CYCLOPHARM

Investor Update
Bell Potter HealthCare Conference

James McBrayer, CEO & Managing Director

10 November 2021

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All references to dollars unless otherwise specified are to Australian dollars.

COMPANY OVERVIEW

Cyclopharm Limited (CYC) is a Leading Diagnostic Lung Imaging Company

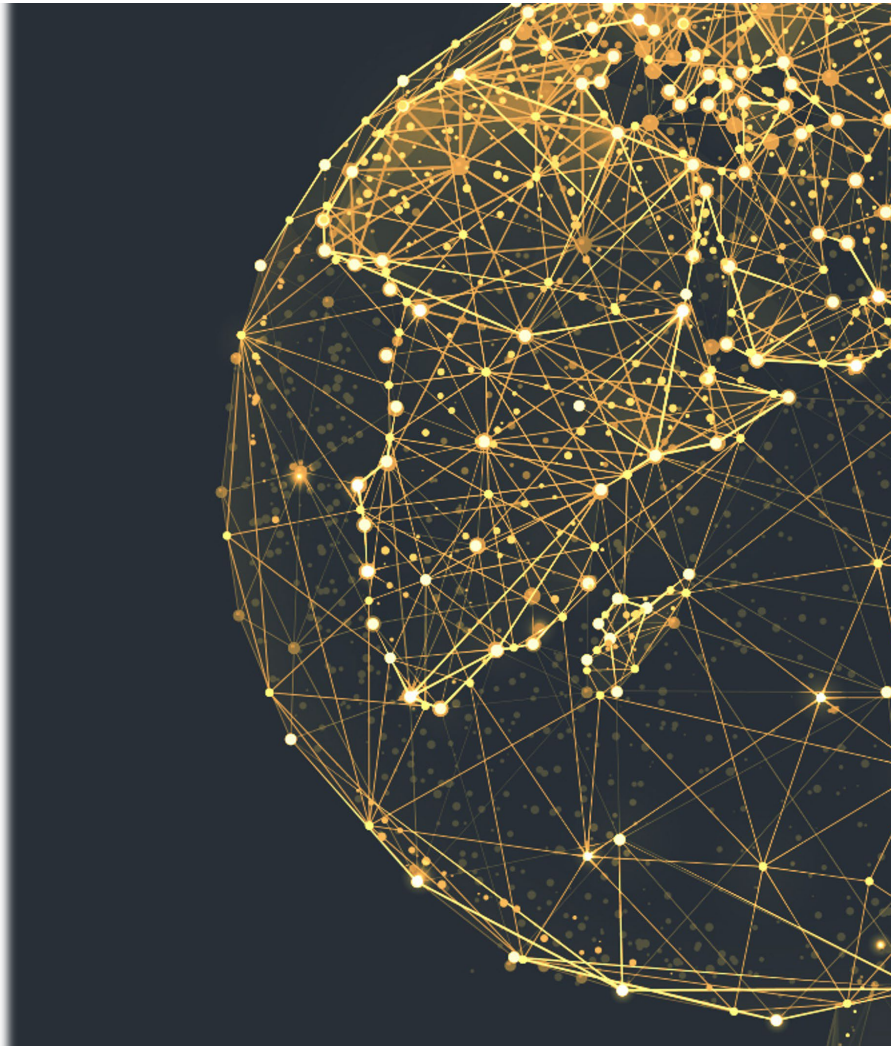
1. Lead nuclear medicine product **Technegas®** is currently available in **60 countries** with significant opportunity to expand into the USA with sales targeted for mid 2022 following completion of **USFDA** Complete Response Letter submission

2. The **gold standard & world leader** in functional lung ventilation imaging technology - supported by 4.4 million patient studies and 100's of peer reviewed published studies with **COVID-19** applications for use

3. **Recurring consumables** and capital equipment revenue streams

4. A **profitable** and **growing** company with a history of **dividend** payments

5. Opportunity to broaden Technegas® applications **Beyond pulmonary embolism** diagnosis into large addressable markets such as COPD and Asthma



PRESENTATION HIGHLIGHTS

Recovery Post COVID and Progress to USA Approval

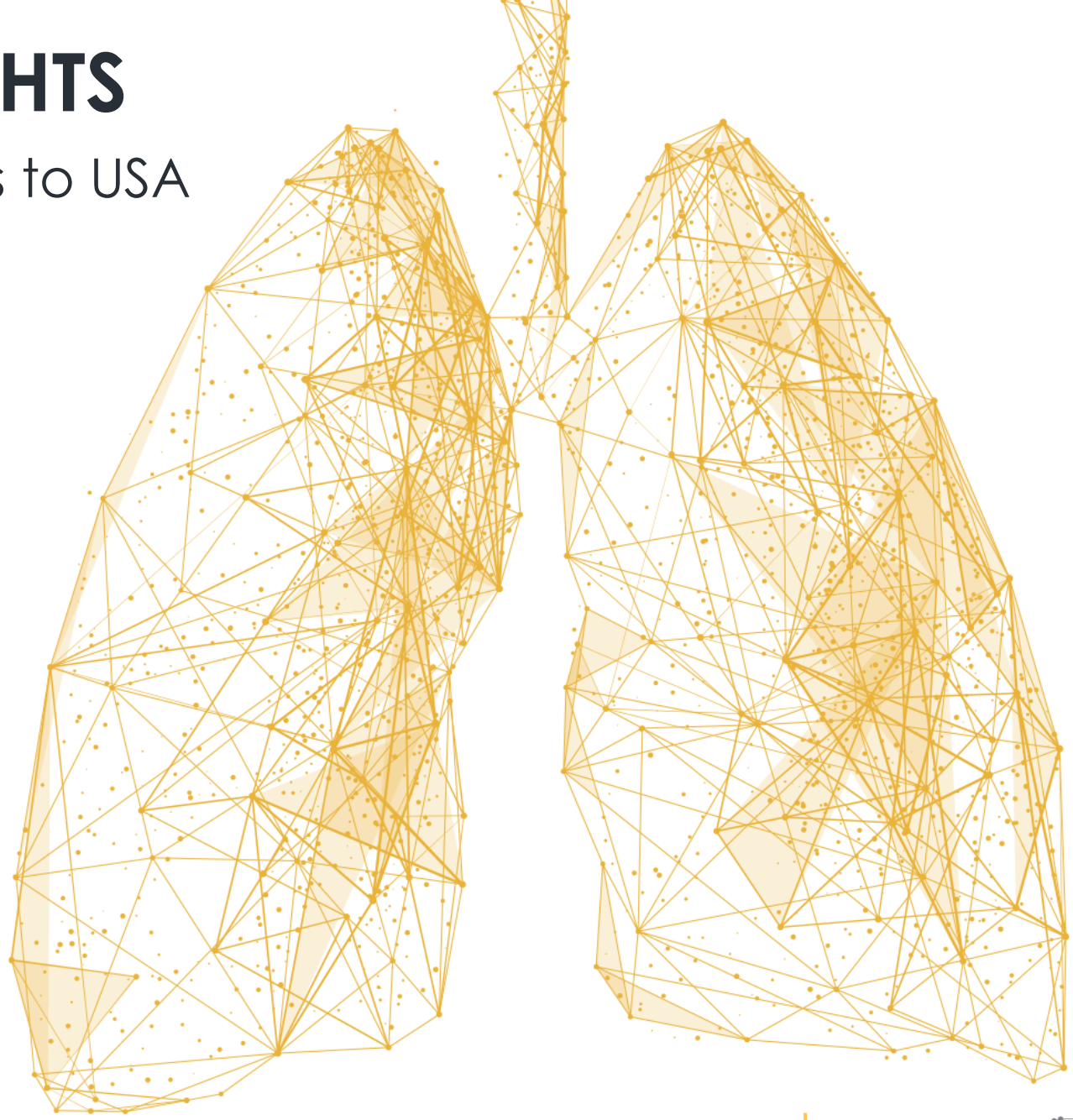
1. **Recovery in FY 2021** from initial COVID-19 impact in primary country markets

