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The Manager
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cyclomedica
molecular imaging
technegas

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Cyclopharm Limited settles claim for US\$1.8m

As previously advised, Clinquest Inc was a company engaged from 2000 to 2007 to obtain approval from the Food and Drug Administration (FDA) to sell Technegas in the United States. Cyclopharm Limited has agreed settle its claim for US\$1.8m.

The YTD legal costs pursuant to this case is AUD \$810k. This settlement represents a net pre-tax cash uplift of approximately AUD \$1.1m. Once taking into account capital cost write downs and tax implications we expect that there will be little or no impact to the profit and loss statement this financial year.

New Drug Application to sell Technegas in the USA

In the half year report, we provided shareholders with an update on the company's strategy to secure marketing approval to sell Technegas in the US market.

Based on the FDA's requirement to conduct an additional Phase III clinical trial, in October 2009 Cyclopharm lodged a Special Protocol Assessment ("SPA") with the Agency targeted at seeking input and agreement prior to commencing the new trial.

A response has been received from the agency requiring modifications to our protocol design. The Agency provided several recommendations and comments that will assist us toward developing a protocol that will ensure success.

The USA remains a major growth opportunity. The director's have agreed to review the strategy for funding the Phase III clinical trial.

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Background

Cyclopharm Limited

Cyclopharm is a radiopharmaceutical company servicing the medical global medical community. The Company's mission is to enable nuclear medicine and other clinicians with the ability to improve patient care outcomes.

Cyclopharm achieves this objective through the provision of radiopharmaceutical products, Technegas (for lung imaging) and Molecular Imaging / PET radiopharmaceuticals (used in cancer, brain and cardiac imaging). Our customers are nuclear medicine departments located within hospitals and clinics.

Technegas

The Technegas technology is a structured ultra-fine dispersion of radioactive labeled carbon, produced by using dried Technetium-99m in a carbon crucible, micro furnaced for a few seconds at around 2,500°C. The resultant gaseous 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 the superior diagnosis of pulmonary emboli (blood clots in the lungs).

Positron Emission Tomography (PET)

PET radiopharmaceuticals target specific tissues / organs, concentrate there, and the attached radioisotope emits radiation, which is then detected by a PET or PET / CT gamma (collectively PET camera). These imaging modalities help physicians improve their ability to detect and determine the location, extent and stage of cancer, neurological disorders and cardiac disease. By improving diagnosis, PET scans aid physicians in selecting better courses of treatment, as well as assessing whether treatment is effective or should be changed.

Macquarie University Hospital and the Macquarie University School of Advanced Medicine

Macquarie University Hospital will establish a major medical precinct within the Macquarie University Research Park to complement the Allied Health teaching services offered by Macquarie University.

The Macquarie University Hospital will be a state of the art facility that will also deliver health education and research on site.