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Nuclear Medicine

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

Managing Director's Address

Slide 7 Managing Director's Address

Thank you, David.

Slide 8 – Delivering on our growth objectives

Cyclopharm delivered another solid financial performance in 2022 and continues to make progress on the execution of all of our four major growth objectives. They are:

- ✓ Grow Technegas™ sales
- ✓ Expand the use of Technegas™
- ✓ Leverage core strengths to continue to accelerate our third-party distribution business
- ✓ Identify, develop and commercialise complementary innovative technology

Against these objectives, during 2022 Cyclopharm continued to deliver record revenue. Our core Technegas™ products are now available in 64 countries, with 8 of our offices directly servicing 18 out of those countries

We also made significant progress towards our transformational growth opportunities. We are now in the final stage of the approval process with the United States Food and Drug Administration (USFDA) to commence US sales in 2023 of Technegas™, our core proprietary technology used in functional lung imaging.

Whilst actively progressing USFDA approval, the company continued to invest in further R&D and support of clinicians to expand the use of Technegas™ in new diagnostic applications as part of our 'Beyond PE' initiatives. Cyclopharm will continue to leverage our expanding global footprint, regulatory expertise and direct marketing capabilities to grow global Technegas™ sales and to continue the rapid expansion of our successful third-party distribution partnerships business.

Slide 9 – 2022 Financial Highlights

Financial Performance

Despite the impact of residual effects of the COVID-19 pandemic and global supply chain disruptions, Cyclopharm generated record sales revenues in 2022 of $23.2 million, a 31.1% increase over the prior year. Revenue from sales of Technegas™ generators and Patient Administration Set (PAS) consumables remained robust, attaining pre-COVID levels for the first time since the pandemic's onset.

Cyclopharm grew new third-party distribution revenue to $9.2M in 2022, more than double the prior year. Third-party distribution consists of a complementary mix of radiopharmaceuticals, capital equipment and associated consumables. Cyclopharm

expects to continue to expand this ancillary revenue stream through a wider range of third-party partnerships to a broader geographic reach in the coming year.

As anticipated, Cyclopharm recorded a loss after tax of $6.6 million, compared to $5.0 million in 2021. This figure included $2.97 million of expenses associated with the USFDA approval process in 2022. In total, $19.2 million has been expensed on the current USFDA approval process over the past 9 years, which reflects the Board's commitment and confidence in the anticipated returns from Technegas™ sales in the USA market..

Throughout 2022 Cyclopharm continued to defend its valuable Intellectual Property vigorously and successfully against the former employees that we allege conspired with each other, unlawfully by using the Cyclopharm's confidential information, and breached their employment and fiduciary duties to the Company. Litigation expenses were $0.95 million in 2022 compared to $1.09 million in 2021.

A judgement totalling approximately €0.4 million in favour of Cyclopharm was handed down in Germany against Mr Bjorn Altmann in December 2022. Given the timing of receipt of the official judgment and the timing of enforcing the judgment, this favourable award is an event subsequent to the close of 2022 financials. As a consequence, the financial benefit will be recorded this year.

The Company will continue to defend its intellectual property in the German and Australian courts. Good progress is being made to resolve these matters and the Company is confident that legal proceedings will conclude by 2024.

Staffing costs increased over the period by $0.31 million predominantly driven by the increasing costs of global regulatory compliance and USFDA readiness.

End of year results were further impacted by a significant increase in distribution costs. Distribution costs of $2.38 million were recorded in 2022.This increase is the combined result of the pleasing growth in the distribution of third-party products and the negative impact the pandemic has had on manufacturing, distribution and logistics globally. Over the past few months, the Company has started to see some encouraging cost-base improvements in the cost of logistics as worldwide supply chains continue to recover.

Cyclopharm ended the financial year with no debt, and $20.3 m in cash. We have a strong balance sheet to fund our growth strategy. This net cash position is reflective of prudent expense and capital management supported by ongoing operational cashflows. This cash balance also ensures the Company remains appropriately capitalised to fund its ongoing USFDA approval process, the anticipated launch of Technegas™ into the US market.

Slide 10 – 2022 Operating Highlights

In 2022 we continued to successfully execute the Company's growth strategy of leveraging its significant intellectual property, technology and technical expertise. As a result we are broadening our sales and service into new countries and expanding end-use product applications with complementary, accretive businesses.

Technegas

167,350 patients benefited from the use of Technegas in 2022, up 8.7% from 2021.

Sales for our proprietary core product Technegas™ grew by 4.1% to $13.7 million, matching pre-pandemic levels.

Canada remains the largest country market by volume followed by France. In total 76 Technegas™ Generators were sold compared to 57 sold in 2021.

