CYCLOPHARM

USFDA Approval Progress Update

05 April 2023

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.

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A World Leading Diagnostic Imaging Company

1. **Recovery in FY 2022 continued** from initial COVID-19 impact in primary country markets with record sales of **$23.2m.** (Technegas sales $13.66m up 4.1% - Third-party sales $9.22 up 124% compared to 2021)

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

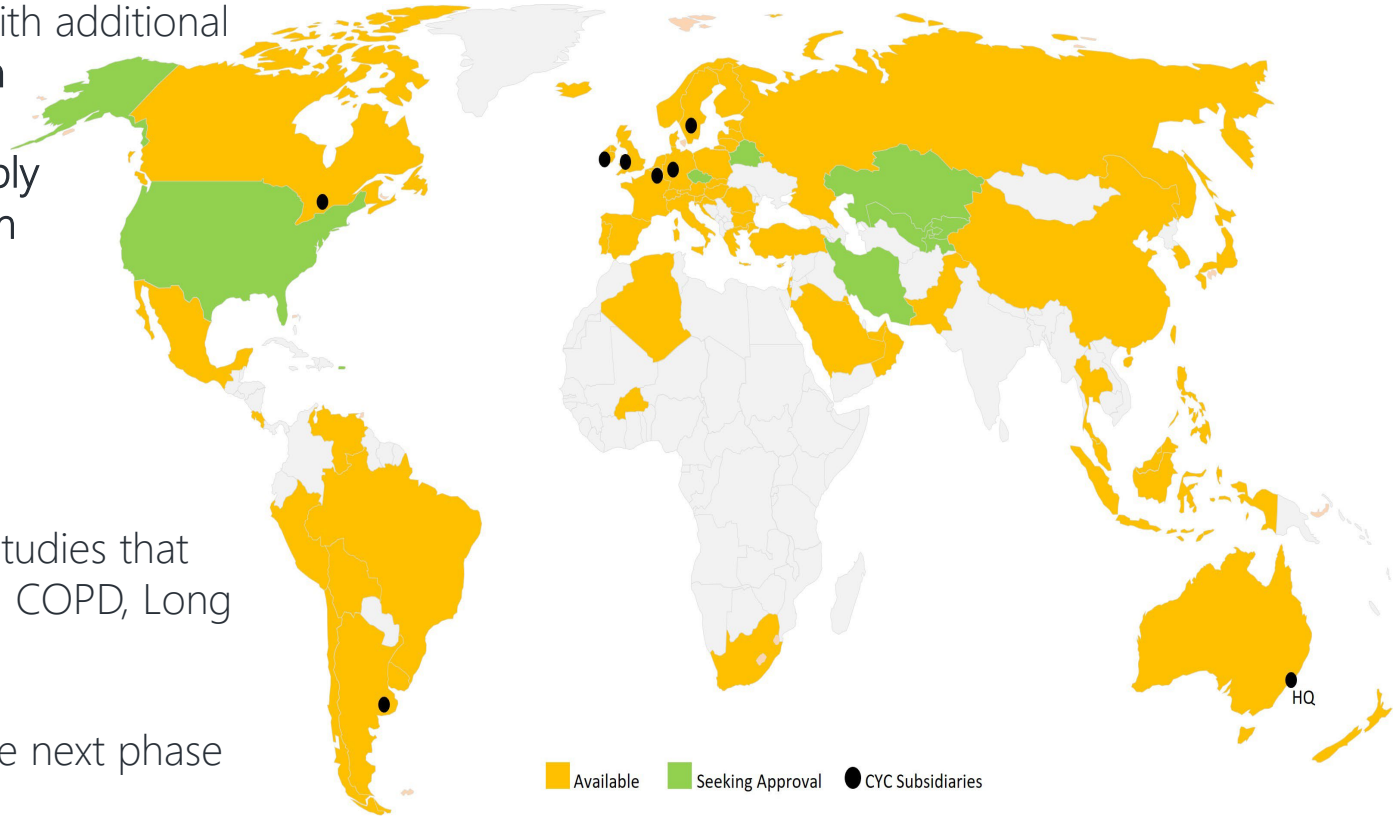
3. Progress towards USA market entry – **CRL Reply submitted 30 March 2023** triggering **six-month** USFDA review

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.....expected mid-2023

6. **Board renewal complete –** skills in place for the next phase of growth

7. **Strong Balance Sheet** to fully fund growth strategy - $20.3 m net cash as at 31 December 2022



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TECHNEGAS

Product Overview

Cyclopharm's leading product is the Technegas technology system

- The Technegas® proprietary technology provides high quality diagnostic functional lung imaging.
- Historically used to diagnose the presence of blood clots in the lung otherwise known as Pulmonary Embolisms (PE). With advances in complementary technology, the potential for use in other indications *Beyond PE* is rapidly evolving.
- In a clinical setting, the patient inhales, in only a few breaths, an ultrafine dispersion of Technegas® particles. Once inhaled and deposited in the lungs, Technegas® images are then captured by using conventional nuclear medicine scanning equipment.

