

Cyclopharm Limited

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

Investor Presentation

May 2017

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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

\$

• **2016 EPS**: 1.63 cents (81%)



• Market Cap: A\$52.8 million

• **12 month TSR**: 36.43%

CYC's 10 Fast Facts



- 1. Technegas is a well-established proprietary world leader in functional lung ventilation imaging technology with an annuity style product and service revenue streams with the majority of sales generated from single patient consumables.
- Technegas is already being sold in 56 countries with significant expansion opportunities in the USA following USFDA approval of Phase 3 clinical trials and the prospect of FDA approval by mid-2018
- 3. Chronic Obstructive Pulmonary Disease (COPD) and asthma represent tremendous opportunities for substantial Technegas growth worldwide
- 4. Ultralute[™], a new, innovative technology with global application, is being commercialised in 1H 2017
- 5. UltraluteTM technology is also a platform for additional product development
- 6. We benefit from deep experience across the management team and workforce
- 7. Cyclopharm recorded another excellent financial result in 2016 with good foundations for growth: an increase of \$1.8 million sales. We have a strong balance sheet with \$4.59 million in cash at 31 December 2016

In summary, in 2016 we were an Australian Biotech that:

- 8. Profitable, generating cash, debt-free and paid dividends.
- 9. Maintained net cash on the balance sheet to fund growth; and
- 10. Positioned to leverage transformational growth opportunities.

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 COPD₁ 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

2016 Achievements



- FY2016 Sales of \$14.39 million
- FY2016 EBIT \$1.44 million
- Payment of recurring dividends
- Cash reserves at 31 December totalling \$4.59 million after repayment of debt & relocation
- USFDA clinical trial program on track (time & budget)
- 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
- Relocation of manufacturing facility to meet the growing global demand
- China strategy paying dividends with single largest Technegas order valued at \$1.3 million delivered December 2016
- Global strategic partnerships under development, including Five Year Collaborative Agreement signed with the Canadian Association of Nuclear Medicine





2016 Financial Results and Performance

Third consecutive year of record underlying results

Year ended 31 December (\$000's)	2016 Change	2015	Change	2014
Sales Revenue				
PAS	10,782 🔺 6.3%	10,145	▲ 8.1%	9,384
Generators/service	3,604 🔺 52.5%	2,363	▲ 12.2%	2,106
Total Sales	14,386 1 5.0%	12,508	▲ 8.9%	11,490
Underlying EBITDA	3,438 ▲ 15.4%	2,980	▲ 13.0%	2,638
Underlying EBITDA Margin	23.9% • 0.2%	23.7%	▲ 0.7%	23.0%
FDA Expenses	(1,098) 🔺 60.0%	(686)	43.5%	(478)
EBITDA	2,340 🔺 2.0%	2,294	▲ 6.2%	2,160
D&A	(106) 22.6%	(137)	38.6%	(223)
EBIT	2,234 △ 3.6%	2,157	▲ 11.4%	1,937

Underlying Results represent results from the Technegas Division excluding one off items (Insurance settlement and costs/lease termination and double rent period costs) and FDA expenses.

- Another record financial result in FY16
- Underlying strong financial performance supports ongoing investment in R&D and costs associated with expansion into new markets and indications
- A third consecutive year of record revenues in FY2016 assisted by the delivery in December 2016 of the single largest order placed for the China market

Cyclopharm Group Balance Sheet



Solid Financial Foundation to Leverage Growth Strategy

(\$000's)	FY 2016	FY 2015	FY 2014
Cash	4,591	6,445	3,268
Other current assets	6,470	6,653	5,582
Non-current Assets	5,354	3,443	2,111
Total Assets	16,415	16,541	10,961
Current Liabilities	3,896	3,176	2,874
Borrowings	-	197	246
Non-current Liabilities	57	66	85
Total Liabilities	3,953	3,439	3,205
Net Assets	12,462	13,102	7,756

- Operating cash flows supported \$1.5m
 Kingsgrove HQ capex, \$0.43m one-off relocation costs, ongoing USFDA trials and recurring dividends
- 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

Our Business....

Business Model Based on Annuity Stream From Consumables







Manufacturer and distributor of lung 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 ventilation imaging agent used predominantly 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)
 - o Service Income

Technegas





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

- Fine tuning in 2016
- IP Secured
- First sales expected in 1H 2017
- Strong International interest as demonstrated by the International Atomic Energy Agency
- Revenues derived from:
 - Cartridge shielding one off sale per site
 - o Disposable cartridges

Technegas Technology



Product Definition

Technegas is composed of Tc-99m labelled carbon nanoparticles dispersed in high purity argon gas.

The particles are consistently well under 500 nm and due to the small, controlled particle size distribution, the dispersed radioactive particulates display pseudo-gas characteristics permitting them to distribute and penetrate to the depth of the alveoli.

Due to the lipophilic and inert nature of the radioparticulates, once deposited, the particulates remain at the site of deposition throughout the imaging procedure.

