



CYCLOPHARM

**CAPITAL RAISING FOR USA
COMMERCIALISATION**

James McBrayer, CEO & Managing Director

25 January 2021



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

Executive Summary

1

Cyclopharm Limited (CYC) is a leading diagnostic lung imaging company

- Cyclopharm's lead nuclear medicine product Technegas® is currently available in **60 countries**
- Over **4,300,000 patient procedures** performed since first approved
- 1,600 Technegas® generators sold globally since first approved
- Underlying business is profitable and the company has a history of paying dividends
- Significant opportunity to expand into the USA with sales targeted for 2021 following completion of USFDA New Drug Application review
- FY20 unaudited revenue in line with prior year at A\$14m

2

Large existing global market

- ~3 million recorded cases of Pulmonary Embolism (PE) p.a. (could be much higher)
- 30% of **pulmonary embolisms** are fatal if left untreated
- PE symptoms are varied with diagnosis confirmed either through CTPA or a nuclear medicine ventilation-perfusion study
- Nuclear Medicine using 3-D imaging is the most accurate method of diagnosis

3

USFDA approval targeted in 2021

- FDA approval for Technegas® expected in **H1 2021** with first US sales expected shortly after approval
- Set to **more than quadruple the size** of Cyclopharm's existing PE business based on significant existing demand
- The USA represents the single largest market for Technegas® with half of the world's nuclear medicine departments
- Generator **placement rollout strategy** to be deployed for rapid market penetration
- Significant **COVID-19 tailwind** resulting from safety concerns that exist with competitive nuclear medicine products

4

High margins and annuity style revenue

- Cyclopharm generates recurring consumables, service and capital equipment revenue streams – customer installations funded for annuity style consumable revenue (high ROI)
- Around 80% of historical revenue is **recurring consumable sales** - (75% in 2019)
- Stable gross margins of greater than 80% - (82% in 2019)
- New customers have high "bottom line" impact

5

New market opportunities

- Opportunity to broaden Technegas® applications Beyond PE diagnosis into **exponentially larger** addressable markets such as COPD and Asthma
- Multiple clinical trials **underway** sponsored by Cyclopharm

6

Cyclopharm is seeking to raise up to A\$31.5m to support pipeline of global growth

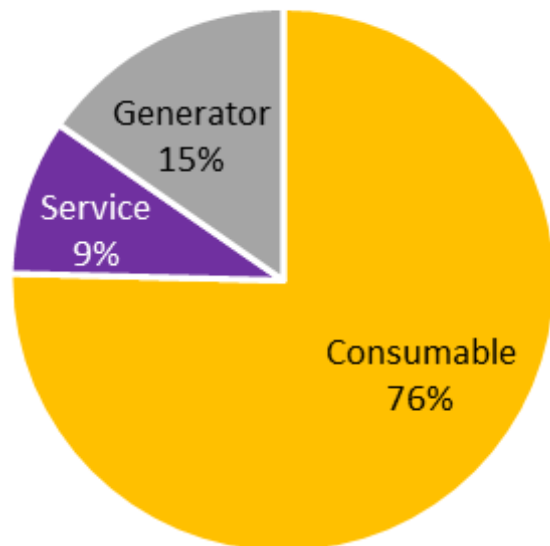
- Funds raised will be used primarily to fund USA expansion, support the underlying business growth and continue Beyond PE R&D programs

BUILDING FOR GROWTH – COMPANY DEVELOPMENT

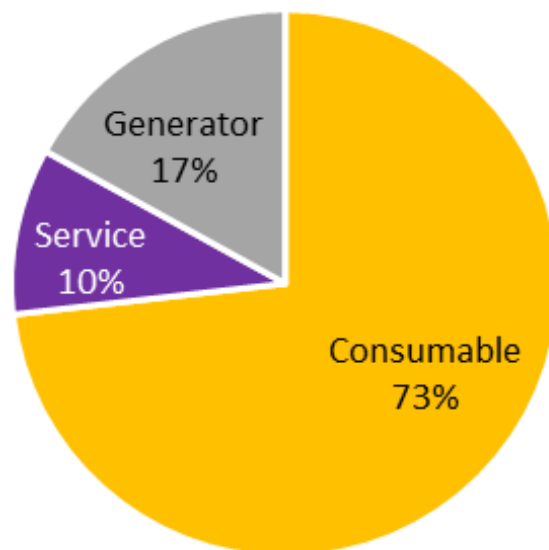


Technegas® is a substantially **de-risked** commercial proposition with significant upside in the **USA market**

