



CYCLOPHARM

2022
Annual General Meeting

17 May 2022



SAFE HARBOUR STATEMENT

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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.



Welcome

Mr David Heaney





CHAIRMAN'S ADDRESS

Mr David Heaney

A World Leading Diagnostic Imaging Company

1

Recovery in FY 2021 from initial COVID-19 impact in primary country markets with record sales of \$17.7m

2

Continued profitability and positive cash flow from sales of Technegas across 60 countries with additional revenues growing from third party distribution

3

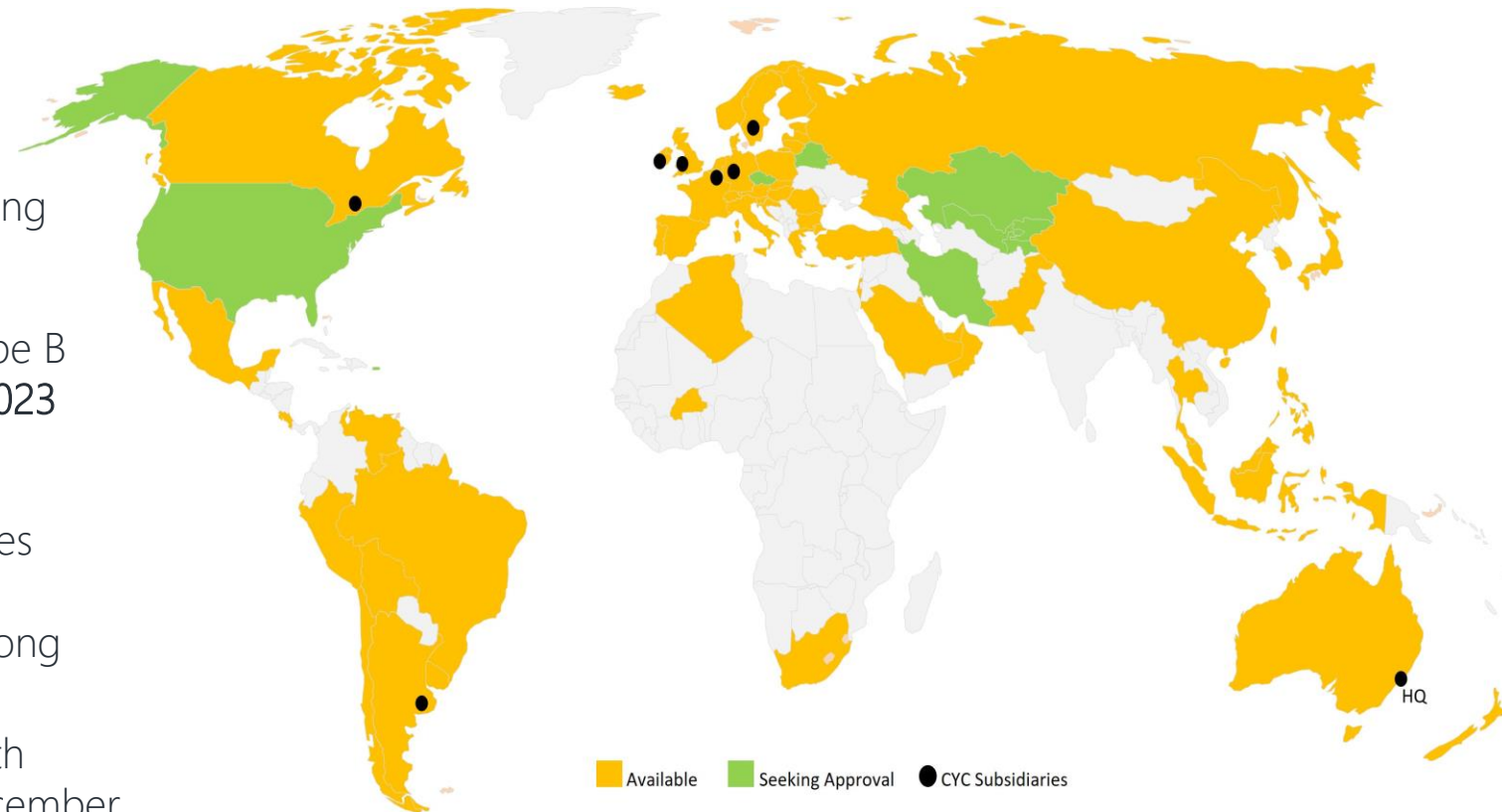
Progress towards USA market entry –Type B Meeting held Jan 2022. Targeting mid-2023 for USFDA approval

4

Soon to be published “Beyond PE” studies targeted to significantly **expand clinical applications** to include asthma, COPD, Long COVID.....

