



CYCLOPHARM

Investor Update

26 September 2023



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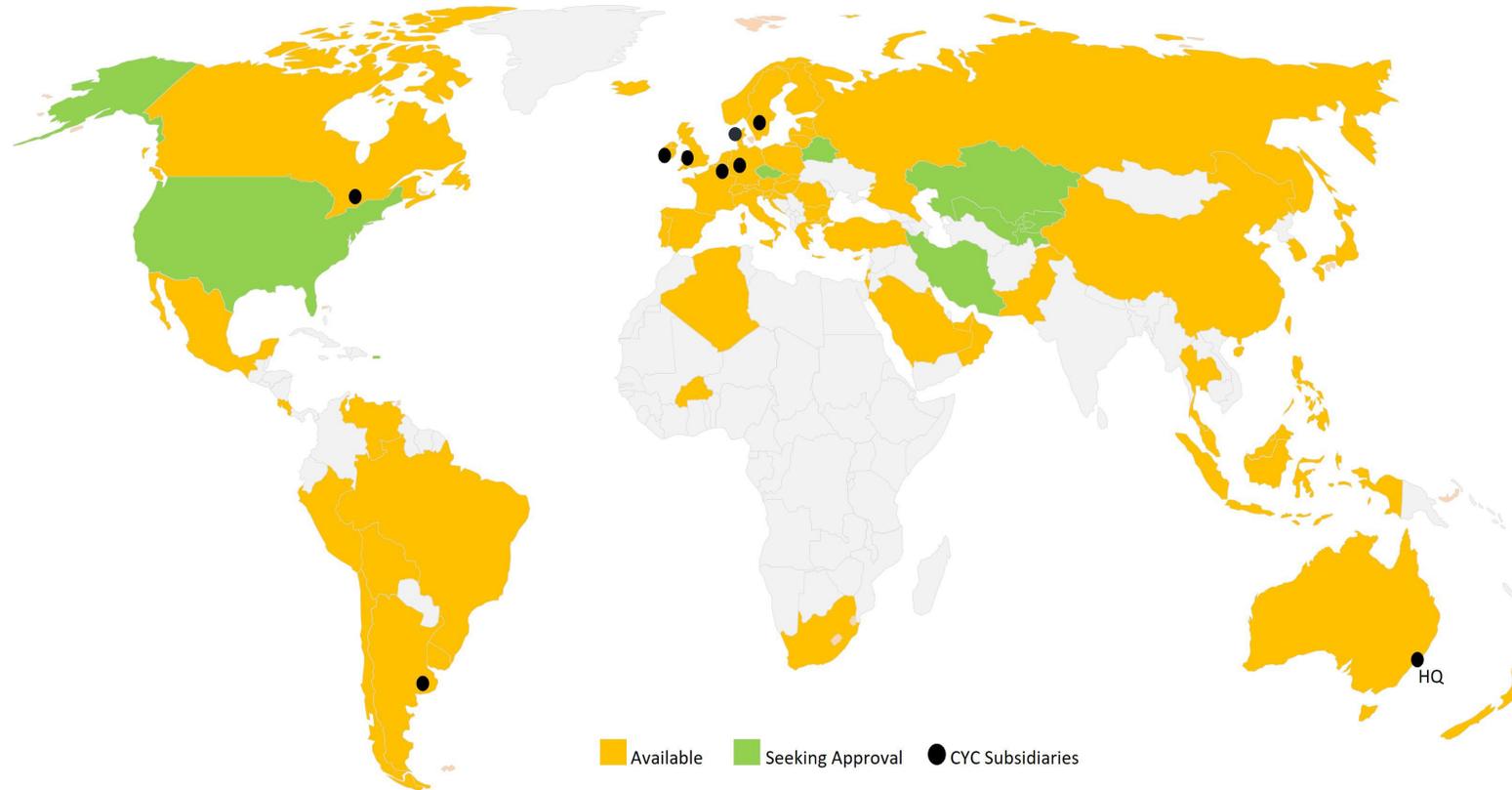
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All references to dollars unless otherwise specified are to Australian dollars.

