



4 July 2022

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

cyclo**medica**
techneg**as**
ultra**lute**

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

1H 2022 BUSINESS UPDATE – RECORD REVENUES

Cyclopharm Limited (ASX:CYC) is pleased to provide the following update on its anticipated preliminary (unaudited) financial performance for the half year to 30 June 2022 with record revenues up 36% on the previous corresponding period (pcp), and 74% higher than pre-COVID revenues recorded in the first half of 2019.

1H FY 2022 Highlights

- **Total unaudited group sales revenue is expected to be approximately \$11.3 million, an increase of approximately 36% compared to pcp.**
- **Technegas™ generator revenues continue to grow strongly across multiple markets, up approximately 42% on pcp.**
- **Revenues from predominantly recurring Patient Administration Sets (PAS) consumables expected to be approximately 21% higher than pcp.**
- **Third party distribution sales continue to deliver exceptionally strong growth, increasing approximately 139% on 1H 2021**
- **Net cash position at the half year is expected to be \$26 million – well placed to fund growth strategy**
- **Good progress in completing USFDA Approval Process – remains on track for first commercial sales in mid-2023 following approval**
- **Developing significant new applications for Technegas beyond Pulmonary Embolism (PE)**

Cyclopharm Managing Director James McBrayer said, “Today’s numbers reflect our ability to leverage our global sales and service infrastructure off our core Technegas technology that we have built across 63 countries and our ability to successfully sell and service other products through this network.”

“With strong growth across all our business lines, the company is delivering record revenues which not only underscore the strength of our core business performance but also highlight the exciting potential for the expansion of our future earnings base.”

“Going forward, our key revenue opportunities include:

- The anticipated USFDA approval for Technegas sales enabling market entry in the US in mid-2023, allowing for the FDA’s stated six-month formal submission review process

- Continuing strong growth in the core business across the 63 countries in which the company's major product is already sold
- Increases in third party distribution revenues.
- New "Beyond PE" applications for Technegas under development, including Long Covid, asthma and COPD

1H 2022 Revenues -Record revenues significantly exceed pre-COVID Levels

Following a review of Cyclopharm's unaudited management accounts for the half year ending 30 June 2022, revenue is expected to be approximately \$11.3 million, 36% higher than pcp and 74% higher than the company's pre-COVID revenues in 1H 2019.

Total Technegas™ consumable revenues (predominantly recurring) are expected to increase by approximately 21% on pcp. Revenues from Technegas™ Generator sales increased by approximately 42% compared to pcp, more than double pre-COVID levels in 1H 2019. This strong growth, driven in part by the recognised safety profile of Technegas™ in comparison to other competing nuclear medicine products, reflects the strong performance and continuing recognition of the Technegas™ technology in the company's core markets such as Canada.

Expanding Indications for Technegas™

This strong revenue performance has also been supported by the adoption of Technegas™, for clinical uses beyond the traditional Pulmonary Embolism diagnosis market, such as identifying Long COVID-related lung disorders¹, and disruption to the supply chains impacting alternative diagnosis technologies.

In an announcement published on 24 May 2022¹, the Company advised that Technegas™ demonstrated the potential to have a key role in the diagnosis and management of patients who are experiencing ongoing impacts from COVID-19.

In a peer reviewed article published in the Canadian Journal of Respiratory, Critical Care and Sleep Medicine, researchers at McMaster University in Ontario using Cyclopharm's Technegas™ product (VQ-SPECT-CT²) as the ventilation agent found it had the potential to be *"a valuable tool for clinicians in the management of patients who are being evaluated after COVID-19 as it permits objective evaluation of functional lung impairment that may underly and help explain post-COVID-19 symptoms"*.

The study concluded that the *"(Technegas™) imaging study revealed ventilation impairment in individuals with no history of lung disease recovering from noncritical COVID-19 that was associated with parenchymal opacities, respiratory symptoms and exercise-capacity."*

Third Party Distribution

Cyclopharm's third party distribution business continues to deliver outstanding growth, with revenue of approximately \$3.7 million in 1H 2022, representing an increase of approximately 139% on pcp.

¹ ASX Announcement (24 May 2022) *"New peer reviewed study reveals Technegas™ potential as a valuable tool for the diagnosis and management of 'Long COVID'"*

² VQ-SPECT-CT – Ventilation Perfusion Single Photon Emission computerised tomography with computed tomography is a multimodality imaging technique that combines nuclear medicine functional imaging with an anatomical reference using CT

The increase in third party distribution revenue was supported by the first significant revenues from the Australian, Nordic and UK markets, as well as strong contributions from other existing markets.

USFDA Approval Process – Continuing Progress, On track for US market entry in mid-2023

Cyclopharm continues to progress toward attaining USFDA approval to commence commercial sales of Technegas™ in the US market in mid-2023, consistent with previous expectations.

The US market represents an opportunity for Cyclopharm to significantly increase sales of our Technegas™ product suite. In addition, it will also accelerate opportunities to explore the expansion of the use of Technegas™ into the treatment and management of additional and much larger indications, such as COPD, asthma and Long Covid.

As previously disclosed, in June 2022 Cyclopharm received a Complete Response Letter (CLR) from the US Food and Drug Administration (USFDA), providing a definitive list of items and recommendations that are currently being addressed prior to granting approval for commercial sales of Technegas™ in the US market. As earlier advised, the Company met with the USFDA in late January 2022 to discuss its progress on the request for additional information and other matters. The company continues to finalise its formal response to the CRL and reaffirms the expectation of approval and subsequent commercial market entry in mid-2023, allowing for the FDA's stated six-month formal submission review process.

Governance

A global search has been initiated to expand the Board in preparation for the next stage of the company's growth.

Cash Position & Half Year 2022 Results

Cyclopharm is well funded with approximately \$26 million of cash reserves at 30 June 2022 and is in a strong financial position to deliver on FDA approval and our Beyond PE strategy.

Cyclopharm anticipates announcing further information about its half year performance in its 1H 2022 results announcement, scheduled for late August 2022.

- ENDS -

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° 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, Long COVID and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.
