



# Cyclopharm Limited

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

## **1H 2016 Results Investor Presentation**

24 August 2016



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## James McBrayer, Managing Director

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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



## CYC's 10 Fast Facts

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1. Technegas is a well established proprietary world leader in functional lung ventilation imaging technology with multiple revenue streams consisting of service, capital equipment with 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 opportunity for substantial growth world wide
4. Ultralute™, a new innovative technology with global application, to be commercialised in 1H 2017
5. Ultralute™ technology is 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 is:**

8. Profitable, Generating cash, Debt free & paying dividends.
9. Net cash on the balance sheet to fund growth and
10. Set to leverage tangible major growth opportunities.

# Our Technology



**Technegas**

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
- Revenues derived from:
  - Technegas Generator
  - Patient Administration Set (Single patient consumable sold in boxes of 50)
  - Service Income



**Ultralute™**

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 interest

**In 2015 Cyclopharm made significant progress on our strategy that delivered a substantial increase in shareholder value through 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 product is the world leader in the functional lung ventilation imaging**
  - Actively endorsed by global industry bodies, including the European Association of Nuclear Medicine
  - Improvements in complementary imaging technology have dramatically increased the utility of the Technegas technology
- **Near term growth opportunities** include:
  - Attaining USA approval for Technegas targeted for H2 2018
  - Expanding the use of Technegas beyond Pulmonary Embolism to include COPD, Asthma, Pulmonary Hypertension and Lung Cancer
  - Introducing new technologies to include Ultralute™ in H1 2017
- **Strong financial position** and cash flows funding:
  - Market growth and R&D initiatives
  - Payment of inaugural dividends

# 1H FY 2016 Highlights

- **Sales of \$6.54 million**
- **EBIT \$0.8 million**
- **Payment of recurring dividends**
- **Strong cashflow from operations significantly strengthened the balance sheet, with 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 to include the Five Year Collaborative Agreement signed with the Canadian Association of Nuclear Medicine**

# 1H FY2016 Prior Year Period Financial Comparison

## Record 1H Sales and Gross Margin

### Half Year ended 30 June

		H1 2016	H1 2015	Inc/(Dec)	% Change
Sales Revenue	\$'000	6,457	5,078	1,379	27%
Gross Margin	\$'000	5,386	3,985	1,401	35%
Gross Margin	%	83.4%	78.5%	4.9%	
Profit before tax and finance costs	\$'000	799	298	501	168%
Net Profit after tax	\$'000	284	179	105	59%
Earnings Per Share	cents	0.51	0.32	0.19	59%

- **Technegas continues to perform strongly**
- **Sales in previous period adversely affected by a timing anomaly in order patterns from a major European customer**
- **Dividend declared for 1H 2016 at 0.5 cents per share**



# 1H 2016 Financials Revenues

## 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 forex	1,386	526	1,580	52
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 Historical Full Year Performance

## Second consecutive year of record results

Year ended 31 December (\$000's)	2015	Change	2014	Change	2013
<b>Technegas Results:</b>					
<b>Sales Revenue</b>					
PAS	10,145	▲ 8.1%	9,384	▲ 9.3%	8,583
Generators/service	2,363	▲ 12.2%	2,106	▲ 12.4%	1,874
<b>Total Sales</b>	<b>12,508</b>	<b>▲ 8.9%</b>	<b>11,490</b>	<b>▲ 9.9%</b>	<b>10,457</b>
<b>Underlying EBITDA</b>	<b>2,980</b>	<b>▲ 13.0%</b>	<b>2,638</b>	<b>▲ 17.5%</b>	<b>2,246</b>
Underlying EBITDA Margin	23.8%	▲ 0.8%	23.0%	▲ 1.5%	21.5%
FDA Expenses	(686)	▲ 43.5%	(478)	–	(478)
<b>EBITDA</b>	<b>2,294</b>	<b>▲ 6.2%</b>	<b>2,160</b>	<b>▲ 22.2%</b>	<b>1,767</b>
D&A	(137)	▼ 38.6%	(223)	–	(220)
<b>EBIT</b>	<b>2,157</b>	<b>▲ 11.4%</b>	<b>1,937</b>	<b>▲ 25.2%</b>	<b>1,547</b>
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

