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

# 2025 AGM - 30 May 2025 MD'S Address

## Slide 7

Thank you, David, and good morning, everyone.

To our valued shareholders joining us here in person, and to those connecting online, thank you for being with us.

I am James McBrayer, Managing Director of Cyclopharm. It is a privilege to share with you what has been a remarkable year for your company—one defined by building momentum and opportunity.

## Slides 8 - 2024 Full Year Financial Results

Let me start with the headline: 2024 was a record year for Cyclopharm.

Most notably, we began commercial sales in the United States following **FDA approval in late 2023**—a landmark moment for Cyclopharm.

First, let's drill into the numbers.

#### Slides 9 - 2024 Financial Overview

During the 2024 Financial Year, Cyclopharm generated record group sales revenue of \$27.6 million up 5% from the previous year and continued to deliver profitable Technegas and third-party sales across its existing 65 markets.

Sales of Technegas reached **\$15.2 million globally**, also up 5%. The second half was particularly strong—up 14%—driven by our early US market entry. **Initial US sales alone totalled \$827,000** in 2024, with that trajectory accelerating.

As anticipated, Cyclopharm recorded a loss after tax of \$13.2 million in 2024. This outcome compared to the loss after tax of \$4.7 million in 2023, which benefitted from \$3.2 million of adjustments. Staffing costs increased by \$4.42 million in 2024 predominantly driven by our growing US presence.

The Company also absorbed the increasing costs of global regulatory compliance and the Company's investment in manufacturing capacity to service the US market demand. I'm pleased to report that all regulatory renewals in the 66 markets we now serve have been



maintained.

Cyclopharm's cash balance at the 31<sup>st</sup> of December 2024 was \$20.6 million, reflecting prudent expense and capital management supported by ongoing operational cashflows and a strongly supported capital raise in mid-2024. This cash position balance allows us to support our growth strategies.

On the back of our launch in the world's largest healthcare market, the **US\$180 million potential** of that market for diagnosing Pulmonary Embolism is beginning to materialise. And it's important to note—this is not a speculative forecast. It's built on the same adoption curve we've seen play out globally, where **Technegas commands 85% of the market**. I'll speak more about that later.

Today, we are establishing the US as the **engine of our next growth phase**.

It is pleasing to see our roll out of Technegas in the US accelerating but it is also pleasing to see the sustained Technegas sales in our other 65 markets around the globe. It is also satisfying to see our Third-Party distribution business continue to grow rapidly from a standing start in 2020. In 2024 Third Party distribution contributed \$12.4 million or 45% of total sales revenues making it a significant additional engine for our next growth phase.

## Slides 10 – 2024 Trading Overview

Our **patient administration sets**—the consumables used for each individual patient scan accounted for nearly 73% of Technegas revenue. This speaks to the power of our annuity model: once a site is installed, it generates ongoing revenue from consumables and service support.

55 Technegas new systems were sold globally in 2024 compared to 58 in the prior year. These sales do not include the 17 systems placed in the US market in 2024. These US systems are charged out at an annual access fee and remain the property of Cyclopharm. Third-party sales in our 17 direct markets grew 4% year-on-year and now account for nearly **half of our total revenue**. That diversification of income has proven strategically valuable.

In 2024, Our Third-Party distribution business generated \$12.36 million of revenue, compared to \$11.91 million in 2023, which boosted total revenues by 4%. This revenue performance was strongly weighted to the second half which was up 54% on the second half of 2023.

This result highlights that Third party equipment sales and installations can be lumpy as they follow competitive tenders or are on a project-by-project basis. In 2024 third party equipment sales revenue was up 83% in the 2nd half but overall was down 35% on the prior year. Consumables and service revenue were up 26% overall and, like equipment sales, also recorded a strong second half.