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

TECHNEGAS® AROUND THE WORLD



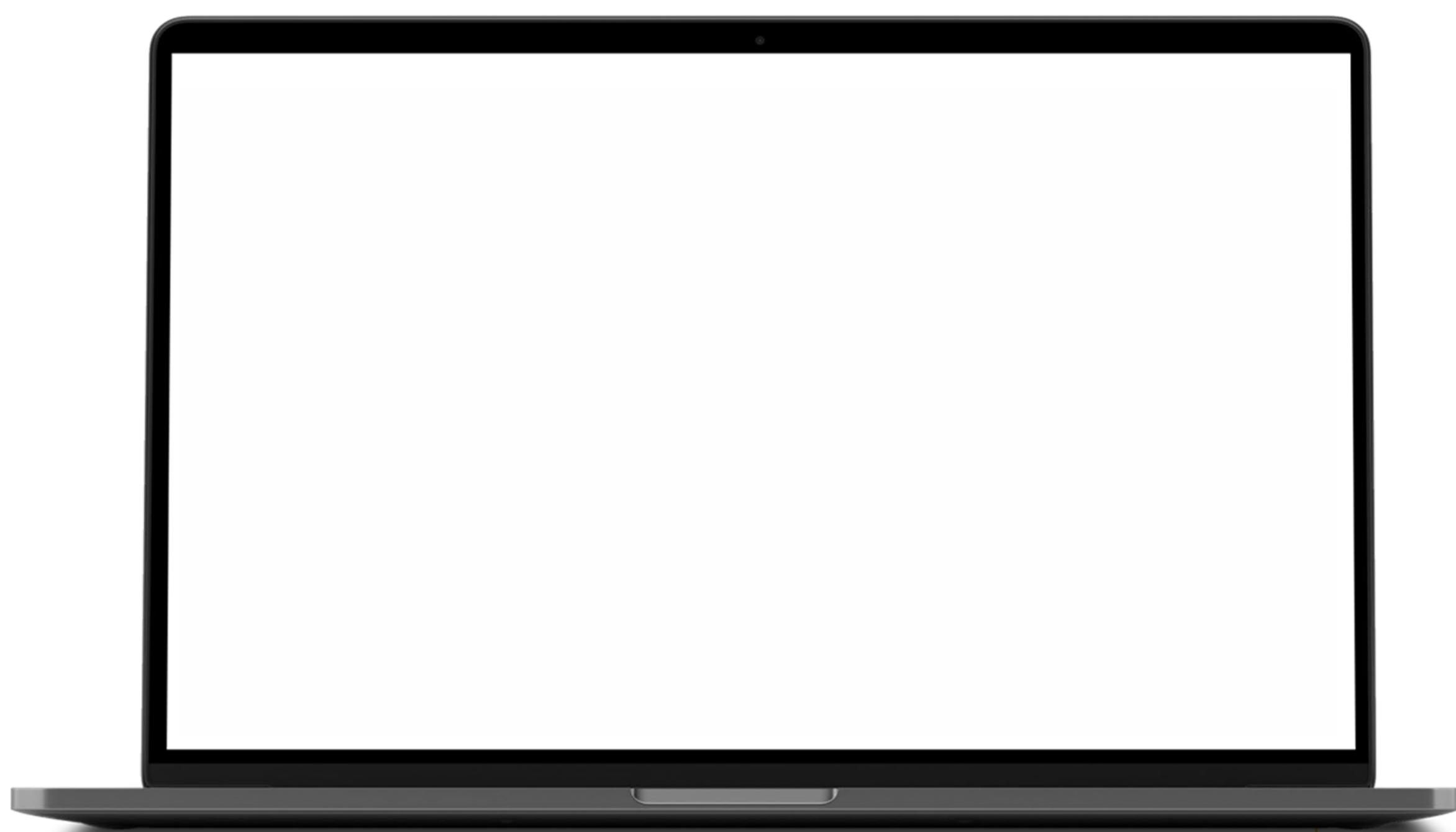
Technegas® was introduced to the medical community **in 1986**