# 1H 2016 Financials Group Balance Sheet

## Solid Financial Foundation to Leverage Growth Strategy

(\$000's)	1H 2016	FY 2015	FY 2014
Cash	6,816	6,445	3,268
Other current assets	6,168	6,653	5,582
Non-current Assets	3,389	3,443	2,111
<b>Total Assets</b>	<b>16,373</b>	<b>16,541</b>	<b>10,961</b>
Current Liabilities	3,838	3,176	2,874
Borrowings	-	197	246
Non-current Liabilities	219	66	85
<b>Total Liabilities</b>	<b>4,057</b>	<b>3,439</b>	<b>3,205</b>
<b>Net Assets</b>	<b>12,316</b>	<b>13,102</b>	<b>7,756</b>

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

# 1H 2016 Financials

## Cash Flow

### Current Solid Cash Position Generated from Recurring Core Business and Significant One-offs

	1H 2016	FY 2015	FY 2014
Operating Activities	749,817	4,154,834	4,468,780
Investing Activities	(252,330)	(651,654)	(238,756)
Financing Activities	(475,570)	(326,664)	(2,171,525)
Net Increase in Cash	21,917	3,176,516	2,058,499
Opening Cash	6,444,995	3,268,425	1,220,646
Foreign Exchange	349,075	54	(10,420)
<b>Closing Cash</b>	<b>6,815,987</b>	<b>6,444,995</b>	<b>3,268,425</b>

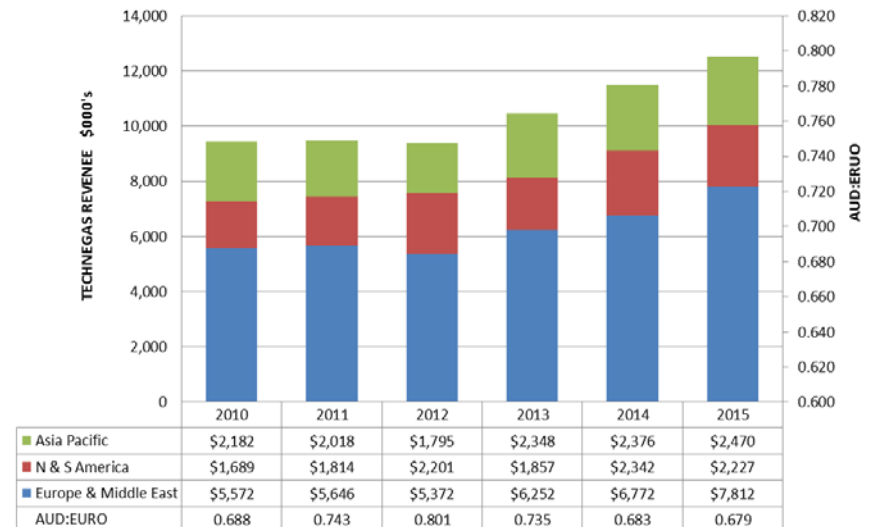
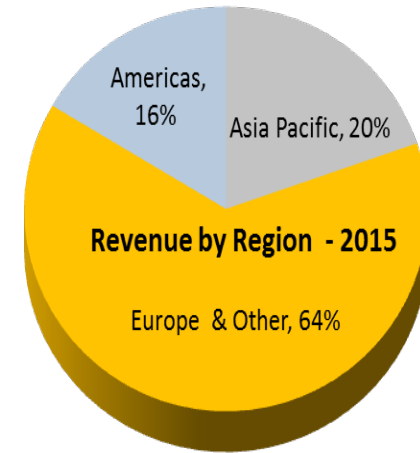
#### Underlying Net Increase in Cash excluding the following categories:

	700,502	2,514,307	2,560,910
Other Income in Operating Activities	–	2,104,689	2,650,000
Payments for FDA Expenditure in Operating Activities	(232,785)	(754,883)	(701,837)
Payments for Deferred Expenditure in Investing Activities	(248,424)	(639,242)	(279,319)
Repayment of Bank Borrowings in Financing Activities	(197,376)	(48,355)	(2,171,255)