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 granted** & targeting **mid-2022** for USFDA approval

4. Ongoing soon to be published studies "Beyond PE" to significantly **expand clinical applications** to include asthma, COPD, Long COVID.....

5. **Strong Balance Sheet** to fully fund growth strategy - $31.7m net cash as at 30 June 2021



TECHNEGAS ®

World's Best Functional Lung Ventilation Imaging Agent

Patient inhales extremely small carbon particles labeled with 99mTechnetium[1]

The small size and hydrophobic properties demonstrates gas like-behavior and alveoli deposition into the lungs[2-3]

Clinicians can visualise functional ventilation using Technegas®

TECHNEGAS ®

Technology System Overview – Capital Equipment + Single Patient Consumables

Technegas®
TechnegasPlus Generator

+

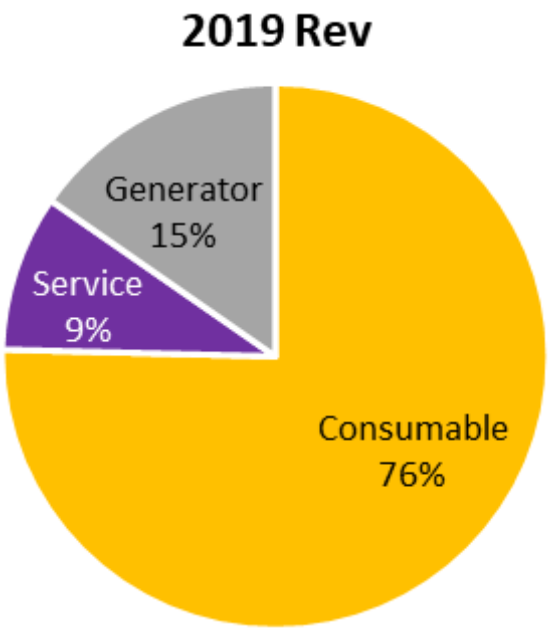
CONSUMABLES
Technegas® Patient Administration Kit
(50 patient administrations)

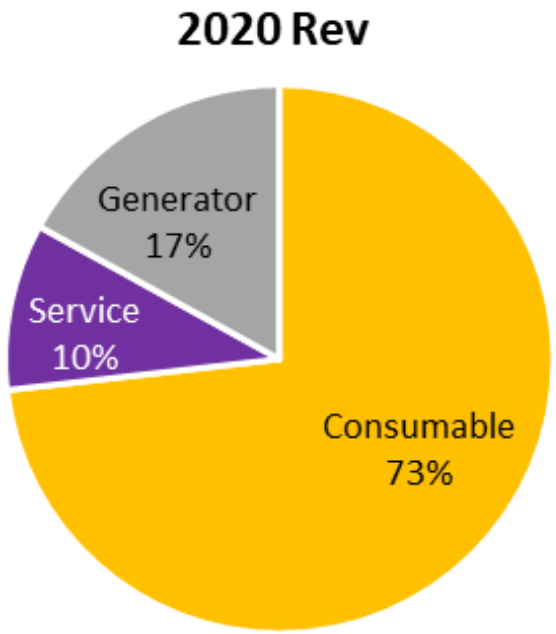
50x
Patient Administration Sets

50x
Pulmotec® carbon crucibles

2x
Brass contacts

BUILDING FOR GROWTH





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

- Total global sales of over $80m AUD from 2015 to 2020
- 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 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 immediate USA demand**

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1H 2021 Financial Highlights

Revenue	Group revenue of $8.5m, up 47%, improved sales revenue recorded over all product lines
Third Party Distribution	$1.6 million of third-party distribution revenue, up 121%
Net Loss Before Tax	$3.6 million loss, improvement of $2.0 million
R&D Tax Incentive	$3.0 million received in Feb 2021
USFDA Expenses	$1.2 million in 1H2021 vs $2.4 million in 1H2020
Dividends	FY20 total dividends maintained at 1.0 cps, 0.5cps dividend to be paid on 13 September 2021
Feb 2021 Capital Raising	Placement & SPP oversubscribed, raising $33m
Net Cash	$31.7 million as at 30 June 2021
COVID Recovery	$6.4 million revenue from Technegas™ products - 30% rebound in 1H2021 after pandemic impacted 1H2020

2H 2021 OUTLOOK

COVID-19 Recovery and Progress to USFDA Approval

1. **Recovery** from initial COVID-19 impact in primary country markets – Technegas revenues are expected to be in line with 2020
2. **Superior Safety profile** of Technegas over competitive products driving smaller customer conversion in established markets
3. **CE Mark renewal** in compliance with updated European Medical Device Regulations (MDR) guidelines in final stages
4. **Clinical trial progress** in applications 'Beyond PE' with both Long Covid and Lung resection studies – Targeting publications to coincide with the American Thoracic Society Meeting in May 2022
5. **Third Party Distribution** opportunities and revenues continue to expand in our **10 direct country markets** with revenues expected to exceed 1H 2021 sales. 2022 order book already in excess of $5m.
6. Significant progress made in addressing outstanding **USFDA** requirements
7. Steps toward **USA commercialisation** continue

