# CYCLOPHARM

## 2024
## Annual General Meeting

27 May 2024

# SAFE HARBOUR STATEMENT

Certain views expressed here contain information derived from publicly available sources that have not been independently verified.

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 McBrayer, Managing Director, CEO and Company Secretary.



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# Welcome

Mr David Heaney

# CHAIRMAN'S ADDRESS

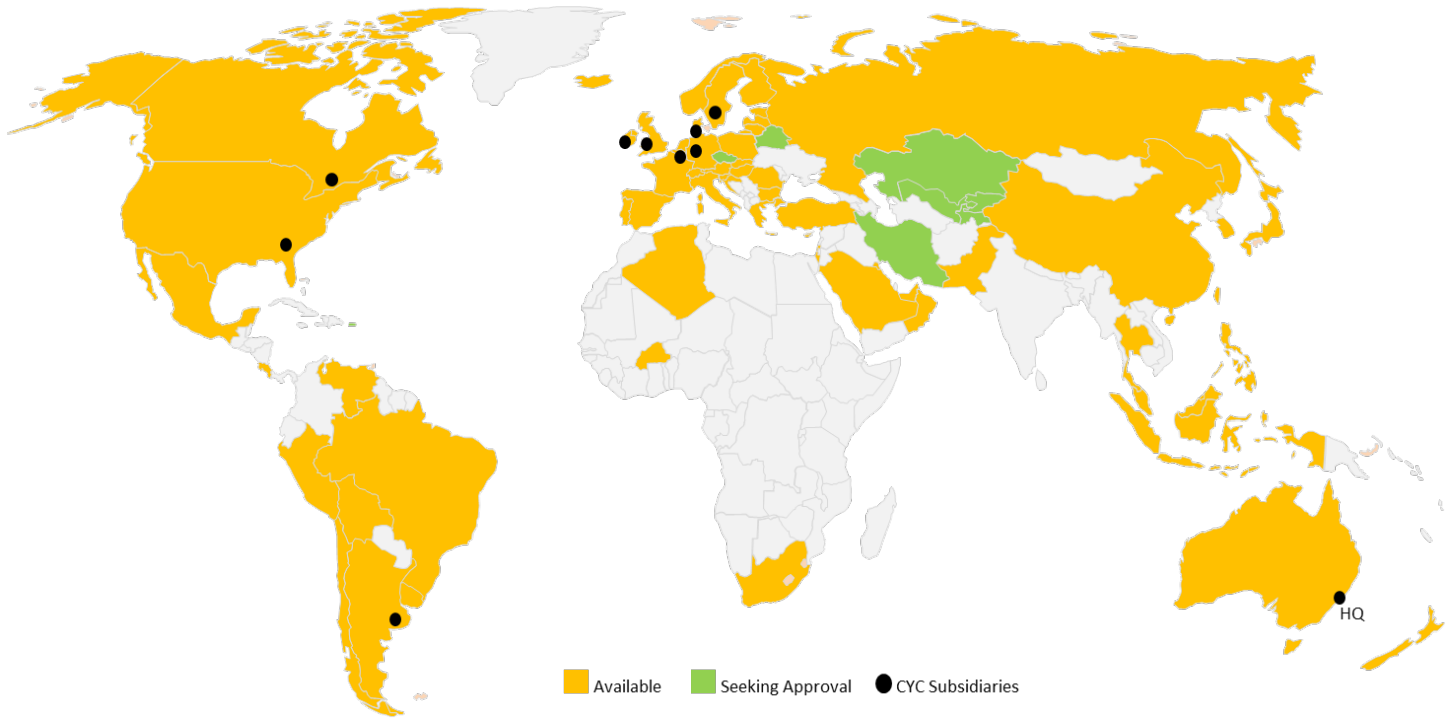
Mr David Heaney

# 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



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# A World Leading Diagnostic Imaging Company

1. **Recovery in FY 2023 continued** from initial COVID-19 impact in primary country markets with record sales of **$26.3m.** (Technegas sales $14.43m up 5.6% - Third-party sales $11.91m up 29.3% compared to 2022)

