



# CYCLOPHARM

**Investor Update**

**Bell Potter HealthCare Conference**

James McBrayer, CEO & Managing Director

**10 November 2021**



# SAFE HARBOUR STATEMENT

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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

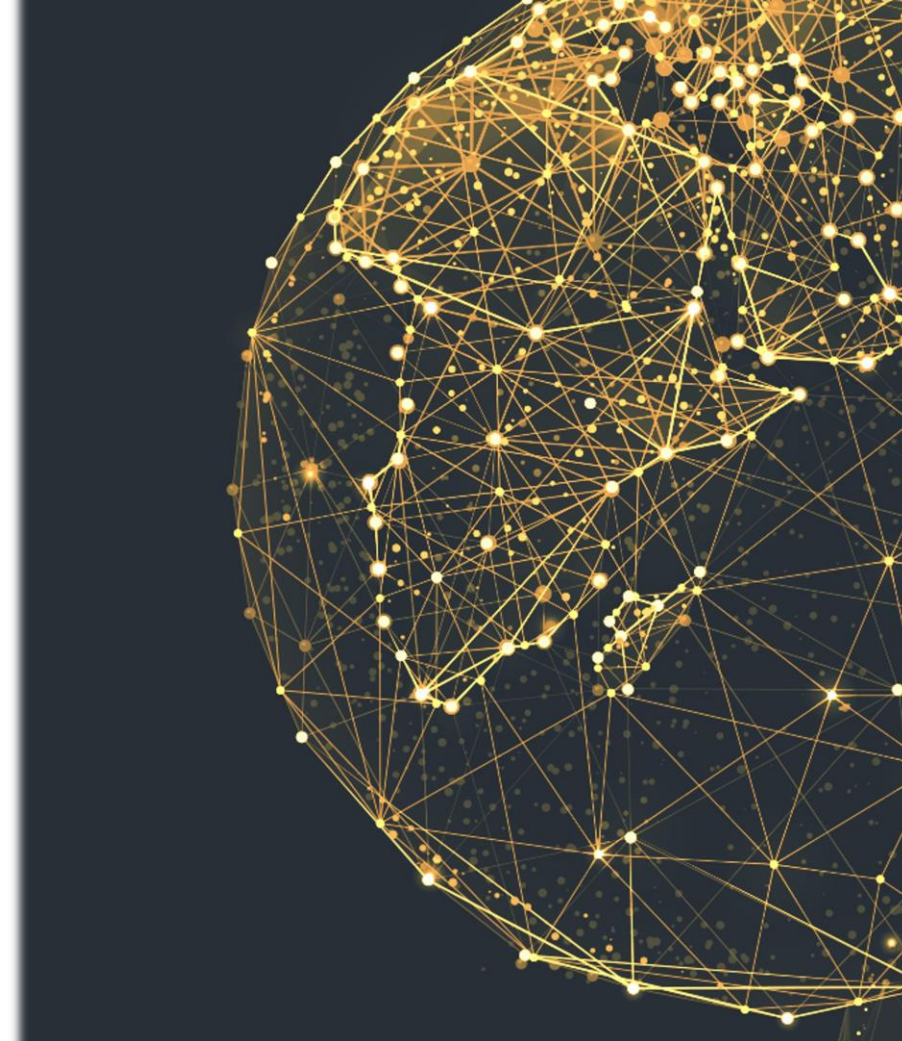
**Recurring consumables** and capital equipment revenue streams

4

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

5

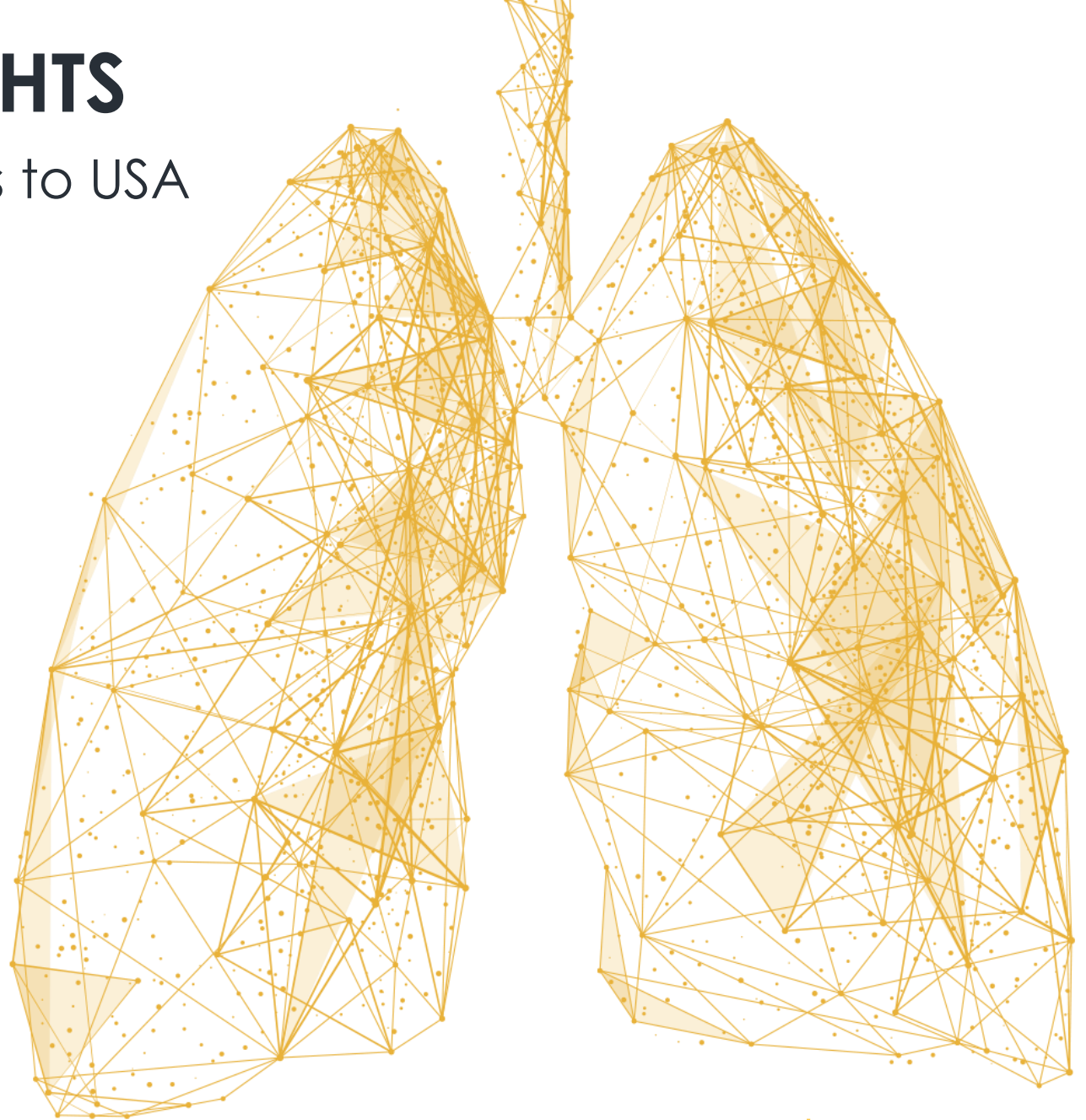
Opportunity to broaden Technegas® applications **Beyond pulmonary embolism** diagnosis into large addressable markets such as COPD and Asthma