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

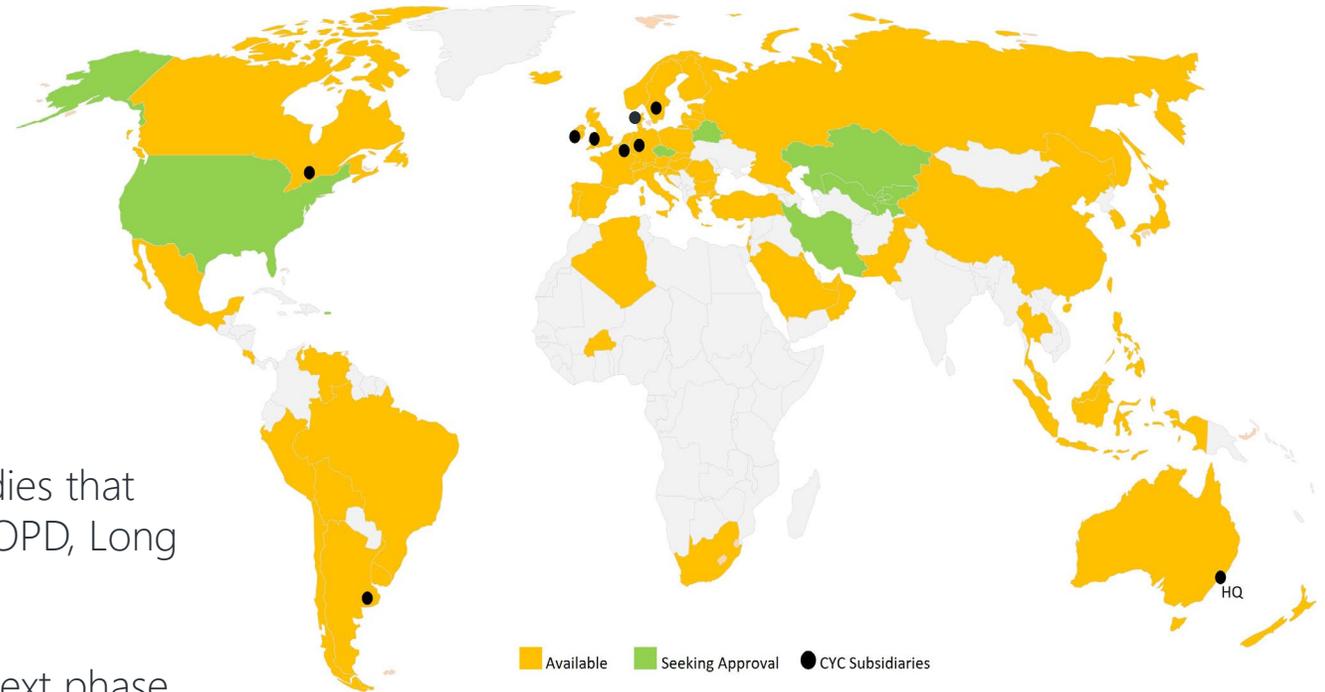
Journal publication highlighting “Beyond PE” studies that expand clinical applications to include asthma, COPD, Long COVID.....expected in the coming months

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 rd party distribution revenue, more than double of FY21 H1 2023: \$7.27 million of 3 rd 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:

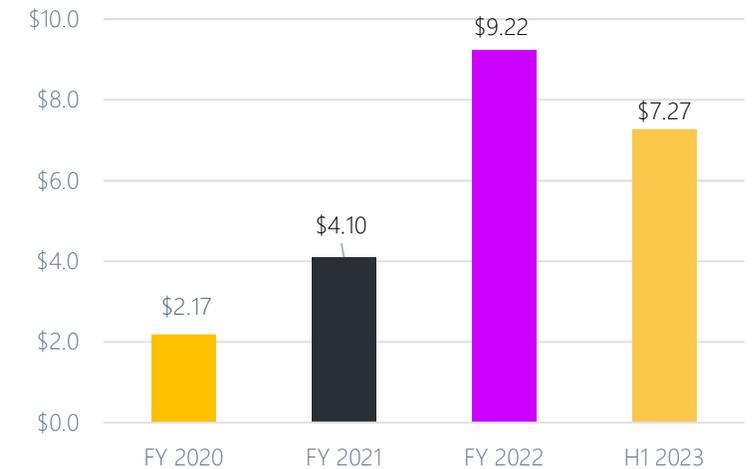
- ✓ Additional revenue stream with only minimal working capital investment
- ✓ Increases utilization of existing staff / assets
- ✓ Additional sales staff increasing engagement opportunities for Technegas

