



USFDA approval of Technegas[®] opens **US\$180m+** market

5 October 2023
Webinar 2.00 pm

Registration: https://cyclopharm-au.zoom.us/webinar/register/WN_O9FzUFoSHuOz1cLQIxsMA



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



USFDA approval highlights:

- Formal Approval granted – **29 September 2023**
- **US is the largest** single nuclear medicine market globally
- **US\$180m+** market potential for diagnosing Pulmonary Embolism with Technegas
- **Immediate rollout** across USA to meet demand
- USA approval marks **65th country market** for Technegas
- **Broad indication** granted to include “Visualization of pulmonary ventilation”
- Access to US market delivers leverage for the Technegas core business and our **exponentially larger Beyond PE** aspirations

Technegas® around the world



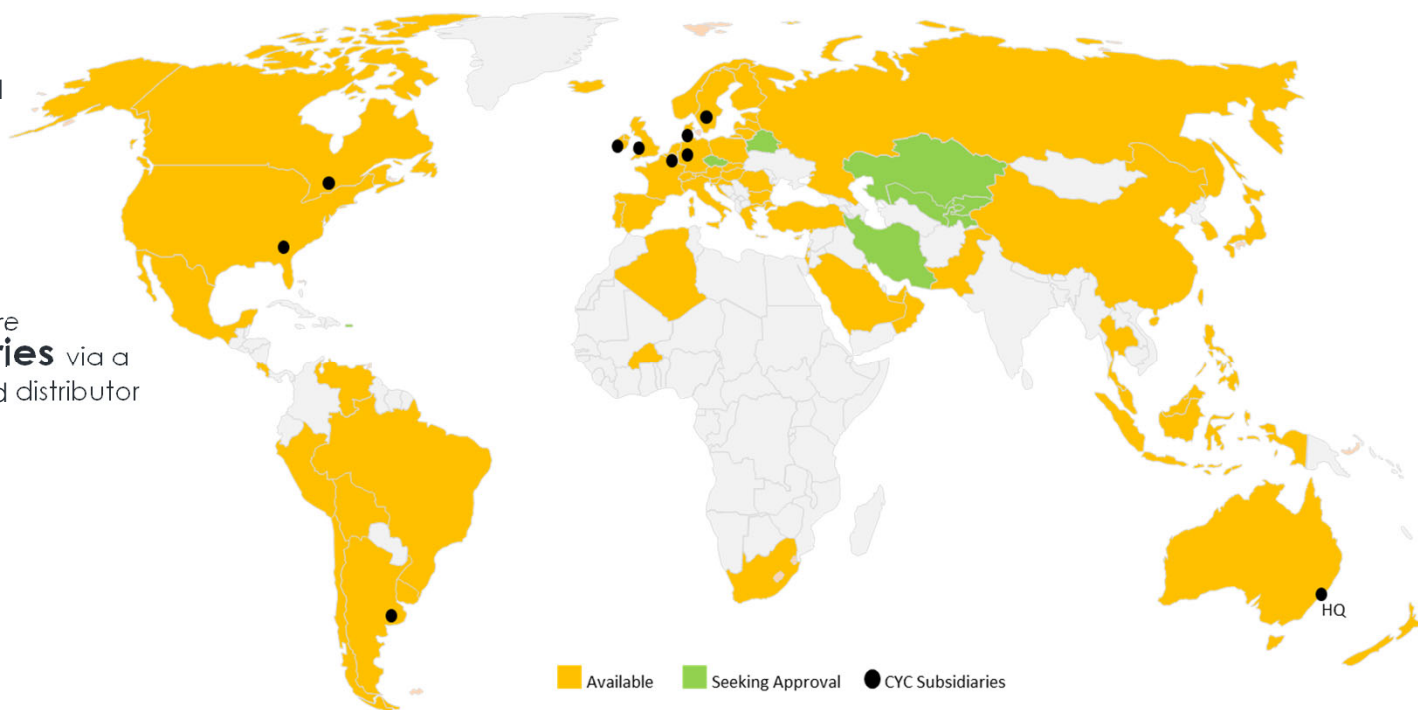
Technegas® was introduced to the medical community **in 1986**



