

Cyclopharm Limited

A profitable and growing market leader in nuclear medical imaging and lung healthcare

Australian Microcap Investment Conference

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James McBrayer, Managing Director

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CYC is a leading player in the global nuclear medicine imaging and lung health markets

• **Technegas**: Diagnosis & monitoring of lung diseases

• **Ultralute**TM: Extends useful life of medical isotopes

\$

• **1H16 Sales**: A\$6.5 million ↑ 27%



• Market Cap: A\$67.5 million

• **12** month TSR: 121%

Our Strategy



CYC has a 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 $COPD_1$ and Asthma, Lung Cancer and Pulmonary Hypertension for both diagnosis and patient management.
- 3. Identifying, developing and commercialising complementary innovative technology such as UltraluteTM
- 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

CYC's 10 Fast Facts



- Technegas is a well established proprietary world leader in functional lung ventilation imaging technology with service and capital equipment revenue streams, the majority of sales generated from single patient consumables
- 2. Technegas is sold in 55 countries with significant expansion opportunities in the USA following USFDA approval of Phase 3 clinical trials
- 3. Chronic Obstructive Pulmonary Disease (COPD) and Asthma represent tremendous opportunities for substantial growth world wide
- 4. Ultralute[™], a new, innovative technology with global application, to be commercialised in 1H 2017
- 5. Ultralute[™] also a platform for additional product development
- 6. Deep experience across the management team and workforce
- 7. Another solid financial result in 1H 2016 with strong foundations for growth: \$6.46m sales. Strong balance sheet with \$6.82m in cash at 30 June 2016

An Australian Biotech that:

- 8. Is Profitable, Generating cash, Debt free & paying Dividends
- 9. Has net cash on the balance sheet to fund growth; and
- 10. Is set to leverage tangible major growth opportunities.

Our Technology....

Business Model Based on Annuity Stream From Consumables





Manufacturer and distributor of pulmonary ventilation imaging devices and equipment

- Invented in 1986
- Track record of growing revenue, profits and cash flows
- USFDA trials for sales in US progressing
- Functional lung ventilation imaging agent historically used in the diagnosis of Pulmonary Embolism (PE)
- Preliminary China trials indicate that Technegas can be an effective tool to diagnose and monitor COPD
- Active clinical program underway targeting indication expansion
- Revenues derived from:
 - Technegas Generator
 - Patient Administration Set (Single patient consumable sold in boxes of 50)
 - Service Income



Technology which extends the useful life of nuclear isotopes by up to 50%

- Fine tuning in 2016
- IP Secured
- First sales expected in 1H 2017
- Strong International as demonstrated by the International Atomic Energy Agency

1H 2016 Achievements



- 1H 2016 Sales of \$6.54 million
- 1H 2016 EBIT \$0.8 million
- Payment of recurring dividends
- Cash reserves at 30 June totalling \$6.8 million after repayment of debt
- USFDA clinical trial program commenced
- Decision to move forward with the USA expansion strategy independently
- Preliminary results of trials in China show Technegas can be an effective tool used to diagnose and monitor COPD
- Ultralute[™] Patent protection secured and commercialisation advanced
- New Generation Technegas Generator project takes shape
- China strategy paying dividends with single largest Technegas order valued at \$1.3 million placed in June 2016 for H2 2016 delivery
- Global strategic partnerships under development, including Five Year Collaborative Agreement signed with the Canadian Association of Nuclear Medicine

Technegas Half Year Results



Record 1H Sales and Gross Margin Result

Half Year ending 30 June (\$000's)	1H 2016	1H 2015	1H 2014	1H 2013
Technegas Division Revenue	6,457	5,033	6,015	4,083
Technegas Division Margin	5,386	3,969	4,608	3,037
Technegas Division Net Profit / (Loss) Before Tax	991	324	1,319	(43)
Net Profit / (Loss) Before Tax	789	285	757	(1,431)
Add back: Molecular Imaging Division Loss Before Tax	202	38	562	1,388
Add back: FDA expenses incurred	418	158	312	141
Less: Realised and unrealised forex (gain) / loss	(23)	45	(51)	(46)
Technegas Division Net Profit / (Loss) Before Tax				
excluding FDA expenses and realised and unrealised	1,386	526	1,580	52
forex				
1H PAS unit sales to France	350	-	500	200