2019 Rev



2020 Rev



- Total global sales of \$67.6m AUD from 2015 to 2019
- Technegas® currently available in **60 countries**
- Over **4,300,000** patient procedures performed since first approved
- **1,600** Technegas® generators sold globally since first approved
- Approximately 182,100 patient procedures in 2019
- **Europe represents 62%** of global revenue in 2019
- **Canada was the largest single country market** by volume (45,400 patients) followed closely by France (42,500 patients) in 2019
- CYC is **underlying business is profitable** and the company has a history of paying **dividends**.
- Stable gross margins of greater than **80%** - (82% in 2019)
- Around 80% of historical revenue is recurring consumable sales - (75% in 2019)
- 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 USA immediate demand

PULMONARY EMBOLISM



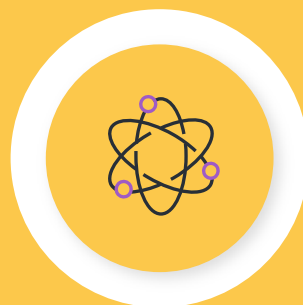
~3 million cases of PE p.a.
but could be much higher



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

TECHNEGAS®

World's Best Functional Lung Ventilation
Imaging Agent



Patient inhales extremely small carbon particles labeled with ^{99m}Tc Technetium¹



The small size and hydrophobic properties demonstrates gas like-behavior and alveoli deposition into the lungs²⁻³



Clinicians can visualise functional ventilation using Technegas®

WHAT THE GUIDELINES SAY ABOUT TECHNEGAS® :

Endorsed by the guidelines from the European¹⁻² and the Canadian³ 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
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



“ 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 ”

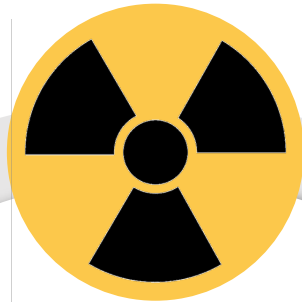
“ **Liquid aerosols are inferior for SPECT** and should not be used unless Technegas® is not available ”

“ 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 ”



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

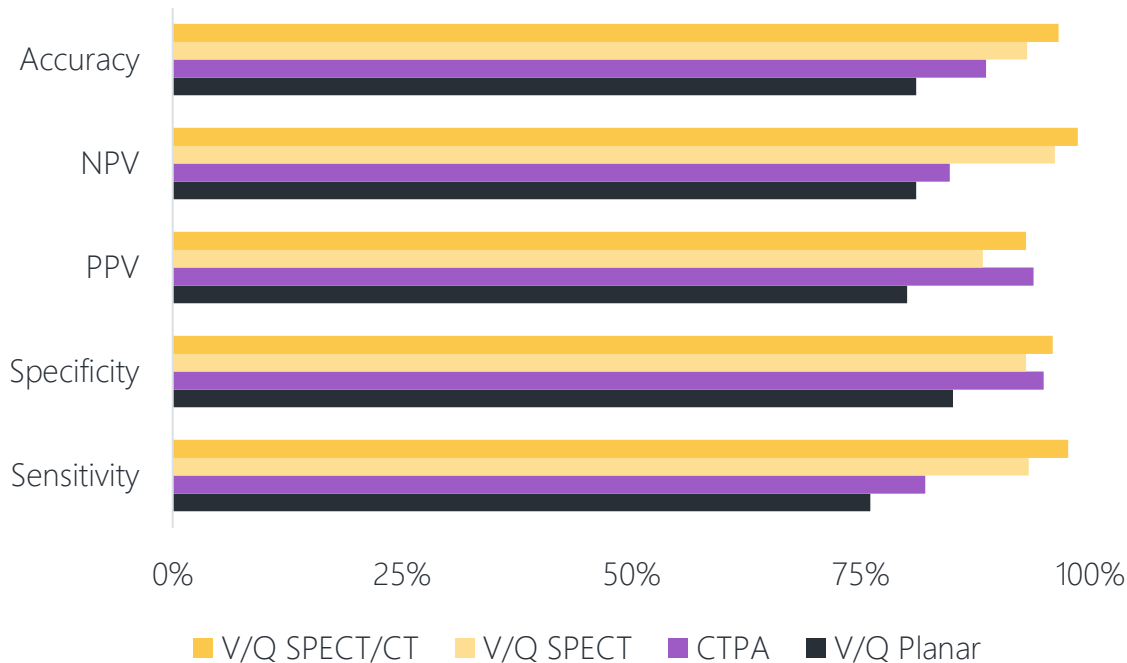


Table: Diagnostic ability of V/Q SPECT/CT¹, V/Q SPECT¹, CTPA¹ and V/Q Planar² to detect PE (adapted from Hess and al, 2016¹ and from Reinartz et al, 2004²)

- 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 performance¹
- 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 reactions³



Its higher accuracy, sensitivity and negative predictive value when compared to CTPA³

