

# Cyclopharm Limited

A profitable and growing market leader in nuclear lung imaging

**2017 Results Presentation** 

March 2018

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# Disclaimer

Certain views expressed here contain information derived from publicly available sources that have not been independently verified.

The presentation includes certain statements, estimates and projections with respect to the anticipated future financial performance of Cyclopharm Limited and as to the markets for the company's products. Such statements, estimates and projections reflect various assumptions made by the directors concerning anticipated results, which assumptions may or may not prove to be correct. Cyclopharm Limited has not sought independent verification of information in this presentation.

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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

- A world leader in functional lung ventilation imaging technology
- Recurring consumables and capital equipment revenue streams
- A profitable and growing company with a history of dividend payments
- Lead nuclear medicine product Technegas is currently available in 56 countries with significant opportunity to expand into USA with sales US targeted for 2019 following completion of FDA trial
- Opportunity to broaden Technegas applications beyond pulmonary embolism diagnosis into large addressable markets such as COPD and Asthma



Share Price (as at 1 March 2018)	\$1.00
Shares on Issue	68.3 million
Market Capitalisation	\$68.3 million
Cash (31 Dec 17)	\$8.7 million
Total Shareholder Returns (12 months)	24.4%

### **Our Strategy**



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

### We will do this by:

- 1. Attaining approval to distribute Technegas in the USA
- 2. Expanding the use of Technegas beyond the traditional diagnosis of Pulmonary Embolism into significantly larger applications such as COPD<sub>1</sub> and Asthma, Lung Cancer and Pulmonary Hypertension for both diagnosis and patient management.
- 3. Identifying, developing and commercialising complementary innovative technology such as Ultralute™
- 4. Leveraging our core global regulatory strengths, fiscal discipline, strong balance sheet and well developed expertise in nuclear medicine and pulmonary healthcare to seek out complementary technologies and businesses

### FY2017 Results Highlights



Group Sales Revenue \$13.19 million

■ Gross Margin \$10.74 million

■ Net Loss After Tax (\$1.52) million

Full Year Dividends
 1.0 cents per share

• Underlying Technegas EBITDA<sup>1</sup> \$2.64 million

■ FDA Trial expenses (\$2.58) million

Strong balance sheet \$8.7 million of cash reserves

■ FY18 Earnings Guidance
Sales and underlying earnings growth supported by the launch of Ultralute™; additional Technegas sales in China and France; and margin expansion in German operations

# Technegas - Product Overview



### Cyclopharm's leading product is the Technegas technology system

- The Technegas proprietary technology provides high quality diagnostic functional lung imaging.
- Predominantly used to diagnose the presence of blood clots in the lung otherwise known as Pulmonary Embolisms (PE). With advances in complementary technology, the potential for use in other indications is rapidly evolving.
- In a clinical setting, the patient inhales, in only a few breaths, an ultrafine dispersion of Technegas particles. Once inhaled and deposited in the lungs, Technegas images are then captured by using conventional nuclear medicine scanning equipment.
- The Technegas images provide the clinician an understanding of how well the patient's lungs are functioning across a range of disease states.
- CYC sells the Technegas Generator to hospitals as a one-off capital item. Consumable components are inserted into the Technegas Generator which then produce the gas like particles that are inhaled by the patient. The consumables which deliver Technegas are single patient use items.

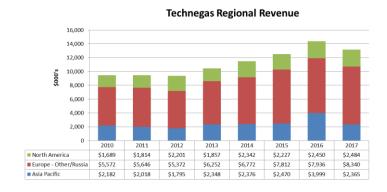


## Technegas - Proven Market Adoption

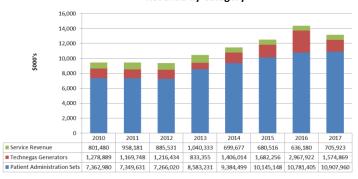


# Technegas is a substantially de-risked commercial proposition with significant upside in the US market

- Total global sales of \$90m from 2010
- Technegas currently available in 56 countries
- Over 200,000 patient procedures in 2017
- Over 3.8 million patient procedures since 1986
- 1,500 Technegas generators sold globally
- CYC is growing, underlying business is profitable and dividend paying company
- Stable gross margins of greater than 80%
- Around 80% of historical revenue is recurring consumable sales