- The Technegas® images provide the clinician an understanding of how well the patient's lungs are functioning across a range of disease states.
- The Technegas® Generator is installed in the nuclear medicine department. Revenue is generated annually from ongoing service contracts.
- Consumable components are inserted into the Technegas® Generator which then produce the gas like particles that are inhaled by the patient. The consumables which deliver Technegas® are single patient use items.

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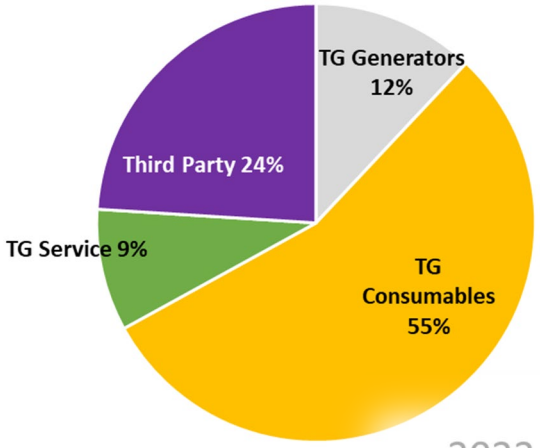
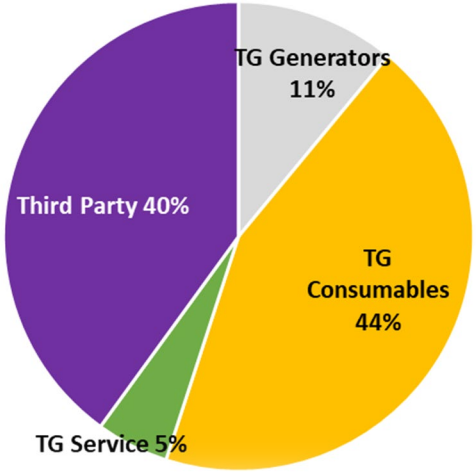
FOUNDATIONS IN PLACE

2021 Revenue Composition



2022 Revenue Composition

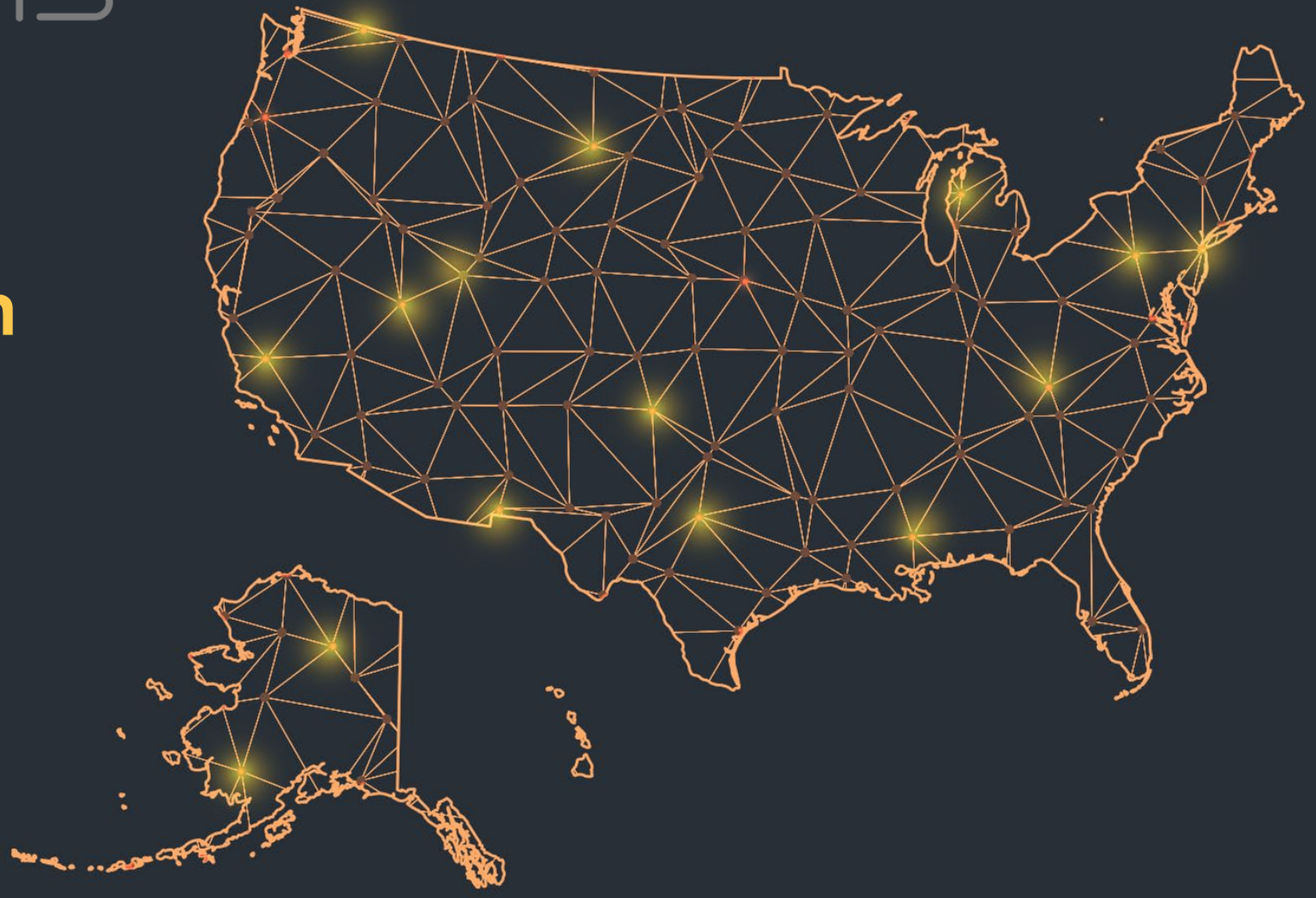


Technegas® is a global market leader with significant near-term growth potential in the **USA market & Beyond PE**

