Clinuvel

COMMUNIQUÉ

October 2008

Overview from CEO

Welcome to the Q3 edition of the Clinuvel Communiqué.

I write to you at historical times where the fall out of the subprime crisis appears to take the world into recession. Equity markets globally are continuing to lose value, and confidence in the capital markets is swiftly being eroded. I realize that these seismic movements may well detract our investors from the daily progress Clinuvel is making. However, value investors look upon these events with different eyes and scavenge for opportunities.

Notwithstanding the liquidity crisis we are witnessing, I am appreciative and feel privileged that Clinuvel has been able to attract support from new and existing, Australian and International investors. In September, we learned that syndicated investors have shown confidence to buy out former substantial shareholder Absolute Capital Management Holdings. The transfer has now resulted in a diversified share register, boding well as we progress towards commercialization of afamelanotide.

On a material front, last semester Clinuvel has – for the first time in its history – received regulatory acknowledgement from the **FDA Orphan Product Group** for the use of afamelanotide. The **Orphan Drug Status** allows Clinuvel to develop afamelanotide in erythropoietic porphyrias, and fast track the development program.

Another highlight was Clinuvel's progress into its 5th indication for afamelanotide, as an adjunct therapy for patients undergoing **Photodynamic Therapy (PDT)**. PDT is significant from a biochemical and development point of view as there is a strong commonality with Erythropoietic protoporphyria (EPP) currently in Phase III trials. The molecules (protoporphyrin IX) causing the severe skin symptoms in EPP patients are of the same family of molecules purposefully used as photosensitizers in PDT to obtain maximum effectiveness in cancer treatment.

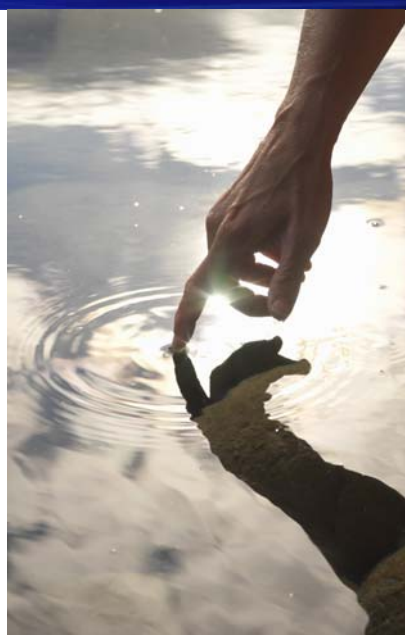
In August, we finally launched the first phase of **clinuvel.com** and the sections on providing 4 dimensions of deeper knowledge online. Clinuvel initially will provide specific **Xptise** on skin, UV and melanin. The online project is novel in our sector.

Clinuvel has recently strengthened its international scope in pharmaceuticals by appointing **Mr Jack Wood** to its Board.

The main focus of our team is to continue its work in developing afamelanotide, remaining vigilant over safety and effectiveness.

A final word to all shareholders and supporters, we deeply believe in the medical benefits of afamelanotide based on past results. The current market conditions are most unfortunate but do not deter us from the focus shown over the past 3 years. We are working around the clock towards realizing our next objectives in Q4.

Philippe Wolgen, MBA, MD



Company Background

Clinuvel Pharmaceuticals Limited is an Australian biopharmaceutical company developing its photoprotective drug afamelanotide (CUV1647) for the treatment of UV-related skin disorders. Clinuvel's pioneering work aims to assist in preventing the global problem of UV-related skin disorders, by developing afamelanotide in areas of the greatest clinical demand.

Share Price

Shares on issue
303,148,665
Australia ASX (CUV), German XETRA (UR9), US ADR(CLVLY)
Average Daily Volume:
(Past 6 months) ASX: 163,171
Cash Balance: A$47million
Average Monthly Cash Burn
~A$1m

Photodynamic Therapy (PDT)

PDT is a treatment mainly used in oncology (gastro-enterology) to endoscopically eradicate incipient pre-malignant lesions of the esophagus ('Barrett's esophagus') and recently as a palliative treatment in bile duct cancer (cholangio-carcinoma). PDT combines the intravenous administration of a photosensitizer (porfimer sodium) with a focal light source to activate photochemical tissue reactions. This combination proves highly selective in cancer treatment.

A consistent side effect and significant clinical disadvantage to the use of porfimer sodium as a photosensitizer is the associated phototoxicity of the skin experienced for up to 3 months following treatment. Consequently, PDT patients are obliged to observe continuous precautions to avoid exposure to light and UV. Exposure to UV results in erythema, acute blistering and severe burns of the skin, causing intense pain and skin damage. Conventional UV sunscreens are of no value in protecting against phototoxic reactions following PDT, and patients are obliged to stay indoors for the duration of three months after PDT treatment. It is anticipated that afamelanotide may offer photoprotection in PDT patients who are at high risk of phototoxicity.

FDA Orphan Drug Designation

The **FDA's orphan-drug designation (ODD)** is reserved for new drugs or therapies being developed to treat rare diseases or conditions that affect smaller populations in the United States. The orphan-drug designation allows for an accelerated review process by the FDA, seven-year market exclusivity in the United States upon obtaining marketing authorization, tax benefits, and exemption from user fees.

In July, Clinuvel was granted an ODD by the FDA for **the treatment of erythropoietic porphyrias in the USA**, where fewer than 200,000 people are affected. This marked the first time Clinuvel has been recognized by regulators in the USA and follows similar recognition from the EMEA and Swissmedic earlier in 2008.

Clinuvel is currently testing afamelanotide in a Phase III trial for EPP in Europe and Australia and intends to file for an Investigational New Drug (IND) in the USA by the end of 2008.

2008's Value Drivers

- Start Phase II PDT Trials ✓
- FDA Orphan Status ✓
- US IND Filing
- Phase III EPP interim results

Meetings & Events

- 2008 AGM, November 2008
- Rodman & Renshaw Healthcare Conference, New York, USA, 10-12 November 2008
- Bio-Europe 2008, Mannheim, Germany, 17-19 November 2008

Clinuvel in the News

25/9/08 Instyle (Germany)
23/9/08 Biotechnology News (Australia)
23/9/08 Australian Life Scientist
8/9/08 Ethical Investor (Australia)
For full media coverage log onto www.clinuvel.com

News from USA & Europe

As Clinuvel expands its clinical activities in Europe, our Zürich office will increase, with 7-10 staff based in Europe by the end of 2008.

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