- Record 1H
 Revenue
- Record 1H Gross
 Margin result
- Revenues are historically stronger in 2H
- French sales in 2014 and 2015 distorted historical 1H results

Technegas Full Year Performance



Second consecutive year of record results

Year ended 31 December (\$000's)	2015 Change	2014 Change	2013
Technegas Results:			
Sales Revenue			
PAS	10,145 🔺 8.1%	9,384 • 9.3%	8,583
Generators/service	2,363 🔺 12.2%	2,106 🔺 12.4%	1,874
Total Sales	12,508 8 .9%	11,490 • 9.9%	10,457
Underlying EBITDA	2,980 1 3.0%	2,638 1 7.5%	2,246
Underlying EBITDA Margin	23.8% • 0.8%	23.0% 🔺 1.5%	21.5%
FDA Expenses	(686) 🔺 43.5%	(478) –	(478)
EBITDA	2,294 🔺 6.2%	2,160 🔺 22.2%	1,767
D&A	(137) 🔻 38.6%	(223) –	(220)
EBIT	2,157 1 1.4%	1,937 ▲ 25.2%	1,547
EBIT Margin	17.2% 🛕 0.3%	16.9% 🛕 2.1%	14.8%

Underlying Results represent results from the Technegas Division excluding one off items (Insurance/Litigation settlement and costs + impairment expense), CLSA deposit, FDA expenses and MMI equity accounted earnings.

- Another record financial result in FY15
- PAS margins enhanced by improved local prices in Asia and Latin America
- Strong financial performance supports ongoing investment in R&D and costs associated with expansion into new markets
- 1H Revenue timing issues are historically compensated in Full Year results
- A third consecutive year of record revenues is expected in FY2016 based on receipt of the single largest order placed in June 2016 for the China market

Cyclopharm Group Balance Sheet



Solid Financial Foundation to Leverage Growth Strategy

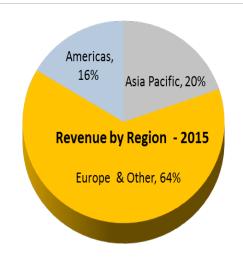
Total Assets	16,373	16,541	10,961
Current Liabilities	3,838	3,176	2,874
Borrowings	3,030	197	2,674
Non-current Liabilities	219	66	85
Total Liabilities	4,057	3,439	3,205
	·	<u>, </u>	<u>·</u>
Net Assets	12,316	13,102	7,756

- Improved cash position driven by strong cash flows from operations
- Capacity to fund growth initiatives and ongoing R&D
- Medium to long term future of the Cyclopet facility at Macquarie University under consideration - includes possible divestment and partnerships
- Debt free Mortgage Debt retired in March 2016

Growth Drivers: Technegas – Expanding the Global footprint



- Technegas sold in 55 countries
 - Europe is the largest regional market for Technegas
 - In 2014 Canada became largest country market for Technegas, surpassing France
- Over 3,500,000 patient studies since 1986
- 1,500 Technegas generators sold globally
- Expanding operations in North America pending completed clinical trials and FDA approval
- Expanding the use of Technegas targeting COPD with trials being finalised in China
- Expansion of clinical development program in 2016
- Patent protection until 2026 with optionality for extension
- 84% of sales are from single patient consumables / patient administration sets (PAS)





Technegas – USFDA clinical trial program.... ON TRACK



USA Market Size:

- Half the world's nuclear medicine departments are in the USA
- USA represents a potential base Pulmonary Embolism market of 480,000 patients per annum. (Current Rest of the World volumes = 200,000 patients per annum)

Study Specifics:

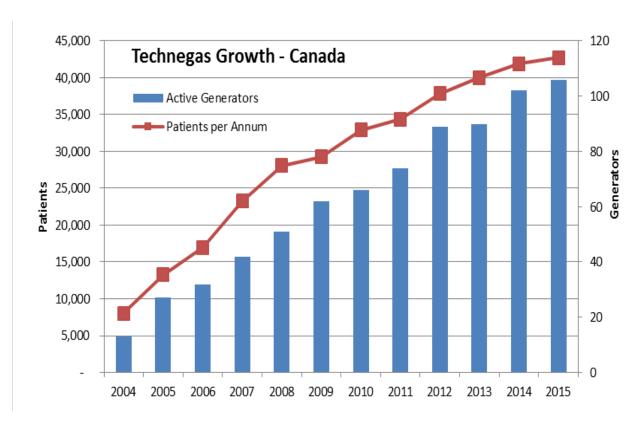
- Non-inferiority structural ventilation study comparing Xe133 vs. Technegas
- Pathway to approval requires a two part study (CYC 010 & CYC009)
 - ✓ CYC 010 Establishes the Inter & Intra reader variability for Xe133 Completed
 - ✓ CYC 009 Compares Xe133 with Technegas requiring patient recruitment SPA Submitted
- "All Comers" protocol to eliminate previous obstacles in patient recruitment
- Total estimated trial cost < \$7 million USD
- Assumes 240 patient study at 10 clinical sites
- CYC has decided at this stage to independently proceed in funding the trial

TIMELINE					
H1 2016	H2 2016	H1 2017	H2 2017	H1 2018	H2 2018
Commence CYC 010	Finalise CYC 010 Submit CYC 009 for SPA Approval	Commence CYC 009	Finalise CYC 009 Recruitment	Submit Clinical Trial Results for USFDA Review	Targeted USFDA Approval





The Generator and Consumable Relationship

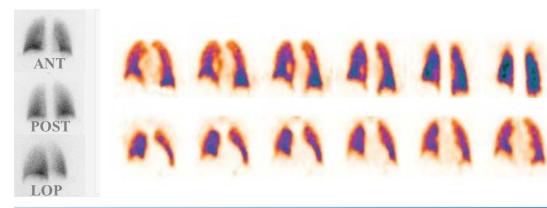


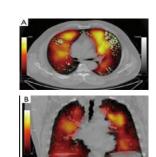
- Canada is our largest single country market with 12 consecutive years of PAS growth
- Canada represents a strong indicator of USA acceptance
- Xe133 rapidly displaced by early adopters
- Direct correlation with the number of active generators and annual consumable sales
- Market driven by public healthcare sector
- Market launch initiated province by province, leveraging off **luminary sites**
- Market leader for diagnosing PE
- Clinical application expansion strategy underway

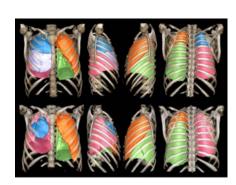


Evolution of Functional Lung Ventilation Imaging

- 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:







980s 2000 2010 2015

Planar Imaging

SPECT Imaging

SPECT with Low Dose CT

SPECT with Low Dose CT & Lobular Quantification

Technegas – Global Indication Expansion



Targeting Chronic Obstructive Pulmonary Disease (COPD) market

Evaluating the effectiveness of Technegas in early detection of COPD and the presence of the comorbidities associated with the disease

Market Size:

- 30x the size of total PE market
- 265m people have moderate to severe COPD
- Estimates show that COPD will be the third leading cause of death by 2030

Timeline:

- ✓ Q2 2016 China trial recruitment completed
 - Q4 2016 Trial Results finalised
- ✓ Extending the COPD initiative to additional markets including in Canada, Australia and several European countries

Australian Study Specifics:

- Patient size: ~60 patients
- Total cost = <\$500K

Additional indication and applications – Asthma, Lung Reduction and CTEPH*

Technegas can provide the clinician the ability to visualise and quantify lung ventilation by region. No other diagnostic tool can provide consistent, accurate and reliable functional imaging in comparison.

