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cyclopharm
Nuclear Medicine

cyclomedica
molecularimaging
technegas

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Managing Directors Report

Good morning ladies and gentlemen.

As your Managing Director I warmly welcome you to Cyclopharm's 2011 Annual General Meeting located here on the beautiful campus of Macquarie University, both the home of Macquarie University Hospital and The Australian School of Advanced Medicine.

This is our first AGM located in New South Wales. In having the meeting here your board believed it was an ideal opportunity to show you the fruits of our labor. Across the street is located a couple of other firsts as well. Located on Basement 2 is our first cyclotron facility, CycloPet, and on the ground floor you can find our first medical imaging joint venture, Macquarie Medical Imaging.

Following the formal meeting today, I welcome you all to join me on a tour of the facilities that your continued support has made possible. I am certain you will be impressed with what you see.

Since 1986, our company has been saving lives every day. Your company was founded and continues to leverage off the global success of Technegas; however, the company's transformation that we delivered in 2010 through diversification can best be summarised by stating that we are no longer a one product company.

In addition to Technegas, we are now involved in the radiopharmaceutical production of isotopes used in Positron Emission Tomography or PET. The third development in our diversification evolution is our involvement in the Joint Venture MMI, a comprehensive imaging practice that also includes interventional radiology.

Both the MMI and CycloPet operations located here at Macquarie University Hospital individually represent the most technologically advanced facilities in Australia. Together, in collaboration with the University the synergies are magnified to provide an integrated imaging and research platform unlike any other location in Australia and arguably the world.

2010 will go down in the company's history as a year of transformation. As a result of the substantial milestones that we delivered last year, I have the privilege of standing before you today representing a very different and dynamic company. In looking at the highlights for 2010, I am pleased to report that our foundation product Technegas remains relevant, strong and consistent.

A major milestone was achieved in December last year when our cyclotron facility earned TGA licensing. This approval has allowed CycloPet to move from its commissioning and licensing phase to commercialisation. In June 2010 we achieved another commercial hurdle when our first patient was imaged at our joint venture imaging facility, MMI.

We also accomplished a significant and long sought after win for Technegas. The much awaited entry into the United States Market was tangibly advanced by reaching agreement with the United States Food and Drug Administration (FDA) on our proposed clinical trial protocol parameters. The significance of attaining Special Protocol Assessment approval is equivalent to achieving a contract with the FDA on the most critical element of any New Drug Application.

Now that we are no longer a one product company, allow me to provide an overview of the segments we are now operating.

Technegas has been the cornerstone of the business since 1986. I am pleased to report that, with the advent of new imaging techniques, Technegas is more relevant than it was even 2 years ago. Technegas has a remarkable safety record. It is safer and more effective than any other competing product. It has the enviable position of having zero contraindications and zero adverse patient events. Technegas itself is a radioactive nanoparticle that is manufactured and administered to patient's onsite within the Nuclear medicine department.

There are 4 components required for a Technegas procedure: a Technegas generator, a single use Patient Administration Set (PAS), a single use patient crucible and the radioactive isotope Technetium 99m. All non-radioactive items are manufactured at either Cyclopharm's Australian facility located at Lucas Heights, NSW or in Europe.

The isotope Technetium 99m is the radioactive component of Technegas. Technetium is made from Molybdenum 99. Last year we were faced with a global shortage of Molybdenum. The shortage was the direct result of a shut-down of the Canadian reactors responsible for producing most of the world's supply of this isotope. We are pleased to report that the reactors are back in production. We are also pleased to report that development is underway to produce Molybdenum in other locations globally.

We have on display here today a Technegas unit. Many of you have been investing in our technology for quite some time. I thought it would be a great opportunity for you to actually see a unit up close.

Cyclopharm is truly a global company with over 85% of our business generated outside of Australia. Technegas is sold in over 55 countries. Over 2.5 million patients have benefited from our technology and nearly 1,200 generators have been sold globally.