Cyclopharm continued to invest in the future by expanding the range of indications Technegas can be used to treat and diagnose respiratory conditions, such as Chronic Obstructive Pulmonary Disease ("COPD") and Asthma. This is our 'Beyond PE' strategy that has the potential to open up much larger markets and longer-term growth for the business.

In 2024 the existing trials into these bigger opportunities continued to progress with the initiation of a new 665 patient multi-centre in France targeted at improving the detection of residual pulmonary vascular obstruction.



## Slide 11 – Understanding Technegas

Let me pause to reinforce what Technegas is and why it is the leading technology in the market.

Technegas is **not** just a device or a pharmaceutical—it's a fully integrated **drug-deviceservice combination**. It's a nanotechnology-based agent that delivers unrivalled **functional lung imaging**, with the capability to reach every part of the lung where oxygen goes. This precise imaging allows physicians to not just see anatomical structure, but the **actual function** of the lung.

#### Slide 12 – Technegas – Proven Technology

Why are we so confident of the US potential? Technegas is already the nuclear medicine **standard of care in over 65 markets** we currently service.

Despite our technology having been safely used across the globe, the unique characteristics of Technegas created a long road to USFDA approval. This lengthy regulatory process was in part because the USFDA characterised Technegas as a combination product, both a device and a pharmaceutical, that was manufactured at point of care. While getting approval was onerous, having it means we are now protected by this high regulatory barrier to entry.

To produce Technegas for inhalation, a Technegas System must be installed within a nuclear medicine department. Each patient administration then requires a crucible, the pharmaceutical component of the product, along with the Patient Administration Set.

We also provide training and support for each system during installation. In markets where we are direct to the customer there is also ongoing service and support revenue streams.

#### Slide 13 – Overview of Third-Party Products

Cyclopharm's Third-Party distribution is driven by our strategy to deal directly with our end user. Having direct sales and service presence in 17 of our 66 markets is a rare asset. This we can do this by leveraging our regulatory expertise, operational footprint and existing sales and service infrastructure to diversify revenue stream.

#### Slide 14 – Overview of Third-Party Products

Like Technegas, many of our Third-Party Products have an equipment, pharmaceutical and service element. This new business has experienced exceptional growth and has supported Cyclopharm's overall revenue performance since launch.

For those of you with us today, we have an example of some of the equipment we distribute for our partners.

Cyclopharm's ability to continue to grow the Third-Party distribution business demonstrates it is core to current and future earnings. This segment provides critical recurring income, helps fund our US growth, and diversifies our earnings base.

#### Slide 15 - Technegas USA Expansion



# Back to the US:

Our strategy in the US has been very deliberate and strategic.

- We have secured our beachhead with a scalable operation targeting some of the most prominent clinical sites in the USA.
- We have established contracts with the largest private and government healthcare providers in the USA.
- We have secured the critically important reimbursement for our product and
- Have grown an enviable pipeline for product launch.

We did incur some delays as the policy frameworks under the new US Government became less certain and our initial traction with hospital administration to install technegas systems has taken longer than anticipated. Accordingly, we revised our growth target for total US installations to 250 – 300 in the second half of 2026. I am encouraged to say that despite the uncertainty, we have continued to sign important new US contracts and, given the clinician demand for our technology, we are very well placed for accelerated growth.

To further derisk our US operations we have plans to establish, when appropriate, US manufacturing and we have long standing relationships and support from the top echelons of US key opinion leaders.

## Slide 16- Technegas USA Implementation Update

As you can see from this slide, Technegas is now clinically used in some of the leading institutions across the USA.

Within a year, **Technegas installations in the US grew from 6 at mid-year to 17 by December 2024**, and as at **today we are at 33** installations. More importantly, our revenue trajectory is following that of our installations:

- At the half last year sales were at AUD \$245,000
- At full year sales grew to AUD \$827,000
- On 1 April this year we announced that we had reached USD \$1m cumulative sales mark or \$1.6 AUD by the end of the first Quarter 2025
- As of today that cumulative revenue number has grown to USD \$1.35 million or AUD \$2.16 million

Initially we prioritised **high-volume**, **high-profile and government-aligned sites**, signing substantial contracts with:

- The US Government that covers Veterans Administration and Department of Defense Hospitals, and
- The **largest private hospital group in the US**, unlocking direct access to 168 sites and influence across a buying group with **1,800 additional locations**.

