



# CYCLOPHARM

## Investor Update

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26 September 2023



# SAFE HARBOUR STATEMENT

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The presentation includes certain statements, estimates and projections with respect to the anticipated future financial performance of Cyclopharm Limited and as to the markets for the company's products. Such statements, estimates and projections reflect various assumptions made by the directors concerning anticipated results, which assumptions may or may not prove to be correct. Cyclopharm Limited has not sought independent verification of information in this presentation.

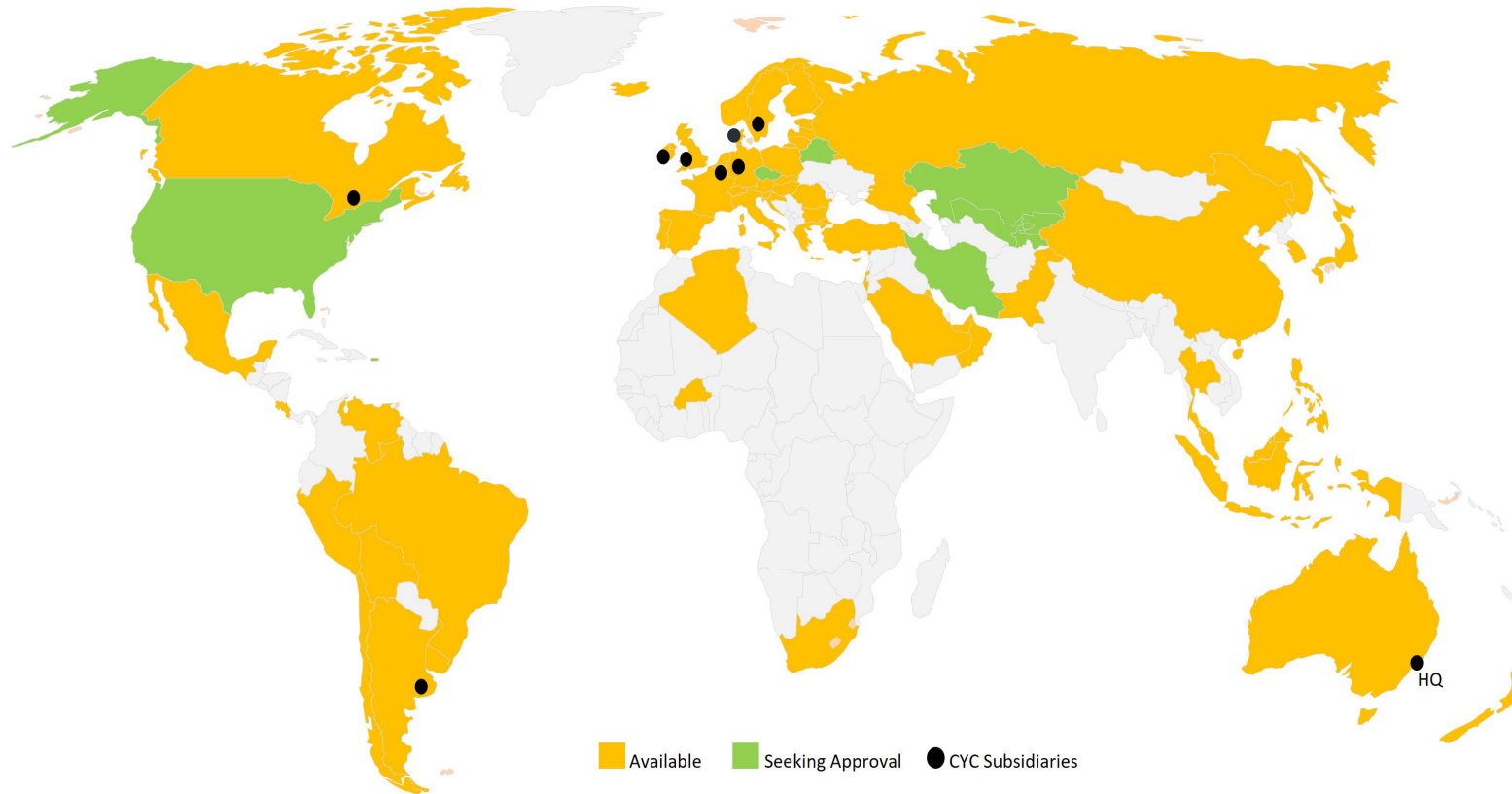
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All references to dollars unless otherwise specified are to Australian dollars.

