

cyclomedica technegas cyclopet

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

26 May 2015

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

Managing Director's Address

Thank you David.

Slide 7 - FY14 Financial Highlights

It is a pleasure to be able to share with you today the great progress we have made in 2014 and the new business opportunities and technological developments that we believe will drive continuing profitable growth for Cyclopharm.

As David has told you, FY14 was a period of strong growth in revenue and profits for your company.

Just as importantly, it was a year of positive transformation in which we resolved important issues overhanging the company's performance and we made significant inroads into new and existing markets.

2014 was a year of records for Cyclopharm. We reported record sales of \$12.1 million, record earnings for our Technegas division of \$2.2 million and record NPAT of \$4.1 million.

Net profit was driven primarily by higher profits from Technegas, our patented nuclear medicine technology for imaging lung disease combined with net litigation proceeds of \$2.2 million from the successful resolution of Cyclopharm's legal action against Petnet Australia making up the remainder.

Our balance sheet is now in a much healthier state. Cyclopharm's technologies are making money, with cash flow from operations of \$4.5 million for the year.

The gains we made in 2014 helped us fully pay off the remaining \$1.5m of debt with the NAB during the year and we started 2015 with \$3.3 million net cash in the bank.

Slide 8 - FY14 Operating Highlights

Undoubtedly the highlight of the year was the performance of Technegas. Sales of Technegas generators and the consumable product, Patient Administration Sets (PAS), rose 10% to \$11.5 million in 2014. Technegas has established itself as an essential tool for diagnosing pulmonary embolism in hundreds of hospitals and clinics worldwide and there is great potential to expand its use to other diseases.



We are moving closer to US FDA approval of Technegas and trialing a new indication for our product in China, which I will speak more about later.

I am pleased to announce we are also on track for our first sales of Ultralute in the current financial year. In 2014 we have secured patent protection for this innovative technology and we are currently in the process of manufacturing our first validation batches.

While we made a business decision to close down commercial production of our PET radiopharmaceuticals business in April 2014 due to commercially unsustainable pricing from government owned competitors, Cyclopet still delivered more than \$500,000 in revenue in those first four months of the year.

We also encountered further challenges with our cyclotron facility in 2014. Our facility suffered significant water damage caused by a car fire in the hospital parking lot in June 2014. Reinstatement is fully covered under our insurance policy. We are currently evaluating which options for this facility will deliver the greatest value for shareholders in the long term.

Slide 9 - Group Profit and Loss

Turning now to the drivers of increased sales and profits last year - Technegas revenue gains were certainly the most important. The positive result was boosted by higher gross margins in this business due to the price increases we were able to achieve, good cost control and the favorable impact of a lower Australian dollar.

In fact, reductions in costs were achieved across almost all the Group's major expense categories. We also reduced our tax burden by recognising prior years' tax losses and by participating in the federal government's R&D tax offset program.

Slide 10 - Group Balance Sheet

Cyclopharm's improved cash position and stronger balance sheet gives us more options to pursue initiatives that will add value for shareholders.

With virtually no debt and \$3.3 million in the bank we started 2015 with a greater capacity to fund growth initiatives and opportunities as they arise as well as ongoing research and development.

We are also evaluating divestment as one of the possible options for our Cyclotron facility.

Slide 11 - Technegas FY14 Performance

To remind you, our Technegas technology is an alternative to Computed Tomography Pulmonary Angiogram ("CTPA"). 3-D lung imaging known as Ventilation Perfusion SPECT imaging or V/P SPECT when utilizing Technegas as the preferred ventilation agent has proven to be more accurate and more sensitive than CTPA in diagnosing pulmonary embolism. Furthermore CTPA is contraindicated with a large percentage of the population due to their medical condition such as patients with



renal impairment. This is not the case with procedures with Technegas. Another competitive advantage that SPECT imaging has over CTPA is that lung imaging with Technegas delivers superior clinical results at a fraction of the high radiation dose received from CTPA.

The strong performance of Technegas in 2014 was driven by continued revenue growth in Canada (now our largest single market) and higher margins in the remaining regions.

Total Technegas sales were 9.3% higher in 2014 and earnings before interest and tax was up 25.2% as margins expanded.

Revenue from Technegas Generator sales was \$2.1 million for the year, up 12.4% on the prior year (2013: \$1.87 million). The increase was a result of higher unit sales than the prior year (up 46% to 51 units) and price increases in Germany, Europe and Asia along with a weakening Australian dollar.

Slide 12 - Technegas Sales Revenue

The Patient Administration Set or PAS Kits used in each Technegas procedure is the engine room of the Technegas division's revenue, comprising 82% in 2014. PAS revenue itself was 9% higher at \$9.4 million in 2014 compared to \$8.6 million in 2013 due to increased PAS prices in Asia and Latin America and favourable foreign exchange movements. A key success was management's decision to alter the distribution channel in targeted Asian markets by moving to an agency model, which resulted in a 74% increase in PAS prices in that region. While the Asian market is relatively small at present, we are executing strategies that have started to bear fruit.

By geography, Technegas sales revenue was 8% higher in Europe, 27% higher in North America and rose 33% in Asia.

Revenues from Technegas were partly offset by a fall in service revenue from \$1 million the prior year to \$700,000 in 2014.

We believe the strong performance of Technegas justifies ongoing investment in R&D and the costs associated with expanding the indications for use for our product as well as into new markets, particularly the expense associated with obtaining FDA approval.