USFDA UPDATE

Progress Towards Approval Mid 2022 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**
   - Significant Documentation Development and Revisions accomplished to date
   - **Facility Modifications** – Workflow and HVAC Upgrade
   - 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
   - **Substantial package submitted** with meeting request
3. USFDA **Type B Meeting Granted** for 27 January 2022
   - 2 – Hour Meeting Granted over a 3-hour period
   - Teleconference Format
   - Likely to receive pre-meeting responses a few days prior to meeting
4. **USA Commercialisation** Readiness Continues
   - Targeting Mid 2022 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

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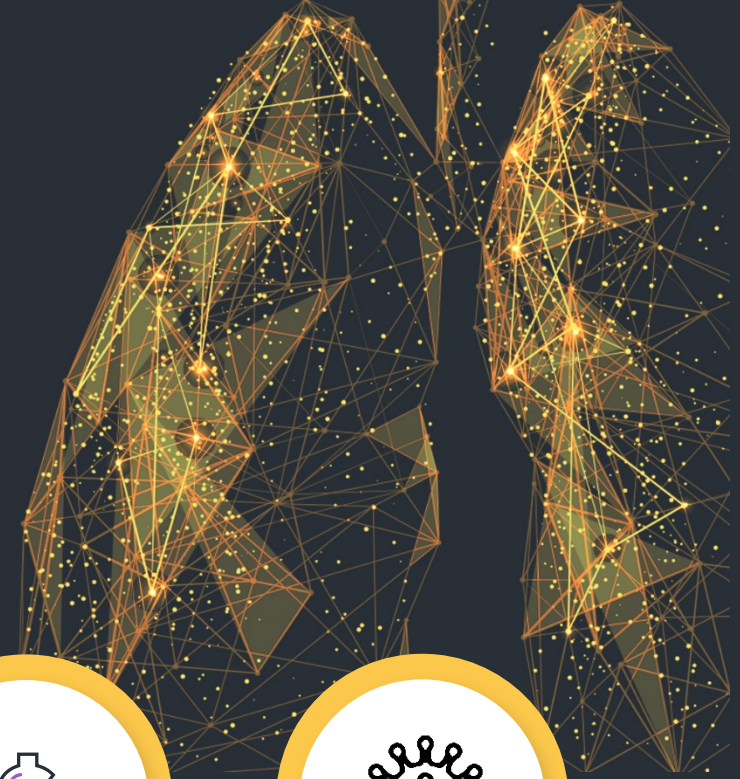
BENEFITS OF USING TECHNEGAS®



Easy
to prepare and administer

Only need
3 to 4 breaths

3D images
provide functional imaging through to the alveolus

NO
contraindications

Cost
effective

COVID-19 Safe

PULMONARY EMBOLISM

~3 million
cases of PE p.a.
but could be much higher

Symptoms
are varied with diagnosis confirmed either through CTPA or a nuclear medicine ventilation-perfusion study

30%
of pulmonary embolisms are fatal if left untreated

Nuclear Medicine
using 3-D imaging is the most accurate method of diagnosis

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

Nuclear Ventilation Imaging Agent Comparison

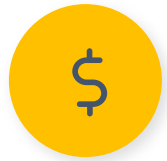
Technegas®

Easy

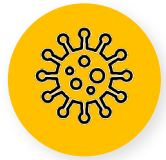
3 to 4 breaths

3D images

No contraindications

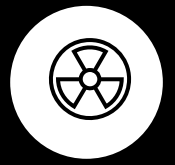


Cost-effective



Covid-19

Xenon - 133



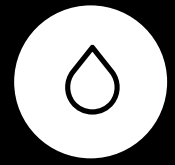
True radioactive gas inhaled with **full face mask**

No 3D images **limited to planar imaging** resulting in inferior clinical outcomes

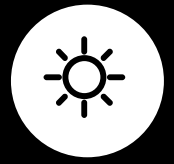
Constant inhale -exhale breathing **for 15 mins increasing the risk of COVID-19 exposure**