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

# TECHNEGAS® AROUND THE WORLD



Technegas® was introduced to the medical community **in 1986**



Technegas® revenues are generated in **64 countries** via a combination of direct and distributor sales models



Over **4.7 million** patient procedures to date

# A World Leading Diagnostic Imaging Company

1

Recovery in FY 2022 continued from initial COVID-19 impact in primary country markets with record sales of **\$23.2m.** (Technegas sales \$13.66m up 4.1% - Third-party sales \$9.22 up 124% compared to 2021)

2

Continued underlying 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 – CRL Reply submitted 30 March 2023 triggering six-month USFDA review to **29 September 2023 US EST**

4

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

5

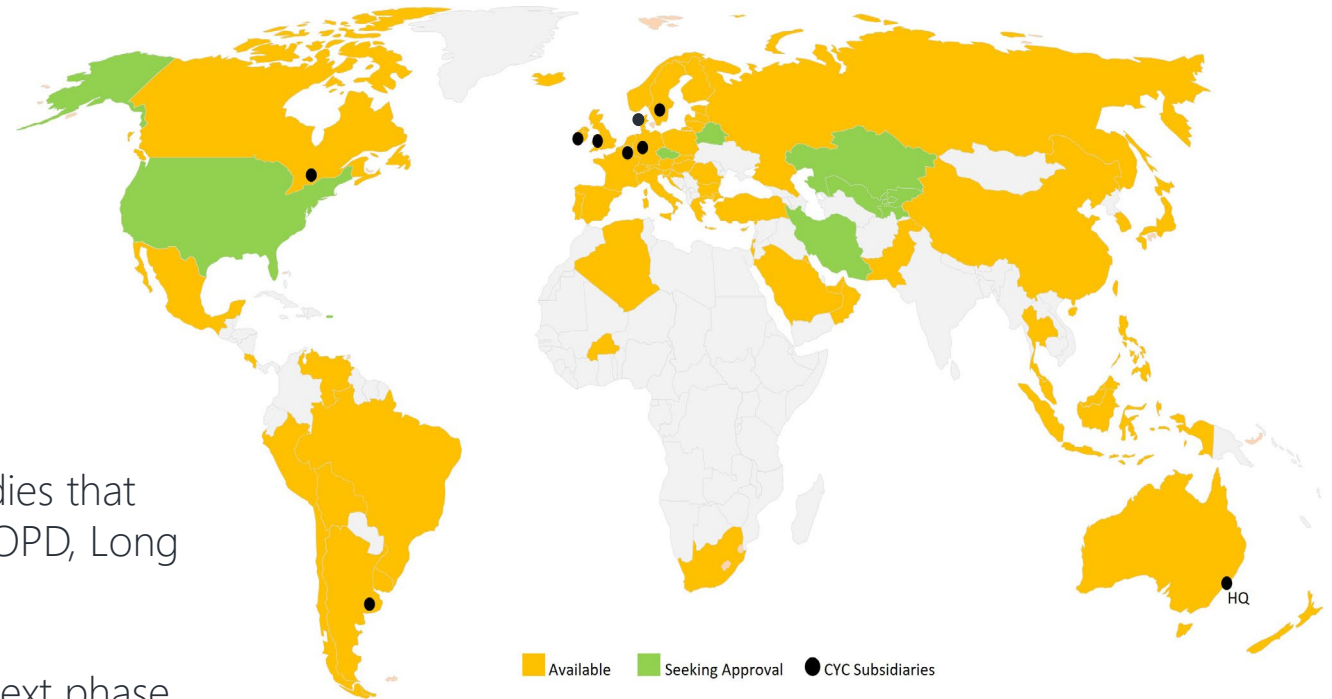
Journal publication highlighting “Beyond PE” studies that **expand clinical applications** to include asthma, COPD, Long COVID.....expected in the coming months

6

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

7

Strong Balance Sheet to fully fund growth strategy - \$18.1 m net cash as at 30 June 2023







