



# Cyclopharm Limited

Building a profitable and growing market leader in  
nuclear medical imaging

Investor Presentation  
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July 2015

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# CYC's 10 FAST FACTS

1. Technegas is a well established proprietary world leader in lung ventilation imaging technology with major revenues generated by single patient consumables
2. Significant growth opportunities for expansion in the USA for the globally accepted indication for Pulmonary Embolism (PE)
3. Chronic Obstructive Pulmonary Disease (COPD) 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

**2000**  
Vita Life Sciences acquires Tetley Medical

**2001**  
USFDA program initiated for Technegas

**2006**  
Cyclopharm Incorporated and listed on the ASX in 2007

**2013**  
Ultralute technology established and commercialisation begins



**1985**

**1990**

**1995**

**2000**

**2005**

**2010**

**2015**

**1988**  
Technegas enters European market

**1996**  
Technegas registered in the EU as a drug

**2003**  
Canadian regulatory approval attained for Technegas

**2007**  
Technegas Plus generator launched

**2009**  
Cyclopharm enters molecular imaging market & establishes MMI imaging JV

**2014**  
Closure of cyclotron production facility and litigation with ANSTO concluded



# Cyclopharm

## Our Business



**(Technegas)**

Manufacturer and distributor of lung ventilation imaging drugs and equipment

- Continues to generate growing revenue, profits and cash flows
- Trials underway to extend usage to COPD treatment & monitoring
- FDA trials progressing



Technology which extends the useful life of Mo99 generators by up to 50%

- Finalised testing in 2014
- IP Secured
- Launch expected in late 2015



Joint Venture with Macquarie University Hospital

- Growth tied to hospital ramp-up
- Now EBIT positive



Cyclotron business (ceased operations in April 2014)

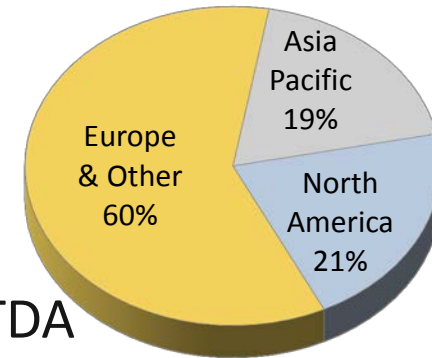
- Received \$2.65m cash from ANSTO/PETNET in 2H 2014
- Facility's medium to long term status under evaluation

# 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
- Exploring partnership opportunities

**Technegas Sales Revenue by Region**



# 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

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**cyclopharm**  
Nuclear Medicine



## 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 dose 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 use Technegas
  - Need all three – 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 460,000 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
- “All Comers” protocol to eliminate previous obstacles in patient recruitment
- Total cost = <\$6m and can be fully funded either with existing cash and future cash flows or through USA partnership opportunities

## 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



# 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



## 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

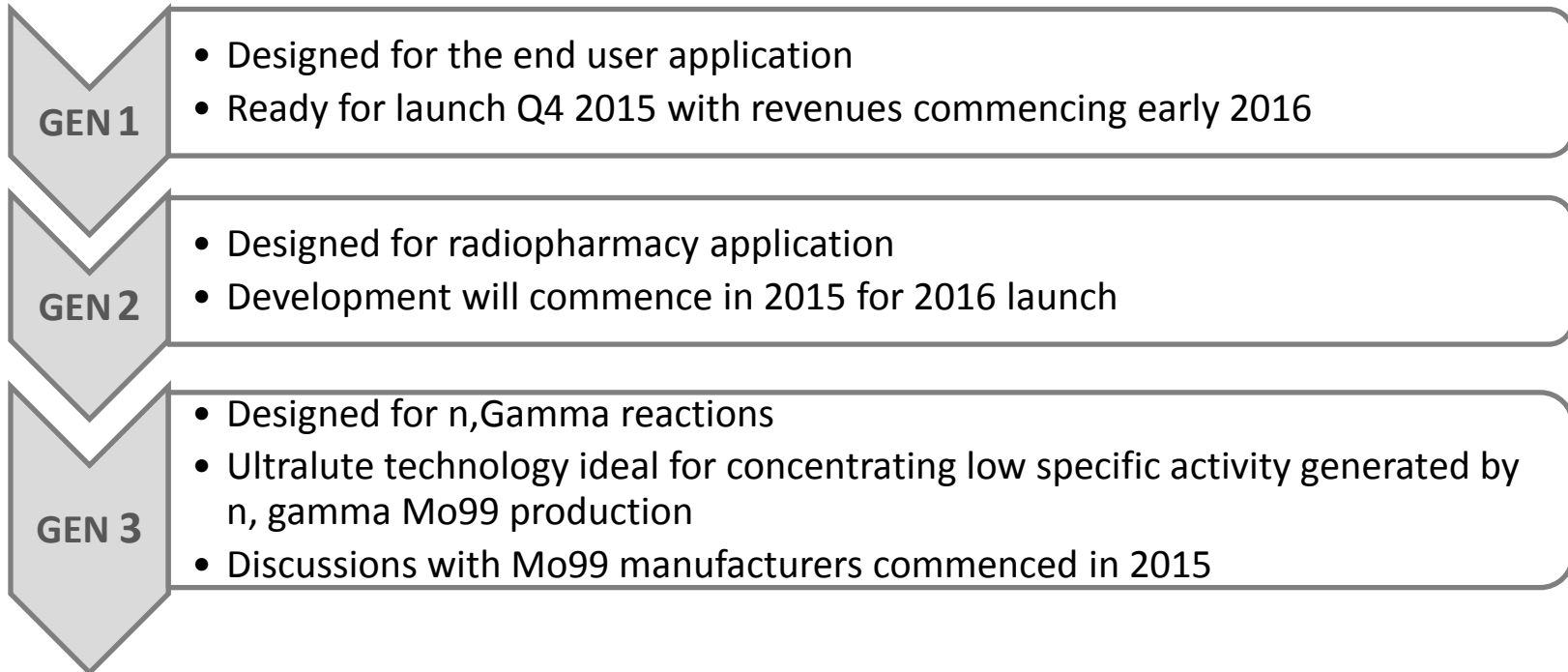
## Technology features:

- 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



### Molybdenum Manufacturing and Supply Chain



- There are 4,000 Mo99 generators sold worldwide **each week**.
- 50% are sold to Radiopharmacy with the other 50% are sold directly to end users



# 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

## Technegas

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	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 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 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 ~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 1 <sup>st</sup> Generation targeted for launch in Germany at the EANM in October with initial sales to follow late 2015
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



## 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 expected
- ✓ 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 trials underway
  - Pursuing options to accelerate commercialisation timetable
  - USA partnership discussions underway
- ✓ Developing additional Technegas indications to include COPD
- ✓ Targeting first Ultralute™ revenue in late 2015
- ✓ Balance sheet strong
- ✓ Next update on capital management will be provided with the 2015 H1 results 26 August 2015

# Disclaimer

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Nuclear Medicine



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



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# 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
  - On track for 2015 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 \$4.5m in line with reported NPAT – assisted by litigation settlement

<i>Year ended 31 December (\$000's)</i>	<b>2014</b>	<b>2013</b>
<b><u>Underlying Results<sup>1</sup>:</u></b>		
<b>Revenue</b>	<b>12,047</b>	<b>11,882</b>
Technegas EBITDA <small>(Excludes FDA costs)</small>	2,638	2,246
Cyclopet EBITDA <small>(FY14 = 4 months ops)</small>	(816)	(1,268)
<b>Underlying EBITDA</b>	<b>1,822</b>	<b>978</b>
Depreciation and amortisation	(266)	(643)
<b>Underlying EBIT</b>	<b>1,556</b>	<b>335</b>
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)

# FY14 Group Balance Sheet



## Balance Sheet strong with Major Debt Retired

	<i>Year ended 31 December (\$000's)</i>	<b>2014</b>	<b>2013</b>
<ul style="list-style-type: none"><li>Improved cash position driven by strong cash flows from operations</li></ul>	Cash	3,268	1,221
	Other current assets	5,582	6,231
	Non-current Assets	2,111	1,067
<ul style="list-style-type: none"><li>Net proceeds from Cyclopet settlement applied to eliminate NAB debt</li></ul>	<b>Total Assets</b>	<b>10,961</b>	<b>8,519</b>
<ul style="list-style-type: none"><li>Capacity to fund growth initiatives and ongoing R&amp;D</li></ul>	Current Liabilities	2,874	2,793
	Borrowings	246	2,417
	Non-current Liabilities	85	138
<ul style="list-style-type: none"><li>Following reinstatement of the Cyclotron facility the medium to long term future of the Cyclopet facility is under consideration to include divestment</li></ul>	<b>Total Liabilities</b>	<b>3,205</b>	<b>5,349</b>
	<b>Net Assets</b>	<b>7,756</b>	<b>3,170</b>



# 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

<i>Year ended 31 December (\$000's)</i>	<b>2014</b>	<b>2013</b>	<b>Change</b>
<b><u>Technegas Results<sup>1</sup>:</u></b>			
<b>Sales Revenue</b>			
PAS	9,384	8,583	↑ 9.3%
Generators	2,106	1,874	↑ 12.4%
<b>Total Sales</b>	<b>11,490</b>	<b>10,457</b>	↑ 9.9%
<b>Underlying EBITDA</b>	<b>2,638</b>	<b>2,246</b>	↑ 17.5%
<i>Underlying EBITDA Margin</i>	23.0%	21.5%	↑ 1.5%
FDA Expenses	(478)	(478)	-
EBITDA	2,160	1,767	↑ 22.2%
D&A	(223)	(220)	-
<b>EBIT</b>	<b>1,937</b>	<b>1,547</b>	↑ 25.2%
<i>EBIT Margin</i>	16.9%	14.8%	↑ 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)

## Consistent Organic Growth

### Patient Administration Sets (PAS)

- PAS revenue up 9.3% from 2013
- PAS volumes down 1.7% from 2013

### Technegas Generators

- Generator revenue up 12.4% from 2013
- Consistent year-on-year demand
- Improved revenue from volume and price increase partly offset by decline in service revenue

Technegas Sales Revenue