- **Strong cash reserves available to fund near to medium term growth opportunities**
- **Investment Activities in 2015 included Ultralute™ & Technegas product development**
- **Significant one-off cash upside in 2014 (\$2.65m) from litigation mediation and in 2015 (\$2.10m) from an insurance settlement**
- **Majority of underlying cash flow in 2015 was generated by Technegas (\$2.74m)**
- **\$1.44m new factory fit out contracted in 2016**
- **Dublin facility mortgage (€128k) 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 clinical trial and approval of United States FDA**
- **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

## USA Market Size:

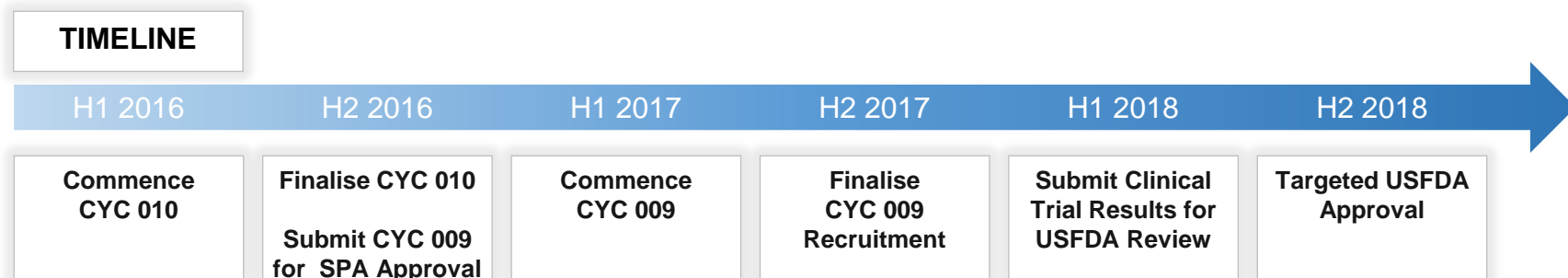
- Half the world's nuclear medicine departments are in the USA
- USA represents a potential base Pulmonary Embolism market of 480,000 patients per annum. (Current Rest of the World volumes = 200,000 patients per annum)

## 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 and Intra reader variability for Xe133 – Currently underway
  - CYC 009 - Compares Xe133 with Technegas requiring patient recruitment
- “All Comers” protocol to eliminate previous obstacles in patient recruitment

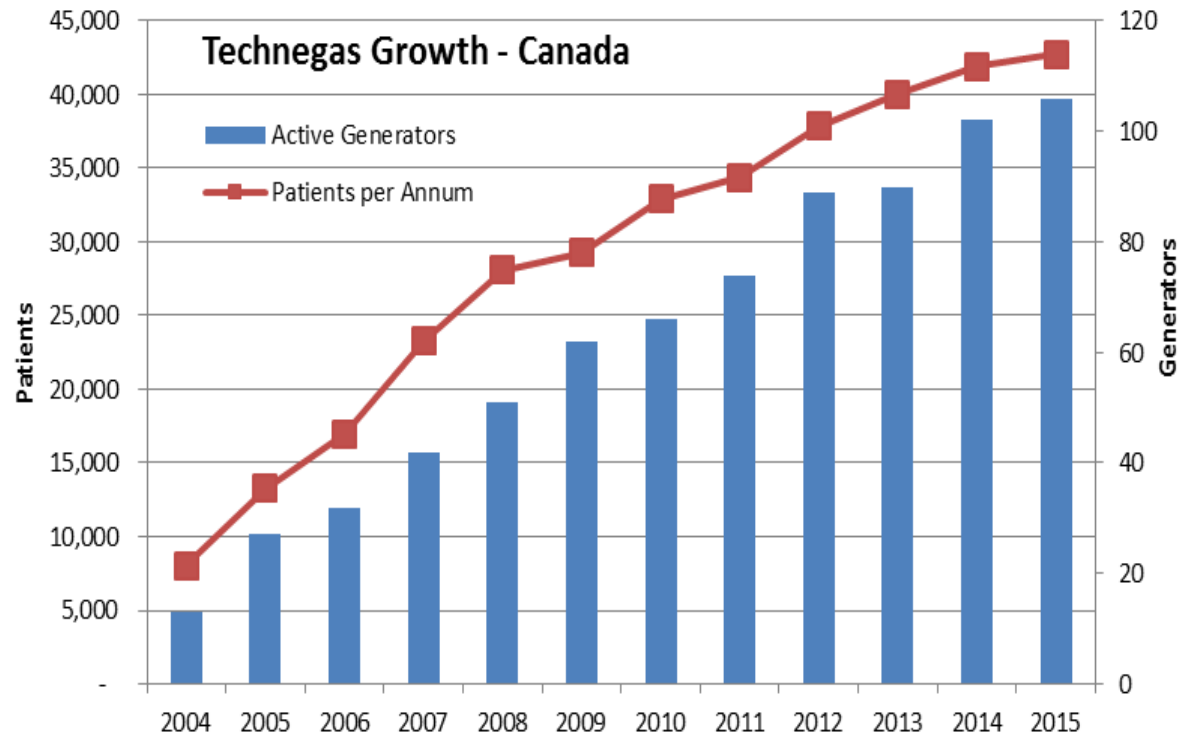
## Total estimated trial cost < \$7 million USD

