Clinuvel

COMMUNIQUÉ

July 2008

Overview from CEO

Welcome to the June 2008 edition of Clinuvel Communiqué. The past quarter has been marked by continued risk aversion in capital markets with a flight to earnings, size and quality affecting the bio-pharmaceutical sector and Clinuvel. The company continues to make steady progress towards registration of its photoprotective drug afamelanotide (CUV1647). With the skin disorders EPP and PLE, we have two indications in Phase III placebo controlled trials.

Our most recent milestone was achieved in June, when we obtained approval to commence clinical trials in our fourth indication, **Solar Urticaria (SU),** a severe and rare light related skin disorder.

Clinuvel also received an earlier than anticipated designation of the generic drug name "**afamelanotide**" assigned by the **World Health Organisation (WHO)**.

Further regulatory progress was made in April, when Swissmedic, the central Swiss supervising authority for therapeutic and medicinal products, granted Clinuvel **Orphan Drug Designation (ODD) in Erythropoietic Protoporphyria (EPP).** The designation follows the two ODD designations granted by the EMEA in March this year.

Pending safety and efficacy in EPP (a variation of porphyria, referred to as absolute sun intolerance) the Company will consider filing for regulatory approval for this indication. Interim results for EPP are expected in 2H08.

With the new season in Europe, our second round of dosing in EPP has begun. This represents the third cohort in our EPP trial schedule.

Our number of trial sites continues to grow. Clinuvel will have some 40 sites, on two continents across five indications by year's end.

During **the second half of 2008** we anticipate progressing to the following milestones:

- start of Phase II trials in **Photodynamic Therapy (PDT)** to reduce phototoxicity associated with cancer treatment
- interim results for our Phase III **EPP** trial;
- filing of an **Investigational New Drug** (IND) in the USA

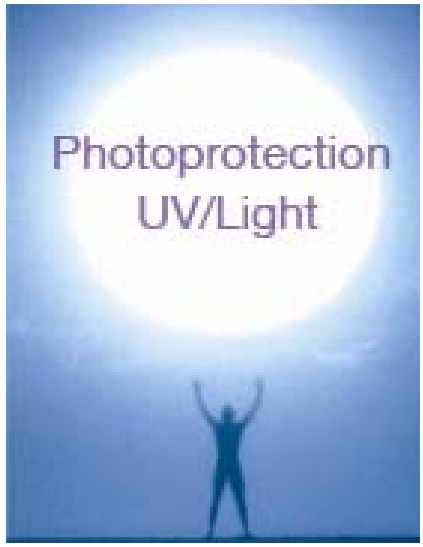
With Clinuvel's strong focus on and expertise in, photoprotection of associated skin disorders, we aided **the Australian Skin & Cancer Foundation** by supporting educational forums for healthcare professionals.

In June Clinuvel presented to the Australian securities industry at the FINSIA Life sciences Showcase, as well as attended **Bio2008 in San Diego**, one of the largest biotech partnering conventions.

Our cash reserves remain strong at AUD$50m, with a burn rate of under AUD$1.0m per month.

We are on course to advance the commercialization of photoprotective afamelanotide (CUV1647) and are working towards meeting all the regulatory objectives.

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 (CUV1647) in areas of the greatest clinical demand.

Share Price

Shares on issue
302,648,655
Australia ASX (CUV), German XETRA (UR9), US ADR(CLVLY)
Average Daily Volume:
(Past 12 months)
ASX: 172,426
XETRA: 44,002
ADR: 3,828
Cash Balance:
AUD$50million
Average Monthly Cash Burn
~AUD$1.0m

About Solar Urticaria (SU)

Solar Urticaria (SU) is an acute and rare light related skin disorder that results from exposure to sunlight and UV. Prolonged exposure can typically result in the development of "wheals" or round red raised areas on the skin, and may aggravate to headache, nausea and breathing difficulty. SU is classified as a severe disorder in dermatology. Currently there is no preventative treatment available. Steroids, immunosuppressants and intravenous immunoglobulins are being used in these patients to suppress symptoms.

The *preventative* use of afamelanotide (CUV1647) offers potentially major advantages over symptomatic treatment and it is postulated that 'at risk' SU patients could experience a significant reduction in severity of attacks following exposure to UV. The clinical trials will need to provide evidence for the choice of testing afamelanotide in SU.

The Phase II SU trials will be conducted in Manchester, Vienna and Düsseldorf. It is anticipated that the Phase II trials will begin by September 2008 and we expect completion within 9 months.

Novel Online Communication

Over the past 7 months we have prepared an extension to our online activities, enabling communication with a wider audience, segmented across the 5 groups of patients, investors, physicians, media and regulators. We are in final stages of the build and are close to revealing an advanced way of communicating. to reach a global audience.

In the pharmaceutical sector, we aim to take a leading role in the area of interactive communication ahead of the growing interest in afamelanotide (CUV1647) and its related therapeutic indications.

Management development

In recent months, we have been fortunate to find new talent to fortify our senior management. With Clinuvel's progress further skills were added to the team in Melbourne and Europe. We also recruited able and enthusiastic staff at junior management level.

Together with the existing personnel, the company has arrived at a blend of talent which has demonstrated the ability and persistence to successfully further the development of photoprotective afamelanotide (CUV1647).

2008's Value drivers

- Start Phase II SU Trials✓
- EMEA orphan status ✓
- Phase III EPP trials interim results
- US IND Filing
- Start Phase II PDT Trials

Meetings & Events

- Bioshares Thredbo Biotech Summit, July 2008
- 6th Annual Australian Biotechnology Summit, Sydney, July 2008
- AusBiotech08 National Conference, Melbourne, October 2008
- European Academy of Dermatology & Venereology, Dr Chris Baker, Paris, September 2008

Clinuvel in the news

17/6/08 Business Spectator (Australia)
12/6/08 Biotechnology News (Australia)
23/4/08 Business Spectator (Australia)
18/4/08 MoneyTV (Germany)
17/4/08 Euro Am Sonntag (Germany)
18/4/08 Biospectrum (Asia)

For all the latest press and online coverage log onto

www.clinuvel.com

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Cautionary Note concerning Forward Looking Statements
Clinuvel is an Australian biopharmaceutical company focused on developing its leading drug candidate, afamelanotide (CUV1647), for a range of UV-related skin disorders resulting from exposure of the skin to harmful UV radiation. Pharmaceutical research and development involves long lead times and significant risks. Therefore, while all reasonable efforts have been made by Clinuvel to ensure that there is a reasonable basis for all statements made in this document that relate to prospective events or developments (forward looking statements), investors should note the following:

- actual results may and often will differ materially from these forward looking statements;
- no assurances can be given by Clinuvel that any stated objectives, outcomes or timeframes in respect of its development program for afamelanotide (CUV1647) can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development program for afamelanotide (CUV1647) is successful, it will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place.

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