cyclopharm
Nuclear Medicine

cyclomedica
technegas
cyclopet
ultralute

Cyclopharm Ltd
ABN 74 116 931 250
Unit 4, 1 The Crescent
Kingsgrove NSW 2208 Australia
T 61 2 9541 0411
F 61 2 9543 0960
www.cyclopharm.com.au

27 May 2024

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

Managing Director's Address

Thank you David.

Slide 7 – Managing Director's address

Good morning ladies and gentlemen, my name is James McBrayer, the Managing Director of Cyclopharm. I would like to extend a warm welcome to shareholders here in the room and to those viewing this recording at a later date.

Slides 8 – 2023 Financial Highlights

It is my pleasure to provide you with a summary of our 2023 performance and our exciting outlook.

I will also highlight key details from our recent successful capital raising and update you on our growth strategy which has prompted such strong support from existing shareholders and attracted new and high-quality institutional investment from Australia and overseas. Cyclopharm is a growing and successful company. We continue to make significant investments in growth initiatives, particularly in the US, which I am excited to say are beginning to bear fruit and deliver returns for shareholders. And there is so much more to come.

For those new to our business, Cyclopharm is a leading, global nuclear medicine company specialising in lung health. Our core business is the supplying our proprietary Technegas radiopharmaceutical technology, used in functional lung ventilation imaging. Technegas is the nuclear medicine ventilation imaging agent of choice around the world in the major markets which we operate. We absolutely expect our experience to be no different as we expand into the United States, our 65th country market. And with regulatory approvals currently being finalised, we expect in the coming months to add three more Eastern European countries to this total.

In terms of scale, the US is the biggest healthcare market in the world. On average, The US spends almost double per person per annum than other comparable countries[1] and their use of diagnostic procedures make the US opportunity for Technegas larger than that of all of the other 64 countries we service combined. As well as its credentials as a global imaging agent of choice for diagnosing pulmonary embolism, Technegas is leveraging complementary technology, including AI, to deliver an expanded range of clinical applications.

Overall, during the 2023 Financial Year, Cyclopharm continued to generate record Group revenue of $32.21 million up 29.0% from the previous year. Revenues from direct sales in 2023 of $26.34 million, were up 15.1% from $22.88 million in the prior year.

[1] https://www.healthsystemtracker.org

Revenue from third-party distribution sales continued to grow strongly, up $2.70 million to $11.91 million, a rise of 29.3%. In 2020 we initiated this diversification strategy in our direct markets. Our success is based on leveraging our sales, service, and regulatory expertise, to include pharmaceutical wholesale licenses, in those markets where we have a direct presence. This revenue, whilst at lower margin than sales of Technegas™ products, is expected to continue to complement revenues in existing markets.

Cyclopharm recorded a loss after tax of $4.70 million in 2023, compared to $6.61 million in 2022. This figure includes $3.49 million of expenses associated with the USFDA approval process which was nearly entirely offset by a $3.16 million reversal of an impairment charge to the Cyclotron facility in recognition of the financial contributions derived from Cyclotek NSW Pty Ltd. It also included $1.28 million of recovered litigation costs from ongoing strategies to actively protect Cyclopharm's commercial interests in Europe and Australia.

A total of $23.41 million has been expensed, over the past 15 years, on securing USFDA approval to sell Technegas™ in the USA. That approval was granted on 29 September 2023.

Cyclopharm ended the financial year with a healthy balance sheet and a cash balance of approximately $11.73 million, reflecting prudent expense and capital management supported by ongoing operational cashflows. This cash balance allowed the Company to launch the rollout of Technegas™ in the US, continue R&D activities into new applications for Technegas and to pay total dividends of 0.5 cents a share for 2023.

Slides 9 – 2023 Operational Highlights

2023 was a milestone year for the company with the granting of USFDA approval for the sale of Technegas in the US, the the world's largest diagnostic imaging market and the largest market for this product globally. This approval is the long-awaited catalyst that we expect will drive significant growth of sales for our core Technegas product, and when combined with our rapidly growing Third-party Distribution business, represents the next growth phase at Cyclopharm.

Sales of our proprietary Technegas™ Systems and PAS consumables, used primarily in the detection of pulmonary embolism, performed well in 2023 with Technegas™ revenues increasing by 5.6% to $14.43 million over the FY2022 performance.

Technegas is now sold in 65 countries globally, including the new US market from the first of this year. While sales into Europe represent a large proportion of our revenue, we continue to rapidly grow Technegas sales in emerging markets such as Asia and South America and remain confident in the returns Technegas can generate in the US. Alongside securing USFDA approval for Technegas in September 2023 we ensured during the year that all regulatory renewals covering the other 64 markets where Technegas is available have been maintained.

