



### Overview from CEO

Welcome to the last edition of the year of the Clinuvel Communiqué.

With much pleasure, I take the opportunity to review the year 2008, a year marked by a multitude of positive clinical and regulatory activities.

Over the past year much has happened within the company, 2008 is the year in which Clinuvel obtained worldwide regulatory acknowledgement of its program.

For the shareholders of the company, it will be difficult at times to interpret the relative quiet times in newsflow as we progress our clinical program. Various reasons exist to be delicate with the information on afamelanotide as we progress. The reality in pharmaceuticals dictates discretion on IP and knowhow, as the company progresses to advanced stages of development. Additionally, I realize that the contraction of the global economy does not aid the confidence and patience needed to maintain positions in biopharmaceuticals.

Against the reality and pressure faced by our shareholders, Clinuvel has met its corporate objectives. We have completed our recruitment of the 'orphan designated EPP' study in Europe and Australia; we started the PDT trial in Europe; we continue the Phase III trial in PLE and Phase II in Actinic Keratosis and Solar Urticaria.

Over the year, Clinuvel continued to monitor the safety of afamelanotide long-term in various studies. The focus on safety-first is, in my view, the most prudent and appropriate way to develop new drugs to market.

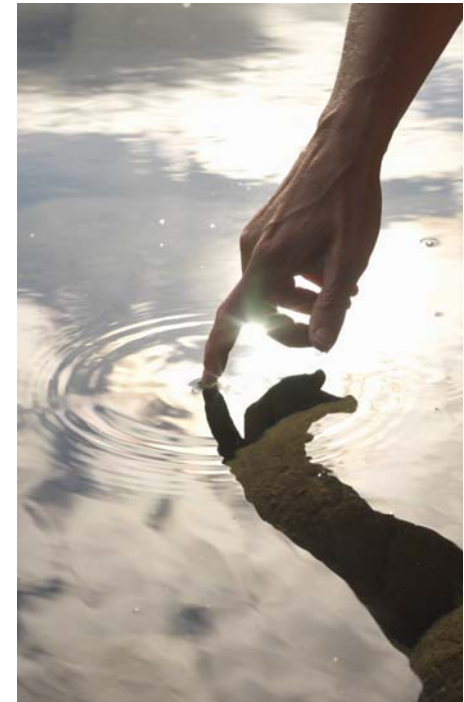
As we speak, **the first IND filing** of Clinuvel is a fact. After more than 14 months of continuous work by our internal team, various third parties and US consultants, we prepared the most comprehensive documentation to support our application. This has been a major objective for Clinuvel for 2008.

Another objective has been to **analyze interim results in the EPP studies**. Currently, we are in the final stages of data analysis and upon final sign off from the Independent Data Management and Review Committee, we will be in the position to release the results.

Looking ahead, 2009 will be a year of many activities at Clinuvel. We have been preparing various corporate activities surrounding the development of afamelanotide which we will be able to reveal by Q1.

We wish you, in anticipation of the newsflow on the company, a healthy and prosperous 2009.

**Philippe Wolgen, MBA, MD  
CEO**



### Company Background

*Clinuvel Pharmaceuticals Limited is an Australian biopharmaceutical company developing its photoprotective drug afamelanotide 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

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

#### Average Daily Volume:

(Past 12 months)

ASX: 260,934

**Cash Balance: A\$45million**

**Average Monthly Cash Burn**

<A\$1.0m



## Clinical Progress Update

At the completion of 2008, all five clinical indications that Clinuvel identified for afamelanotide have entered clinical trials. Whilst trial progression is never linear, Clinuvel has set internal target for all its trials. Here's a quick snapshot of our clinical progress to December 2008:

Condition	Phase	Trial Duration*	Locations
Erythropoietic Protoporphyrin (EPP)	III	12 months	12 centers – Australia and Europe
Photodynamic Therapy (PDT)	II	3 months	5 centers – France
Polymorphic Light Eruption (PLE)	III	18 months	11 centers – Australia and Europe
Actinic Keratosis in Organ Transplant Recipients (OTRs)	II	24 months	11 centers – Australia and Europe
Solar Urticaria (SU)	II	3 months	1 center – United Kingdom

\* Trial duration refers to the length of time a patient receives treatment and monitoring during the course of the study. As every study has a built in 'recruitment' period, it may take much longer to complete each trial than the trial duration period. Generally, longer trials will have longer recruitment periods.

Clinuvel successfully completed two pharmacokinetic studies (announced April 2008) which proved the administration of afamelanotide in a 16mg implant every 28 days is safe and doesn't increase human plasma (blood) levels, demonstrating the tolerability of the drug beyond clinical need. Clinuvel will continue to conduct similar studies to ensure the safety and efficacy of afamelanotide. Clinuvel has recently announced it will seek approval for a pediatric trial in EPP.

### Value drivers to look out for

- US IND approval – Jan 09
- Phase III interim results (EPP) - Jan 09
- Phase III interim results (PLE) – 1H 09
- Phase II full results (PDT) – 1H 09

### Meetings & Events

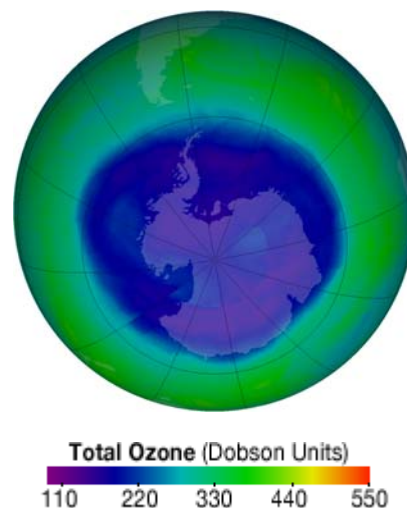
Clinuvel will be presenting at the *Late stage opportunities in Australian Life Sciences* meeting (San Francisco) in January 2009, coinciding with the JP Morgan Healthcare Conference.

Further meetings will be scheduled and posted online at [www.clinuvel.com](http://www.clinuvel.com).

### Ozone layer depletion

On September 12, 2008, the ozone 'hole' above the Antarctic Circle peaked for the year, resulting in the fifth largest hole on record, the largest being recorded on October 9 2006. It is anticipated that continued depletion of the ozone layer may result in greater levels of skin cancer in the community, particularly those closer to the Circle.

Right: ozone levels at 12/9/08 over the Antarctic Circle. Source: NASA.



#### Contact Us:

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

[www.clinuvel.com](http://www.clinuvel.com)

#### Head Office Australia:

Clinuvel Pharmaceuticals Ltd  
11/330 Collins St  
Melbourne, Victoria 3000

Tel: +61 3 9660 4900  
Fax: +61 3 9660 4999

#### US Office:

Suite 560  
353 Sacramento St  
San Francisco  
CA 94111

Tel: +1 415 722 9100  
Fax: +1 415 772 0919

#### Swiss Office:

Hauserstrasse 14  
8032 Zürich  
Switzerland

Tel: +41 44 253 750 0  
Fax: +41 44 253 750 1

#### 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.