



**cyclo**medica  
**molecula**rimaging  
**techneg**as

15 May 2013

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

Cyclopharm Ltd  
ABN 74 116 931 250  
Bldg 75 Business & Technology Park  
New Illawarra Road  
Lucas Heights NSW 2234 Australia  
POB 350 Menai Central NSW 2234  
T 61 2 9541 0411  
F 61 2 9543 0960  
[www.cyclopharm.com.au](http://www.cyclopharm.com.au)

## **Managing Director's Report**

### **Introduction**

Thank you Vanda and good morning ladies and gentlemen. Once again, I am delighted that our AGM is located here at Macquarie University, the home of Macquarie University Hospital, Macquarie Medical Imaging and Cyclopet.

Another year has passed and Cyclopharm's mission and values remain unchanged. We continue to be focussed on our core skill set of nuclear medicine. We also remain persistent in seeking and leveraging our strategic partnerships.

The diversification of our business endures and the consistent growth of the Macquarie Medical Imaging business is such that it now complements the global strength of our core Technegas division.

In our Annual Report for 2012, I wrote that I saw last year as a turning point for Cyclopharm. I truly believe this. Our unrelenting focus on achieving our business goals was the principal driver of the progress that we made last year and are building on in 2013.

Cyclopharm's 2012 financial result was both reasonable and encouraging considering the challenges that we faced last year. In 2013 I believe we are well- positioned to overcome the difficulties that impacted the 2012 financial results.

Each of our core businesses is now in the market generating revenue. Cyclopet and MMI remain small in terms of volume and earnings but both are showing significant promise.

Technegas remains the financial foundation of the group and continues to grow profitable sales volume in each of our markets. Importantly, the commencement of clinical trials in the United States is a major step towards our longer-term goal of penetrating the US market. As the Chairman noted, the US market represents 50% of the nuclear medicine departments in the world, and gaining a foothold in this massive market will be a significant achievement for Cyclopharm.

## **2012 FINANCIALS**

In turning to our Financial Results, 2012 Revenues were up over \$430,000 primarily from expanding sales from our Molecular Imaging group. Despite increasing our PAS volumes by 6%, as a result of unfavourable exchange movements, Technegas sales were flat for the year.

Due to Cyclopharm's minority shareholding in MMI, profit and losses are recorded on an equity-accounted basis. As a result, MMI's revenues are not reported in our accounts, but rather our accounts incorporate our proportion of MMI's investment.

Thanks to the support of you our shareholders our net asset position improved in 2012. Technegas cash flows offset the operating costs of our Cyclotron and investment activities to include the \$342,000 spent on the USFDA clinical trial development.

## **SEGMENTAL ANALYSIS**

### ***Technegas***

In looking at Cyclopharm by segment let's first look to the foundation of our business, Technegas.

Technegas is sold in 55 countries throughout the world. Since 1986 there have been almost 3 million patient studies conducted. Despite holding a significant position in the nuclear medicine market for over 27 years, this Australian invention, with expanding indications and new imaging techniques available, it is remarkable that Technegas is even more relevant today than it is ever been.

In driving our strategy forward we are engaged in a number of initiatives that will deliver growth with Technegas. During 2012, Technegas passed a major milestone in having its first patient study enrolled under the United States Food and Drug Administration (USFDA).

We announced to the ASX in November 2012 that the patient trial had commenced at New York's Columbia Presbyterian Hospital. A total of 750 patients are required for the study which is now expected to be completed by late 2014. Despite enrolling nearly 50 patients in the study, less than 10 have been imaged to date. We have identified elements within the protocol that if modified will allow for a more aggressive enrolment and clinical site roll-out. We will be meeting with the FDA next month to discuss the proposed changes.

The size of the United States nuclear medicine market has meant that getting USFDA approval has long been one of Cyclopharm's major strategic priorities. We are well on our way now and I share my fellow Directors' confidence that our application will ultimately be successful. We expect that approval for Technegas in United States will in the first 2 years equate to \$17m in additional sales and \$5.7m in EBITDA.

In addition to the potential offered by expanding into new geographies, recent research by Cyclopharm and others independently indicate there is an even greater opportunity for Technegas sales growth. Earlier this month, we were delighted to announce we had initiated a 500 person pilot clinical trial in China, targeting the use of Technegas for the diagnosis of Chronic Obstructive Pulmonary Disease or COPD.

The commencement of this trial coincided with the results of a study published in the North American Journal of Nuclear Medicine by Canadian researchers from McMaster University and the Firestone Institute for Respiratory Health, which demonstrated that Technegas detected changes in lung ventilation and perfusion before structural changes in the lungs were detected by CT scans. Stated simply, Technegas has the potential to be used not only for early diagnosis of COPD but also on a recurrent basis for COPD management.

I cannot overstate the significance of this development for Cyclopharm. It is no exaggeration to say that the opportunity presented by this discovery, may lead to a significant expansion of the use of Technegas globally. The COPD diagnosis market is many times larger than the market in which Technegas is currently predominantly used. For example, 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.

