

# CYCLOPHARM

# 2021 Annual General Meeting

4 May 2021

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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.





# Welcome

Mr David Heaney





# CHAIRMAN'S ADDRESS

Mr David Heaney



# **TECHNEGAS® AROUND THE WORLD**

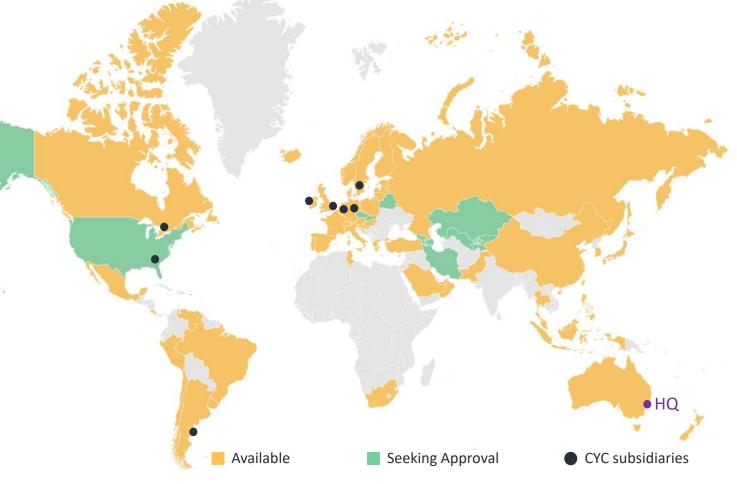
Technegas<sup>®</sup> was introduced to the medical community **in 1986** 



#### Technegas<sup>®</sup> revenues are generated in over **60 countries** via a combination of direct and distributor sales models



Over **4.3 million** patient procedures to date







## MANAGING DIRECTOR'S ADDRESS

Mr James McBrayer





2020 Financial Highlights

Sales Revenue	Record Group Sales revenue of \$14.7m, up 4.2%
Third Party Distribution	\$2.2 million of new third-party distribution revenue
Net Loss Before Tax	\$5.8 million loss (includes \$3.9m from USFDA expenses + Forex on refunded FDA fees)
R&D Tax Incentive	\$3.0 million received in Feb 2021
USFDA Expenses	\$3.3 million in 2020 vs \$3.8 million in 2019
Dividends	FY20 total dividends maintained at 1.0 cps
Feb 2021 Capital Raising	Placement & SPP oversubscribed, raising \$33m





2020 Operating Highlights

Covid Recovery	Technegas™ sales rebound by 51.4% in 2H after pandemic impacted first half
USFDA	Phase 3 trials confirmed to meet Primary and Secondary Efficacy Endpoints in Sept 2020
US Commercialisation	Investing to build inventory reserves; distribution, service and installation outsourcing providers identified and administrative support in place
Market Expansion	Technegas now supplied to 60 countries. New offices established in Belgium and the UK
Beyond PE	Progressed trials for new clinical applications providing long term growth opportunities



# **BUILDING FOR GROWTH**

2019 Rev Generator 15% Service 9% Consumable 2020 Rev 76% Generator 17% Service 10% Consumable 73%



Technegas<sup>®</sup> is a substantially **de-risked** commercial proposition with significant upside in the **USA market** 