- Record Revenues of $23.2m in 2023 up 31% ($17.7m in 2021)
- Total global sales of over $123.2m AUD from 2015 to 2022
- Technegas® currently available in over 64 countries
- Over 4,600,000 patient procedures performed since first approved
- 1,600 Technegas® generators sold globally since first approved
- Europe represents 54% of global revenue in 2022
- 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 69% in 2022- (72% in 2021)
- Over 70% of historical revenue is recurring consumable sales - (72% in 2020)
- Significant growth in Third Party Sales equaling $9.2m in 2022 ($4.1m in 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 immediate USA demand

TECHNEGAS™

Counting Down to USA Launch



Complete Response Letter Reply

Submitted 30 March 2023 Initiating USFDA Six Month Review

1. Drug Substance
2. Manufacturing Process
3. Device

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USA Demand Established

The Wait Is Nearly Over

1. **Technegas generator placement strategy** targeting rapid deployment and drive highly profitable consumable sales
2. Multiple letters from **leading clinicians, front-line workers and the SNMMI have petitioned** the USFDA for the approval of Technegas™. *Clinical Nuclear Medicine journal article published 27 Oct 2022 states Technegas "*is an excellent imaging option for assessing pulmonary airways and offers **unique advantages** during the COVID-19 pandemic*" and "*once approved in the USA is likely to cause a shift (**clinical shift**) to SPECT*".
3. **Demand already established** in the US from:
   - ✓ Extensive body of **clinical evidence** underscoring clinical superiority
   - ✓ **Real World Evidence** in over 64 countries
   - ✓ Well known and **established technology** globally with significant support of KOL's
   - ✓ **COVID-19 safe** as compared to competing nuclear medicine products
   - ✓ **420 and growing Expressions of interest** registered to date by prospective customers
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 framework is based on procedure codes

*Le Roux P, et al. **Ventilation Scintigraphy With Radiolabeled Carbon Nanoparticulate Aerosol (Technegas),** J Clinical Nuc Med Oct 2022, doi: 10.1097/RLU.0000000000004426

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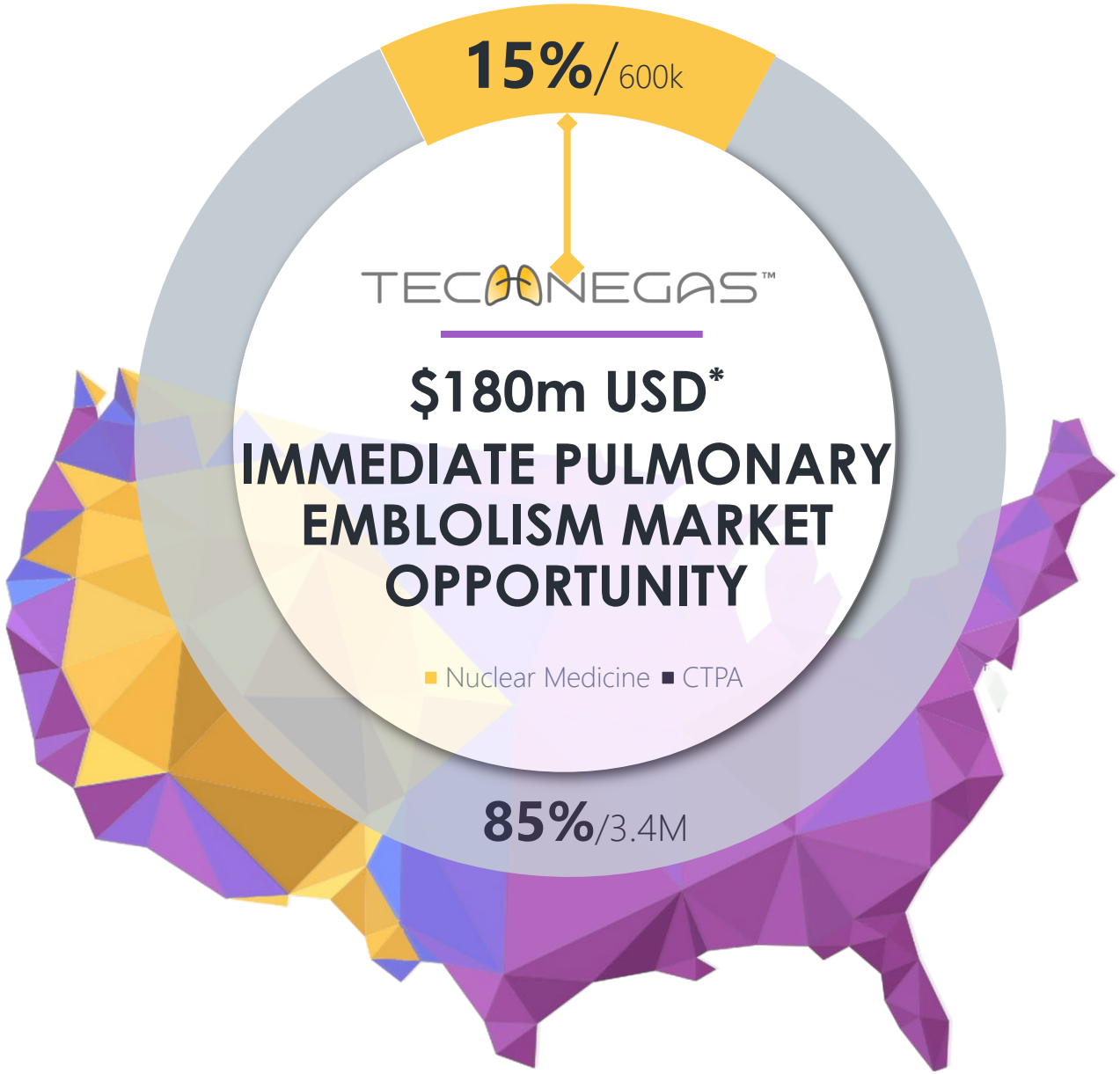