5

Strong Balance Sheet to fully fund growth strategy - \$29.25m net cash as at 31 December 2021 with an additional R&D incentive grant of \$2.3m received in January 2022





MANAGING DIRECTOR'S ADDRESS

Mr James McBrayer



2021 Financial Highlights

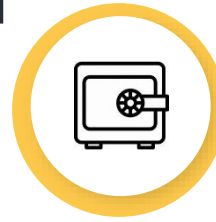
Sales Revenue	Record Group Sales revenue of \$17.7m, up 20.6%
Third Party Distribution	\$4.1 million of new third-party distribution revenue, up 89%
Net Loss Before Tax	\$4.3 million loss (includes \$1.3m from USFDA expenses)
R&D Tax Incentive	\$2.3 million received in Jan 2022
USFDA Expenses	\$1.3 million in 2021 vs \$3.3 million in 2020
Dividends	FY21 total dividends maintained at 1.0 cps
Feb 2021 Capital Raising	Placement & SPP oversubscribed, raising \$33m
Strong Cash Position	Net cash position of \$29.25m as at 31 Dec 2021 with an addition \$2.3m R&D incentive grant received in Jan 2022



2021 Operating Highlights

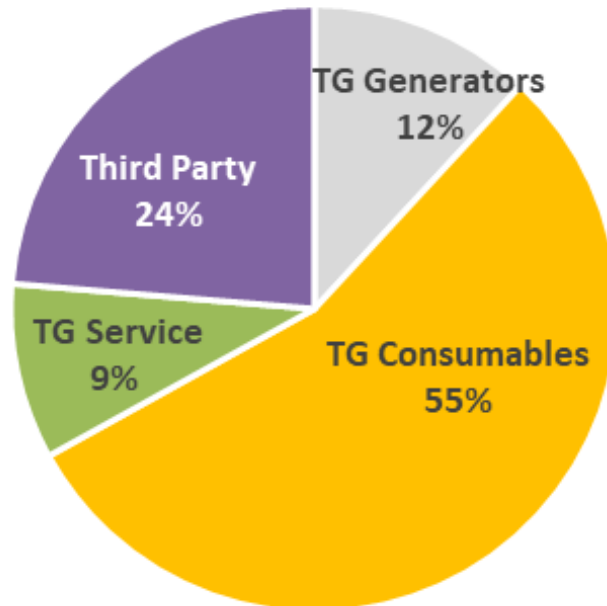
Sales Revenue	Record Group Sales revenue of \$17.7m, up 20.6% with \$4.1 million of new third-party distribution revenue
USFDA	Investment in the final stages of the USFDA regulatory approval
US Commercialisation	Preparations for subsequent rapid commercialization in the United States
Increasing Direct Customer Access	CYC leveraging direct sales and service in 10 markets with the establishment of offices in Belgium and the UK during 2021
Beyond PE	Solid progress in trials for new clinical applications providing new business growth opportunities for Technegas™
Regulatory	CE Marketing Authorisation renewal achieved under new and extensively revised European Medical Device Regulations (MDR)

BUILDING FOR GROWTH



Technegas® is a global market leader with significant growth potential in the **USA market**