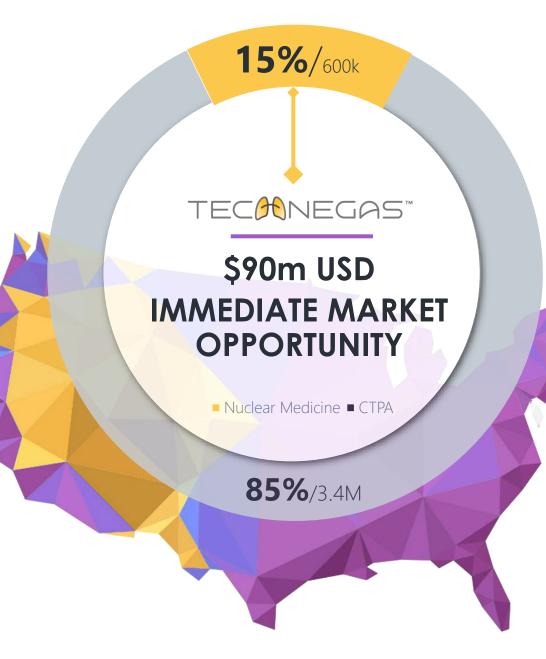
- Total global sales of over \$80m AUD from 2015 to 2020
- Technegas<sup>®</sup> currently available in over **60 countries**
- Over 4,300,000 patient procedures performed since first approved
- 1,600 Technegas<sup>®</sup> generators sold globally since first approved
- Europe represents 57% of global revenue in 2020
- Canada was the largest single country market by volume followed closely by
  France
- CYC's **underlying business is profitable,** and the company has a history of paying **dividends**.
- Stable gross margins of greater than **75%** (76% in 2020)
- Over 70% of historical revenue is recurring consumable sales (73% in 2020)
- ROW Revenues (ex USA) are expected to gradually return to pre-COVID19 levels in the second half of 2021
- Significant COVID-19 tailwind resulting from safety concerns that exist with competitive nuclear medicine products
- Generator **placement rollout strategy** to be deployed for rapid USA market penetration and USFDA compliance
- Significant USA immediate demand