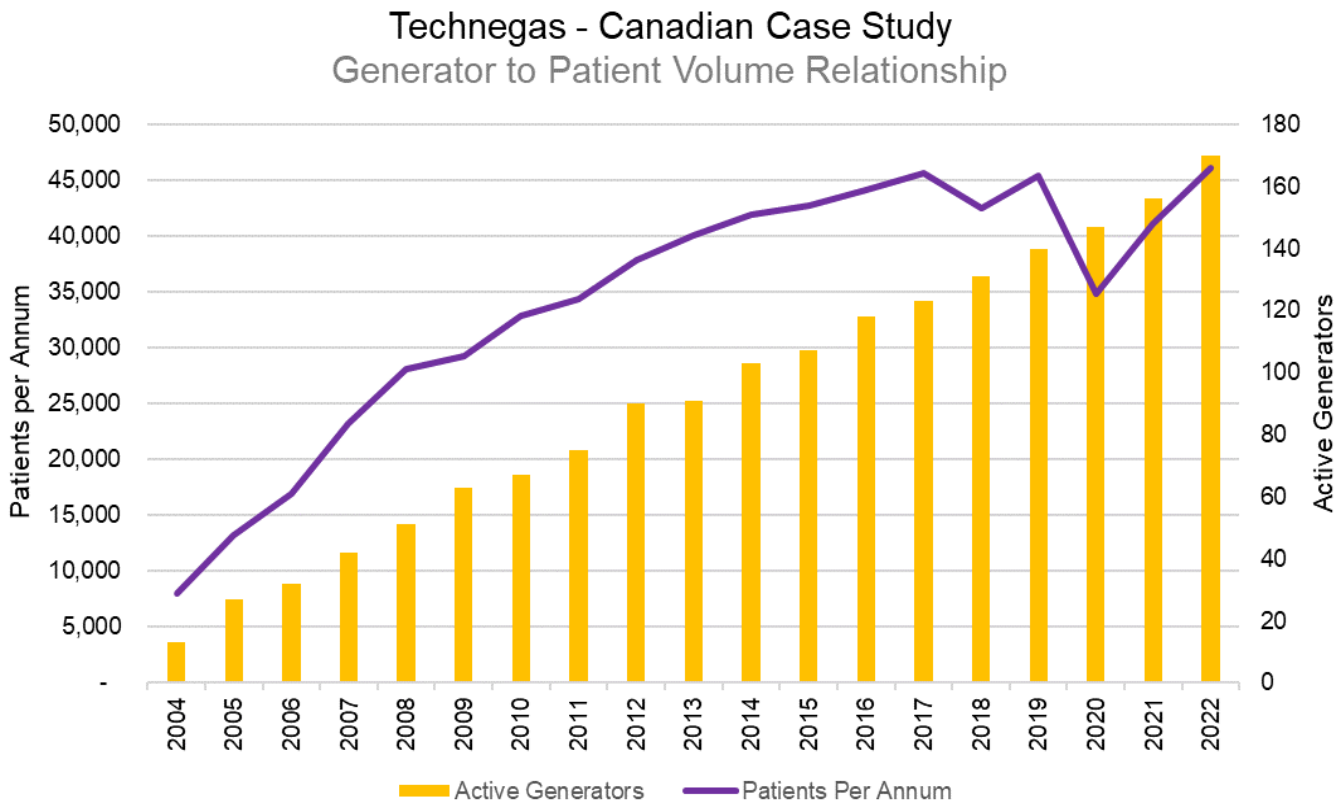
600K Nuclear Medicine Ventilation Procedures p.a.