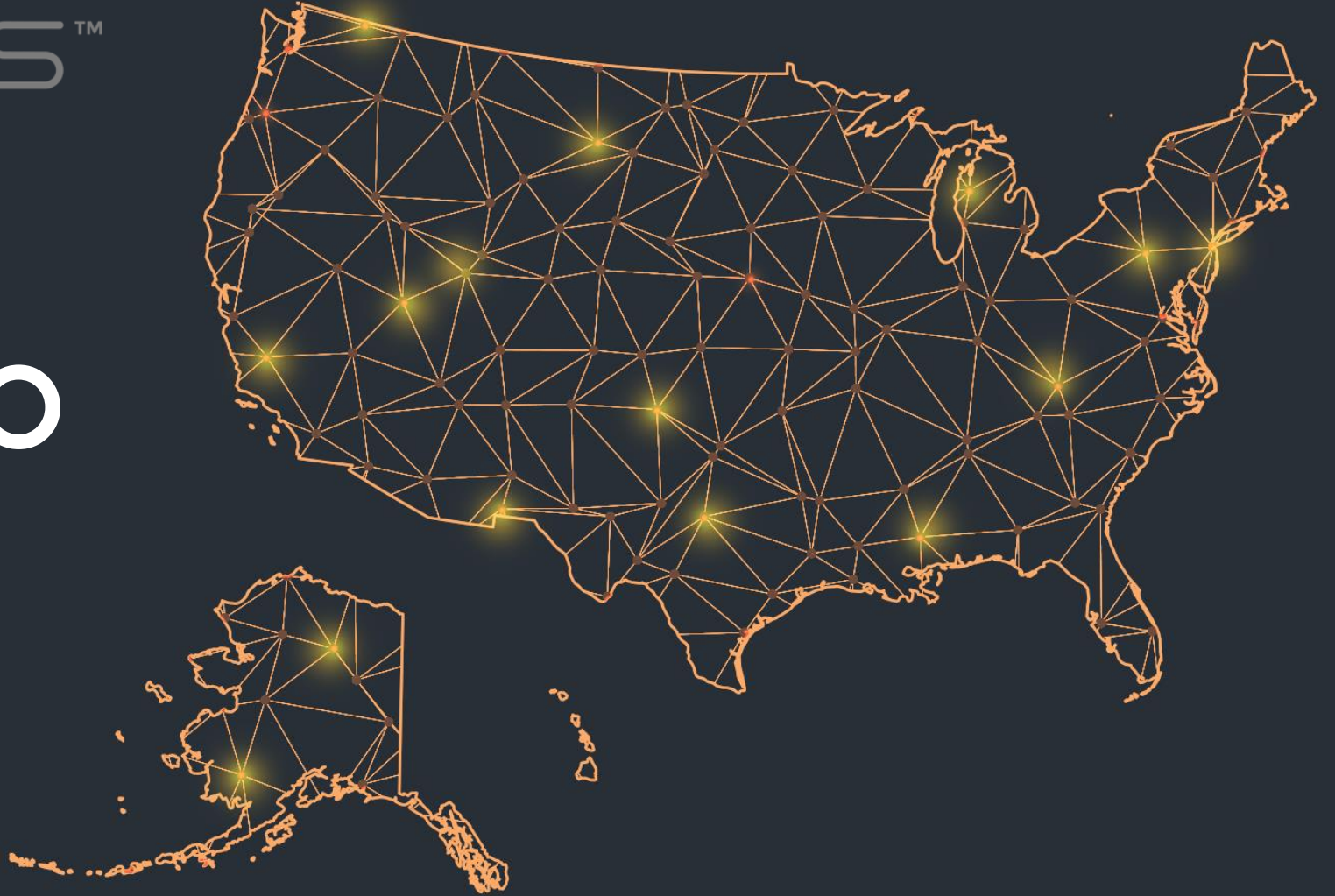
2021 Revenue Composition



- Total global sales of over **\$93.1m** AUD from 2015 to 2021 (\$17.7 in FY 2021)
- Technegas® currently available in over **60 countries**
- Over **4,400,000** patient procedures performed since first approved
- **1,600** Technegas® generators sold globally since first approved
- **Europe** represents **66%** of global revenue in 2021
- **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 **72%** - (76% in 2020)
- Over 70% of historical revenue is **recurring consumable sales** - (73% in 2020)
- ROW Revenues (ex USA) gradually returning to pre-COVID19 levels
- 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 immediate USA demand

TECO  NEGAS™

**COMING TO
AMERICA**





USFDA UPDATE

**Progress Towards Approval
Mid 2023 with Significant
Commercialisation Progress
Achieved**

1

Pre-Approval Inspection (PAI) conducted 30 March to 7 April 2021

- Inspection based on Drug-Device **Combination Product**
- Currently providing USFDA updates **every 60 Days**
- Significant Documentation Development and Revisions accomplished to date
- **Facility Modifications** – Workflow and HVAC Upgrade Completed
- In process **data capture** of legacy equipment