# TECINEGAS

# COMING TO AMERICA IN 2021



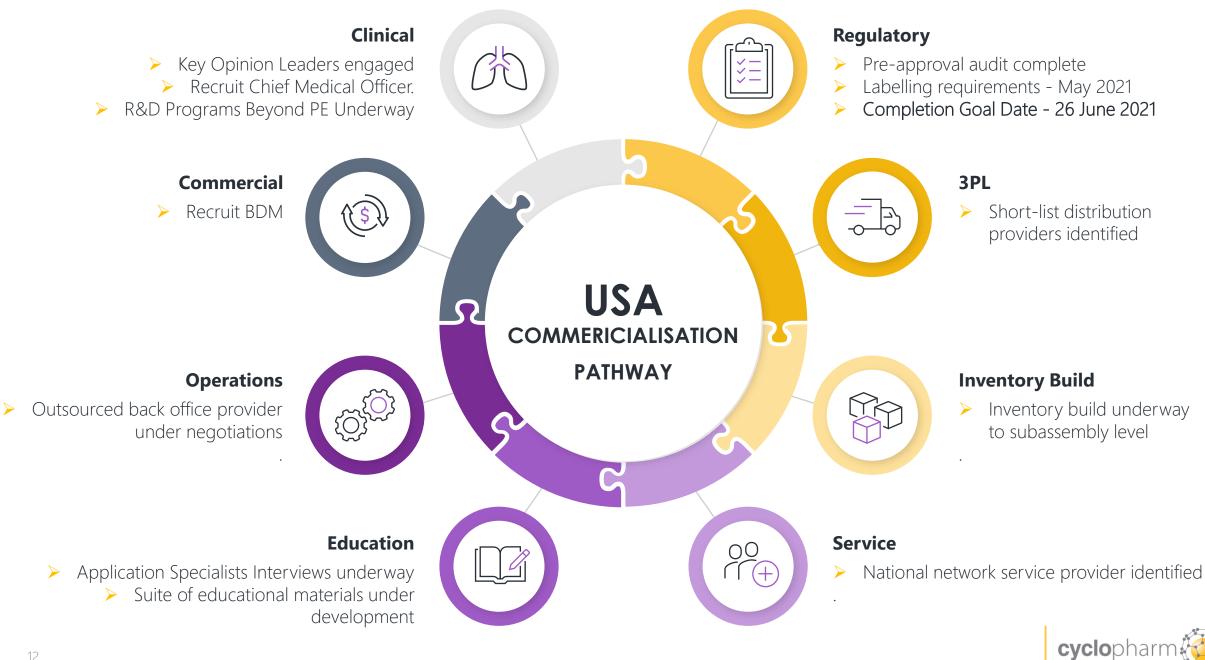




#### 600K Nuclear Medicine Ventilation Procedures p.a.

- 4,000,000 patient procedures conducted in the USA per annum to diagnose pulmonary embolism (15% Nuclear Medicine 85% CTPA)
- 600,000 Nuclear Medicine Ventilation procedures equals \$90m USD
- Target market for Technegas<sup>®</sup> in the USA equates to ~480,000 patient procedures of the total 600,000 procedures.
- The USA represents the single largest market for Technegas<sup>®</sup> with half of the world's nuclear medicine departments
- Subject to a successful FDA approval, the Company is targeting US commercialisation in 2021
- First priority following USFDA approval is to repeat our Canadian experience by first **displacing Xe133 followed by DTPA** as the standard of care diagnostic product
- 3D SPECT imaging using Technegas<sup>®</sup> is proven to be **clinically superior and safer than CTPA**. Once commercialised Cyclopharm will target to **double the existing nuclear medicine PE market** dominated by CTPA from **15% to 30%**.
- Once established in the USA market, the company will seek to expand the use of Technegas<sup>®</sup> into disease states exponentially larger than the existing markets **Beyond PE**
- COVID-19 tailwind







# **USA Pricing & Business Model**



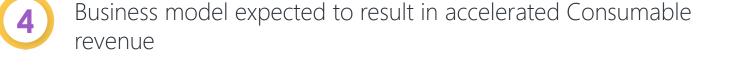


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Generators are to be placed at no cost removing potential CAPEX roadblocks

Once off installation and training fee charged

Ongoing annual fee attributed to preventative maintenance, training and product support





# **USA Demand Established**

#### No requirement for large sales team due to pre-approval demand

9 sites in the US already have generators installed from clinical trials

Multiple letters from leading clinicians and front-line workers petitioning the USFDA to expedite approval of Technegas™. The most recent correspondence sent to the USFDA on 21 January 2021 from the 16,000-member SNMMI requesting 'Fast Track Approval' for Technegas™.

Demand already established in the US from:

- Extensive body of clinical evidence underscoring clinical superiority
- ROW evidence in 60 countries
- Well known technology globally with the support of KOL's
- ✓ COVID-19 safe as compared to competing nuclear medicine products

US based sales, technical training and accounts team <10 FTE's in the first year

Unlike most newly approved medical devices, our focus will be on installation and training staff, as opposed to a large sales team due to inbound demand

Distribution, Installation and service to predominantly to be outsourced – keep fixed cost base low, can scale up or down easily

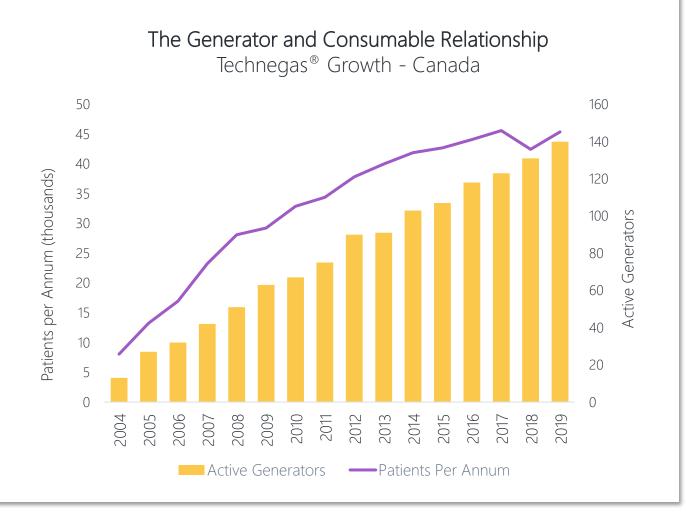
Reimbursement is already established – reimbursement is based on procedure codes as opposed to product codes