# PRESENTATION HIGHLIGHTS

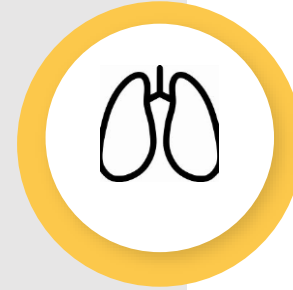
## Recovery Post COVID and Progress to USA Approval

- 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  $^{99m}\text{Tc}$ 1



The small size and hydrophobic properties demonstrates gas like-behavior and alveoli deposition into the lungs<sup>2-3</sup>



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)

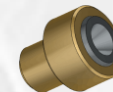
50x  
Patient Administration Sets



50x  
Pulmotec® carbon crucibles



2x  
Brass contacts

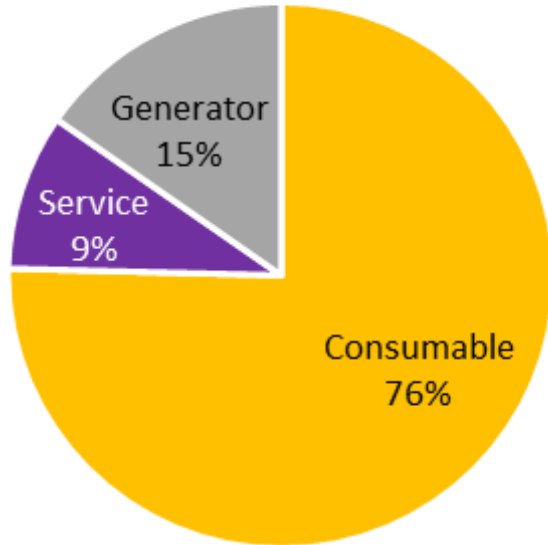


# BUILDING FOR GROWTH

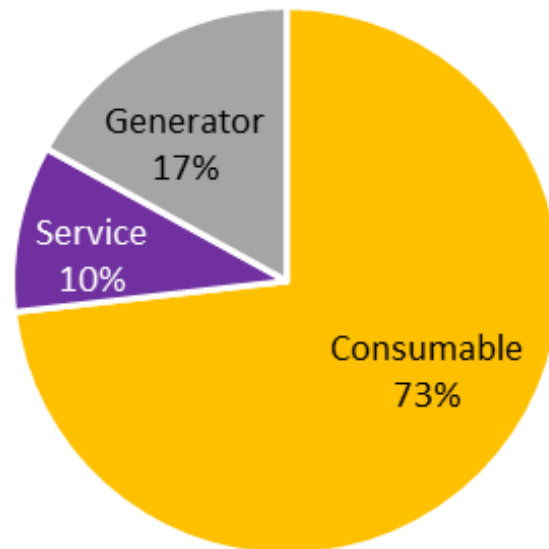


Technegas® is a global market leader with significant growth potential in the **USA market**

2019 Rev



2020 Rev



- 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



# 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 USFDA 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



# 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

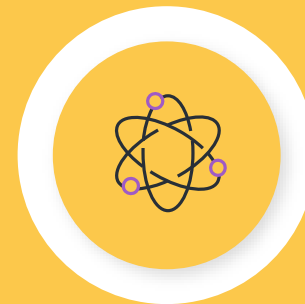


## Symptoms

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<sup>1-2</sup> and the Canadian<sup>3</sup> Associations of Nuclear Medicine (EANM & CANM)

1. Bajc M, et al. Eur J Nucl Med Mol Imaging 2019; [Epub ahead of print]; <https://link.springer.com/content/pdf/10.1007%2Fs00259-019-04450-0.pdf>
2. Bajc M, et al. Eur J Nucl Med Mol Imaging 2009; 36(8): 1356-70; [https://eanm.org/publications/guidelines/gl\\_pulm\\_embolism\\_part1.pdf](https://eanm.org/publications/guidelines/gl_pulm_embolism_part1.pdf)
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](https://canm-acmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%2012_.pdf) 2.a

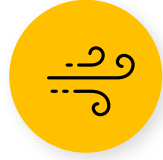
- “ Using 99m-Tc-Technegas is according to clinical experience **better than the best aerosols** ”
- “ Technegas® **facilitates interpretation**, particularly in COPD ”
- “ For ventilation, **99m-Tc Technegas® is the best-aerosol** particularly in patients with COPD ”
- “ **Liquid aerosols are inferior for SPECT** and should not be used unless Technegas® is not available ”
- “ The **best widely available agent for ventilation** is 99m-Tc-Technegas ”
- “ Because of the very small particle size, this agent is distributed in the lungs almost like a gas and deposited in alveoli by diffusion, where they remain stable, thus **providing the best possible images for ventilation SPECT** ”
- “ Another advantage is that only a few breaths are sufficient to achieve an adequate amount of activity in the lungs, **reducing time and personnel exposure to radiation** ”
- “ Technegas® 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 ”

# Nuclear Ventilation Imaging Agent Comparison

## Technegas®



Easy



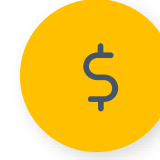
3 to 4 breaths



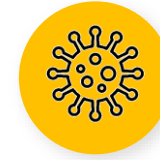
3D images



No contraindications

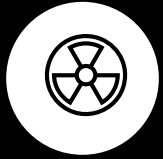


Cost-effective

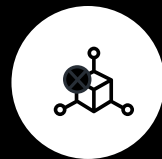


Covid-19

## Xenon - 133



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



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

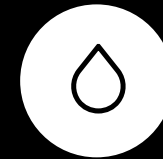


Constant inhale-exhale breathing for **15 mins** increasing the risk of **COVID-19 exposure**

