

# Company Update

18 March 2025

James McBrayer CEO & Managing Director Jason Smith Chief Financial Officer

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# Agenda

- 2024 Overview & Financial Results
- Third Party Distribution
- Technegas Technology
- USA Update
- Beyond PE
- Q&A







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





# 2024 Overview



# Technegas around the world



Technegas was introduced clinically in **1986.** New era of Technegas imaging developing driven by A



Technegas generators are available now in 66\* countries. Direct distribution in 17 countries

**₽=** 

Over **5.0 million** patient procedures to date



Leveraging global infrastructure with **Business Partner Product** distribution



# A World Leading Diagnostic Imaging Company

Ramp up of **US sales of Technegas accelerating**, with key opinion leaders emerging as early adopters and revenue up 131% in the second half of 2024 compared to the first half.

Technegas installed at 17 US sites in 2024 with a further building upon a strong and growing opportunity pipeline.

Technegas US growth underpinned by **Pass Through reimbursement** through in the Center for Medicare and Medicaid Services (CMS) for clinical use.

Technegas now in 66 countries and a **strong second half** of 2024 supported **record global sales up 5%** on the prior corresponding period (pcp).

Continued **growth in Third-Party distribution sales**, including an **increase of 57%** in the second half, to deliver a 4% increase in revenues on the pcp.

Cyclopharm's **Beyond PE strategy** to expand the use of Technegas<sup>™</sup> validated by ongoing clinical trials, including a **new French trial** into residual pulmonary vascular obstruction.

Successful **\$20 million Capital Raising** followed by over-subscribed **\$4 million Share Purchase Plan** in 2024 underscores shareholder support for Cyclopharm's growth strategy.

Strong balance sheet with \$20.6 million of net cash at 2024-year end to support US growth.

**2025** commenced with **significant US sales and supply contracts secured** to allow the ease of adoption of Technegas across public and private hospitals.





# 2024 Full Year Financial Results

### 2024 Financial Overview



<b>Record Sales Revenue</b>	\$27.6m up 5% from \$26.3m in the pcp			
Technegas	Global sales revenue up 5% from the pcp to \$15.2 million, with a strong second half up 14%, driven by initial US sales.			
3 <sup>rd</sup> Party Distribution	Global revenue up 4% from the pcp to \$12.4 million			
Technegas US	<ol> <li>Initial US Technegas sales drive 5% increase in group revenue</li> <li>Total US sales of \$827k includes 131% growth in 2<sup>nd</sup> half sales</li> <li>2<sup>nd</sup> half driven by early adoption by Key Opinion Leaders</li> </ol>			
Net Loss After Tax	\$13.2m loss up 181% on \$4.7m loss in the PCP, which benefited from \$4.5 million of positive adjustments			
Balance Sheet	\$20.6 m of cash reserves as @ 31 December 2024 to drive our growth strategies			



# 2024 Trading Overview and Underlying Business

#### 2024 Trading Highlights

Technegas	<ul> <li>Underpinned by PAS<sup>1</sup> sales delivering 72.6% of revenue compared to 70.7% in the pcp</li> <li>55 system sales compared to 58 in the pcp (excluding USA)</li> </ul>
Third Party Distribution	<ul> <li>Capital projects revenue up 83% in the 2<sup>nd</sup> half but overall was down 35% on the pcp</li> <li>Consumables and service revenue was up 26% overall, including a strong 2<sup>nd</sup> half, up 54% on the pcp</li> </ul>
Regulatory Renewals	All regulatory renewals in existing 66 country markets maintained
Indication Expansion	Existing 'Beyond PE' clinical trials progressing. French trial use of Technegas™ to improve detection of residual pulmonary vascular obstruction initiated

#### Group Revenue Trend by Category (last 3 years)





<sup>1</sup> Patient Administration Set (PAS) box equals 50 patient Technegas™ procedures.



# Third-Party Products Overview



# **Overview of Third-Party Products**

### Leveraging our Sales, Service & Regulatory Footprint in our Direct Markets

Third-Party Products comprise the following components



Direct sales and Service in 17 out of 66 approved markets

> Equipment sales – tender / project driven (non-linear)

Razor - Razorblade Model business model with consumables linked to equipment sales

Pharmaceutical wholesale licenses required





# Technegas Overview

### Technegas – Proven Technology

Technegas is **the** nuclear medicine functional ventilation imaging **agent of choice** - Technegas shows **true functional ventilation** with operational and clinical advantages over competitive agents<sup>4</sup>.

Technegas **unlocking the clinical potential** of lung imaging by leveraging **state of the art techniques** (SPECT, SPECT/CT & analytical software with AI)<sup>1,2</sup>.