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# **TECHNEGAS®** The Canadian Case Study



#### Canada is Cyclopharm's largest single country market

Market leader for diagnosing PE

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- 14 consecutive years of pre-Covid19 procedure growth
- Represents a strong indicator of USA acceptance

Xe-133 rapidly displaced by early adopters

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

Market driven by public healthcare sector

Market launch initiated province by province, leveraging off pilot sites



# $\frac{\mathsf{EXPANDING}}{\mathsf{NDICATIONS}}$



# **Building from Strong Foundations!**

# What The Guidelines Say About TECHNEGAS<sup>®</sup>:

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)

- 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
- 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
- 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

" 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 "

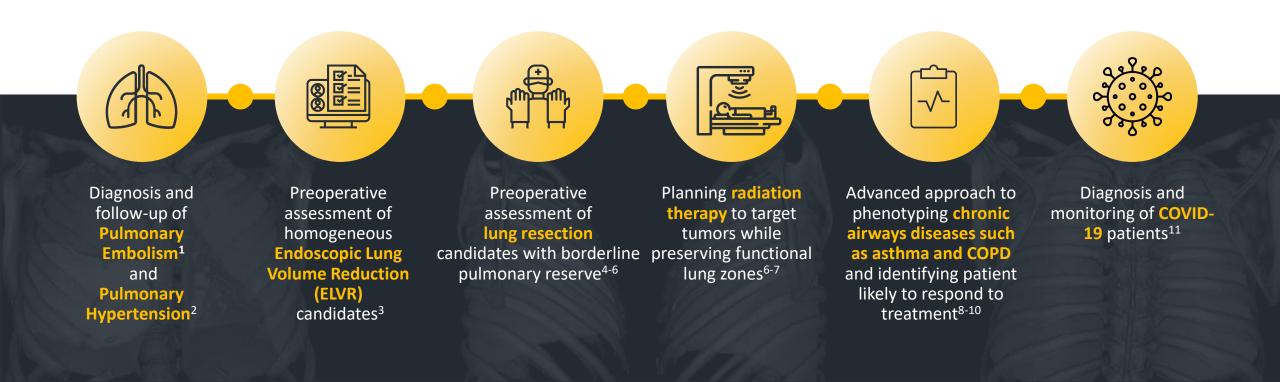
" Because of the very small particle size, this agent is distributed in the lungs almost like a gas and deposited in alveoli by diffusion, where they remain stable, thus **providing the best possible images for ventilation** SPECT "

" 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 "



# **Beyond PE applications of V/Q SPECT(/CT)**



- 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

Technegas<sup>®</sup> is a registered product of Cyclomedica Australia Pty Ltd Technegas<sup>®</sup> is not clinically available in the USA



