

# Cyclopharm Limited

A profitable and growing market leader  
in nuclear lung imaging

**8<sup>th</sup> Annual Australian Microcap Investment  
Conference**

**18 October 2017**

# 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 FDA trial completion expected in Q3 2018
- Opportunity to broaden Technegas applications beyond pulmonary embolism diagnosis into large addressable markets such as COPD and Asthma

**Cyclopharm Share Price (last 3 years)**



Share Price (as at 17 October 17)	\$0.84
Shares on Issue	68.3 million
Market Capitalisation	\$57 million
Cash (30 Jun 17)	\$10.6 million

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

# 1H2017 Results Highlights



- **Group Sales Revenue** \$6.06 million
- **Gross Margin** \$5.00 million
- **Net Loss After Tax** (\$1.43) million
- **Interim Dividend** 0.5 cents per share
- **Underlying Technegas EBITDA<sup>1</sup>** \$861,000
- **FDA Trial expenses** (\$1.58) million
- **Strong balance sheet** \$10.62 million of cash reserves
- **Guidance Affirmed** Excluding the positive impact of the large Chinese order in FY16, the Board expects continuing modest growth in underlying Technegas volumes for FY17

Note 1: Underlying Results represent results from the division excluding realised and unrealised foreign exchange gains and losses and FDA Expenses

# Company 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 use items which are sold exclusively by CYC.

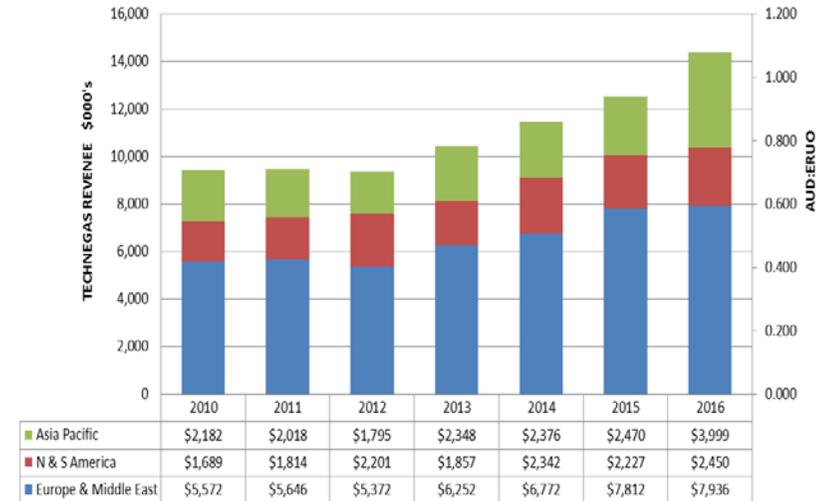


# Proven Market Adoption

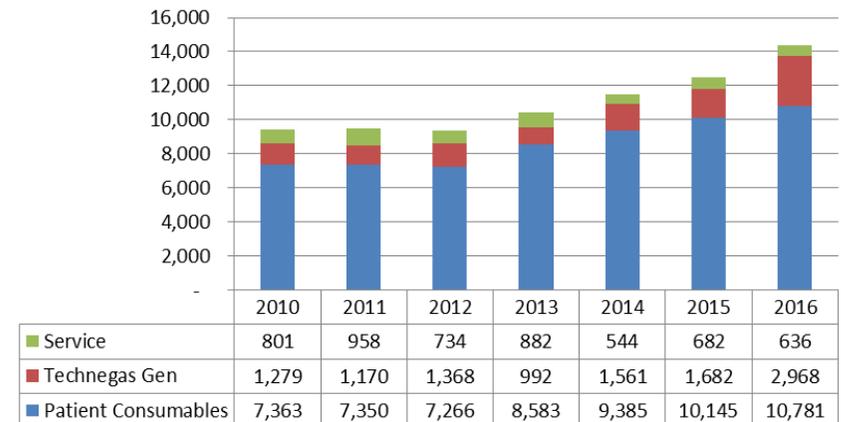
**Technegas is a substantially de-risked commercial proposition with significant upside in the US market**