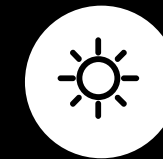


**Requires special rooms** to contain radioactive gas in the event of a release

## 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

# SUPERIOR TO COMPETITIVE IMAGING MODALITIES

## Technegas®



Easy



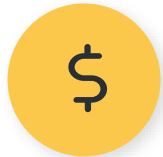
3 to 4 breaths



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<sup>1</sup>



### Contraindications

CTPA should not be performed with pregnancy<sup>1-2</sup>, renal impairment<sup>3</sup>, contrast media allergy<sup>3</sup>, diabetes<sup>4</sup>



### Acute kidney injury (AKI)

AKI occurs in up to 13% of CTPA cases<sup>5</sup>



### Lower clinical sensitivity

V/Q planar<sup>6</sup> = 76%  
CTPA<sup>7</sup> = 82%  
V/Q SPECT<sup>7</sup> = 93%



### Availability

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

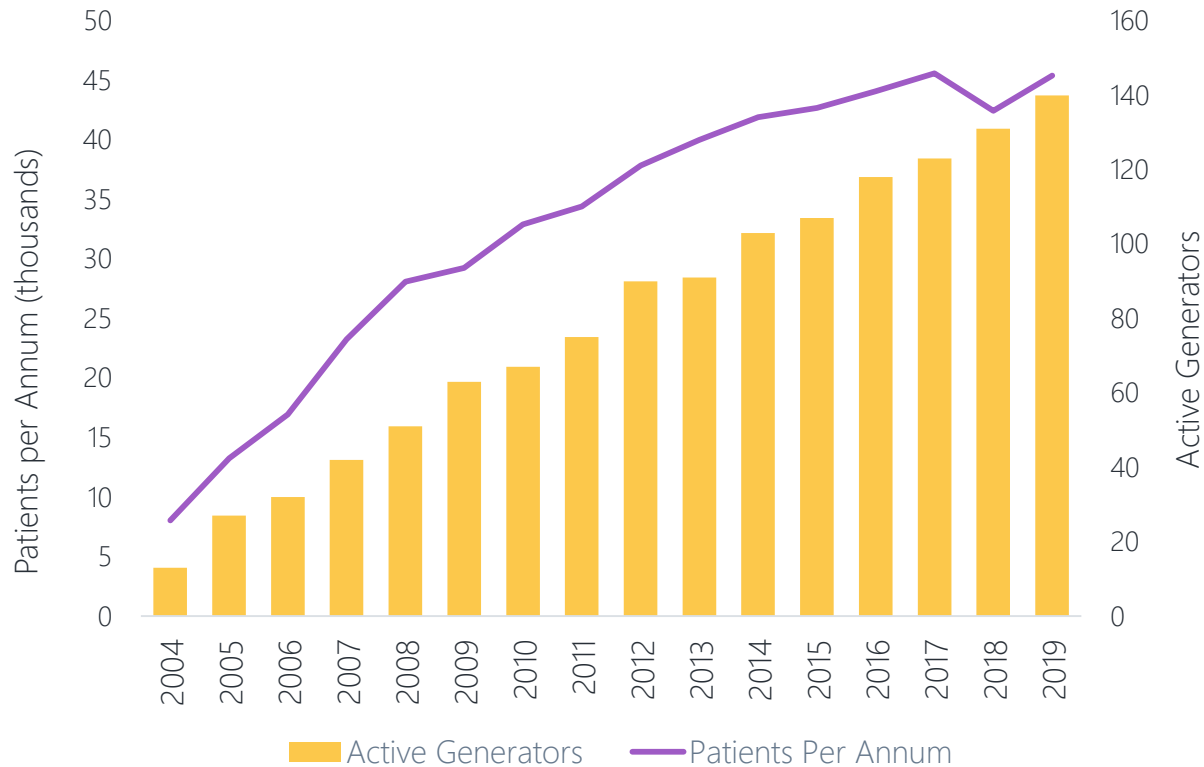
1. Isidoro J, et al. Phys Med 2017; 41: 93-96
2. Bajc M, et al. Eur J Nucl Mol Imaging 2015; 42: 1325-1330
3. Miles S, et al. Chest 2009; 136: 1546-1553
4. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596
5. Doganay S, et al. Renal Failure 2015; 37(7): 1138-1144
6. Reinartz P, et al. J Nucl Med 2004;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