- 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 pre-COVID 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 CTPA[1]. Once commercialised Cyclopharm will target to double the existing nuclear medicine PE market dominated by CTPA from 15% to 30%.
- In addition to seeking USFDA approval the company will continue 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://canm-acmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%2012_.pdf 2.a

TECHNEGAS®

The Canadian Case Study



Canada is Cyclopharm's largest single country market

1. Market leader for diagnosing PE
2. COVID – Patient volumes have recovered with further site conversion
3. Represents a strong indicator of USA acceptance
4. Xe-133 rapidly displaced by early adopters
5. Close correlation with the number of active generators and annual consumable sales
6. Canadian Market driven by public healthcare sector and budget cycles
7. Market launch initiated province by province, leveraging off pilot sites

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WHAT THE GUIDELINES SAY ABOUT TECHNEGAS® :

Endorsed by the guidelines from the European[1-2] and the Canadian[3] 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® 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 "

1. 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
2. 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. 3. 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

Beyond PE

Exponential Global Growth Potential

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)

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]

Diagnosis and monitoring of **COVID-19** patients[11, 12,18,19,21,22]

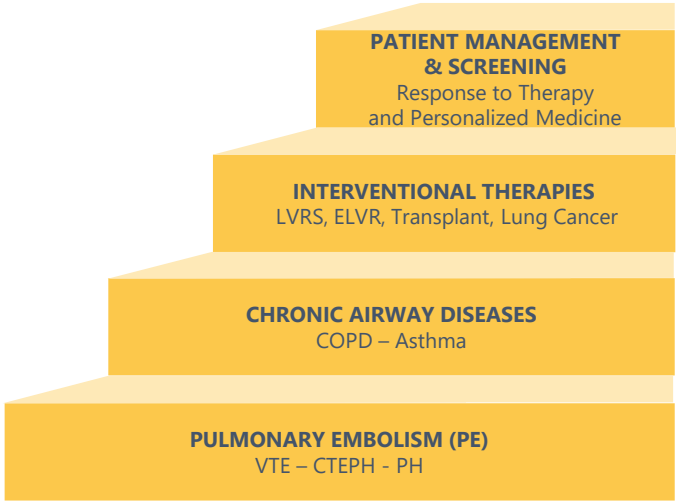
1. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596
2. Ohira H, et al. J Nucl Cardiol 2015;22(1): 141-157
3. Hsu K, et al. J Bronchology Interv Pulmonol 2018; 25(1): 48-53
4. Mortensen J, Berg RMG. Semin Nucl Med 2019; 49(1): 16-21
5. Wechalekar K, et al. Semin Nucl Med 2019; 49(1): 22-30
6. Elojeimy 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

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

Beyond Pulmonary Embolism Initiatives Underway

6 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 * Imaging Analysis Underway * Case Study Published,
2. **Woolcock Institute (Sydney, AU):** Diagnosis and response therapy in mild to moderate COPD[3]
   25 Patient / 75 Scan Protocol * 61% Completed
3. **CHUM (Montreal, CA):** Early detection of COPD in asymptomatic smokers[4]
   30 Patient Study * 100% Recruited * Analysis complete * First Draft Underway
4. **Dalhousie (Halifax, CA):** Post-lung transplant patients
   30 Patient Study * 30% Recruited – COVID Hold
5. **McMaster University Firestone Institute (Hamilton, CA):** Ventilation in lung cancer patients pre and post lung resection [2]
   50 Patients (100 scans) 100% Recruited * Abstract presented at American Thoracic Society May 2022 Preliminary Paper approved by the Canadian Journal of Respirology with publication pending in the Journal of Frontiers in Physiology
6. **McMaster University Firestone Institute (Hamilton, CA):** COVID-19 Related Lung Ventilation and Perfusion Injury[5]
   42 (84 scans) 85% Recruited * Abstract to be presented at the American Thoracic Society May 2023



