

Clinuvel Pharmaceuticals Ltd

Leadership in Photoprotection

March 2009

ASX: CUV; US ADR: CLVLY; XETRA/DAX: UR9

SAFE HARBOR STATEMENT March 2009

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 program for afamelanotide can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development program 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.



Overview

- Clinuvel is an Australian biopharmaceutical company developing its photoprotective drug afamelanotide for the treatment of UV related skin disorders
- With US, European, Swiss and Australian regulatory acknowledgement and A\$43m in cash, the company is well placed to pursue its late stage clinical program in 5 areas of unmet medical need
- Commercialization in European, Australian and US markets is in sight



Market value



Market cap: \$62m
Cash on hand: \$43m
Burn rate: \$1.1m/month
Shares on issue: 303,148,665

Volume: 506,950/day
Value: \$152,601/day
Share Price: \$0.20
 β : 1.21

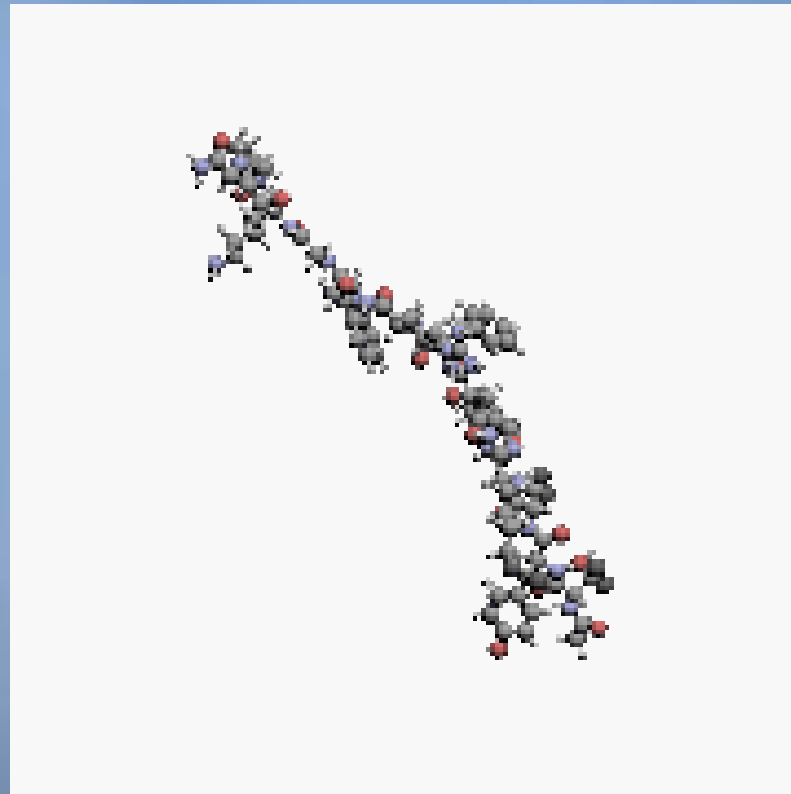


Progress 2006-2009

- New management team reset the corporate strategy
- Identified 5 medical uses for afamelanotide
- Raised AUD\$67M to fund clinical program
- Strengthened patent position to 2024
- Granted Orphan Drug Designations (ODD) in Europe and US
- Granted Investigational New Drug (IND) status by FDA in US
- Advanced to Phase III clinical trials
- Scaling up manufacturing for commercialization



