

cyclomedica technegas cyclopet ultralute

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

## Managing Director's Address

Thank you David.

### SLIDE 4: 2017 AGM – Managing Director's Review

It's a pleasure to provide you today with an update on your company's achievements and prospects here at our new premises. These new facilities alone are a sign of our optimism and confidence for our growth ambitions.

### SLIDE 5: Our Business

Cyclopharm has two primary business lines:

- Cyclomedica, the division which markets and sells Technegas, our proprietary functional lung imaging system our core business.
- Ultralute, our new technology for extending the useful life of Mo-99 generators. Mo99 is the precursor to the isotope Tc-99m. Tc99m is the isotope used in approximately 85% of all nuclear medicine procedures. We have received a great deal of interest from the nuclear medicine industry worldwide and we are now on the cusp of commercialization.

#### SLIDE 6: Investment Highlights – Record Results

2016 was a year of considerable success for Cyclopharm as we advanced our position as a leading player in the global diagnostic nuclear medicine imaging market.

We achieved record financial results while taking further strategic steps to build a larger, more profitable health care company, with growing sales in new markets, wider diagnostic applications and the profitable development of complementary technologies.

Our Total Shareholder Returns grew over the period and we continued the payment of dividends whilst preserving cash to fuel the growth of the business.

## SLIDE 7: 10 Fast Facts

In presenting the Cyclopharm story to shareholders and investors I always like to begin with what I call our '10 Fast Facts'. These facts hopefully explain in simple language who we are, what we do and our transformational growth opportunities. They are:



- 1. Technegas is a well-established proprietary world leader in functional lung ventilation imaging technology. With annuity style product and service revenue streams, the majority of Technegas sales are generated from single patient consumables.
- 2. Technegas is already being sold in 56 countries with significant expansion opportunities in the USA following FDA approval of our Phase 3 clinical trial with the prospect of approval by mid-2018.
- 3. Chronic Obstructive Pulmonary Disease (COPD) and asthma represent tremendous opportunities for substantial Technegas growth worldwide
- 4. Ultralute<sup>™</sup>, a new innovative technology with global application, is being commercialised in 2017
- 5. Ultralute<sup>™</sup> technology is also a platform for additional product development
- 6. We benefit from deep experience across the management team and workforce
- 7. Cyclopharm recorded another excellent financial result in 2016 with good foundations for growth: an increase of \$1.8 million sales. We have a strong balance sheet with \$4.59 million in cash at 31 December 2016

In summary, we are an Australian Biotech in 2016 that was:

- 8. Profitable, generating cash, debt-free and paid dividends.
- 9. We maintained net cash on the balance sheet to fund growth; and
- 10. Is set to leverage transformational growth opportunities.

Following our strategic decision in 2014 to focus our business on leveraging our core patented technologies, Cyclopharm is now a better-targeted, profitable, cash-generating business supported by a healthy balance sheet and an active R&D pipeline.

#### SLIDE 8: Our Strategy

In 2016 Cyclopharm delivered substantial increases in shareholder value through the global manufacture and supply of innovative nuclear medicine technologies.

Technegas is the world leader in functional lung ventilation imaging, clinically endorsed by global industry bodies such as the European Association of Nuclear Medicine (EANM). Our complementary technology Ultralute<sup>™</sup> was first made known to the world in 2015. Following two more years of development we are now ready for commercialisation and expect sales for Ultralute<sup>™</sup> to commence in the coming weeks.

We continue to implement our strategic priorities which are to:

- 1. Attaining approval to distribute Technegas in the USA
- 2. Expanding the use of Technegas beyond the traditional diagnosis of Pulmonary Embolism into significantly larger applications such as COPD, Asthma, Lung Cancer and Pulmonary Hypertension for both diagnosis and patient management.
- 3. Identifying, developing and commercialising complementary innovative technology such as Ultralute<sup>™</sup>
- 4. Leveraging our core global regulatory strengths, fiscal discipline, strong balance sheet and well developed expertise in nuclear medicine and pulmonary healthcare to seek out complementary technologies and businesses

Our unremitting focus on these priorities delivered solid financial results in 2016, supporting further investment in growth opportunities and dividend payments to shareholders.