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

SUPERIOR TO COMPETITIVE NUCLEAR MEDICINE PRODUCTS

Technegas®



Easy



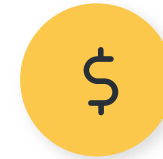
3 to 4 breaths



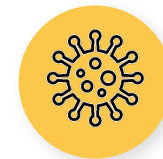
3D images



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



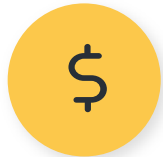
3 to 4 breaths



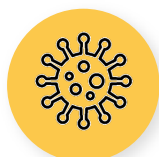
3D images



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 SPECT¹



Contraindications

CTPA should not be performed with pregnancy¹⁻², renal impairment³, contrast media allergy³, diabetes⁴



Acute kidney injury (AKI)

AKI occurs in up to 13% of CTPA cases⁵



Lower clinical sensitivity

V/Q planar⁶ = 76%
CTPA⁷ = 82%
V/Q SPECT⁷ = 93%



Availability

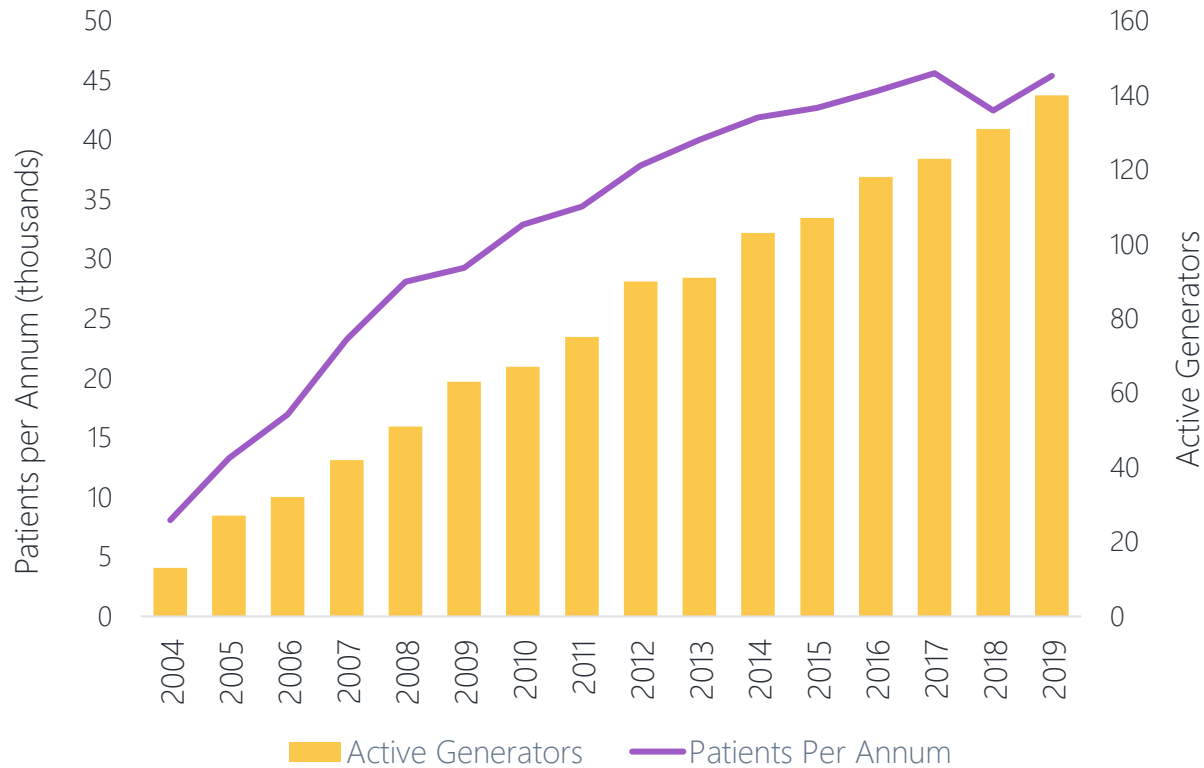
Radiology ED services are generally provided 24/7 vs. nuclear medicine after hours on call service

