cyclopharm

23 February 2022

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

FULL YEAR 2021 RECORD REVENUES SUPPORT PIPELINE EXPANSION, PREPARATIONS FOR USFDA REGULATORY APPROVAL AND DIVIDENDS

Radiopharmaceutical company, Cyclopharm Limited (ASX: CYC) today announced results for the financial year ending 31 December 2021. The results include record sales revenue of $17.70 million, despite persistent disruption from COVID 19 throughout the year, and a 0.5 cents per share final dividend.

Key features of the 2021 Financial Year results include:

- **Record Sales revenue of $17.70 million, up 20.6% on the prior year.**
- **Technegas™ sales increased by 7.0% to $13.21 million in FY21, third-party distribution revenues increased 89% to $4.10 in FY21.**
- **Net cash position at year-end of $29.25 million means Cyclopharm is fully funded for the next phase of growth.**
- **$1.30 million investment in the final stages of the USFDA regulatory approval for Technegas™ and preparations in place for subsequent rapid commercialization in the United States.**
- **Solid progress in developing new, 'Beyond PE', clinical applications providing large, long term growth opportunities for Technegas™.**
- **Increasing Direct Customer access with the establishment of offices in Brussels, Belgium and Bristol, United Kingdom.**
- **Final dividend maintained at 0.5 cents per share (cps), bringing total unfranked dividends for FY21 to 1.0 cps.**

James McBrayer, Managing Director, noted "Cyclopharm delivered a record revenue performance in 2021 and entered the final stage of the approval process to commence sales of Technegas™ in the US market. Group Revenue including Technegas™ sales, third-party distribution and joint venture activity increased by 20.6%.

The Company maintained a strong focus on supporting the United States Food and Drug Administration (USFDA) approval process, while continuing to invest in clinical research validation of the use of Technegas™ in broader diagnostic applications as part of our 'Beyond PE' pipeline initiatives. Additional R&D activities include continuous improvement initiatives relating to both our proprietary products and manufacturing equipment.

We enter the new financial year with momentum and expect 2022 to be another successful and productive year. We look forward to increasing sales in offshore markets, continuing to

expand our addressable market opportunities, and securing FDA approval to commence commercial operations in the US in 2023."

FY21 Financial Year Summary

Cyclopharm generated record total revenues in FY21 of $17.70 million, up 20.6% on the prior year. Revenue from sales of Technegas™ generators and Patient Administration Set (PAS) consumables have remained robust while earnings from the distribution of 3rd Party products in Europe and APAC grew 89% and added $4.10 million of additional revenues for FY 2021.

SALES BY REGION ($MILLIONS)		2020	2021	CHANGE FY21 VS FY20
Canada	Technegas™	1.76	2.44	39%
Europe	Technegas™	8.27	8.51	3%
	3RD Party Sales	2.17	3.00	38%
APAC	Technegas™	2.26	2.17	(4%)
	3RD Party Sales	0	1.10	100%
***ROW**	Technegas™	0.06	0.09	50%
TOTAL		14.52	17.31	19%

***REST OF THE WORLD**

In line with trends observed with many diagnostic procedures globally, sales of Technegas™ continued to be impacted by delays in medical procedures being performed in certain country markets caused by the ongoing COVID-19 pandemic. Against this backdrop, it is pleasing that consumables revenue increased modestly, by 5% year on year, from $9.07m to $9.54m.

Cyclopharm recorded a net loss before tax for the year of $4.35 million, a $1.49 million improvement compared to a net loss before tax of $5.84 million in the prior year. This result includes a $1.30 million investment required for the final stages of the USFDA approval process and additional costs linked to establishing sales and service operations in Belgium and the United Kingdom to help drive sales of Technegas™ and our 3rd party distribution business across Europe.

USFDA Regulatory Approval Process

USFDA approval to sell Technegas™ in the US market is in its final stages, following a request from the USFDA in June 2021 for additional information. The Company met with the USFDA in late January 2022 to discuss progress. The dialogue was constructive and the Company remains confident it is on track to submit the requested information in Q3 2022. Once submitted the USFDA will have up to six months to review the data. Based on those timelines the Company expects sales of Technegas™ will commence in the first half of 2023.

US Market Entry and Sales Model

Alongside supporting the USFDA approval process, Cyclopharm is undertaking a number of activities to assist with the rapid commercialisation of the US market upon approval. These activities include, building inventory reserves, pursuing agreements for third-party distribution, service and installation, and administrative support. The Company has grown its inventories from $4.7 million to $5.5 million at year end.

It is very important to emphasize that US reimbursement for Technegas™ will be based on established nuclear medicine procedures that are agnostic to the approved agents being used. Therefore, in the US market, Technegas™ will be reimbursable from day-one. Cyclopharm

estimates the US market for Technegas™ in the diagnosis of Pulmonary Embolism to be upwards of US$180 million annually.

Capital Management
As at 31 December 2021 cash balances equal $29.25 million following a successful $33.0 million capital raising in February 2021.

BEYOND PE – New Pipeline Growth Opportunities
Cyclopharm continues to sponsor a number of clinical trials that are investigating applications for Technegas™ in new markets including the diagnosis and monitoring of COPD, asthma and other respiratory disease states. The Company estimates the global COPD market is approximately 30 times the size of the PE market and over 500 million patients suffering with COPD and Asthma could benefit from the use of Technegas™ in diagnosis and ongoing patient monitoring/management.

Cyclopharm is also involved in clinical research investigating the use of Technegas™ for patients suffering from Long-COVID.

The results to date from these sponsored initiatives indicate promising clinical utility of Technegas™ in these additional disease states with peer reviewed published results expected to be published in the first half of 2022.

Outlook
Cyclopharm expects 2022 to be another successful and productive year. The company remains well capitalised to fund the final stages of the USFDA approval process for Technegas™ and anticipated launch of Technegas™ in the US market, alongside ongoing Technegas™ pipeline development and business growth.

Revenue from Technegas™ Generator and PAS sales in existing markets is expected to continue to rebound to pre-pandemic levels or beyond in 2022. The Company's complementary third-party distribution revenues are contributing strongly to earnings and profits and the Company expects to continue to expand this revenue stream in the current financial year.

The combination of the Company's resilient financial performance and strong capital position have supported the Board's decision to maintain a consistent dividend policy and a final dividend of 0.5 cents per share (CPS), giving a total dividend for 2021 of 1.0 cps.

Cyclopharm is well placed to extend its market leadership in lung imaging and drive ongoing growth in FY22.

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^{o} 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.

Ultralute™
Cyclopharm's patented nuclear medicine technology Ultralute™ extends the useful life of Molybdenum-99 (Mo-99) generators by up to 50%. This technology potentially gives nuclear medicine departments the ability to dramatically improve operating efficiencies and health outcomes for patients. Mo-99 generators are used in diagnostic imaging to harvest Technetium-99m, or Tc-99m, which is the primary isotope used in diagnostic imaging throughout the world. This isotope accounts for approximately 80% of all nuclear medicine diagnostic imaging procedures.