Sales of generators and other service revenue in 2022 represented 27.0% of Technegas™ total revenue. The remaining 73% of Technegas is from the sale of Patient Administration Sets (PAS).

Service revenue and PAS consumable sales are effectively recurring revenues.

Third-party distribution

The Technegas™ division benefited significantly from the more than doubling of third-party distribution revenues to $9.22 million. This new strategy to drive diversified ancillary revenues leveraging our expertise and leading market reputation, is delivering exceptional results. Third-party revenue was driven by a strong performance in Europe and exceptional growth in the Asia-Pacific.

Cyclopharm is leveraging its regulatory expertise and operational footprint to scale this third-party distribution business. The Company entered into agreements for Europe in 2020, followed by agreements in the Asia Pacific region in 2021. In 2022, our third-party distribution business more than doubled its revenue contribution in 2022 at solid, albeit lower, margins than Cyclopharm's proprietary Technegas™ products.

Third-party revenue is a combination of capital works projects and ongoing sales from consumables and related service support. Of the total $9.2 million third-party revenues generated in 2022, capital works projects equalled $2.4 million with the remaining $ 6.8 million are ongoing revenues associated with recurring consumable sales, radiopharmaceutical sales and service support.

These growing third-party partnerships continue to reinforce the Company's strategy of pursuing additional and complementary revenue streams whilst leveraging off of our Technegas sales and service infrastructure. The continued and substantial growth of the Company's third-party distribution business in 2022 demonstrates that it is now delivering a material contribution to the overall business.

Corporate Governance

Another highlight that occurred in 2022 was the strengthening of the Cyclopharm Board. In the previous address by our Chairman, David highlighted the addition of Kevin Barrow and Professor Greg King to our board. I too want to acknowledge the exceptional skills and experience they bring to the Company.

REGULATORY APPROVAL IN EXISTING MARKETS ACHIEVED

Cyclopharm is pleased to advise that during 2022 the Company renewed its Technegas™ CE mark under the updated European Medical Device Regulations (MDR). This achievement demonstrates Technegas™ conforms to rigorous European health and safety standards and may continue to be freely sold in any part of the European Economic Area.

In addition, during 2022 Cyclopharm renewed licensing under the Medical Device Single Audit Process (MDSAP) for participating countries. Countries we currently supply under this regime include Canada, Australia, Brazil and Japan.

BEYOND PE – SUBSTANTIALLY EXPANDING THE USE OF TECHNEGAS™

Let me move to Cyclopharm's second transformational growth opportunity – new applications Beyond PE. Technegas is best known for diagnosing pulmonary embolism (PE). However, Technegas is an analogue to the physiological distribution of oxygen in the

lung. As a result, we have a part to play in significantly broader respiratory medicine applications.

As part of our Beyond PE initiatives, Cyclopharm continues to sponsor several clinical trials that investigate new respiratory medicine applications. Our Beyond PE trials were impacted by COVID-19, particularly during 2020-2021, with a reduction in the rate of patient recruitment. Those conditions eased during the course of 2022 as patient recruitment recommenced.

As the result of our commitment in maximising the utility of our Technegas technology, we received $1.64 million R&D Tax Incentive refund that contributed to our end of year cash balance totalling $20.3 million.

Further to our existing clinical R&D program, additional initiatives related to the diagnosis and monitoring of COPD, asthma, occupational disease conditions like silicosis along with other respiratory disease states, are being evaluated. I will provide more information about these valuable activities and the substantial opportunities these initiatives represent later in my address.

USFDA APPROVAL PROCESS

Cyclopharm continues to progress toward attaining the USFDA approval required to commence commercial sales of Technegas™ in the US market later this calendar year.

The US market represents an opportunity for Cyclopharm to significantly and immediately increase sales of our Technegas™ product suite. To date we have received hundreds of formal expressions of interest to access our Technegas technology as soon as we are approved in that market. This high level of support reinforces the Board's expectation there will be strong initial demand for Technegas™ following USFDA approval.

As previously disclosed, in June 2021 Cyclopharm received a Complete Response Letter (CLR) from the USFDA. The letter outlined a definitive list of items and recommendations that are required to be addressed prior to granting approval for commercial sales of Technegas™ in the US market. A few weeks ago the Company submitted its response to the USFDA on 30 March initiating a six-month review by the USFDA. Subsequent to that lodgement, the USFDA have confirmed a target date to complete its review by 29 September this year. The USFDA has also notified the Company that they will conduct an inspection of our manufacturing facilities commencing on 31 July this year. Due to a scheduling conflict at the USFDA, this date has shifted by a week than previously advised. We are pleased that the timing of the inspection is well within the six-month review period. The Company is highly confident of commencing sales in the US market in late 2023.