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



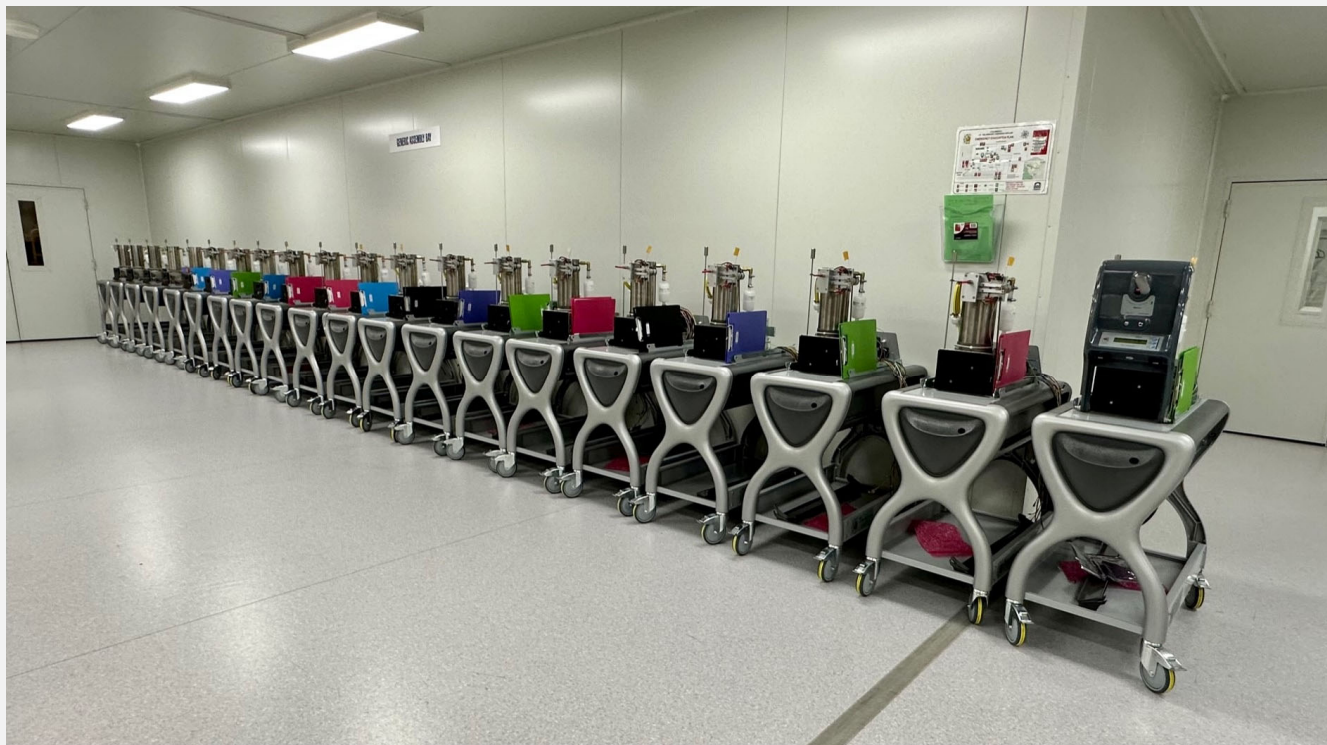
Over **4.7 million** patient procedures to date





USFDA Launch

Readying the Fleet



4 October 2023

USA Commercialisation

USFDA Approval 29 September 2023

- **200** Generators for launch – components purchased and built to sub-assembly level
- **2000** target nuclear medicine sites
- **20** generator placements targeted by 31 December 2023
- **up to 300** generators placed by 31 December 2024
- National network **service provider selected** with CYC service and installation program training commenced
- **3rd Party distribution** provider selected – outsourced back-office provider under negotiations
- Distribution, installation and service to be predominantly outsourced – **keeping fixed cost base low - easily scalable**
- Recruitment of US based BDM, training and support team commenced (**<10 FTE's in the first year**)
- **Strong Pre-existing demand** allows a focus on building up installation and training staff, as opposed to a large sales team