Cyclopharm continued to develop opportunities to broaden Technegas applications, beyond our traditional indication for diagnosing pulmonary embolism, into exponentially larger addressable markets such as Chronic Obstructive Pulmonary Disease ("COPD"), Asthma and lung cancer. These markets are strategically important as they have the potential to underpin much larger, longer-term growth for the business.

Our key focus is to ensure the company is well placed to take advantage of our growth opportunities to accelerate delivery of shareholder value. This next growth phase will be driven by the roll out of Technegas into the US, which as I have said, is the largest and, as yet, untapped single market for our core product. We expect this growth phase to be enhanced by the continued expansion of our third-party distribution business and sustained

over the longer term by our Beyond PE initiatives targeting access to even bigger respiratory markets. In combination these elements have the potential to deliver an exponential step change in our business' performance.

To ensure we have the firepower to maximise these growth opportunities, we announced last Friday a share placement to sophisticated, professional and other institutional investors to raise $20 million at a price of A$1.42 per new share. As you've heard from David, the placement was oversubscribed, with strong support from existing shareholders and new, high quality domestic and international institutions. We view this support for the institutional placement as a clear endorsement of our growth strategy. The addition of these funds ensures that we are fully funded to deliver on our expectation of profitability in H2 2025.

As David mentioned, our retail shareholders will have an opportunity to participate in this capital initiative through a Share Purchase Plan to raise up to $2 million. This will allow eligible shareholders in Australia, New Zealand and United Kingdom to apply for up to $30,000 of new shares at the same price as the placement shares, subject to scale back.

The combination of the $20 million institutional placement, the SPP, our existing cash balances and a growth strategy that has strong backing from shareholders means the business is well positioned to accelerate into this new growth phase and maintain ongoing research and development activities and product and systems enhancements.

I would like to thank those shareholders, both new and existing, that have shown such strong support for our company at such an exciting moment in Cyclopharm's development.

Slide 10 – Largest addressable market globally

Clearly, our primary focus is on expanding our sales footprint in the US. USFDA approval to commence commercial sales in the US market provides Cyclopharm access to the single largest market for Technegas™ globally. There are approximately 4 million procedures conducted annually, in the US, to rule out the presence of PE. Of those procedures, 85% are imaged through Computed Tomography Pulmonary Angiography, commonly known as a CT scan. The remaining 15%, or around 600,000 procedures, use nuclear medicine to diagnose PE.

Cyclopharm estimates these 600,000 nuclear medicine procedures represent an initial addressable market worth approximately US$90 million annually, for the diagnosis of Pulmonary Embolism (PE). Cyclopharm's rollout plan for Technegas™ in the US is targeting up to 2,000 facilities. In advance of this rollout, the company built up inventory levels to assemble 200 systems for deployment within the US market. In fact, we produced more Technegas systems in the past six months, to include Christmas and New Year's, than we have the entire history of the company in any full year.

Cyclopharm's roll out plan in the US includes a Horizon 1 target of 600,000 procedures as Technegas displaces less effective, incumbent technologies. Most studies performed in the US to diagnose pulmonary embolism is through CTPA. Nuclear medicine 3D SPECT imaging in Pulmonary Embolism (PE), using Technegas, is proven to be clinically superior at diagnosing PE at a significantly lower radiation dose to CT scans. We continue to leverage lessons learned from the successful entry of Technegas into our existing 64 established country markets, including Canada, our current largest country market. Here the company displaced the same competitive products currently being used in the US to a level where almost all of Canada's nuclear medicine ventilation procedures are now imaged using Technegas™.

Based on Cyclopharm's experience in the Canadian market and globally, the company reaffirms expectations that we can achieve at least 80% share of this existing 600,000

procedure market within 5 years. In addition, we believe the superior imaging and safety profile of Technegas will allow us to double the existing US nuclear medicine PE market, currently dominated by CTPA, from 15% to 30% within 8 years, which translates into a total US$180 million US opportunity for PE.

Another benefit from entry into the US market is it significantly broadens the opportunity to drive our Beyond PE strategy. Beyond PE is targeting the use of Technegas for the diagnosis and treatment of additional chronic respiratory disease states such as COPD, Asthma, lung cancer, silicosis and Long COVID, which represent markets exponentially larger than the markets for the diagnosis of acute Pulmonary Embolism.

Slide 11 – US customer demand established

Prior to USFDA approval, the existence of significant pre-existing demand for Technegas™ in the US healthcare market saw US clinicians and their representative bodies lobbying heavily for access to Technegas™. Cyclopharm logged over 420 individual expressions of interest even before USFDA approval was secured. Following approval, our first commercial contract for the use of Technegas in the US was signed in December 2023 with our first commercial revenues commencing in February 2024. As recently announced to the market, we have since issued 136 Proposals and Contracts representing over 400 US locations with 6 Technegas revenue generating systems fully installed, with a further 6 sites under contract and scheduling implementation.