# TECHNEGAS®

## The Canadian Case Study

The Generator and Consumable Relationship  
Technegas® Growth - Canada

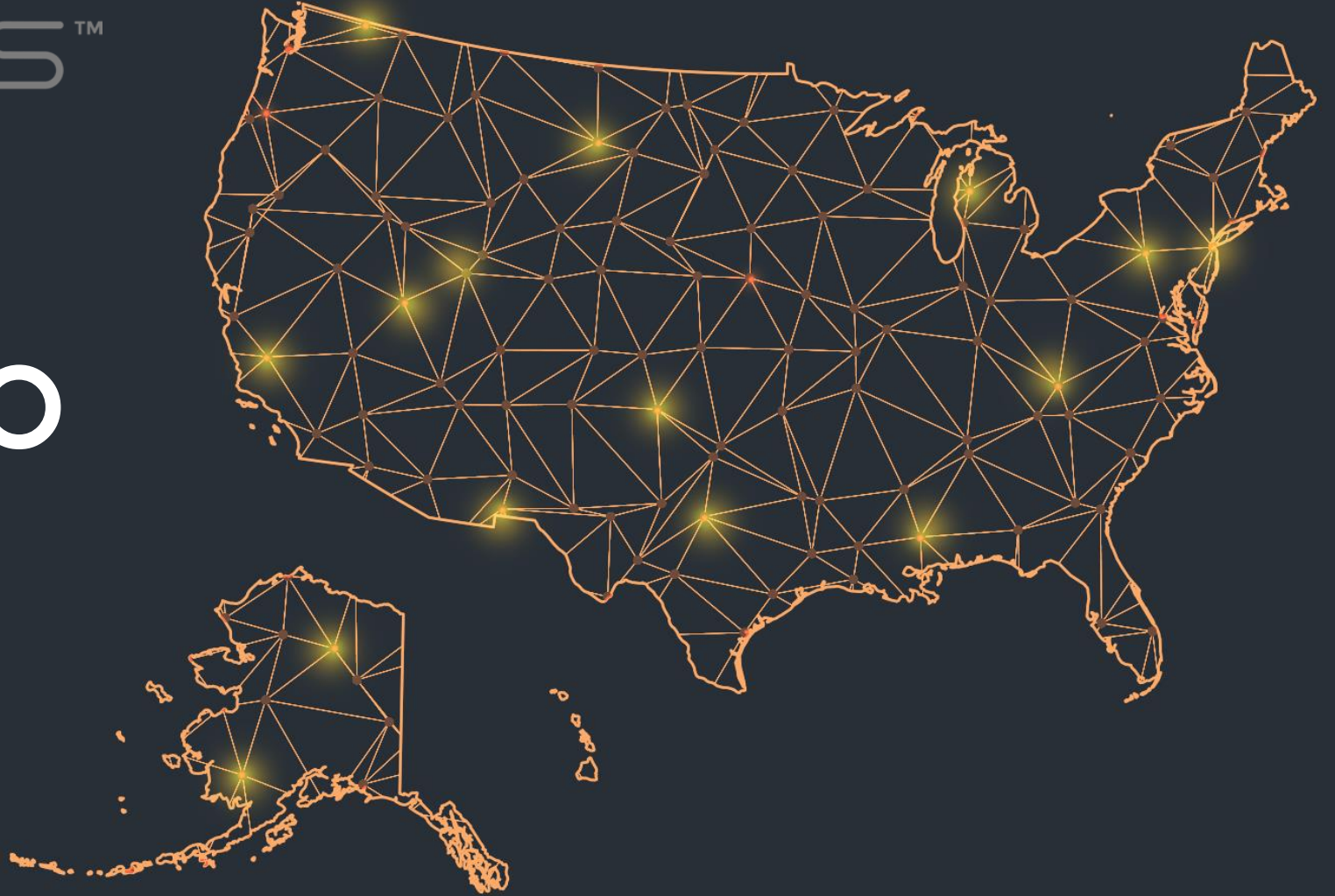


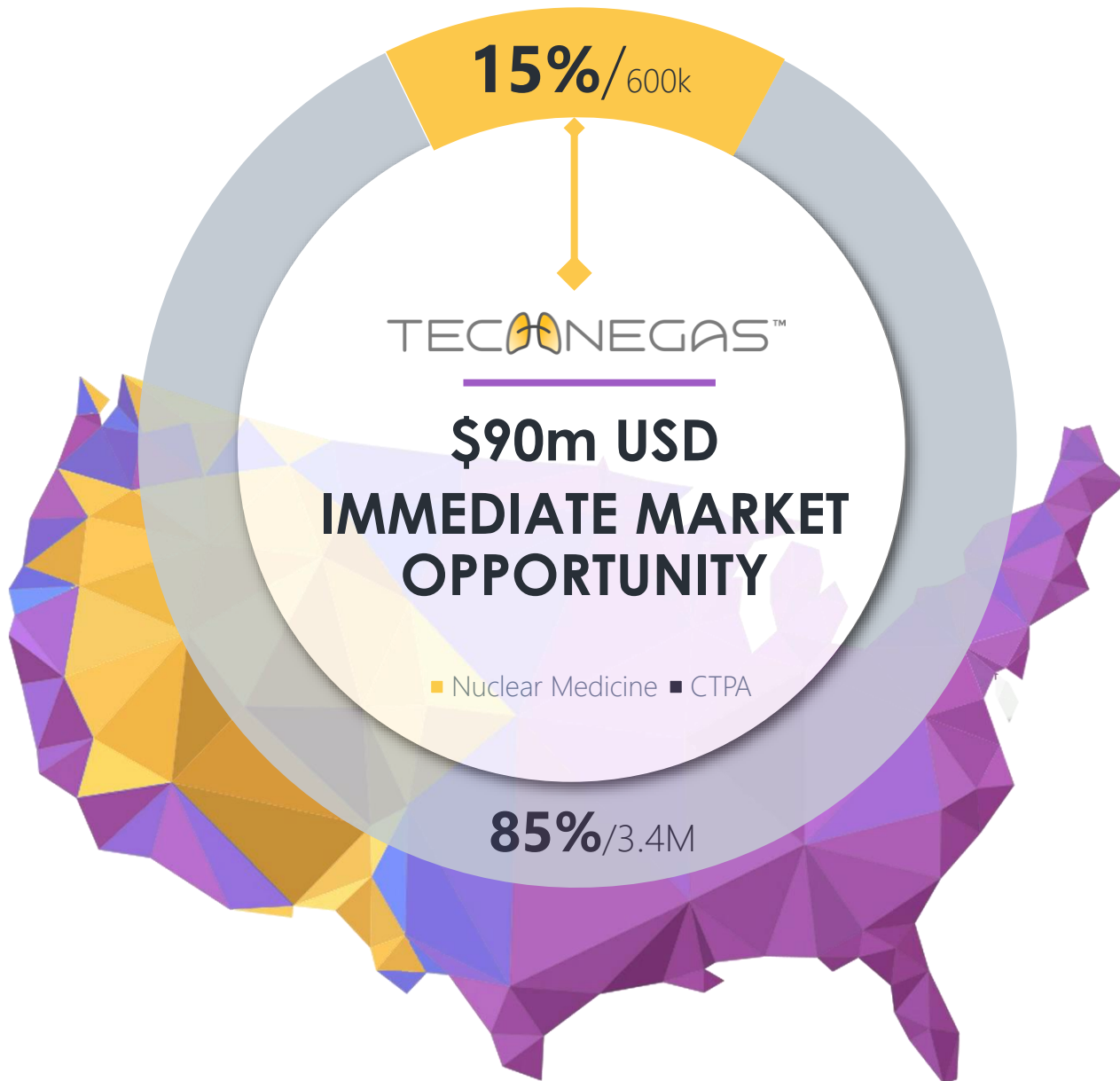
Canada is Cyclopharm's largest single country market

- 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

TEC  NEGAS™

**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

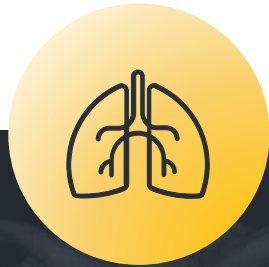
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# EXPANDING INDICATIONS

