



# CYCLOPHARM

**2022**

**Bell Potter Healthcare Conference**

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9 November 2022



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

# A World Leading Diagnostic Imaging Company

1

Recovery in FY 2021 from initial COVID-19 impact in primary country markets with record sales of \$17.7m. Recovery continues in 1H 2022 with record \$7.7 million revenue from Technegas™ products – 21% up from 1H2021, 19% above 1H2019 (pre-COVID19)

2

Continued profitability and positive cash flow from sales of Technegas across 64 countries with additional revenues growing from third party distribution

3

Progress towards USA market entry –Type B Meeting held Jan 2022. Targeting mid-2023 for USFDA approval

4

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

5

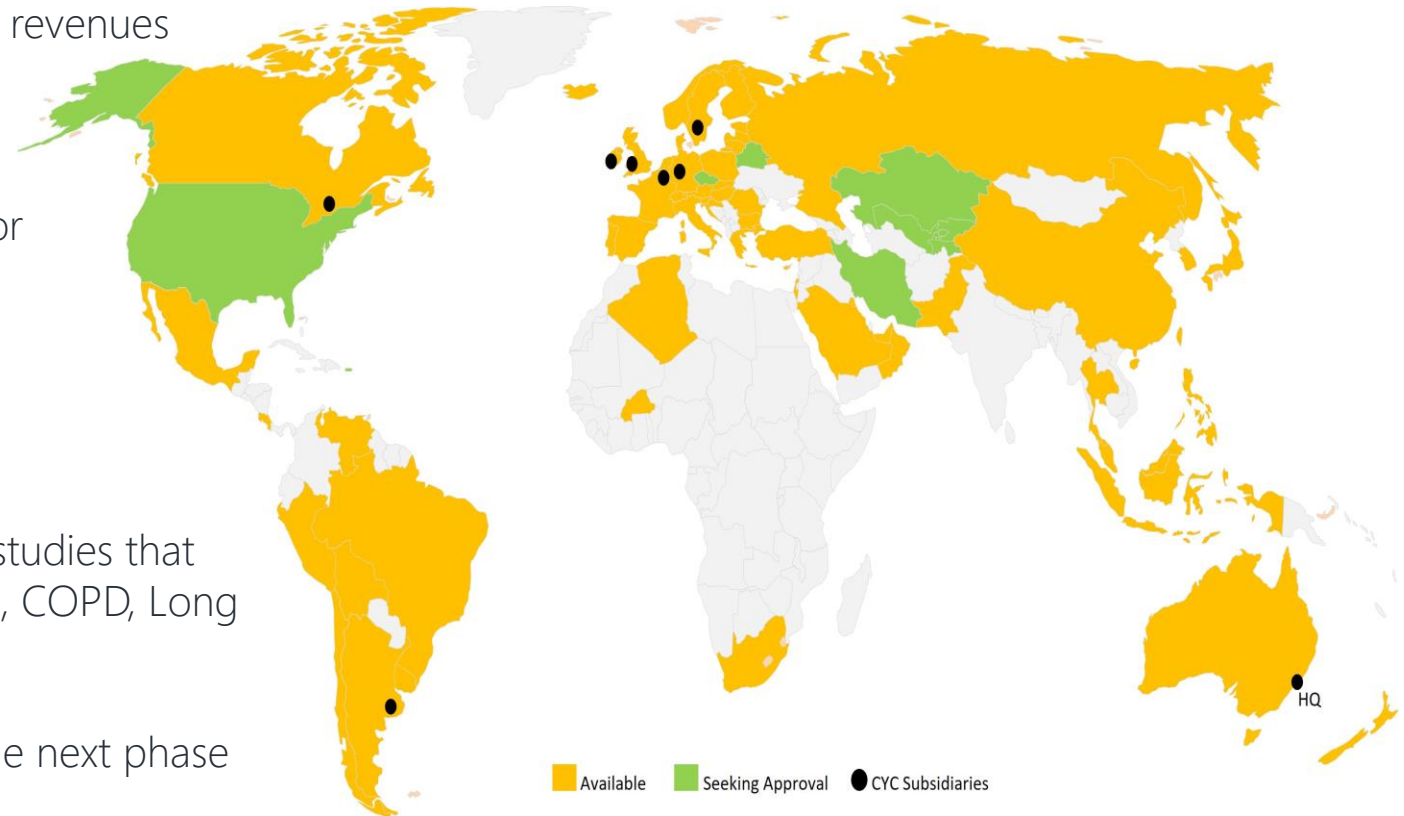
Journal publication highlighting “Beyond PE” studies that expand clinical applications to include asthma, COPD, Long COVID.....

