

## Cyclopharm Limited

Building a profitable and growing market leader in nuclear medical imaging

Investor Presentation
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### CYC's 10 FAST FACTS



- Technegas is a well established proprietary world leader in functional lung ventilation imaging technology with major revenues generated by single patient consumables
- 2. Partnering with DraxImage to leverage significant growth opportunities in the USA for the globally accepted indication for Pulmonary Embolism (PE)
- 3. Chronic Obstructive Pulmonary Disease (COPD) and Asthma represents a tremendous opportunity for substantial growth world wide
- 4. Ultralute, a new innovative technology with global application, will be launched late 2015
- 5. The Ultralute technology represents a platform for additional product development
- 6. Stable management and workforce

### A Rare Australian Biotech that is:

- 7. Profitable
- 8. Generating cash with near term capital management opportunities under consideration
- 9. Net cash on the balance sheet
- 10. Set to leverage tangible growth opportunities

## Vision and strategy



- "CYC has clear strategy to leverage our position as a leading player in the global nuclear medicine imaging market by expanding the use of our proprietary products and introduce new innovative technology.
- Leverage core strengths and well developed expertise in lung health management.
- Having developed a leading suite of products CYC is now focussed on driving sales in established and new markets, gaining FDA approval in the USA and expanding product indications to significantly larger applications such as COPD
- " CYC's primary focus is to increase awareness and acceptance amongst referring clinicians to drive sales. Strong progress is being made.
- FY14 was a "year of records": \$12.1m sales; \$4.1m NPAT (Including \$2.65m mediation proceeds, and \$4.5m operating cash flow (\$2.2M from Technegas)
- CYC is profitable, with positive cash flow and net cash on the balance sheet. Well placed to accelerate corporate development and capital management to drive shareholder value.

## **Our History**





1984
Technegas
discovered &
commercialisation

trading as Tetley

Medical



1992 European markets established



2001 USFDA program initiated for Technegas



2007
Technegas
Plus
generator
launched



2013
Ultralute
technology
established and
commercialisation
begins

1985

1990

1995

2000

2000

Vita Life

Sciences

acquires

Tetley

Medical

2005

2010

2015

1988

Technegas enters European market 1996

Technegas registered in the EU as a drug 2003 anadian

Canadian regulatory approval attained for Technegas 2006

Cyclopharm Incorporated and listed on the ASX in 2007 2009

Cyclopharm enters molecular imaging market & establishes MMI imaging JV 2014

Closure of cyclotron production facility and litigation with ANSTO concluded 2015

Cyclopharm signs agreement with DraxImage to commercialise Technegas in the USA













## Cyclopharm Our Business



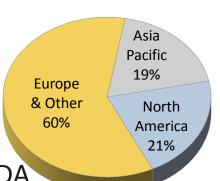
Manufacturer and distributor of functional lung ventilation imaging drugs and equipment	<ul> <li>Continues to generate growing revenue, profits and cash flows</li> <li>Trials underway to extend usage to COPD treatment &amp; monitoring</li> <li>FDA trials progressing</li> <li>Partnership with DraxImage for USA commercialisation</li> </ul>
Technology which extends the useful life of Mo99 generators by up to 50%	<ul><li>Finalised testing in 2014</li><li>IP Secured</li><li>Launch expected in late 2015</li></ul>
Joint Venture with Macquarie University Hospital	<ul><li>Growth tied to hospital ramp-up</li><li>Now EBIT positive</li></ul>
Cyclotron business (ceased operations in April 2014)	<ul> <li>Received \$2.65m cash from ANSTO/PETNET in 2H 2014</li> <li>Facility's medium to long term status under evaluation</li> </ul>
	distributor of functional lung ventilation imaging drugs and equipment  Technology which extends the useful life of Mo99 generators by up to 50%  Joint Venture with Macquarie University Hospital  Cyclotron business (ceased operations in

