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The Manager Company Announcements Office Australian Securities Exchange Limited 20 Bridge Street Sydney NSW 2000 **techne**gas **ultra**lute

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Chairman's address

Good morning ladies and gentlemen, fellow shareholders.

Before, we begin, I note a copy of this presentation has been lodged with the ASX and is also available for download from the Cyclopharm website. May I also kindly request if you have a mobile phone with you, please switch it off, or turn it to silent mode for the duration of this meeting.

Thank you for joining us for today's Annual General Meeting of the shareholders of Cyclopharm Limited. My name Is David Heaney, I am the Chair of the Board of Cyclopharm Limited and I will also chair this meeting.

I am joined today by my fellow Directors, Ms Diane Angus, Mr Kevin Barrow, Professor Greg King and James McBrayer, our Managing Director and Company Secretary. I also welcome Mr Stephen Fisher and Mr Andrew Luu of Nexia Sydney, the Company's Auditor.

I have been advised that a quorum is present – by virtue of the proxies I hold as Chair, and those shareholders in attendance today – and I now formally declare the meeting open.

The agenda for today's meeting will be as follows:

- I will provide the Chairperson's address;
- Followed by a business update from the Company's Managing Director, James McBrayer;
- After which, we'll proceed to the formal matters to be considered at today's AGM; and
- Finally, there will be an opportunity for general questions and discussion.

I will now proceed with the Chairman's Address.

In 2022, Cyclopharm delivered another year of solid financial performance and continued to make significant progress in executing our growth initiatives. Our financial performance was underpinned by exceptional growth in our Third-Party distribution business, while we continued to work closely with the United States Food and Drug Administration on the final stage of the approval process to sell the company's core Technegas[™] products in the US market.

Technegas is currently available in 64 countries and is considered the gold standard and world leader in nuclear medicine functional lung ventilation imaging. We have over 4.6 million patient studies to date, supported by hundreds of peer reviewed



publications. We have recurring revenue and operating earnings that are generated predominantly from single patient consumables.

Cyclopharm's record revenue performance in 2022, was driven by increased sales across all our business units but, in particular, our third-party distribution business, which demonstrated the resilience of our business and the financial benefits derived from revenue diversification. This record performance was achieved despite some end of year residual challenges and disruptions to our markets resulting from temporary shortages of Technetium, the isotope used to make Technegas[™].

Throughout 2022, we continued to support and advance our 'Beyond PE' growth initiatives. 'Beyond PE' aims to extend the use of Technegas[™] into new and exponentially larger applications beyond its traditional Pulmonary Embolism market.

We also continued to work with the United States Food and Drug Administration (USFDA) to progress the final stage of the approval process to sell the company's core Technegas[™] products in the US market, which represents a transformational business opportunity that is estimated to be worth US\$180 million annually.

During 2022 we addressed the definitive list of items and recommendations provided by the USFDA in their Complete Response Letter. Importantly, the additional information requested by the USFDA did not relate to the demonstrated efficacy and safety of Technegas[™].

On 30 March 2023, post year-end, Cyclopharm submitted its reply to the Complete Response Letter. The company has received a formal response from the USFDA confirming both that our submission is complete and eligible for review and that their target completion date for their review is 29th September 2023. On that basis, with our commercialisation plan already underway, we anticipate attaining approval to commence commercial sales of Technegas[™] in the US later this year, which is consistent with previous expectations.

Pleasingly, Cyclopharm's third-party distribution business demonstrated excellent growth in 2022 by securing additional distribution agreements in Europe and the Asia-Pacific region. This business, which comprises a ,mix of radiopharmaceuticals, capital equipment and associated consumables, continues to reinforce a key pillar of the Company's growth strategy by developing additional revenue streams by leveraging our expertise and infrastructure. In 2022, the third-party distribution business contributed a substantial \$9.2 million in revenue, up from \$4.1 million in revenue for the prior year. In the current financial year, the Company is continuing to grow third-party distribution revenue by establishing new partnerships and expanding into new markets. For example, our global footprint recently expanded with the acquisition of DuPharma in Denmark, consolidating our coverage throughout the Nordic region. This Company is a Third-Party medical distribution company based in Copenhagen, that has been a long-term distributor of Technegas[™] and other nuclear medicine products in Denmark for several years.

Cyclopharm also continued to sponsor several clinical trials into new applications for Technegas[™], throughout 2022, as part of the 'Beyond PE' growth initiative. The potential uses of Technegas[™] for managing 'Beyond PE' applications have been enhanced by the advent of improved nuclear medicine imaging techniques, cameras and software.

During 2022, Technegas[™] was recognised in peer reviewed articles and abstracts for clinical applications that include long-COVID and lung cancer. The Company is



confident that the clinical benefits seen in these early publications have the potential to materially expand the addressable market for Technegas[™] globally.

In 2022, Cyclopharm renewed its Technegas[™] CE mark under the updated European Medical Device Regulations (MDR), meaning Technegas[™] may continue to be sold freely in any part of the European Economic Area. In addition, Cyclopharm renewed licensing under the Medical Device Single Audit Process (MDSAP) for participating countries to include Canada, Australia, Brazil and Japan.

Cyclopharm ended the 2022 financial year with a strong balance sheet and a cash balance of \$20.3 million. Our cash balance combined with ongoing operational cash flows and prudent expense and capital management means we are appropriately capitalised to fund the ongoing USFDA approval process and the anticipated launch of Technegas[™] into the US market..

The availability of Technegas[™] in the US is also expected to be a catalyst for the acceleration of 'Beyond PE' trials that have the potential to lead to exponential growth in the use of Technegas[™] in additional clinical applications, including long-COVID and lung cancer alongside Chronic Obstructive Pulmonary Disease (COPD) and asthma. We expect 2023 to be a milestone year for Cyclopharm as we enter a new growth phase

, underpinned by a return to normal growth patterns in sales revenue from our existing Technegas[™] business, post-COVID and a continued focus on the improved utilisation of the company's sales and service infrastructure globally. In particular, we expect the much anticipated commencement of Technegas[™] sales in the US will significantly improve the underlying profitability of the Company.

In line with good corporate governance practice, Cyclopharm's Board continually evaluates its skills and composition to ensure they appropriately support the Company's growth and governance requirements. In 2022, the Board appointed Mr. Kevin Barrow and Professor Gregory King as Non-Executive Directors. Dr King is a world-renowned clinician and respiratory physiologist who brings over 25 years' experience as a clinician, educator and researcher to the Cyclopharm Board. Mr. Barrow brings to Cyclopharm more than 20 years of experience in the healthcare industry, which includes numerous governance and senior executive roles in both the pharmaceutical and diagnostic imaging equipment sectors.

On behalf of the Board, I wish to thank our Managing Director, all our staff and wider stakeholders for their commitment to the company and I thank you, the shareholders, for your continuing support.

We are confident that Cyclopharm is in a strong position, both financially and operationally, to extend its clinical leadership in lung imaging and drive ongoing growth in revenue and earnings. We remain absolutely committed to delivering positive health outcomes for our patients and achieving long-term, sustainable growth in profits and shareholder value.

I now invite our Managing Director, James McBrayer to provide an update on the company's operations and performance. Thank you, James.

David Heaney Chairman



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

For more information, please refer to our website at <u>www.cyclopharm.com</u> or contact:

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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° 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.