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USFDA APPROVAL PROGRESS FOR TECHNEGAS AND BUSINESS UPDATE

Cyclopharm Limited (ASX: CYC) is pleased to provide the following update on its progress towards gaining United States Food and Drug Administration ("USFDA") approval to begin sales of Technegas™ into the US, preliminary (unaudited) revenue performance for FY20 and other operational matters.

Highlights

- **USFDA approval targeted for Q2 on track and progressing well with a pre-approval audit scheduled for the week commencing 29 March 2021.**
- **Strong support for Technegas™ in the USA expressed from frontline healthcare workers based on safety concerns of competitive products.**
- **Total unaudited revenue for 2020 was in line with prior year at $14m AUD.**
- **Technegas™ procedures rebound following initial reactions to the COVID-19 pandemic.**
- **Technegas™ H2 consumable sales recover sharply post initial COVID-19 impact: revenues up 39.2% in H2 over H1.**
- **3rd Party Distribution up 79.1% in H2 over H1 to $1.3m AUD.**
- **In anticipation of US market entry, the Board is considering appointing an additional Director during 2021.**
- **Favourable progress is being made with regard to the litigation process against former employees. CYC remains confident it will achieve a successful and complete resolution to all matters in 2021.**

USFDA Approval Process

Cyclopharm's Phase 3 trials to support its USFDA application for USA market entry were confirmed to have met their Primary and Secondary Efficacy Endpoints in September 2020. The Company continues its ongoing positive dialogue with the USFDA to support their final steps towards granting final approval of Technegas™.

Based on these discussions and consistent with previous disclosure, the Company remains highly confident the approval process is on track to complete in 1H 2021.

In March 2020 the USFDA announced, as a result of the COVID-19 pandemic, that it was suspending all onsite inspections and will utilise alternatives to include desk-top and virtual audits. In an update

to this policy, in August 2020 the Agency issued further guidance[1] that stated the Agency would "cautiously resume Domestic audits and address Foreign pre-approval and for-cause inspection assignments that are not deemed mission-critical remain temporarily postponed, while those deemed mission-critical will still be considered for inspection on a case-by-case basis".

We are pleased to inform our shareholders that the USFDA Office of Regulatory Affairs, Office of Pharmaceutical Quality Operations have confirmed that they will conduct an onsite pre-approval audit of the Company's manufacturing facility located at Kingsgrove, NSW during the week commencing 29 March 2021.

Given the current backlog of regular surveillance and pre-approval audits globally, the Company views this audit as acknowledgement to the clinical importance of Technegas™ in the fight against COVID-19.

Strong Clinical Support in the USA

In June 2020, 77 US based Nuclear Medicine physicians wrote to the USFDA requesting an expedited NDA review for Technegas. In November 2020, a second letter was sent to the FDA with 90 physicians' signatures imploring both Cyclopharm and the FDA to move quickly towards approval.

With the USA in the grips of another significant surge in COVID-19 cases as foreshadowed in the November physician letter, a group of 102 front-line Nuclear Medicine Technologists have sent further correspondence to the FDA. These frontline healthcare professionals have implored the USFDA to expedite the approval of Technegas™ stating: "We ask the FDA to finalize the approval of the Technegas™ application with utmost expediency to bring this ventilation agent with the least likelihood of spreading the virus to healthcare professionals supervising the performance of ventilation scintigraphy".

This recent correspondence along with the previous Nuclear Medicine Physicians' letter, reinforces the Board's expectation there will be strong initial sales demand for Technegas™ following USFDA approval.

US Market Entry and Sales Model

As previously announced, Cyclopharm has been undertaking a number of activities to ensure it is well placed to rapidly roll out Technegas™ in the USA once USFDA approval has been achieved. These activities have included, building inventory reserves, finalising agreements for 3rd Party distribution, service and installation, and administrative support.

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

[1] Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers (https://www.fda.gov/media/141312/download)

In order to accelerate entry into the US market, the Company plans to supply Technegas™ Generators to US Hospitals and generate revenues through a Service Model rather than upfront sales of Generators. This approach moderates the upfront capital expenditure processes in adopting Technegas™.

Under the Service Model, Cyclopharm will retain ownership of the Generators over their lifecycle and provide consumables, generator maintenance and operator training on an ongoing basis to hospitals, in return for a continuing service fee and consumable sales. This approach also allows Cyclopharm to adhere to the ongoing regulatory requirements for Technegas™, as a drug-device combination product, that is expected by the USFDA

The financial impact of this model will result in Cyclopharm expanding the value of the plant and equipment on its balance sheet and replacing lumpy generator and consumables sales revenue with a more predictable and growing recurring revenue base over the generators' lifecycle.

The initial existing market for nuclear medicine ventilation imaging in the USA is estimated to be approximately US$90 million annually, representing approximately 600,000 individual procedures. Based on Cyclopharm's experience in the Canadian market, it 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.

FY20 Revenue

Following a review of Cyclopharm's unaudited management accounts for the full year ending 31 December 2020, we are pleased to report that in an unprecedented and challenging year with revenues impacted by COVID-19, sales have rebounded in the second half with total FY20 revenue expected to be in line with that of FY19 at approximately $14m AUD.

Our core proprietary technology Technegas™ used in functional lung imaging primarily for the detection of pulmonary embolism was initially impacted, similarly to many diagnostic procedures globally. Following the introduction of improved patient processing procedures and the availability of personal protection equipment (PPE) for health care workers, Technegas™ procedures rebounded strongly with consumable revenue increasing by 39.2% in H2 over the previous half from $3.7m to $5.1m AUD.

A recovery in H2 consumable sales, (39.2% increase) compared to H1 was driven by the fulfillment of the resumption of orders from France, an additional order from China and an overall improvement of trading conditions in other markets.

In addition, 3rd Party distribution revenue continued to grow during H2, in line with expectations. FY20 H2 revenue was $1.25m AUD compared to $700k for H1. 3rd Party distribution revenue is driven by a mix of radiopharmaceuticals, capital equipment and associated consumables. These products, whilst at lower margins than our proprietary Technegas™ products are expected to be an ongoing source of complementary profits.

The Company anticipates announcing further information about its full year performance in its FY20 results announcement, scheduled for late February 2021.

Litigation Update

As previously announced, 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").

In 2020, further actions were launched in both German and Australian courts. Favourable progress is being made in both jurisdictions and the Board remains confident that it will achieve successful outcomes from these actions in 2021.

Corporate Governance

In line with good corporate governance practices, Cyclopharm's Board continues to evaluate its skills and composition to ensure they appropriately support the Company's growth and governance requirements.

Specifically, in anticipation of US market entry and the ongoing work required to expand the use of Technegas® beyond the PE market, the Board is considering appointing an additional director, with the requisite skills and experience during 2021.

No final decision has been made regarding such appointment, and an appointment will only be made following a thorough and rigorous selection process.

This ASX announcement was approved and authorised for release by James McBrayer, Managing Director, CEO and Company Secretary.

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^{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.