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

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

SUPERIOR TO COMPETITIVE IMAGING MODALITIES

Technegas®

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

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%

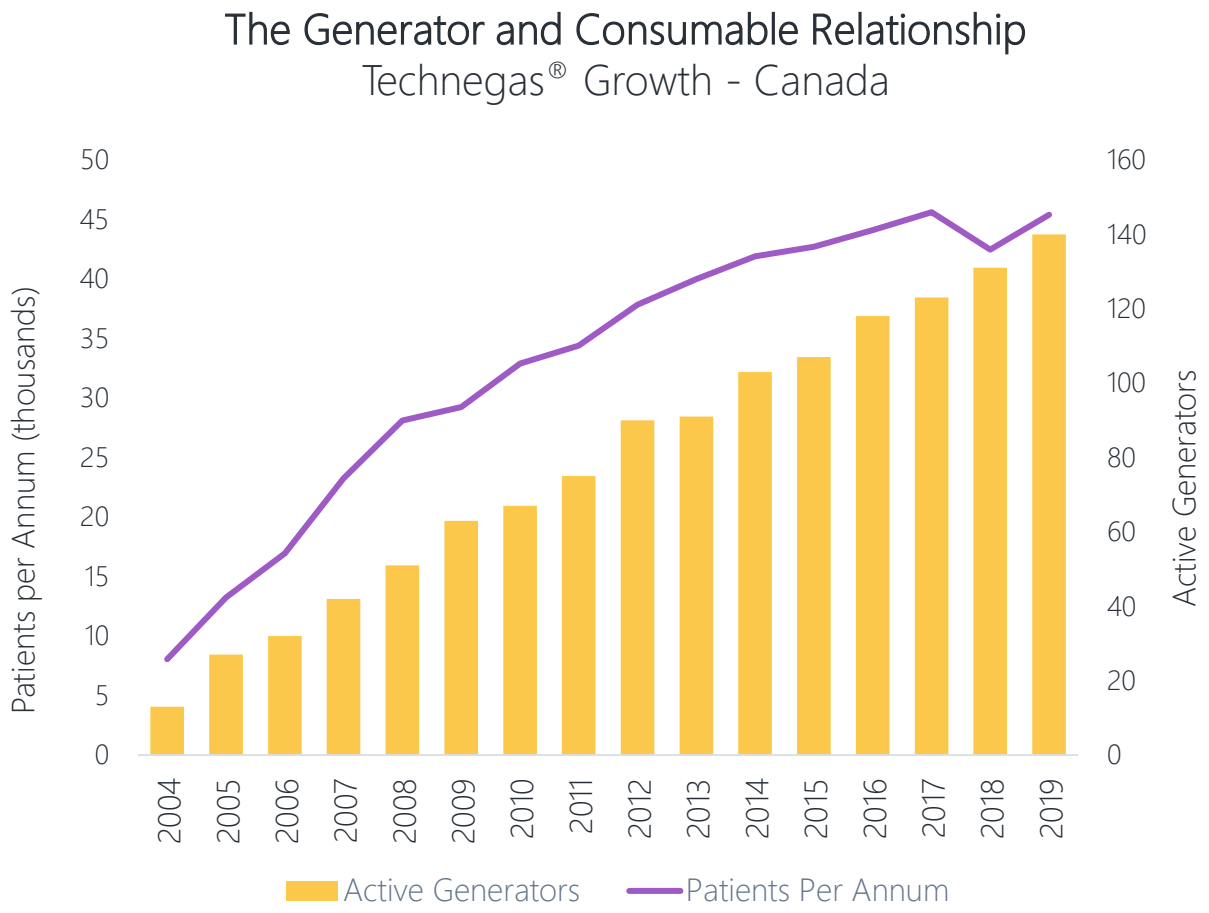
Availability

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

TECHNEGAS®

The Canadian Case Study

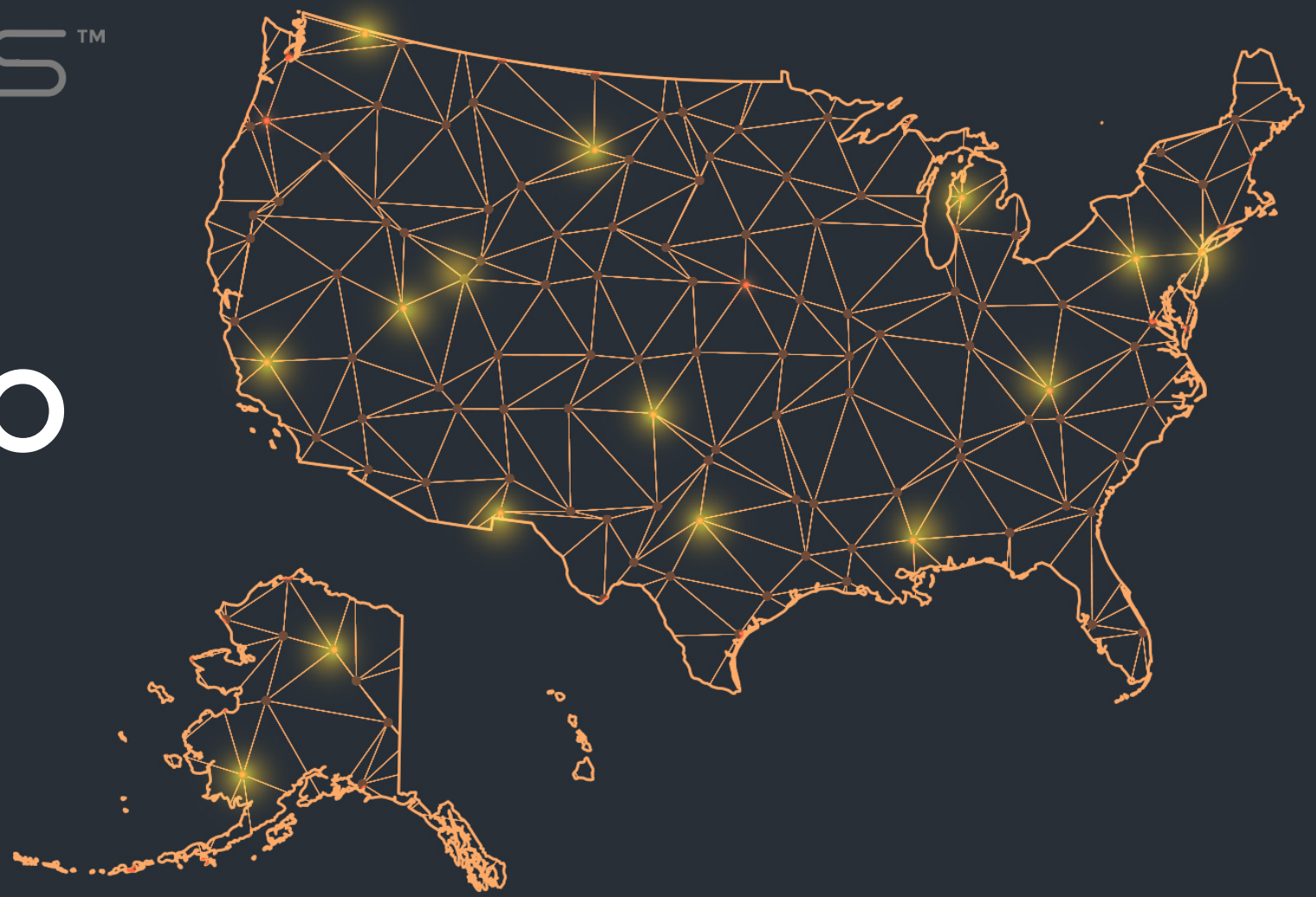


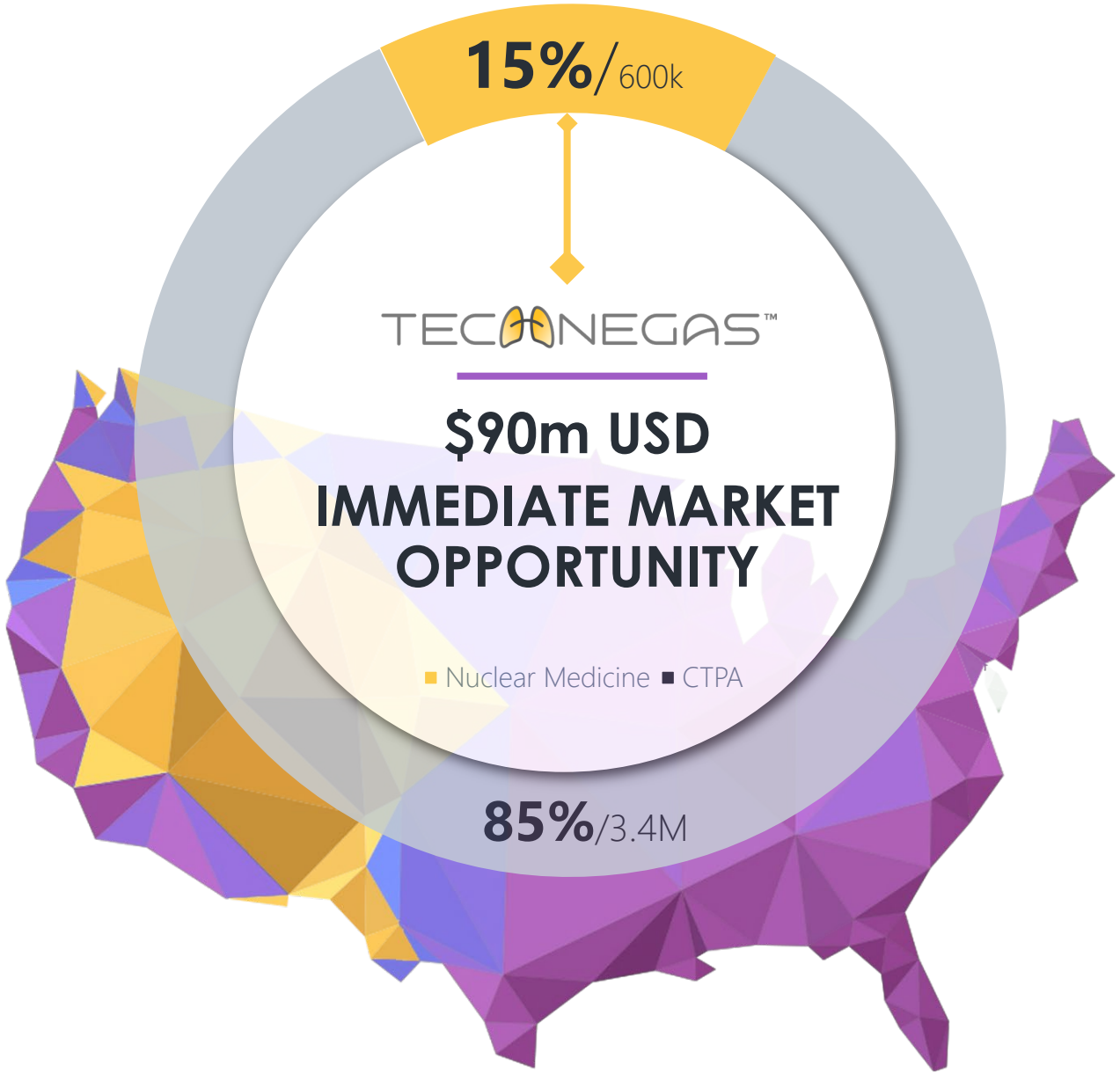
Canada is Cyclopharm's largest single country market