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 3rd party products in FY 2022 & 43% in H1 2023 were consumable sales and service – i.e., like Technegas, a predictable annuity-like revenue stream

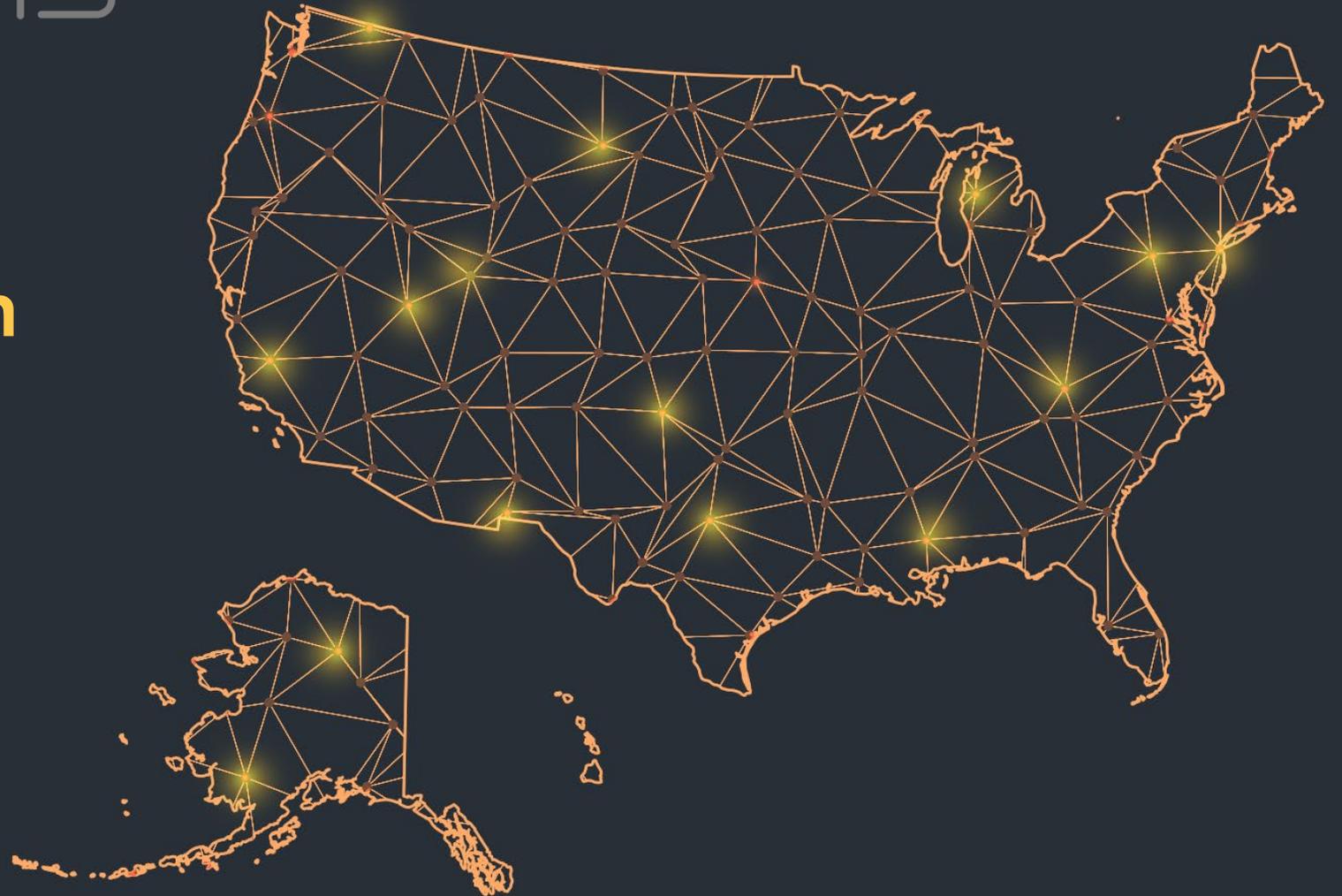
6 Based on current pipeline of new third-party deals, we are expecting similar levels of growth into the future.