6

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

7

Strong Balance Sheet to fully fund growth strategy - \$26 m net cash as at 30 June 2022

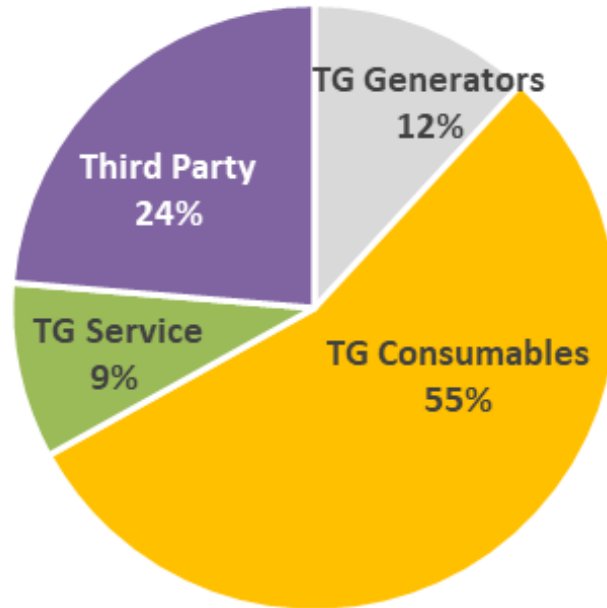


# FOUNDATIONS IN PLACE



Technegas<sup>®</sup> is a global market leader with significant near-term growth potential in the **USA market & Beyond PE**

2021 Revenue Composition



- Total global sales of over **\$93.1m AUD** from 2015 to 2021 (\$17.7 in FY 2021)
- Technegas<sup>®</sup> currently available in over **64 countries**
- Over **4,600,000** patient procedures performed since first approved
- **1,600** Technegas<sup>®</sup> generators sold globally since first approved
- **Europe represents 66%** of global revenue in 2021
- **Canada was the largest single country** market by volume followed closely by France
- CYC's underlying business is **profitable**, and the company has a history of paying **dividends**.
- Stable gross margins of greater than **72%** in 2021 - (76% in 2020)
- Over 70% of historical revenue is **recurring consumable sales** - (73% in 2020)
- ROW Revenues (ex USA) gradually returning to pre-COVID19 levels
- Significant **COVID-19 tailwind** resulting from safety concerns that exist with competitive nuclear medicine products...
- Generator **placement rollout strategy** to be deployed for rapid USA market penetration and USFDA compliance
- **Significant immediate USA demand**





# USFDA UPDATE

**Progress Towards Approval  
Mid 2023 with Significant  
Commercialisation Progress  
Achieved**

1

Pre-Approval Inspection (PAI) conducted 30 March to 7 April 2021

- Inspection based on Drug-Device **Combination Product**
- Currently providing USFDA updates **every 60 Days**
- Documentation Development and Revisions related to PAI are largely finalised
- **Facility Modifications** – Workflow and HVAC Upgrade Completed to ISO 8 Standards
- In process **data capture** of legacy equipment Completed

2

Complete Response Letter (CRL) Received 26 June 2021

- Engaged additional resources for product characterisation study
- Some activity **cross-over** from the pre-approval inspection
- Additional Technegas **product characterisation** required by the FDA currently underway in both the USA and Australia. Current shortage of Tc99m is causing a short term delay in finalisation.