Cyclopharm will leverage this market advantage in 2016 by initiating a clinical program targeting Technegas indication expansion to include:

Asthma

334 million people globally

Lung Reduction Intervention

 Application in determining ventilation pre and post lung reduction intervention

Chronic Thromboembolic Pulmonary Hypertension

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

Technegas Indication expansion – Targeting COPD in China



- The Global incidence of Chronic Obstructive Pulmonary Disease (COPD) is 30x greater than that of Pulmonary Embolism (PE)
- By 2030 COPD is estimated to be world's 3rd highest cause of death
- Between 2003 and 2033, it is predicted that China will see 65 million deaths from COPD and 18 million deaths from lung cancer
- Following successful initial Chinese COPD trial progress, single largest Technegas order placed in June 2016 for H2 2016 delivery



Drivers of the Chinese COPD market

- Greatest producer and user of tobacco in the world*
- Rapidly Aging Population
- High use of biomass burning at home for cooking
- Elevated incidence of post-pulmonary tuberculosis
- Poor air quality in metropolitan areas

China Trial assessing Technegas for COPD diagnosis & management

- Trial Results expected in Q4 2016
- Preliminary trial results suggest earlier detection than traditional Spirometry

China Market Potential

- Total public hospitals 13,326
- Private hospitals: 13,153
- 520 Hospitals with nuclear medicine departments
- Additional 800 tertiary hospitals that are certified to have nuclear medicine

Expanding the use of Technegas Australian Pilot Clinical Trial to Commence



- 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 is a treatable trait of obstructive airway disease.

- The pilot study will be seeking to ascertain:
 - 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 to be finalised
 - Q1 2017 Patient recruitment to commence
 - 2.5 Year Project Term
 - ~\$500k AUD Project Cost







Ultralute[™]



Product Overview

- Disruptive Technology changes 60 years of how radiopharmaceuticals are manufactured
- Extends the effective use of Mo99 generator up to 50%
- Each cartridge consumable designed for a maximum of 10 uses
- Patents secured in 2014
- Will be designated as laboratory equipment
- Market introduction represents a base platform for additional applications
- Revenues commencing 1H 2017
- Strong support from the International Atomic Energy Association (IAEA) where they refer to Ultralute[™] as"a new innovation...that has significant global potential in the nuclear medicine supply chain".

Technology Features

- Enables a user to extend the usable life of a Mo99 Generator
- Allows the user to purchase a smaller Mo99 Generator
- Provides greater flexibility in manufacturing products
- Provides a saving of between 30% to 40% in the cost of Tc-99m
- Enhances radiolabelling efficiency and imaging quality
- Purifies contaminants from the Tc99m eluate
- Provides a platform for further product development



UltraluteTM Generation overview



GEN 1

Designed for the end user application

 Introduced to market Q4 2015 with revenues commencing 1H 2017

GEN 2

- Designed for radiopharmacy application
- Development will commence in 2017 for 2018 market introduction

GEN 3

Designed for n,Gamma reactions

- Ultralute technology ideal for concentrating low specific activity generated by n.Gamma Mo99 production
- Discussions with Mo99 manufacturers commenced in 2015

- There are 4,000 Mo99 generators sold worldwide each week.
- Approximately 50% are sold to Radiopharmacies with the remaining sold directly to end users in hospitals and clinics