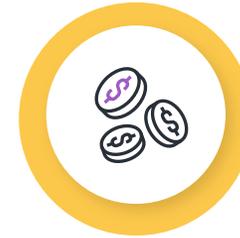
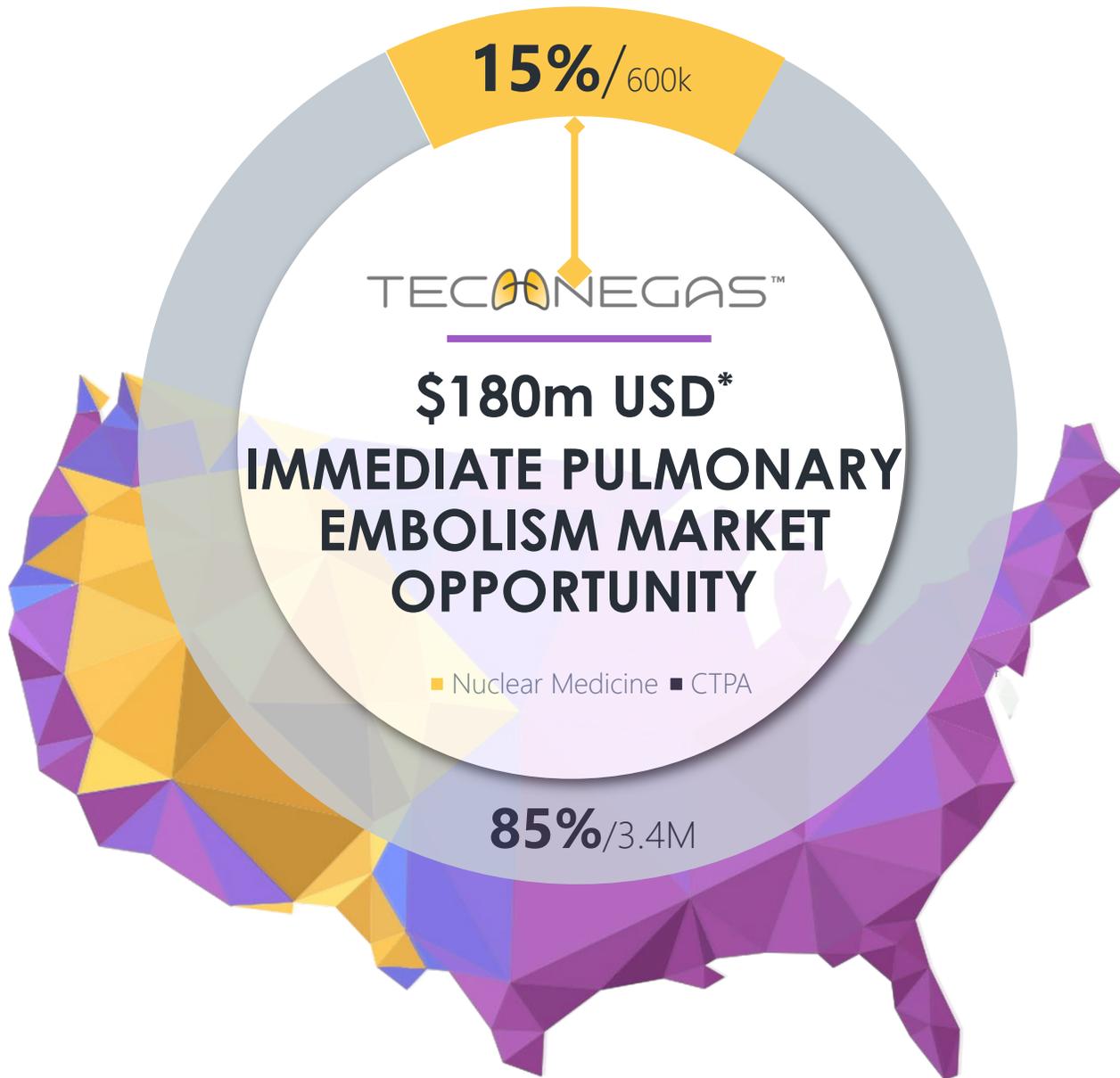
Third-Party Product Sales \$ Millions



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 CTPA¹. 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 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