2012 sales revenue of \$9.37 million for the two key Technegas products, Generators and PAS, was consistent with the previous year. However, while we sold 6% more PAS units than we did in 2011, our PAS revenue was flat at \$7.27 million. Our Generator sales revenue for 2012 was consistent with prior year despite selling 2 units less. This variation between sales volume and value is primarily attributable to EUR/A\$ exchange rate movements.

In terms of a regional breakdown of the Technegas business, both our Europe and Asia-Pacific operations declined in sales revenue for the year. Sales to Europe fell from \$5.5 million in 2011 to \$5.2 million in 2012, despite selling roughly the same quantity of PAS boxes and only two less Generators to Europe this year. Demand has remained resilient in spite of the prolonged economic malaise in the EU.

Sales revenue for the Asia-Pacific region fell by 11% in 2012. In particular, total revenues for Australia fell by 15% as our generator sales were half that of 2011 a very strong year for us and PAS sales slightly lower by 2%. Fortunately, this was partly offset by a 61% increase in sales revenue for Asia, driven largely by strong growth in PAS to China.

Our performance in North America was very pleasing with generator sales to Canada almost twice the number of the previous year. This resilient demand for PAS in Canada has now risen for the 9<sup>th</sup> consecutive year. In fact, the total PAS that we sold into the Canadian market was more than any other single market in the world. We are delighted with our success in Canada and we are encouraged by the potential growth for Technegas in the United States once we receive USFDA approval.

## ***Cyclopet***

I am happy to report that our Molecular Imaging division, Cyclopet achieved sales growth of 62% in 2012, despite facing tremendous competitive headwinds in NSW.

Our ability to grow this market continues to be significantly hindered as a consequence of the NSW tender to supply PET radiopharmaceuticals to NSW public hospitals being awarded to Petnet Australia, on the basis of a tender that we believe was fundamentally unfair. Most of you will know that Petnet is a wholly owned subsidiary of the Australian Nuclear Science and Technology Organisation (ANSTO). Based on our complaint to the Productivity Commission, Petnet was investigated and found to be in ex-ante breach of the Government's competitive neutrality requirements. Competitive Neutrality guidelines mandate that, Petnet, as a government-owned enterprise, must not enjoy a competitive advantage by virtue of its public sector ownership. Petnet was found to be selling its products at below commercially viable rates.

As ANSTO refuted the finding by the Productivity Commission Cyclopharm had to resort to the commencement of proceedings in the Australian Federal Court. We are committed to vigorously prosecuting what we believe to be not only a serious breach of competition law but also an inappropriate and wasteful use of taxpayer funds by a government-owned enterprise competing on unjust terms against the private sector.

Unfortunately, the short term losses sustained as result of the action against ANSTO has meant that your company will operate at a loss until such time as the various legal actions we have undertaken lead to a rectification of this situation.

We are hopeful that the matter will come before the Federal Court for full hearing in late 2013 and will continue to update you as the case progresses.

Despite the setbacks in NSW, we see Queensland as a strong market to expand into. In fact, while ANSTO is blocking us from competing in the NSW market, we have grown our business through distribution into Queensland.

The majority of our current volume is shipped north to Queensland on a daily basis. The attractiveness of this market is such that we entered into a tripartite agreement last year with the Queensland X-Ray and the Mater Hospital in Brisbane to locate a cyclotron facility at the Mater, currently the largest single healthcare precinct in Australia. The cyclotron site will be located in a new development within the precinct. Given the extensive construction required, we expect that we will be commercially operational in the second half of 2015 to early 2016.

Positron Emission Tomography more commonly known as PET is primarily used in the diagnosis of cancer. Of the 20 indications approved in Australia, 19 are cancer related. However, there is a global push in research beyond cancer to include neurodegenerative diseases like Alzheimer's and Parkinson's disease. Given our infrastructure, we are in a particularly strong position to take advantage of these emerging PET radiopharmaceuticals and indications.

Despite its somewhat burgeoning use today in Australia, PET is an extremely important diagnostic technique. Given the nature of the disease states it which it is used, the demand for PET is expected to grow dramatically not only for its clinical significance but also out of necessity of a rapidly aging population.

According to the Australian Bureau of Statistics over the next thirty years the age group as a percentage of overall population between the ages of 65 and 85 is expected to increase 43%. However, this growth is dwarfed by the fastest growing segment of the population,. By 2041, Australians over the age of 85 are expected to more than triple from 1.8% to 7% of total population.

Why are these demographics significant? The longer we live, the more likely we will succumb to illnesses such as cancer and neurodegenerative disease. For example 1 in 2 males and 1 in 3 females will be directly affected by cancer before the age of 85. Alzheimer's disease, the most prevalent neurodegenerative disease, affects 1 in 8 or 13% of Australian's over the age of 65. The incidence of Alzheimer's disease increases dramatically to 46% of those over age 85.