These two contracts combined represent a potential of up to 300 nuclear medicine department installations.

This sales growth acceleration has been supported by our ability to secure full Transitional Pass-Through reimbursement for Technegas<sup>™</sup> by the Center for Medicare and Medicaid Services (CMS) in the US in July 2024, an essential step to drive customer conversion to



# Technegas™.

With reimbursement now in hand and a substantial and growing sales pipeline, we are now expanding our sales force in the US.

# Slide 17 - Broad Indication for use approved by USFDA

As Technegas<sup>™</sup> is more widely adopted in the US market it is expected to accelerate our Beyond PE growth initiatives with a potential global addressable market of US\$900 million. The USFDA approval for Technegas<sup>™</sup> is a broad indication that includes its stated use 'for the visualisation of pulmonary ventilation'. This expansive indication allows use of Technegas<sup>™</sup> in the US across multiple applications beyond PE in the field of respiratory medicine without the need for additional USFDA approvals. This broad indication is expected to facilitate independent US clinical trials that will likely accelerate Cyclopharm's Beyond PE initiatives targeting other respiratory disease states, such as Chronic Obstructive Pulmonary Disease (COPD), Asthma, long COVID and lung cancer.

## Slide 18 - Nuclear medicine published Survey

Earlier I mentioned that Technegas holds an 85% market share in our established markets. This statement is supported by an independent survey conducted before Technegas'™ US approval. This independent conclusion reinforces our confidence Technegas will displace incumbent technologies – thanks to clinical demand, contracts in place and reimbursement certainty - to become the dominant nuclear medicine functional lung imaging technology in the US and support its broader adoption across other respiratory disease states, Beyond PE.

## Slide 19 - US Economic Model

The US Roll out strategy is built on an economic model that is slightly different to the model we use elsewhere. We do not sell Technegas systems in the US, rather we effectively lease them to US nuclear medicine departments for an annual fee of US\$7,000 with a one-off US\$7,000 installation and training fee.

This model avoids nuclear medicine departments having to go through a protracted capital expenditure approval process. Importantly, this model unlocks the annuity stream of revenue from the sales of the patient consumables for each system. We have been targeting high use US sites in the early roll out of Technegas which we estimate will generate US\$70, 0000 per site per annum.

Our initial target is to install Technegas at 2,000 of the existing 8,000 US nuclear medicine departments. As I mentioned, we expect to have 250 – 300 units operational in the US by the second half of 2026. We are looking at three stages of value creation in the US. Stage one displacing the incumbent nuclear imaging technology for PE which we estimate to be approximately US\$90 million per annum.

Stage 2 increasing the total US PE diagnostic market that is imaged through nuclear medicine from 15% to 30% by replacing the use of CTPA, a procedure that subjects patients to considerably higher radiation doses than a nuclear medicine study. This CTPA conversion target raises the total potential PE market for Technegas<sup>™</sup> in the US to US\$180 million annually.

The third stage goes back to the USFDA approval for a broad indication that supports future



use across a wide range of other respiratory disease states to include Chronic Obstructive Pulmonary Disease (COPD), Asthma, Long-COVID and lung cancer. We estimate this longer term beyond PE indications to be worth over US\$1 billion globally. For example, we estimate the global COPD market to be approximately 30 times the size of the PE market.

# Slide 20 - Technegas – Proven Technology – De-risked Opportunity

- Our market opportunity in the US is substantial: -Technegas is established as the bestin-class technology across multiple global markets.
- We have a broad USFDA indication that allows an expansion of Technegas beyond PE.
- We have already secured US Government and private contracts,
- We have increased US inventory, and
- We have in place Medicare and Medicaid reimbursement, which is absolutely accelerating adoption.