- Total **global sales of \$83m** since 2010
- Technegas currently available in **56 countries**
- Over **210,000 patient procedures** in 2016
- Over **3,800,000 patient procedures** since 1986
- **1,500 Technegas generators** sold globally
- CYC is a growing, profitable and dividend paying company
- Stable gross margins of greater than 80%
- 79% of historical revenue is generated through recurring consumable sales

Technegas Regional Revenue



Technegas Revenue by Category



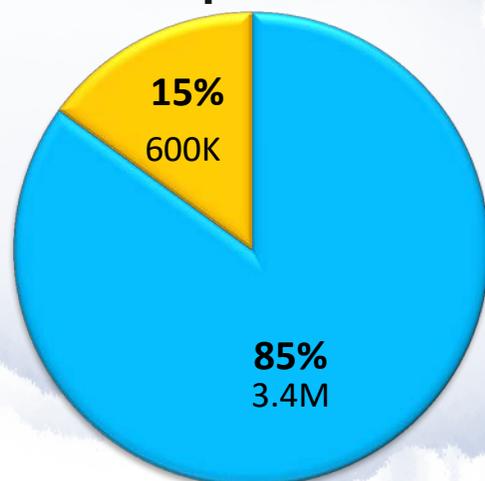


# **FDA Trial and USA Commercialisation**

# USA Market Opportunity

## 600K Nuclear Medicine Ventilation

Procedures p.a. = \$90m USD



■ CTPA ■ Nuclear Medicine

- 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

- 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 Q4 2018
- First priority following USFDA approval is to repeat our Canadian experience by displacing Xe133 as the standard of care diagnostic product
- 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

# 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 style="list-style-type: none"><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 style="list-style-type: none"><li>▪ Inferior images in patients with obstructive lung disease (COPD)</li></ul>

## 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 \$2.4 m 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 Q1 2018

### TIMELINE

2H 2017

Finalise  
Trial Site  
Recruitment

1H 2018

Submit  
Preliminary Trial  
Results for FDA  
Review

Q3 2018

Complete US  
Clinical Trial &  
Submit NDA

Q4 2018

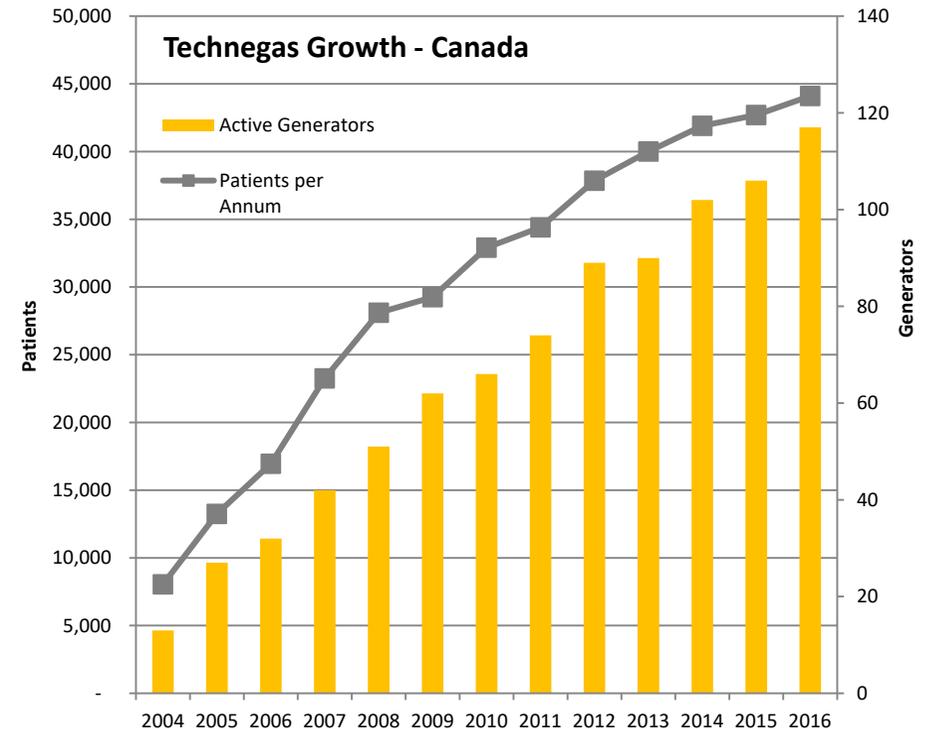
Commence US  
Commercialisation

# Technegas – The Canadian Case Study

## Canada is Cyclopharm's largest single country market

- Market leader for diagnosing PE
- 13 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