We are utilizing various business models throughout the world in order to distribute our products. Our review of how, where and who we do business with is a dynamic process. I look forward to informing you of upcoming changes as our business develops.

In looking at the distribution of our global sales, Technegas is still heavily weighted to Europe. Sales there account for 60% of revenue. I am pleased to report that despite the global shortages of Molybdenum both our Canadian and Asian markets grew during 2010.

We are looking to expand our operations in the US with an FDA trial commencing this year. The USA remains the largest single market with over half of the nuclear medicine departments located there. The opportunity to participate in this trial has been enthusiastically received by several of the leading research institutions known throughout the world and we expect to commence in Q3 this year.

In looking at our Molecular Imaging Business, I would first like to state that it is a thrill to be a part of this growing and important area of health care. PET allows physicians to differentiate between healthy and active diseased tissue. This differentiation enables physicians to detect cancer more accurately and earlier than conventional methods. Ultimately PET provides better patient care.

Molecular imaging or positron emission tomography is undoubtedly the future of nuclear medicine and, arguably in broader sense, radiology. PET distinguishes itself from other imaging modalities through the identification of disease states at a metabolic level.

94% of PET studies are used in the detection of cancer. The remaining indications generally fall equally in either neurological applications or in cardiology applications. However neurological product developments are starting to surge ahead.

Even traditional pharmaceutical companies recognise the benefits of PET. In November 2010 Eli Lilly purchased Avid Pharmaceuticals for $800m USD. Avid is a leading radiopharmaceutical development company specialising in PET imaging agents. Lilly was particularly interested in Avid's pipeline product used in the diagnosis of Alzheimer's disease and dementia.

Recent changes announced in the Federal Budget will expand the use of PET in Australia. From 1 July 2011, there will be a two fold increase from 10 to 20 in the PET procedures listed on the Medicare Benefit Scheme. Site restrictions will also be lifted allowing all Medicare eligible locations access to the expanded MBS item codes.

Before we discuss our latest venture into diagnostic imaging, it is important to describe to you significance of the facilities here at Macquarie University. Macquarie University Hospital is situated on the campus Macquarie University. Adjacent to this building is a 183 bed facility specializing in oncology and neurology. There are 12 specialised operating theatres.

This building is the home of the Australian School of Advanced Medicine. ASAM is the first medical school in Australia to be linked to a private teaching hospital on a university campus. ASAM offers advanced training for doctors, in surgery and medical research and brings together world class clinicians, researchers and medical educators to create an innovative training program with a focus on future trends in medicine. Also in this building there will be up to 18 specialist suites supporting the ongoing clinical requirements of the hospital.

In the hospital next door, adjacent to our cyclotron facility, is radiation oncology. Within that department is a gamma knife, the first of its kind in Australia. The gamma knife allows surgeons to perform brain surgery on a day surgery basis without the need for any incision. Brain tumours that were once considered inoperable can now be eradicated with this surgical tool. These facilities combined with our cyclotron and imaging practice ensure that there is truly no other healthcare facility like it in Australia.

Macquarie Medical Imaging (MMI) represents a rare strategic opportunity to provide a fully aligned and integrated diagnostic, therapeutic and research platform at Macquarie University Hospital (MUH). MMI is a joint venture between Alfred Health Solutions (AHS) and CycloPet. The company structure of MMI consists of 80% ownership held by AHS, the business arm of the Alfred Group, and 20% owned by CycloPet, the wholly owned subsidiary of Cyclopharm.

Our Joint Venture provides patients at the new hospital and neighbouring suburbs access to state of the art imaging facilities including Positron Emission Tomography (PET) scanning. AHS and CycloPet together bring unique skills to the venture. MMI will set a benchmark for the medical imaging fraternity by providing clinical and research models that focus on optimising patient outcomes. Further, collaborations between medical imaging specialists and University staff will establish MUH as Australia's premier research and educational centre for advanced imaging throughout the region.

