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cyclomedica 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

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

# 1H 2023 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 2023 with record operating revenue of \$15.3 million, up 39% on the previous corresponding period (pcp).

1H FY 2023 Unaudited Highlights:

- ✓ Record revenue \$15.3 million, up approximately 39% on pcp, including:
  - Technegas<sup>™</sup> revenues steady on pcp, at approximately \$7.6 million
  - Third-party distribution sales up approximately 116% on 1H 2022, to approximately \$7.7 million.
- ✓ USFDA Approval Process remains on track and as previously advised:
  - an expected approval date of 29 September 2023
  - A 2-week USFDA inspection of Cyclopharm's manufacturing facilities scheduled to begin on 31 July 2023, well within the review period
- ✓ USFDA costs for the half-year were approximately \$2.3 million, largely associated with the work attributed to the final submission lodged on 31 March 2023
- ✓ \$18.9 million Net Cash as of 30 June 2023– well placed to deliver on USA launch and progress Cyclopharm's 'Beyond PE' strategy

Cyclopharm Managing Director James McBrayer said, "Our financial performance for the first half of 2023 reflects the underlying strength of our core business. A standout performance in Third-party sales also highlights the ability to leverage our global sales, service and regulatory infrastructure, to not only support our core Technegas technology across 64 countries, but to continue to expand our earnings base with the successful sale and service of Third-party products in Cyclopharm's 18 direct markets."

## 1H 2023 Revenues - Record revenues

Following a review of Cyclopharm's unaudited management accounts for the half year ending 30 June 2023, operating revenue is expected to be approximately \$15.3 million, 39% higher than pcp, largely driven by the standout performance in Third-party sales.

Total Technegas<sup>™</sup> revenues, predominantly generated from consumables, remained steady on pcp at approximately \$7.5 million, a reflection of the resilience of Technegas<sup>™</sup> as a leading imaging technology in the Company's core markets.

Cyclopharm's Third-party distribution business continues to deliver exceptional growth, with revenue of approximately \$7.7 million in 1H 2023, from \$3.7 million previously. Third-party sales revenue exceeded Technegas<sup>™</sup> sales for the first time, supported by \$3.1 million of equipment and installation sales, with the remainder from recurring service and consumable revenues.

## USFDA Approval Process – Continuing progress, on track for US market entry in late 2023

Cyclopharm continues to progress toward attaining USFDA approval to commence commercial sales of Technegas<sup>™</sup> in the US market in the second half of calendar 2023, consistent with previous expectations. The USFDA approval date remains 29 September 2023.

USFDA cost incurred during the half-year totaled approximately \$2.3 million. Those costs were largely associated with the work attributed to the Complete Response Letter (CRL) submission on 31 March 2023. Cyclopharm's CRL submission initiated the USFDA's stated six-month review and response period.

Since the submission date, Cyclopharm has continued to engage in active productive dialogue with the USFDA. As previously advised, part of the review process includes the USFDA's two-week inspection of the Company's manufacturing facilities in Sydney which is expected to be completed well within the 6-month review period.

The US market represents an opportunity for Cyclopharm, to not only significantly increase sales of the Technegas<sup>™</sup> product suite but to accelerate opportunities to explore the expansion of the use of Technegas<sup>™</sup> in the treatment and management of additional and much larger indications, such as COPD, asthma and Long COVID.

## Cash Position & Half Year 2023 Results

Cyclopharm is well funded with approximately \$18.9 million of cash reserves at 30 June 2023 and is in a strong financial position to deliver on launching Technegas in the US and advancing initiatives our Beyond PE strategy.

Cyclopharm expects to provide further information about its half year performance in its 1H 2023 results announcement, scheduled for mid-August 2023.

- 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<sup>®</sup> used in functional lung ventilation imaging.

#### **Technegas**<sup>®</sup>

The Technegas<sup>®</sup> 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<sup>®</sup>, 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.