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

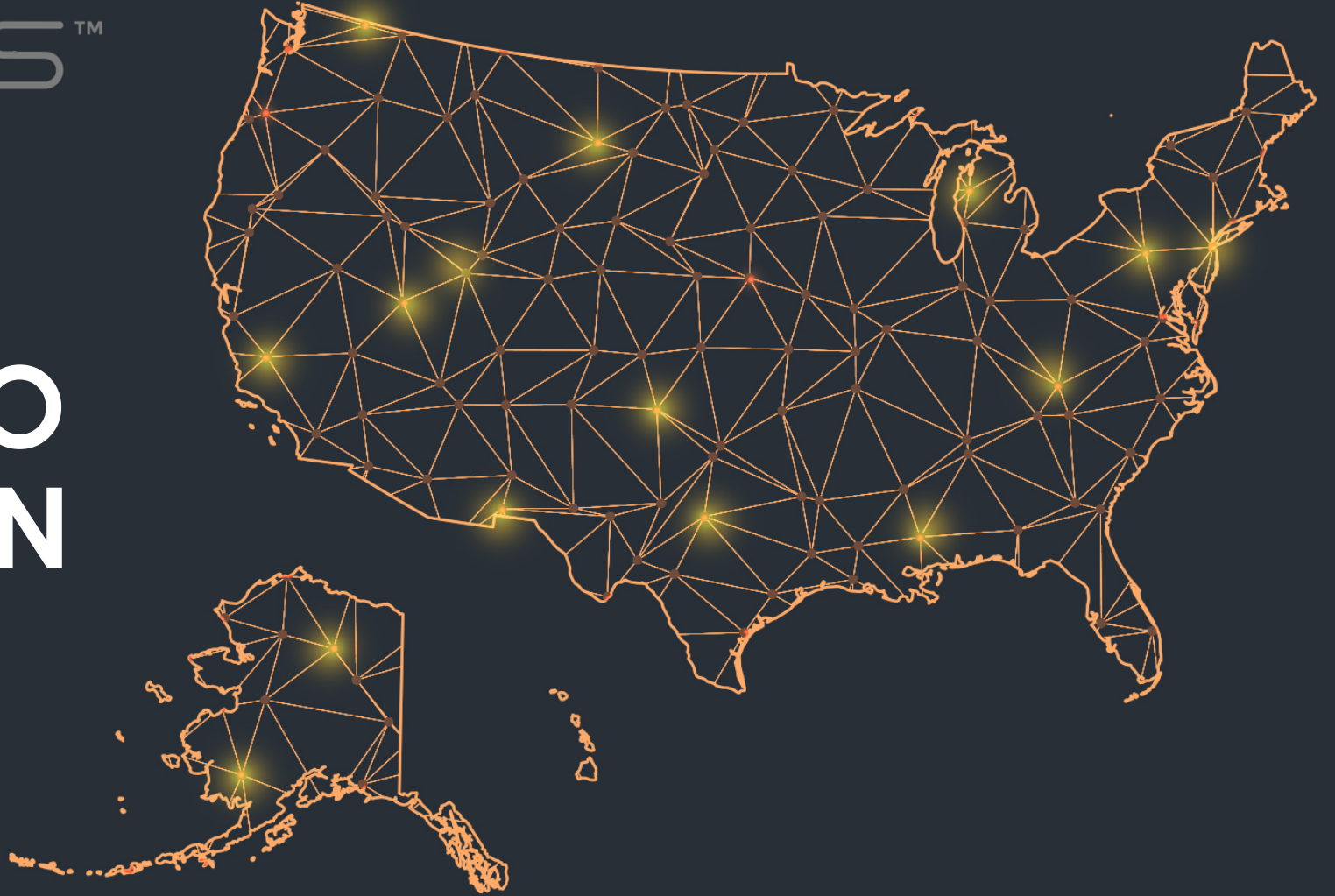


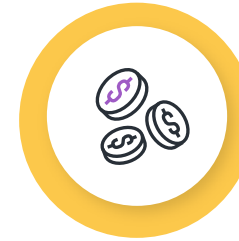
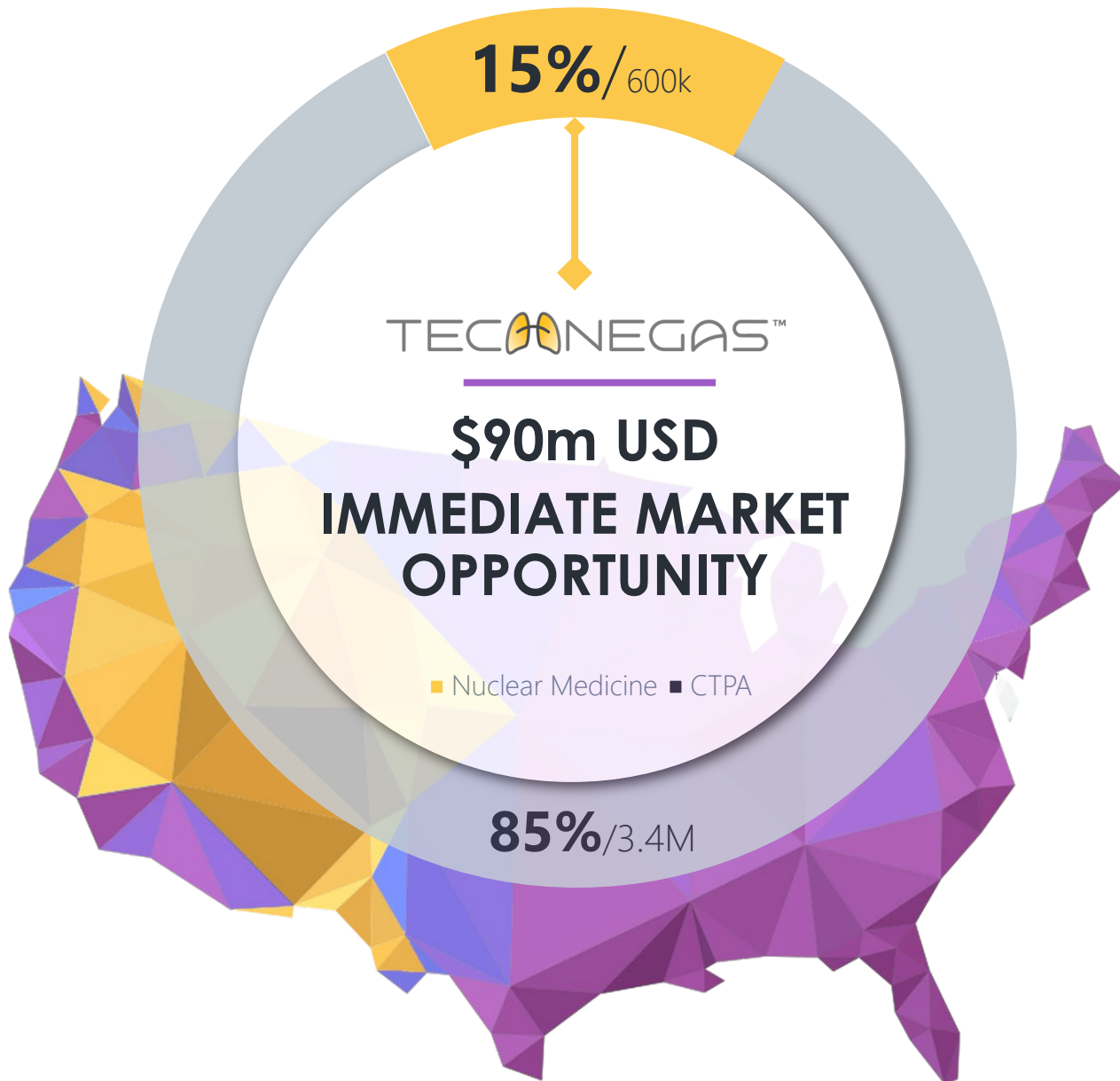
Canada is Cyclopharm's largest single country market

- 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

TECO  NEGAS™

**COMING TO
AMERICA IN
2021**





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 2021
- 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**
- COVID-19 tailwind

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

USA PRICING & BUSINESS MODEL

Generators placed “free” for quick penetration and to build consumable revenue

- Generators to be placed at no cost to US sites
 - Allows for rapid market penetration
 - No roadblocks from hospital administration as it avoids CAPEX
 - Cost of manufacture of ~US\$10k borne by CYC
- US pricing rates:
 - ~US\$120 per test for consumable (90%+ gross margin), reimbursed
 - Installation fee of ~US\$3k per site
 - Annual service fee of ~US\$5k per generator p.a
- Generators have a useful life of 15+ years
- Capital raising will fund the placement of up to 300 generators in the US under this model
- Focus on high volume sites initially – those that generate 500 or more tests per generator p.a

Key takeaways:

- Payback of approximately 2.5 months per generator
- Lifetime annuity revenue of circa US\$900k per generator¹

Example Return Metrics For First 100 Generators in US

Generators Placed	100
Manufactured Cost borne by Cyclopharm	US\$1m
Avg No. Tests Per Generator P.A (assuming high volume site)	500
Total no. Tests	50,000
Consumable Pricing Per Test	US\$120
Gross Margin For Consumable	90%
Gross Margin Per Test	US\$108
Gross Margin P.A	US\$5,400,000

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 and front-line workers petitioning the USFDA to expedite approval of Technegas™. The most recent correspondence sent to the USFDA on 21 January 2021 from the 16,000-member SNMMI¹ requesting 'Fast Track Approval' for Technegas™ citing both clinical and safety concerns that exist with competitive products².