# Technegas Expanding the global footprint



- Technegas sold in 55 countries
  - In 2014 Canada became largest single market for Technegas overtaking France
- "Over 3,500,000 patient studies since 1986
- " 1,350 Technegas generators sold globally
- " FY2014 Technegas sales \$11.49M generating an EBITDA of \$2.16M, a 10% increase over 2013.
- Increasing market in North America pending simplified clinical trial and approval of United States FDA
- " Seeking regulatory approval to commence sales in Russia
- October 2013 received marketing approval in Japan
- Expanding the use of Technegas targeting COPD with trials underway in China
- " USA licensing agreement with DraxImage being finalised with primary commercial terms agreed







## Technegas



- ✓ More accurate and sensitive imaging agent primarily used in Pulmonary Embolism
- ✓ Three parts to the technology: generator, aerosol tubing (Patient Administration Set / "PAS") and crucible(creates nanoparticles)
- ✓ PAS is a consumable used in every Technegas procedure.
- ✓ Technegas generators used on-site to manufacture Technegas
  - Third generation Technegas Generator under development
- ✓ Sales and marketing initiatives targeting technicians, clinicians and referring physicians (pulmonologists/respirologists)
- ✓ Strong growth in CY2014 sales in Europe +8%, North America +27% and Asia +33% despite global downward pressures for healthcare products
- ✓ Positive pricing trends continue
- ✓ Shift in distribution model in some markets to agents to improve margins and accelerate sales
- ✓ Revenue model based on recurrent sales and ongoing service fees

# Nuclear imaging: Technegas' superior performance



### **Technegas advantages**

- Over 3.5m patient studies without a single adverse patient event
- A superior alternative to CTPA (angiograms) in nuclear medicine imaging
- Better clinical results at a fraction of the high radiation does used in CTPA
- More accurate and sensitive measurement in diagnosing Pulmonary Embolism
- Works well with conditions CTPA is contraindicated ...eg renal impairment
- Dry nanoparticle aerosol that mimics a true gas.
- " Improved patient comfort with only 3-4 breaths required for delivery
- " Allows for 3D images

### **Competitive Nuclear Medicine products**

- Xenon 133, being a true gas patient has to re-breathe gas patient discomfort, can't provide 3D images
- " DTPA, liquid aerosol, coalesces into larger droplets reduced penetration with inferior images in patients with COPD. Off-label use in the USA
- Generic Barrier to Entry
  - R&D on 2nd generation generators that can only uses Technegas
  - Need all three to capture market share generator, PAS and service capability

# TECHNEGAS OVERVIEW Agency vs Distributor Models



- The majority of Technegas sales are generated through Distributors
- Technegas is distributed directly in Australia, New Zealand, Canada and Germany
- Distributors allow for low cost market entry at the compromise of full market penetration and control
- From 2015 Cyclopharm is currently piloting an agency program in Japan, China and Benelux
- Agency agreements in place run through the end of 2015 at which time the program will be reviewed

### **Agency Model:**

- CYC controls end-user sell price
- CYC gets to see every customer invoice
- CYC receives the agent's margin
- CYC pays agent's out-of-pocket expenses
- CYC pays the agent a consulting fee
- CYC pays the agent a commission
- CYC owns stock on consignment to distributor

### **Distributor Model:**

- Distributor purchases goods from CYC
- Distributor controls the end-user sell price
- " CYC does not see customer invoices
- Margin remains with distributor
- Stock is owned by distributor



# Technegas – Clinical Trial Program Overview



USA – Region Expansion
Targeting existing Pulmonary
Embolism (PE) market

Structural ventilation study comparing Xe133 vs. Technegas to allow the sale of Technegas in the USA

#### Market Size:

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

#### Timeline:

- Q4 2015- Finalise Clinical trial program
- H1 2016 Stage one trial completed
- > H1 2017 Stage two trial completed
- Mid 2017 USFDA Approval

#### **Study Specifics:**

- Patient size: To be determined but the USFDA proposal is targeting <300 patients</p>
- "All Comers" protocol to eliminate previous obstacles in patient recruitment
- Total cost = <\$6m will be funded predominantly through the USA partnership with DraxImage

