

cyclomedica molecularimaging technegas

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

# Managing Director's Report

Good morning ladies and gentlemen.

As your Managing Director I warmly welcome you to Cyclopharm's Annual General Meeting. I am delighted that this AGM, our second in NSW, is again located here at Macquarie University; home of Macquarie University Hospital, The Australian School of Advanced Medicine our Cyclotron Facility and our Joint Venture Imaging business, Macquarie Medical Imaging.

In today's presentation, I will provide you with a brief overview of our operations and how they performed during 2011; summarise our financial performance; present our outlook for the current financial year; and talk about where I see Cyclopharm's opportunities going forward.

Cyclopharm's mission and values remain unchanged. They represent the bedrock of how we operate and seek to deliver shareholder value. Our strategy is to be the recognised world leader in pulmonary imaging and the Australasian manufacturing leader of radiopharmaceuticals used in Positron Emission Tomography (PET). As we move to an operating position in each of our new businesses it is clear that shareholder value is being built, by all the while, remaining focussed on our core expertise in nuclear medicine and seeking to leverage our strategic partnerships.

Today, each one of our core businesses is in the market generating revenue. Given the hard work undertaken since implementing the company's diversification strategies in 2010, this is a very pleasing position to be in. Technagas has been operational since 1986, and remains the nucleus for revenue and profit generation. The Cyclopet and MMI businesses are still in their infancy but are showing significant promise.

Both the MMI and CycloPet operations are located here at Macquarie University Hospital. These businesses are demonstrating the benefits of strategic partnerships. In collaboration with our Clinician partners and the University, the research and product development synergies available provide a world leading integrated imaging and research platform.

2011 was a year of delivering on our strategy – albeit with a few speed bumps along the road.

The Technegas business continues to perform strongly and underpins the company's financial performance, recording 92% of the group's sales for the year. Technegas' sales continue to grow and significant upside exists in the US market now that we have FDA approval to proceed with our Phase III trial. This trial will commence within the next few weeks. We have suffered somewhat of a setback recently in commencing this trial due to a shortage of Xenon-133. Xenon is the competitive Nuclear Medicine product which will be used as a control standard for the trial.

In 2011 Cyclopet, our Cyclotron facility located here at Macquarie University completed its first year of operations. While this business is expected to deliver important diversity and growth

potential, in its start up phase, Cyclopet negatively impacted our 2011 financial performance. A key reason for this related to the actions of Petnet, a Federal government owned subsidiary of the Australian Nuclear Science and Technology Organisation (ANSTO). Based on a complaint lodged by Cyclopharm, Petnet has been subject to an investigation by the Productivity Commission. I will speak about this in more detail shortly.

Our MMI joint venture is continuing its ramp up and finished the year with Macquarie University taking a 30% stake in the joint venture.

And lastly our capital raising completed last December has ensured your company remains on a sound financial footing.

Let's now look to our business segments individually. Technegas has been the cornerstone of our business since 1986, and since that time our life saving product has clocked up some impressive statistics. With sales in over 55 countries, the majority of our revenue is sourced from outside Australia. Over 2.6 million patients have benefited from our technology and over 1,200 Technegas generators have been sold globally.

As you can see from the chart of sales in 2011, Technegas' business is still heavily weighted to Europe. Expansion of our distribution in Asia and in the Americas in 2011, has reduced our reliance somewhat on the European market. Going forward, we will be seeking to establish our operations in the US with an FDA trial commencing shortly. The USA is the only major western market we do not sell into and represents the largest single nuclear medicine market with over half of the world's nuclear medicine departments located there. Clearly, the US opportunity is significant and is a key priority for us.

Our Molecular Imaging Business, CycloPet, moved from development to commercial phase in 2011. This is a business we are very excited about. PET allows physicians to accurately differentiate between healthy and active diseased tissue, that is, to detect cancer and other disease states more precisely and earlier than conventional methods.

The success of this technology globally was finally recognised by the Federal Government who, in July last year, doubled the number of PET procedures covered by the Medicare Benefit Scheme from 10 to 20. However, the application of this technology in Australia is in its early stages.

Further opportunities exist to expand the uses of PET into the areas of Cardiology and Neurology. In particular, neurological product developments focusing on Alzheimers and Parkinsons disease are increasing significantly.