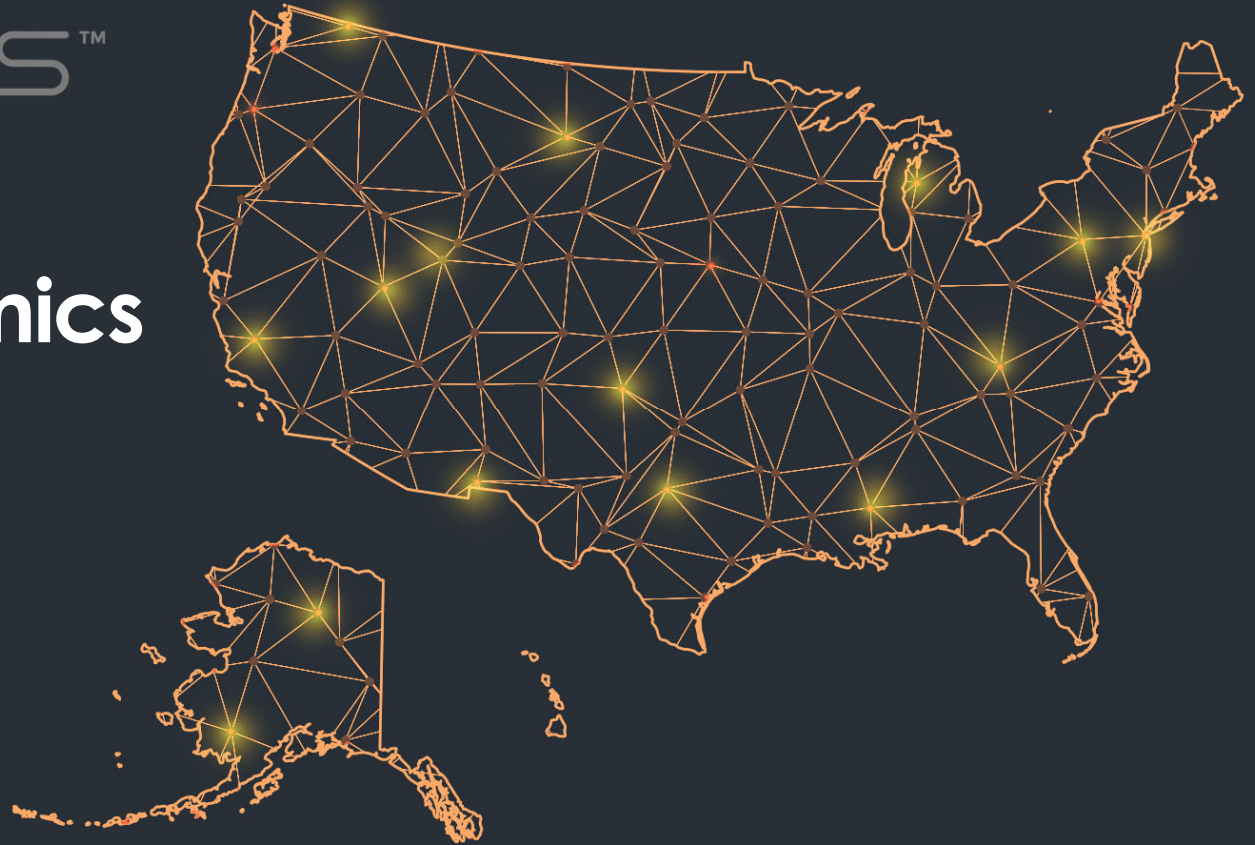
Novel Economic Model

Placement Model to Expedite Consumable Demand

- **\$5k** one-off installation and training fee
- **\$7k p.a.** technology fee, includes servicing
- **US\$140** per patient introductory fee, consumables sold in 50 patient units
- **US\$70k** revenue per system per annum expected from larger sites
- **>15 yrs** average life per system
- **System Placement model** supports rapid uptake by US customers by removing 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
- ~\$5 million operating costs per annum by 2025
- High consumable annuity like gross margins expected at greater than 80%