TEC  NEGAS™



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



Diagnosis and follow-up of **Pulmonary Embolism**<sup>1</sup> and **Pulmonary Hypertension**<sup>2</sup>



Preoperative assessment of homogeneous **Endoscopic Lung Volume Reduction (ELVR)** candidates<sup>3</sup>



Preoperative assessment of **lung resection** candidates with borderline pulmonary reserve<sup>4-6</sup>



Planning **radiation therapy** to target tumors while preserving functional lung zones<sup>6-7</sup>



Advanced approach to phenotyping **chronic airways diseases such as asthma and COPD** and identifying patient likely to respond to treatment<sup>8-10</sup>



Diagnosis and monitoring of **COVID-19** patients<sup>11</sup>

1. Roach PJ, et al. J Nucl Med 2013; 54: 1588-1596  
2. Dhira 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

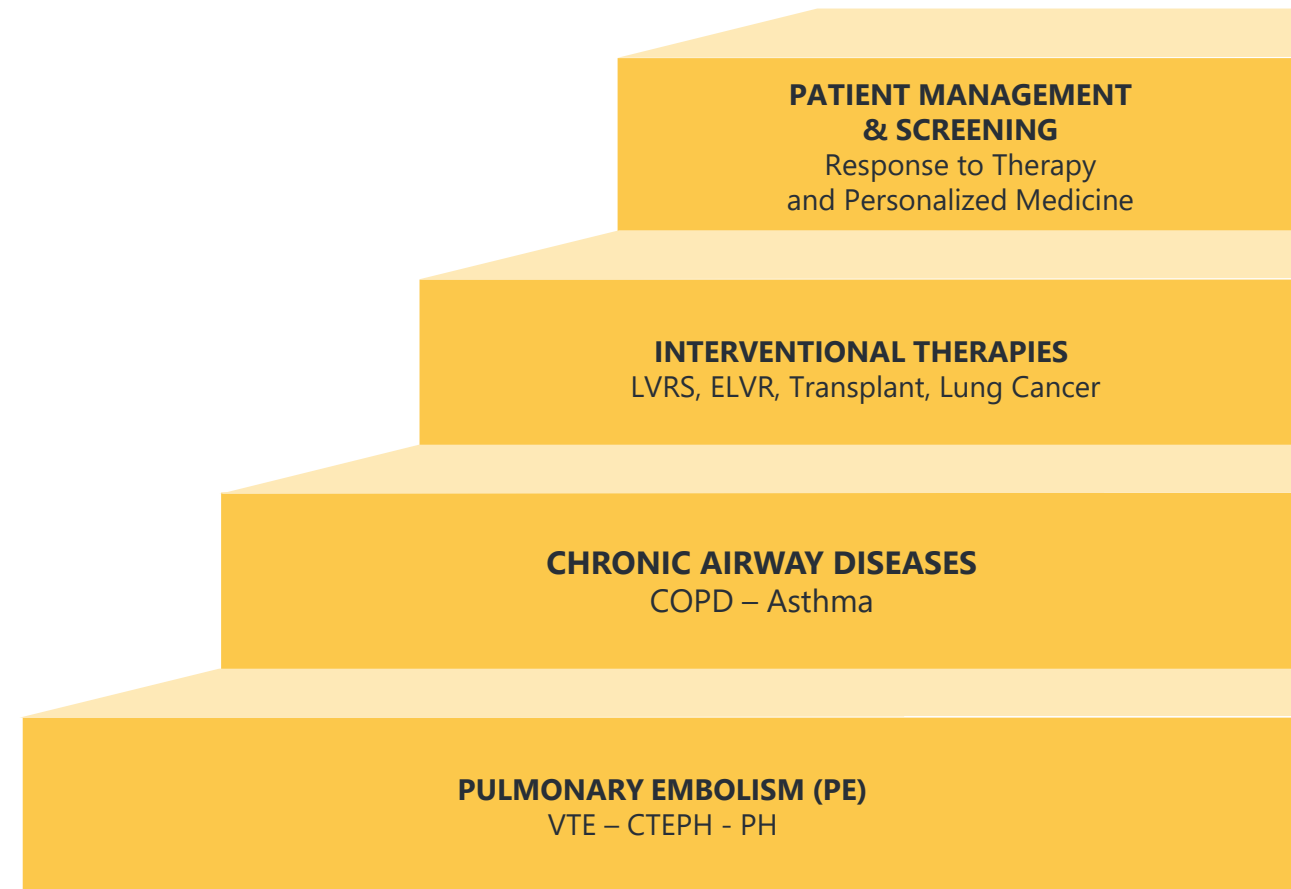
- **Hunter Medical Research Institute (Newcastle, AU):**  
Diagnosis and response to therapy in severe asthma and COPD<sup>1</sup>
- **Woolcock Institute (Sydney, AU):**  
Diagnosis and response therapy in mild to moderate COPD<sup>3</sup>
- **CHUM (Montreal, CA):**  
Early detection of COPD in asymptomatic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

