

CYCLOPHARM

Investor Presentation

24 May 2022

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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.



A World Leading Diagnostic Imaging Company

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

Over 4.4 million patient procedures to dated supported by several guidelines with 100's of peer reviewed papers highlighting the clinical use of Technegas

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

Significantly expanding market opportunities "Beyond PE". Key clinical studies soon to be published **expanding clinical applications** to include asthma, COPD, Long COVID.....

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





CYC's STRATEGIC PRIORITIES



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CYC has clear strategy to leverage our position as a leading player in the global nuclear medicine imaging market and lung health space to expand the use of our proprietary products and introduce new innovative technology. We will do this by:

Attaining approval to distribute Technegas in the USA

Expanding the use of Technegas beyond the traditional diagnosis of Pulmonary Embolism into significantly larger applications such as **COPD¹ and Asthma**, **Lung Cancer**, Pulmonary Hypertension and **Long COVID** for both diagnosis and patient management.

Identifying, developing and commercialising complementary innovative technologies

Leveraging our core global regulatory strengths (**MDR & MDSAP renewal**), fiscal discipline, strong balance sheet and well-developed expertise in nuclear medicine and pulmonary healthcare to seek out **complementary technologies** and businesses

BUILDING FOR GROWTH



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

- 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



2021 Revenue Composition



TECINEGAS

COMING TO AMERICA



USFDA UPDATE

Progress Towards Approval Mid 2023 with Significant Commercialisation Progress Achieved

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

- Inspection based on Drug-Device Combination Product
- Currently providing USDFDA 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

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

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

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).Current contrast media shortages may be shifting volumes back to nuclear medicine.
- 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

* Revenue and patient volume projections based on internal company analysis **Leblanc M, et al. CANM 2018; https://canmInvestor Update



USA Demand Established

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



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

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

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 is viewed as the safest nuclear medicine ventilation agent globally

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Potential Operator and Environmental Exposure:

Xe-133 requires continuous rebreathing for up to 15 minutes. DTPA requires 3-5 minutes of periodic administration to deliver the target dose Technegas only requires 3-5 tidal breaths (~30 seconds)

Small hydrophobic particles:

DTPA is an aqueous droplet measuring ~1,700 nm in size is an ideal carrier for the COVID-19 virus Technegas is made up of carbon-Tc99m particles ~250 nm in size that adheres to the alveolar & is not likely to carry the COVID-19 virus equal to ~125 nm

Less likely to induce cough reflex:

Xe-133 – patient likely to experiencing coughing during the prolonged procedural administration DTPA- method of administration is likely to stimulate the cough reflex

Technegas- ~50ug of hydrophobic particles combined with ultrashort administration is not likely to cause bronchospasm

Significant US Clinical Support

22 June 2020 – **77 USA Nuclear Medicine Physicians** petition the USFDA to expedite the review of Technegas

2 November 2020 – **90 USA Nuclear Medicine Physicians** petition as a matter of clinical urgency the approval of Technegas in light of the surge in COVID-19 patients

30 December 2020 – 102 Front Line Technologists petition USFDA on occupational safety concerns

21 January 2021 – The 16,000 Member Society of Nuclear Medicine and Molecular Imaging

(SNMMI) based in the USA petition USFDA for an expedited approval for Technegas citing clinical and safety concerns related to competing nuclear medicine ventilation agents.

8 August 2021 – **144 USA Nuclear Medicine Physicians and Front-Line Technologist** respond to the FDA's CRL and petition for approval

Current CT Contrast Shortage expected to drive additional demand:

Recent disruptions in the pharmaceutical supply chain critical to radiologic imaging has impacted the global availability of iohexol iodinated contrast media (ICM). The shortage of iohexol has created an international crisis in the ability of radiology departments to provide healthcare to patients needing contrast-enhanced exams