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

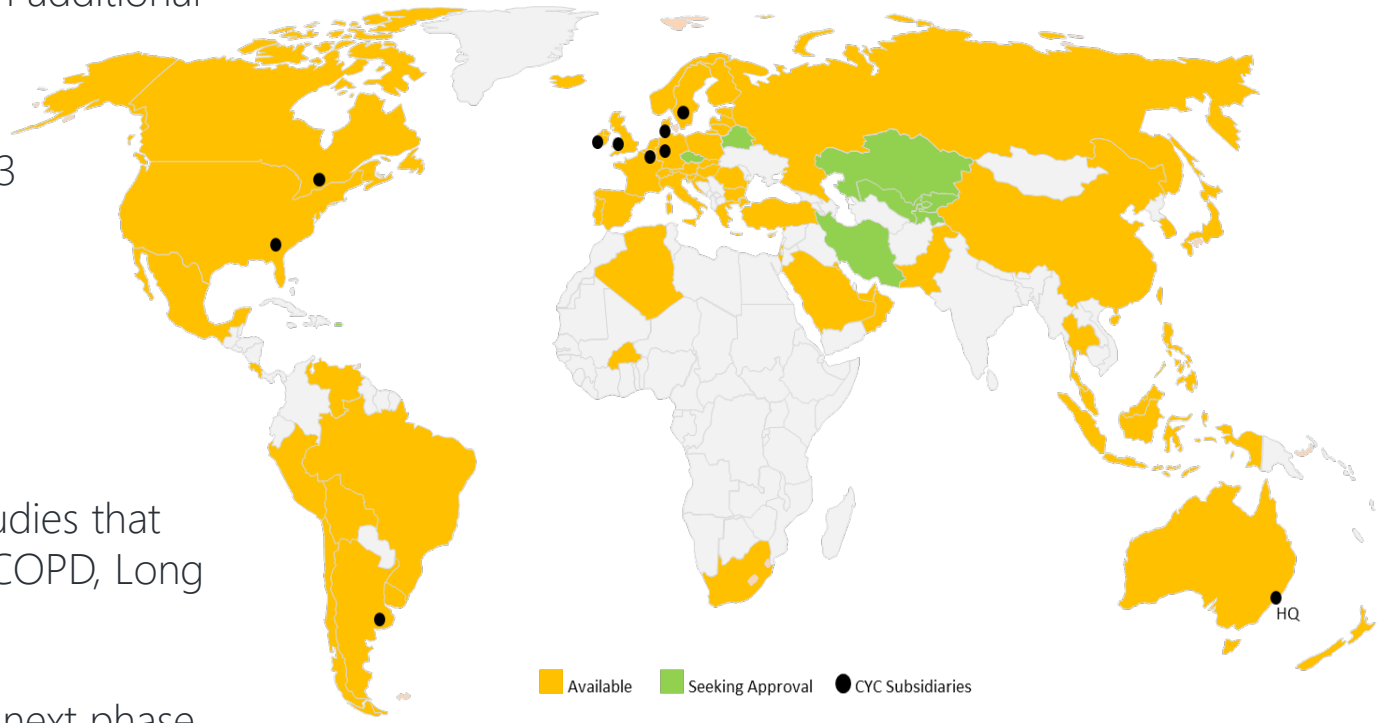
3. USFDA approval received on 29 September 2023

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. **Balance Sheet** to launch Technegas into the USA- $11.7 m net cash as at 31 December 2023

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# MANAGING DIRECTOR'S ADDRESS