Since launching in the US, medical institutions currently using Technegas in the US have been reimbursed under a Center for Medicare/Medicaid Services ("CMS") via a miscellaneous product code. Since USFDA approval, Cyclopharm has engaged with CMS to secure our own formulary code and I am pleased to report that, from 1 July 2024, Technegas will have its own unique CMS formulary code that will streamline the reimbursement administration process.

Technegas pricing in the US is at a premium cost to existing products. To enable clinicians to introduce Technegas without a financial impact, we have also applied for Pass-Through Status through CMS. Pass-Through status will allow each site to be fully reimbursed for the use of Technegas for a period of up to three years. A decision on Pass-Through Status is expected by 1 October 2024.

While the timing of take-up of Technegas since USFDA approval in late 2023 has been impacted by variable internal sign-off processes at each medical institution, as well as the timing of the Pass-Through decision by CMS, levels of clinical demand remain exceptionally strong throughout the US nuclear medicine community. A positive decision on Pass-Through Status is expected to accelerate the take up of our product.

Our rollout strategy is clear. Cyclopharm is prioritising US medical facilities in the following order:

1. US Clinical trial sites involved in Technegas'™ New Drug Application (NDA).
2. Key Opinion Leaders involved in the NDA process
3. Advocates that have supported Technegas™ during the NDA process
4. Large Government and Large Private Health Care Groups
5. Large University affiliated teaching hospitals

And while we are following this prioritization strategy, we continue to engage with key opinion leaders, build our US team, support US based Beyond PE programs and develop educational material to raise awareness of Technegas.

Next month at the annual Society of Nuclear Medicine and Molecular Imaging conference, will be our first opportunity to engage on a large scale with the nuclear medicine since gaining USFDA approval. Historically at this meeting we could only provide information.

We are thrilled to finally be able to move our dialogue from clinical information with potential customer to planned implementation.

Slide 12 – USA Commercialisation Pathway

As this slide shows, our commercialisation pathway in the US is comprehensive and well established with many of the 'boxes ticked' to date. During the lengthy USDFA approval process we proactively engaged with hospitals and clinicians and established a demand and delivery pathway for the Technegas product.

We are now working with medical institutions across the USA to help them navigate their various internal approval phases to convert the significant latent demand for Technegas into executed contracts.

Slide 13 – Three distinct value horizons

Horizon 1 – As I mentioned, Cyclopharm is targeting the existing 600,000 nuclear medicine imaging procedures for PE, a market which it estimates to be approximately US$90 million per annum. The company expects that it can achieve an 80% share of this existing market within 5 years.

Horizon 2 – During this stage we believe the superior clinical and safety profile of Technegas will allow us to double the existing US nuclear medicine PE market, currently dominated by CTPA, from 15% to 30% within 8 years, which translates into a combined Horizon 1 and 2 US$180 million opportunity for diagnosing PE with Technegas.

Horizon 3 – While our Beyond PE strategy is a global initiative, the US represents the largest individual market in the world for diagnostic lung imaging. The USFDA approval is for a broad indication that supports our Beyond PE strategy for future use across a wide range of other respiratory disease states to include Chronic Obstructive Pulmonary Disease (COPD), Asthma and lung cancer.

Cyclopharm is confident that the extension of Technegas™ into these new applications in the US will drive substantive opportunities globally to exponentially expand the use of Technegas™ beyond its traditional PE market.

Slide 14 – Indication Expansion

By way of background, lung disease in 2019 accounted for **6 million deaths** worldwide (**12%** of all deaths). By 2030, COPD, Lower Respiratory Infections and Lung Cancer will be the **3rd, 4th and 6th largest causes of death** by 2030. As a result, highly accurate diagnosis of these diseases will not only save lives but save squandered treatment costs from the misdiagnosis utilising current techniques. And misdiagnosis can be fatal. These factors alone highlight the exceptional growth potential for Technegas.

Slide 15 - Beyond PE applications of V/Q SPECT(/CT)

Technegas™ is the pre-eminent functional ventilation imaging agent used in diagnosing Pulmonary Embolism as referenced in both the recently published Canadian Association of Nuclear Medicine Guidelines[2] and the updated 2019 European Association of Nuclear Medicine Guidelines[3]. Both guidelines also reinforce the superior use of Technegas™ particularly in patients with COPD and the potential for nuclear medicine imaging.

[2] Leblanc, M., et al. 2024. Guidelines for ventilation/perfusion (V/P SPECT) in pulmonary embolism. Journal of Medical Imaging and Radiation Sciences, 55(1), pp.158-162EANM Guidelines
[3] Bajc M, Schümichen et al. EANM guideline for ventilation/perfusion single-photon emission computed tomography (SPECT) for diagnosis of pulmonary embolism and beyond. European Journal of Nuclear Medicine and Molecular Imaging. 2019;46(12): 2429–2451.