Global Shortage of CT Contrast Media

Creating Opportunities for Nuclear Medicine

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In This Section		lohexol (Omnin	aque) and Iodixan	ol (Visinaque) S	hortage		
News and Media SNMMI News Press Releases Coding & Reimburser Government Relation Molecular Imaging N Media Center Social Media + Newsletters + Journals + Books	ment News ns News Jews	May 12, 2022 May 12, 2022 According to a communication from GE Healthcare, a shortage of iohexol (Omnipaque) is occurring as a result of the Chinese government lockdowns related to COVID-19. Secondarily to the iohexol (Omnipaque) shortage, the alternative agent, iodixanol (Visipaque), is in short supply due to an increase in demand. At the recommendation of GE Healthcare, distributors have implemented a 20% allocation on iohexol (Omnipaque) that is expected to continue through the remainder of this shortage. Nearly all of the U.S. supply for this product comes from the Shanghai plant. According to GE Healthcare, the supply impact is not related to quality, raw material supply, or supply chain issues. GE Healthcare will utilize their secondary manufacturing facility in Ireland to supplement U.S. labeled iohexol (Omnipaque) supply. GE Healthcare has communicated that the impact is temporary, and the Shanghai facility is re-opened and ramping up production as allowed by local COVID-19 mitigation protocols. Total global production of iodine, excluding U.S. production data, was estimated at 32,000 metric tons in 2021 which is equivalent to pre-pandemic levels. GE Healthcare expects to have intermittent supply of iohexol (Omnipaque) until the end of June 2022 and does not have additional information on iodixanol (Visipaque) availability at this time. This mitigation strategy is intended to provide guidance for present and future shortages. Read the full announcement here.			RELATED CONTEN Grants, Awards Novartis Annou Halt in Producti and Pluvicto Active Brown A Protects Agains SNMMI and Par Hearing for the JNM Publishes Establishment of Centers	NT a, and Scholarships inces Temporary ion of Lutathera dipose Tissue st "Pre-Prediabetes" thers Request a FIND Act Joint Guide for the of Theranostics	
		SNMMI is hopeful th practitioners that ra excellent alternativ scanning should be Similarly, stress ca excellent alternativ	his supply issue will soo adiopharmaceuticals rer e for some diagnostic p considered as an altern rdiac nuclear studies inc rdias nuclear studies inc	n be resolved, but main available and rocedures. For exa lative to CTA of the cluding PET or SPEC o are scheduled for	reminds are an mple, V/Q lung pulmonary arteries. CT may serve as cardiac CTA.		
		The American College guidance on the contr conserve contrast me	of Radiology Committee o ast agent shortage and ha dia including delaying elect	n Drugs and Contrast s suggested a numbe tive procedures.	t Media has issued er of strategies to		
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"VQ Lung Scanning should be considered as an alternative to CTA"





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



Business model expected to result in accelerated consumable revenue



$\frac{\mathsf{EXPANDING}}{\mathsf{INDICATIONS}}$



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



Beyond Pulmonary Embolism Initiatives Underway

392 Patients enrolled globally across 6 Cyclopharm sponsored Beyond PE clinical trials⁷



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

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

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

PATIENT MANAGEMENT & SCREENING Response to Therapy and Personalized Medicine

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 ² 115 Patient (230 Scan) Study * 47% Recruited * Abstract presented at American Thoracic Society 2022 Conference

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 2022 Conference * Preliminary Paper approved by the Canadian Journal of Respiratory, Critical Care and Sleep Medicine⁶



CYCLOPHARM:

Long COVID Study Update



Abstract Presented at the American Thoracic Society 2022 Conference:

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Early Findings Published in the Canadian Journal of Respiratory, Critical Care, and Sleep Medicine¹:

Trial Findings Thus Far :

VQ-SPECT-CT² using Technegas[™] as the ventilation agent found it had the potential to be "a valuable tool for clinicians in the management of patients who are being evaluated after COVID-19 as it permits objective evaluation of functional lung impairment that may underly and help explain post-COVID-19 symptoms".

The imaging study revealed ventilation impairment in individuals with no history of lung disease recovering from noncritical COVID-19 that was associated with parenchymal opacities, respiratory symptoms and exercisecapacity

Long COVID³

US CDC study reports post-COVID conditions can vary from 13.3% at one month or longer after infection; 2.5% at three months or longer, based on self-reporting; to more than 30% at 6 months among patients who were hospitalised.

CANADIAN JOURNAL OF RESPIRATORY, CRITICAL CARE, AND SLEEP MEDICINE https://doi.org/10.1080/24745332.2022.2054047



Check for upda

ORIGINAL RESEARCH

Ventilation and perfusion abnormalities following recovery from noncritical COVID-19

Carmen Venegas^{a,b} , Christopher J.C. Marriott^{c,d,e}, Terence Ho^{a,b} , Kiho Son^b, Rameen Jamil^b, Meher Jamal^c, Melanie Kjarsgaard^a, Chynna Huang^a, Katherine Radford^a, Myrna B. Dolovich^{a,b,e}, Catherine E. Farrow^{f,g}, Troy H. Farncombe^{c,d}, Matthew Lubanovic^d, Ehsan Haider^d, Parameswaran Nair^{a,b}, Manali Mukherjee^{a,b} and Sarah Svenningsen^{a,b,e}