3

USFDA Type B Meeting Held 27 January 2022

- 2 – Hour Meeting Granted over a 3-hour period
- Clarification received on outstanding elements related to the CRL
- Most activities were required to be progressed sequentially

4

USA Commercialisation Readiness Continues

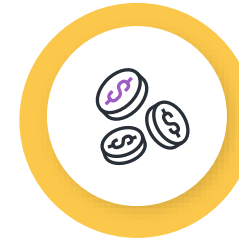
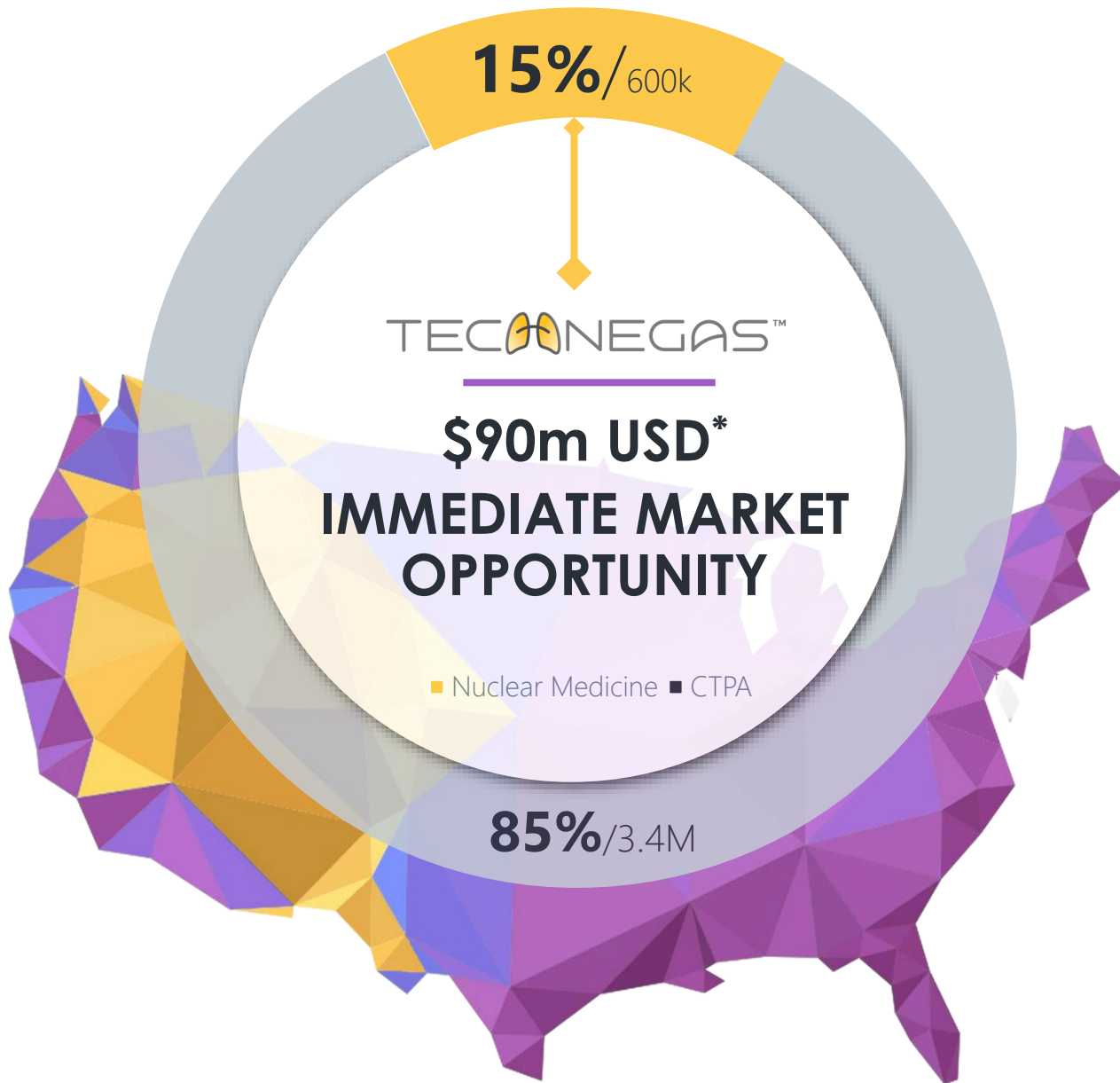
- Targeting Mid 2023 for USFDA Approval
- Training of USA service personnel underway
- Inventory Build of 200 Generators for USA Launch in process