1. Market leader for diagnosing PE
2. 14 consecutive years of PAS growth
3. Represents a strong indicator of USA acceptance
4. Xe-133 rapidly displaced by early adopters
5. Direct correlation with the number of active generators and annual consumable sales
6. Market driven by public healthcare sector
7. Market launch initiated province by province, leveraging off pilot sites
8. Near 100% market conversion to Technegas following COVID-19 safety concerns related to competitive products

TECNEGAS™

COMING TO AMERICA





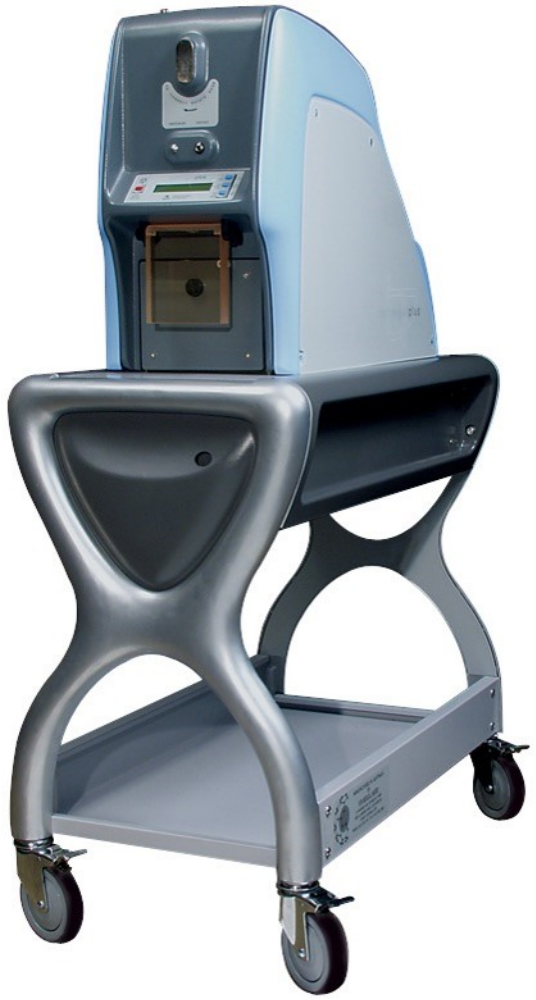
600K Nuclear Medicine Ventilation Procedures p.a.

- 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® 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 2022
- 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® 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® 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 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

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EXPANDING INDICATIONS

TECNEGAS™

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)** candidates[3]

Preoperative assessment of **lung resection** candidates with borderline pulmonary reserve[4-6]

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]

Diagnosis and monitoring of **COVID-19** patients[11]

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

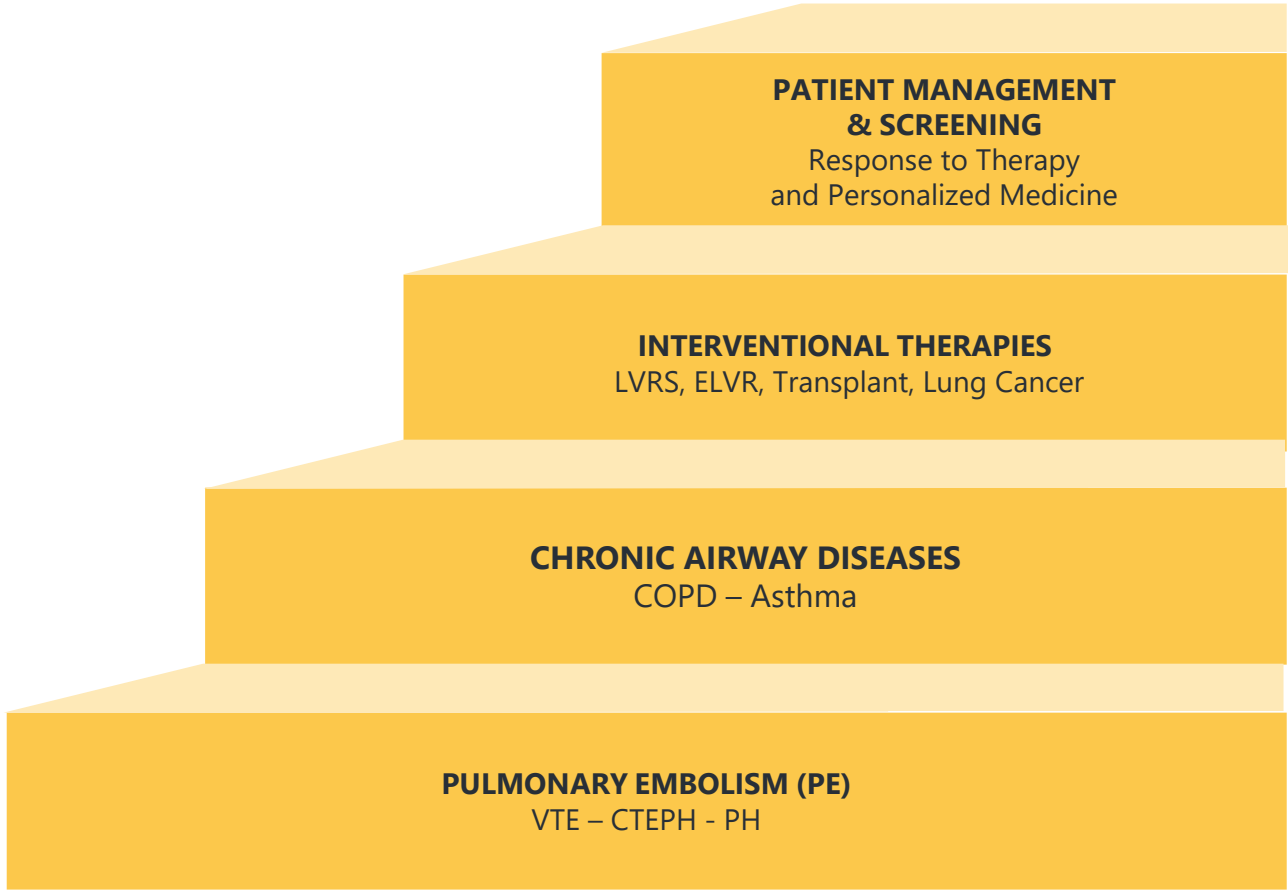
BEYOND PE : Clinical Initiatives Underway