Components required for a Technegas study:

Cyclopharm Supplied	 Technegas Generator A single use Patient Administration Set (PAS) A single use patient crucible (Pulmotec) Sales and Service support Authorised Spare Parts
Nuclear Medicine Deparment Supplied	 99.9% Argon Ethanol Tc-99m Sodium Pertechnetate sourced either from an onsite Mo-99 Generator or from a local Radiopharmacy

Technegas is a System

In order to deliver efficacious clinical outcomes, Technegas requires the combination of <u>authorised</u>:

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



Manufacture and Delivery of Technegas

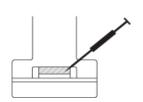


Manufacture



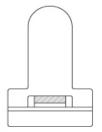
Turn on unit and argon flow to Generator.

Insert crucible

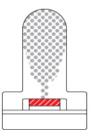


Moisten crucible with Ethanol.

Add 250 – 700 MBq Tc99m Sodium pertechnetate.



Close drawer and initiate simmer stage



Initiate burn sequence (2,700° C) to create Technegas

Administer within 10 minutes of production

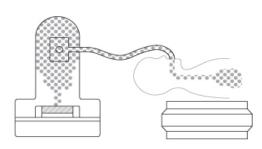
Technegas



Technegas is composed of Tc-99m cores encapsulated within layers of graphite to form individual hexagonal plate-like particles.

These particles agglomerate to reach a dynamic equilibrium with regard to particle size distribution with a mean and median particle size between 100 to 200 nm.

Delivery



Attach single use Patient-Administration Set and deliver Technegas to the patient

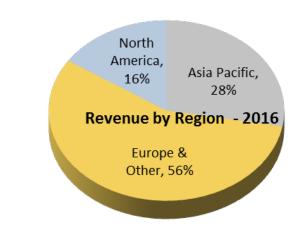
Technegas is inhaled by the patient until the required count rate is achieved in the lungs (1,000 - 2,500 cps equivalent to 15-37 MBq)

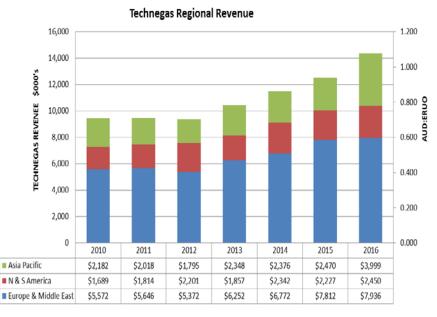


Growth Drivers: Technegas – Expanding the Global footprint



- Technegas sold in 56 countries
 - Europe is the largest regional market for Technegas
 - In 2014 Canada became largest country market for Technegas, surpassing France
- Over 210,000 patient studies in 2016
- Over 3,700,000 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 China COPD trial completed in 2016
- Expansion of clinical development program in 2016 and 2017
- Patent protection until 2026 with optionality for extension
- 75% of sales are from single patient consumables / patient administration sets (PAS)





Technegas – USFDA Approval Within Reach



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 = 210,000 patients per annum)

Study Specifics:

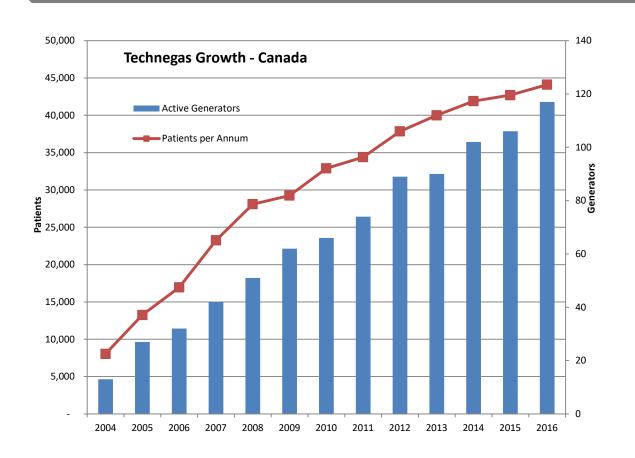
- Non-inferiority structural ventilation study comparing Xe133 vs. Technegas
- Pathway to approval requires a two part study (CYC 010 & CYC009)
 - ✓ CYC 010 Establishes the Inter & Intra reader variability for Xe133 Completed
 - ✓ CYC 009 Compares Xe133 with Technegas requiring patient recruitment <u>SPA Approved & Clinical Trial Underway</u>
- "All Comers" protocol to eliminate previous obstacles in patient recruitment
- Total estimated trial cost < \$7 million USD with \$1.1 m AUD spent in 2016
- Assumes 240 patient study at 10 clinical sites
- CYC has decided at this stage to independently proceed in funding the trial

TIMELINE						
1H 2016	2H 2016	1H 20	17	1H 2018	H1 2018	H2 2018
Commence CYC 010	Finalise CYC 010 Submit CYC 009 for SPA Approval	Commence CYC 009	Submit 1 st 40 patients for Review	Finalise CYC 009 Recruitment	Submit Clinical Trial Results for USFDA Review	Targeted USFDA Approval