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

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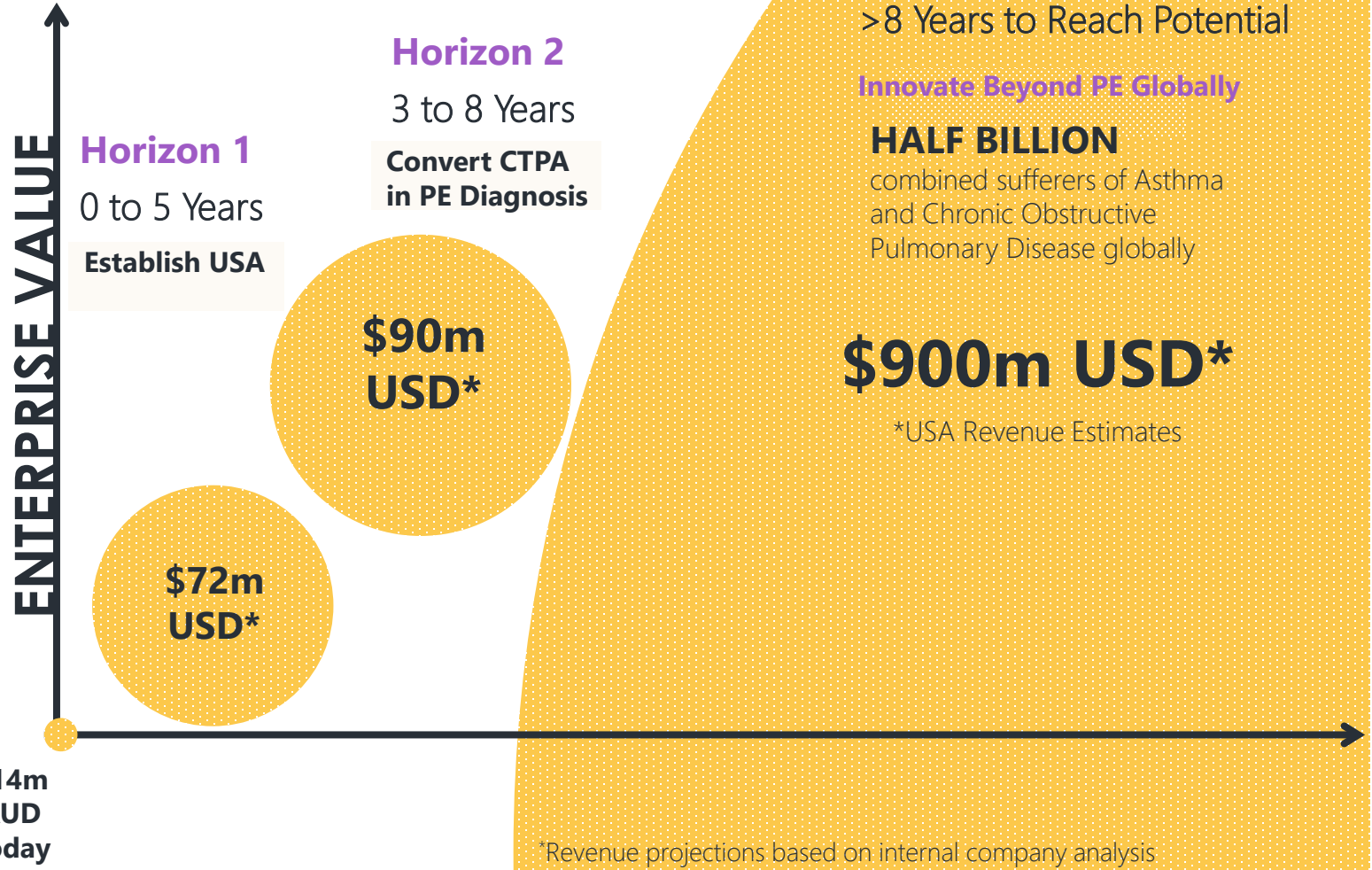
THREE VALUE HORIZONS

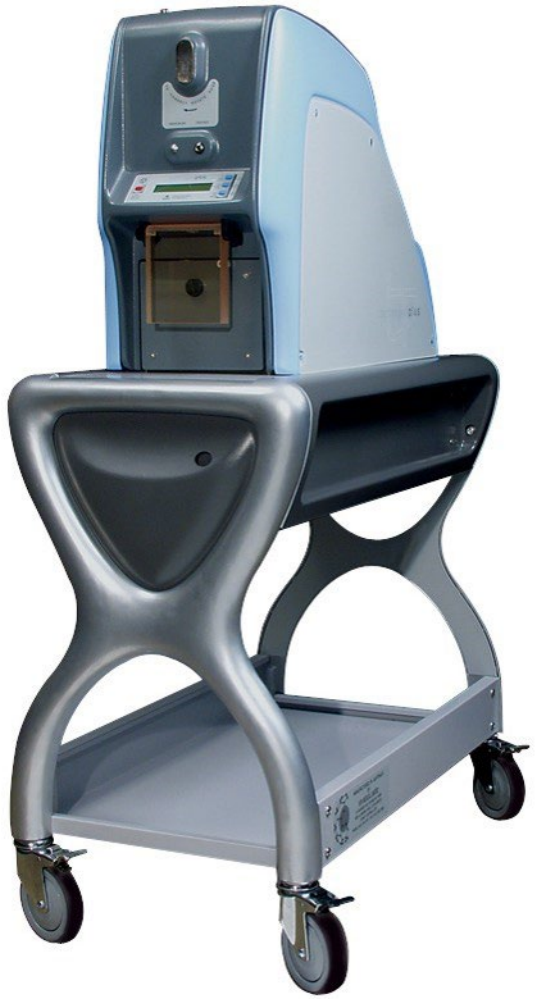


*Revenue projections based on internal company analysis

THE FUTURE IS NOW

1. Clinical trial program – commenced 2016
2. KOL Engagement – detailing directly to Australian Respiratory Physicians
3. Infrastructure Development – 8 Offices directly servicing 18 out of the 64 countries globally where Technegas is available

   On 31 March 2023 CYC finalized the acquisition DuPharma based in Copenhagen Denmark
4. Global Installed Footprint to leverage Growth Objectives



KEY Catalysts for the Next 2 Years

1. FDA approval for Technegas expected late 2023
2. First sales in US announce (shortly after approval)
3. Ongoing updates on Generators placed in US
4. Clinical proof of concept & validation in new substantive respiratory indications

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CYCLOPHARM INVESTMENT CASE

TECHNEGAS™

Profitable and Growing MedTech

Underlying business is cash positive and issuing dividends

First in Class

Established Gold Standard

Proprietary product sales to 64 countries with over 4.6 million patient procedures to date

Clinical Agent of Choice referenced by name in multiple clinical guidelines

Recurring Revenue

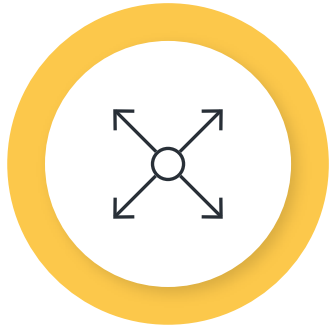
From single patient consumables

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

Indications beyond PE into chronic respiratory disease management could deliver exponential growth. Market Development already underway!