Slide 11 – USA Entry Market for Pulmonary Embolism

Our first priority, following USFDA approval, is to repeat our Canadian success and market leadership by progressively displacing the current nuclear medicine ventilation imaging agents available in the United States with Technegas™ as the new standard of care.

In the United States there are approximately 4 million procedures conducted annually to rule out the presence of pulmonary embolism. Of those procedures 85% are imaged through CTPA. The initial existing market for nuclear medicine ventilation imaging in the USA for pulmonary embolism alone is estimated to be approximately US$180 million annually and the Company will be active in two stages. The first stage is the current addressable market of US$90 million, representing approximately 600,000 individual procedures conducted via nuclear medicine imaging.

Based on Cyclopharm's experience in the Canadian market, the Board reaffirms its confidence that Technegas™ can achieve a 50% share of the USA market over 2 to 3 years, post US market entry, with up to an 80% share representing around 480,000 procedures per annum achievable over a 5 to 7-year period.

In light of the rebound and growth that we have seen with Technegas as a result of the pandemic in our existing markets, we believe that we can do even better and we are upgrading our growth ambitions. We are currently evaluating how we can deliver both a faster market penetration and deliver a total market potential greater than 80% in the initial rollout.

The second stage of converting the US$180 million market is through increasing the pulmonary embolism diagnostic market imaged through nuclear medicine from 15% to 30%. Based on global experience, the unique properties of Technegas™ and the reliability of imaging outcomes enabled by our product, it is projected that the USA nuclear medicine market will adopt the 3-D imaging technique referred to as Single Photon Emission Tomography (SPECT) as opposed to the predominant current 2-D imaging or Planar Imaging. SPECT imaging provides superior outcomes to both Planar and CTPA in the diagnosis of PE

It is very important to emphasize that reimbursement for Technegas™ is based on established nuclear medicine procedures that are agnostic to the approved agents being used. Therefore, Technegas™ will be reimbursable utilising existing procedural codes.

Slide 12 – USA Customer Demand Established

Given that Technegas is seen as the nuclear medicine agent of choice for nuclear medicine ventilation imaging in all markets where we are approved, the clinical support and market demand for our technology is already established. To date we currently have more than 420 expressions of interest registered for locations in the United States.

Slide 13 – USA Commercialisation Path

Cyclopharm is well placed to leverage this immediate market demand. In 2022 Cyclopharm continued to undertake numerous activities to ensure it is well placed to rapidly commercialise Technegas™ in the USA once USFDA approval has been achieved. These activities include building inventory reserves by $2.78 million to $8.29 million as at December 2022. As part of our USA launch strategy we are targeting 200 generators in the first wave of deployment and based on the positive support to date I am confident those 200 generators already have homes. I have spent, and will continue to spend, significant time in the US to oversee the execution of these growth plans.

In order to accelerate the clinical use of Technegas in the United States once approved, the company has decided to vary our business model. We will maintain ownership of the Technegas generators and effectively lease them out.

This accelerated rollout strategy is a model where we will provide the generator with an annual license fee at no capital cost. We expect that by removing the impediment for an initial capital outlay, supported by existing procedural reimbursement codes for products such as Technegas™, clinicians and frontline workers will be enabled to drive our technology adoption.

The initial rollout of Technegas generators will be focused on high volume sites to ensure that our technology is placed in the locations where it can have the greatest clinical impact. This strategy has the economic benefit of also providing greater repeat demand for consumables and generating a faster and higher return on our initial investment.

In addition to our inventory build, in preparation for launch in the US, Cyclopharm is finalising agreements for third-party distribution, generator service and installation, and administrative support for Technegas™.

Slide 14 – Three Value Horizon

Technegas is more relevant today than when it was first invented. What has changed since the Technegas was first invented? Complementary technology has evolved. The significant advancements include better cameras, hybrid imaging, better analytical software and advancements in Artificial Intelligence … collectively they are enabling Technegas to leverage its full capabilities.

When we think about the growth potential of Technegas, we see the potential delivered in three distinct value horizons.

Once we are established in the United States and displace the inferior competitive nuclear medicine products (like we have successfully done all around the world) we will then target CTPA by seeking to double nuclear medicine's market share in diagnosing PE. These two initiatives bring our US market potential for Technegas in diagnosing pulmonary embolism to approximately USD $180 million. Because of COVID19 we are re-evaluating Horizons 1 & 2, as we believe these commercial outcomes may be achieved more rapidly than initially estimated.

Whilst the US remains our nearest opportunity, the greatest opportunity for "next level" growth is the work that we are doing to expand the use of Technegas into new indications.

Diagnosing pulmonary embolism is traditionally a one-off procedure. Most studies are negative but if you do have a blood clot, it is a life-threatening condition that they treat straight away. We typically don't see follow-up exams for PE.