Nuclear Medicine delivers **superior clinical outcomes** in diagnosing PE at **exponentially lower** radiation dose than CTPA<sup>3</sup>.

Nuclear medicine with Technegas paired with **AI** and analytical software, is unlocking **a new era** in lung imaging.

Hess S, et al. Semin Thromb Hemost 2016; 42(8): 833-845
 Reinartz P, et al. J Nucl Med 2004; 45: 1501-1508
 Leblanc M, et al. CANM guidelines; Nov 2018: www.canm-acmn.ca/guidelines
 Le Pennec, et. al. Clinical Nuclear Medicine 49(11):p 997-1003, November 2024. | DOI: 10.1097/RLU.00000000005396

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### Technegas Aerosol for Inhalation

### Functional Imaging showing where Oxygen is distributed within the lung



Technegas is manufactured by heating Technetium-99m in a carbon crucible within an argon environment for a few seconds at

Technegas is composed of 99mTc cores

Image source: Blanc-Béguin et al. 2020 Its very small particle size (>80 less than 1 micron or 1,000 nm<sup>4</sup>) allows distribution into the lungs like a gas and deposited in alveoli by diffusion, providing for Planar, SPECT and SPECT/CT ventilation imaging.



#### How big is a nanometre?

- 100,000 nm = Sheet of paper thickness
- 75.000 nm = Human hair thickness
- 7,000 nm = Red Blood Cell diameter
- 2.5 nm = DNA strand diameter



- 1. Wiebe LI, et al. Current Radiopharmaceuticals 2010; 3(1): 49-59
- Blanc-Béguin F, et al. Mol Imaging Biol 2020;
- Lemb M, et al. Eur J Nucl Med 1993; 20(576-579)

Pharmaceutics 2023, 15(4), 1108; https://doi.org/10.3390/pharmaceutics15041108

### Technegas – Proven Technology

### Unique Drug + Device + Service combination = regulatory barrier to entry

#### Technegas comprises the following components



USFDA Drug-Device Combination product

Razor - Razorblade Model business model

Per-patient consumables drive an annuity-like revenue stream

All Technegas components are manufactured / assembled by Cyclopharm



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





# Nuclear medicine published Survey

Technegas - the ventilation imaging agent of choice in established markets

ORIGINAL ARTICLE

### Performance and Interpretation of Lung Scintigraphy

An Evaluation of Current Practices in Australia, Canada, France, Germany, and United States

Romain Le Pennec, MD, \* Wolfgang Schaefer, MD, PhD, † Mark Tulchinsky, MD, ‡ François Lamoureux, MD, § Paul Roach, MD, PhD,// Christoph Rischpler, MD,¶ Katherine Zukotynski, MD, PhD, \*\* Christopher O'Brien, MD PhD, †† Declan Murphy, MD,// Pierre Pascal, MD, ‡‡ Grégoire Le Gal, MD, PhD,§§ Pierre-Yves Salaun, MD, PhD, \* and Pierre-Yves Le Roux, MD, PhD\*

- *"The most striking result of this survey is the discrepancy in practices in the United States compared with other countries.....*
- *"The different physical physiological properties of ventilation agents may explain the differences in the choice of acquisition protocols (in the USA).....*
- *"The recent FDA approval of <sup>99m</sup> Tc-Technegas may change practices....."*

Survey conducted before Technegas USA launch highlights that:

- 85% of nuclear medicine ventilation studies ex-USA are performed using Technegas
- Xenon-133 has been displaced in all markets where Technegas is available
- SPECT imaging used in >95% outside the USA vs 32% in the USA
- Some USA nuclear medicine departments have not resumed ventilation imaging since COVID
- Beyond PE applications gaining traction in CTEPH, Interventional Respiratory medicine, radiation therapy planning, lung transplant & PE follow-up





# Technegas USA Expansion

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# Broad Indication for use approved by USFDA

Potential applications across the entire field of respiratory medicine

Technegas (kit for the preparation of technetium Tc99m labeled carbon inhalation aerosol) for oral inhalation use – NDA 022335

------USFDA APPROVED 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

# Overview of the US market opportunity

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

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**Estimated 4,000,000 pulmonary embolism procedures** in the USA p/a (15% Nuclear Medicine / 85% CTPA)

~600,000 (15%) Nuclear Medicine procedures represents an initial **US\$90m** addressable market

Initial target for Technegas<sup>®</sup> ~480,000 patient procedures

Technegas expected to **displace Xe133 followed by DTPA** as the standard of care nuclear medicine diagnostic product in the US

3D SPECT imaging using Technegas is proven to be **clinically superior** and safer than CTPA\*\*