# FY2022 & H1 2023 Financial & Operational Highlights

Sales Revenue	FY 2022: \$22.88 million - a pcg increase of 32% H1 2023: 14.92 million – a pcg increase of 35%
Third Party Distribution	FY 2022: \$9.22 million of 3 <sup>rd</sup> party distribution revenue, more than double of FY21 H1 2023: \$7.27 million of 3 <sup>rd</sup> party distribution revenue
Net Loss After Tax	FY 2022: \$6.61 million loss including US-FDA related expenses H1 2023: \$2.90 million loss including US-FDA related expenses
USFDA Expenses	FY 2022: \$2.974 million H1 2023: \$2.966 million
Dividends	FY22 total dividends maintained at 1.0 cps
Strong Balance Sheet	\$20.30 million of cash reserves as @ 31 December 2022 \$18.08 million of cash reserves as @ 30 June 2023
Technegas	FY 2022: Sales increased pcg 4.1% to \$13.76 m H1 2023: Sales Stable at \$7.65 million
Regulatory Renewals	FY 2022: All regulatory renewals in existing 64 country markets maintained YTD 2023: 5 External inspections completed
Indication Expansion	Continued progress in developing 'Beyond PE' clinical applications providing significant, long-term growth opportunities for Technegas

# THIRD PARTY DISTRIBUTION

A Unique Asset Built Over the Past Six Years – 8 Offices Directly Servicing 18 of 64 Existing Markets

1

Cyclopharm has established a respected global distribution and service network for nuclear medicine and molecular imaging products

2

Other industry manufactures leveraging off our regulatory, sales and service infrastructure

3

Third party distribution has multiple advantages:

- ✓ Additional revenue stream with only minimal working capital investment
- ✓ Increases utilization of existing staff / assets
- ✓ Additional sales staff increasing engagement opportunities for Technegas

4

Experienced significant revenue growth of circa 124% on pcp FY 2022 and 120% pcp H1 2023

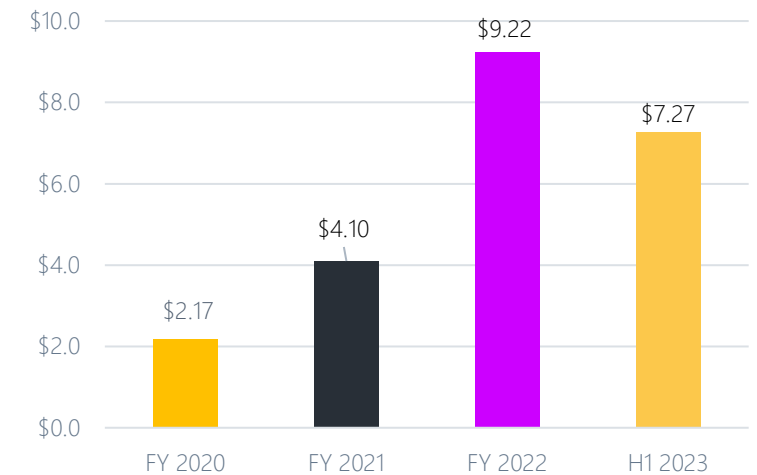
5

Mix of capital equipment, sales and service. 72% of 3<sup>rd</sup> party products in FY 2022 & 43% in H1 2023 were consumable sales and service – i.e., like Technegas, a predictable annuity-like revenue stream