2

Complete Response Letter (CRL) Received 26 June 2021

- Engaged additional resources for product characterisation study
- Some activity **cross-over** from the pre-approval inspection
- Additional Technegas **product characterisation** required by the FDA currently underway in both the USA and Australia

3

USFDA Type B Meeting Held 27 January 2022

- 2 – Hour Meeting Granted over a 3-hour period
- Teleconference Format
- Clarification received on outstanding elements related to the CRL

4

USA Commercialisation Readiness Continues

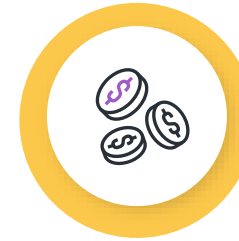
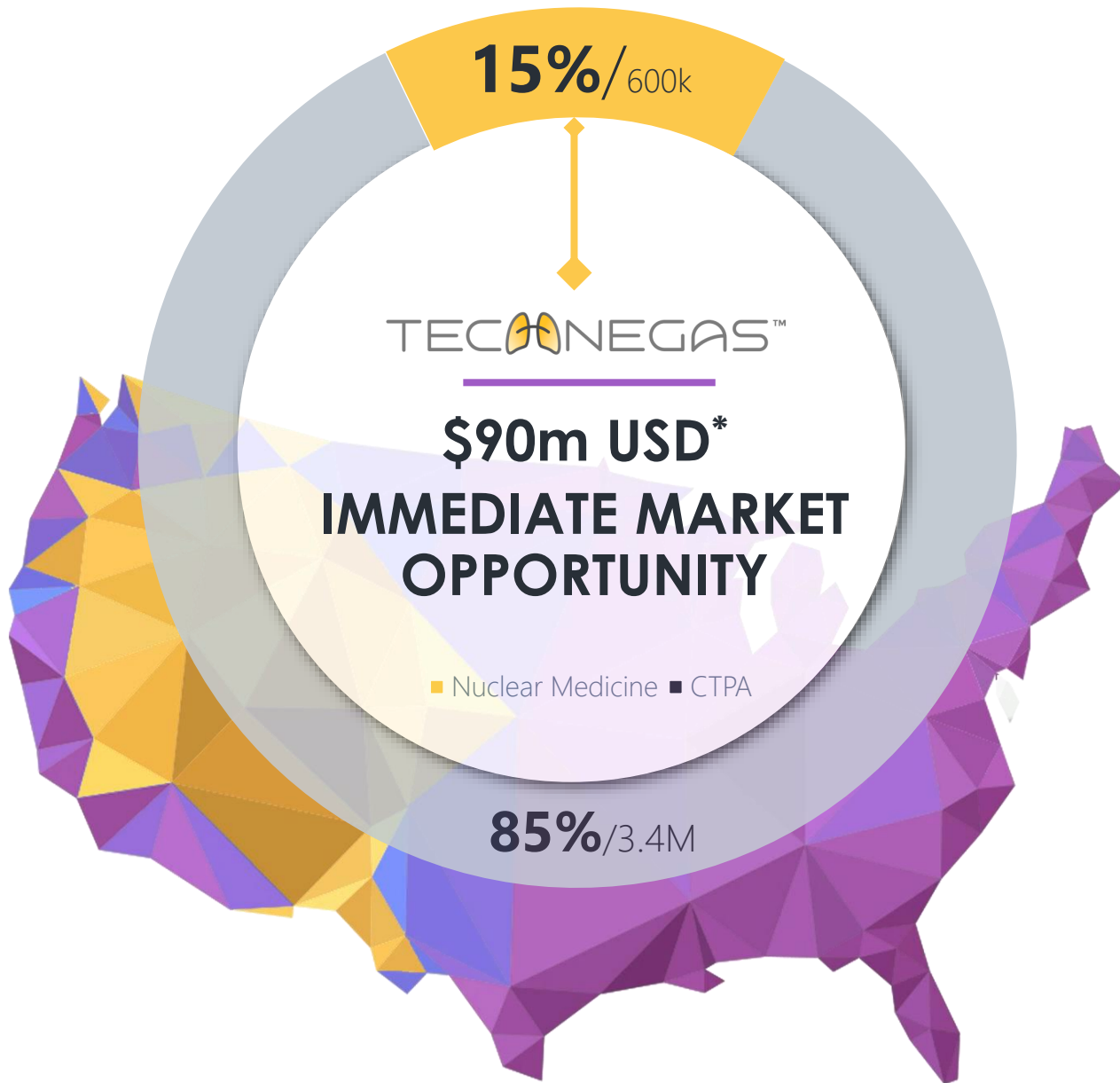
- Targeting Mid 2023 for USFDA Approval
- Training of USA service personnel underway
- Inventory Build of 200 Generators for USA Launch in process