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THANK YOU

USFDA UPDATE

Progress Towards Approval Late 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 USDFDA updates **every 60 Days**
   - **Facility Modifications** – Workflow and HVAC Upgrade Completed to ISO 8 Standards
   - All items identified in the PAI have been **completed**

2. Complete Response Letter **(CRL)** Received 26 June 2021
   - Majority of CRL focused on:
     - Drug Product
     - Production
     - Device

3. USFDA **Type B Meeting Held** 27 January 2022
   - 2 – Hour Meeting Granted over a 3-hour period
   - Clarification received on outstanding elements related to the CRL
   - Most activities were required to be progressed sequentially

4. CRL Reply submitted 30 March 2023
   - USFDA six-month review initiated

5. USA **Commercialisation Readiness** Continues
   - Targeting late 2023 for USFDA Approval
   - Training of USA service personnel underway
   - Inventory Build of 200 Generators for USA Launch in process

USA COMMERICIALISATION PATHWAY

Clinical

- Key Opinion Leaders engaged
- Recruit Chief Medical Officer.
- R&D Programs Beyond PE Underway

Regulatory

- CRL Reply submitted 30 March 2023
- USFDA Six Month Review following CRL Reply submission
- USA application process to distriubute state by state underway

Commercial

- Recruit BDM August 2022

3PL

- Short-list distribution providers identified

Operations

- Outsourced back office provider under negotiations

.

Inventory Build

- Inventory build underway to subassembly level
- 200 Generators to launch

.

Education

- Application Specialists Interviews underway
- Suite of educational materials under development

Service

- National network service provider identified
- CYC Engineers training and managing service and installation program
- Training commenced

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SUPERIOR TO COMPETITIVE NUCLEAR MEDICINE PRODUCTS

Technegas®

- Easy
- 3 to 4 breaths
- 3D images
- No contraindications
- Cost-effective
- Covid-19 Safe

Xenon - 133

- **True radioactive gas** inhaled with **full face mask**
- **No 3D images** **limited to planar imaging** resulting in inferior clinical outcomes
- **Constant inhale -exhale breathing** **for 15 mins increasing the risk of COVID-19 exposure**
- **Requires special rooms** to contain radioactive gas in the event of a release

DTPA Tc99m

- **Wet Aerosol** **impacts efficacy, bronchospasm, Covid-19 carrier**
- **Creates hotspots** in presence of small airways lung diseases, a frequent comorbidity in PE, & impacts clinician interpretations

SUPERIOR TO COMPETITIVE IMAGING MODALITIES

Technegas®

- Easy
- 3 to 4 breaths
- 3D images
- No contraindications
- Cost-effective
- Covid-19 Safe

CTPA

High radiation burden

CTPA delivers at least 27 times more radiation to the breast as compared to V/Q SPECT[1]

Contraindications

CTPA should not be performed with pregnancy[1-2], renal impairment[3], contrast media allergy[3], diabetes[4]

Acute kidney injury (AKI)

AKI occurs in up to 13% of CTPA cases[5]

Lower clinical sensitivity

V/Q planar[6]	= 76%
CTPA[7]	= 82%
V/Q SPECT[7]	= 93%

Availability

Radiology ED services are generally provided 24/7 vs. nuclear medicine after hours on call service

1. Isidoro J, et al. Phys Med 2017; 41: 93-96
2. Bajc M, et al. Eur J Nucl Mol Imaging 2015; 42: 1325-1330
3. Miles S, et al. Chest 2009; 136: 1546-1553
4. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596
5. Doganay S, et al. Renal Failure 2015; 37(7): 1138-1144
6. Reinartz P, et al. J Nucl Med 2004; 45: 1501-1508
7. Hess S, et al. Semin Thromb Hemost 2016; 42(8): 833-845

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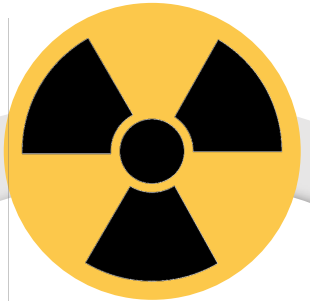

RADIATION DOSIMETRY

A nuclear medicine V/Q scan is **exponentially lower** in dose than CTPA

Technique	Effective dose (mSv/MBq)	Effective dose (mSv)	Breast absorbed dose (mGy)	Lung absorbed dose (mGy)
Ventilation Technegas (20MBq) [1-3]	0.015	0.30	0.13	2.2
Ventilation ^{99m}Tc-DTPA (20MBq) [1-2]	0.007	0.14	0.04	0.30
Ventilation ^{133}Xe (800MBq) [1]	0.0014	1.12	0.09	0.89
Perfusion MAA (120MBq) [1-3]	0.012	1.44	0.60	7.92
Low dose CT non-contrast [4]	NA	~ 1.00	-	-
CTPA 16 slice [1]	NA	14.4	10-20	10
CTPA 64 slice [1,3]	NA	19.9	22	20