# USA UPDATE Building The Fleet

200 Technegas Generators  
Being Built for Market  
Launch





## 600K Nuclear Medicine Ventilation Procedures p.a.

- The Company estimates 4,000,000 patient procedures are conducted in the USA per annum to diagnose pulmonary embolism (15% Nuclear Medicine – 85% CTPA)
- ~600,000 Nuclear Medicine Ventilation pre-COVID procedures equals \$90m USD
- Target market for Technegas® in the USA equates to ~480,000 patient procedures of the total 600,000 procedures.
- The USA represents the single largest market for Technegas® with half of the world's nuclear medicine departments
- Subject to a successful FDA approval, the Company is targeting US commercialisation in mid 2023
- First priority following USFDA approval is to repeat our Canadian experience by first displacing Xe133 followed by DTPA as the standard of care nuclear medicine diagnostic product
- 3D SPECT imaging using Technegas® is proven to be clinically superior and safer than CTPA<sup>1</sup>. Once commercialised Cyclopharm will target to double the existing nuclear medicine PE market dominated by CTPA from 15% to 30%.
- In addition to seeking USFDA approval the company will continue to expand the use of Technegas® into disease states exponentially larger than the existing markets **Beyond PE**

\* 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.%202012\\_.pdf](https://canm-acmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%202012_.pdf)

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# USA Demand Established

## The Wait Is Nearly Over

1 9 sites in the US already have practical experience from recent clinical trials

2 Multiple letters from leading clinicians, front-line workers and the SNMMI have petitioned the USFDA for the approval of Technegas™. \*Clinical Nuclear Medicine journal article published 27 Oct 2022 states Technegas "is an excellent imaging option for assessing pulmonary airways and offers unique advantages during the COVID-19 pandemic" and "once approved in the USA is likely to cause a shift (clinical shift) to SPECT".

Demand already established in the US from:

- 3
- ✓ Extensive body of clinical evidence underscoring clinical superiority
  - ✓ Real World Evidence in over 64 countries
  - ✓ Well known and established technology globally with significant support of KOL's
  - ✓ COVID-19 safe as compared to competing nuclear medicine products
  - ✓ 420 Expressions of interest registered to date by prospective customers

4 US based sales, technical training and accounts team <10 FTE's in the first year

5 Unlike most newly approved medical devices, our focus will be on installation and training staff, as opposed to a large sales team due to inbound demand

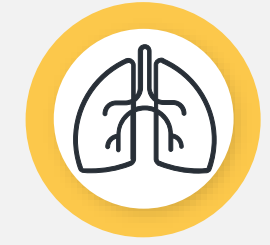
6 Distribution, Installation and service to predominantly to be outsourced – keep fixed cost base low, can scale up or down easily