6

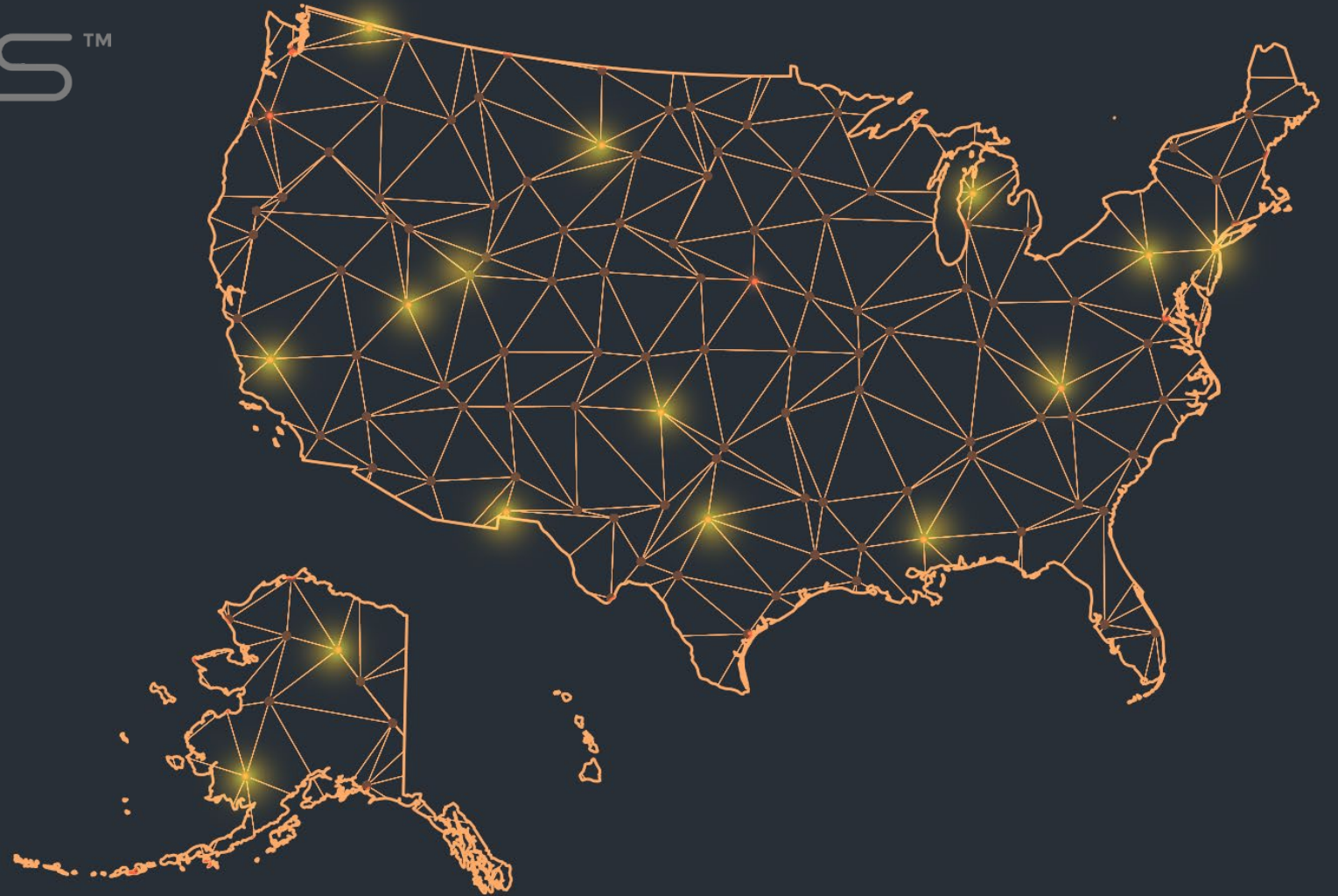
Based on current pipeline of new third-party deals, we are expecting similar levels of growth into the future. Part of this capital raise is to expand our warehouse capacity in multiple regions and working capital, due to anticipated new contract