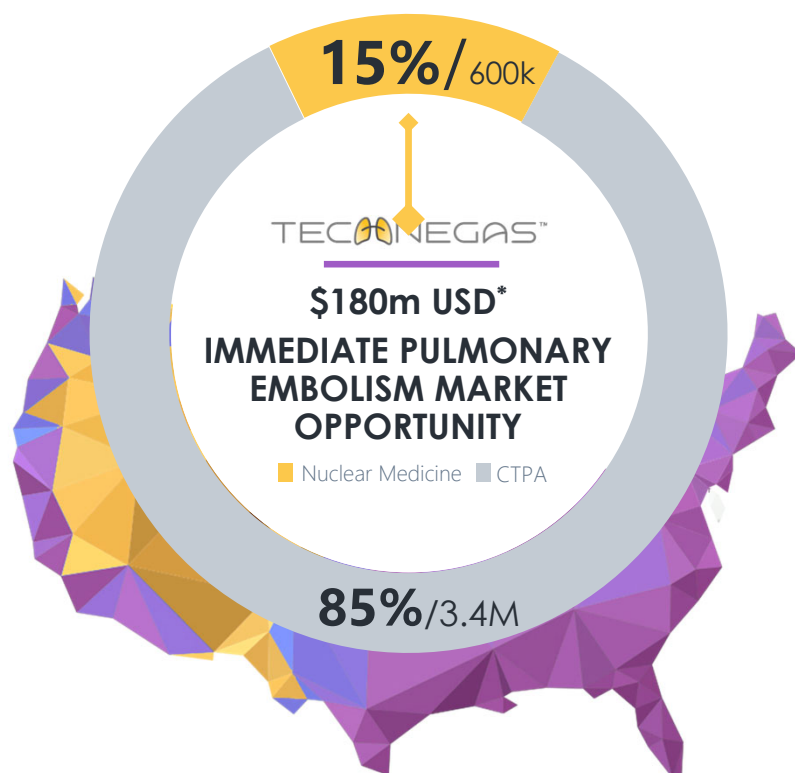


US Market Dynamics



Largest addressable market globally

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



- 1 Cyclopharm estimates **4,000,000 pulmonary embolism procedures** in the USA per annum (15% Nuclear Medicine / 85% CTPA)
- 2 ~600,000 Nuclear Medicine Ventilation procedures represents an initial **\$90m USD** 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 Entry into US 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 2.a

Three Distinct Value Horizons

Exponential Growth Opportunity Over The Next Decade

Pulmonary Embolism:

1	Horizon 1 – Full displacement of existing nuclear medicine tests for PE	0 - 5 years	15%	US\$90m
2	Horizon 2 – Commence converting CTPA exams to Technegas	0 - 8 years	30%	US\$180m*

Beyond PE:

Beyond PE:		Timeline USA & R.O.W.	US\$ Revenue potential p.a.
3	Horizon 3 – Expanding Beyond PE into new indications such as asthma and chronic obstructive pulmonary disease	> 8 years	US\$900m
		Total long term revenue opportunity	>US\$1.2bn

*Assumes Combined Nuclear Medicine and CTPA Market

US Customer Demand Established

Over 420 Expressions of interest already recieved

1

First sales in US are imminent followed by regular **updates on Generators** placed in US

2

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

3

Leading clinicians, front-line workers and the SNMMI have petitioned the USFDA for the approval of Technegas*

4

Clinical Nuclear Medicine journal stated Technegas *"is an excellent imaging option for assessing pulmonary airways"* and *"once approved in the USA it is likely to cause a shift (**clinical shift**) to SPECT"* *

5

Demand in the US underpinned by:

- ✓ 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

6

Key US Opinion Leaders engaged; recruitment of a Chief Medical Officer initiated and US Beyond PE R&D Programs underway to accelerate US clinical demand

7

Application Specialists recruitment underway and a suite of educational materials are under development to drive awareness of Technegas superior profile and drive demand

Compelling US Clinical Support

Society of Nuclear Medicine and Molecular Imaging Press Release

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.