In turning to the financial results 2010, the global shortage of Molybdenum combined with a slow ramp up of the hospital were only magnified by the regulatory delays we had in licensing the cyclotron. Combined, they resulted in rather disappointing results. Technegas volume sales were flat; however, the reduction in sales revenue was largely attributed to the strengthening Australian dollar.

We posted a profit after tax of $450,000. Our largest profit impact was the direct consequence of our investment into the future. $864,000 loss was the result from our cyclotron operations and a loss of $311,000 was attributed to our investment in MMI.

It is important to highlight the underlying strength of the company. Even though we were impacted by a surging Australian dollar, our net profit before tax position of our base business excluding one-offs and investment activities has remained constant.

As stated previously, 2010 sales were dampened by the global molybdenum crisis. Molybdenum is the precursor to Technetium, the isotope used to manufacture Technegas. Despite this set-back, volumes in both Patient Administration Sets and Generators remained consistent. Given that we were able to hold our market share through the worst isotope shortage impacting nuclear medicine globally is a testament to the strength of our technology.

This slide is to remind our shareholders that we historically have stronger second half results than first. 2010 was no different.

Our balance sheet remained consistent in 2010 as compared to the previous year at $13.8m. Since becoming operational in December 2010, the cyclotron facility was reclassified as Plant Property and Equipment. Our debt facility of $5.1m is expected to be renewed in June 2011. Our closing cash position at the end of 2010 was $1.5m, significantly down from the previous year. Significant cash was expended in the start up phase of both the cyclotron facility and MMI.

I would like to now share with you our business outlook for 2011.

We will continue to sensibly pursue United States FDA approval. While we are disappointed that there have been delays in entering the United States market, we now know what we have to do to achieve a successful outcome. It is a prize worth having. Of the 15,000 nuclear medicine departments in the world, half are in the United States.

Following approval of our Special Protocol, the next step in commencing the clinical trial will be the submission of an Investigational New Drug (IND) application. We anticipate lodgment of the IND will occur early Q3 this year with the trial to commence by the end of Q3.

We are constantly on the lookout for new applications for our product. We are currently participating in developing a bid for a new Clinical Research Cooperative (CRC) that will assist our efforts in expanding the use of Technegas.

Both chronic obstructive pulmonary disease and pre and post operative lung resection patients will feature in this initiative. Our pursuit of an expanded indication is fueled by the market potential. The COPD market is 15 to 20 times the size of that of the pulmonary embolism market we currently occupy.

Now that the molybdenum crisis is over, we will continue to leverage the recently published European guidelines. These guidelines name Technegas as the agent of choice in determining pulmonary embolism.

As for our Molecular Imaging business, we will continue to focus on the ramp up of our facility here at Macquarie University Hospital. We intend to continue explore new product opportunities in this rapidly evolving imaging modality. Our cyclotron manufacturing facility is considered to be world class. Discussions are currently underway with clinicians on-site at Macquarie and overseas into the development and collaborations of clinical research opportunities.

Our growth at Macquarie Medical Imaging is directly related with the hospital. Unfortunately the hospital ramp-up to date has been slower than expected. Further investment will be required in 2011. We anticipate to continue to invest in the working capital requirements equal to that of our 20% equity stake. We are confident that the initiatives being implemented at MUH to include a new breast clinic, cancer care services and expanded PET indications will continue to generate patient volumes.

In conclusion I want to express my gratitude to my staff and management team, many of whom are here today. I want to thank our trading partners. I also want to take this opportunity to acknowledge the support I have received over the past year from the Chairman, Mr. Vanda Gould and my fellow Directors Mr. John Sharman and Mr. David Heaney. I also want to welcome our newest Director Mr. Sandy Beard to the table. Sandy has followed the company for many years and will be a definite asset to the organisation.

Lastly I want to thank you our Shareholders for your continued support and patience. The investments we have made over the past years are now beginning to bear fruit. I believe that 2011 is destined to be an exciting year for the Cyclopharm and I look forward to sharing with you the milestones we will achieve this year as we move closer to becoming Australia's leading nuclear medicine company.

James McBrayer

Managing Director and CEO