3 Demand already established in the US from:

- ✓ Extensive body of clinical evidence underscoring clinical superiority
- ✓ ROW evidence in 60 countries
- ✓ Well known technology globally with the 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

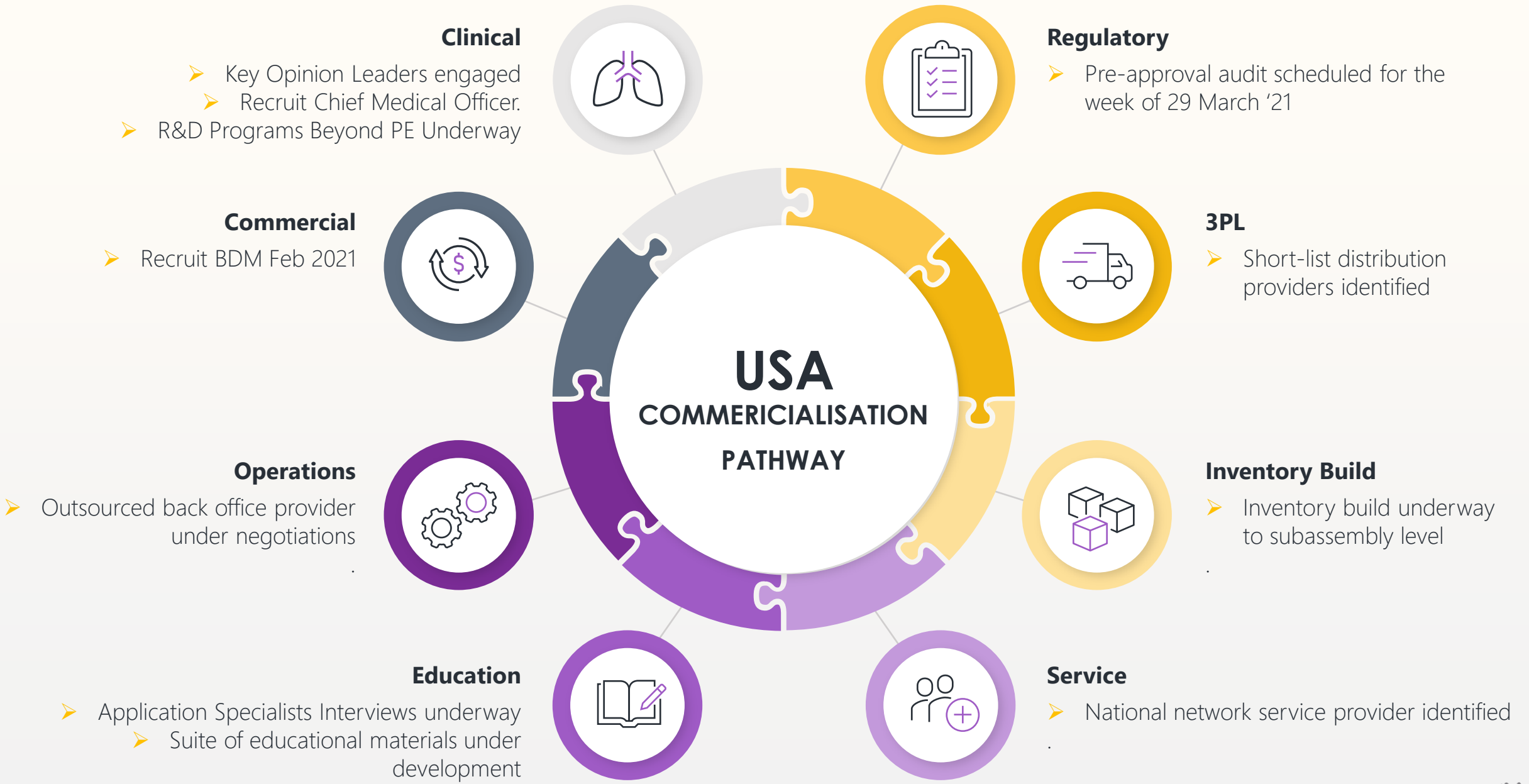
5 Unlike most newly approved medical devices, our focus will be on installation and training staff, as opposed to a large sales team due to inbound demand

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

¹SNMMI- The Society of Nuclear Medicine and Molecular Imaging – www.snmmi.org

² https://s3.amazonaws.com/rdcms-snmmi/files/production/public/FileDownloads/SNMMI-TS_Technegas_FDA-Fast-Track_Letter_1-18-2021_FINAL.pdf



CYCLOPHARM:

Additional US tailwinds from the use of Technegas in COVID-19



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.

