



22 May 2014

The Manager  
Company Announcements Office  
Australian Securities Exchange Limited  
20 Bridge Street  
Sydney NSW 2000

### **Managing Director's Address**

Thank you Vanda and good morning ladies and gentlemen and welcome to our AGM.

As Vanda outlined in his address, 2013 was a year of opportunities and challenges for our businesses.

Despite the disappointing outcome for Cyclopet, our molecular imaging business, our core Technegas business continued to grow strongly in 2013 and is performing very well in the current year, benefiting from expansion into the Canadian and Asian markets along with the positive influence of a slight weakening in the Australian dollar.

Technegas underpinned the financial performance of the company in 2013, and represented 88% of group sales. In its largest market, Patient Administration Sets, both sales volume and profitability improved during the year.

Clinical trials in the United States continued, bringing us closer to our goal of penetrating the US market which represents 50% of the nuclear medicine departments in the world.

We are working hard to commercialise our new patented Ultralute™ technology, and are actively seeking opportunities to further diversify and expand our sales.

Notwithstanding our recent decision to cease CycloPet's operations, our Cyclotron facility located here at Macquarie University Hospital recorded consistent sales in 2013, with the number of Fluoro Deoxy Glucose (FDG) patient doses sold improving by 11% for the year. Similarly our Macquarie Medical Imaging (MMI) diagnostic imaging joint venture achieved a robust 32% increase in sales compared with 2012. But, as the Chairman has explained, the business remained unprofitable, as a direct result of unfair competition in the marketplace, and had poor prospects for a return to profitability.

Hence we reluctantly made our decision to cease radiopharmaceutical commercial operations.

While we pursue our legal claim against ANSTO, we will continue to utilise the Cyclotron facility at Macquarie University Hospital to progress some of the company's research and development activities until a longer-term use for the facility is ascertained to include the potential sale of the asset.



## **2013 FINANCIALS**

Turning to our Financial Results, 2013 Revenues were \$11.9 million, more than \$1.1 million higher than in the prior year. This improvement was principally as a result of increased sales of the Company's key products, TechnegasPlus generators (Generators) and Patient Administration Sets (PAS), which increased by 11.6% to \$10.46 million for the year.

The company's reported Net Loss for the period was \$9.8 million, which included a non-cash impairment charge of \$8.9 million attributable to the closure of the CycloPet business and an operating loss for that Division of \$2.7 million.

Taking into account the one off impairment impact and the closure of our CycloPet business, it is abundantly clear that the quality of our financial performance in the current year and beyond will improve markedly in conjunction with the simplification of our business structure.

The financial performance of the ongoing Technegas business can be seen, in part, in our Operating Cashflows which improved from \$369,000 in 2012 to \$1.19 million in 2013.

## **SEGMENTAL ANALYSIS**

### ***Technegas***

Turning to our Divisional performance, Technegas once again generated strong sales and cash flows.

Since 1986 over 3 million patients have benefited from the Technegas system. As in prior years, this Division faces challenges from strong competition from Computed Tomography Pulmonary Angiogram ("CTPA"); however, with the numerous contra-indications attributed to CTPA along with concerns relating to the high levels of radiation exposure resulting from a CTPA exam, Technegas remains a highly efficacious product in the diagnosis of blood clots in the lungs known as Pulmonary Emboli.

Based on our efforts to expand into new markets and ongoing research and product development activities, it is clear that Technegas has significant opportunity to expand its sales and profitability for many years to come. Specifically, the large North American market remains untouched by Technegas and we are hopeful our current clinical trials will enable accelerated entry into this market following FDA approval.

In addition to expanding into new geographies, we are continuing to invest in research and development activities targeting expansion of the indications for which Technegas is used. For example, research by Cyclopharm and others independently indicate there is a greater opportunity for Technegas targeting both the diagnosis and ongoing monitoring of Chronic Obstructive Pulmonary Disease or COPD.

In May 2013, we were pleased to announce we had initiated a 500 person pilot clinical trial in China, targeting the use of Technegas for the diagnosis of COPD. And in February this year, site initiation at five hospitals in China was completed with patient recruitment commencing.