Notwithstanding the considerable potential PET represents, our Cyclopharm business faced tremendous headwinds in 2011. As I outlined in my AGM address last year CycloPet had tendered for a contract to supply PET radiopharmaceuticals to public hospitals in NSW. Notwithstanding being the lowest cost commercial GMP producer in NSW, CycloPet failed to win the Tender. Instead the tender was awarded to the Federal Government owned ANSTO subsidiary PetNet.

A cornerstone operational requirement of any Government owned commercial enterprises is the concept of Competitive Neutrality. At its heart, this concept is simple – that a government owned enterprise must not enjoy a competitive advantage by virtue of its public sector ownership. Adherence to Competitive Neutrality was also a key requirement of the NSW tender.

Notwithstanding this absolute requirement under law and also under the NSW tender requirements, ANSTO through PetNet submitted prices propped up by government subsidisation and, as a result, excluded Cyclopharm from participating in the NSW public hospital market. After this fact came to light, in August 2011 Cyclopharm submitted a complaint to the Australian Government Competitive Neutrality Complaints Office, a department within the Productivity Commission.

Since being founded 16 years ago the AGCNCO has chosen to investigate only 15 of the many complaints and queries it has received. We view this finding as a landmark case in that never before has the Productivity Commission has found in such clear favour of a private sector complaint as it found in our case against ANSTO.

The Productivity Commission, finding ANSTO in breach of its competitive neutrality requirements, handed down its report last month on April 4<sup>th</sup>. This finding is significant on a number of grounds, being

- it requires ANSTO to review its PetNet business model to conform with competitive neutrality;
- requires the Science Minister and Treasurer to respond to the Productivity Commission finding within ninety days;
- opens up other legal avenues to seek remedy;
- highlights a significant shortcoming with NSW Health's tendering processes; and
- brings to light the fact that there is a significant inadequacies in ANSTO's corporate governance processes.

Unfortunately, what the finding does not do is to wind back the clock on the NSW tender. It is now up to the NSW Health Minister, Jillian Skinner, to do the right thing and cancel PetNet's contract which was awarded on unfair terms. Rather than allowing ANSTO and NSW Health to bury the issue in layers of public service red tape and obfuscation, your Board is seeking action now.

I am also hopeful that the Federal Minister for Science and Research, Senator Chris Evans, in his new portfolio will step up and insist on a root and branch review of ANSTO's governance, board representation, management and operations.

At Cyclopharm, we will not let this matter rest, as it represents a significant risk to shareholder value and goes to the heart of our ability to provide the Australian public a sustainable supply of quality assured radiopharmaceticals.

Let's now move on to our Joint Venture investment, Macquarie Medical Imaging (MMI). MMI provides a fully aligned and integrated diagnostic, therapeutic and research platform here, at Macquarie University Hospital.

In December 2011, we were pleased to announce the MMI joint venture between Alfred Health Solutions and CycloPet expanded with Macquarie University Hospital becoming a 30% shareholder. Throughout the investment, CycloPet has maintained its 20% interest in MMI. The expanded alliance also represents a key milestone in Cyclopharm's mission to continue to develop solutions that improve patient care outcomes.

This Joint Venture provides patients at Macquarie University Hospital and neighbouring suburbs access to state of the art imaging facilities including 3T MRI, CT, X-ray, Ultrasound, Positron Emission Tomography (PET) scanning and interventional radiology services.

Turning to the financial results for 2011, Consolidated Sales increased 9.0% to \$10.3 million, while the group's Earnings Before Interest and Tax, fell by \$1.8 million to a loss of \$836,000. The decrease in profit was driven by the impact of the losses incurred in the Molecular Imaging business in its first year of commercial operations and the strengthening Australian dollar.

On a divisional basis, Technegas' sales revenue in 2011 was \$9.47 million, sourced from the sale of its core products of Generators and Patient Administration Sets (PAS). This sales figure was consistent with the prior year. The 4% increase in PAS volumes, was offset by the impact of movements in the Australian dollar on prices received by Technegas. The impact of higher volumes on constant sales, saw margins contract compared to the prior year, resulting in the division's Earnings Before Interest and Tax , before one offs, reducing from \$1.85 million to \$1.7 million.

Looking over a longer period, Technegas' sales volumes have risen consistently. We expect this trend to continue.

Our MMI JV is accounted for on an equity accounting basis. As such, Molecular Imaging sales of \$850,000 for the year represent only CycloPet's radiopharmaceutical sales. Cyclopharm's share of MMI's loss is included at the PBT line. Clearly, we are disappointed with Molecular Imaging's loss of \$2.5 million for the year. This loss was driven by the impact of ANSTO's competitive actions in the NSW market and a slower than expected ramp up of MMI's activities.