18



#### In recent literature

- 1. King GG, et al. Dismantling the pathophysiology of **asthma** using imaging. Eur Respir Rev 2019; 28(152): pii: 1801111
- 2. Yang L, et al. Changes in ventilation and perfusion following lower lobe endoscopic lung volume reduction (ELVR) with endobronchial valves in severe COPD. Clin Respir J 2019; [Epub ahead of print].
- 3. Kjellberg M, et al. Ten-year-old children with a history of bronchopulmonary dysplasia have regional abnormalities in ventilation perfusion matching. Pediatr Pulmonol 2019; 54(5): 602-609
- 4. Paludan JPD, et al. Improvement in image quality of Tc-99m-based ventilation/perfusion single-photon emission computed tomography in patients with chronic obstructive pulmonary disease through pretest 20. Righini M, et al. Diagnosis of acute pulmonary embolism. J Thromb Haemost. 2017; 15: 1251-1261 continuous positive airway pressure treatment. World J Nucl Med 2019; 18(2): 185–186
- 5. Myc LA, et al. Role of medical and molecular imaging in COPD. Clin Transl Med 2019; 8(1): 12
- 6. Ling T, et al. Ventilation/perfusion SPECT/CT in patients with severe and rigid **scoliosis**: An evaluation by relationship to spinal deformity and lung function. Clin Neurol Neurosurg 2019; 176: 97-102
- 7. Farrow CE, et al. SPECT Ventilation imaging in asthma. Semin Nucl Med 2019; 49(1): 11-15
- 8. Mortensen J, et al. Lung scintigraphy in COPD. Semin Nucl Med 2019; 49(1): 16-21
- 9. Sanchez-Crespo A, et al. Lung VQ SPECT in infants and children with nonembolic chronic pulmonary disorders. Semin Nucl Med 2019; 49(1): 37-46
- PE. Semin Nucl Med 2019; 49(1): 4-10
- 11. Sanchez-Crespo A, et al. Lung scintigraphy in the assessment of aerosol deposition and clearance. Semin Nucl Med 2019: 49(1): 47-57
- 12. Bailey DL, et al. V/Q SPECT Normal Values for Lobar Function and Comparison With CT Volumes. Semin Nucl Med 2019; 49(1): 58-61
- 13. Lawrence NC, et al. Ventilation perfusion single photon emission computed tomography: Referral practices and diagnosis of acute pulmonary embolism in the quaternary clinical setting. J Med Imaging Radiat Oncol 2018; 62(6): 777-780.
- 14. Leblanc M, et al. CANM Guidelines for Ventilation/Perfusion (V/P SPECT) in pulmonary embolism.www.canm-acnm.ca/guidelines
- 15. Hsu K, et al. Endoscopic Lung Volume Reduction in **COPD**: Improvements in Gas Transfer Capacity Are Associated With Improvements in Ventilation and Perfusion Matching. J Bronchology Interv Pulmonol. 2018; 25(1): 48-53

#### 66% of references citing Technegas<sup>®</sup> in the past 24 months are for indications Beyond PE



- Dimastromatteo J, et al. Molecular imaging of pulmonary diseases. Respir Res 2018; 19(1): 17 16.
- 17. Jögi J, et al. Diagnosing and grading heart failure with tomographic perfusion lung scintigraphy: validation with right heart catheterization. ESC Heart Fail 2018; 5(5): 902-910
- 18. Waxman AD, et al. Appropriate use Criteria for Ventilation-Perfusion imaging in Pulmonary embolism : Summary and Excerpts. J Nucl Med 2017; 58(5): 13N-15N
- 19. Isidoro J, et al. Radiation dose comparison between V/P SPECT and CT-angiography in the diagnosis of pulmonary embolism. Phys Med 2017; 41: 93-96
- 21. Le Roux PY, et al. New developments and future challenges of nuclear medicine and molecular imaging for pulmonary embolism. Thromb Res 2018; 163: 236-241
- 22. Farrow CE, et al. Peripheral ventilation heterogeneity determines the extent of bronchoconstriction in asthma. J Appl Physiol (1985). 2017; 123(5): 1188-1194
- 23. Tulchinsky M, et al. Applications of Ventilation-Perfusion Scintigraphy in Surgical Management of Chronic Obstructive Lung Disease and Cancer. Semin Nucl Med. 2017; 47(6): 671-679
- 24. Cheimariotis GA, et al. Automatic lung segmentation in functional SPECT images using active shape models trained on reference lung shapes from CT. Ann Nucl Med. 2017; 10: 25-30
- 10. Bajc M, et al. Ventilation/Perfusion SPECT Imaging Diagnosing other cardiopulmonary diseases beyond 25. Bajc M et al. Identifying the heterogeneity of COPD by V/P SPECT: a new tool for improving the diagnosis of parenchymal defects and grading the severity of small airways disease. Int J Chron Obstruct Pulmon Dis 2017; 12: 1579-1587
  - 26. Nasr A, et al. Ventilation defect typical for COPD is frequent among patients suspected for pulmonary embolism but does not prevent the diagnosis of PE by V/P SPECT. EC Pulmonology and Respiratory Medicine. 2017; 4(3): 85-91
  - 27. Provost K, et al. Reproducibility of lobar perfusion and ventilation guantification using SPECT/CT segmentation software in lung cancer patients. J Nucl Med Technol 2017; 45(3): 185-192
  - 28. Metter DF, et al. Current status of ventilation-perfusion scintigraphy for suspected pulmonary embolism. AJR Am J Roentgenol 2017; 208(3): 489-494
  - 29. Stubbs M, et al. Incidence of a single subsegmental mismatched perfusion defect in SPECT and planar ventilation/perfusion scans. Nucl Med Commun 2017; 38(2): 135-140
  - 30. El-Barhoun EN, et al. Reproducibility of a semi-guantitative lobar pulmonary ventilation and perfusion technique using SPET and CT. Hell J Nucl Med 2017; 20(1): 71-75