# 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
- ➤ 65 million people have moderate to severe (COPD).
- Estimates show that COPD becomes by 2030 will be the third leading cause of death worldwide

#### Timeline:

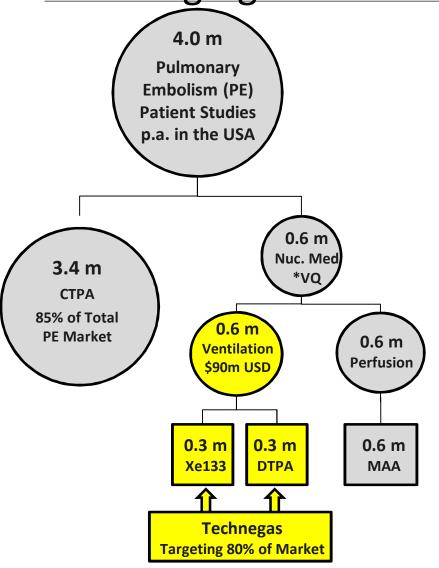
- Q4 2015 China trial completed
- Q4 2015 Results published and presented at the Asian Pacific Society of Respirology Congress
- Plans to extend COPD initiative to additional markets following China results. Preliminary discussions underway in Canada, South Africa and several European countries

### China Study Specifics:

- Patient size: 200 patients
- > Total cost = <\$400K

# USA Existing Market Potential & cyclopharm Licensing Agreement with DraxImage





### **USA Target Market**

- DraxImage is the USA market leader in nuclear medicine lung imaging radiopharmaceuticals
- By teaming with DraxImage more resources can be allocated at capturing CPTA's 85% PE market share
- Cyclopharm with DraxImage is targeting 80% of the \$90m ventilation radiopharmaceutical market

### **DraxImage Licensing Agreement:**

- DraxImage to take the lead on USFDA Phase 3 clinical trial Draximage places up to \$5.25m at risk for the USFDA clinical trial program with no upfront dilution to existing shareholders
- License agreement will generate 17.5% royalty on sales revenue & 15% margin on COGS
- \$2m upfront inventory purchase prior to market launch
- DraxImage converts USFDA trial cost investment into a maximum of 15% equity stake in CYC
- DraxImage to nominate a CYC board position
- CYC holds USA marketing authorisation and maintians global patents
- No impact outside of USA
- Equity and board position subject to USFDA success

# Technegas Indication Expansion – COPD



- The Global incidence of Chronic Obstructive Pulmonary Disease (COPD) is 30x greater than that of Pulmonary Embolism (PE)
- It is estimated that by 2020, C.O.P.D. 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
  - Preliminary research with Technegas suggests early detection than traditional Spirometry
  - Spirometry- a basic measurement of forced air volume provides no underlying pathophysiology
  - 200 patient trial expected to conclude in late 2015
- 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

### Ultralute<sup>™</sup>



### **Product Overview:**

- Cyclopharm patented technology
- Extends the effective life of Mo-99 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
- " Product launch anticipated in late 2015 with revenues commencing early 2016

### 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 Generational Overview



GEN 1

- Designed for the end user application
- Ready for launch Q4 2015 with revenues commencing early 2016

GEN 2

- Designed for radiopharmacy application
- Development will commence in 2015 for 2017 launch

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

### **Molybdenum Manufacturing and Supply Chain**



- There are 4,000 Mo99 generators sold worldwide each week.
- 50% are sold toRadiopharmacy with the other50% are sold directly to endusers



## 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
- "Sales revenue increased in 2014 as outpatient initiatives implemented at Macquarie University Hospital
- " EBIT Positive as of mid CY 2014