#### **Revenue By Category**



# Advantages of Technegas



### Technegas provides clinically superior outcomes to its competitors

- Better clinical results at a fraction of the high radiation doses used in CTPA (angiograms)
- No contraindications
- More accurate and sensitive measurement in diagnosing pulmonary embolism
- Particularly effective when CTPA is contraindicated e.g. renal impairment
- Improved patient comfort and tolerance with only 3-4 breaths required for delivery
- Allows for 3D images and regional quantification
- Named as the preferred ventilation imaging agent of choice in the European Association of Nuclear Medicine Guidelines

### **IP/Generic protection**

- Technegas is a system needs the generator, patient administrator set (PAS) and service capability
- R&D on 3rd generator generation underway set to extend IP protection

#### **Competitive Nuclear Medicine Products**

Product	Comparison to Technegas	
Xenon 133	<ul> <li>Patient has to continually re-breathe gas causing patient discomfort / anxiety</li> <li>Can't provide 3D images</li> <li>Costly air-handling infrastructure required in order to administer</li> </ul>	
DTPA	<ul> <li>Inferior images in patients with obstructive lung disease (COPD)</li> </ul>	



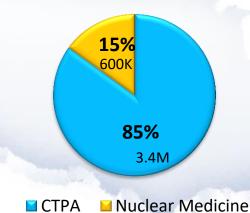
# FDA Trial and USA Commercialisation





### **600K Nuclear Medicine Ventilation**

Procedures p.a. = \$90m USD



- Target market for Technegas in the USA equates to ~480,000 patient procedures of the total 600,000 procedures conducted p.a.in that market (Current Rest of the World volumes for Technegas = ~200,000 patients p.a.)
- Subject to a successful trial and FDA approval, the Company is targeting US commercialisation in 2019
- Once commercialised Cyclopharm will target the much larger PE market dominated by CTPA where 3D SPECT imaging using Technegas is proven to be clinically superior and safer than CTPA
- 4 Million Patient Studies Performed in the USA per annum to Diagnose Pulmonary Embolism (PE).
- The USA represents the single largest market for Technegas with half of the world's nuclear medicine departments
- First priority following USFDA approval is to repeat our Canadian experience by displacing Xe133 as the standard of care diagnostic product

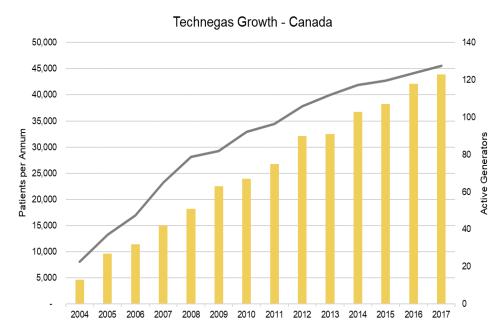
# Technegas – The Canadian Case Study



### Canada is Cyclopharm's largest single country market

# Market leader for diagnosing PE 14 consecutive years of PAS growth Represents a strong indicator of USA acceptance Xe-133 rapidly displaced by early adopters Direct correlation with the number of active generators and annual consumable sales Market driven by public healthcare sector Market launch initiated province by province, leveraging off pilot sites

### The Generator and Consumable Relationship





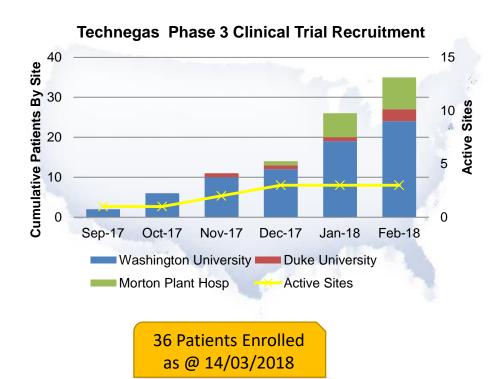
### Study Specifics:

- Non-inferiority structural ventilation study comparing Xe133 vs. Technegas
- Pathway to approval requires a two part study
  - ✓ CYC 010 Establishes the Inter & Intra reader variability for Xe133 Completed
  - ✓ CYC 009 Compares Xe133 with Technegas requiring patient recruitment SPA Approved.
- Total estimated trial cost \$7.0 million USD with \$3.3m AUD spent to date
- Assumes 240 patient study at up to 15 clinical sites
- Patient recruitment commenced at Washington University, St Louis on 25 September 2017
- CYC will complete a preliminary 40 patient trial for submission to the FDA in 1H 2018



### **USFDA** Patient Recruitment Update





### Sites Actively Enrolling Patients

- Washington University St Louis Missouri
- Duke University Durham North Carolina
- Morton Plant Clearwater Florida

### Site Initiation Completed – Patient enrolment mid-March

- University of Texas South Western Dallas Texas
- Scott & White Temple Texas

### **Final Stages of Site Recruitment**

- Loyola University Hospital Maywood Illinois
- Emory University Hospital Atlanta Georgia

### Mid Stage Site Initiation - 6 Locations

Early Stage Site Initiation – 7 Locations

### Pathway to US commercialisation



- New Manufacturing Facility Q4 2016 Increased capacity to meet future demand & regulatory requirements
- Target preliminary study completion Q1 2018 Conclude a preliminary study of 40 patients and receive feedback from the FDA
- Target FDA Trial completion Assuming positive feedback from the preliminary study, the Company will continue with the comprehensive FDA trial throughout 2018
- Target commercial launch 2019 Following the preliminary 40 patient study the Company will invest in Technegas inventory
  and, after successful completion of FDA trial and issue of FDA approval, target commercial launch in the US during 2019
- US market penetration Based on experience in other markets, the Company is targeting greater than 50% of the \$90m
   USD competitive product market conversion in the US over the medium term
- Increased gross margin in US market The Company expects to maintain or improve its historical gross margin on both consumable and capital equipment sales in the US market, based on competitive product pricing
- Develop Market for New Indications Following US launch, expand the use of Technegas beyond Pulmonary Embolism



# **Technegas Expanding Indications**

# **Evolution of Functional Lung Ventilation Imaging**



- Improvements in 3D imaging techniques, hybrid imaging and the advent of analytical software have dramatically improved the sensitivity and specificity in functional lung imaging with Technegas
- Traditionally used in the diagnosis of Pulmonary Embolism, nuclear medicine functional lung ventilation imaging utilising improved imaging techniques are expanding the potential clinical utility for Technegas
- The following Technegas images underscore the advancement in complementary technology Cyclopharm is leveraging today:



1980s 2010 2010 2015

**Planar Imaging** 

**SPECT Imaging** 

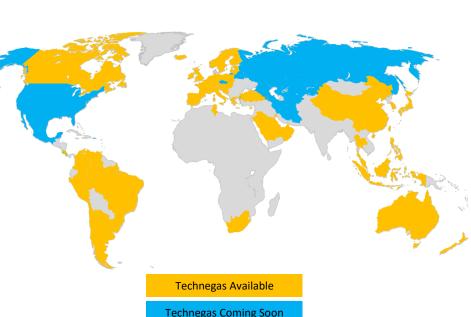
SPECT with Low Dose CT

SPECT with Low Dose CT & Lobular Quantification

# **Existing Market Development Strategy**



- Sales and marketing program targeting referring respiratory physicians
- Implemented educational programs for Distributors
- Updating Technegas distribution contracts to include detailing to respiratory physicians
- Leveraging New Complementary Technologies
- Strengthening relationships with KOL's and industry bodies
- Guideline Development
- Product Renewal & Enhancements
- Initiated pilot clinical trials targeting expanded indications
- Introduction of new products by leveraging off of existing network - Ultralute