### **SLIDE 9: 2016 Achievements**

2016 was another significant year of achievement for Cyclopharm. Our more focussed business, leveraging off our existing proven technologies and sales network, continued to deliver on its potential. This allowed shareholders to benefit directly from a profitable, growing business through continuing dividend payments.

Revenue of \$14.39 million was received, generating EBIT of \$1.44 million. As I indicated earlier, cash reserves at 31 December totalled \$4.59 million after payment of debt and relocation expenses.

Our United States FDA clinical trial program for Technegas is progressing on time and on budget, and we have made a decision to pursue our United States expansion strategy independently. Concurrently, our New Generation Technegas Generator project proceeded satisfactorily.

Our Technegas business grew organically at a healthy pace last year and we made good progress with our strategy of expanding our existing presence in China and seeking entry to new markets such as Russia and of course the United States.

We have been informed that the paper based on the clinical work we sponsored in China has been accepted for publication. The peer reviewed paper will highlight that Technegas can be an effective tool used in the early diagnosis of COPD. Through early diagnosis and improved monitoring, we believe that Technegas has a part to play in the ongoing management of this incipit disease.

Last year we secured patent protection for our nuclear medicine technological innovation Ultralute <sup>TM</sup> and our commercialisation program for this exciting new product is on track.

At a global level, Cyclopharm continued to form important strategic partnerships, including a Five Year Collaborative Agreement signed with the Canadian Association of Nuclear Medicine.

#### SLIDE 10: Financial Results and Performance

Reviewing Cyclopharm's financial results in greater depth, I am pleased to report that in 2016 we achieved record underlying results for the third consecutive year.

Total Revenue of \$14.39 million was 15% higher than in 2015, driven by higher unit sales of Technegas generators, up 95%, and a 10% growth in unit sales of Patient Administration Sets (PAS) kits.

This result was assisted by an order from our Chinese distributor consisting of 50 Technegas Generators and 250 boxes of PAS (12,500 patient studies), valued at \$1.38 million.

Patient Administration Set consumable sales increased by \$0.64 million, driven by volume growth in Australasia, Europe and Latin America. Revenue from Generator sales grew 76% over the year to \$2.97 million, while service revenue fell by 7% to \$0.64 million.

Reflecting the change in sales mix towards Technegas Generators in the second half of the year, the group's gross margins declined marginally versus the prior year from 80% to 78%.



An ongoing focus on managing operating expenses enabled the Company to expand its underlying EBITDA margins, which improved slightly to 23.9% in 2016 from 23.7% in the prior year, and underlying EBITDA of \$3.4 million, \$458,000 higher than in 2015.

Reported NPAT for the year was \$891,368, representing Basic Earnings per Share of 1.55 cents.

Continued growth in underlying EBITDA supported the Board's decision to declare a final full year dividend of half a cent per share, bringing total dividends for 2016 to 1.0 cent per share, which we expect to grow over time.

Our 2016 results provide clear evidence that Cyclopharm's financial fundamentals are strong and provide an excellent platform for further profitable growth in the current year and beyond.

### SLIDE 11: Balance Sheet

In 2016 we continued to invest in the future of Cyclopharm with operating cash flows supporting the \$1.5m in capex used to fitout our new home here at Kingsgrove.

The other substantial investment made in 2016 was the \$1.1m investment in our United States FDA program bringing our FDA investment for this protocol to \$2.43m AUD to date.

In 2016 we became debt free after retiring the mortgage held over our European facilities, we paid dividends to our shareholders totalling 1 cent per share and finished the year with cash reserves of \$4.6m.

We continue to monitor our cash position in balance with our immediate and long term objectives, particularly with our goals for Technegas in the United States.

## SLIDE 12: Technegas – A Global Success Story

Our largest division, Technegas, is and will remain in the foreseeable future the engineroom that drives Cyclopharm's growth. Already Technegas is sold in 56 countries, with Europe being its largest regional market and Canada the biggest single country market.

Since 1986, 3.7 million patient studies have been conducted, of which 210,000 were completed in 2016. Over that thirty-year period, 1500 generators have been sold.

Technegas sales volumes continued to grow during the year, with volume growth experienced in the Australasian, North American and European markets. Revenue from sales of PAS units grew 6% over the prior year, benefiting from a 10% increase in volumes and a stable Australian dollar.

Revenue from Technegas Generator sales grew by 76% over the prior year. The significantly higher sales of Generators was driven by the large order from China. This order is expected to provide a platform for significantly greater, higher margin, PAS kit sales in that market from 2018.