- Assumes <300 patient study at 10 clinical sites
- CYC has decided at this stage to independently proceed in funding the trial



# Technegas – The Canadian Case Study

## 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**

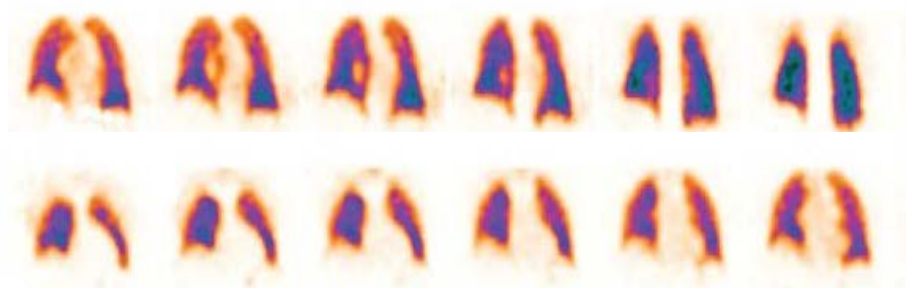
# Evolution of Functional Lung Ventilation Imaging

- 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:



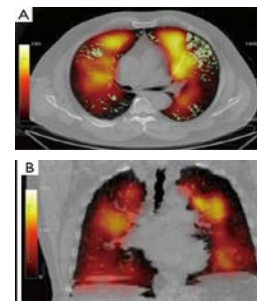
1980s

Planar Imaging



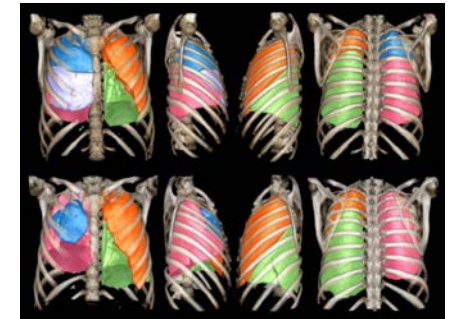
2000

SPECT Imaging



2010

SPECT with Low Dose CT



2015

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
- 65m people have moderate to severe COPD
- Estimates show that COPD becomes by 2030 will be the third leading cause of death

### **Timeline:**

- ✓ Q2 2016 China trial recruitment completed
- Q4 2016 Results published
- Plans to extend COPD initiative to additional markets including in Canada, Australia and several European countries

### **China Study Specifics:**

- Patient size: ~100 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 the recommended
- Up to 40 million people globally

\* CTEPH = Chronic Thromboembolic Pulmonary Hypertension

# 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)**

**It is estimated that by 2020, COPD will be the 4<sup>th</sup> highest cause of death globally. By 2030 COPD will be the 3<sup>rd</sup> highest cause of death globally.**



**Cyclopharm is undertaking a trial in China to assess the use of Technegas for the diagnosis and management of COPD**

- Patient enrolment concluded in April 2016
- Preliminary research with Technegas suggests early detection than traditional Spirometry with 3 abstracts presented at the 2015 Asia Pacific Society of Respiriology conference in December 2016
- Spirometry – a basic measurement of forced air volume provides no underlying pathophysiology and required significant disease progression to diagnose

**Expanding the use of Technegas from Pulmonary Embolism (PE) diagnosis to COPD would represent significant expansion of the market size**