Cyclopharm's target is to **double the existing nuclear medicine PE market** in the US, which is dominated by CTPA, from 15% to 30% increasing the addressable market for PE to US\$180m

US entry expected to drive our **Beyond PE** strategy leveraging **AI** 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

# USA Implementation Update

### Establishing a Network of Key Opinion Leader (KOL) Locations





# Understanding the US Opportunity

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# US Economic Model

### Placement Model to Expedite Consumable Demand

- **US\$7k** one-off installation and training fee
- US\$7k p.a. technology fee, includes servicing
- Annuity Revenue Per patient fee for consumables (sold in 50 patient units)
- **US\$70k** revenue per system per annum expected from larger sites<sup>1</sup>
  - >15 yrs average life per system

- Targeting 2,000 of the 8,000 US nuclear medicine departments. 250-300 total installations achieved during the second half 2026.
- System Placement model supports rapid uptake by US customers by removing the 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
- Modest cost base for US roll-out ~US\$6.5m operating costs per annum in 2025
- High consumable annuity gross **margins** expected at **greater than 80%**
- \$180m USD market for diagnosing PE. Beyond PE applications to significantly grow the global market

Calculation based on expected demand and market price for competing products (e.g. Xe133).

## Total value creation opportunity

### Exponential Growth Opportunity Over The Next Decade

	Pulmonary Embolism:	Timeline	USA PE Market Share	Market size
	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*
		Timeline		
	Beyond Pulmonary Embolism:	Timeline Global		Market size
3	<b>Beyond Pulmonary Embolism:</b> <b>Horizon 3</b> – Expanding Beyond PE Globally into new indications such as asthma and chronic obstructive pulmonary disease			<b>Market size</b> US\$900m



\*Assumes Combined Nuclear Medicine and CTPA Market



# Beyond PE: Blue Sky

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### Beyond PE applications

### Clinical trials already underway



\*Including PE applications. On a long-term basis. See Slide 26 'Horizon 3 for further details.

- Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596
- Ohira H, et al. J Nucl Cardiol 2015;22(1): 141-157
- Hsu K, et al. J Bronchology Interv Pulmonol 2018; 25(1): 48-53 11. 3 Mortensen J, Berg RMG. Semin Nucl Med 2019; 49(1): 16-21 Δ
- Wechalekar K, et al. Semin Nucl Med 2019; 49(1): 22-30 -5
- Elojeimy S, et al. AJR Am J Roentgenol 2016; 207(6): 1307-6. 1315
- 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.
- 10. Bajc M, et al.. Int J Chron Obstruct Pulm Dis 2017; 12: 1579-17. 1587
- 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- 20. 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
- Jögi J, et al. Int J Chron Obstruct Pulmon Dis 2014; 10: 25-30 16. Ozguven, S, et al; Mol Imag Rad Therapy; 2021: 30:28-33

- Tee, et al; Intrevent Pulmonology; 2021, DOI 10.1159/000515336
- Le Roux, et al, J Nuc Med July 2022, 63 (7) 1070-1074 18. Berhouse, et al, Respiratory Research 2022; 23: 296 19. Ridiadia, et al, ATS Abstract; doi.org/10.1164/ajrccm-
- conference.2022.205.1\_MeetingAbstracts.A2554 Venegas C, et al, ATS Abstract; doi.org/10.1164/airccm-21. conference.2022.205.1
- 22. Le Roux, et al; Clinical Nuclear Medicine, 27 Oct 2022; doi: 10.1097/RLU.000000000004426



# Beyond Pulmonary Embolism CYC Initiatives

#### 7 Cyclopharm sponsored Beyond PE clinical trials – US approval expected to drive clinician led studies

**Hunter Medical Research Institute (Newcastle, AU):** Diagnosis and response to therapy in severe asthma and COPD<sup>1 -</sup> 100 Patient Study \* 100% Recruited \* **Study Published6**,

- Woolcock Institute (Sydney, AU): Diagnosis and response therapy in mild to moderate COPD<sup>3</sup> 44 Patient\* 100% Completed
- **CHUM (Montreal, CA):** Early detection of COPD in asymptomatic smokers<sup>4</sup> 30 Patient Study \* 100% Recruited \* Analysis complete \* Paper submitted for publication
- Dalhousie (Halifax, CA): Post-lung transplant patients 30 Patient Study \* 30% Recruited

PATIENT MANAGEMENT & SCREENING Response to Therapy INTERVENTIONAL THERAPIES LVRS, ELVR, Transplant, Lung Cancer CHRONIC AIRWAY DISEASES COPD – Asthma PULMONARY EMBOLISM (PE) VTE – CTEPH - PH

**McMaster University Firestone Institute (Hamilton, CA):** Ventilation in lung cancer patients pre and post lung resection <sup>2</sup>; 100% Recruited \* **Study Published** bridging research initiatives with clinical applications using Technegas .