To provide some context for the significant of the COPD market, in Australia, 1 in 5 Australians can expect to suffer from COPD in their lifetime, and in China it has been estimated that there will be 65 million deaths from COPD and 18 million deaths from lung cancer between 2003 and 2033.

As I mentioned earlier, Technegas' 2013 sales revenue increased 11.6% on the prior year to \$10.46 million. Gross profit margins as a percentage of sales increased from 74% to 75%. PAS, or consumable revenue, representing 82% of the segment's revenue, was 18% higher at \$8.58 million in 2013 compared to the previous year (2012: \$7.27 million), driven by a 7% volume increase in units sold of 192,550 units (2012: 179,450 units) and foreign exchange benefits.

Sales of Technegas Plus Generators contracted during the year which resulted in Technegas generator and other sales revenues ending the year at \$1.87 million, 10.9% lower than the prior year. This reduction was partly offset by a 17% rise in service revenue to \$1.04 million.

### ***Cyclopet***

Cyclopet completed its third year of operations with a consistent sales growth of 4% achieved on \$1.43 million (2012: \$1.38 million) revenue generated from the Cyclotron facility located at MUH despite facing tremendous anticompetitive headwinds in NSW primarily from Petnet, ANSTO's fully owned subsidiary.

The Division's overall loss before tax for the year increased to \$11.79 million, due to an impairment charge of \$8.9 million writing down the Division's assets as a result of the decision to cease commercial production, legal fees of \$738,000 arising from the proceedings and shared losses of MMI amount to \$253,000.

The decision to shut down our Cyclotron operation was forced upon us when it became known that ANSTO was entering into new contracts at prices considerably lower than those already raised in our legal claim as predatory.

Despite Cyclopet's growth in sales volumes and its being one of Australia's lowest cost producers of nuclear medicine isotopes, the failure by ANSTO to apply competitive neutrality principles and of the Commonwealth Government to take action following the Productivity Commission's findings, have created a market environment in which the Directors concluded that the Cyclopet business was unlikely to generate satisfactory returns for shareholders in the near term. This view was informed by the knowledge that we cannot successfully maintain a position in a market which is structurally unfair as private enterprise seeks to compete against government enterprises heavily subsidised by taxpayer funding.

In order to protect shareholder value, we will continue to pursue the Company's claim against ANSTO in the Federal Court. The matter has been set down for a three-week hearing commencing on 1 September 2014 before His Honour Justice Wigney.

In addition to the cessation of the commercial Cyclotron operations at Macquarie University Hospital, in August 2012 we notified the market of our intention to establish a Cyclotron facility in Brisbane. As a result of the uneconomic market conditions established by the actions of ANSTO in this sector, the Brisbane Cyclotron has also become financially unviable and the company will not be moving forward with this project.

### ***Macquarie Medical Imaging***

Cyclopharm's medical imaging joint venture, MMI, provides patients at Macquarie University Hospital and in neighbouring suburbs with access to state-of-the-art imaging facilities.

Growth in MMI is tied closely to the hospital's ramp-up. Sales revenue continues to increase – up 32% in 2013 - as initiatives being implemented at MUH, including a new breast cancer clinic and expanded specialties such as cardiothoracic services, cancer care services and expanded PET indications take effect.

Due to Cyclopharm's 20% shareholding, profit and losses from MMI are recorded as an equity accounted investment. In 2013, an equity accounted loss of \$252,640 was recorded in our accounts for this joint venture. The investment in MMI has been fully written down in our accounts.

### ***Ultralute™***

Early last year, we announced the development and patent of a new Nuclear Medicine technology – Ultralute™. Cyclopharm's Ultralute™ technology extends the useful life of Molybdenum-99 (Mo-99) generators by up to an additional 50%.

For shareholders with a technical interest, Mo-99 generators are used in diagnostic imaging to harvest Technetium-99m, or Tc-99m, which is used in diagnostic imaging. This isotope accounts for approximately 80% of all nuclear medicine diagnostic imaging procedures.

Mo-99 has a half-life of around 2.75 days, which then decays to the 6 hour half life Tc-99m. As Mo-99 decays there comes a time when the amount of Tc-99m eluted from the generator is so diluted that it becomes virtually unusable. Consequently, by increasing the useful life of Mo-99, Ultralute™ potentially gives nuclear medicine departments the ability to dramatically improve their operating efficiencies and health outcomes for patients.

