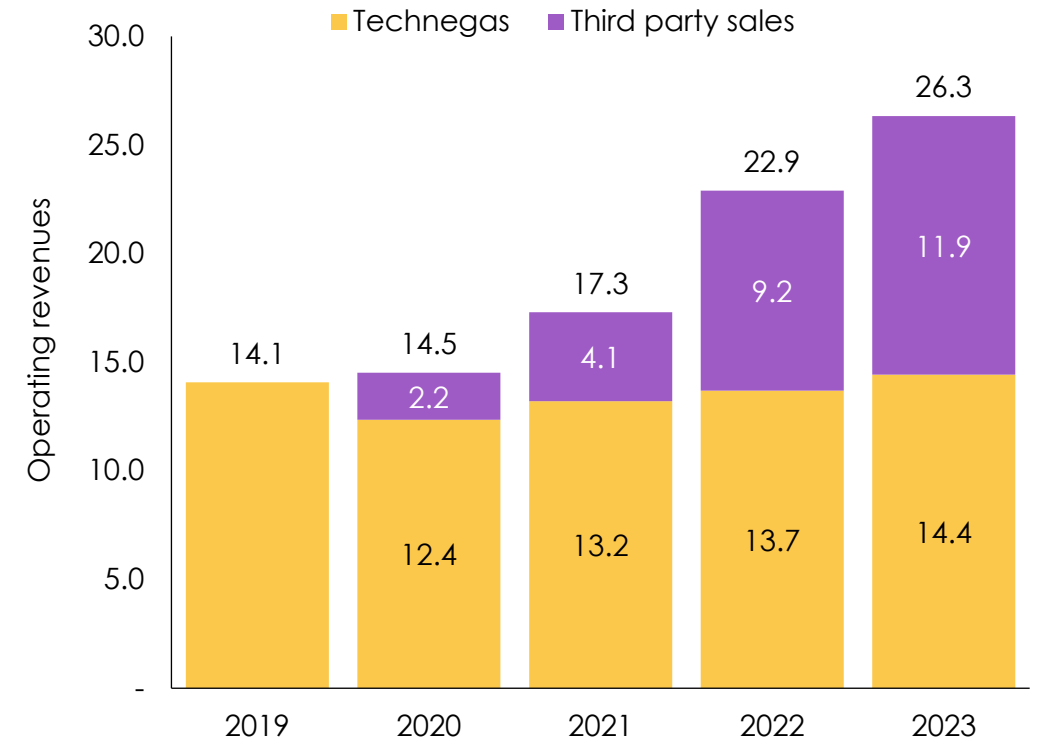
# 2023 Trading Highlights and Underlying Business

An established global nuclear medicine company

## Cyclopharm 2023 Trading Highlights

<b>Technegas</b>	Sales increased 5.6% to \$14.4m
<b>Third Party Distribution</b>	\$11.9m of third-party distribution revenue, an increase of 29.3%
<b>Regulatory Renewals</b>	All regulatory renewals in existing 64 country markets maintained
<b>Indication Expansion</b>	Continued progress in developing 'Beyond PE' clinical applications providing significant, long-term growth opportunities for Technegas
<b>USFDA</b>	Approval received on 29 September 2023

## Cyclopharm operating revenues over time





# 2023 Financial Highlights

Sales Revenue	\$26.34 million - an increase of 15.1%
Third Party Distribution	\$11.91 million of third-party distribution revenue, an increase of 29.3%
Net Loss After Tax	\$4.70 million loss including US-FDA related expenses
USFDA Expenses	\$3.49 million
Reversal of impairment	\$3.16 million reversal of impairment to the cyclotron facility
Dividends	FY23 total dividends at 0.5 cps, no final dividend declared
Balance Sheet	\$11.73 million of cash reserves as @ 31 December 2023