Whilst a change in clinical practice doesn't happen overnight, The Future is Now. Over the past several years we have been executing a deliberate strategy to include:

- The positive clinical outcomes generated from our clinical R&D program;
- The successful Respiratory Clinician Key Opinion Leader engagement;
- Infrastructure development to engage more closely with respiratory referrers in the 18 markets we are directly servicing as well as leveraging our Global Installation base in the 64 countries we are present; and lastly
- Educating our direct nuclear medicine customers and referring respiratory clinicians on the clinical uses of Technegas Beyond PE. A more recent example of education was the recent webinar presented by the Canadian Association of Nuclear Medicine that featured updates from three of our Beyond PE initiatives.

Slide 15 – Indication Expansion Imperative

Why are we confident of delivering such growth? For those of you new to Technegas, you may not fully appreciate what makes our technology so special. Simply put, Technegas shows the clinician exactly where Oxygen is delivered and used in the lung. We are not an algorithm. We are not software. We are the actual technology that analytical software is applied to.

From that simple concept of understanding how well a lung is actually being ventilated, Technegas can potentially be used across a number of different respiratory conditions. What does that market potential look like?

According to the World Health Organisation, 3 of the top 10 causes of death are related to the lungs.

There are over half a billion sufferers in the world suffering from the chronic diseases of asthma and COPD. Of these 500 million sufferers of Asthma and COPD, there are 125 million reside in markets where nuclear medicine is well established….North America, Australasia and Europe... these are our existing markets. These are our Beyond PE markets.

Slide 16 – Beyond PE Applications

As I said before. The future is now

There is already a growing body of actual clinical papers across numerous conditions Beyond PE that Technegas is used in. These are just a few of the peer reviewed publications in support of our growth potential. Our challenge is to ensure that they become mainstream.

Slide 17 – Beyond Pulmonary Embolism Initiatives Underway

We are making that future happen in part through our R&D clinical trial program. Cyclopharm is confident that the extension of Technegas™ into new applications such as the diagnosis and monitoring of COPD, asthma, Long-COVID, lung cancer and other respiratory disease states like silicosis will create substantive opportunities globally to exponentially expand the market for Technegas™ beyond its traditional PE market.

Slide 18 – Key Catalysts

As investors, these are the milestones that you can expect to see over the next 2 years.

- Certainly, the USA is our nearest term significant opportunity;
- Once approved, we expect rapid market penetration; and
- From that launch we also expect to leverage off that momentum as we expand into more substantive applications Beyond PE.

Slide 19 – CYC Investment Case

To summarise….Cyclopharm is:

- A Growing Medtech with a very strong balance sheet;
- Technegas is clinically recognised First in Class in diagnosing Pulmonary Embolism across the 64 countries where available;
- Technegas generates recurring revenues with high margins;
- Diversification in the provision of our successful and growing third-party product distribution offering allows us to leverage our Technegas infrastructure.
- Entry into the USA market is our nearest term large growth opportunity;
- The use of Technegas in chronic indications like COPD and Asthma will transform our market potential.

Put simply, Technegas is a best in class de-risked technology generating sustained revenues in 64 countries. It has substantial upside, both through our market expansion plans in the US following USFDA approval and our clinical expansion plans Beyond PE.

In closing, I thank all my colleagues, the Cyclopharm Board, with a special thanks to my entire global team, who collectively have contributed to the growth of the Company over recent years.
Finally, to you our shareholders…. I want to thank you for your support and confidence. It is a privilege to work for a company that makes such a significant impact in people's lives every day. The future is bright for your company and I look forward to providing you updates to our goals as and when they occur.

Slide 20 – Business Q&A

I will now answer any questions relating to the company's business activities.

James McBrayer
Managing Director and Company Secretary

This ASX announcement was approved and authorised for release by James McBrayer, Managing Director, CEO and Company Secretary.

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Cyclopharm Limited
Cyclopharm is an ASX Listed radiopharmaceutical company servicing the global medical community. The Company's mission is to provide nuclear medicine and other clinicians with the ability to improve patient care outcomes. Cyclopharm achieves this objective primarily through the provision of its core radiopharmaceutical product, Technegas™ used in functional lung ventilation imaging.

Technegas™
The Technegas™ technology is a structured ultra-fine dispersion of radioactive labelled carbon, produced by using dried Technetium-99m in a carbon crucible, micro furnaced for a few seconds at around 2,700^{o} C. The resultant gas like 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 evaluating functional ventilation imaging. Historically used in the diagnosis of pulmonary embolism, Technegas™, together with advancements in complementary technology to multimodality imaging and analytical software, is being used in other disease states to include COPD, asthma, pulmonary hypertension and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.