# Growth Opportunities and Key Performance Indicators



Currency	< 15% 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 2014 the average selling price for PAS=\$49.5 AUD & Technegas Generators = \$41.6k AUD. Despite downward pressure on healthcare products globally, Technegas has been able to achieve price increases. Consolidated GM of 76.5% in 2014 made up of PAS, the profitability engine room, accounting for 81.6% of total Technegas revenues.
Sales Volumes	PAS boxes sold in 2014 = 3,784 equating to 189,200 patient studies Technegas generators average 50-60 units per year
Competitive Products	<ul> <li>Xe133 has been eliminated from the Canadian market with the introduction of Technegas. Xe133 only used in the USA is a \$USD 38M product</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 generated 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 resection The incidence of COPD is 30x that of PE. Furthermore, COPD represents an opportunity for ongoing patient mgt
Regional Markets	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 $\sim$ 460,000 patients per annum
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	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 early 2016
Margins	Product launch estimates 50% GM with margin improvement expected from leveraging volume growth
Product Development	1 <sup>st</sup> Generation targeting end users in hospitals and clinics to be launched in 2015 2 <sup>nd</sup> Generations targeted for Radiopharmacy will be introduced in 2017
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	EBIT positive as of mid CY 2014
MRI Licensing	Significant increase in profitability if Government funded MRI licensing is achieved
Cyclopet	
Molecular Imaging	Following competition for government owned enterprises, Cyclopharm's Board decided to cease 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 disposal of the facility

### 2015 & Outlook



## Solid growth prospects and healthy capital position

- ✓ Leveraging off record financial results in 2014
- ✓ Softer Year on Year 2015 1H results due to timing differences in purchases
- ✓ Underlying profitability expected to continue with stronger 2H 2015 confirmed with significant end of year orders received
- ✓ Technegas organic revenue and earnings growth to continue, driven by:
  - Emergence of Canada as largest single market
  - Improved demand and pricing in Europe and China
  - Education program focused on referring physicians commenced
- ✓ USFDA trial development underway
  - Pursuing options to accelerate commercialisation timetable
  - USA partnership secured with Jubilant DraxImage
- ✓ Developing additional Technegas indications to include COPD
- ✓ Targeting first Ultralute<sup>™</sup> revenue in early 2016
- ✓ Balance sheet strong
- ✓ Maiden fully franked interim dividend of 0.5c per share to be issued on 14 October 2015.

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



# **APPENDIX SECTION**

## **FY14 Financial Highlights**



- ✓ Record sales of \$12.1 million
- ✓ Record Technegas division operating EBITDA of \$2.2 million
- ✓ Record NPAT of \$4.1 million (vs 2013 loss of \$10.1m), includes:
  - Technegas division NPAT: \$2.4 million; and
  - Net litigation proceeds of \$2.2 million
- ✓ Technegas division operating expenses down 5.3% vs 2013 leveraging off implemented cost containment program
- ✓ Cashflow from operations of \$4.5 million
- ✓ NAB debt fully repaid with net cash of \$3.3 million at year end.



## **FY14 Operating Highlights**



- ✓ Technegas' sales revenue grew in all major markets
  - Sales of Technegas Generators & Patient Administration Sets up 10% on pcp
  - Canada now represents our no.1 market
- ✓ Commenced Technegas COPD trials in China
- ✓ Progress in obtaining FDA approval for Technegas in the US market
- ✓ Secured IP protection for high value Ultralute technology
  - Targeting early 2016 sales
- ✓ Resolved Cyclopet matter in our favour
  - Operations ceased in April 2014
  - Cyclotron facility reinstatement fully funded by insurance is currently underway
  - Medium to long term status under evaluation



## **FY14 Group Profit & Loss**



### **Record Sales and Profit**

- Technegas continues to perform strongly
- Price increases and lower A\$ drove improved gross margins
- Costs management initiatives saw cost reductions across almost all major expense categories
- Low tax rate driven by recognition of prior year tax losses and R&D tax offset
- Operating cash flow of \$4.5min line with reported NPAT –assisted by litigation settlement