- In China, at any time more than 56.6 million people in China have COPD
- According to the Lancet 2008, it is predicted that China will see 65 million deaths from COPD and 18 million deaths from lung cancer between 2003 and 2033

**Key drivers of the Chinese COPD market include:**

- China is the 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 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

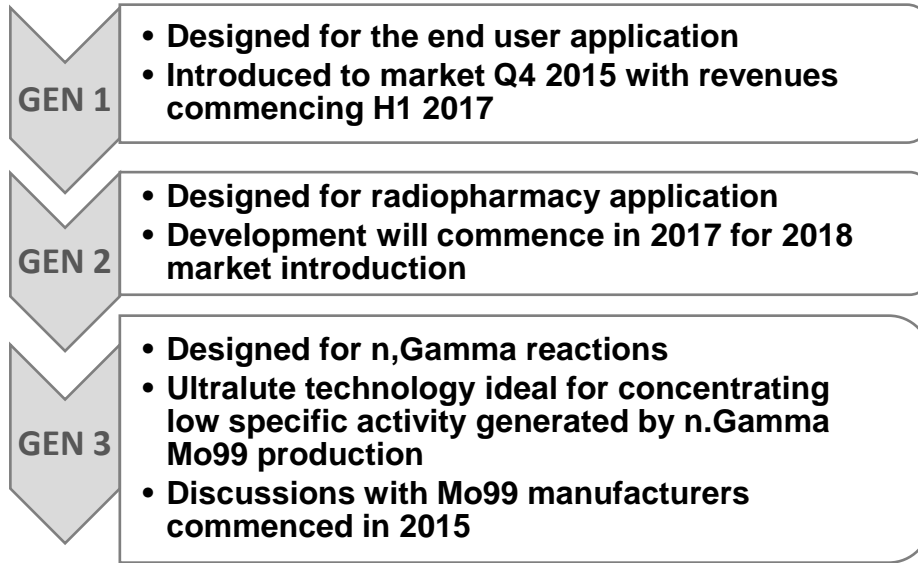
## Product overview

- 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 interest from the International Atomic Energy Association (IAEA)

## 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

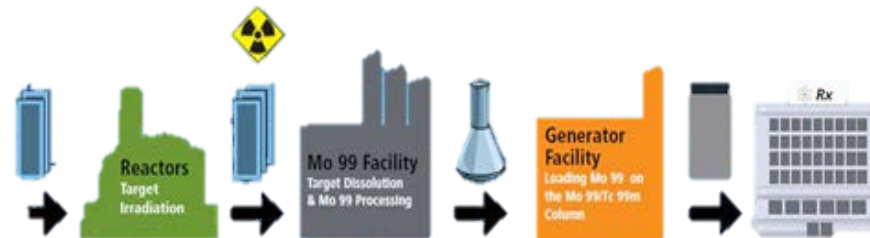
# Ultralute™ Generation overview



- 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

- Ultralute™ 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 been determined 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
<b>United States FDA approval</b>	<ul style="list-style-type: none"> <li>• Proceeded on an independent path to USA market approval</li> <li>• USFDA clinical trial program commenced</li> <li>• Relocate the Cyclopharm manufacturing premises and commence USFDA manufacturing compliance readiness</li> </ul>	<p>Q2 2016</p> <p>Q2 2016</p> <p>Q4 2016</p>
<b>Indication Expansion</b>	<ul style="list-style-type: none"> <li>• Implemented clinical marketing strategy targeting the referring physicians</li> <li>• Complete COPD Trial in China and publish results</li> </ul>	<p>Q2 2016</p> <p>Q4 2016</p>
<b>New Product – Ultralute™</b>	<ul style="list-style-type: none"> <li>• First sales of Ultralute™</li> </ul>	<p>H1 2017</p>
<b>Expand Product &amp; Service Offering</b>	<ul style="list-style-type: none"> <li>• Identify and evaluate business prospects targeting growth, product extension, diversification, accretion and enhanced returns</li> </ul>	<p>Ongoing</p>
<b>Full Year Guidance</b>	<ul style="list-style-type: none"> <li>• China order combined with consistent underlying results are expected to deliver record sales result</li> <li>• Dividend program expected to be maintained</li> <li>• Profits impacted significantly due to USFDA clinical trial expenses</li> </ul>	<p>FY 2016</p>

