cyclopharm

19 December 2018

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POSITIVE BUSINESS AND TRADING UPDATE

- **New Canadian Guidelines name Technegas as the best ventilation agent for diagnosing Pulmonary Embolism**
- **Existing USFDA clinical trial program progressing well with 96 patients currently enrolled**
- **Protocol to accelerate USFDA approval process to be lodged this month for review**
- **FY18 Revenue expected to be in line with FY17**

New Guidelines from the Canadian Association of Nuclear Medicine

The Canadian Association of Nuclear Medicine ("CANM") have released new Guidelines for Ventilation/Perfusion (V/P SPECT) in Pulmonary Embolism which recommend the benefits of 3-D imaging (SPECT) over 2-D imaging (planar)[2].

Specifically, the CANM Guidelines strongly recommend clinicians use Technegas above all other ventilation agents in the diagnosis of Pulmonary Embolism particularly in the presence of other lung conditions, such as Chronic Obstructive Pulmonary Disease ("COPD").

In particular, Cyclopharm note the following excerpts from the CANM Guidelines that specifically reference Technegas:

> *"**For ventilation, 99mTc-Technegas is the best radio-aerosol**, particularly in patients with COPD. Liquid aerosols produced in nebulizers such as 99mTc-DTPA are inferior for SPECT and should not be used unless Technegas is not available."*
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> *"Liquid aerosols produced in nebulizers, such as 99mTc-DTPA, are inferior for SPECT, and should not be used unless Technegas is not available. **Overall, Technegas remains the best radio-aerosol, particularly in patients with obstructive lung disease**. Another advantage is that only a few breaths are sufficient to achieve an adequate amount of activity in the lungs, reducing time and personnel exposure to radiation."*
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> *"In situations of COPD up to 31% of patients may have PE and up to 10% may die. Even those patients who have abnormal Chest X ray can still undergo V/P SPECT and in selected patients, V/P SPECT with low dose non-contrast CT could be considered. **Technegas is considered the***

[2] https://canm-acmn.ca/resources/Documents/Guidelines_Resources/MasterDocument_Final_Nov_21_incl-Exec-Sum_ver3_Dec.%2012_.pdf

agent of choice i*n this population as there is less central airway deposition, better peripheral penetration, and it does not wash out as quickly as traditional aerosols."*

James McBrayer, Cyclopharm's Managing Director and CEO stated "We are thrilled about the release of the CANM Guidelines. Canada has grown to become the largest single country market for Technegas globally. The company views its success in expanding sales in Canada, along with the recent endorsement by the CANM, as a very positive indication of Technegas' sales potential into the significantly larger US market, following the anticipated USFDA approval."

Update on United States Food and Drug Administration ("USFDA") approval process

Cyclopharm advises that, as at 14 December 2018, the Company had enrolled 96 patents in its existing Phase 3 Trial (CYC-009). On 16 November 2018 Cyclopharm made a submission to the USFDA requesting the remove of a second day follow-up visit required for trial subjects. If approved, this change is expected to speed recruitment of trial participants.

As announced to the ASX on 12 October 2018, in parallel with our current Phase 3 clinical trial program, Cyclopharm is pursuing an alternate pathway for USFDA approval, known as a '505(b)2' application. This pathway will allow the use of historical clinical data of Technegas compared to competing products and technologies along with information obtained from the current CYC-009 trial.

Cyclopharm advises it intends to submit to the USFDA its 505(b)2 literature review protocol on 27 December 2018 for comment. If successful with the 505(b)2 New Drug Application, referred to as CYC-011, the Company intends to terminate patient recruitment for the CYC-009 trial ahead of previous expectations.

In this regard, Cyclopharm remains on track to achieve its target commencement of Technegas sales into the US in late 2019.

FY18 Trading Update

Following a review of Cyclopharm's unaudited management accounts to date and expectations for the remainder of the 2018 financial year, the company anticipates sales for the financial year will be in line with the prior year. As anticipated in the outlook provided in its half year results, sales for the year have benefited from higher volumes in France and a resumption in sales to China, partly offset by a decline in volumes in the German market.

During the second half of 2018, the company has progressed its German litigation, with the first civil case awarding its subsidiary, Cyclomedica Australia, a payment of A$310,000.

Based on anticipated earnings and cash flows for the period, the company reconfirms it will have sufficient cash to complete the USFDA submission, fund R&D and near term growth initiatives.

The company expects to release its full year audited accounts to the ASX in late February, 2019.

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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.