cyclopharm

Technegas™
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

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

HALF YEAR 2022 RESULTS – CONTINUED STRONG REVENUE GROWTH

Radiopharmaceutical company, Cyclopharm Limited (ASX:CYC) today announced results for the six month period ending 30 June 2022. The results include record consolidated group revenue of $11.4 million, 76% higher than the same period in 2019, delivering a strong rebound from the COVID-19 disruptions during the previous couple of years. A 0.5 cents per share dividend for the half year was declared.

Key features of the 2022 Half Year results include:

- **Record Group revenue of $11.4 million, up 35% on pcp.**
- **Revenues from Patient Administration Sets grew 18% vs pcp to $5.26 million.**
- **Technegas Generator revenue rose 32% vs pcp to $1.65 million.**
- **3rd party distribution revenue more than doubled to $3.30 million.**
- **Gross margin was 69.7% of sales.**
- **Strong balance sheet with a net cash position of $26.5 million.**
- **Interim dividend maintained at 0.5 cents per share.**

Financial Results

During the period, Cyclopharm recorded total consolidated revenue of $11.43 million, up from $8.48 million in 1H2021 and 76% higher than the same period in 2019, demonstrating the business continues to deliver better than pre-COVID-19 revenue performance. The increase in total revenue of 35% compared to the pcp was driven by improved Sales and Service revenues achieved across all product lines in 1H2022, and in particular third-party Sales

Revenue from Technegas™ products rose 21% in 1H2022 to $7.74 million up from $6.39 million in the prior corresponding period (**pcp**). Technegas™ Patient Administration Sets (PAS) revenue was 18% higher at $5.26 million up from $4.46 million in the pcp, with more consumable sales reported in higher margin markets. Technegas™ Generator revenues grew 32% to $1.65 million up from $1.25 million in the pcp. Technegas™ Service revenue of $0.83 million in 1H2022 was 21% higher than 1H2021 and 36% higher than pre-COVID-19 service revenue in 1H2019.

Cyclopharm's complementary revenue stream from the sale of third-party products continues to deliver exceptional growth, rising 114% from the prior corresponding period to $3.30 million in 1H2022. Third party distribution revenue is expected to continue to grow strongly and represents an important supplementary revenue stream for Cyclopharm. The Company will continue to target opportunities to expand this revenue stream in new markets, including Australia.

Gross sales margins for the period fell from 73.5% to 69.7% as lower margin third party products increased their relative contribution to total revenue. The net loss after tax for the period was $2.56 million, a 35% improvement on the net loss after tax of $3.93 million in 1H2021.

Cyclopharm continues to enhance its quality processes, systems and management depth. In particular, during the period, the Company made further investments in its internal ERP and financial management systems and appointed a new Head of People & Culture. Together, these actions have materially improved management processes, ensuring Cyclopharm's systems and operations are well placed to support its strong growth prospects.

USFDA Approval of Technegas™ for sale in the US

The launch of Technegas™ into the USA remains a strategic priority for Cyclopharm.

As previously disclosed Cyclopharm lodged a New Drug Application (NDA) for Technegas™ with the USFDA in March 2020. On 26 June 2021, we received a Complete Response Letter (CRL) from the USFDA containing a definitive list of items and recommendations that needed to be addressed prior to approval to commence sales in the US market. The information requested centres primarily around additional processes in support of the manufacturing of Technegas components and information describing the unique characteristics of the Technegas particle.

In late January 2022 the Company met with the USFDA to discuss its progress on responding to the CRL and other matters. As a result of the feedback from that meeting and delays associated with sourcing equipment required in providing further bench-top testing, Cyclopharm expects it will submit its formal response to the USFDA CRL during the second half of 2022.

Despite the delay, our expectations of approval and subsequent commercial market entry in mid-2023 remain consistent and allows for the FDA's stated six-month formal submission review process. The Company is ready to execute a rapid market entry, supported by an ongoing investment in inventory to allow the supply of Generators across chosen US hospitals once approval has been received.

Entry into the US market is also expected to help accelerate progress of our 'Beyond PE' strategy to expand the use of Technegas™ into the treatment and management of additional and much larger indications.

'BEYOND PE'

Cyclopharm continues to sponsor a number of clinical trials that investigate new applications for Technegas™. The diagnosis and monitoring of COPD, asthma and other respiratory disease states, including Long COVID-related lung disorders, are all being considered.

The strong revenue performance in the June 2022 half year 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 disorders, and to help manage disruption to the supply chains impacting alternative diagnosis technologies.

In its ASX announcement dated 24 May 2022, 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. Specifically, an independent peer reviewed study by researchers at McMaster University in Ontario and published in the Canadian Journal of Respiratory, Critical Care and Sleep Medicine, found using Cyclopharm's Technegas™ product as the ventilation agent during *VQ-SPECT-CT*1 imaging 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*".

These initiatives could expand the use of Technegas™ to improve the diagnosis and management of patients suffering from respiratory disease more broadly. For example, Cyclopharm estimates that the global COPD market is 30 times the size of the PE market, with over 500 million patients suffering with COPD and Asthma who may benefit from the use of Technegas™ in their chronic disease management. These markets represent significant opportunities to grow sales of Technegas™ and drive shareholder value.

Capital Management

Cyclopharm is well funded with approximately $26.5 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.

The Board has also declared an unfranked dividend of 0.5c per share for the half year. This dividend will be paid on 12 September 2022 to shareholders on the register on the record date of 5 September 2022.

Outlook

The Board remains highly confident that demand for Technegas™ will continue to grow across our existing markets. Clinicians reiterate their strong support for Technegas™ as the functional ventilation imaging agent of choice in determining PE. Significant opportunities exist for the Company to grow its sales through accessing new markets, including the USA, and expanding the use of Technegas™ to conditions such as COPD and long COVID.

Commenting on the outlook, Cyclopharm Managing Director, James McBrayer said, "The higher number of generator sales made in the first half of 2022 gives us confidence of continued robust growth in PAS revenue as these new sales will lead to ongoing repeat PAS orders though the life of these new assets.

"In addition, we expect the solid growth from third party sales to continue to provide a significant source of additional revenue for our business.

"We are actively working with the USFDA to address the outstanding technical issues required for approval of Technegas™ into the USA and remain confident these issues can be addressed over the coming year. As such, we remain excited by the major opportunity to significantly grow sales and profitability in the United States market.

[1] 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

"Finally, the ongoing development of new applications for Technegas™, as part of the Beyond PE growth strategy, is designed to move Technegas™ into diagnosis and management of other respiratory diseases like COPD and long-COVID, and remains a key priority for the Company."

- 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 and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.