



### Overview from CEO

Welcome to our April edition of Clinuvel Communiqué. Clinuvel has reached some important achievements early in 2009, and I take this opportunity to look at the year ahead.

Clinuvel has matured to a point where the team is able to see the end-game of the drug in development, afamelanotide. For over a decade the company has refined and optimized its lead drug afamelanotide under regulatory guidance (ICH/GCP). The Clinuvel technology is highly complex and allows the drug to be available at picogram quantities in order to fine-regulate its photoprotective characteristics. The drug and its applications are proprietary to Clinuvel and it is exciting to see how much progress we have made to serve a relatively unattended global population of patients. The ability to treat diseases in unaddressed groups of patients is rewarding for all of us. In this respect, the gratitude shown by patients and physicians is meaningful and is our key motivator on a daily basis.

The regulatory progress is in line with our expectations. Significantly, our regulatory team is speaking to the various global agencies to have its final path to market validated and endorsed. The process of involving regulatory bodies is instrumental in modern drug development.

Clinuvel recently stated how the patients in Switzerland unanimously requested from

Swissmedic to make afamelanotide available after the trial had finished. Although a cost to the company, the request for compassionate supply signifies a positive sign of clinical efficacy. However, the company has confirmed publicly that it will not be in the position to expand its compassionate program indefinitely to the rest of the world.

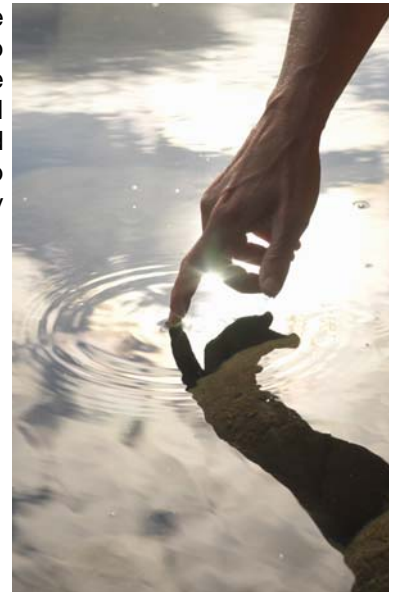
This coming semester, we anticipate the first results from the Phase II trials in photodynamic therapy (PDT) and we will then decide on the next steps for this indication, pending results.

Communication remains a key area for the company. All interested in Clinuvel may have witnessed how we continuously add to our online facilities to report on progress, and additional online tools will be released shortly.

Following our first IND obtained from the FDA in January, we will be relocating from San Francisco. Various strategic reasons have led us to open our office on the East Coast of the US.

A final note on the stock performance of the company urges me to look ahead with caution but reasonable optimism. Despite global decline in equities, the team at Clinuvel is not affected by its efforts to bring this drug to market. We at Clinuvel have a steadfast belief in our work and objectives.

Two factors define our intrinsic value: people and drug. Both hold more than a promise.



### Company Background

Clinuvel Pharmaceuticals Limited is Australia's photoprotective company. The company prides itself as the pioneer in the field of medicinal treatment of UV-related skin disorders. Clinuvel's pioneering work aims to address rare but significant skin disorders, by developing afamelanotide in areas of the highest clinical demand.

### Philippe Wolgen

#### Share Price

##### Shares on issue

303,148,665

Clinuvel is listed on XETRA (UR9) and has a level 1 ADR (CLVLY)

##### Average Daily Volume:

(Past 6 months)

ASX: 282,318

**Cash Balance:** A\$39.4million (March 30)

**Average Monthly Cash Burn Jan-Apr '09**

<A\$1.2m



## Clinuvel – supporting Science, the Medical Community and Patients

Clinuvel has recently undertaken to support several academic projects in the medical community, to assist with the understanding of photoprotection globally. The company recently supported the American Academy of Dermatology's 67<sup>th</sup> Annual Meeting in San Francisco.

Clinuvel will continue to support to raise the awareness of the need for medicinal photoprotection worldwide.

In May, Clinuvel will be a lead sponsor of the meeting organized by the Skin Care in Organ Transplant Patients Europe (SCOPE) group in Thessaloniki, Greece. SCOPE's work aims to increase the awareness and quality of dermatological care for organ transplant recipients

In June, Clinuvel will attend the International Conference hosted by the European Porphyria Initiative (EPI) in Stockholm.

## A Change to Communications

As Clinuvel gets closer to market, the company is exploring more ways to better reach its stakeholders. You will notice some new communications in the coming months, with the Clinuvel Communiqué set to be published every 2 months, and more projects on the horizon.

We welcome your questions and feedback addressed to [investorrelations@clinuvel.com](mailto:investorrelations@clinuvel.com)



## Next Value Drivers

- PDT Phase II results
- PLE Phase III interim results
- Start of US trials
- Brand name afamelanotide

## Meetings & Events April-May

- Corporate Roadshow – Australia and Europe
- SCOPE meeting – Thessaloniki
- Porphyria International Conference - Stockholm

## Webcast Series

Clinuvel recently launched the first in a series of webcasts. These videos will focus on the company's activities and some of the pressing issues in the field of photoprotection.

Non-Executive Director Jack Wood features in the first webcast, discussing commercialization options where Clinuvel can explore for afamelanotide. More of these presentations will follow soon

To view the new webcast and for more company updates, log onto Clinuvel's corporate website at [www.clinuvel.com](http://www.clinuvel.com).

### Contact Us:

If you have a question related to Clinuvel Pharmaceuticals Ltd investor relations, please email us at [investorrelations@clinuvel.com](mailto:investorrelations@clinuvel.com)

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### US Office:

Our US office is relocating shortly. More information will be available soon.

Please contact the Head Office for all enquiries.

### Cautionary Note concerning Forward Looking Statements

Clinuvel is an Australian biopharmaceutical company focused on developing its leading drug candidate, afamelanotide, 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 programme for afamelanotide can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for afamelanotide 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.