USA UPDATE Building The Fleet

200 Technegas Generators
Being Built for Market
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 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%.
- Once established in the USA market, the company will seek to expand the use of Technegas® into disease states exponentially larger than the existing markets Beyond PE

USA Demand Established

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

1 9 sites in the US already have generators installed from clinical trials

2 Multiple letters from leading clinicians, front-line workers and the SNMMI have petitioned the USFDA for the approval of Technegas™.

3 Demand already established in the US from:

- ✓ Extensive body of **clinical evidence** underscoring clinical superiority
- ✓ **Real World Evidence** in over 60 countries
- ✓ Well known and **established technology** globally with significant support of KOL's
- ✓ **COVID-19 safe** as compared to competing nuclear medicine products

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

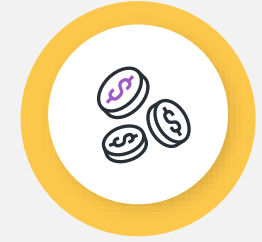
5 Unlike most newly approved medical devices, our **focus will be on installation and training** staff, as opposed to a large sales team due to inbound demand

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 is based on procedure codes as opposed to product codes



USA Pricing & Business Model



- 1 Generators are to be placed at no cost removing potential CAPEX roadblocks
- 2 Once off installation and training fee charged
- 3 Ongoing annual fee attributed to preventative maintenance, training and product support
- 4 Business model expected to result in accelerated consumable revenue

EXPANDING INDICATIONS

TEC  NEGAS™



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



Diagnosis and follow-up of **Pulmonary Embolism**¹ and **Pulmonary Hypertension**²



Preoperative assessment of homogeneous **Endoscopic Lung Volume Reduction (ELVR)** candidates³



Preoperative assessment of **lung resection** candidates with borderline pulmonary reserve⁴⁻⁶



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



Diagnosis and monitoring of **COVID-19** patients¹¹

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

Beyond Pulmonary Embolism Initiatives Underway

392 Patients enrolled globally across 6 Cyclopharm sponsored Beyond PE clinical trials

1 **Hunter Medical Research Institute (Newcastle, AU):** Diagnosis and response to therapy in severe asthma and COPD¹
100 Patient Study * 100% Recruited * Imaging Analysis Underway * Case Study Published

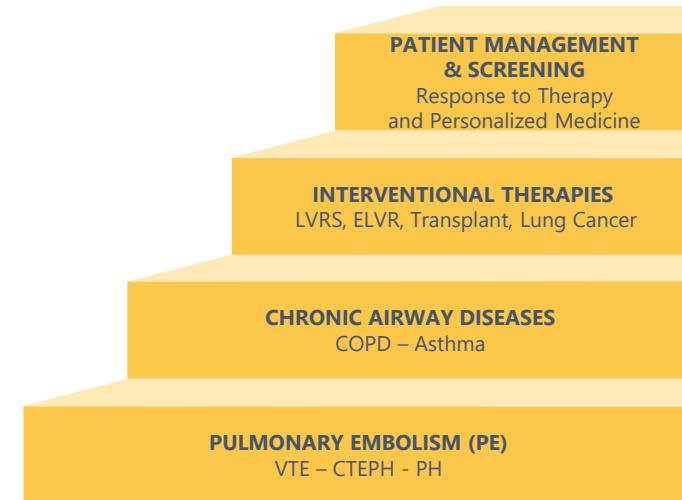
2 **Woolcock Institute (Sydney, AU):** Diagnosis and response therapy in mild to moderate COPD³
25 Patient / 75 Scan Protocol * 36% Recruited