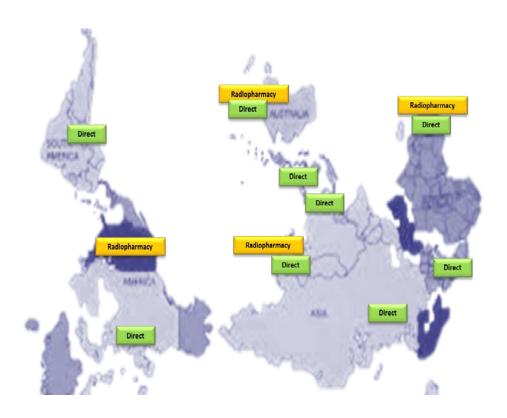
Molybdenum Manufacturing and Supply Chain



Ultralute[™] Targeting direct users of Mo99



- UltraluteTM v1 is targeted at the clinical end-user market that sources Mo99 Generators directly from manufacturers
- The European Mo99 generator market is completely Direct
- Ultralute[™] registration in the EU has determined it to be a laboratory apparatus
- The largest single market for Mo99 generators in Europe is Germany
- Ultralute[™] v2 is being developed for the Radiopharmacy user market





2016 Strategic Priorities and Outlook

Strategic Goals & Guidance	Activity	Timeframe
United States FDA approval	Proceeded on an independent path to USA market approval	Q2 2016
•	USFDA clinical trial program commenced	Q2 2016
	 Relocate the Cyclopharm manufacturing premises and commence USFDA manufacturing compliance readiness 	Q4 2016
Indication Expansion	 Implemented clinical marketing strategy targeting the referring physicians 	Q2 2016
	 Complete COPD Trial in China and submit results for publication 	Q4 2016
New Product – Ultralute™	 First sales of UltraluteTM Conduct multi-centre multi-country review through the IAEA 	H1 2017 H1 2017
Expand Product & Service Offering	 Identify and evaluate business prospects targeting growth, product extension, diversification, improved distribution models, accretion and enhanced returns 	Ongoing
	Finalise protocol with UoN-HMRI-JHH	Q4 2016
Full Year Guidance	 China order combined with consistent underlying results are expected to deliver record sales result Dividend program expected to be maintained Profits impacted significantly due to USFDA clinical trial expenses 	FY 2016

Overview of Cyclopharm



Over the past 2 years, Cyclopharm has delivered a substantial increase in shareholder value through executing our strategy in the global manufacture and supply of innovative nuclear medicine technologies

- Well established, profitable and fiscally disciplined biotech, with recurring cash flows predominantly generated from a line of consumable products
 - Second year of consecutive record revenue and profit
- Technegas system is the world leader in functional lung ventilation imaging
 - Endorsed by global industry bodies, including the European Association of Nuclear Medicine
 - Improvements in imaging technology have dramatically increased the utility of Technegas
- Near term growth opportunities include:
 - Attaining USA approval for Technegas targeted for 2H 2018
 - Expanding the use of Technegas beyond Pulmonary Embolism to include COPD, Asthma, Pulmonary Hypertension and Lung Cancer
 - Introducing new technologies, including commercial sales of Ultralute™ in 1H 2017
- Strong financial position and cash flows funding:
 - Market growth and R&D initiatives
 - Payment of dividends



Cyclopharm Limited

Appendix Section

- Cyclopharm History
- MMI
- Growth Opportunities and Key Performance Indicators
- Disclaimer

Our History













1984 Technegas discovered and commercialised

1992 European markets established

2000 Vita Life Sciences acquires **Tetley Medical**

2001 **USFDA** program initiated for Technegas

2007 Technegas Plus generator launched

2013 Ultralute™ technology established

2000

2005

2010

2015

2016

1988 Technegas enters European market

1996 Technegas registered in the EU as a drug

2003 Canadian regulatory approval attained for Technegas

2007 Cyclopharm Ltd listed on the ASX

2009 Entered molecular imaging market & establishes MMI imaging JV

2015 Maiden Dividend. Ultralute™ launched

2016 **USFDA Clinical** Trial Launched for Technegas











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
- EBIT positive since 2014
- Sales revenue increased 5% in 2015 as outpatient initiatives implemented at Macquarie University Hospital take effect
- Satellite Outpatient Clinic to open in 2H 2016 at nearby Macquarie Shopping Center