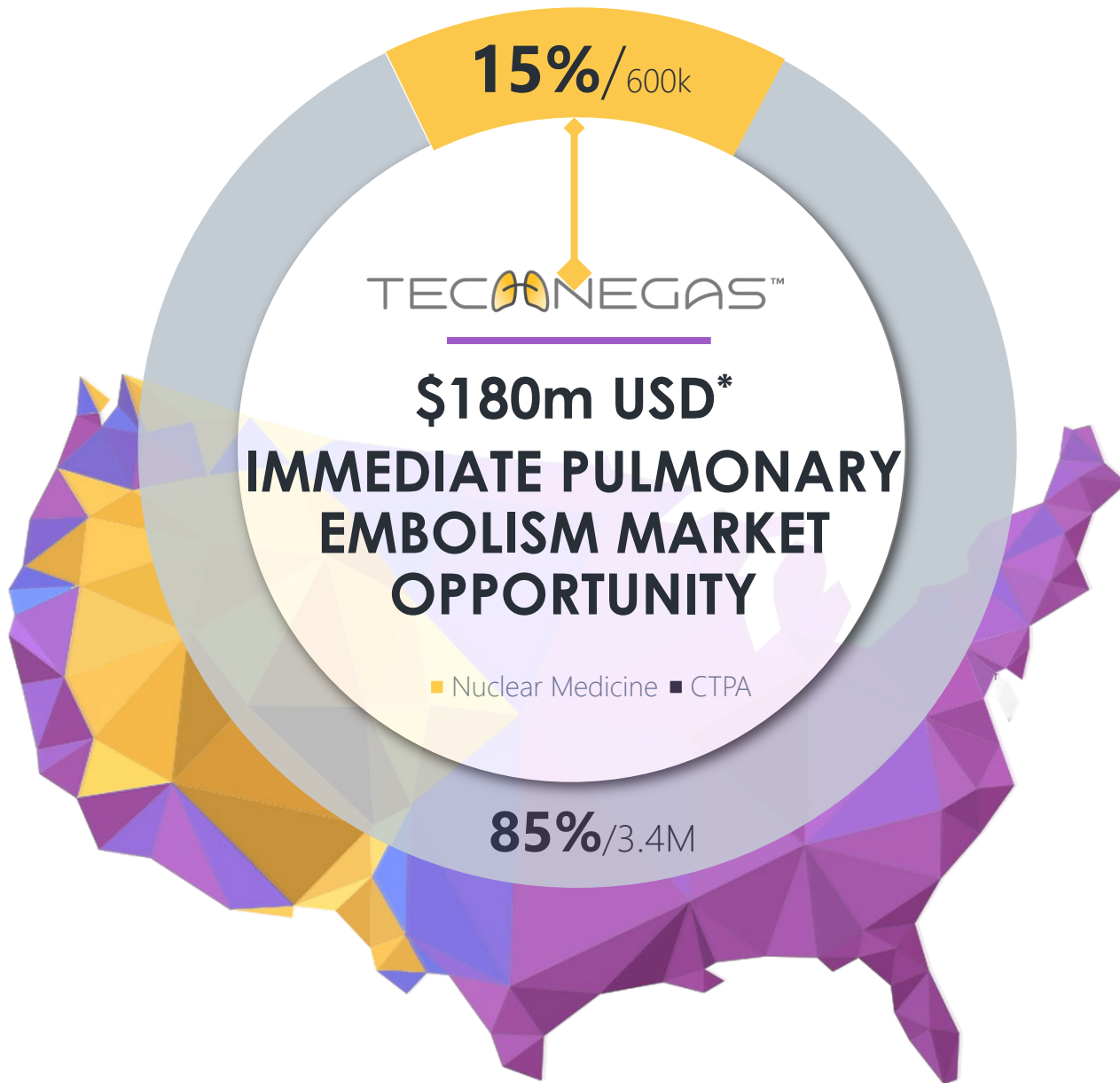
Third-Party Product Sales \$ Millions



TEC  NEGAS™

# Counting Down to USA 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.%2012.pdf](https://canm-acmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%2012.pdf) 2.a



# USA Customer Demand Established

## The Wait Is Nearly Over

1

Technegas generator placement strategy targeting rapid deployment and drive highly profitable consumable sales

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".

3

Demand already established in the US from:

- ✓ 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 and growing 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, due to inbound demand, our **focus will be on installation and training** staff as opposed to a large sales team

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

# USA Economic Model

USFDA Six Month Approval Review Concludes 29 September 2023 US EST

1

Generator Placement Strategy designed to rapidly deploy the technology

- ✓ 2000 target nuclear medicine sites
- ✓ 200 generators at subassembly stage ready for final assembly
- ✓ 20 Generator placement targeted by 31 December 2023
- ✓ Up to 300 Generators placed by 31 December 2024