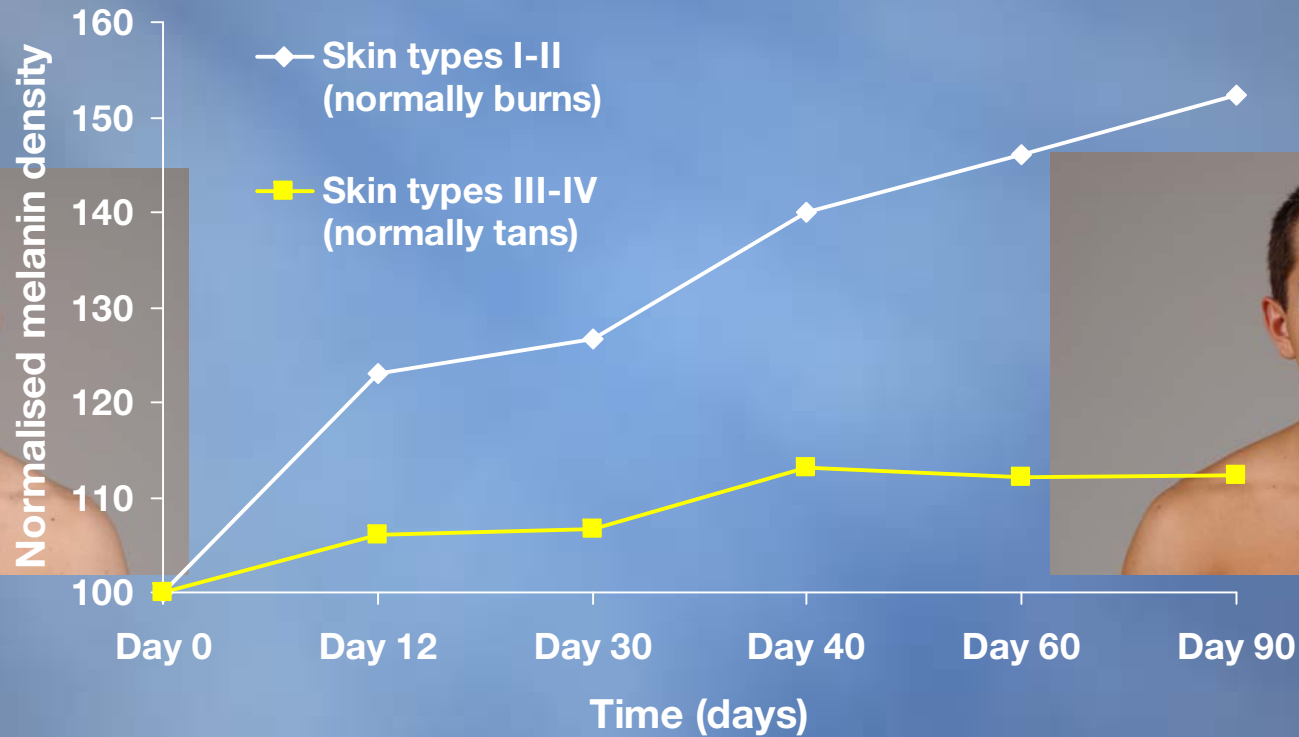
Afamelanotide our first-in-class drug



Afamelanotide increases melanin density

Melanin is known for its photoprotective properties

Normalised Abdomen Melanin Density vs Time



Photoprotection for fair skin (Fitzpatrick type 1, 2, 3)

Drug released over 10 days

Melanin increase for 60 days

Unique delivery technology

- Subcutaneous absorbable implant formulation, 16 mg
- Stimulates melanin production (melanogenesis) in the skin
- Used to treat UV related skin disorders (photodermatoses)



Afamelanotide targets 5
unmet medical needs

5 indications in the clinic

Indication	Description	2006 US market est. US\$m	Clinical stage
Erythropoietic Protoporphyrin (EPP)	Absolute sun intolerance 5,000 patients est. globally	25	Phase III
Polymorphous Light Eruption (PLE)	Sun poisoning 10m patients est. globally	40	Phase III
Actinic Keratosis (AK) / Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTR)	Skin cancer in OTRs who have an absolute, dramatic risk to skin cancers 1m OTR patients est. globally	240	Phase II
Solar Urticaria (SU)	Acute anaphylactic reaction to sun <5,000 patients est. globally	12	Phase II
Photodynamic Therapy (PDT), systemic	Phototoxicity associated with cancer treatment 50,000 patients est. globally	200	Phase II