3 **CHUM (Montreal, CA):** Early detection of COPD in asymptomatic smokers⁴
30 Patient Study * 100% Recruited * Analysis complete * First Draft Underway

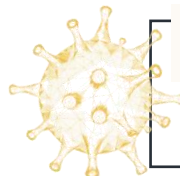
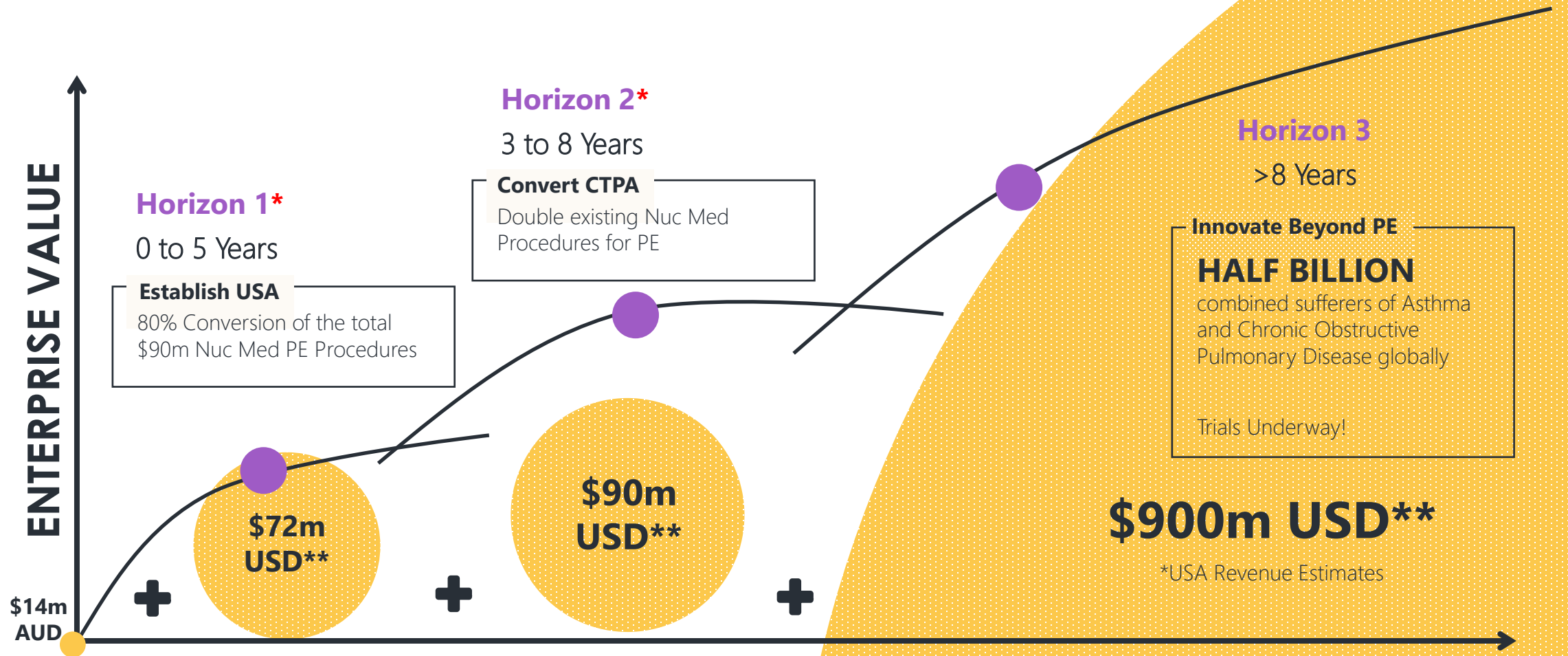
4 **Dalhousie (Halifax, CA):** Post-lung transplant patients
30 Patient Study * 30% Recruited

5 **McMaster University Firestone Institute (Hamilton, CA):** Ventilation in lung cancer patients pre and post lung resection²
115 Patient (230 Scan) Study * 47% Recruited * Abstract presented at American Thoracic Society **today*** Preliminary Paper approved by the Canadian Journal of Respirology with publication pending