Mr James McBrayer

# 2023 Financial Highlights

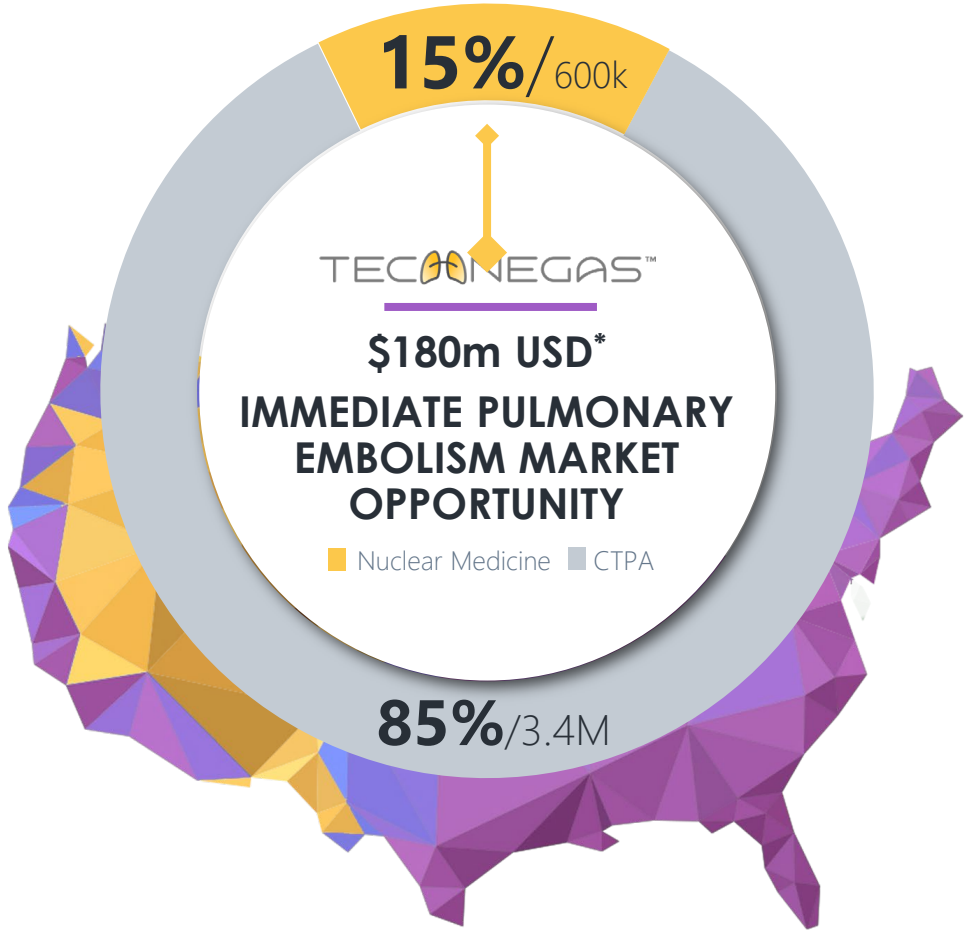
| | |
|---|---|
| Sales Revenue | $26.34 million - an increase of 15.1% |
| Third Party Distribution | $11.91 million of third-party distribution revenue, an increase of 29.3% |
| Net Loss After Tax | $4.70 million loss including US-FDA related expenses |
| USFDA Expenses | $3.49 million |
| Reversal 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 |

# 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



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# US Customer Demand Established

## 136 Proposals and Contracts representing over 400+ locations

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 expected on or before 1 October 2024**
5. **Targeting over 300 generators placed by 31 December 2025**



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**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

**Education**

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

**Service**

- ✓ National network service provider Contracted
- ✓ CYC Employees Engaged



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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 **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 Pulmonary Embolism: | Timeline Global | Market size |
|---|---|---|
| 3 **Horizon 3** – Expanding Beyond PE Globally into new indications such as asthma and chronic obstructive pulmonary disease | > 8 years | US$900m |
| | **Total long term revenue opportunity** | **>US$1.1bn** |

*Assumes Combined Nuclear Medicine and CTPA Market



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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 **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 costs**[2]"
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)

## >US$1.1bn global market size*

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 zones[6-7]

Advanced approach to phenotyping **chronic airways diseases such as asthma and COPD** and identifying patient likely to respond to treatment[8-10]


Use of alternate isotopes to make Galligas™ for **PET Molecular Imaging**[14, 15]

*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. 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-Beguin 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




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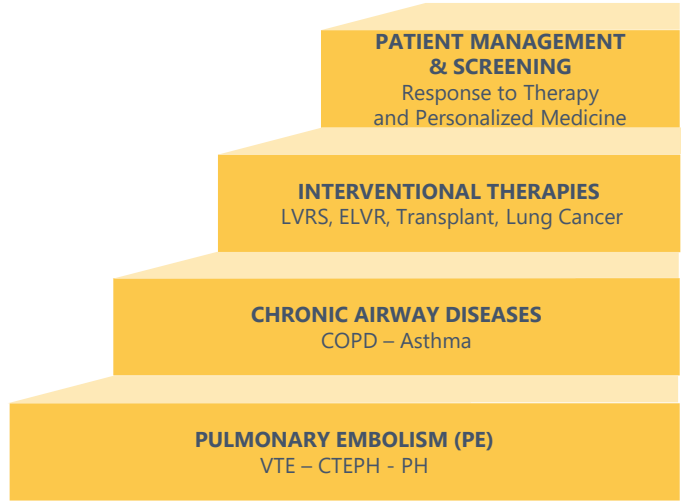
# Beyond Pulmonary Embolism Initiatives Underway