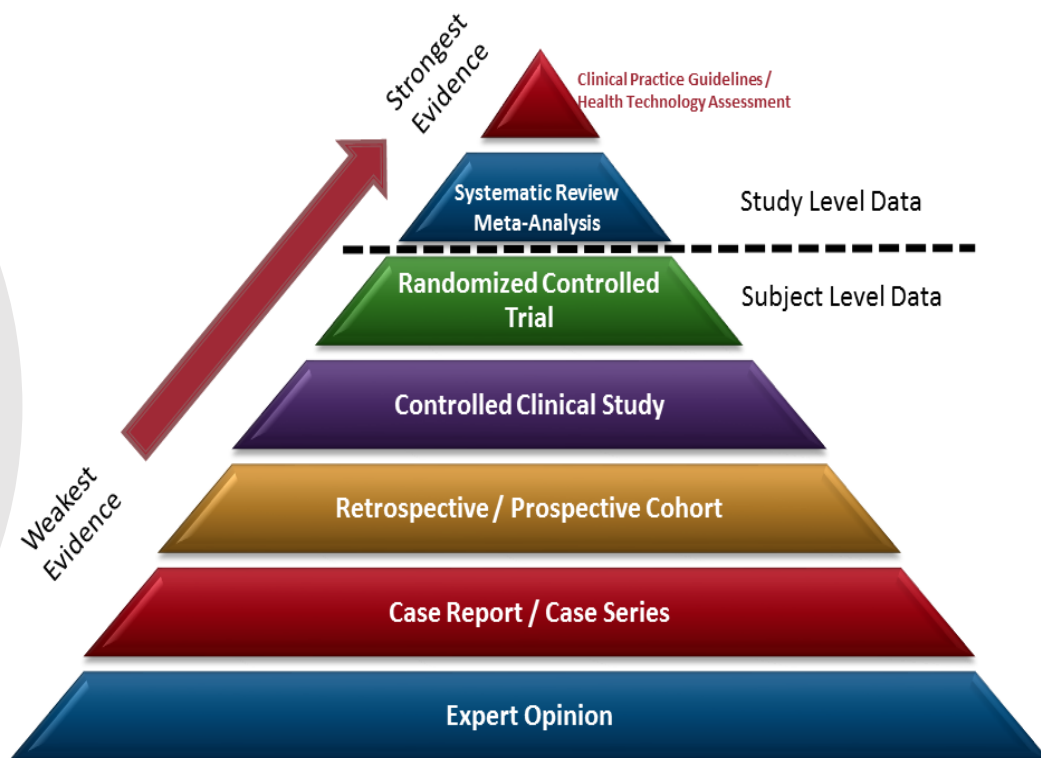
- "Recognised standard for ventilation studies"
- "Diagnostic Accuracy"
- "Improved workflow"
- "Patient Comfort"
- "Large impact on those undergoing imaging for pulmonary disease"

