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25 February 2021

The Manager
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FINANCIAL YEAR 2020 RESULTS

Cyclopharm Limited (ASX: CYC) is pleased to provide the following update on its business and financial performance for FY2020, including progress towards gaining United States Food and Drug Administration ("USFDA") approval to distribute Technegas in the USA in 2021.

Highlights

- **Significant progress made with the FDA to secure approval of Technegas in the US – first commercial sales expected to start in H2 2021. Strong support from clinicians and front-line technicians, who want a safer lung imaging agent**
- **Record Group revenue of $14.68 million, up 4.2% on the prior comparable period (PCP)**
- **Technegas™ sales rebound by 51.4% in 2H after pandemic impacted first half. Full year decline in revenue by 12% to $12.35 million**
- **Good progress in developing new clinical applications providing large, long term growth opportunities for Technegas™ – Beyond PE, includes Asthma and COPD**
- **Net cash position at year-end of $1.87 million, successful share placement and retail share purchase plan completed, raising $33 million, in February 2021. Cyclopharm is now fully funded for the next phase of growth**
- **Final dividend maintained at 0.5 cents per share (cps), bringing total unfranked dividends for FY20 to 1.0 cps.**

James McBrayer. Managing Director noted, "Cyclopharm delivered another solid underlying financial performance in 2020 with record revenues. We also continued to make good progress in executing on our growth strategies to expand our addressable markets for Technegas. We are developing new applications for our market leading technologies in new large long term growth markets beyond Pulmonary Embolism, such as Asthma and COPD. Importantly, we have entered the final stage of the approval process to commence sales of Technegas™ in the USA market in 2021. With the successful completion of the capital raise in February we are fully funded for our next exciting stage of growth."

FY20 Financial Summary

We are pleased to report that in a challenging year with revenues impacted by COVID-19, Technegas™ sales along with new revenues generated from third-party distribution agreements resulted in achieving record revenues of $14.52 million AUD.

SALES BY REGION ($MILLIONS)	2017	2018	2019	2020	CHANGE FY19 TO 20
Technegas™ - Canada	2.20	2.14	2.55	1.76	(31%)
Technegas™ - Europe	8.34	8.35	8.74	8.27	(5%)
3RD Party sales - Europe	0	0	0	2.17	100%
Technegas™ - Asia Pacific	2.37	2.66	2.35	2.26	(4%)
Technegas™ - Rest of World	0.28	0.25	0.44	0.06	(86%)
Total	**13.19**	**13.40**	**14.08**	**14.52**	**3%**

Cyclopharm recorded a loss before tax of approximately $5.84 million, an increase of $3.42 million loss on the prior year's loss of $2.42 million. This performance primarily reflects the ongoing investment required for Cyclopharm to meet global regulatory requirements, which include the heavy investment required for the USFDA approval process.

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.

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.

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 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, following the anticipated USFDA approval. These activities have included, building inventory reserves, finalising agreements for 3rd Party distribution, service and installation, and administrative support.

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.**

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 financial impact on US hospitals of adopting Technegas™ compared to the upfront Generator sales and Consumable sales model used in other international markets.

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. It also allows Cyclopharm to adhere to the regulatory requirements for Technegas™ that was requested by the FDA as a combination product.

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.

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

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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.