McMaster University Firestone Institute (Hamilton, CA): COVID-19 Related Lung Ventilation and Perfusion Injury<sup>5</sup>

100% Recruited \* Abstract presented at the American Thoracic Society May 2023 with paper to follow.

**PRONOSPECT (France):** 665 Patient multicentre 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<sup>8</sup>. Recruitment commenced.

- 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

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- 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





# Cyclopharm Investment Case

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### CYCLOPHARM INVESTMENT CASE

### Outlook: 250 - 300 Technegas USA Installations achieved during Second Half 2026



#### Profitable and Growing MedTech

Underlying business (ex-USA) is cash positive



#### First in Class Established Gold Standard

Proprietary product sales to 66 countries with over 5 million patient procedures to date

Clinical Agent of Choice referenced by name in multiple nuclear medicine **clinical guidelines** 

Technegas **IP Expansion** Program Underway



#### **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

Full Reimbursement Granted from 1 July 2024



#### **Recurring Revenue**

From single patient consumables

Similar to an **annuity model** 

Generating **Recurring Revenues** from all USA installations



#### Technegas Product expansion

Indications Beyond PE leveraging AI into chronic respiratory disease management in large uses such as asthma, COPD and lung cancer could deliver exponential growth

Market Development already underway





# Questions

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# Attachment Section

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# Compelling US Clinical Support

### SNMMI Technegas Press Release – USA Catching up with the R.O.W.

### 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://snmmi.org/Web/News/Articles/FDA-Approves-Widely-Used-Imaging-Agent-for-Respiratory-Disease

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# WHAT THE GUIDELINES SAY

### Technegas is the nuclear medicine agent of choice in established markets



Endorsed by the guidelines from the <u>European<sup>1-2</sup></u> and the <u>Canadian<sup>3</sup></u> 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<sup>®</sup> 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 "



<sup>2.</sup> 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

 <sup>33 3.</sup> 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

### Recent USA Nuclear Medicine Publications

### Recent Research and Articles Driven by Clinicians and End Users:

**Technegas** - *Technegas at Last!* Implementing Technegas into Clinical Practice in the United States: Considerations, Challenges, and Recommendations

Delynn Silvestros and Tina M. Buehner; Journal of Nuclear Medicine Technology March 2025, 53 (1) 7-10; DOI: https://doi.org/10.2967/jnmt.124.269231

Comparability of Quantifying Relative Lung Ventilation with Inhaled 99mTc-Technegas and 133Xe in Patients Undergoing Evaluation for Lung Transplantation

Ashwin Singh Parihar, Joyce C. Mhlanga, Henry D. Royal and Barry A. Siegel

Journal of Nuclear Medicine December 2024, jnumed.124.268801; DOI: https://doi.org/10.2967/jnumed.124.268801

Ventilation Lung Imaging: Technegas

Mary Beth Farrell, Kathy S. Thomas, Eleanor S. Mantel and Jessica Settle; Journal of Nuclear Medicine Technology February 2025, jnmt.125.269536; DOI: https://doi.org/10.2967/jnmt.125.269536



### Diagnosing Pulmonary Embolism: V/Q SPECT +/- CT vs CTPA



**Peer Reviewed clinical studies** have shown that V/Q SPECT/CT is **superior** compared to CTPA across most clinical measures with better overall diagnostic performance<sup>1</sup>.



Nuclear Medicine VQ radiation dose, even combined with low dose noncontrast CT, is **exponentially lower** than CTPA

3. Leblanc M, et al. CANM guidelines; Nov 2018: www.canmacmn.ca/guidelines

# Track Record - Rapid adoption of Technegas®

### The Canadian Case Study - a strong indicator of USA acceptance



Canada is Cyclopharm's largest single country market to date

Technegas® is market leader for diagnosing PE and is nearing 100% nuclear medicine market share

Xe-133 rapidly displaced by early adopters

Close correlation with the number of active generators and annual consumable sales

Market launch initiated province by province, leveraging off pilot sites

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

# Nuclear Ventilation Imaging Agent Comparison







### Indication Expansion

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The importance, urgency and opportunity 'Beyond PE" underway



Lung Disease in 2019 accounted for 6 million deaths worldwide (12% of all deaths)

COPD and Lower Respiratory Infections and Lung Cancer will be the **3rd**, **4th and 6th largest causes of death** by 2030.

"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>"

Misdiagnosis can be **fatal** 

**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