# Technegas – Global Indication Expansion



- ✓ Applications in chronic disease has the potential to dwarf the use of Technegas in Pulmonary Embolism
- ✓ In 2015 Cyclopharm commenced a clinical program targeting Technegas indication expansion to include:

### **Chronic Obstructive Pulmonary Disease**

- 30x the size of total PE market
- 1 in 7 Australians over the age of 40
- In 2008, the total economic impact of COPD was estimated to be \$98.2 billion of which \$8.8 billion was attributed to financial costs and \$89.4 billion to the loss of wellbeing.
- COPD is a leading cause of death and disease burden after heart disease, stroke and cancer
- Global estimates show that COPD will be the third leading cause of death by 2030

### **Lung Reduction Intervention**

 Application in determining ventilation pre and post lung reduction intervention

#### **Asthma**

- 334 million people globally
- 1 in 9 Australians have asthma
- \$655 million was spent on asthma in 2008-9; which is 0.9% of all direct health spend on diseases.
- 34% of people report that asthma interferes with their daily living, and 21.8% of people aged 15-25 required time off work, school or study due to their asthma

#### **CTEPH**

- Ventilation/Perfusion imaging is recommended
- Up to 40 million patients globally





Strategic Goals & Guidance	Activity	Timeframe
United States FDA Approval	Continue patient recruitment Expand clinical trial sites Complete Extended Technegas particulate study Submit preliminary 40 patient report to the USFDA Finalise paediatric plan and submit to USFDA Finalise patient recruitment Complete internal review of pharmaceutical and device manufacturing requirements to comply with USFDA requirements Submit New Drug Application to the USFDA	Ongoing Ongoing 1H 2018 1H 2018 1H 2018 2H 2018 2H 2018
Indication Expansion	<ul> <li>Continue UoN-HMRI-JHH clinical trial</li> <li>Commence new pilot trials in Canada and Australia</li> </ul>	Ongoing 1H 2018
New Product – Ultralute™	<ul> <li>First sales of Ultralute<sup>™</sup></li> <li>Initiate multi-centre multi-country trial design with the IAEA</li> </ul>	1H 2018 1H 2018
Expand Product & Service Offering	<ul> <li>Identify and evaluate business prospects targeting growth, product extension, diversification, improved distribution models, accretion and enhanced returns</li> <li>Integrate acquired nuclear medicine distributor covering BeNeLux region</li> <li>Complete restructuring of German operations including new distribution model</li> </ul>	Ongoing 1H 2018 2H2018
2018 Guidance	<ul> <li>Technegas sales and underlying earnings growth supported by additional sales in China and France</li> <li>Higher margins in Germany as restructuring efficiencies gain traction</li> <li>First commercial revenue of Ultralute™ in Europe</li> <li>Expenditure of approximately AUD \$5.3 million on FDA approval process and regulatory / operational readiness for US launch</li> <li>Finalise operational and regulatory readiness for USFDA launch</li> <li>Ongoing investment in trials to support expanded use of Technegas supported by AusIndustry R&amp;D grants</li> </ul>	FY 2018



Expected rapid adoption of Technegas in US is based on our Canadian experience and views of US Clinicians.

Hear what our Clinicians have to say:



Go to Testimonials @ http://cyclopharm.com.au/clinical/



# **Appendix**

- FY17 Results
- Technegas
- Newcastle Trial
- Ultralute<sup>TM</sup>
- MMI
- Disclaimer