Ultra-sound







Growth Opportunities and Key Performance Indicators



Technegas	
USA	 The USA represents the single largest market with half of the world's nuclear medicine departments located there Existing market for PE in the USA equates to ~480,000 patients per annum First priority following USFDA approval is to repeat our Canadian experience by replacing the Xe133 market valued at \$47m USD
Currency	< 20% of revenues are \$AUD related; Currently > 60 % of Technegas revenues linked to Euro.
Seasonality	Historically 2H revenues are stronger due to higher procedures volume during northern hemisphere winters
Pricing & Product Margins	In H1 2016 the average selling price for a per patient PAS=\$53.20 AUD & Technegas Generators = \$26.6k AUD. Despite downward pressure on healthcare products globally, Technegas continues to maintain our margins. Consolidated GM of 82.8% in 2016 made up of PAS, the profitability engine room, accounting for 84% of total Technegas revenues.
Sales Volumes	PAS boxes sold in 1H 2016= 2,049 equating to 102,450 patient studies Underlying Technegas generators volumes continue to average 50-60 units per year in 2015 plus a additional 50 units to be delivered to China by end of 2016
Competitive Products	 Xe133 has been eliminated from the Canadian market with the introduction of Technegas. Xe133 only used in the USA is a \$USD 47M product in 2015 Kr89 – excellent imaging properties. Only available in a few countries due to limited availability and high cost DTPA in low patient volume sites continue where Technegas is available. Used in the USA off-label CTPA continues to dominate the PE space; however concerns with high CTPA radiation dose and improved nuclear medicine imaging techniques are bringing referrers back to nuclear medicine VQ imaging
Intellectual Property	TechnegasPlus Generator patented until 2026 A new generation of Technegas generators is under development with the goal to extend patent protection
Clinical Indications	Primarily used for PE. Also used in preplanning and post surgical evaluation for lung reduction intervention The incidence of COPD is 30x that of PE. Furthermore, COPD represents an opportunity for ongoing patient management
Distribution	Cyclopharm continues to evaluate the effectiveness of Distributors/Agents/Partnerships/Independent
Facility Relocation	After 20 years of tenancy, ANSTO has notified Cyclopharm that our lease will not be renewed. The cost of relocation will have an impact in 2016 with an ongoing increase in facility costs.

Growth Opportunities and Key Performance Indicators



Ultralute	
Market Penetration	 Europe targeted as the primary market to launch due to the highest concentration of end user Mo99 generators in the world 1st Generation targeted for launch in Germany at the EANM in October with initial sales to follow 1H 2017
Margins	Product launch estimates 50% GM with margin improvement expected from leveraging volume growth
Product Development	 1st Generation targeting end users in hospitals and clinics to be commercialised in 2017 2nd Generations targeted for Radiopharmacy will be introduced in 2018
Other Applications	Discussions underway with interested parties for extended applications with other isotopes

MMI	
Revenue	Volumes closely aligned with the hospital. Continued double digit growth expected per annum in the foreseeable future
Profitability	EBITDA positive as of mid CY 2014
MRI Licensing	Significant increase in profitability if Government funded MRI licensing is achieved
Expansion	New outpatient facility due to open at Macquarie Centre 2H 2016

Cyclopet	
Molecular Imaging	Following competition from government owned enterprises, Cyclopharm's Board decided to suspend commercial operations. Subsequent to this decision the company successfully mediated an outcome that resulted in ANSTO paying \$2.65M to Cyclopharm. Cyclopharm has no immediate intention of reentering this market under the current competitive landscape.
Facility	Fully written off. Discussions underway relating to the long term to include partnerships and disposal of the facility



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

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