While there is some policy uncertainty in the US healthcare market, the underlying clinical support for our technology is overwhelming.

## Slide 21 – Beyond PE

The next evolution for Technegas is already underway. The broad USFDA approval for Technegas establishes a platform to maximise Technegas' clinical use across a wide range of respiratory applications. Having access to top-tier US clinicians and to the patients they serve is expected to help drive our Beyond PE strategy.

## Slide 22 - Evolution of Ventilation Imaging

As stated in the independent survey referenced earlier, the availability of Technegas in the US is expected to be game-changing. Prior to our entry into the market, US clinicians were primarily using basic 2D imaging. Now that Technegas is available there is the opportunity to access much more effective 3D lung imaging using Technegas in combination with single-photon emission computed tomography or SPECT scans. This provides clinicians the best of both worlds, the ability to see both anatomy and function.

Using the true functional imaging capabilities of Technegas, combined with advanced imaging techniques, analytical software and AI, we are seeing the Beyond PE opportunities opening up in not only diagnosis but patient management of chronic conditions that are exponentially larger in potential that the PE market alone.

## Slide 23 – Beyond PE applications

This combination of Technegas with modern imaging technologies, quantification software and AI analysis enhances the effectiveness of Technegas in managing PE. These technological advancements are also expected to accelerate its use into chronic conditions, such as COPD and Asthma. These are our Beyond PE initiatives.

We estimate the combination of our existing PE market and our Beyond PE targets to be at least a US\$1.1 billion market. And one that will only grow from here as these technologies advance to provide better clinical and patient outcomes.



## Slide 24 – Beyond Pulmonary Embolism Initiatives

We are currently supporting several Beyond PE clinical trials. The most recent is the multicentre 665 patient PRONOSPECT clinical trial in France to enable improved detection of residual pulmonary vascular obstruction which can cause life threatening recurring pulmonary embolisms.

Alongside the trials we are supporting, we are confident that our wide USFDA approval will facilitate independent US clinical trials and publications that will also likely accelerate our Beyond PE initiatives. We have already seen the first of these published in the past few months.

#### Slide 25 – Cyclopharm Outlook

Looking ahead:

#### Slide 26 – Upcoming Milestones and Growth Catalyst

- We are on track for 250–300 US installations during the second half of 2026,
- We are building a **scalable US operation** with contracts, inventory, and support infrastructure,
- We are expanding our sales force to meet demand,
- We are targeting clinical initiatives to expand the use of Technegas Beyond PE, and
- We are pursuing **new third-party opportunities** to further broaden our reach.

The work we have done this year lays the foundation for exponential growth. In the near term, current trading is as expected with low double digit revenue growth driven by the US Technegas sales and Business Partner products.

#### Slide 28 – Investment Case

**To summarise:** Cyclopharm is an established and growing medical technology business with a proprietary product range that is recognized as the gold standard for lung ventilation imaging by clinicians.

Our entry into the US market is Cyclopharm's next growth phase and is set to quadruple Technegas sales in our existing PE business and drive profitability, underpinned by full US Medicare Medicaid reimbursement that was put in place in 2024.

The US roll out plan allows Technegas installations to generate recurring revenues, similar to an annuity stream, and we are already seeing proof of that from those systems already installed in the US.

Our Beyond PE initiatives are creating the opportunity to access growth across exponentially larger respiratory medicine indications and our core business is supported by a significant Third Party distribution business.



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 over the course of the year.

**In closing,** To our shareholders—thank you for your trust and continued support. We have come a long way, but the best is yet to come.

To our team, including our growing US cohort—thank you for your commitment. And to our Board—thank you for your guidance.

The opportunity ahead is clear. The strategy is in motion. And the momentum is real.

Thank you.