# **BEYOND PE : Clinical Initiatives**

Clinical Trials Sponsored by Cyclomedica

- Hunter Medical Research Institute (Newcastle, AU): Diagnosis and response to therapy in severe asthma and COPD<sup>1</sup>
- Woolcock Institute (Sydney, AU): Diagnosis and response therapy in mild to moderate COPD<sup>3</sup>
- CHUM (Montreal, CA): Early detection of COPD in asymptomatic smokers<sup>4</sup>
- Dalhousie (Halifax, CA): Post-lung transplant patients
- McMaster University Firestone Institute (Hamilton, CA): Prevalence and clinical relevance of ventilation heterogeneity and luminal cellular inflammation in lung cancer patients pre and post lung resection<sup>2</sup>
- McMaster University Firestone Institute (Hamilton, CA):
  COVID-19 Related Lung Ventilation and Perfusion Injury<sup>5</sup>

Other Non-Sponsored Clinical Initiatives

- Macquarie University (Sydney, AU): ELVR with endobronchial valves in severe COPD patients
- Macquarie University (Sydney, AU): Bronchial Thermoplasty procedure in asthma patients



#### INTERVENTIONAL THERAPIES LVRS, ELVR, Transplant, Lung Cancer

CHRONIC AIRWAY DISEASES COPD – Asthma

PULMONARY EMBOLISM (PE) VTE – CTEPH - PH

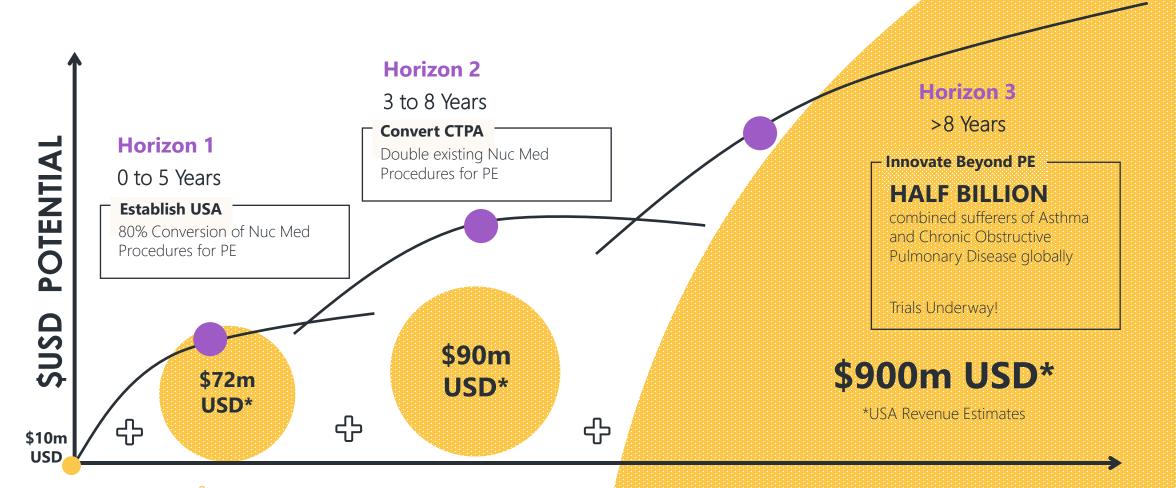
<sup>1.</sup> ACTRN12617001275358 - Can functional lung ventilation imaging identify treatable traits in obstructive airway disease?