Slide 13 - Technegas, Expanding the Global Footprint

We have now sold 1,350 Technegas generators in 55 countries globally.

In 2014, Canada became our largest single market, overtaking France. We continue to seek approval to market the product in new countries, such as the USA and Russia. Approval from the Japanese regulatory authorities for the TechnegasPlus Generator was received in October 2013 and with our focus in this market we expect strong sales growth in Japan in the near future.

However, the most important initiative for growing revenue from Technegas in the near term remains obtaining approval for its use in the United States from the US



Food & Drug Administration. I am happy to say we are much closer to that goal than we were a year ago.

Recruiting a sufficient number of suitable patients in our previous clinical trial proved to be an insurmountable barrier. We have since been in very productive discussions with the FDA regarding a significant variation to our previous clinical trial program. We are requesting a meeting with the FDA to finalise a new and less complicated protocol that if accepted should deliver USA approval faster and less costly than previous attempts.

Furthermore, the success of Technegas globally has attracted the interest of companies eager to partner with us in the United States. We are currently evaluating our options whether or not to take on a partner or proceed independently. I will be in a position to update you in the very near future.

Slide 14 - Technegas – new indications, COPD

China remains a particularly promising market for Technegas. In 2014 we commenced trials there to establish efficacy for the diagnosis of Chronic Obstructive Pulmonary Disease (COPD). COPD is a major problem in that country due to its high levels of air pollution, the high incidence of smoking and the use of biofuels in everyday life.

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. We hope Technegas will be able to assist in reducing that toll.

I would like to provide you with some background as to why so many believe that Technegas has a place in diagnosing and managing patients with COPD. Today COPD is diagnosed and graded by the use of Spirometry. Spirometric indices measure the degree of airflow obstruction, predominantly in large and intermediate airways; however, the simple technique of Spirometry provides no explanation of the underlying pathophysiology.

We believe that the use of Ventilation Perfusion SPECT functional imaging using Technegas as the ventilation agent in COPD patients might serve as a new tool to clarify patient's symptoms and the extent of the disease. Furthermore, our technique also helps diagnosing associated diseases that often coexist that may have a significant impact on the patient prognosis such as heart failure, lung cancer, pulmonary vascular disease, pulmonary embolism (PE) and atherosclerosis which are commonly found in COPD patients. These associated diseases cannot be identified by Spirometry.

Preliminary studies have shown that some smokers identified as healthy may have lung function impairment that can be identified early by a V/P SPECT assessment; this early pathogenesis was not detected by Spirometry. These studies demonstrate that spirometry was not sensitive enough to diagnose early COPD, which is a long standing diagnostic gap in the clinic. Furthermore, as shown in animal studies, CTPA is not sensitive enough to identify early changes in COPD that can readily be visualized with V/P SPECT.

For example, the start of our Chinese trial coincided with the results of a study published in the North American Journal of Nuclear Medicine which demonstrated



that Technegas detected changes in lung ventilation and perfusion before structural changes in the lungs were detected by CT scans.

Another study published in the January 2015 Annals of Nuclear Medicine found that ventilation scans with Technegas can detect ventilatory impairment and airway obstruction even in apparently healthy long-term smokers not shown with spirometry or CT scans.

Simply put, Technegas has the potential to be used not only for early diagnosis of COPD but also on a recurrent basis for COPD management. COPD is 30 times the market size of Pulmonary Embolism. The opportunity presented by these discoveries may lead to a significant expansion of the use of Technegas globally.

Our trial is expected to be completed in late 2015 with a final report available by the end of the year. I am pleased to inform you that the trial is going well with nearly half of the targeted 200 patients completed.

Slide 15 - UltraluteTM

In addition to the exciting future potential for Technegas we are also very pleased with the targeted introduction of our new nuclear medicine technology Ultralute later this year with Germany being our target market for launch.

Up to 85% of all nuclear medicine studies, even our own Technegas studies, are based on Technetium-99 an isotope produced from a Mollybdenum-99 generator. The key fact to take away here is that Ultralute has the potential to extend the useful life of Mollybdenum-99 (Mo-99) generators up to 50% therefore making the use of this isotope more economical and improving operational efficiency.

Nuclear medicine is expensive, so understandably global industry interest in this technology is strong and continues to accelerate.

Slide 16 - Macquarie Medical Imaging

Sales revenue at MMI, our medical imaging joint venture at Macquarie University Hospital, continued to increase in 2014 – up 25%.

MMI provides patients at Macquarie University Hospital and neighboring suburbs access to state of the art imaging facilities including 3T MRI, CT, X-ray, Ultrasound and Positron Emission Tomography (PET) scanning.

Revenue from MMI should grow as patient numbers at the hospital expand and other 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 are also helping boost revenues.

The JV is accounted for on an equity basis due to Cyclopharm's minority shareholding, therefore MMI's full accounts are not consolidated into our accounts.



Slide 17 - Summary and Outlook

As we look to the future, there are many reasons to be confident in continued profitable growth at Cyclopharm.

We are a cash positive business that is increasing sales and profits. We own highly valuable, patented technologies that provide a strong platform for growing sales in new and existing markets.

After a historically important year for the company in 2014, we expect to pass further milestones this year that we are confident will see us in an even stronger position when we meet again in 2016.

Assuming that the business maintains its trajectory and cash flows remain strong, this opens up the possibility of future capital management initiatives which will drive sustainable increases in shareholder value.

Janes & MC Breyer

James McBrayer Managing Director and Company Secretary

For more information, please contact:

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