7 Cyclopharm sponsored Beyond PE clinical trials

1. **Hunter Medical Research Institute (Newcastle, AU):** Diagnosis and response to therapy in severe asthma and COPD[1]
   100 Patient Study * 100% Recruited * **Study Published**[6],
2. **Woolcock Institute (Sydney, AU):** Diagnosis and response therapy in mild to moderate COPD[3]
   25 Patient / 75 Scan Protocol * 88% Completed
3. **CHUM (Montreal, CA):** Early detection of COPD in asymptomatic smokers[4]
   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 [2]; 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[5]
   100% Recruited * Abstract presented at the American Thoracic Society May 2023 with paper to follow.
7. **PRONOSPECT (France):** 665 Patient multicenter 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[8]





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
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

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# Upcoming Milestones and Growth Catalysts

- ✓ Technegas formal **commercial launch** at the First North American Society of Nuclear Medicine and Molecular Imaging (SNMMI) conference since FDA approval June 2024
- ✓ **Market expansion** beyond Cyclopharm's 65 established country markets
- ✓ **Pass Through** status approval expected by 1 October 2024 to accelerate growth
- ✓ Updates on publications and Cyclopharm supported clinical trial initiatives featuring indications **Beyond PE**
- ✓ Material Business Partner Product **distribution contracts** or initiatives
- ✓ Regular updates highlighting **USA progress**

Leveraging an established global commercial footprint



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# CYCLOPHARM INVESTMENT CASE

TECHNEGAS™

**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 4.7 million patient procedures to date

Clinical Agent of Choice referenced by name in multiple clinical guidelines

**USFDA Approval Granted**

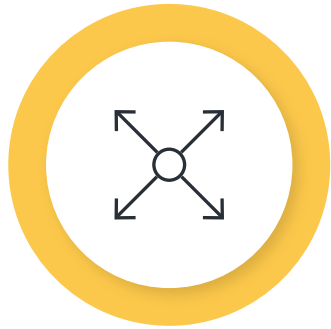
Set to quadruple the size of the existing PE business, based on significant existing demand

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 in large markets such as asthma, COPD and lunch cancer could deliver exponential growth

Market Development already underway



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# FORMAL BUSINESS

Mr David Heaney

# 2024 AGM – Formal Business

## Resolutions

1. Financial – (b) Remuneration Report
2. Election of Mr John Wigglesworth as Director
3. Share Buy-back
4. Approval of Loan Share Plan



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# CYC AGM 2024 Resolutions

1(b) That the Remuneration Report as set out in the Annual Report of the Company for the financial year ended 31 December 2023 be adopted.

| Resolution | For | Against | Discretionary | Abstain |
|---|---|---|---|---|
| Remuneration Report | 23,716,701 | 84,566 | 37,988,457 | 155,923 |

**Questions?**

# CYC AGM 2024 Resolutions

2 That, for the purposes of ASX Listing Rule 14.4 and for all other purposes, Mr John Wigglesworth, being eligible and having consented to act, be elected as a Director of the Company.

| Resolution | For | Against | Discretionary | Abstain |
|---|---|---|---|---|
| Election of Mr John Wigglesworth as Director | 26,309,179 | 56,673 | 38,119,900 | 152,000 |

**Questions?**

# CYC AGM 2024 Resolutions

3 That pursuant to and in accordance with section 257C(1) of the Corporations Act, as amended, and for all other purposes, the shareholders approve, with effect from when the Directors make the relevant announcement to the ASX, the on-market buy-back of up to 25% of the fully paid ordinary shares in the Company expiring on the anniversary of the passage of this resolution and otherwise on the terms and conditions set out in the Explanatory Statement.

| Resolution | For | Against | Discretionary | Abstain |
|---|---|---|---|---|
| Share Buy-back | 26,443,759 | 84,716 | 38,099,277 | 10,000 |

## Questions?

# CYC AGM 2024 Resolutions

4 That the Cyclopharm Loan Share Plan (LSP), a summary of which is set out in the Explanatory Statement, be approved for the purposes of ASX Listing Rule 7.2 (Exception 13), sections 200E, 259B(2) and 260C(4) of the Corporations Act and for all other purposes.