<sup>2.</sup> https://clinicaltrials.gov/ct2/show/NCT04191174?term=technegas&draw=2&rank=3

<sup>3.</sup> http://investor.cyclopharm.com/site/PDF/1561\_0/BetterDefiningAirwaysDiseasewithTechnegas

https://ichgcp.net/clinical-trials-registry/NCT03728712
 https://clinicaltrials.gov/ct2/show/NCT04549636

# **THREE REVENUE HORIZONS**



Jose .



## KEY Catalysts for the Next 2 Years



FDA approval for Technegas expected mid 2021

First sales in US announce (shortly after approval)

Ongoing updates on No. Generators placed in US



2

Additional guidelines and clinical papers to come out on the use of Technegas in both pulmonary embolism and additional indications



# 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 60 countries with over 4.3 million studies to date

Clinical Agent of Choice referenced by name in multiple clinical guidelines

#### **Recurring Revenue**

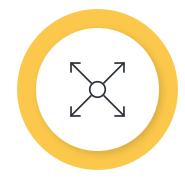
From single patient consumables Similar to an annuity model



#### USFDA Approval

Set to quadruple the size of the existing PE business, based on significant existing demand with a COVID-19 as an accelerator.

> Further leverage penetration into the CTPA market



#### Optionality

Into indications beyond PE into chronic respiratory disease management could deliver exponential growth





## Business Q&A

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# FORMAL BUSINESS

Mr David Heaney



# 2021 AGM – Formal Business



(a) Financial Statements(b) Remuneration Report

Re-election of Director – Mr Tom McDonald

Ratification of the Prior Issue of Placement Shares

Approval of Loan Share Plan

Amendment of Constitution

Approval of Non-executive Director Remuneration



# **Online Attendees – Registration Process & Voting**

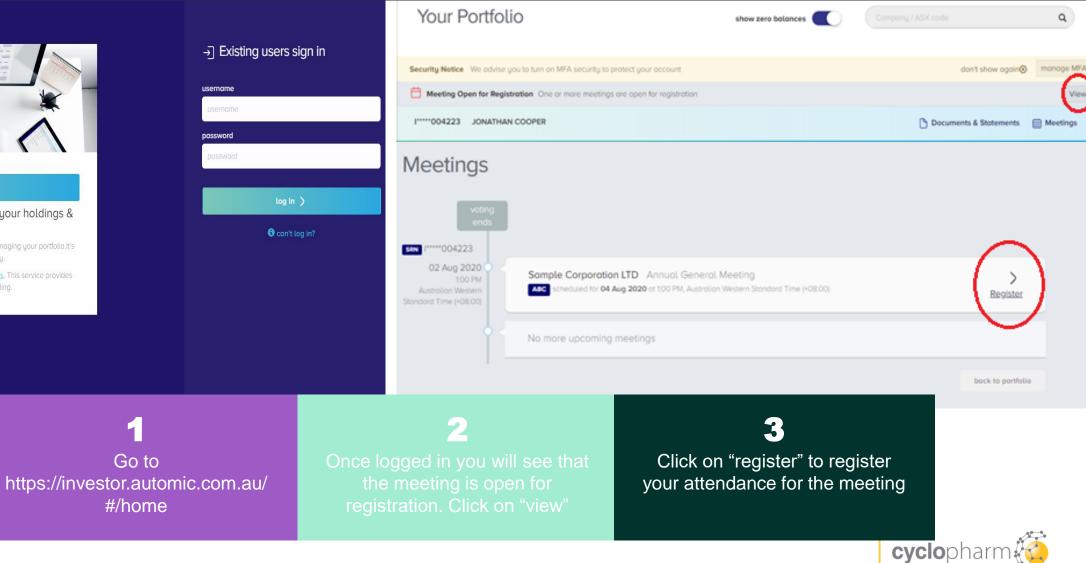


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Sign up and add your HIN/SRNs to start managing your portfolio.It's fast, secure, and easy.