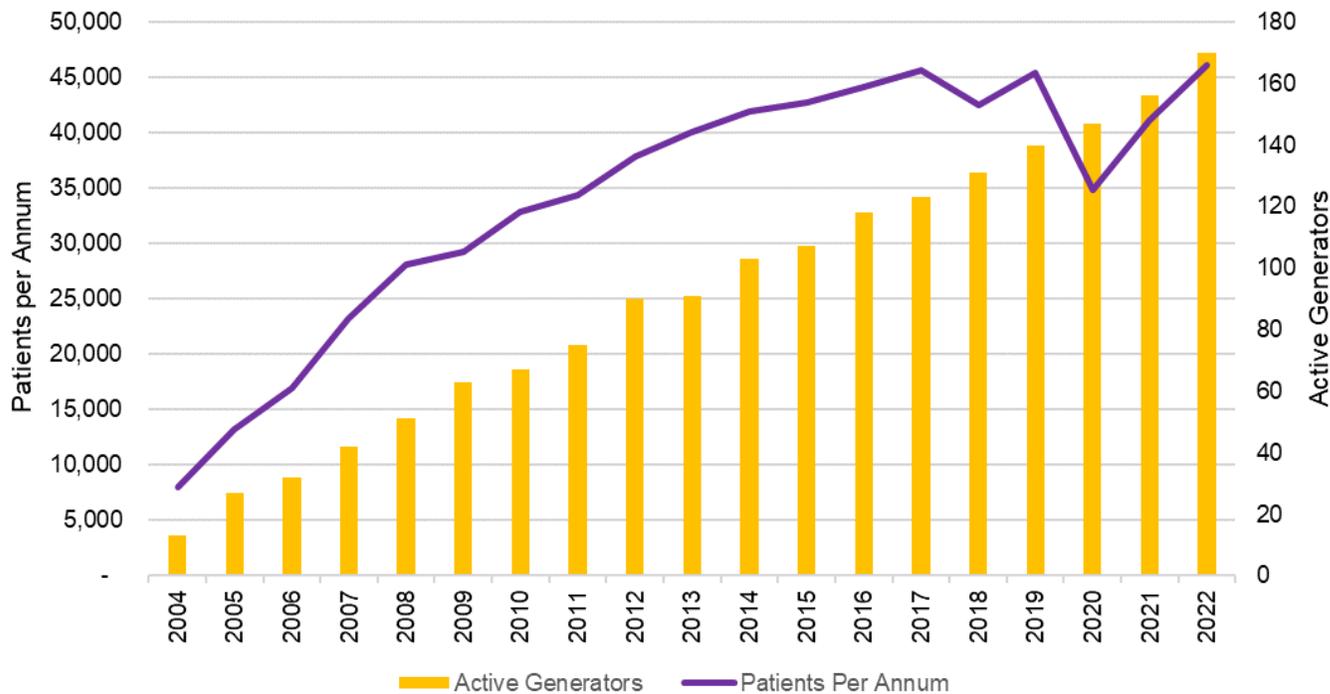
Six Month Approval Review Completes 29 September 2023 US EST