## Other Non-Sponsored Clinical Initiatives

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

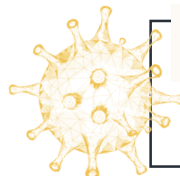
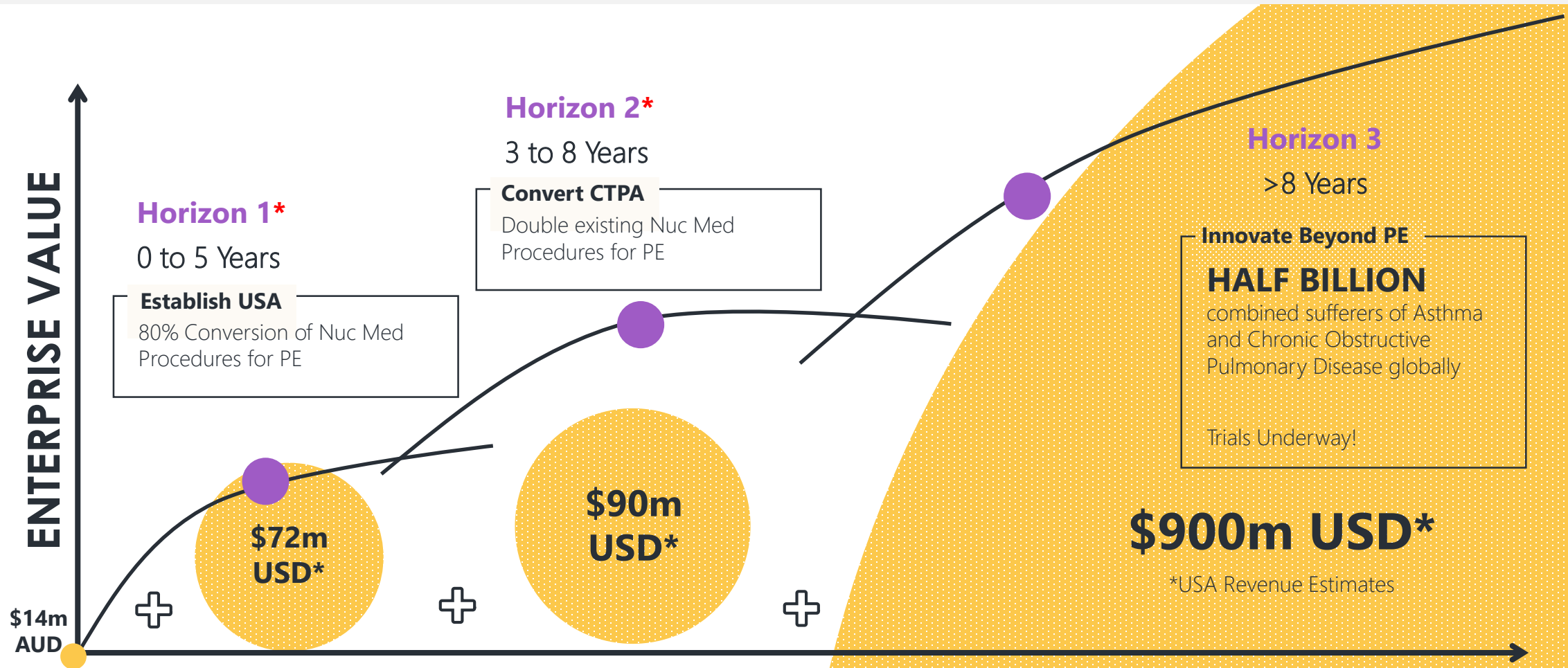
1. ACTRN12617001275358 - Can functional lung ventilation imaging identify treatable traits in obstructive airway disease?  
2. <https://clinicaltrials.gov/ct2/show/NCT04191174?term=technegas&draw=2&rank=3>  
3. [http://investor.cyclopharm.com/site/PDF/1561\\_0/BetterDefiningAirwaysDiseaseWithTechnegas](http://investor.cyclopharm.com/site/PDF/1561_0/BetterDefiningAirwaysDiseaseWithTechnegas)  
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

# CYCLOPHARM INVESTMENT CASE

TECONEGAS™



## 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

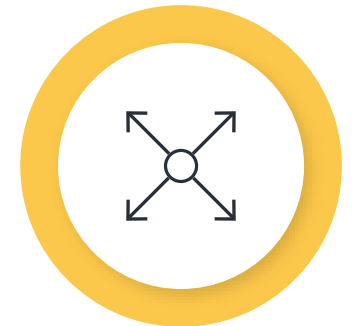
From single patient consumables  
Similar to an annuity model



## 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:

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# 2020 FINANCIALS





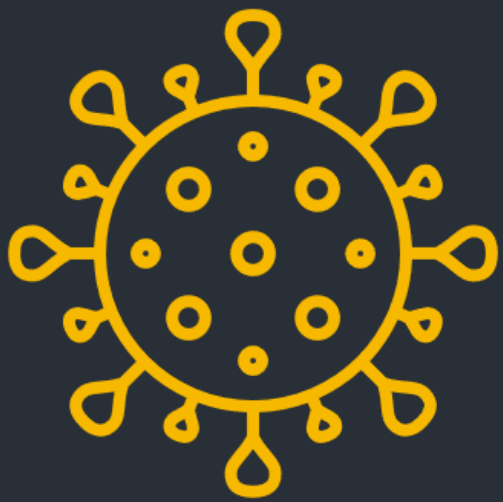
# 2020 Financial Highlights

|                          |   |
|--------------------------|---|
| 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   |



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# Technegas™

Helping patients and  
frontline workers during  
the COVID-19 pandemic

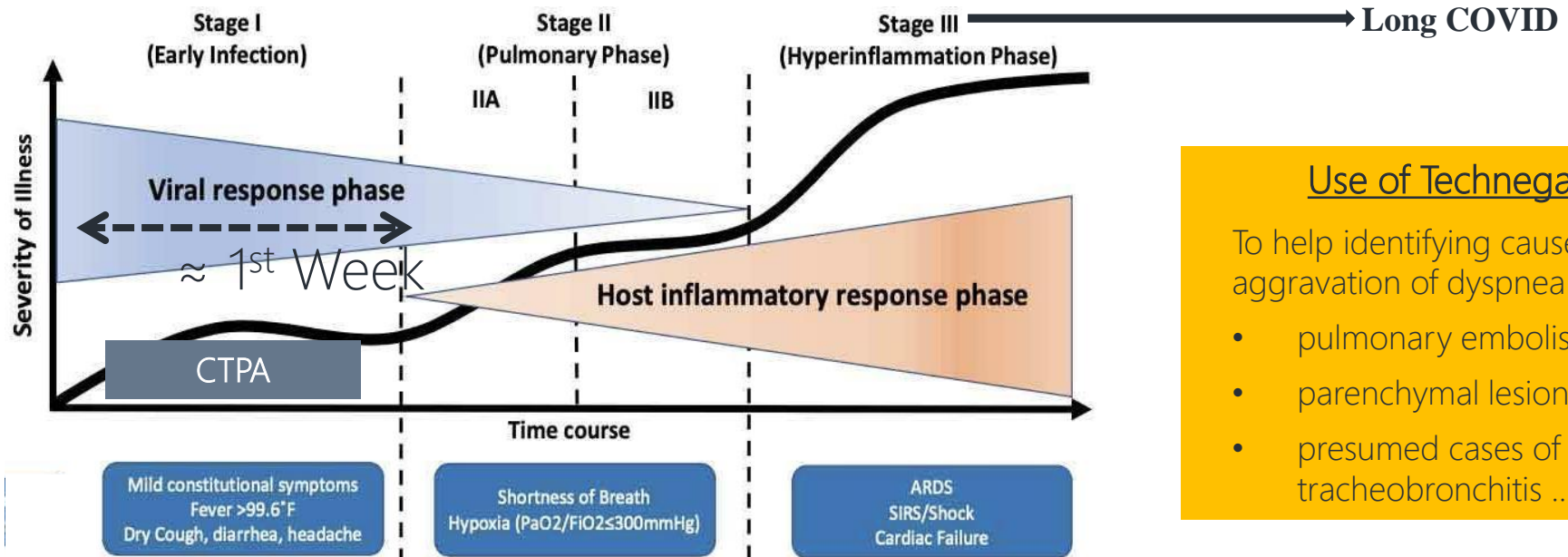
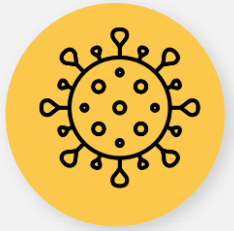
Technegas® is a registered product of Cyclomedica Australia Pty Ltd  
Technegas® is not clinically available in the USA