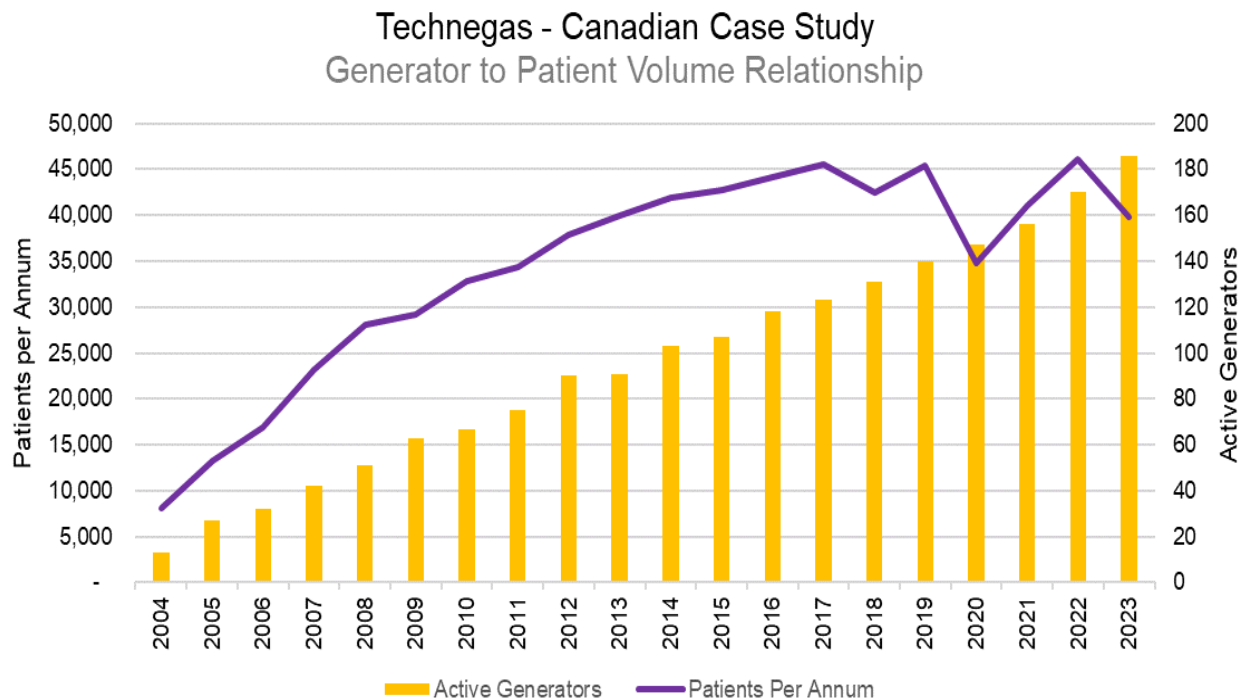


# 2023 Operating Highlights

Technegas	Sales increased 5.6% to \$14.43 m
Third Party Distribution	\$11.91 million of third-party distribution revenue, , an increase of 29.3%
Regulatory Renewals	All regulatory renewals in existing 64 country markets maintained
Indication Expansion	Continued progress in developing 'Beyond PE' clinical applications providing significant, long-term growth opportunities for Technegas
USFDA	Approval received on 29 September 2023

# Track Record - Rapid adoption of Technegas®

## The Canadian Case Study - a strong indicator of USA acceptance



1

Canada is Cyclopharm's largest single country market to date

2

Technegas® is market leader for diagnosing PE and is nearing 100% nuclear medicine market share

3

Xe-133 rapidly displaced by early adopters

4

Close correlation with the number of active generators and annual consumable sales

5

Market launch initiated province by province, leveraging off pilot sites

6

Patient volumes continue to recover post COVID (to include temporary gains in 2022 from the global CT contrast media shortage) with further conversion of additional lower volume sites in 2023



# US Customer Demand Established

136 Proposals and Contracts representing over 400+ locations as @ 6 May 2024

1

**Over 420 expressions of interest already received**

2

**6 Technegas systems have been installed and are delivering Revenue; 6 further sites under contract**

3

**Additional 40 sites linked to the first 12 locations under contract**

4

**Strong pipeline of further rollout opportunities with 136 Proposals and Contracts issued**

- 10 contracts in review stage: 15 installations with potential for a further 23 linked sites
- 6 contracts in committee stage: 9 initial installations with potential 28 additional sites
- 103 Issued proposals: contracts in early discussions connected to ~ 50 additional affiliated sites
- 15 proposals provided to the Veterans Administration Healthcare and Military Hospital Systems
- 18 other opportunities pending outcome of Pass-Through Status from CMS: 22 locations