# 2017 Operating Highlights



- **Technegas continuing to perform well** Technegas volumes performing to expectations healthy growth in Canada and Europe. 2017 saw an expected absence of sales in China following 2016 seeding initiative and destocking in France. China and France sales to resume / increase in 2H 2018.
- **Ultralute**<sup>TM</sup> First commercial batch of Cyclopharm's new patented Ultralute<sup>TM</sup> technology validated and ready for sales with revenue expected in first half 2018
- Capital Raising \$6.59 million raising (after costs) completed 30 June 2017 with 90% shareholder participation.
- R&D Tax Incentive AusIndustry has allow some overseas R&D activity to be included in the costs of R&D tax incentive program resulting in Other Income of \$2,390,586 compared to \$495,083 in 2016
- US commercialisation Trial design FDA approved The clinical trial design has been approved by the FDA substantially reducing the risk of any adverse regulatory obstacles during the approval process
- **USFDA 240 patient trial** On track to submit interim 40 patient study in 1H 2018 which will provide valuable feedback for full 240 patients clinical trial. Completion of the US clinical trial and FDA approval will clear the path for the immediate large scale commercialisation of Technegas across the US market in 2019. As at 14 March 2018, 36 patients have been imaged.
- Commencement of 100 patient small airways disease trial −100 patient clinical trial targeting the use of Technegas beyond Pulmonary Embolism. As at 9 March 2018, 32 patients have been imaged
- Acquisition of Agency in BeNeLux Expanding our offering and implementing our strategy of targeting respiratory
  physicians and direct customer engagement in key markets
- Restructure of German Operations German operations restructured in December in order to deliver on CYC's long term objectives

# Group Underlying Performance



### **Solid Underlying Financial Results**

Year ended 31 December (\$000's)	2017	2016
Sales revenue, ex China seeding sales	13,189	13,008
China seeding sales	<del>-</del>	1,378
Consolidated sales	13,189	14,386
Gross margin	10,740	11,182
Gross margin % sales	81.4%	77.7%
Consolidated EBITDA	1,043	2,041
Add back:		
CPET / Ultralute <sup>tm</sup> division EBITDA	457	366
Other non-operating expenses <sup>1</sup>	677	428
FDA expenses and other pilot trial expenses	2,855	1,098
R&D Tax Incentive	(2,391)	(495)
Gross margin on China seeding sales	-	(767)
Technegas Underlying EBITDA, ex China	2,641	2,671

During the year, CYC continued to implement its strategic priorities, which are to:

- Grow the core business, based on expanding Technegas sales in existing markets;
- Accelerate the path to regulatory approval to sell Technegas into the world's largest and new highly prospective US market;
- Pursue sales of Technegas in new applications: Chronic Obstructive Pulmonary Disease ("COPD") and Asthma which are significantly larger markets than the Pulmonary Embolism market where CYC traditionally operates; and
- Commence commercial production of our exciting Ultralute<sup>™</sup> nuclear medicine complementary technology ahead of sales in the first half of 2018.\*

<sup>1.</sup> Office relocation expenses and provisions related to Almedis Germany

# Group Balance Sheet



### **Financial Foundation to Leverage Growth Strategy**

Year ended 31 December (\$000's)	2017	2016
Cash	8,690	4,591
Other current assets	8,139	6,470
Non-current Assets	6,548	5,354
Total Assets	23,377	16,415
0	<b>5.040</b>	0.550
Current Liabilities	5,212	3,556
Non-current Liabilities	916	397
Total Liabilities	6,128	3,953
Net Assets	17,249	12,462

- Low debt & \$8.7m cash on hand provides
   balance sheet and funding flexibility
- Funding used toward USFDA clinical trial enrolment and New Drug Application submission
- Strong financial position supports ongoing investment in R&D and expansion into new markets and indications

# Group Cash Position



### **Solid Cash Generation & Funded for Growth**

Year ended 31 December (\$000's)	2017	2016
Operating Activities	(282)	655
Investing Activities	(1,536)	(2,221)
Financing Activities	5,828	(754)
Net Increase in Cash	4,010	(2,320)
Opening Cash	4,591	6,445
Foreign Exchange	89	466
Closing Cash	8,690	4,591

### **Successful Capital Raising**

- Completed a fully-underwritten
   Entitlement Offer that raised \$6.59
   million after costs.
- Capital raising sub-underwritten by Australian Ethical Investments.