Investor Update

EXPANDING INDICATIONS

TEC  NEGAS™



BEYOND PE : Clinical Initiatives

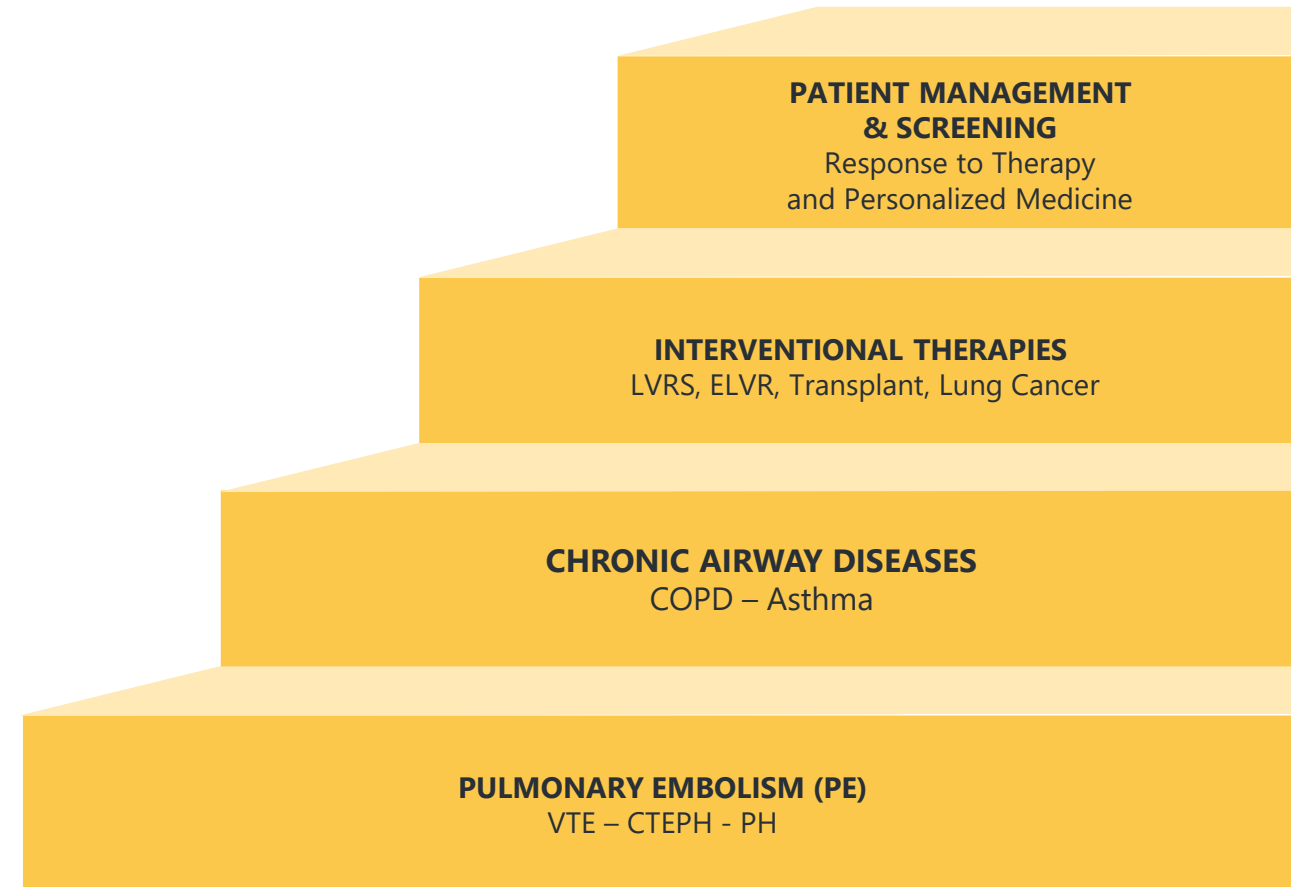
Clinical Trials Sponsored by Cyclopharm⁶

- **Hunter Medical Research Institute (Newcastle, AU):**
Diagnosis and response to therapy in severe asthma and COPD¹
- **Woolcock Institute (Sydney, AU):**
Diagnosis and response therapy in mild to moderate COPD³
- **CHUM (Montreal, CA):**
Early detection of COPD in asymptomatic smokers⁴
- **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 resection²
- **McMaster University Firestone Institute (Hamilton, CA):**
COVID-19 Related Lung Ventilation and Perfusion Injury⁵