4

**Pass-Through decision received will allow Technegas to be fully reimbursed**

5

**Targeting over 300 generators placed by 31 December 2025**

**US Pass-Through  
Approval To Trigger  
accelerated uptake**

# Nuclear Ventilation Imaging Agent Comparison

## Technegas®



Easy



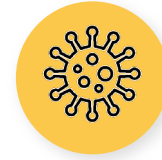
3 to 4 breaths



3D images



No contraindications



Covid-19

## Xenon - 133



**True radioactive gas** inhaled with **full face mask**



**No 3D images limited to planar imaging** resulting in lower sensitivity & specificity



**Constant inhale-exhale breathing for 15 mins** increasing the risk of **COVID-19 exposure**



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

## DTPA Tc99m



### Wet Aerosol

**impacts efficacy, bronchospasm, COVID-19 concerns**



### Creates hotspots

in presence of small airways lung diseases, a frequent comorbidity in PE, & impacts clinical interpretations

# Diagnosing Pulmonary Embolism with V/Q SPECT vs CTPA

Technegas is the “V” in “V/Q”

V/Q COMPARED TO CTPA:

**Primary imaging procedure**

when PE is suspected<sup>1</sup>

**Excellent diagnostic performance<sup>2</sup>**

Sensitivity 93.0%  
Specificity 93.3%  
NPV 96.1%

**Detects PE**  
at subsegmental level<sup>3</sup>

**Minimally invasive**  
Aids patient comfort and compliance<sup>4</sup>, even in COPD patients<sup>5</sup>

**Less radiation burden**

V/Q SPECT delivers 27 times less radiation to the breast as compared to CTPA<sup>6</sup>

**Minimal exclusion criteria**

V/Q SPECT can be performed in case of pregnancy<sup>6-7</sup>, renal impairment<sup>8</sup>, contrast media allergy<sup>8</sup> and diabetes<sup>3</sup>