Historically, Technegas' sales have been cyclical – weighted towards the second half. The 2011 financial year was no different. Indeed Technegas' 2011 sales almost mirrored 2010, half on half, with the only difference being sales from PET.

Breaking this down even further, you can see the impact of the highly seasonal sales into the European market. With approximately 60% of our sales generated in Euro's, and with that markets economic instability in mind, we are currently considering the appropriateness of hedging our foreign exchange exposure in the important Q4 sales period.

In 2011 your Board and management focussed heavily on ensuring Cyclopharm's balance sheet remained strong and that the company could comfortably fund not only the operating costs of Cyclopet as it ramped up but also the initial costs of the US clinical trial of Technegas. Particular actions to achieve this aim include:

- the November renewal of our \$5.1 million bank facility with NAB;
- the 1-for-3.2 rights issue, which raised approximately \$2 million; and
- a \$760,000 reduction in our inventory holdings

As a consequence of these actions, our net assets rose to \$14.6 million at year end and our net cash was \$2.0 million compared to \$1.5 million in the previous year.

From a cash flow perspective, our core operating activities were again a positive contributor to our cash position.

In 2011, we invested an additional \$400,000 into MMI, bringing our total investment into that business to \$900,000. As MMI is operating at a loss in its start-up period, Cyclopharm attributes a nil carrying value to that investment.

In addition to the MMI investment, approximately \$239,000 was invested in FDA activities associated with our efforts in bringing Technegas to the US market. We expect the US phase III clinical trial process with consume further cash resources in the near term. However, the potential pay-off for Technegas in entering the US market is expected to significantly exceed this investment.

I would like to now share with you our business outlook for 2012.

Technegas' Generators and PAS continue to be a strongly demanded product globally. In the current financial year, we expect Technegas will again deliver a solid financial performance, driven by volume growth in every market and a modest increase is the average local currency selling price. On a division basis, the A\$ value of sales will of course be subject to movements in the exchange rate and any decision by the company around foreign exchange hedging. Over the medium term Technegas' outlook continues to improve.

We continue to sensibly pursue United States FDA approval and expect clinical trials to complete in 2014, enabling us to begin sales into that market in 2015.

We continue to develop new indications for Technegas and extend sales of the product into new markets. Disease states to include Chronic Obstructive Pulmonary Disease (COPD) and Lung Cancer have significant market potential for Technegas and are currently being targeted with clinical studies now underway. To share with you the potential of what a new indication could mean for Technegas, we estimate the COPD market is 15 to 20 times the size of that of the pulmonary embolism market we currently occupy.

In relation to entering the US pulmonary embolism market, we estimate Technegas has the potential to generate over \$30 million in sales and around \$12 million in EBITDA in the first three years post market entry. The cost of trials are expected to be US\$4million.

Our ability to fund this trial in a timely manner out of operating cash flows without the need to raise further equity will be dependent on a favourable outcome from our efforts in establishing a fair and level playing field in the NSW PET radiopharmaceutical market.

In the near term, Cyclopet will pursue additional FDG customers in NSW and evaluate opportunities for expansion within the Australasian region. Clearly, successful resolution of the competitive neutrality position of PetNet offers the most immediate upside for this business.

With the introduction of Macquarie University to the Macquarie Medical Imaging joint venture in late 2011, this union puts MMI in a solid financial and strategic position. Growth in that business is tied closely to the hospital's ramp-up. We are confident that the initiatives being implemented at MUH to include a new breast clinic, expanded specialties like cardiothoracic services, cancer care services and expanded PET indications will continue to generate increased patient volumes.

In conclusion I want to express my gratitude to my staff and management team, many of whom are here today, our bankers, our joint venture partners and our trading partners. I also want to take this opportunity to echo our Chairman's thanks to John Sharman and Sandy Beard for their support while they served as Directors.

Also I want to personally thank both our Chairman Vanda Gould and my fellow Director David Heaney for their support, experience and advice. I am truly fortunate to have such wise counsel available to me.

Lastly I want to thank you our Shareholders for your continued support. We are delivering on our investor promise and I anticipate further achievements over the near term will further drive shareholder value.

Finally, following the conclusion of the formal parts of today's meeting, I welcome you all to stay and meet members of our management team who are here today, and join me on a tour of our facilities.

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James McBrayer Managing Director and Company Secretary

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## 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 furnaced 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.