This slide illustrates the volume of research to date and underway into the many additional applications, Beyond PE, where Technegas' superior profile give it an advantage, including the management and diagnosis of Pulmonary Hypertension, COPD, Lung cancer and Asthma.

Slide 16 – Beyond PE Initiatives Underway

In 2023, Cyclopharm continued to accelerate opportunities to develop our Beyond PE strategy with clinical trials designed to expand the use of Technegas™ into the treatment and management of additional and exponentially larger chronic indications, such as COPD, Asthma, Long-COVID and lung cancer.

Outputs of these initiatives included two clinical trial results published in 2023. The first publication was by McMaster University in Hamilton, Canada, on the use of Technegas™ as part of the surgical planning for lung cancer patients. McMaster University published a paper entitled "*Comparison of ventilation defects quantified by Technegas SPECT and hyperpolarized ^{129}Xe MRI*"[4]. The publication assessed lung cancer patients undergoing lung resection surgery. The results of the study underscored the clinical utility of Technegas™ in assessing more broadly ventilation abnormalities in pulmonary obstructive disease.

The second publication by the Hunter Medical Research Institute (HMRI), a research institute affiliated with the University of Newcastle in Australia, found Technegas™ to be a predictive indicator or 'Treatable Trait' for drug response in patients with severe asthma. The HMRI publication entitled "*Ventilation Heterogeneity (VH)Is a Treatable Trait in Severe Asthma*"[5] found that a scoring system leveraging the unique properties of Technegas "*provided a quantitative metric that correlated to the severity of adverse clinical outcomes in severe asthma and corresponding improvement with biologic therapy. These results support the growing body of work that shows that VH is clinically significant, measurable, and treatable, which establishes VH as a treatable trait in severe asthma and, potentially, other respiratory diseases*."

Both these encouraging results adding to an already growing body of clinical research, from globally respected respiratory medical institutions, underscore the strength and the opportunity our Beyond PE strategy represents.

Slide 17 – Upcoming milestones and growth catalysts

We look forward to updating shareholders on some upcoming milestones during the coming months.

- Next month we have the formal launch of Technegas at the First North American Society of Nuclear Medicine and Molecular Imaging (SNMMI) conference, where we will have a significant presence
- As I mentioned earlier, we are at the final stages of regulatory approval and expect to expand the use of Technegas in three more Eastern European countries, bringing our total footprint to 68 countries globally.
- By October 1 we will hear from CMS in the US about the outcome of our Pass-Through status
- We will share updates about Technegas in publications and Beyond PE clinical trial initiatives
- Any material business partner product distribution contracts or initiatives
- Regular updates on USA progress

[4] Radadia N, et al. Comparison of ventilation defects quantified by Technegas spect and hyperpolarized 129Xe MRI. Frontiers in Physiology. 2023; 14.
[5] Gibson PG, et al. Ventilation heterogeneity is a treatable trait in severe asthma. The Journal of Allergy and Clinical Immunology: In Practice. 2024; 12(4): 929-935

Slide 18 – Cyclopharm Investment Case

Following USFDA approval, the Company is entering its next growth phase from a position of strength, having delivered record 2023 sales revenues, including robust sales of Technegas™ and increasing third-party sales. The Company has already commenced sales in the USA and we expect that to continue at pace in 2024.

Technegas is the world's best imaging agent for functional lung ventilation and allows clinicians to make more accurate diagnoses for Pulmonary Embolism compared to conventional imaging. Technegas is recommended by the relevant peak industry bodies throughout Europe and North America; and more recently was the subject of significant industry support in the US by clinicians asking for its approval by the USFDA, as competitor products proved to be inferior. The Company's entry into the US market is also expected to accelerate our Beyond PE strategy.

An essential part of delivering our overall strategy is to attract and retain top talent within our growing team.

As David mentioned earlier, Cyclopharm announced the appointment of Mr Jason Smith as Chief Financial Officer (CFO), effective 26 February 2024. Jason brings a wealth of industry experience in Financial Control and Accounting, both at Cochlear and at a large multinational in the United Kingdom.

Cyclopharm has never been better placed to extend its market leadership in lung imaging and drive ongoing growth in revenue and earnings. I look forward to continuing to report to our shareholders on the progress the company is making.

Finally, I would like to thank all my colleagues who have contributed to the growth of the Company over recent years and assure you that the Cyclopharm management team, with the ongoing support of the Board, remains absolutely committed to delivering positive health outcomes for our patients and growing financial rewards to our shareholders.

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.

For more information, please contact:

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

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.