cyclopharm

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Business Update – FDA Progress, Record Revenues and Positive Clinical Trial Results

Cyclopharm Limited (ASX: CYC) is pleased to provide the following business update.

Highlights

- **USFDA approval process on track – update meeting scheduled 27 January 2022**
- **FY21 record revenues expected in range of A$17.5-18.0 million - driven by growth in sales of Technegas™ generators, Technegas™ consumables and 3rd party distribution income**
- **A$2.3 million R&D Tax Incentive payment received from the ATO, $28m net cash to fund growth strategy**
- **Technegas™ CE mark renewed supporting continued sales across European and associated markets**
- **Clinical Update supports expanded clinical applications**

James McBrayer, Managing Director, commented, "We are pleased to report record sales growth for 2021, while continuing to make solid progress in securing approval for Technegas to be sold commercially in the US and investing to significantly expand our addressable markets beyond pulmonary embolism, (PE). We expect 2022 to be another successful and productive year with the FDA process coming to a conclusion in 2H enabling commercial sales of Technegas in the US. With our strong balance sheet and broad scope of supportive clinical studies we are well placed to extend our market leadership in lung imaging and drive ongoing growth".

USFDA Approval Process

Cyclopharm continues to make ongoing progress in addressing the information requested by the United States Food and Drug Administration (USFDA) in relation the company's application for approval to commence sales of the company's core proprietary technology Technegas™ into the US market.

The Company notes a scheduled meeting with the USFDA later this week on 27 January to discuss its progress on outstanding requests and other matters. Based on work undertaken and the significant engagement with the regulator to date, the company remains committed to meeting the information requirements for USFDA Technegas' regulatory approvals and to commencing sales into the US in the second half of 2022. Progress on US commercialisation readiness, including personnel training and inventory build, also continues.

Accordingly, Cyclopharm expects to provide further details regarding the approval process and as part of its FY2021 Financial Results announcement next month.

FY2021 Financial Performance - Record Revenue Result

Following a review of Cyclopharm's unaudited management accounts for the full year ending 31 December 2021, the company is pleased to report record sales growth with total FY2021 revenue expected to be between approximately A$17.5 million and A$18.0 million, representing growth of between 19% - 22% increase over the prior corresponding period.

Record sales figures have been driven primarily by increased third party distribution agreements and achieved despite reductions in medical diagnostic procedures associated with the ongoing global COVID-19 pandemic.

- Revenue from sales of Technegas™ generators and Patient Administration Set (PAS) consumables have remained robust, slightly exceeding FY2020 revenues, with unit sales of each also exceeding those of FY2020.
- Technegas™ service revenue declined marginally over the period, with generator servicing continuing to be impacted globally by travel and access restrictions associated with the COVID-19 pandemic.
- Revenue from third party distribution agreements continues to grow strongly, more than doubling FY2020 revenues. This revenue, whilst at lower margin than sales of proprietary Technegas™ products, is expected to continue to contribute to sales growth and be an ongoing source of profits.

Cyclopharm ended the financial year with a strong balance sheet and a cash balance of approximately $28 million, reflecting the capital raising undertaken during the financial year, and ongoing operational cashflows. This cash balance ensures the company remains appropriately capitalised to fund its ongoing FDA approval process, the anticipated launch of Technegas into the US market, R&D activities and working capital to fund continuing organic growth.

The Company will provide detailed financial information regarding its full year performance in its FY21 results announcement, scheduled for late February 2022.

Cyclopharm Receives A$2.3 million AusIndustry R&D Incentive Payment

Cyclopharm confirms it has completed its Research and Development Tax incentive claim for the 2021 financial year and has received a cash payment in January 2022 of A$2.3 million from the ATO (vs 2020 A$3.1 million).

Based on ongoing and planned research and development activities, Cyclopharm also expects to receive an R&D tax incentive in respect of the current financial year. The exact amount of any future R&D tax incentive will be subject to the nature, timing and value of R&D activities undertaken each year, some elements of which are outside of the company's control.

European Regulatory Approval

Cyclopharm is pleased to advise that Technegas™ has achieved renewal of its CE mark under the extensive new European Medical Device Regulations.

In light of sweeping European regulatory changes associated with the transition of medical device regulation from the MDD directive to the new MDR regulation, this approval is a major achievement for the company. It reflects significant investment and commitment to updating our quality management system to current regulatory standards and has been achieved in an environment when many other device manufacturers have either been unsuccessful in their renewal or have abandoned their European region aspirations.

Clinical Update

There are several Cyclopharm supported clinical trial initiatives being conducted targeting Beyond Pulmonary Embolism applications to include Asthma, COPD, Lung Transplant and, more recently, in indications related to the identification and management of Long-COVID. Indicative results from sponsored initiatives like the following case study and abstract indicate the clinical utility in these disease states with published results expected in the first half of 2022.

- McDonald - Imaging for precision medicine: can V-P SPECT measure mepolizumab response in asthma? (DOI: https://doi.org/10.1002/rcr2.717)
- Tahir - Investigating the Origin of the Frequency Dependence of Respiratory Resistance to Airflow in Post Lung Transplant Patients as a Marker for Chronic Lung Allograft Dysfunction (https: ajrccm-conference.2021.203.1_MeetingAbstracts.A4612 (atsjournals.org)

With the extensive clinical use of Technegas globally, during any given year publications, independent of the company, highlight the importance of functional ventilation imaging with Technegas in numerous respiratory conditions. A sampling of the independent 2021 publications referencing Technegas include:

- Bajc - Assessment of Ventilation and Perfusion in patients with COVID-19 discloses unique information of pulmonary function to a clinician: case reports of V/P SPECT (https: 10.1177/11795484211030159. eCollection 2021)
- Currie G - A Technical Overview of Technegas as a Lung Ventilation Agent (https://doi.org/10.2967/jnmt.121.262887)
- Blanc-Beguin - 68Ga-Labelled Carbon Nanoparticles for Ventilation PET/CT Imaging: Physical Properties Study and Comparison with Technegas® (https://doi.org/10.1007/s11307-020-01532-6)
- Bahloul - Signs of tracheobronchitis may constitute the principal finding on the lung SPECT/CT images of COVID-19 patients (https://doi.org/10.1007/s00259-020-05139-5)
- Ma - A Feasibility Study on Using Single-Photon Emission Computed Tomography Pulmonary Perfusion/Ventilation Imaging for the Diagnosis of Chronic Thromboembolic Pulmonary Hypertension and Patient Risk Assessment (https://doi.org/10.2147/IJGM.S335051)
- Rutting - Effect of combination inhaled therapy on ventilation distribution measured by SPECT/CT imaging in uncontrolled asthma (https://doi.org/10.1152/japplphysiol.01068.2020)
- Bajc - Pulmonary Functional Imaging, Basics and Clinical Application of Nuclear Medicine and Hybrid Imaging (https://doi.org/10.1007/978-3-030-43539-4_7)
- Al-Mashat -Pulmonary perfusion and NYHA classification improve after cardiac resynchronization therapy (https://doi.org/10.1007/s12350-021-02848-8)

Whilst achieving USFDA approval remains a major objective for Cyclopharm, the potential in applications Beyond PE represents a significant opportunity 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 refer to our website at www.cyclopharm.com or 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.