# 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 Q3 2018** - Assuming positive feedback from the preliminary study, the Company will continue with the comprehensive FDA trial which it anticipates will be completed during Q3 2018.
- **Target commercial launch Q4 2018** - 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 Q4 2018
- **Market dominance in Canada** - The Company achieved market dominance in Canada (and a number of other markets) at gross margins of ~75% over approximately 10 years.
- **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 a period of 5 to 7 years.
- **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
- **Continue to Develop New Indications** – Expand the use of Technegas beyond Pulmonary Embolism

# 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.**

- 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 finalised
  - 2H 2017 - Patient recruitment commenced 19 September 2017
  - Patient size = 100
  - 1.5 Year Project Term
  - ~\$600k AUD - Project Cost



**Health**  
Hunter New England  
Local Health District

For more information go to:

<https://hmri.org.au/news-article/nuclear-imaging-clear-airway-diagnosis>

# 2017 Strategic Priorities and Outlook

cyclopharm

Nuclear Medicine



Strategic Goals & Guidance	Activity	Timeframe
<b>United States FDA Approval</b>	<ul style="list-style-type: none"> <li>• \$7m raised to fund USFDA clinical trial with &gt;90% shareholder participation</li> <li>• Patient recruitment initiated</li> <li>• Complete clinical site recruitment</li> <li>• Complete Technegas particulate study</li> <li>• Submit preliminary 40 patient report to the USFDA</li> <li>• Finalise patient recruitment</li> <li>• Submit New Drug Application to the USFDA</li> </ul>	<p>Q2 2017 Q3 2017 Q4 2017 2H 2017 1H 2018 1H 2018 2H 2018</p>
<b>Indication Expansion</b>	<ul style="list-style-type: none"> <li>• Peer reviewed publication for China COPD study published</li> <li>• UoN-HMRI-JHH clinical trial initiated</li> <li>• Identify additional sites for pilot clinical trials targeting Technegas indication expansion</li> </ul>	<p>Q2 2017 Q2 2017 2H 2017</p>
<b>New Product – Ultralute™</b>	<ul style="list-style-type: none"> <li>• First sales of Ultralute™</li> <li>• Finalise multi-centre multi-country trial design with the IAEA</li> <li>• Complete IAEA trial</li> </ul>	<p>2H 2017 2H 2017 1H 2018</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, improved distribution models, accretion and enhanced returns</li> <li>• Purchased nuclear medicine distributor covering BeNeLux region</li> </ul>	<p>Ongoing  Q3 2017</p>
<b>Trading Update – Ongoing Underlying Growth (excluding China)</b>	<ul style="list-style-type: none"> <li>• FY2017 Trading YTD is in line with Board's Expectations</li> <li>• Continued growth in core underlying sales</li> <li>• Modest increase in generator and PAS volumes in existing markets</li> <li>• Investing in transformational growth</li> </ul>	<p>FY 2017</p>
<b>Full Year Guidance Affirmed</b>	<ul style="list-style-type: none"> <li>• Excluding the positive impact of the large Chinese order FY16, the board expects continuing modest growth in underlying Technegas volumes for FY17. Guidance affirmed.</li> <li>• Timing of orders in the pipeline could affect 1H/2H split hence guidance focused on full year outlook</li> <li>• Ultralute™ revenues, following launch in late H1 2017. Small contribution to FY17 results expected as new product builds traction. Larger contribution expected in FY18 and beyond.</li> </ul>	<p>FY 2017</p>