Patent protection of Technegas will continue until at least 2026, with optionality for extension with a new model of Technegas generator under development.



# SLIDE 13: Technegas - USFDA Approval Within Reach

At last year's AGM I made the point that 50% of the world's nuclear medicine departments are in the US and therefore that country has the potential to become the largest single market for Technegas.

That fact alone underlines the critical importance of Cyclopharm's achieving its goal of securing regulatory approval for Technegas and thus gaining access to a market which, for Pulmonary Embolism alone, represents a potential base of 480,000 patients p.a. compared with just over 200,000 patients per annum we are currently supplying to the rest of the world.

We remain on track to achieve FDA approval by the middle of next year following the completion of our clinical trial program and the submission of results to the FDA for final review.

I do not intend today to go into fine clinical detail concerning the trial program but, as FDA approval of Technegas is so important to Cyclopharm's future prospects, shareholders may find a general outline of the process and expected timing to be of interest.

In United States nuclear medicine, ventilation imaging is performed either with the radiopharmaceutical Xe-133 or Tc99m-DTPA. The market is split 50:50 between these two agents. Despite the extensive use of DTPA, it is not officially approved for use in lung imaging; therefore, the only approved agent for our comparison purposes is Xe133.

The overall FDA trial design for Technegas seeks to show how well our patented product compares with Xe133 in ventilating on a non-inferiority basis.

The pathway to approval requires the completion of a two-part study (CYC 010 and CYC 009). The first step, CYC 010, which established the inter and intra reader variability of Xe133, was completed last year. This step was required in defining the parameters in the head to head study.

It was a desktop review performed by nuclear medicine clinicians using images from existing Xe133 scans.

The output was a statistical analysis that defined how well and how consistently Xe133 scans were read by the clinicians. As a consequence the analysis determined 240 patients were to be required for the final stage of the clinical trial.

The current stage, CYC 009, is comparing Xe133 with Technegas head-to-head in an allcomer patient protocol. It is important to note that our protocol is looking at structural/functional ventilation instead of reaching a specific diagnosis. This means that patients suffering any number of lung disease states may be enrolled in the trial, not just those suffering from a suspected pulmonary embolism. The 240 patients will be imaged at 10 clinical sites located throughout the United States.

As part of our Special Protocol Assessment agreement, we will be submitting the analysis of our first 40 patients for review to the USFDA. This will be a significant milestone in the clinical program and I look forward to providing our shareholders updates as we commence and progress with patient recruitment.



The two-part study has been calculated to cost up to USD\$7 million, with AUD\$2.243 million having been invested to date.

Recruitment for the CYC 009 trial is expected to be finalised in the first half of next calendar year, with clinical trial results submitted to the FDA for review by mid-2018.

## SLIDE 14: Ultralute <sup>™</sup> - The Next Phase of Growth

Moving now to our exciting new product development Ultralute<sup>™</sup>, it is no exaggeration to claim this patented technology as truly disruptive as it has the capacity to change 60 years of radiopharmaceutical manufacturing practice.

Cyclopharm introduced Ultralute<sup>™</sup> in Germany in October 2015 and I have recently returned from Germany where we connected directly with potential customers.

Simply stated, Ultralute<sup>™</sup> is a unique device that extends the useful life of Molybdenum-99 (Mo-99) generators by up to 50%. Mo99 is the precursor to Tc99m, the most commonly used medical isotope in the world. We estimate that the use of Ultralute<sup>™</sup> will lead to cost savings from the purchase of Mo-99 generators of 30-40%. Ultralute is a complementary technology and in no way competes with our core technology Technegas.

Global interest in Ultralute<sup>™</sup> is strong, with initial revenue from Ultralute<sup>™</sup> sales expected to be recorded in 2017 from the European market.

Ultralute<sup>™</sup> has multiple benefits for nuclear medicine clinics, patients and the nuclear medicine industry more broadly.

We have received a great deal of interest internationally with respect to our Ultralute<sup>™</sup> technology. Most notably, The International Atomic Energy Agency, the peak global body for co-operation on nuclear matters, has recognised the importance of Ultralute<sup>™</sup>. The IAEA represents 168 member countries and has referred to Ultralute <sup>™</sup> as a "*new innovation…that has significant global potential in the nuclear medicine supply chain.*"

## SLIDE 15: Ultralute <sup>™</sup> Generation Overview & Mo99 Supply Chain

To provide some context for Cyclopharm's Ultralute<sup>™</sup> opportunity, it is worth noting that more than 5,000 Mo99 generators are sold worldwide each week.