#### **R&D Tax Incentive**

Benefited from expanded R&D tax
 Incentive Program resulting in
 Other Income of \$2.39 million

# What is Technegas?



# Technegas is the world leader in functional lung ventilation imaging.

- Technegas is a structured ultra-fine dispersion of radioactive gas like substance which is inhaled by the patient. It allows imaging for evaluating functional ventilation.
- Primarily used to diagnose the presence of blood clots in lungs (Pulmonary Embolism)
- Produced by heating Technetium-99m in a carbon crucible for a few seconds at 2,750 degrees Celsius
- The resultant gas-like substance is produced in a Technegas generator
- The small size and hydrophobic properties together confirm ideal characteristics for gas-like behaviour on inhalation into the lungs
- Technegas, used in the ventilation part of the low radiation dose V/Q SPECT imaging, is cost-effective, simple to perform and accurate





# Technegas is a System

In order to deliver the best clinical outcomes,
Technegas requires the combination of authorised:

- Equipment and consumable sales and support
- ✓ Regulatory representation
- ✓ Technical provision of equipment installation and maintenance
- ✓ Applications education in the use of the Technegas technology

### FDA Approved Trial Design



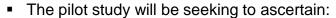
- De-risked clinical trial strategy In order to mitigate regulatory risk the Company adopted the FDA Special Protocol Assessment (SPA) pathway for its US clinical trial
- FDA approved trial design The SPA pathway provided the Company with the opportunity to reach agreement with the FDA on the overall protocol design (including entry criteria, dose selection, endpoints and planned analysis).
- Regulatory risk substantially eliminated The key benefits of the SPA pathway are the value of preliminary input from the
  FDA around trial design and the elimination of the risk that clinical endpoints can be called into question at the time of the
  New Drug Application submission.
- Broad patient selection criteria The trial is designed on an 'all comers basis' meaning broad selection criteria which will facilitate the expeditious recruitment completion of the trial in 2H 2018.
- Short timeframe to FDA approval and commercial launch The Company has diligently de-risked the FDA clinical trial
  process and looks forward to concluding the trial and obtaining FDA approval with the aim of recording first sales in 2019

### Technegas Indication expansion – Australian Initiative



- Partnership with the University of Newcastle, John Hunter Hospital and Hunter Medical Research Institute
- Targeting Clinical Applications in COPD Patients
- Clinical Hypothesis:

Small airway dysfunction assessed using Technegas functional lung ventilation imaging with quantification identifies treatable traits of obstructive airway disease.



- Is there ventilation heterogeneity among patients with severe obstructive airway diseases that can be assessed using Technegas functional lung ventilation imaging with quantification?
- Is Technegas functional lung ventilation imaging with quantification responsive to changes following intervention in patients with severe obstructive airway diseases?
- Study Specifics
  - Q4 2016 Protocol finalised
  - 2H 2017 Patient recruitment commenced 19 September 2017
  - Patient size = 100
  - 1.5 Year Project Term
  - ~\$600k AUD Project Cost
  - 32 Patients enrolled as at 9 March 2018





NEWCASTLE AUSTRALIA

### Ultralute<sup>™</sup>



# Innovative, first-in-class, disruptive, proprietary technology used to improve radiopharmaceutical manufacturing efficiency and deliver health care cost effectiveness



Ultralute™

- Extension of Generator life the Ultralute will extend the effective use of an Mo99 generator by up to 50%
- Reduced purchase volumes Allows the user to purchase a smaller (lower cost) Mo99 Generator
- Cost effective Provides a saving of between 30% to 40% in the cost of Tc-99m
- Large market there are over 5,000 Mo99 generators sold worldwide each week.
- Commercialisation Sales expected to commence H1 2018
- Strong IP Patents secured in 2014
- Supportive peak body Strong relationship with the International Atomic Energy Association (IAEA)
- Established clinical trial strategy Multi-centre multi-country trial planned in conjunction with the IAEA

# Macquarie Medical Imaging





- Joint venture with:
  - 50% Alfred Health Solutions
  - 30% Macquarie University
  - 20% Cyclopharm
- Comprehensive suite of imaging modalities
- State of the art research platform
- Growth and profitability linked to ramp-up of Macquarie University Hospital
- Satellite Outpatient Clinic opened in 2H 2016 at nearby Macquarie Shopping Center
- JV accounted for on an equity basis due to Cyclopharm's minority shareholding















SPECT



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