Please click here for <u>Single Holding Access</u>. This service provide limited access to a holding.



# **Online Attendees – Registration Process & Voting**

Registration	Voting
Sample Corporation LTD - Annual General Meeting	TBC Sample Corporation LTD - Annual General Meeting
Complete - Step 2 of 2 Registration Complete! The voting is not open yet. Refresh this page or come back here later. You can join the meeting online using the following link https://us02web.zoom.us/j/85784417406?pwd=TFF0TTdGTEhGSENIbUN5NzF3bJJUOT09;	Refeesh    Poll - Step 1 of 3      Refeesh    You can join the meeting online using the following link: https://us02web.zoom.us/J857844174067pwd.rTFF0TTdGTEhGSENIbUN5NzF3bLUUCTO9:      Nu must vote on all resolutions, except for those minisked as withdrawn.      1    Remuneration Report      2    Re-Election Of Jonathan Cooper as Notional Head of Client Services
4 Once the Chair of the Meeting declares voting open, you should select "refresh"	5 To vote simply select the direction in which you would like to cast your vote, the selected option will change colour.
	<b>cyclo</b> pharm 🖗

1 That the Remuneration Report as set out in the Annual Report of the Company for the financial year ended 31 December 2020 be adopted.

Resolution	For	Against	Discretionary	Abstain
1(b) Remuneration Report	27,808,324	67,474	29,050,049	261,846
Question	s?			

2 That, for the purposes of ASX Listing Rule 14.5 and for all other purposes, Mr Tom McDonald, who retires at the close of this Annual General Meeting and, being eligible, and having consented to act, be re-elected as a Director of the Company.

	Resolution	For	Against	Discretionary	Abstain
2	Re-election of Director	30,435,886	35,099	29,062,537	14,833
	Question	s?			

3 That for the purposes of ASX Listing Rule 7.4 and for all other purposes, shareholders ratify the issue of 11,538,462 fully paid ordinary shares at an issue price of \$2.60 per share, issued by way of a placement to sophisticated and institutional investors on 27 January 2021.

	Resolution	For	Against	Discretionary	Abstain
3	Ratification of the Prior Issue of Placement Shares	16,431,535	35,099	29,050,049	14,089,264
	Questions	?			

4 That the Cyclopharm Loan Share Plan, 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
4	Approval of Loan Share Plan	27,770,786	76,451	29,050,049	18,691
	Questions	s?			

5 That the current constitution of the Company be amended, effective from the close of the AGM, as set out in the document tabled at the 2021 Annual General Meeting and signed by the chairperson for the purposes of identification.

	Resolution	For	Against	Discretionary	Abstain
5	Amendment of Constitution	30,490,338	45,099	29,050,049	20,461
			9/3//		
	Questions	;?			

6 That for the purposes of Listing Rule 10.17 and for all other purposes, the shareholders of the Company approve the increase of the maximum aggregate amount payable to non-executive directors by way of directors' fees from \$250,000 to \$350,000.

	Resolution	For	Against	Discretionary	Abstain
6	Approval of Non-executive Director Remuneration	27,780,660	93,793	29,050,049	263,191
	Questions	s?			

# 2021 AGM – Proxy Summary

Resolution	For	Against	Discretionary	Abstain
1(b) Remuneration Report	27,808,324	67,474	29,050,049	261,846
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6 Approval of Non-executive Director Remuneration	27,780,660	93,793	29,050,049	263,191

# **Technegas:** World's Best Functional Lung Ventilation Imaging Agent

# **Votes are Being Tabulated**



# THANK YOU