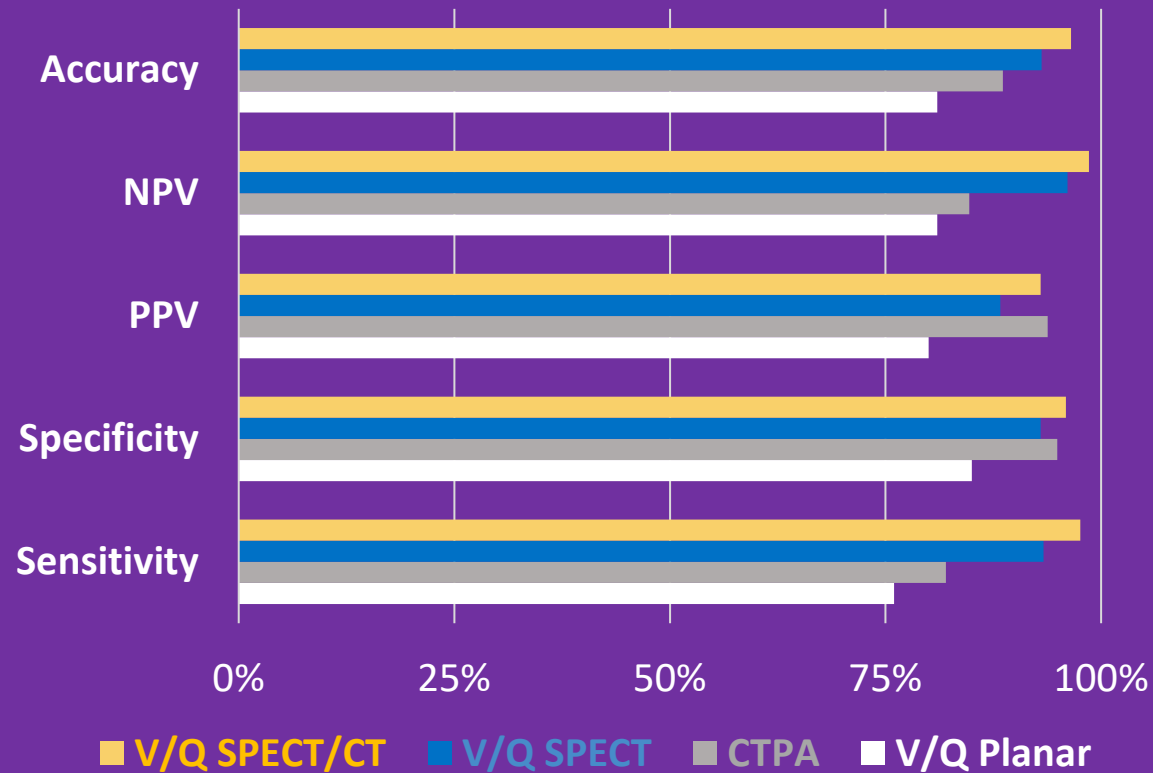
**Higher clinical sensitivity**

V/Q SPECT has a higher sensitivity to diagnose PE compared to CTPA (93% vs 82% respectively)<sup>2</sup>.

1. Waxman AD, et al. J Nucl Med 2017; 58: 13N-15N  
2. Hess S, et al. Semin Thromb Hemost 2016; 42(8): 833-845  
3. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596  
4. Sánchez-Crespo A, et al. Nucl Med Commun 2008; 29(2): 173-177

5. Nasr A, et al. ECPRM 2017; 4(3): 85-91  
6. Isidoro J, et al. Phys Med 2017; 41: 93-96  
7. Bajc et al. Eur J Nucl Mol Imaging 2015; 42: 1325-1330  
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# Diagnosing Pulmonary Embolism: V/Q SPECT +/- CT vs CTPA



V/Q SPECT and V/Q SPECT/CT have shown that V/Q SPECT/CT is **superior** in most clinical settings with better overall diagnostic performance<sup>1</sup>.

In situation of acute PE, chronic PE pregnancy, paediatrics and the COPD population, V/Q SPECT, with or without low-dose CT, can be considered as a first-line investigation to detect PE<sup>3</sup> due to:



Its higher accuracy, sensitivity and negative predictive value when compared to CTPA<sup>3</sup>



Its low radiation and no adverse reactions<sup>3</sup>

**Table:** Diagnostic ability of V/Q SPECT/CT<sup>1</sup>, V/Q SPECT<sup>1</sup>, CTPA<sup>1</sup> and V/Q Planar<sup>2</sup> to detect PE (adapted from Hess and al, 2016<sup>1</sup> and from Reinartz et al, 2004<sup>2</sup>)

1. Hess S, et al. Semin Thromb Hemost 2016; 42(8): 833-845  
 2. Reinartz P, et al. J Nucl Med 2004; 45: 1501-1508

3. Leblanc M, et al. CANM guidelines; Nov 2018: [www.canm-acmn.ca/guidelines](http://www.canm-acmn.ca/guidelines)

# USA COMMERCIALISATION PATHWAY

## Clinical

- ✓ Key Opinion Leaders engaged
- ✓ Medical Affairs Director Recruited
- ✓ Clinical Affairs Director Recruited
- Recruit Chief Medical Officer 2025.
- ✓ R&D Programs Beyond PE Underway



## Regulatory

- ✓ Australian Site Manufacturing Approved
- ✓ USFDA Approval Granted
- ✓ State Pharmaceutical Wholesale Licenses being Granted
- ✓ US Regulatory support in place



## Commercial

- ✓ Customer Success Roles Filled
- Scaling up to match inflow opportunities to include BDM roles



## 3PL

- ✓ 3PL Service Under Contract



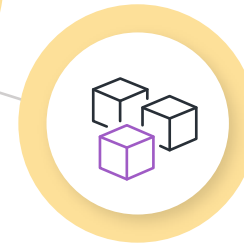
## Operations

- ✓ Outsourced back office provider Contracted.



## Inventory Build

- ✓ Stock is building in the USA
- ✓ Sydney manufacturing facility expanded- capacity is future-proofed



## Education

- ✓ Application Specialists hired
- ✓ Utilising Coverage from established markets
- ✓ Suite of educational materials Developed



## Service

- ✓ National network service provider Contracted
- ✓ CYC Employee Hired