First to market in Europe in 2010 in EPP



Erythropoietic Protoporphyrria (EPP)

- A rare Orphan disease (2008 - EMEA, Swissmedic, FDA)
- A serious and chronic condition with no methods of treatment
- Clinuvel estimates around 5,000 sufferers worldwide
- “It's like sticking your hands in boiling water and having 100 bees sting you at the same time”



EPP Phase III interim result

- Positive results announced Jan 2009
- First 14 Swiss patients to complete 1 year trial
- Maximum severity of phototoxicity reduced ($p < 0.001$)
- Total severity of phototoxic reactions reduced ($p = 0.028$)
- Skin melanin density increased ($p = 0.048$)
- No afamelanotide related serious adverse events
- Compassionate use - continuation request by all 14 patients
- Clinical benefit in reduction of EPP symptoms
- Final Phase III results Dec Q 2009 (N=101)

Afamelanotide reduces suffering of EPP patients



Polymorphous Light Eruption (PLE)

- A seasonal dermatological disorder
- Phototoxicity described as sun poisoning
- Itching, rashes, unsightly
- Global incidence around 10% of whom 10% are severe
- Interim Phase III results 1H09



Afamelanotide aims to alleviate and reduce symptoms suffered by PLE patients

Skin cancer (AK/SCC) in OTRs

- Organ Transplant Recipients (OTRs) are vulnerable to skin cancer
- OTRs are vulnerable for life due to immunosuppressive drugs
- OTRs have 65x higher chance of skin cancer
- US OTR population 447,515
- 30,000 new US patients pa

(Source: Organ Procurement and Transplantation Network, At-Risk Foundation and ITSCC)



**Afamelanotide aims to lower skin cancers
in OTR**

Solar Urticaria (SU)

- Solar Urticaria (SU) is an acute anaphylactic reaction to sun
- Following limited exposure to sunlight, sufferers experience rapid swelling and burning of the skin
- Estimated <5,000 sufferers worldwide



Afamelanotide aims to lower phototoxicity
suffered by SU patients

Photodynamic Therapy (PDT)

- Systemic PDT is a surgical treatment for solid mass cancers (eg esophagus, pancreatic, gall bladder)
- Systemic PDT patients treated with Photofrin photosensitiser suffer acute phototoxicity for 60 days after surgery
- Phototoxic reactions mirror those seen in EPP patients
- Esophagus cancer incidence 500,000 pa
- 10% of cases use PDT