**Thank you & Questions**



# Appendix

- 1H FY17 Results
- Technegas
- Ultralute™
- MMI
- Disclaimer

# 1H2017 Operating Highlights

- **Technegas continuing to perform well** – Volume of Technegas generators sold increased 7% vs pcp. Unit sales of PAS, excluding the French and Chinese markets, increased 6% vs pcp.
- **Ultralute on track for 2H sales** – First commercial batch of Cyclopharm’s new patented Ultralute™ technology under final validation, with first sales expected in second half of 2017
- **Successful Capital Raising** - \$6.59 million raising (after costs) completed 30 June 2017 with 90% shareholder participation.
- **Clear path to 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
- **Commencement of 240 patient trial** - Funds raised from the capital raising will facilitate the recruitment of the 240 patients required for the clinical trial across 10 to 15 sites with a 40 patient interim USFDA submission expected 1H 2018. 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
- **Commercial sales targeted to commence Q4 2018** - The Company anticipates that the clinical trial will be completed in Q3 2018 with the aim of achieving commercial US sales in Q4 2018

# Group 1H2017 Underlying Performance



## Solid Underlying Financial Results

Half Year ended 30 June (\$000's)	2017	2016
<b>Consolidated sales</b>	<b>6,057</b>	<b>6,457</b>
Gross margin	4,996	5,386
<i>Gross margin % sales</i>	82.5%	83.4%
<b>Consolidated EBITDA</b>	<b>(1,023)</b>	<b>824</b>
Add back:		
<i>CPET / Ultralute<sup>tm</sup> division EBITDA</i>	242	202
<i>Other non-operating expenses<sup>1</sup></i>	59	(23)
<i>FDA expenses</i>	1,583	418
<b>Technegas Underlying EBITDA<sup>2</sup></b>	<b>861</b>	<b>1,421</b>

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

1. Grow the core business, based on expanding Technegas sales in existing markets;
2. Accelerate the path to regulatory approval to sell Technegas into the world's largest and new highly prospective US market;
3. 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
4. Commence sales of our exciting Ultralute<sup>TM</sup> nuclear medicine complementary technology in the second half of 2017.

1. Realised and unrealised foreign exchange gains and losses

2. Underlying Results represent results from the division excluding realised and unrealised foreign exchange gains and losses and FDA Expenses

# Group 1H2017 Balance Sheet



## Financial Foundation to Leverage Growth Strategy

(\$000's)	30 June 2017	31 Dec 2016
Cash	10,620	4,591
Other current assets	5,710	6,470
Non-current Assets	5,562	5,354
<b>Total Assets</b>	<b>21,892</b>	<b>16,415</b>
Current Liabilities	4,206	3,896
Borrowings	-	-
Non-current Liabilities	273	57
<b>Total Liabilities</b>	<b>4,479</b>	<b>3,953</b>
<b>Net Assets</b>	<b>17,413</b>	<b>12,462</b>

- **Debt free & \$10.6m 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

# Cash Position



## Solid Cash Generation & Funded for Growth

(\$000's)	HY 2017	FY 2016
Operating Activities	(189)	655
Investing Activities	(546)	(2,221)
Financing Activities	6,311	(754)
Net Increase in Cash	5,575	(2,320)
Opening Cash	4,591	6,445
Foreign Exchange	454	466
<b>Closing Cash</b>	<b>10,620</b>	<b>4,591</b>
<b>Underlying Net Increase in Cash excluding the below categories:</b>	<b>754</b>	<b>1,008</b>
Net proceeds from share issue	6,589	–
Payments for FDA Expenditure	(1,377)	(1,035)
Kingsgrove facility PP&E	–	(1,670)
Payments for Deferred Expenditure	(391)	(426)
Repayment of Bank Borrowings	–	(197)

## Successful Capital Raising

- Completed a fully-underwritten Entitlement Offer that raised \$6.59 million after costs.
- The Offer supported by approximately 90% of eligible shareholders
- Sub underwritten by Cyclopharm's largest institutional investor Australian Ethical Investments.

# 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

### Technegas Consumable - Patient Administrator Set



# 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 eliminating 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 completion of the trial in Q3 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 commencing US commercialisation during Q4 2018



## 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 H2 2017
- **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
- EBIT positive since 2014
- Sales revenue increased 8% in 2016 as outpatient initiatives implemented at Macquarie University Hospital take effect
- Satellite Outpatient Clinic opened in 2H 2016 at nearby Macquarie Shopping Center





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

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