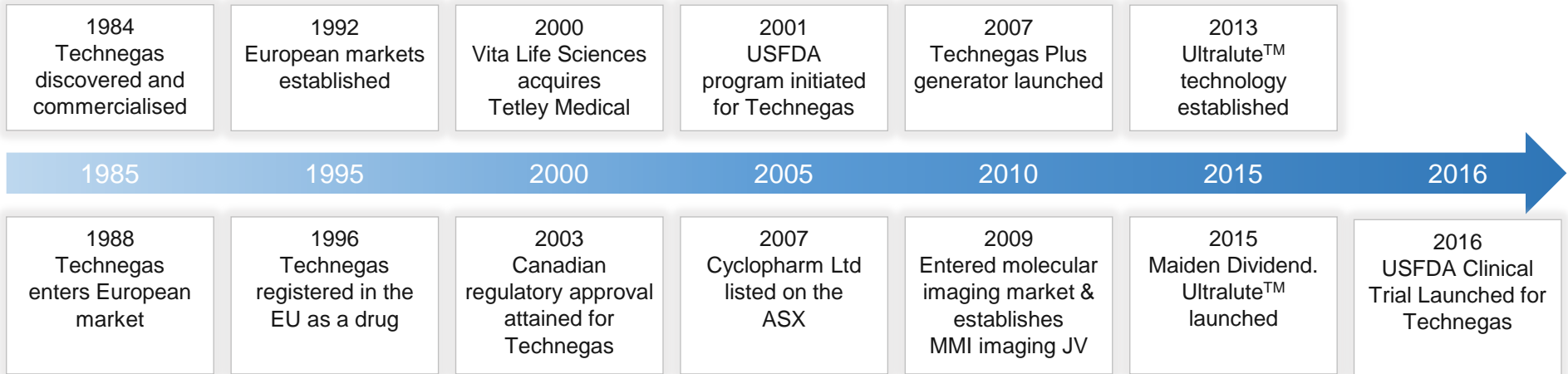


# Cyclopharm Limited

## **Appendix Section**

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

# Our History





# 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



# Growth Opportunities and Key Performance Indicators

## Technegas

USA	<ul style="list-style-type: none"> <li>The USA represents the single largest market with half of the world's nuclear medicine departments located there</li> <li>Existing market for PE in the USA equates to ~480,000 patients per annum</li> <li>First priority following USFDA approval is to repeat our Canadian experience by replacing the Xe133 market valued at \$47m USD</li> </ul>
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	<ul style="list-style-type: none"> <li>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</li> <li>Kr89 – excellent imaging properties. Only available in a few countries due to limited availability and high cost</li> <li>DTPA in low patient volume sites continue where Technegas is available. Used in the USA off-label</li> <li>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</li> </ul>
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 likely.

# Growth Opportunities and Key Performance Indicators

Ultralute	
Market Penetration	<ul style="list-style-type: none"> <li>Europe targeted as the primary market to launch due to the highest concentration of end user Mo99 generators in the world</li> <li>1<sup>st</sup> Generation targeted for launch in Germany at the EANM in October with initial sales to follow 1H 2017</li> </ul>
Margins	Product launch estimates 50% GM with margin improvement expected from leveraging volume growth
Product Development	<ul style="list-style-type: none"> <li>1<sup>st</sup> Generation targeting end users in hospitals and clinics to be commercialised in 2017</li> <li>2<sup>nd</sup> Generations targeted for Radiopharmacy will be introduced in 2018</li> </ul>
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 re-entering 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.

### **Corporate Head Office**

Cyclopharm Limited  
Building 75 Business & Technology Park  
New Illawarra Road  
Lucas Heights NSW 2234 Australia  
PO Box 350, Menai Central  
NSW 2234 Australia  
T: +61 (2) 9541 0411  
F: +61 (2) 9543 0960

### **Enquiries**

E: [enquiries@Cyclopharm.com.au](mailto:enquiries@Cyclopharm.com.au)

### **Share Registry**

RB Registries  
Level 16  
1 Market Street  
Sydney NSW 2000  
T: +61 (2) 9032 3000  
F: +61 (2) 9251 1275