6 **McMaster University Firestone Institute (Hamilton, CA):** COVID-19 Related Lung Ventilation and Perfusion Injury⁵
92 Patient (184 Scan) Study * 46% Recruited * Abstract presented at the American Thoracic Society **tomorrow**



THREE VALUE HORIZONS



***Timelines Under Review**
COVID-19 Likely to be an **accelerant** to **Horizons 1 & 2**

**Revenue projections based on internal company analysis



KEY Catalysts for the Next 2 Years



- 1 FDA approval for Technegas expected mid 2023
- 2 First sales in US announce (shortly after approval)
- 3 Ongoing updates on No. Generators placed in US
- 4 Clinical proof of concept & validation in new substantive respiratory indications

CYCLOPHARM INVESTMENT CASE

TEC  NEGAS™



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 4.4 million patient procedures to date

Clinical Agent of Choice
referenced by name in multiple clinical guidelines



Recurring Revenue

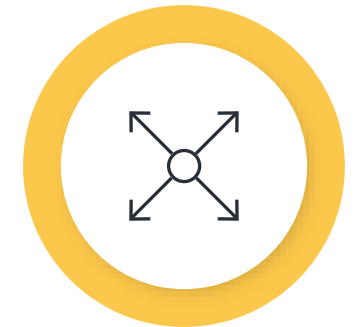
From single patient consumables
Similar to an annuity model



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



Technegas Product expansion

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



Business Q&A






FORMAL BUSINESS

Mr David Heaney



Online Attendees – Registration Process & Voting



[register >](#)

Automatic helps you manage your holdings & securities

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

Please click here for [Single Holding Access](#). This service provides limited access to a holding.

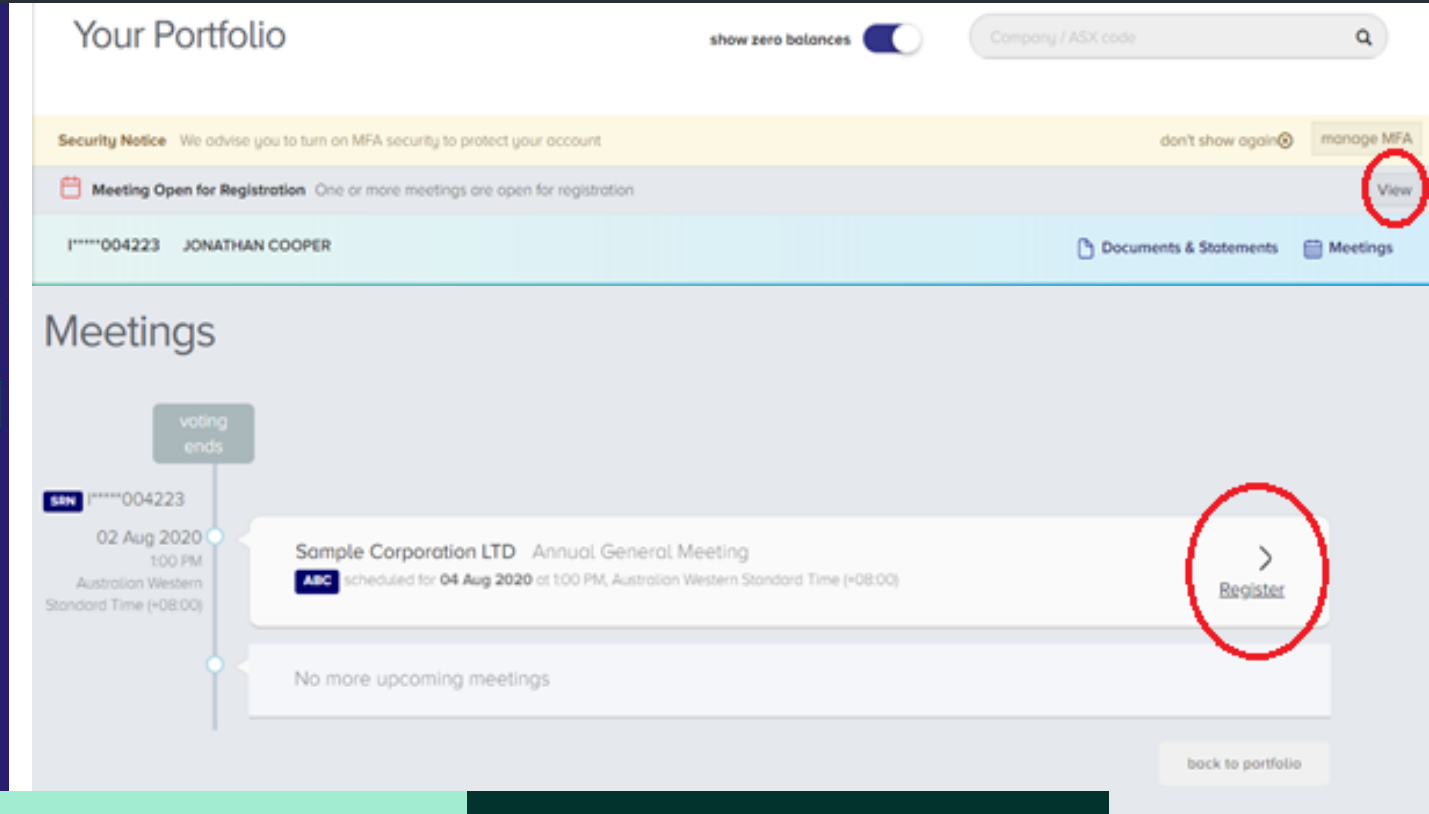
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Meeting Open for Registration One or more meetings are open for registration [View](#)