<https://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=45004>



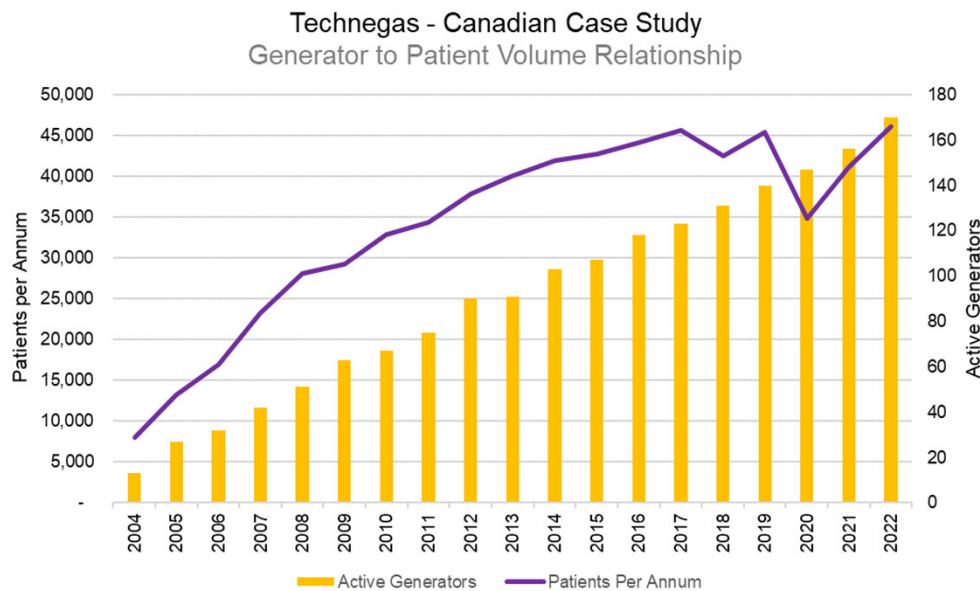
Technegas has the
Highest Standard
of Clinical Evidence
to **Drive Adoption** in
Traditional & Beyond
PE Applications

Hierarchy of Evidence



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
- 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 have recovered post COVID with further site conversion



Beyond PE

**US Entry to Accelerate 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 with USA availability expected to drive expansion

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** and **Pulmonary Hypertension**^{1,5}



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}



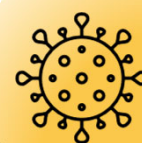
Planning **radiation therapy** to target tumors while preserving functional lung zones⁶⁻⁷



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
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13. Bajc M, et al. Clin Med Insights 2021; Vol 14 1-4
14. Blanc-Beguín F, et al. Mol Imag 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

Technegas® is a registered product of Cyclomedica Australia Pty Ltd



KEY Catalysts for the Next 2 Years



- 1 First sales in the USA announced
- 2 Ongoing updates on Systems placed in the USA
- 3 Clinical proof of concept & validation in new substantive Beyond PE respiratory indications
- 4 Continued growth in the other existing 64 established country markets

CYCLOPHARM INVESTMENT CASE



Profitable and Growing MedTech

Underlying business is cash positive and issuing dividends



First in Class

Established Gold Standard

Proprietary product sales to 65 countries with over 4.7 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

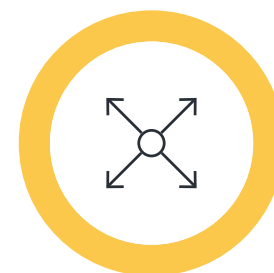
Further leverage penetration into the CTPA market



Recurring Revenue

From single patient consumables

Similar to an annuity model



Technegas Product expansion

Indications beyond PE into chronic respiratory disease management could deliver exponential growth

Market Development already underway!



Thank you



WHAT THE GUIDELINES SAY ABOUT TECHNEGAS®:

Endorsed by the guidelines from the European^{1,2} and the Canadian³ Associations of Nuclear Medicine (EANM & CANM)



“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”

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://canmacmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%2012_.pdf 2.a

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 65 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 - FY22 audited revenue 31% above prior year at A\$23.2m; H1 23 audited revenue 44% above prior year at A\$16.5 million
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® granted on 29 September 2023 US EST with first US sales targeted for Q4 2023 - 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 - Targeting to double PR market share of nuclear medicine PE vs CTPA in 0-8 years time – growing consumable revenues for PE diagnosis to US\$180m p.a.
4	High margins and annuity style revenue	- Generating recurring revenues from per patient consumables 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