2

Installation and Training - \$5k one off fee

3

Annual technology fee to include servicing of \$7k

4

Introductory per patient fee of USD \$140 – Consumables sold in 50 patient units

5

~\$5 million operating costs per annum by 2025

6

High consumable gross margins expected at greater than 80%

# USA Timeline

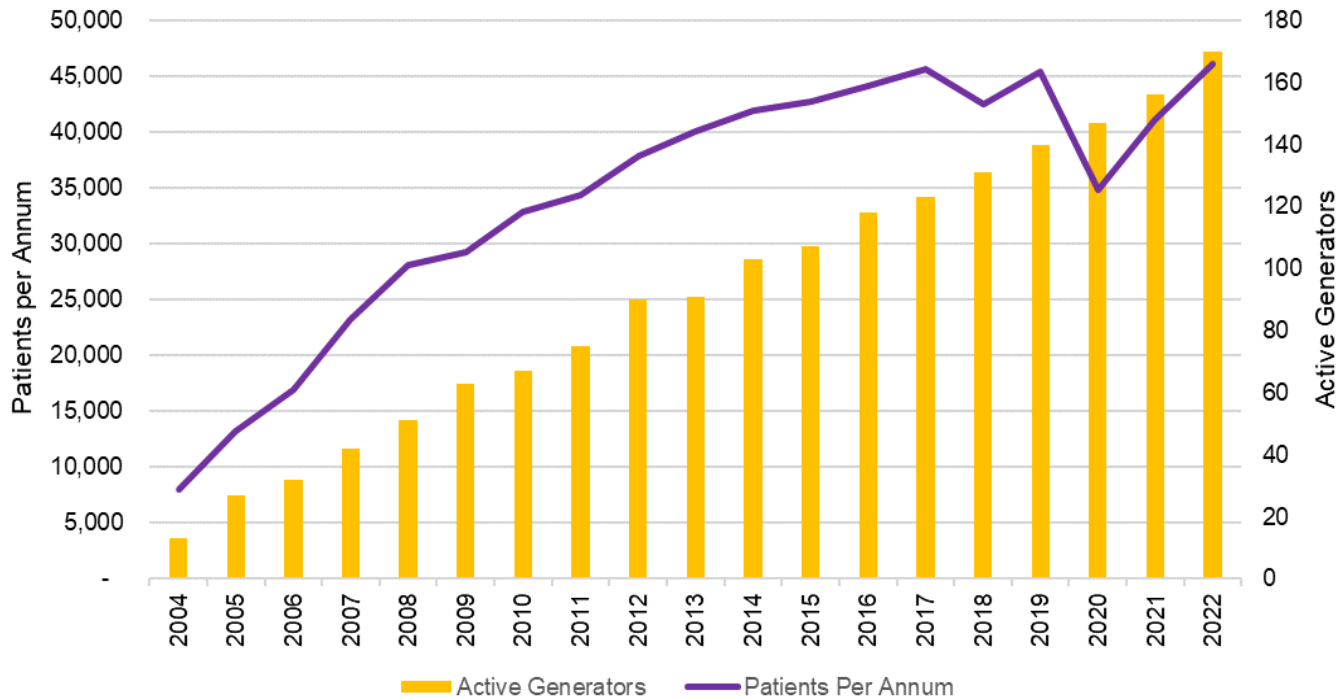
Six Month Approval Review Completes 29 September 2023 US EST

- 1 ✓ Completion of all required external testing – January 2023
- 2 ✓ Complete Response Letter Reply Submitted – 30 March 2023
  - The CRL contained over 145 supporting attachments, which comprehensively addresses the definitive list of items and recommendations requested by the USFDA on 25 June 2021
  - The majority and more complex elements of the response pertains to the manufacturing and product characteristics related to the components that make up the unique Technegas system.
- 3 ✓ Manufacturing Facility Inspected – 31 July 2023 to 9 August 2023
- 4 ✓ 200 Generators being readied for launch- components purchased and built to sub-assembly level
- 5 ✓ Labelling discussions have concluded with FDA
- 6 FDA Review Completion Target Date - 29 September 2023 US EST