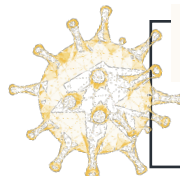
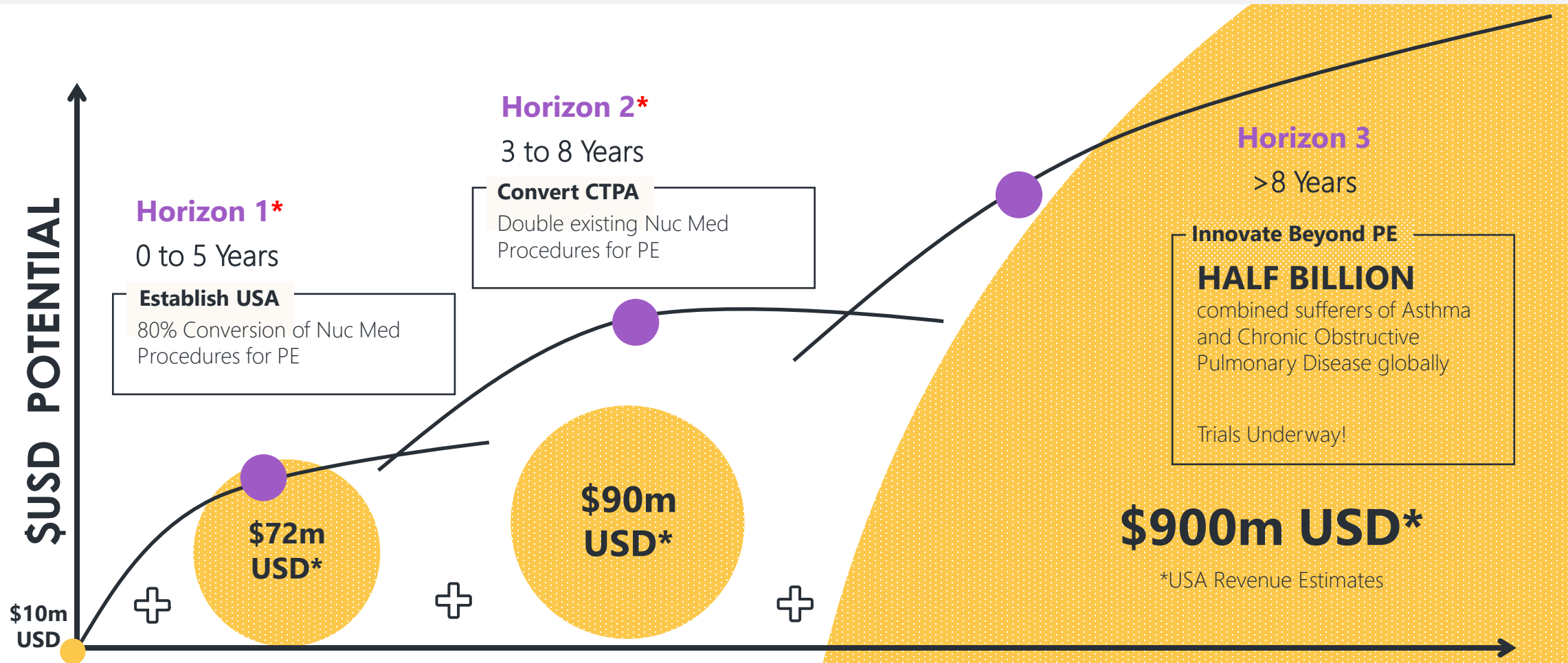
Other Non-Sponsored Clinical Initiatives

- **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>



THREE REVENUE 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 by H1 2021
- 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

TEC  NEGAS™



Profitable and Growing MedTech

Underlying business is cash positive and issuing dividends



First in Class

Established Gold Standard
Proprietary product sales to 60 countries with over 4.3 million studies to date
Clinical Agent of Choice referenced by name in multiple clinical guidelines



Recurring Revenue

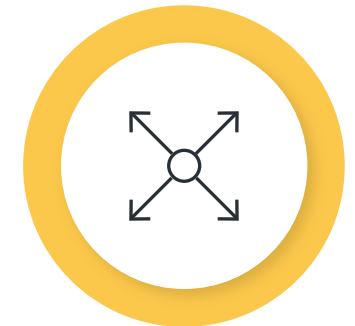
From single patient consumables
Similar to an annuity model



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

CAPITAL RAISING DETAILS

TECONEGAS™

Offer Details

Placement	<p>Placement to institutions, sophisticated and professional investors to raise up to approximately A\$30.0 million via the issue of up to 11.5m shares:</p> <p>Issue Price A\$2.60 per share</p> <p>Placement of up to approximately A\$30.0m under the company's existing 15% Placement capacity under ASX Listing Rule 7.1</p>
Pricing	<p>The Offer Price of A\$2.60 represents an approximate:</p> <ul style="list-style-type: none">• 11.6% discount to the closing price on 20 January 2021• 4.1% discount to the 1-month Volume Weighted Average Price (VWAP) equal to A\$2.71 up to and including 20 January 2021
Share Purchase Plan	<p>Cyclopharm Limited intend to offer eligible shareholders an opportunity to subscribe for up to A\$30,000 of new shares under a Share Purchase Plan (SPP) at the same price as the Placement. It is intended the SPP will be capped at approximately A\$1.5 million.</p>
Use of Funds	<p>Funds raised will be used primarily to fund USA expansion, support the underlying business growth and continue Beyond PE R&D programs</p>
Lead Manager	<p>Bell Potter Securities Limited</p>

Offer Timetable

Trading halt	Thursday, 21 January 2021
Transaction announced & Company resumes trading	Monday 25 January 2021
Placement Settlement of new shares	Friday, 29 January 2021
Placement Allotment of new shares	Monday 1 February 2021



THANK YOU