Clinical Trials Sponsored by Cyclomedica

- **Hunter Medical Research Institute (Newcastle, AU):** Diagnosis and response to therapy in severe asthma and COPD[1]
- **Woolcock Institute (Sydney, AU):** Diagnosis and response therapy in mild to moderate COPD[3]
- **CHUM (Montreal, CA):** Early detection of COPD in asymptomatic smokers[4]
- **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 [2]
- **McMaster University Firestone Institute (Hamilton, CA):** COVID-19 Related Lung Ventilation and Perfusion Injury[5]

Other Non-Sponsored Clinical Initiatives

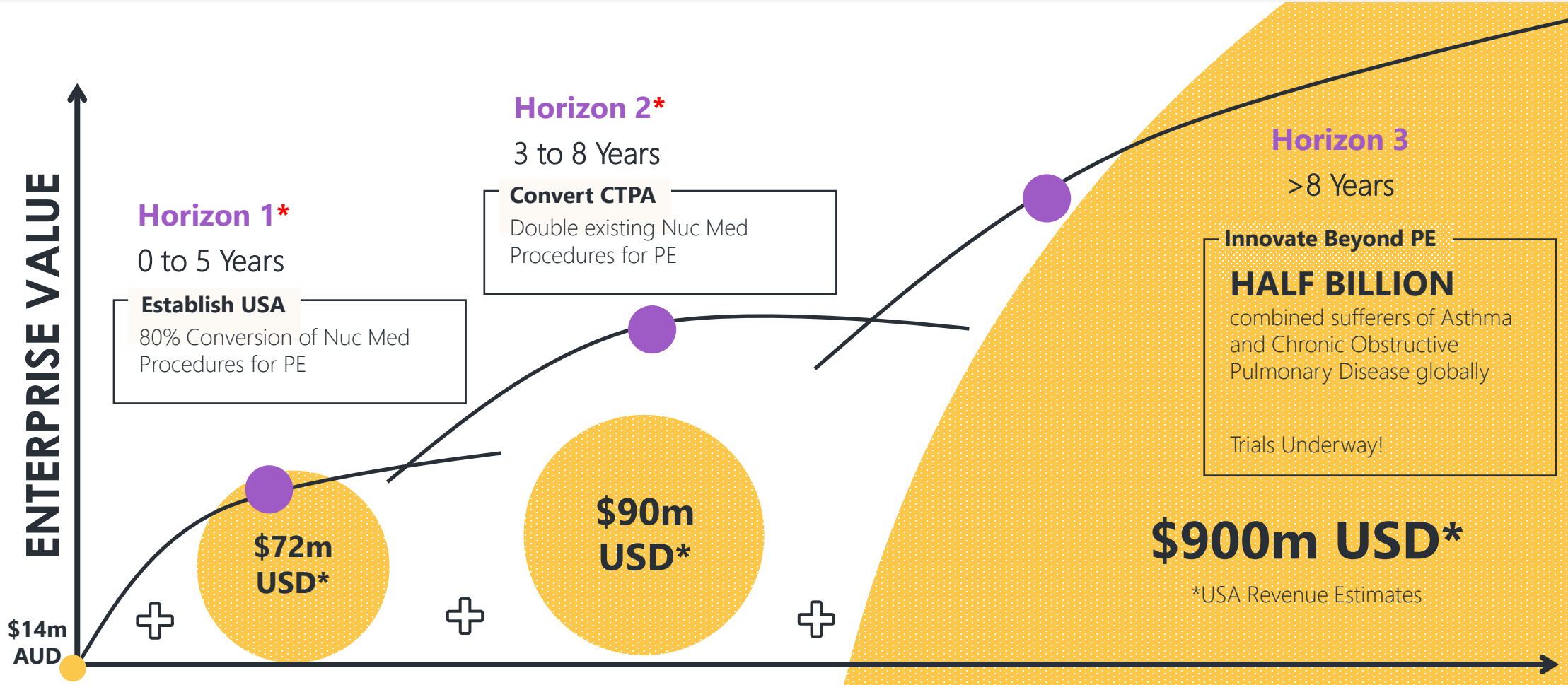
- **Macquarie University (Sydney, AU):** ELVR with endobronchial valves in severe COPD patients
- **Macquarie University (Sydney, AU):** Bronchial Thermoplasty procedure in asthma patients



