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HALF YEAR 2020 FINANCIAL RESULTS SUPPORT DIVIDEND AND PREPARATIONS TO ENTER US MARKET

Radiopharmaceutical company, Cyclopharm Limited (ASX:CYC) today announced financial report for the six month period to 30 June 2020, including sales revenue of \$5.8 million, in line with previous guidance, and a 0.5 cents per share dividend.

Key features of the financial results for the 2020 half year include:

- Sales revenue \$5.8 million, impacted by deferral of sales to France and lower PAS kit sales due to COVID-19 related delays in medical procedures
- Total revenue up 14%, ex-France, including \$0.7 million of new revenues from distributing third party products in Europe
- Good progress in securing FDA approval - first commercial sales expected in US in 2021
- Executing strategies to significantly expand Technegas™'s addressable markets "Beyond PE" - into COPD and asthma
- Strong net cash position of \$8.064 million at 30 June 2020
- Interim dividend maintained at 0.5 cents per share

Financial Results

During the period, Cyclopharm generated revenues of \$5.8 million with gross margins of 79.0% of sales (vs 1H19: 82.8%). As previously announced to the ASX on 7 July 2020, revenue for the period was impacted by generally lower PAS volumes in most markets, relating to factors associated with the COVID-19 pandemic, and a delay in the scheduled late 2Q France order valued at \$1.26 million.

Excluding sales to France, consolidated revenue increased by approximately 14% on the prior corresponding period (pcp). The Company anticipates sales orders from France will resume in the second half of this financial year along with an increase in volumes to the rest of the world.

During the period the Company received approval to sell Technegas™ Products in Russia and secured its first orders from that market. New revenue streams from distributing third party products in Europe contributed \$700k to revenues.

Net loss after tax for the period was \$5.65 million, which includes \$2.36 million of pre-tax expenses associated with the Group's United States Food and Drug Administration (USFDA)

clinical trial of Technegas™. Underlying EBITDA¹ in the core Technegas™ division was \$1.57 million loss. As at 30 June 2020, cash balances equal \$8.1 million.

USA Market Entry

Following lodgment of its New Drug Application (NDA) submission for Technegas™ during the period, the Company remains in active discussions with the USFDA to assist with its assessment and approval processes. Based on feedback to date, the Company remains highly optimistic of gaining entry into the US market in 2021.

To support rapid market entry, the company intends to increase its investment in inventories of both Technegas™ Generators and PAS kits over the coming 6 months.

The US market accounts for around half of the total nuclear medicine departments in the world, with the US market for nuclear medicine ventilation imaging estimated to be approximately US\$90 million annually. This represents approximately 600,000 individual procedures per annum. Based on Cyclopharm's experience in the Canadian market and demand expressed by US medical professionals, Cyclopharm remains confident that Technegas™ can achieve a 50% share of the USA market over 2 to 3 years, post US market entry, with an 80% share representing around 480,000 procedures per annum achievable over a 5 to 7 year period.

BEYOND PE – New Growth Opportunities

The company's balance sheet strength is also supporting delivery of Cyclopharm's other strategic priorities, including expanding the use of Technegas™ beyond pulmonary embolism (Beyond PE).

A result of successfully expanding the use of Technegas™ to improve the diagnosis and management of patients with COPD and other small airways diseases would be access to a global market 30 times the size of the PE market. The Company's Beyond PE initiatives are linked to significant Research and Development activities. These activities are being impacted by COVID-19 as the rate of patient recruitment for trials slowed during the first half of 2020 and in some cases have been put on hold.

European Third-party Distribution

During the period Cyclopharm benefited from a new revenue stream generated from the distribution of third party products in Europe. Revenue from third-party distribution agreements with TEMA and ROTOP totaled approximately \$700k during the first half of 2020. We expect second half 2020 revenues from third-party products will exceed first half revenues as we continue to grow this new revenue stream.

Litigation Update

Cyclopharm continues to defend its valuable Intellectual Property vigorously and successfully. In 2019, the company successfully brought an initial civil case against its former employee in the German market, Mr Bjorn Altmann and Almedis Altmann GmbH ("Almedis").

¹ Underlying basis adjusts for USFDA expenses and foreign exchange and includes expenditure to ensure compliance with USFDA guidelines as well as the new International Medical Device Single Audit Program (MDSAP)

Further actions have been subsequently launched in both German and Australian courts with favourable progress being made. The company expect decisions to be handed down in two additional actions in Germany in the coming weeks. It is difficult to predict a timeframe for these separate Australian proceedings to be concluded; however, we are confident that we will achieve a successful outcome from these actions.

COVID-19

The global impact of the COVID-19 pandemic is unprecedented and continues to evolve. Technegas™ is primarily used to diagnose the life-threatening condition Pulmonary Embolism (PE). Dyspnea or shortness of breath is a key symptom exhibited in both COVID-19 and PE.

In many markets around the world, imaging procedures were temporarily delayed. It appears that the delays in the use of Technegas™ have been short term and the Company is seeing volumes returning to pre-COVID-19 levels.

During this time of pandemic where concerns of infection control is heightened, Technegas™, with its unique product characteristics and method of administration, is considered to be the safest ventilation imaging agent in its class. Combined with its exceptional clinical support and strong safety profile, we believe demand for Technegas™ will grow in our existing markets where other competitive products are still in use.

Outlook

Technegas™ is established in 60 countries around the world with over 4.2 million procedures completed to date. Technegas™ is extensively documented in hundreds of peer reviewed papers and clinical guidelines as the functional ventilation imaging agent of choice in determining PE^{2,3}. Furthermore, particularly during this time of pandemic where concerns of infection control is heightened, Technegas™, with its unique product characteristics and method of administration, is considered to be the safest ventilation imaging agent in its class. Given this exceptional clinical support and strong safety profile, we believe demand for Technegas™ will continue to expand in our existing markets.

Developing additional Technegas™ indications, particularly for COPD, remains a key priority as they have the potential to significantly expand Technegas™'s revenue and profitability over the medium to longer term in indications valued at \$900 million per annum.

The Directors are excited by the near-term major opportunity to significantly expand Cyclopharm's sales and profitability that USFDA approval to market Technegas™ into the US market provides. We anticipate approval by the USFDA to commence sales in 2021 and are investing in the systems, infrastructure, personnel and inventory required to introduce Technegas™ to the United States market.

² European Association of Nuclear Medicine Guidelines for Ventilation/Perfusion Scintigraphy Part 1. Pulmonary imaging with ventilation/perfusion single photon emission tomography. Eur J Nucl Med Mol Imaging (2009) 36:1356–1370 DOI 10.1007/s00259-009-1170-5

³ CANM Guidelines for Ventilation/Perfusion (V/P SPECT) in Pulmonary Embolism. November 2018

Over the full year, Cyclopharm expects ongoing growth in its core business in 2020 as well as further progress in the development of the company's key growth initiatives and opportunities.

Having regard to the underlying financial results and the company's strong balance sheet position, for the half year period, The Directors have declared an unfranked interim dividend of 0.5 cents per share which will be paid on 14 September 2020 to shareholders on the register on 7 September 2020.

"The strong clinical support for Technegas™ will not only support demand in our existing markets but also accelerate the sales and profitability that would result from approval to market Technegas™ into the US market. We have had positive interactions with the USFDA; are confident we are on track to commence sales in the US in 2021 and are making preparations for a rapid expansion into the United States market." Mr. McBrayer added.

For more information, please 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.