Initial testing and prototype designs of the Ultralute™ technology have provided exceptional results.

We have commenced the regulatory approval process of the Ultralute™ technology and are entering in discussions with potential commercial partners.

Global industry interest in our Ultralute™ technology is strong and continues to accelerate.

We look forward to making further announcements this year regarding Ultralute's™ progress towards commercialisation and are excited about its potential to form the basis of Cyclopharm's next stage of growth.

### **BUSINESS OUTLOOK**

In 2014, your Directors expect continued growth in Technegas revenues from targeted marketing in Europe and China as well as growth following regulatory approval in Japan and Russia. We forecast a change in the mix of Technegas products. We anticipate more generators (lower margins) relative to PAS box sales and therefore lower profit margins.



We look forward to introducing Technegas to the United States market following successful completion of our Phase 3 clinical trial, and subsequent approval by the FDA. Despite bringing new centres on, we are very disappointed with the patient enrolment. To that point we are requesting a formal meeting with the FDA to discuss the current trial and propose an alternate strategy that should provide us with a less complicated and costly pathway to approval. I look forward to updating shareholders following the outcome of our FDA discussions.

The opportunities for developing additional Technegas indications to include COPD will be a key priority for the company. If successful, the potential to expand Technegas' revenue and profitability over the medium to longer term is undoubtedly significant.

As a result of the restructuring of our business and ceasing operations that compete directly with tax payer subsidised businesses, Cyclopharm will become much simpler and more profitable going forward. We will be in a significantly stronger position to realise the potential of our highly profitable and cash-generating Technegas business in international markets and to continue the development of our patented Ultralute™ technology.

To protect shareholder value, we will continue our claim against ANSTO and look forward to announcing a positive outcome from the court process (or mediation) later this year.

Ladies and gentlemen, as I mentioned at the beginning of my presentation, 2013 presented the Company with significant challenges and opportunities. While we are deeply disappointed that anti-competitive market behaviour prevented Cyclopet from realising its potential, the diversity of your company combined with identified business opportunities ahead of us demonstrate that your Company is on the right track to deliver value to shareholders over time.

In conclusion I wish to express my gratitude to my staff and management team, particularly those from our Cyclopet business, and our trading partners for their contributions. I also take this opportunity to note my appreciation for the support and counsel of the Board.

Lastly I want to thank you, our shareholders, for your continued support.

James McBrayer  
**Managing Director and Company Secretary**

**For more information, please contact:**

James McBrayer  
Managing Director, CEO and Company Secretary  
Cyclopharm Limited  
T: +61 (02) 9541 0411



---

## **Background**

### **Cyclopharm Limited**

Cyclopharm is a radiopharmaceutical company servicing the global medical community. The Company's mission is to provide nuclear medicine and other clinicians with the ability to improve patient care outcomes.

Cyclopharm achieves this objective through the provision of radiopharmaceutical products, Technegas (for lung imaging) and Molecular Imaging / PET radiopharmaceuticals (used in cancer, brain and cardiac imaging). Our customers are nuclear medicine departments located within hospitals and clinics.

### **Technegas**

The Technegas technology is a structured ultra-fine dispersion of radioactive labeled carbon, produced by using dried Technetium-99m in a carbon crucible, micro furnace for a few seconds at around 2,700°C. The resultant gas like substance is inhaled by the patient (lung ventilation) via a breathing apparatus, which then allows multiple views and tomography imaging under a gamma or single photon emission computed tomography (SPECT) camera for the superior diagnosis of pulmonary emboli (blood clots in the lungs).

### **Positron Emission Tomography (PET)**

PET radiopharmaceuticals target specific tissues / organs, concentrate there, and the attached radioisotope emits radiation, which is then detected by a PET or PET / CT gamma (collectively PET camera). These imaging modalities help physicians improve their ability to detect and determine the location, extent and stage of cancer, neurological disorders and cardiac disease at a metabolic level. By improving diagnosis, PET scans aid physicians in selecting better courses of treatment, as well as assessing whether treatment is effective or should be changed at a much earlier stage.