Year ended 31 December (\$000's)	2014	2013
<u>Underlying Results¹:</u> Revenue	12,047	11,882
Technegas EBITDA (Excludes FDA costs)	2,638	2,246
Cyclopet EBITDA (FY14 = 4 months ops)	(816)	(1,268)
Underlying EBITDA	1,822	978
Depreciation and amortisation	(266)	(643)
Underlying EBIT	1,556	335
Reported EBIT	3,578	(9,994)
Interest	(107)	(270)
Tax (expense)/benefit	595	146
Reported NPAT	4,066	(10,119)
Reported Basic EPS (cents)	7.0	(17. 6)

Underlying Results represent results from Continuing Operations excluding one off items related to discontinued Cyclopet business (Litigation settlement and costs + impairment expense), CLSA deposit, FDA expenses and MMI equity accounted earnings. (Net totals: FY14: \$2.0m; FY13: -\$ 10.3m)

## **Technegas – FY14 Performance**



### Record financial result

- Technegas recorded a record financial result in FY14
- PAS margins enhanced by improved local prices in Asia and Latin America and forex
- Generator revenue increased from higher volumes and prices offset by lower service revenue
- Strong financial perform supports ongoing investment in R&D and costs associated with expansion into new markets

Year ended 31 December (\$000's)	2014	2013	Change
Technegas Results1:			
Sales Revenue			
PAS	9,384	8,583	<b>1</b> 9.3%
Generators	2,106	1,874	<b>1</b> 2.4%
<b>Total Sales</b>	11,490	10,457	<b>1</b> 9.9%
<b>Underlying EBITDA</b>	2,638	2,246	<b>1</b> 7.5%
Underlying EBITDA Margin	23.0%	21.5%	<b>1</b> .5%
FDA Expenses	(478)	(478)	-
EBITDA	2,160	1,767	<b>1</b> 22.2%
D&A	(223)	(220)	-
EBIT	1,937	1,547	<b>1</b> 25.2%
EBIT Margin	16.9%	14.8%	<b>1</b> 2.1%

Underlying Results represent results from Continuing Operations excluding one off items related to discontinued Cyclopet business (Litigation settlement and costs + impairment expense), CLSA deposit, FDA expenses and MMI equity accounted earnings. (Net totals: FY14: \$2.0m; FY13: -\$ 10.3m)

## H1 2015 Group Profit & Loss



### **Continued Solid Sales and Profits**

- Technegas continues to perform strongly
- Price increases and lower A\$ drove improved gross margins
- Costs management initiatives saw cost reductions across almost all major expense categories
- Timing of sales orders to France impacted H1 Revenue.

Half Year ended 30 June (\$000's)	H1 2015	H1 2014
<u>Underlying Results1:</u> Reported Revenue	5,078	6,554
Technegas PBT (Excludes FDA costs and PAS sales to France)  Cyclopet P/(L)BT (2014 = 4 months ops)	526 (38)	476 (749)
Underlying PBT	488	(273)
Powerted DDT	205	75.6
Reported PBT Tax (expense)/benefit	285 (106)	756 167
Reported NPAT	179	923
Reported Basic EPS (cents)	0.31	1.61

Underlying Results represent results from Continuing Operations excluding one off items related to discontinued Cyclopet business (Litigation costs), CLSA deposit, FDA expenses and PAS sales to France

## **H1 2015 Group Balance Sheet**



## Balance Sheet Strong with Major Debt Retired

- Improved cash position driven by strong cash flows from operations
- Net proceeds from Cyclopet settlement applied to eliminate NAB debt
- Capacity to fund growth initiatives and ongoing R&D
- Following reinstatement of the Cyclotron facility the medium to long term future of the Cyclopet facility is under consideration to include divestment

Balance as at (\$000's)	30/6/2015	31/12/2014
Cash	3,613	3,268
Other current assets	5,392	5,582
Non-current Assets	2,360	2,111
Total Assets	11,365	10,961
Current Liabilities	3,348	2,874
Borrowings	214	246
Non-current Liabilities	91	85
Total Liabilities	3,653	3,205
Net Assets	7,712	7,756