7 Reimbursement is already established – reimbursement framework is based on procedure codes





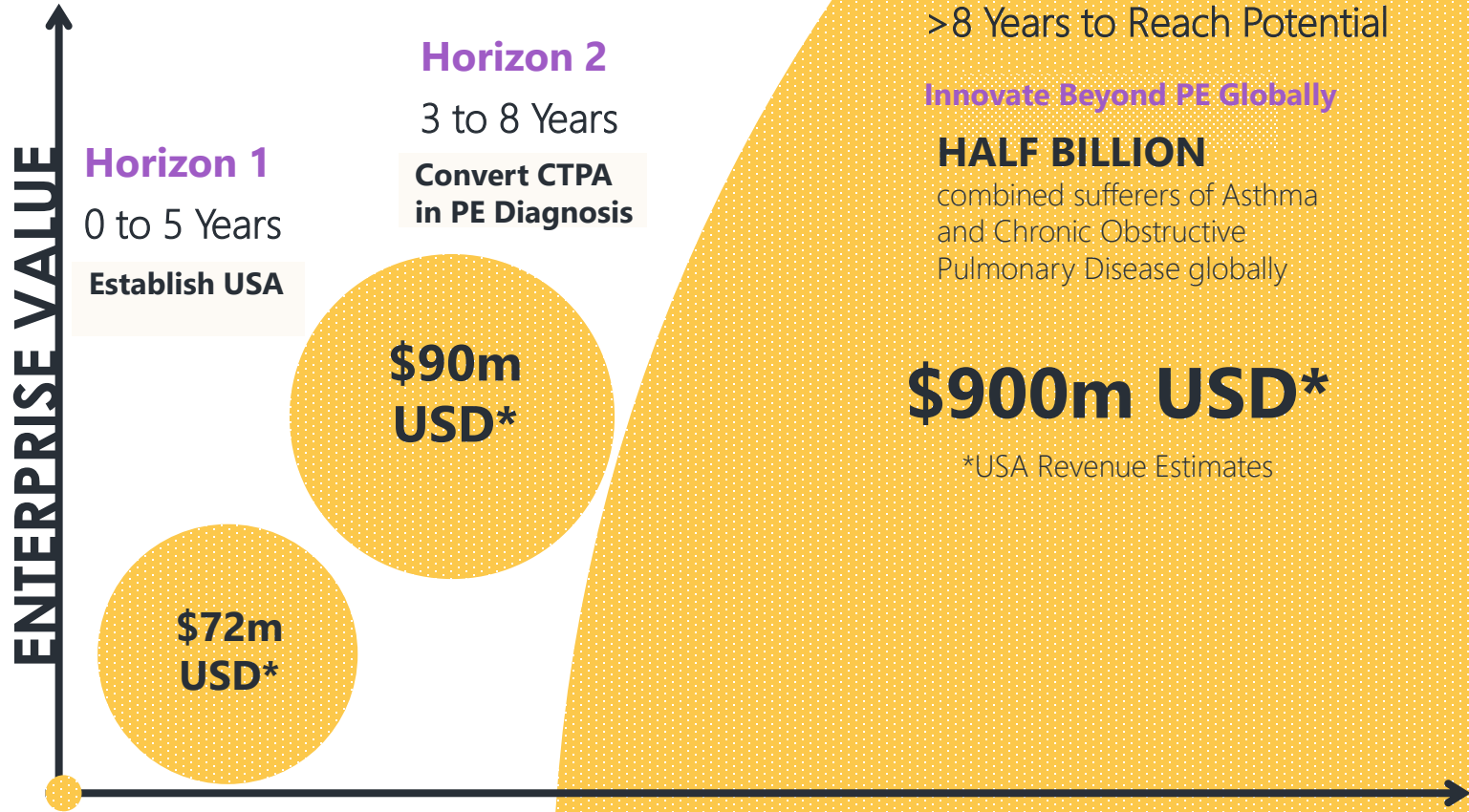
## Indication Expansion – The Importance, Urgency & Opportunity Beyond PE



- 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>

# THREE VALUE HORIZONS

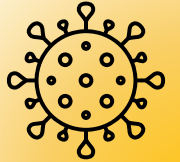


## THE FUTURE IS NOW

- 1 Clinical trial program – commenced 2016
- 2 KOL Engagement – detailing directly to Australian Respiratory Physicians
- 3 Infrastructure Development – 7 Offices directly servicing 17 out of the 64 countries globally where Technegas is available
- 4 Global Installed Footprint to leverage Growth Objectives

\*Revenue projections based on internal company analysis

# Beyond PE applications of V/Q SPECT(/CT)



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>

Diagnosis and monitoring of **COVID-19** patients<sup>11, 12,18,19,21,22</sup>

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. Elojeimy 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 el, 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 Initiatives Underway

6 Cyclopharm sponsored Beyond PE clinical trials

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 \* Imaging Analysis Underway \* Case Study Published,