# CYCLOPHARM:

Helping in the fight against COVID-19

## Nuclear Medicine Imaging In COVID19



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

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

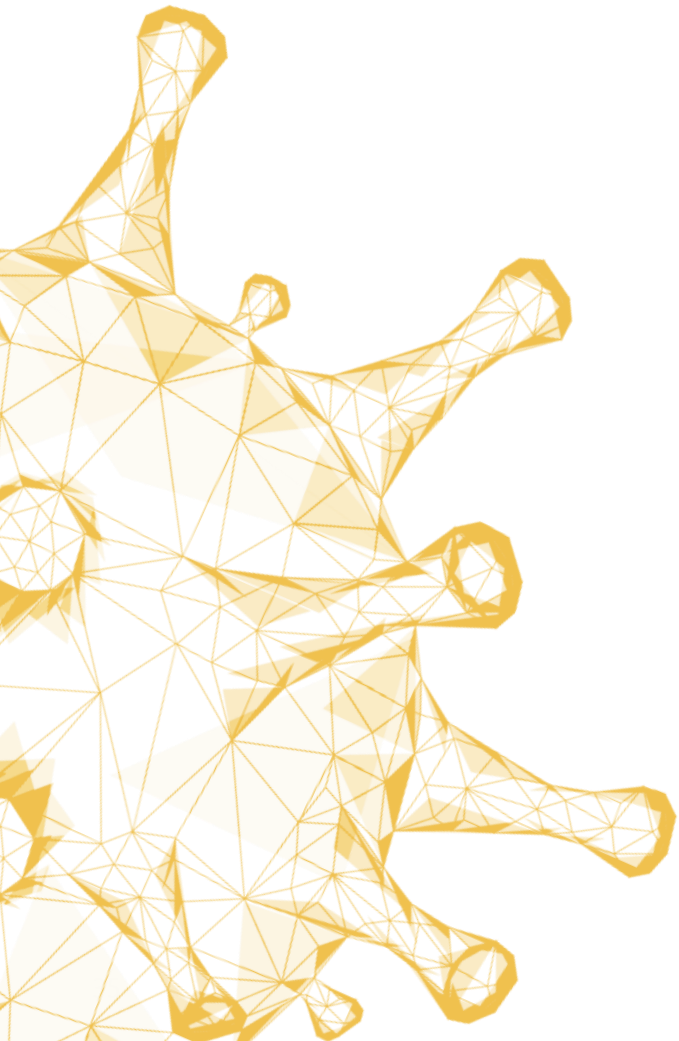
30 December 2020 – **102 Front Line Technologists** petition USFDA on occupational safety concerns

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



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

1

Primary Endpoint:

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

2

Secondary Endpoints:

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

3

Exploratory Objective:

To determine if COVID-19 infection related ventilation and perfusion injury)  $\leq 4$ -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.

Investor Update  
10/11/2021



\*<https://clinicaltrials.gov/ct2/show/NCT04549636>

# NUCLEAR MEDICINE PROVIDES BETTER DIAGNOSTIC OUTCOMES IN DIAGNOSING PE

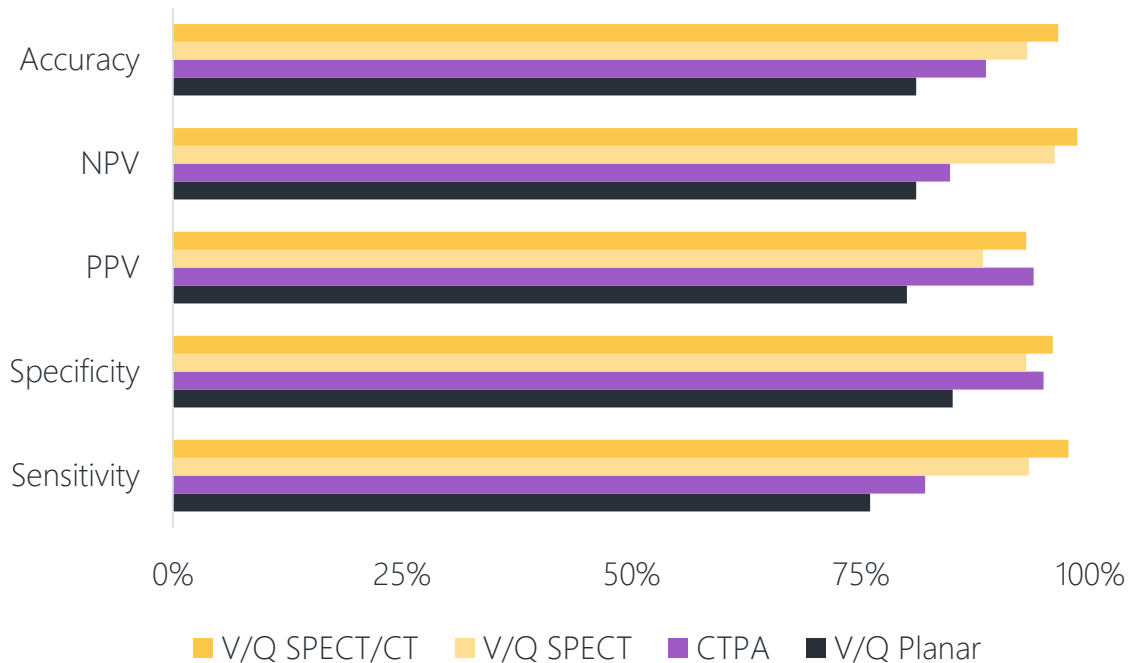


Table: Diagnostic ability of V/Q SPECT/CT<sup>1</sup>, V/Q SPECT<sup>1</sup>, CTPA<sup>1</sup> and V/Q Planar<sup>2</sup> to detect PE (adapted from Hess and al, 2016<sup>1</sup> and from Reinartz et al, 2004<sup>2</sup>)