| Resolution | For | Against | Discretionary | Abstain |
|---|---|---|---|---|
| Approval of Loan Share Plan | 23,699,592 | 243,825 | 37,973,457 | 2,589,435 |

**Questions?**

# 2024 AGM – Proxy Summary

| Resolution | For | Against | Discretionary | Abstain |
|---|---|---|---|---|
| 1(b) Remuneration Report | 23,716,701 | 84,566 | 37,988,457 | 155,923 |
| 2 Election of Mr John Wigglesworth as Director | 26,309,179 | 56,673 | 38,119,900 | 152,000 |
| 3 Share Buyback | 26,443,759 | 84,716 | 38,099,277 | 10,000 |
| 4 Approval of Loan Share Plan | 23,699,592 | 243,825 | 37,973,457 | 2,589,435 |

# BUSINESS Q&A

# THANK YOU

# Appendix

# Technegas® Aerosol for Inhalation

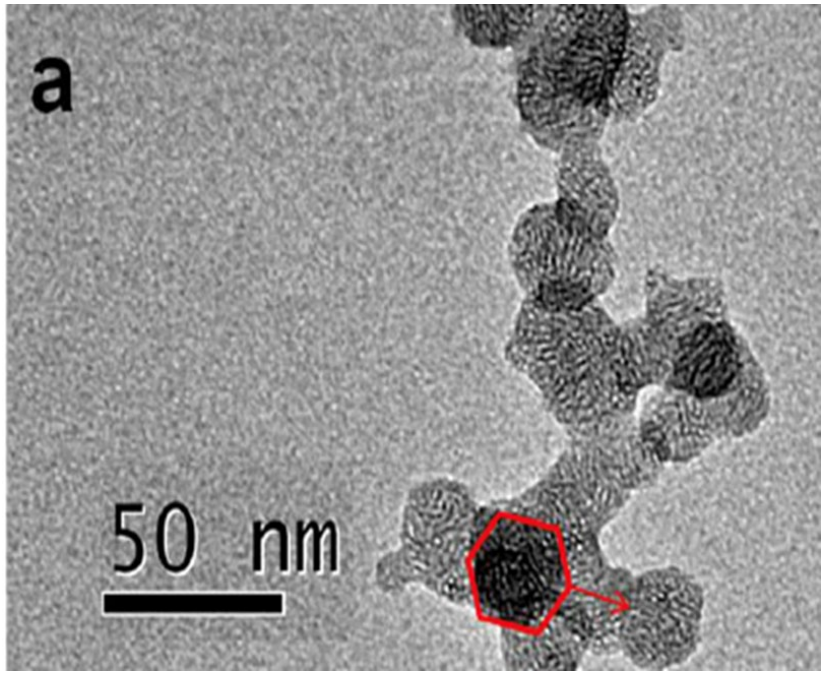
## Functional imaging of Oxygen distribution within the lung

Image source:
Blanc-Béguin et al, 2020

Technegas® is composed of 99mTc cores encapsulated within layers of graphite to form individual hexagonal plate-like particles.[1-2]

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

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.




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)