Between our interest in PET radiopharmaceutical manufacturing, our joint venture partnerships in diagnostic imaging and the overseas relationships we are fostering with drug development companies we are in a particularly strong position to leverage this important technology.

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

As you all are aware, Cyclopharm's medical imaging joint venture, MMI, provides patients at Macquarie University Hospital and neighbouring suburbs access to state- of- the-art imaging facilities. In December 2011, Macquarie University Hospital took a 30% share in the joint venture. The CEO of the Hospital and CFO of the University now sit on MMI's Board. Patient volumes continue to gradually increase as initiatives being implemented at Macquarie University Hospital, including a new breast clinic, expanded specialties such as cardiothoracic services, cancer care services and expanded PET indications take effect.

To this point, I am pleased to share with you that driven by our outstanding clinical deliverables and growth in hospital occupancy rates, patient volumes at MMI are 30% higher than they were this time last year

### ***Ultralute™***

Last month we announced the development of a new Nuclear Medicine technology – Ultralute™. Developed here on site at Macquarie University. We have on display today Ultralute™. Following our AGM today I welcome you to have a closer look.

As some of you may be aware, Technetium-99m, or Tc-99m, is the primary isotope used in diagnostic imaging throughout the world. This isotope accounts for approximately 80% of all diagnostic imaging procedures. Tc-99m is harvested from Molybdenum-99

generators. Commercial manufacture of Mo-99 requires a nuclear reactor. It 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. Cyclopharm's patented Ultralute™ technology extends the useful life of Mo-99 generators by up to an additional 50%.

Consequently, it's very easy to appreciate the potential of this technology to give 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 are now moving toward the regulatory approval process while in parallel 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**

During the past year, the economic landscape has provided us with a challenge in terms of maintaining demand across our Technegas products. Exporters across the board have been hit hard by the strong Australian dollar and I believe we have performed reasonably well in the face of this difficulty. This is an outstanding testament to the exceptional value of our technology.

Technegas sales volumes grew in Europe despite the region's ongoing issues and demand increased in the Asia-Pacific and North American markets. This result underpins the strength of the Technegas business and, with your directors, I will endeavour to realise the division's potential. I believe that the Technegas business will continue to be a stable source of growth for Cyclopharm's business.

The commencement of clinical trials in the United States marks a huge step towards penetrating the US market. While we hope to achieve this by 2015, we are also awaiting approval from the Japanese regulatory authorities for the Technegas Plus Generator which we expect to drive sales higher in Japan. We also await regulatory approval in Russia. Other growth drivers we have in place include marketing throughout Europe and China.

The opportunities afforded to us by expanding the use of Technegas into the COPD market and from our Ultralute™ technology are undoubtedly exciting. In the coming year, we will place significant effort on simultaneously progressing our Technegas COPD trials in China and gaining regulatory approval to use Ultralute™ technology in a number of markets as well as developing commercial demand in those markets.

With respect to our Molecular Imaging Business, we will continue our fight against unfair competition in NSW and look forward to our day in court. As for our Queensland expansion opportunity, I look forward to updating you as the new project progresses.

Ladies and gentlemen, the Company's achievements in 2012 and in early 2013 mark major milestones in our company's history and I genuinely believe that our business 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, and our trading partners for their contribution towards our progress. In particular I would like to acknowledge Professor Nabil Morcos, our Director of Science. I also take this opportunity to note my appreciation to the Chairman, Mr Vanda Gould and my fellow director, Mr David Heaney for their wise counsel.

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



James McBrayer  
**Managing Director and Company Secretary**

**Contact details:**

Mr James McBrayer  
Managing Director & CEO  
Cyclopharm Limited  
T: +61 2 9541 0411

## **Background**

### **Cyclopharm Limited**

Cyclopharm is a radiopharmaceutical company servicing the medical global medical community. The Company's mission is to enable 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 2,500°C. The resultant gaseous 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. 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.

### **Macquarie University Hospital and the Macquarie University School of Advanced Medicine**

Macquarie University Hospital is a major medical precinct within the Macquarie University Research Park to complement the Allied Health teaching services offered by Macquarie University.

The Macquarie University Hospital is a state of the art facility that delivers health education and research on site.

### **Macquarie Medical Imaging**

Cyclopharm formed a joint venture with Alfred Health Solutions and Macquarie University Hospital to provide all imaging services on-site at the hospital. The new venture named Macquarie Medical Imaging ("MMI") represents a rare strategic opportunity to provide a fully aligned and integrated diagnostic, therapeutic and research platform. MMI offers a range of diagnostic radiology, interventional radiology, nuclear medicine and molecular imaging services for inpatient and outpatients.

The combination of state of the art imaging equipment, a GE cyclotron located on the grounds of MUH, leading surgeons, clinicians and academics will ensure that MMI will become the leading centre of imaging excellence.