^aFirestone Institute for Respiratory Health, St Joseph's Healthcare Hamilton, Hamilton, Ontario, Canada; ^bDepartment of Medicine, Division of Respirology, McMaster University, Hamilton, Ontario, Canada; ^bDepartment of Nuclear Medicine, Hamilton Health Sciences and St. Joseph's Healthcare, Hamilton, Ontario, Canada; ^bDepartment of Radiology, McMaster University, Hamilton, Ontario, Canada; ^aImaging Research Center, St Joseph's Healthcare, Hamilton, Ontario, Canada; ^bDepartment of Respiratory Medicine, Westmead Hospital, Westmead, New South Wales, Australia; ^aWestmead Clinical School, The University of Sydney, Sydney, Australia



¹https://doi.org/10.1080/24745332.2022.2054047

²VQ-SPECT-CT – Ventilation Perfusion Single Photon Emission computerised tomography with computed tomography is a multimodality imaging technique that combines nuclear medicine functional imaging with an anatomical reference using CT ³https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html

THREE VALUE HORIZONS





KEY Catalysts for the Next 2 Years



FDA approval for Technegas expected mid 2023

First sales in US announce (shortly after approval)

Ongoing updates on No. Generators placed in US



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Clinical proof of concept & validation in new substantive respiratory



CYCLOPHARM INVESTMENT CASE









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





THANK YOU



APPENDIX SECTION





FY 2021 FINANCIALS



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



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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)



$\begin{array}{c} \mathsf{PULMONARY}\\ \mathsf{IMAGING} \text{ with}\\ \mathsf{TEC} \text{ is constructed} \end{array}$



WHAT THE GUIDELINES SAY ABOUT TECHNEGAS®:

Endorsed by the guidelines from the <u>European¹⁻²</u> and the <u>Canadian³</u> Associations of Nuclear Medicine (EANM & CANM)

- 1Bajc 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
- 2Bajc 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

- " Using 99m-Tc-Technegas is according to clinical experience **better than the best aerosols** "
- " Technegas® facilitates interpretation, particularly in COPD"

" For ventilation, $99m\mathcal{F}$ Technegas $^{\mbox{\tiny B}}$ 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 "





USA REIMBURSEMENT IS ESTABLISHED



MEDICARE HOPPS (HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM) \$USD

WWW.SNMMI.ORG

CPT/		Trade	Oct 2019	Jan F 2020	Oct 2019	Jan F 2020	Oct 2019	Final January CY 2020	%
HCPCS	Description Name		APC	APC	SI	SI	Payment Rate	Payment Rate	Change
78579	Pulmonary ventilation imaging (eg, aerosol or gas)			5591	S	S	\$353.49	\$368.08	4.0%
78580	Pulmonary perfusion imaging (eg, particulate)			5591	S	S	\$353.49	\$368.08	4.0%
78582	Pulmonary ventilation imaging (eg, aerosol or gas) and perfusion imaging			5592	S	S	\$455.52	\$471.93	3.5%
78597	Quantitative differential pulmonary perfusion, including imaging when performed			5591	S	S	\$353.49	\$368.08	4.0%
78598	Quantitative differential pulmonary perfusion and ventilation (eg aerosol or gas), including imaging when performed			5592	S	S	\$455.52	\$471.93	3.5%
78599	Unlisted respiratory procedure, diagnostic nuclear medicine		5591	5591	S	S	\$353.49	\$368.08	4.0%

Nuclear medicine lung imaging reimbursement is based on established procedures and is agnostic as to the ventilation agent used





EVOLUTION OF FUNCTIONAL LUNG VENTILATION IMAGING

- Improvements in 3D imaging techniques, hybrid imaging and the advent of analytical software have dramatically improved the sensitivity and specificity in functional lung imaging with Technegas
- Traditionally used in the diagnosis of Pulmonary Embolism, nuclear medicine

functional lung ventilation imaging utilising improved imaging techniques are expanding the potential clinical utility for Technegas

• The following Technegas images underscore the advancement in complementary technology Cyclopharm is leveraging today:



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• The following Technegas images underscore the advancement in complementary technology Cyclopharm is leveraging today:



NUCLEAR MEDICINE IMAGING TECHNOLOGY HAS EVOLVED BEYOND CTPA IN DIAGNOSING PE



3. Waxman AD, et al. J Nucl Med 2017; 58: 13N-15N 4. Roach PJ, et al. J Nucl Med 2013; 54:1588–1596





Third Party Products



CYCLOPHARM BUSINESS PARTNERS AROUND THE GLOBE :















CYCLOPHARM

BUILDING FOR GROWTH