# TECHNEGAS®

## The Canadian Case Study

Technegas - Canadian Case Study  
Generator to Patient Volume Relationship



Canada is Cyclopharm's largest single country market

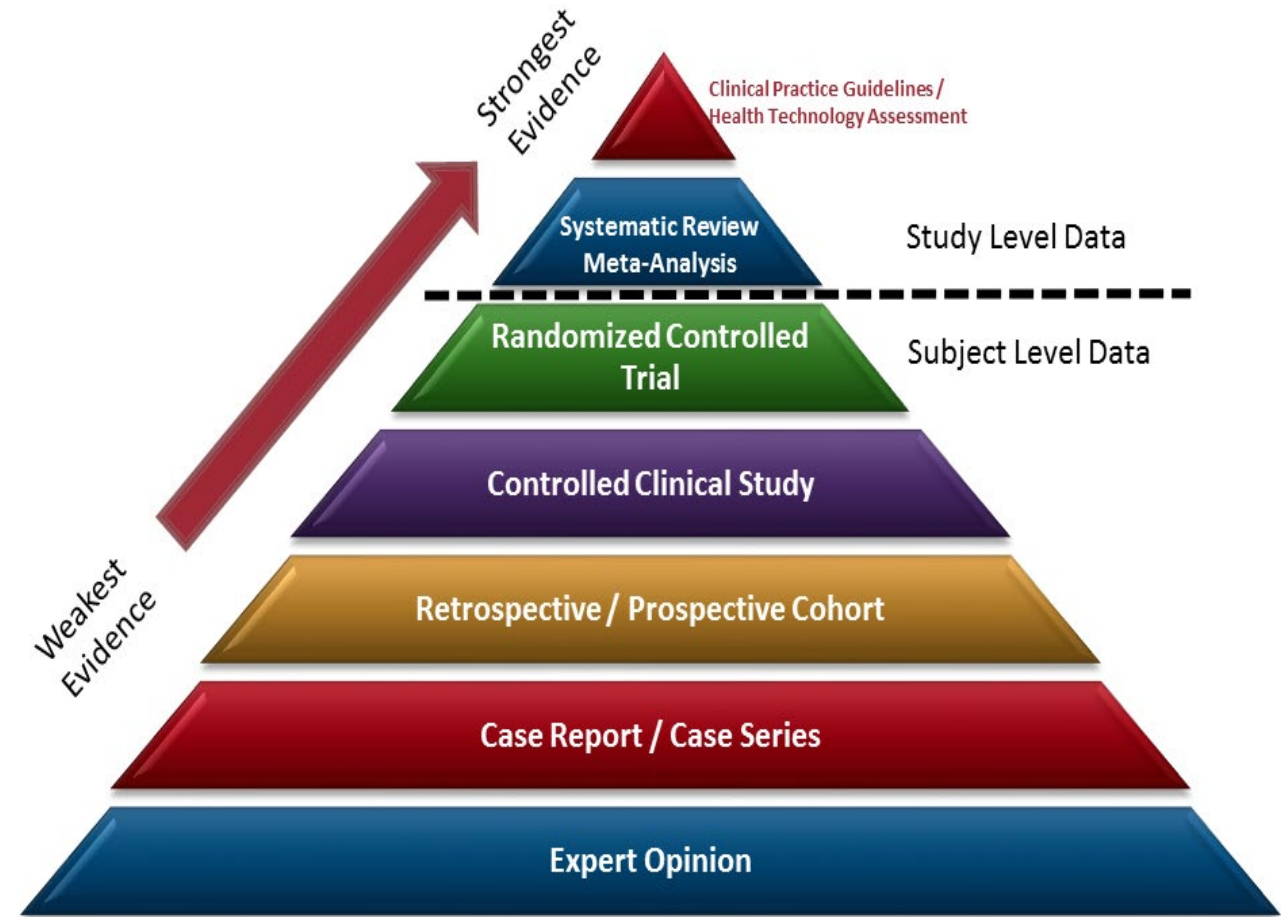
- 1 Market leader for diagnosing PE
- 2 COVID – Patient volumes have recovered with further site conversion
- 3 Represents a strong indicator of USA acceptance
- 4 Xe-133 rapidly displaced by early adopters
- 5 Close correlation with the number of active generators and annual consumable sales
- 6 Canadian Market differs from US market as it is driven by public healthcare sector and budget cycles
- 7 Market launch initiated province by province, leveraging off pilot sites