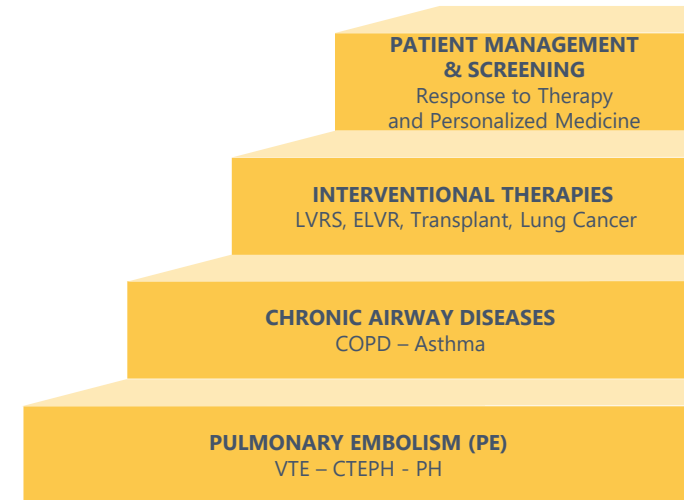
2 **Woolcock Institute (Sydney, AU):** Diagnosis and response therapy in mild to moderate COPD<sup>3</sup>  
25 Patient / 75 Scan Protocol \* 61% Completed

3 **CHUM (Montreal, CA):** Early detection of COPD in asymptomatic smokers<sup>4</sup>  
30 Patient Study \* 100% Recruited \* Analysis complete \* First Draft Underway

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

5 **McMaster University Firestone Institute (Hamilton, CA):** Ventilation in lung cancer patients pre and post lung resection<sup>2</sup>  
50 Patients (100 scans) 100% Recruited \* Abstract presented at American Thoracic Society May 2022 Preliminary Paper approved by the Canadian Journal of Respiratory with publication pending

6 **McMaster University Firestone Institute (Hamilton, CA):** COVID-19 Related Lung Ventilation and Perfusion Injury<sup>5</sup>  
42 (84 scans) 85% Recruited \* Abstract presented at the American Thoracic Society May 2022







# Cyclopharm Board of Directors



David Heaney  
Chairman



James McBryer  
Managing Director & CEO



Dianne Angus  
Director



Kevin Barrow  
Director



Professor Greg King  
Director



## KEY Catalysts for the Next 2 Years



- 1 FDA approval for Technegas expected mid 2023
- 2 First sales in US announce (shortly after approval)
- 3 Ongoing updates on No. Generators placed in US
- 4 Clinical proof of concept & validation in new substantive respiratory indications

# CYCLOPHARM INVESTMENT CASE

TEC  NEGAS™



## Profitable and Growing MedTech

Underlying business is cash positive and issuing dividends



## First in Class

Established Gold Standard  
Proprietary product sales to 64 countries with over 4.6 million patient procedures to date

Clinical Agent of Choice referenced by name in multiple clinical guidelines



## Recurring Revenue

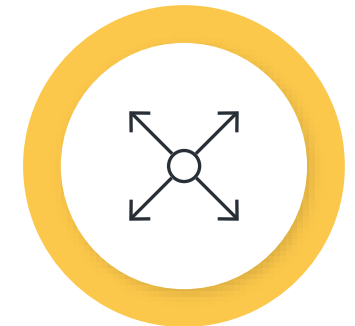
From single patient consumables  
Similar to an annuity model



## USFDA Approval

Set to quadruple the size of the existing PE business, based on significant existing demand with a COVID-19 as an accelerator.

Further leverage penetration into the CTPA market



## Technegas Product expansion

Indications beyond PE into chronic respiratory disease management could deliver exponential growth. Market Development already underway!

# In Closing Today:

Professor Greg King  
MB ChB FRACP PhD  
Cyclopharm Director

Appointed 27 September 2022



<https://youtu.be/m9iEajOEkos>







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**THANK YOU**





# 1H 2022 Highlights

<b>Covid Recovery</b>	Record \$7.7 million revenue from Technegas™ products – 21% up from 1H2021, 19% above 1H2019 (pre-COVID19)
<b>USFDA</b>	Significant investment in facilities, processes in response to CRL & Inspection
<b>US Launch</b>	Investing to build inventory reserves
<b>Market Expansion</b>	Technegas now supplied to 64 countries.
<b>Beyond PE</b>	Progressed trials for new clinical applications providing long term growth opportunities
<b>Revenues 1H 2022</b>	Record Group revenue of \$11.4 million, up 35%, improved sales revenue recorded over all product lines, 76% higher than 2019 (pre-COVID19)
<b>Focus on People and Culture</b>	Several new hires and key personnel along with CYC Board addition: Mr Kevin Barrow and Professor Greg King