- 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<sup>1</sup>
- 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 PE<sup>3</sup> due to:



Its low radiation and no adverse reactions<sup>3</sup>



Its higher accuracy, sensitivity and negative predictive value when compared to CTPA<sup>3</sup>

# Diagnosing Pulmonary Embolism with V/Q SPECT

Technegas is the “V” in “V/Q”

COMPARED TO CTPA:

Primary imaging procedure

when PE is suspected<sup>1</sup>

Excellent diagnostic performance<sup>2</sup>

Sensitivity 93.0%  
Specificity 93.3%  
NPV 96.1%

Detects PE at subsegmental level<sup>3</sup>

Minimally invasive  
Aids patient comfort and compliance<sup>4</sup>, even in COPD patients<sup>5</sup>

Less radiation burden

V/Q SPECT delivers 27 times less radiation to the breast as compared to CTPA<sup>6</sup>

Minimal exclusion criteria

V/Q SPECT can be performed in case of pregnancy<sup>6-7</sup>, renal impairment<sup>8</sup>, contrast media allergy<sup>8</sup> and diabetes<sup>3</sup>

Higher clinical sensitivity

V/Q SPECT has a higher sensitivity to diagnose PE compared to CTPA (93% vs 82% respectively)<sup>2</sup>.

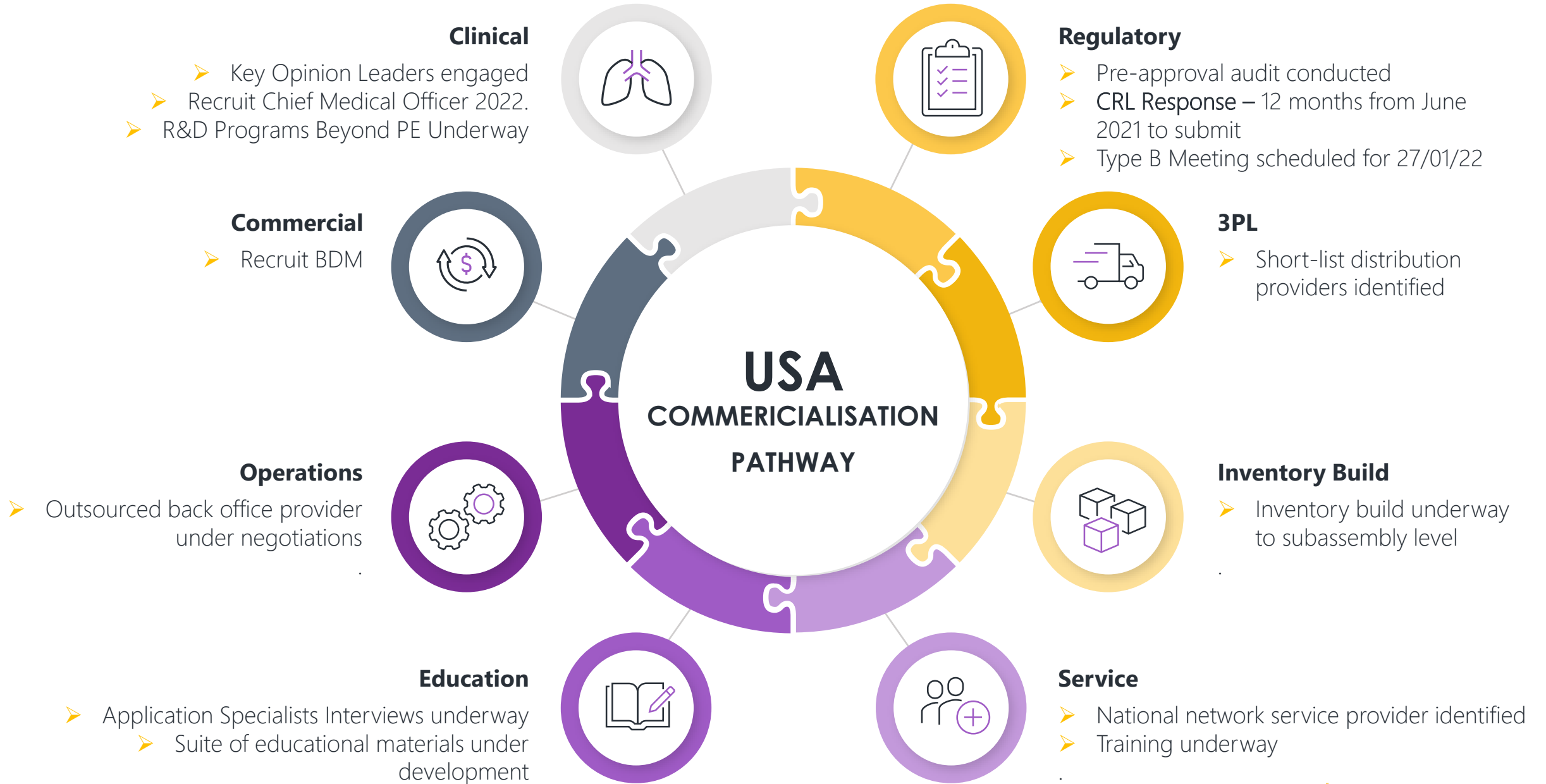
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2. Hess S, et al. Semin Thromb Hemost 2016; 42(8): 833-845  
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7. Bajc et al. Eur J Nucl Mol Imaging 2015; 42: 1325-1330  
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Technegas® is a registered product of Cyclomedica Australia Pty Ltd  
Technegas® is not clinically available in the USA

cyclomedica





# USA REIMBURSEMENT IS ESTABLISHED



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

WWW.SNMMI.ORG

| CPT/<br>HCPCS | Description   | Trade<br>Name | Oct<br>2019<br>APC | Jan F<br>2020<br>APC | Oct<br>2019<br>SI | Jan F<br>2020<br>SI | Oct 2019<br>Payment Rate | Final January<br>CY 2020<br>Payment Rate | %<br>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**

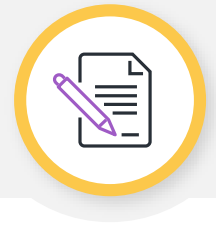
2

**Technegas will be reimbursed in the USA from Day 1**

# TECHNEGAS®

## In recent literature

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



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# CYCLOPHARM BUSINESS PARTNERS AROUND THE GLOBE

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