- 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®

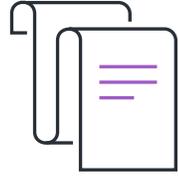
The Canadian Case Study

Technegas - Canadian Case Study
Generator to Patient Volume Relationship



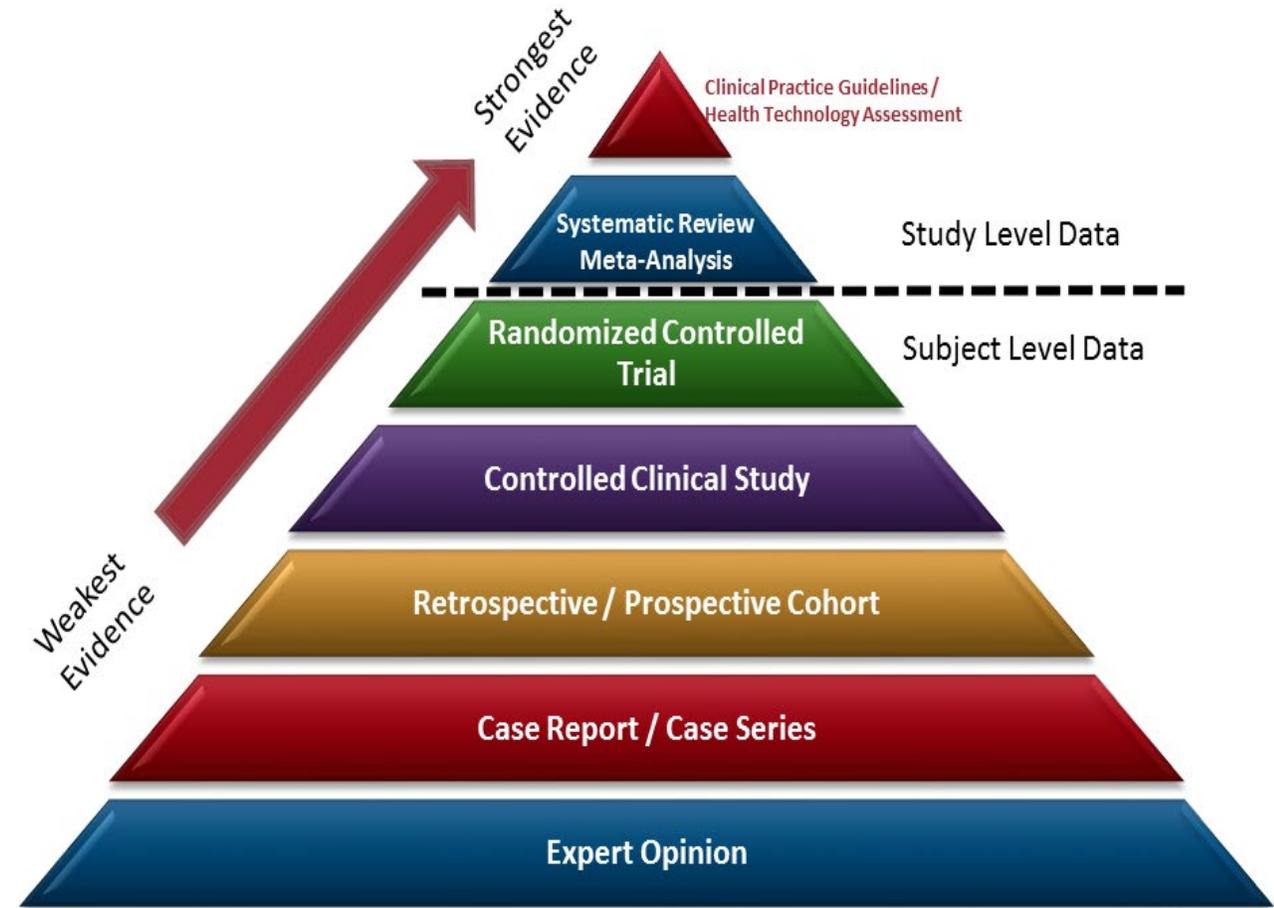
Canada is Cyclopharm's largest single country market

- 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 European¹⁻² and the Canadian³ 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
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 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





Indication Expansion – The Importance, Urgency & Opportunity Beyond PE

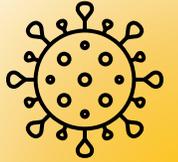


- 1 Lung Disease in 2019 accounted for **6 million deaths** worldwide (**12%** of all deaths)
- 2 COPD and Lower Respiratory Infections and Lung Cancer will be the **3rd, 4th and 6th largest causes of death** by 2030.
- 3 “Over and underdiagnosis of Lung Disease has a **huge economic impact**. COPD misdiagnosis 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 costs²**”
- 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**¹ and **Pulmonary Hypertension**^{2, 15, 16,18, 22}

Preoperative assessment of homogeneous **Endoscopic Lung Volume Reduction (ELVR)** candidates^{3,17,}

Preoperative assessment of **lung resection** candidates with borderline pulmonary reserve^{4,5,6,20}

Planning **radiation therapy** to target tumors while preserving functional lung zones⁶⁻⁷

Advanced approach to phenotyping **chronic airways diseases such as asthma and COPD** and identifying patient likely to respond to treatment⁸⁻¹⁰

Use of alternate isotopes to make Galligas™ for **PET Molecular Imaging**^{14, 15}

Diagnosis and monitoring of **COVID-19** patients^{11, 12,18,19,21,22}

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 approval for Technegas expected this week
- 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



THANK YOU