Image: John Crawford/National Cancer Inst. 1988

**Afamelanotide aims to lower phototoxicity
suffered by PDT patients**

Regulatory progress and route to market

Regulatory progress in the US

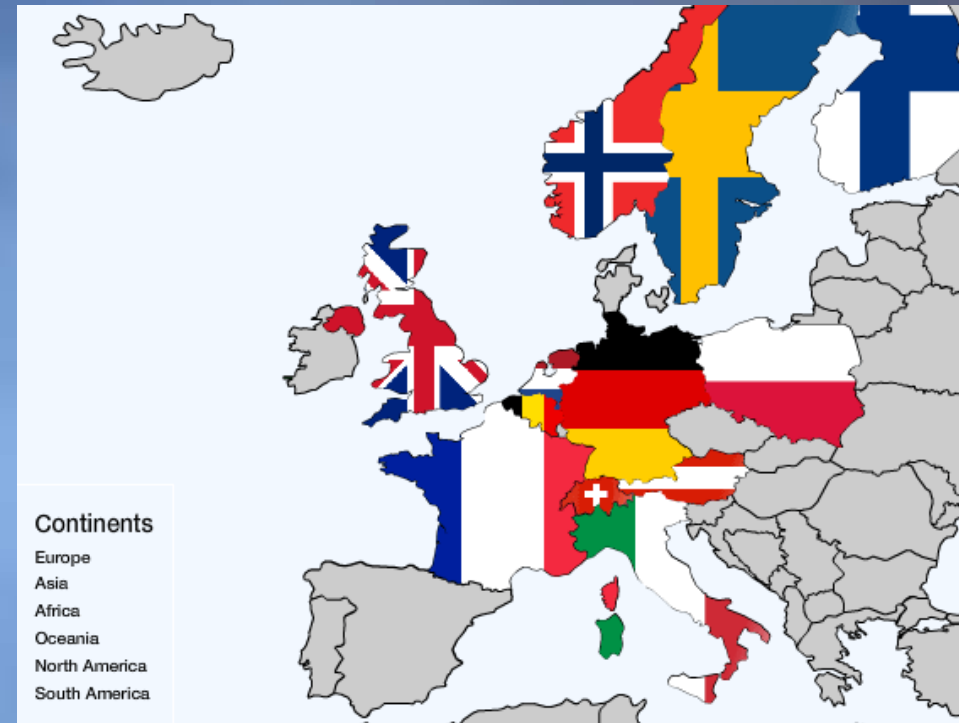
- US FDA granted afamelanotide ODD status for treatment of EPP in Jul 2008
- US FDA granted afamelanotide IND status in Jan 2009 to treat EPP
- First trial – a confirmatory pharmacokinetic
- Followed by Phase II PDT and Phase III EPP trials



Pathway open to world's largest pharmaceutical market

Regulatory progress in Europe

- Early support from physicians and regulators
- Trials commenced in 2006
- Progressed well into Phase III
- Over 40 clinics in trials
- 450 patients treated
- EMEA and Swissmedic granted afamelanotide ODD status for treatment of EPP in 2008
- ODD provides financial and regulatory support and market exclusivity



Phase III (EPP) trial to complete in DQ09 shortly followed by marketing authorization application (MAA)

Commercialization in sight

Competition

- No competitor in field of melanogenesis in clinical trials
- Afamelanotide is the only systemic preventative UV treatment
- First mover advantage

Manufacturing

- Afamelanotide peptide manufactured in Europe
- Implant manufactured in US
- Scaling up to commercial quantities
- Compliant with GMP standard required by regulators worldwide



Distribution & pricing

- Licensing & partnering options
- Regional licensing potential in Eu/US/Aus
- Global market opportunity
- High value niche markets
- Meeting unmet medical needs
- Sales through physicians: dermatologists, hematologists, oncologists, transplant specialists
- Premium pricing probable given ODD status

*Clinuvel expects
first afamelanotide revenues
in 2010*



Appendix

Financials

<i>Balance Sheet</i>	2008	2007	2006
Cash & Financial Assets	50.8	62.3	10.6
Total Assets	55.0	67.8	17.0
Total Liabilities	3.1	2.4	3.0
Total Equity	51.8	65.4	14.0
<i>P&L</i>			
Net Profit (Loss)	(14.7)	(9.2)	(10.8)
<i>Cash flow</i>			
Net cash provided by operating activities	(7.2)	(8.2)	(11.4)

Capital raising	\$m raised	# shares m	Price
May 2006 placement	\$5.0	14.7	\$0.34
Sep 2006 rights issue & placement	\$35.2	91.4	\$0.38
Apr 2007 placement	\$26.0	24.3	\$1.07

Share ownership

- Shares on issue 303m
- Top 20 shareholders own 42%
- Substantial shareholders
 - JM Asset Management 6.9%
- Total number of shareholders 3,780

Directors & Executives

- Dr Philippe Wolgen: CEO, Director
- Ms Brenda Shanahan: Non-Executive Chair
- Dr Hank Agersborg: CSO, Director
- Dr Roger Aston: Director
- Mr Stan McLiesh: Director
- Mr Jack Wood: Director
- Mr Darren Keamy: CFO
- Dr Dennis Wright: VP Scientific Affairs

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