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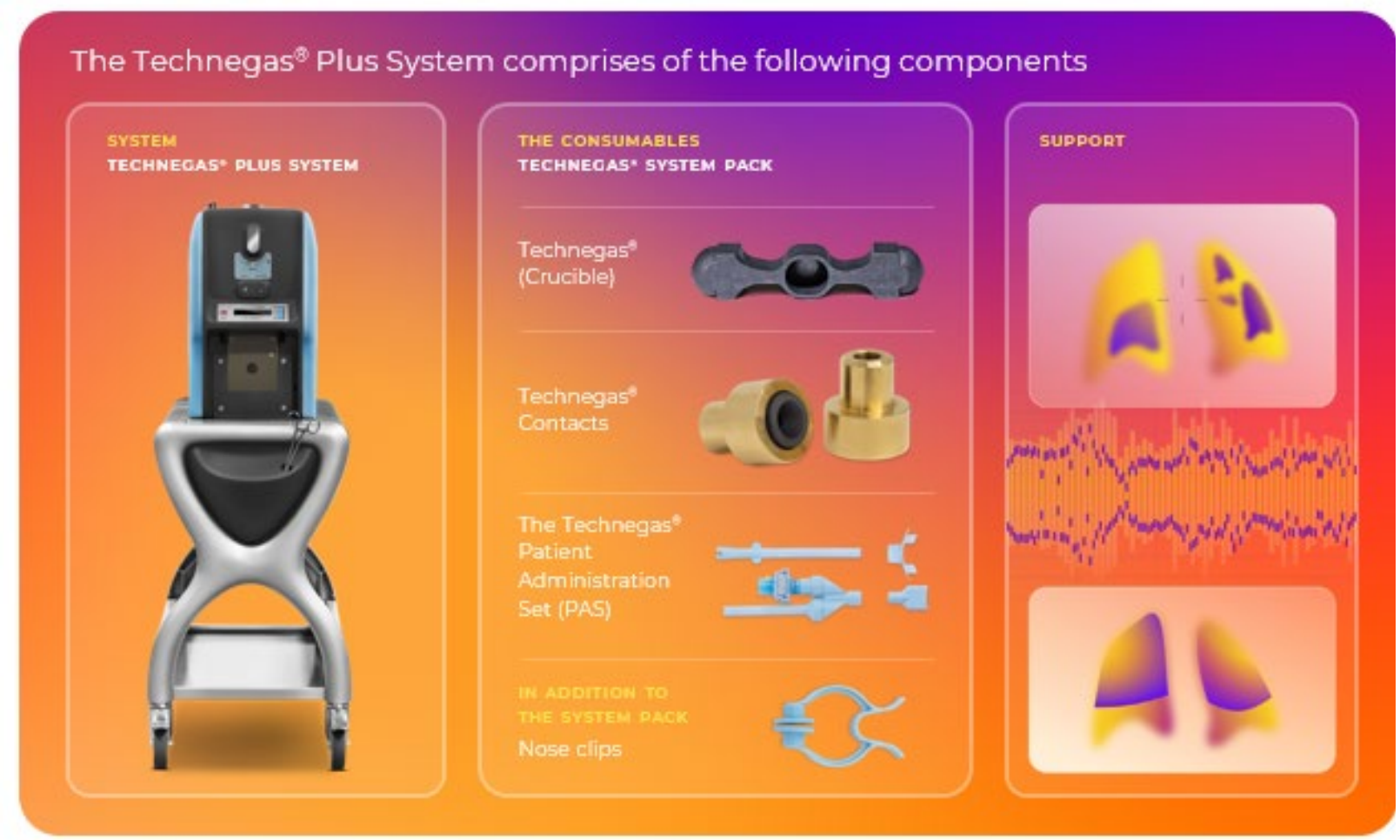
# Overview of the Technegas® Plus System, Patient Consumables and package insert




## USA 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



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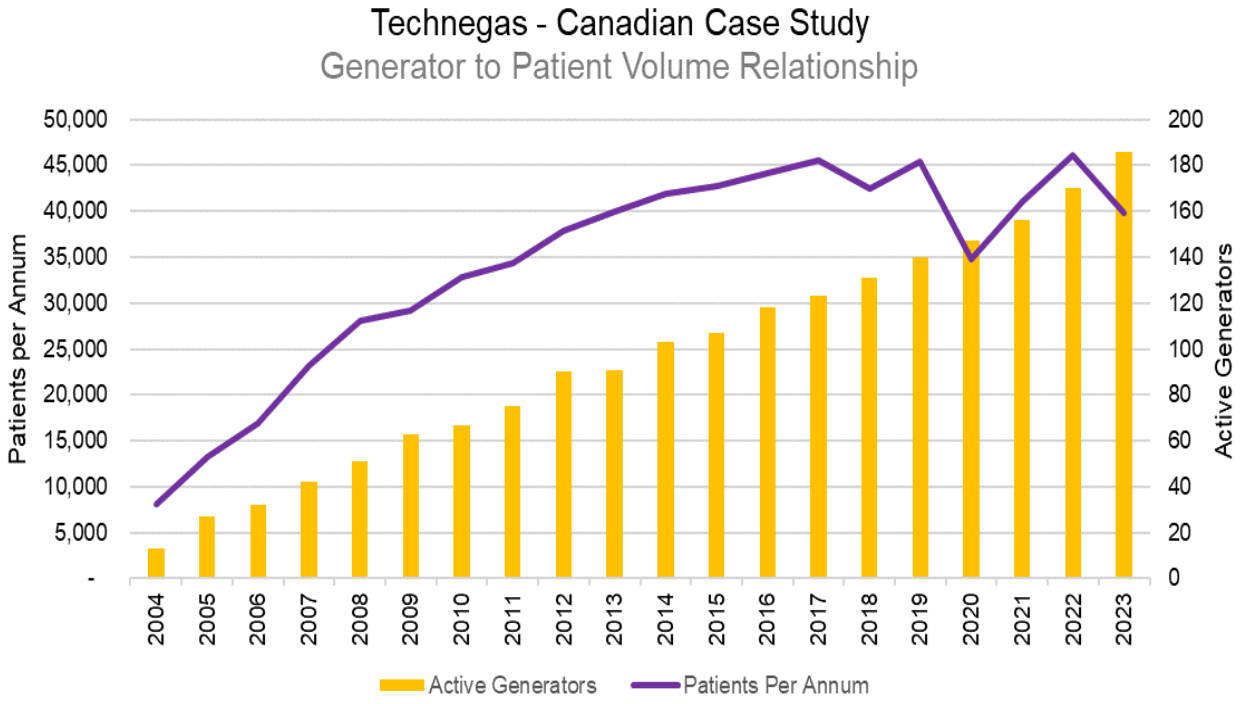
# Track Record - Rapid adoption of Technegas®