The Generator and Consumable Relationship



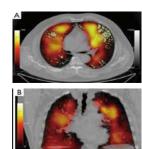
- Canada is our largest single country market with 13 consecutive years of PAS growth
- Canada represents a strong indicator of USA acceptance
- Xe-133 rapidly displaced by early adopters
- Direct correlation with the number of active generators and annual consumable sales
- Market driven by public healthcare sector
- Market launch initiated province by province, leveraging off 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 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
- 65m 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 submitted for publication
- ✓ Extending the COPD initiative to additional markets including in Canada, Australia and several European countries

Australian Study Specifics:

- Patient size: 100 patients
- Total cost = \sim \$600K

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

- Preliminary trial results suggest earlier detection than traditional Spirometry
- Trial finalised in Q4 2016
- Peer review paper submitted Q4
 2016 awaiting publication

China Market Potential

- Total public hospitals 12,747
- Private hospitals: 16,004
- 620 Hospitals with nuclear medicine departments (~35% of tertiary hospitals)
- 85% of Nuclear Medicine have SPECT/CT capabilities
- 62 installed Technegas Generators in China

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 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
 - 1H 2017 Patient recruitment to commence
 - Patient size = 100
 - 1.5 Year Project Term
 - ~\$600k AUD Project Cost







Ultralute[™]



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

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 5 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".

Technical Features

- Enables a user to extend the usable life of a Mo99 Generator
- Allows the user to purchase a smaller (lower cost) Mo99 Generator
- Provides greater flexibility and product optimisation in manufacturing radiopharmaceuticals
- 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 Generational Overview & Mo99 Supply Chain





There are over 5,000
 Mo99 generators sold
 worldwide <u>each week</u>.

50% are sold to
 Radiopharmacy with
 the remaining 50% sold
 directly to end users

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 commenced in 2016 for 2018 launch

GEN 3

- Concept to target Mo99 production via n,Gamma reactions
- Ultralute technology ideal for concentrating low specific activity generated by n, gamma Mo99 production
- Discussions with Mo99 manufacturers commenced in 2015





Cyclopharm 2017 Launch - Targeting Direct Generator Users of Mo99 Medicine



- UltraluteTM v1 is targeted at the clinical end-user market
- 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**
 - Germany accounts for almost 50% of European generator market
- UltraluteTM v2 is being developed for the Radiopharmacy user market



2017 Strategic Priorities and Outlook

Strategic Goals & Guidance	Activity	Timeframe
United States FDA Approval	 Commence patient recruitment Complete 10th clinical site installation Complete Technegas particulate study Submit preliminary report to the USFDA Finalise patient recruitment Submit New Drug Application to the USFDA 	May 2017 Q3 2017 2H 2017 2H 2017 1H 2018 1H 2018
Indication Expansion	 Peer reviewed publication for China COPD study approved Initiate UoN-HMRI-JHH clinical trial Identify additional sites for pilot clinical trials targeting Technegas indication expansion 	Q2 2017 Q2 2017 2H 2017
New Product – Ultralute™	 First sales of UltraluteTM Finalise multi-centre multi-country trial design with the IAEA Complete IAEA trial 	1H 2017 1H 2017 2H 2017
Expand Product & Service Offering	 Identify and evaluate business prospects targeting growth, product extension, diversification, improved distribution models, accretion and enhanced returns 	Ongoing
Trading Update – Ongoing Underlying Growth (excluding China)	 FY2017 Trading YTD is in line with Board's Expectations Continued growth in core underlying sales Modest increase in generator and PAS volumes in existing markets Investing in transformational growth 	FY 2017
Full Year Guidance Affirmed	 Excluding the positive impact of the large Chinese order FY16, the board expects continuing modest growth in underlying Technegas volumes for FY17. Guidance affirmed. Timing of orders in the pipeline could affect 1H/2H split hence guidance focused on full year outlook UltraluteTM 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. 	FY 2017



Cyclopharm Limited

Appendix Section

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









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	< 30% of revenues are \$AUD related; Currently > 55 % 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 2016 the average selling price for a per patient PAS=\$50.33 AUD & Technegas Generators = \$24.9k AUD. Despite downward pressure on healthcare products globally, Technegas continues to maintain our margins. Consolidated GM of 77.7% in 2016 made up of PAS, the profitability engine room, accounting for 75% of total Technegas revenues.
Sales Volumes	PAS boxes sold in 2016= 4,284 equating to 214,200 patient studies Underlying Technegas generators volumes continue to average 50-60 units per year in 2016 plus an additional 50 units delivered to China end 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, in 2016 ANSTO notified Cyclopharm that our lease would not be renewed. One-off cost of relocation amounted to approximately \$0.43M 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 launched in Germany in May 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 opened at Macquarie Centre H2 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

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









Ultra-sound











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

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