# Hierarchy of Evidence

Technegas –  
Leveraging off the **Highest Standard** of Clinical Evidence in Traditional & Beyond PE Applications



# 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\\_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

“ 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 ”



# Beyond PE

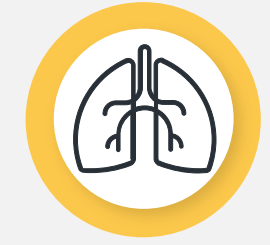
**Exponential Global Growth Potential**

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

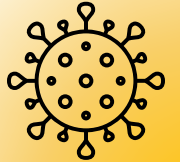


- 1 Lung Disease in 2019 accounted for **6 million deaths** worldwide (**12%** of all deaths)
- 2 COPD and Lower Respiratory Infections and Lung Cancer will be the **3<sup>rd</sup>, 4<sup>th</sup> and 6<sup>th</sup> largest causes of death** by 2030.
- 3 “Over and underdiagnosis of Lung Disease has a **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 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 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.00000000000004426

# THREE DISTINCT VALUE HORIZONS IN THE US & R.O.W.

## Exponential Growth Opportunity Over The Next Decade

Pulmonary Embolism:	Timeline	USA PE Market Share	US\$ Revenue potential p.a.
Horizon 1 – Full displacement of existing nuclear medicine tests for PE	0- 5 years post approval	15%	US\$90m
Horizon 2 – Commence converting CTPA exams to Technegas	5 -8 years post approval	30%	US\$180m*
Beyond PE:	Timeline		US\$ Revenue potential p.a.
Horizon 4 – Expanding Beyond PE into new indications such as asthma and chronic obstructive pulmonary disease	8 years post approval		US\$900m
		Total long term revenue opportunity	>US\$1bn

# CYC Business Case Summary

1

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

- Cyclopharm's lead nuclear medicine product Technegas® is currently available in **64 countries**
- Over **4,700,000 patient procedures** performed since first approved with **1,700 Technegas®** generators sold globally
- Underlying business is profitable and the company has a history of paying dividends
- Significant opportunity to expand into the USA with sales targeted for Q4 2023
- FY22 audited revenue **31%** above prior year at A\$23.2m; H1 23 audited revenue 44% above prior year at A\$16.5

2

Large existing global market

- ~3 million recorded cases of Pulmonary Embolism (PE) p.a. (could be much higher)
- 30% of **pulmonary embolisms** are fatal if left untreated
- PE 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

3

USA Commercial Launch De-risked

- The USA represents the single largest market for Technegas® with half of the world's nuclear medicine departments
- FDA approval for Technegas® expected by **29 September 2023 US EST** with first US sales expected shortly after approval
- Generator **placement rollout strategy** to be deployed for rapid US market penetration – avoiding hospital capex budgets
- Initial target of 2,000 nuclear medicine departments, 420 Expressions of interest received
- US launch focused on execution – no large sales force required
- Expecting to place more than 200 generators in first CY post approval
- Targeting to fully displace competitive nuclear products in 3-5 years time – US\$90m p.a consumable revenue

4

High margins and annuity style revenue

- Generating recurring revenues from consumable for each test plus annual service fees – number of tests is predictable
- Around 80% of historical revenue is **recurring consumable sales and service-** (81.2% in 2022)
- Stable gross margins for Technegas of greater than 80% - (85% in 2022, 81% in 2021)
- New customers have high "bottom line" impact

5

New market opportunities

- Opportunity to broaden Technegas® applications Beyond PE diagnosis into **exponentially larger** addressable markets such as COPD and Asthma. Significant existing supporting evidence available with additional clinical trials **underway** sponsored by Cyclopharm.
- Distributing third party products through Cyclopharm existing global distribution network is growing rapidly - contributing revenue \$9.22m in 2022 up 124% pcp

6

Cash Position

- \$18.1 million as at 30 June 2023 with capex already invested for US generator launch



## KEY Catalysts for the Next 2 Years



- 1 FDA review for Technegas finalised by 29 September 2023 US EST
- 2 First sales in US announce (shortly after approval)
- 3 Ongoing updates on Generators placed in US
- 4 Clinical proof of concept & validation in new substantive 'Beyond PE' respiratory indications





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**THANK YOU**