I****004223 JONATHAN COOPER [Documents & Statements](#) [Meetings](#)

Meetings

voting ends

SRN I****004223

02 Aug 2020
1:00 PM
Australian Western Standard Time (+08:00)

ABC Sample Corporation LTD Annual General Meeting
scheduled for **04 Aug 2020** at 1:00 PM, Australian Western Standard Time (+08:00) [Register](#)

No more upcoming meetings

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1

Go to
<https://investor.automic.com.au/#/home>

2

Once logged in you will see that the meeting is open for registration. Click on “view”

3

Click on “register” to register your attendance for the meeting

Online Attendees – Registration Process & Voting

Registration

Sample Corporation LTD - Annual General Meeting

Registration Complete

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=TFf0TTdGTEhGSENIbUN5NzF3bJlUQT09>

Refresh

Voting

Sample Corporation LTD - Annual General Meeting TBC

Poll Review Complete

Poll - Step 1 of 3

You can join the meeting online using the following link

<https://us02web.zoom.us/j/85784417406?pwd=TFf0TTdGTEhGSENIbUN5NzF3bJlUQT09>

Resolutions

You must vote on all resolutions, except for those marked as withdrawn.

1 Remuneration Report

2 Re-Election Of Jonathan Cooper as National Head of Client Services

for against abstain

for against abstain

next

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.

6

Once voting is declared closed you must select “next” and then “confirm” to submit your vote.

2022 AGM – Formal Business

1

- (a) Financial Statements
- (b) Remuneration Report

2

Election of Ms Dianne Angus as Director

CYC AGM 2022 Resolutions

- 1 That the Remuneration Report as set out in the Annual Report of the Company for the financial year ended 31 December 2021 be adopted.

Resolution	For	Against	Discretionary	Abstain
1(b) Remuneration Report	49,395,573	56,376	14,320,270	14,597

Questions?

CYC AGM 2022 Resolutions

- 2 That Ms Dianne Angus, being eligible and having consented to act, be elected as a Director of the Company.

Resolution	For	Against	Discretionary	Abstain
2 Election of Ms Dianne Angus as Director	51,527,799	19,074	14,847,931	7,174

Questions?

2022 AGM – Summary of proxies received at closing date

Resolution	For	Against	Discretionary	Abstain
1(b) Remuneration Report	49,395,573	56,376	14,320,270	14,597
2 Election of Ms Dianne Angus as Director	51,527,799	19,074	14,847,931	7,174

Technegas: World's Best Functional Lung Ventilation Imaging Agent

Votes are Being Tabulated





THANK YOU