1. Bajc M, et al. Eur J Nucl Med Mol Imaging 2009; 36(8): 1356-1370
2. Schembri GP, et al. Semin Nucl Med 2010; 40: 442-454
3. Isidoro J, et al. Phys Med 2017; 41: 93-96
4. Ling IT, et al. Intern Med J 2012; 42(11): 1257-1261

NUCLEAR MEDICINE PROVIDES BETTER DIAGNOSTIC OUTCOMES IN DIAGNOSING PE

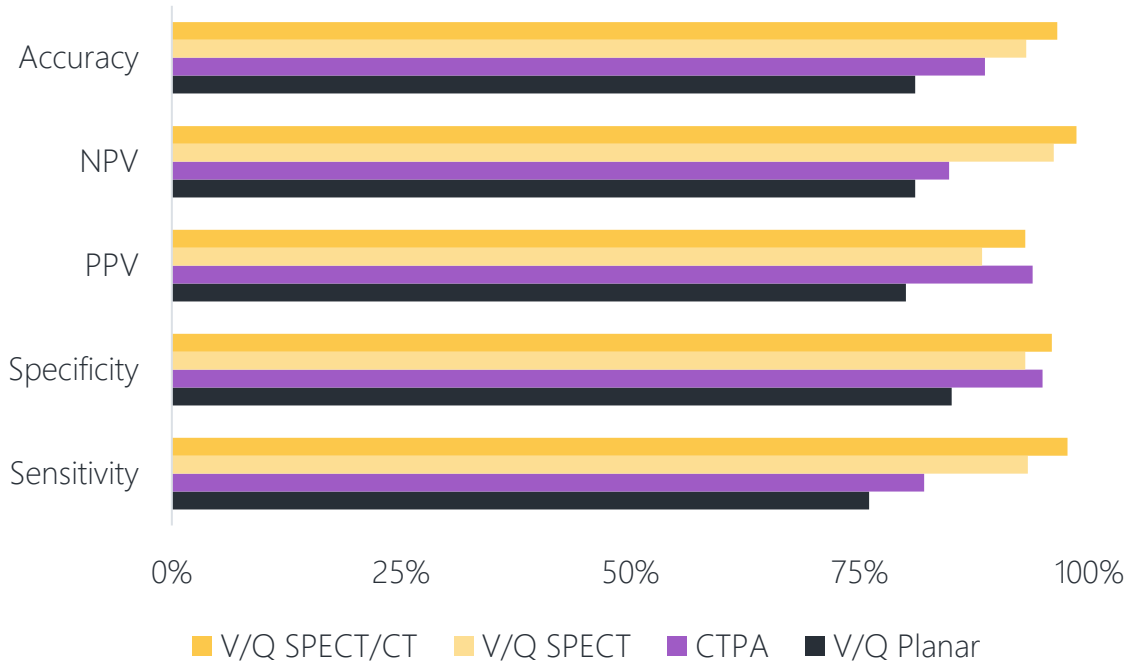

Table: Diagnostic ability of V/Q SPECT/CT[1], V/Q SPECT[1], CTPA[1] and V/Q Planar[2] to detect PE (adapted from Hess and al, 2016[1] and from Reinartz et al, 2004[2])

- V/Q SPECT and V/Q SPECT/CT have shown that V/Q SPECT/CT is superior in most clinical settings with better overall diagnostic performance[1]
- In situation of acute PE, chronic PE pregnancy, paediatrics and the COPD population, V/Q SPECT, with or without low-dose CT, can be considered as a first-line investigation to detect PE3 due to:

Its low radiation and no adverse reactions[3]

Its higher accuracy, sensitivity and negative predictive value when compared to CTPA[3]

1. Hess S, et al. Semin Thromb Hemost 2016; 42(8): 833-845
2. Reinartz P, et al. J Nucl Med 2004; 45: 1501-1508
3. Leblanc M, et al. CANM guidelines; Nov 2018: www.canm-acmn.ca/guidelines

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	5591	S	S	$353.49	$368.08	4.0%
78580	Pulmonary perfusion imaging (eg, particulate)		5591	5591	S	S	$353.49	$368.08	4.0%
78582	Pulmonary ventilation imaging (eg, aerosol or gas) and perfusion imaging		5592	5592	S	S	$455.52	$471.93	3.5%
78597	Quantitative differential pulmonary perfusion, including imaging when performed		5591	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	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%

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

2. **Technegas® will be reimbursed for the full cost of its consumable in the USA from Day 1**

1. SNMMI - Final Rule 2020 Compared to October 2019 Rates (APC) Medicine Procedures, Radiopharmaceuticals, and Drugs Medicare Hospital Outpatient Prospective Payment System HOPPS

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Appointed 27 September 2022

https://youtu.be/m9iEajOEkos