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

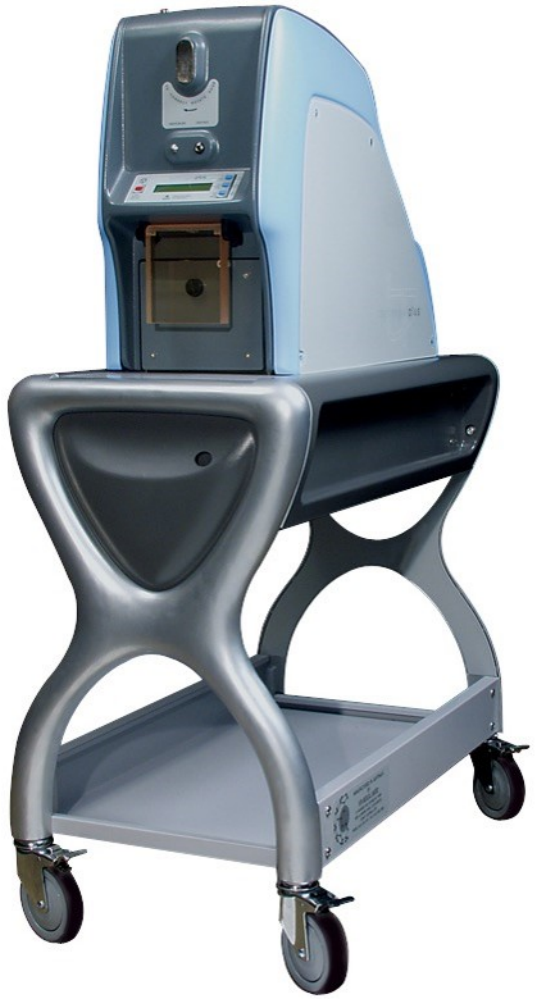
Results to be Published 1H 2022

THREE VALUE HORIZONS



***Timelines Under Review**

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



KEY Catalysts for the Next 2 Years

1. FDA approval for Technegas expected mid 2022
2. First sales in US announce (shortly after approval)
3. Ongoing updates on No. Generators placed in US
4. Additional guidelines and clinical papers to come out on the use of Technegas in both pulmonary embolism and additional indications

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CYCLOPHARM INVESTMENT CASE

TECNEGAS™

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 studies to date

Clinical Agent of Choice referenced by name in multiple clinical guidelines

Recurring Revenue

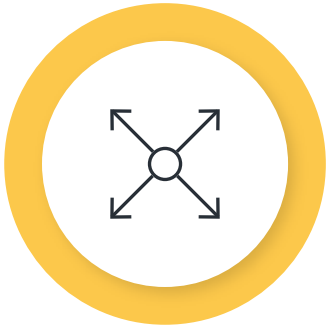
From single patient consumables

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

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THANK YOU

For additional information:

jmcbrayer@cyclopharm.com.au

2020 FINANCIALS

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

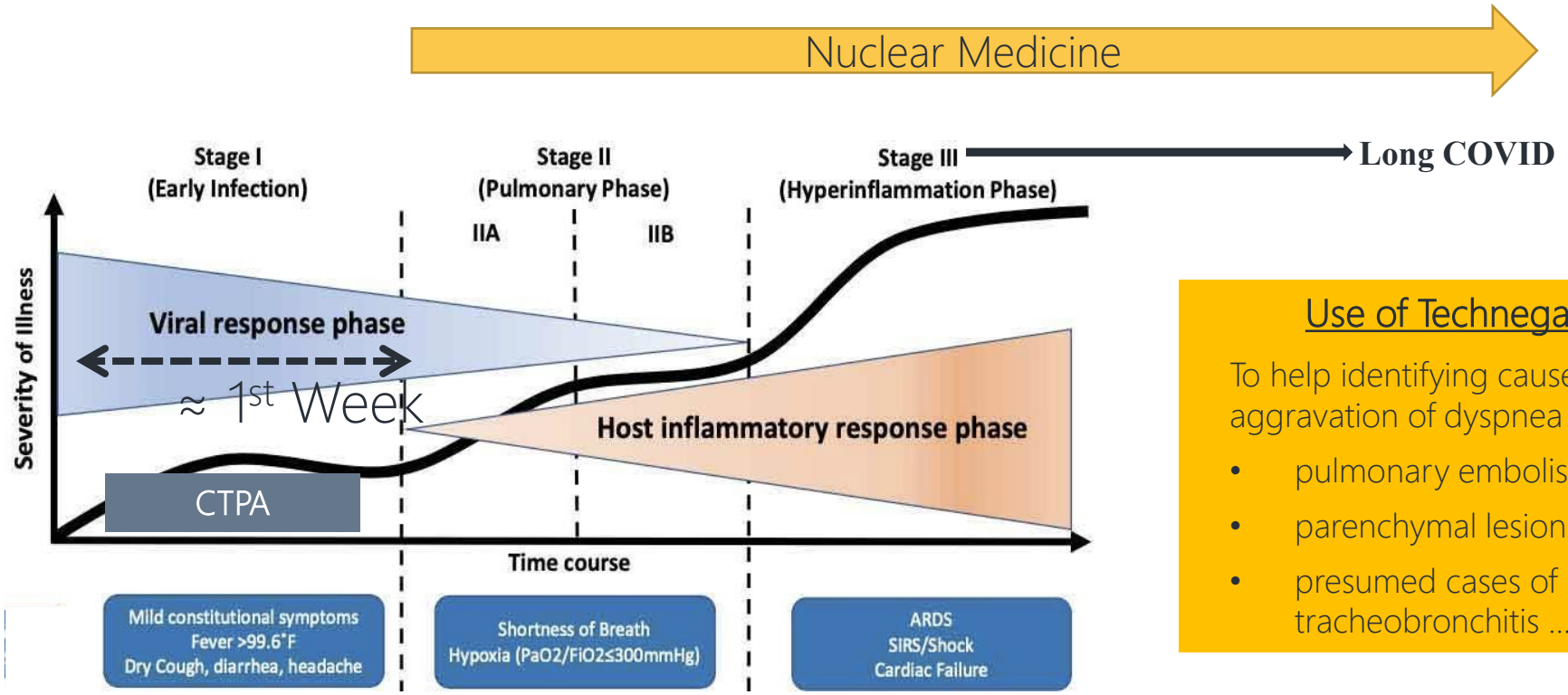
Technegas™

Helping patients and frontline workers during the COVID-19 pandemic

CYCLOPHARM:

Helping in the fight against COVID-19

Nuclear Medicine Imaging In COVID19



J Heart Lung Transplant 2020;39(5):405.

Use of Technegas

To help identifying causes of aggravation of dyspnea

- pulmonary embolism,
- parenchymal lesions,
- presumed cases of tracheobronchitis …

Increased clinical demand for Technegas during the COVID-19 pandemic

Technegas is viewed as the safest nuclear medicine ventilation agent globally

1

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)

2

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

3

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

4

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

CYCLOPHARM:

Helping in the fight against COVID-19

McMaster University

100-patient clinical trial designed to use ventilation perfusion SPECT-CT with Technegas*:

1

<u>Primary Endpoint:</u>

To investigate and characterize the extent of COVID-19 infection related ventilation and perfusion injury at ≤4-weeks and 6-months post infection recovery in asthmatic and healthy populations.