The first generation of Ultralute <sup>™</sup>, introduced in Europe two weeks ago, is targeting clinics while the second generation will be designed for radiopharmacies with the third generation potentially involved in the manufacturer of Mo-99 generators.

Every nuclear medicine facility in the world can potentially benefit from using Ultralute<sup>™</sup> and the device has applications throughout the production and dispensing chain for nuclear medicine.

Importantly for shareholders, we expect each stage of development of Ultralute<sup>™</sup> will offer Cyclopharm expanded revenue and profit opportunities.



## SLIDE 16: 2017 Strategic Priorities, Trading Update and Outlook

To summarise our priorities and outlook for the current year, let me repeat the Chairman's statement that Cyclopharm's underlying EBITDA is expected to record consistent growth in 2017, benefiting from additional volume growth in our core markets and supported by a growing awareness of our core products internationally. We define underlying EBITDA to exclude USFDA trial costs and the large China order in 2016. Due to the fact that we will be expensing our FDA trial costs, we expect that CYC will report a statutory Net Loss After Tax in 2017.

As we have seen in previous years, the timing of Technegas orders in the pipeline could affect the First Half/ Second Half split, hence our guidance is based on full year outlook. To this point we affirm that YTD FY2017 trading and that guidance given to date is in line with the Board's expectations.

We expect Ultralute<sup>TM</sup> revenues, following launch in late H1 2017 to provide a small contribution to FY17 with contributions growing from FY18 and beyond.

As a result of simplifying its business strategy, Cyclopharm's operating model has become more focused and our profitability and growth prospects have been greatly enhanced, as evidenced by our third consecutive year of record operating results.

The expected United States FDA approval of Technegas is the key to a prosperous future for the Company in the huge American market and will provide Cyclopharm with the opportunity to significantly expand sales and profitability.

We are also in a strong position to realise the potential of the Technegas business in promising new markets such as Russia, and to continue the development of Ultralute<sup>TM</sup>. We are excited about the potential of Ultralute<sup>TM</sup> as a major driver of the next stage of Cyclopharm's growth.

The opportunities for developing additional Technegas indications, particularly for COPD, will continue to be a key priority in the current year and beyond. If successful, there is significant potential to expand Technegas' revenue and profitability over the medium to longer term as we engage respiratory physicians in established markets such as Canada, Europe and here in Australia.

As a management team, we are continually reviewing our organisational readiness to ensure that we have the appropriate level of managerial and governance expertise to deliver on our objectives. Examples of our preparedness can be seen in this building, our recently-opened new manufacturing facility, the new clinical expertise recently brought into the company to assist in the delivery of our growth objectives, and the expansion of our management team.

To that point I would like to take the opportunity to welcome Mathew Farag to the team as our new Chief Operating Officer and Mr Tom McDonald to the board of directors.

Whilst we cannot predict precisely when Cyclopharm will achieve key commercial milestones (such as entry into the US market and generating Technegas sales in relation to COPD), the prospects for your Company are very promising.

Cyclopharm will continue to identify and develop new opportunities for expansion and diversification, leading to steady growth in shareholder value. The Company has a clear road-map ahead of us and are looking in line with our strategic objectives, a number of



opportunities that will add shareholder value. In parallel with these opportunities the board is ever vigilant in responsibly balancing our funding capacity for these opportunities.

In closing, may I thank all of my colleagues who have contributed to the growth of the Company over recent years and express my gratitude to my fellow Board members for their unflagging support and wise counsel.

Lastly, may I thank you, our shareholders, for staying the course with Cyclopharm through some difficult times and now continuing on the path with us during a highly prospective time in the Company's history.

I am honoured as Managing Director to be given the opportunity to reward shareholders who entrust us with their investment in Cyclopharm, but it is also a privilege to work to improve patient healthcare outcomes globally as we deploy Cyclopharm's products and services in an ever-increasing number of countries and applications.

Thank you for your attention. I will now hand back to the Chairman.

Janes & MCBreyer

James McBrayer Managing Director and Company Secretary

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