## 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



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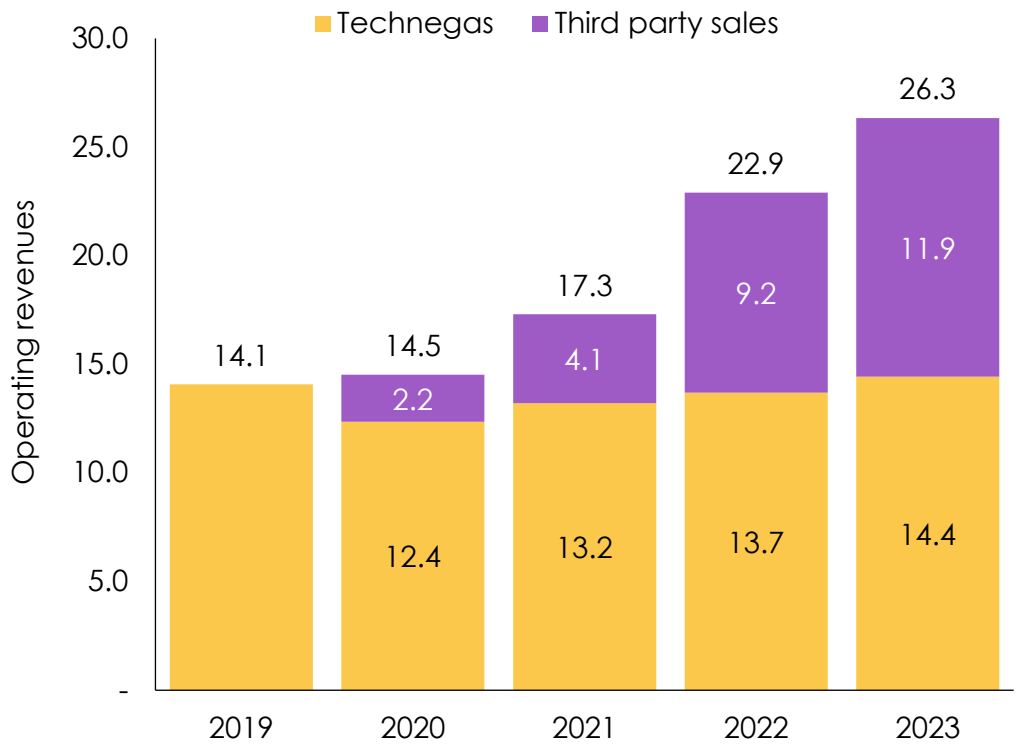
# 2023 Trading Highlights and Underlying Business

## An established global nuclear medicine company

### Cyclopharm 2023 Trading Highlights

| | |
|---|---|
| **Technegas** | Sales increased 5.6% to $14.4m |
| **Third Party Distribution** | $11.9m 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 |

### Cyclopharm operating revenues over time



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