2

<u>Secondary Endpoints:</u>

To investigate if COVID-19 infection related ventilation and perfusion injury ≤4-weeks and 6-months post infection recovery is related to inflammatory markers, symptoms (quality of life, dyspnea, exercise limitation) and clinical measurements (airflow in asthmatic and healthy populations

To investigate if COVID-19 infection related ventilation and perfusion injury ≤4-weeks post infection recovery is predictive of symptoms and clinical outcomes 6-months post infection recovery in asthmatic and healthy populations

3

<u>Exploratory Objective:</u>

To determine if COVID-19 infection related ventilation and perfusion injury) ≤4-weeks and 6-months post SARS-CoV2 infection recovery is less pronounced in asthmatic compared to healthy populations and if this difference can be explained by protective mechanisms due to skewing of immune response (Th2/Th1 in asthma) and/or dampening of Th1 cytokine storm due to maintenance corticosteroid therapies.

*https://clinicaltrials.gov/ct2/show/NCT04549636

NUCLEAR MEDICINE PROVIDES BETTER DIAGNOSTIC OUTCOMES IN DIAGNOSING PE

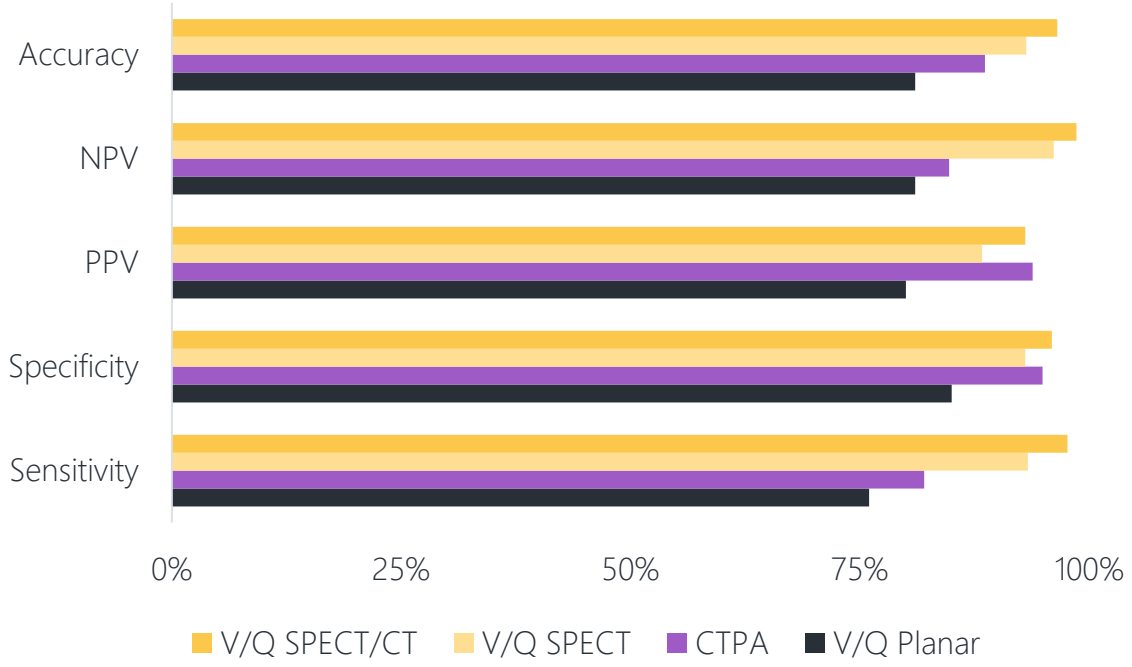


Table: Diagnostic ability of V/Q SPECT/CT[1], V/Q SPECT[1], CTPA[1] and V/Q Planar[2] to detect PE (adapted from Hess and al, 2016[1] and from Reinartz et al, 2004[2])

- 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

Diagnosing Pulmonary Embolism with V/Q SPECT

Technegas is the “V” in “V/Q”

Primary imaging procedure
when
PE is suspected[1]

Excellent diagnostic performance[2]
Sensitivity 93.0%
Specificity 93.3%
NPV 96.1%

Detects PE
at subsegmental level[3]

Minimally invasive
Aids patient comfort and compliance[4], even in COPD patients[5]

COMPARED TO CTPA:

Less radiation burden
V/Q SPECT delivers 27 times less radiation to the breast as compared to CTPA[6]

Minimal exclusion criteria
V/Q SPECT can be performed in case of pregnancy[6-7], renal impairment[8], contrast media allergy[8] and diabetes[3]

Higher clinical sensitivity
V/Q SPECT has a higher sensitivity to diagnose PE compared to CTPA (93% vs 82% respectively)[2].

1. Waxman AD, et al. J Nucl Med 2017; 58: 13N-15N
2. Hess S, et al. Semin Thromb Hemost 2016; 42(8): 833-845
3. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596
4. Sánchez-Crespo A, et al. Nucl Med Commun 2008; 29(2): 173-177
5. Nasr A, et al. ECPRM 2017; 4(3): 85-91
6. Isidoro J, et al. Phys Med 2017; 41: 93-96
7. Bajc et al. Eur J Nucl Mol Imaging 2015; 42: 1325-1330
8. Miles S, et al. Chest 2009; 136: 1546-1553

Clinical

- Key Opinion Leaders engaged
- Recruit Chief Medical Officer 2022.
- R&D Programs Beyond PE Underway

Regulatory

- Pre-approval audit conducted
- CRL Response – 12 months from June 2021 to submit
- Type B Meeting scheduled for 27/01/22

Commercial

- Recruit BDM

3PL

- Short-list distribution providers identified

Operations

- Outsourced back office provider under negotiations

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Inventory Build

- Inventory build underway to subassembly level

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Education

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

Service

- National network service provider identified
- Training underway

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USA REIMBURSEMENT IS ESTABLISHED

MEDICARE HOPPS (HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM) $USD

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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 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

TECHNEGAS®
In recent literature

66% of references citing Technegas® in recent months are for indications Beyond PE

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 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
10. Bajc M, et al. Ventilation/Perfusion SPECT Imaging - Diagnosing other **cardiopulmonary diseases** beyond PE. Semin Nucl Med 2019; 49(1): 4-10
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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
16. Dimastromatteo J, et al. Molecular imaging of pulmonary diseases. Respir Res 2018; 19(1): 17
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
20. Righini M, et al. Diagnosis of acute pulmonary embolism. J Thromb Haemost. 2017; 15: 1251-1261
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
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27. Provost K, et al. Reproducibility of **lobar perfusion and ventilation quantification** using SPECT/CT segmentation software in lung cancer patients. J Nucl Med Technol 2017; 45(3): 185-192
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30. El-Barhoun EN, et al. Reproducibility of a **semi-quantitative lobar pulmonary ventilation** and perfusion technique using SPET and CT. Hell J Nucl Med 2017; 20(1): 71-75

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