

**Louis Capital Markets
 (Hong Kong) Ltd.**

Author: D. Gorton
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Stocks Mentioned

Name	Symbol
Clinuvel	CUV.AX Reuters CUV AU Bloomberg

Market Listings

CUV: ASX
 UR9: XETRA-DAX
 CLVLY: ADR

Market Cap: A\$114.82
 Major Industry: Drugs, Cosmetics
 & Health Care
 Sub Industry: Ethical Drug
 Manufacturers

2007 Total Revenues: 2,553,901
 Employees: 16

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Description:

Clinuvel Pharmaceuticals Ltd. (CUV AU) is a biopharmaceutical company headquartered in Melbourne, Australia with a presence in San Francisco and Zurich, focused on developing its photo-protective drug, CUV1647, for ultraviolet (UV) and light related skin disorders. CUV1647 is an analog of the biological α -Melanocyte Stimulating Hormone (α -MSH). Through a biodegradable rice-size implant injected underneath the skin CUV1647 protects against UV radiation by increased levels of melanin, the body's natural photo-protective pigment. CUV1647 targets skin disorders including Actinic Keratosis (AK, a precursor to skin cancer), Polymorphic Light Eruption (PLE), Erythropoietic Protoporphyrria (EPP) and Solar Urticaria (SU). The firm is currently conducting two Phase III and one Phase II clinical trials in Europe, Australia, and the United States (expected) which could treat millions world-wide suffering from UV-related skin disorders.

Investment Thesis:

Due to nature of the biotechnology industry extended periods of clinical trials and fundraising can obscure a firm's underlying value, as well as the qualitative factors necessary to bring a new drug to market. What the street doesn't realize about Clinuvel, aside from the potential market of its leading drug candidate CUV 1647, is the experience and track record of the management team leading the regulatory effort.

In 2006 Clinuvel raised over \$35 M in new equity, and in 2007 \$23 M, the highest of any Australian biotech firm. CUV is also one of only three Australian companies to advance to Phase III clinical trials. According to research estimates from the Tufts Center for the Study of Drug Development, only 44% of phase II drugs make it to phase III clinical trials and 69% of phase III drugs receive approval. More than 300 patients have been treated so far while CUV1647 has demonstrated a good safety profile. CUV currently has two indications undergoing phase III clinical trials with results expected by late-2008.

Products:

Clinuvel's program includes five UV-related indications: two clinical applications in cancer therapies and three in dermatology and hematology, indications where there is no standard of care.

Indication	Description	Clinical Trial	Status
Polymorphic Light Eruption (PLE / PMLE)	Sun poisoning / Sun allergy	Phase III	UK trials underway May 2007, results by mid-2008
Erythropoietic Protoporphyrria (EPP)	Absolute sun intolerance	Phase III	European and Australian trials underway June 2007, results expected mid-2008
Squamous Cell Carcinoma (SCC) and Actinic Keratosis (AK) in organ transplant patients	Non-melanoma skin cancers / precursor to skin cancers Organ Transplant Recipients	Phase II	European and Australian trials underway November 2007, results expected by 2009
Solar Urticaria (SU)	Acute anaphylactic reaction to sun exposure	Phase II	Trials planned to begin 1H 2008
Photo toxicity associated with Photodynamic Therapy (PDT)	Photo-sensitivity following cancer	Phase II	trials planned to begin 1H 2008

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The following catalysts are expected to drive the share price in 2008:

2008 Catalysts	Status	Comment
File IND in US	On-going	On target with 30 days to review
Phase III EPP second cohort begins in European summer	On-going	On target
Second generation CUV1647	On-going	On target for continued formulation development
Application for possible orphan drug indication for Phase III EPP	On -going	Major milestone with continued recruitment of European patients
World Health Organisation (WHO) generic name for CUV1647	On -going	On target
2008 Financial Year result	On -going	Will provide information on cash burn rate
Brand name for CUV1647	On-going	A small commercialization step
Interim result Phase III EPP	On-going	Major milestone
Interim result Phase III PLE	On-going	Major milestone
Start Phase II oncology (photodynamic therapy)	Planned	Key milestone, as further indication in cancer medicine
Start Phase II Solar Urticaria (SU) in Europe	Planned	Key milestone in diversification and progress of Clinuvel
Start US trials following IND	Planned	Opens up third geographic of clinical activity and investor interest
Phase II Solar Urticaria results	Planned	Major milestone

The company intends to complete Phase III clinical trials (Europe, Australia and Switzerland) by 2009 while working with regulators to register the same year. To register a drug must provide a clinical medical benefit, which is followed by commercialization. Clinuvel is currently testing several delivery platforms with leading firms which will likely involve subcutaneous injection of CUV1647 by the physician. Announcements on 2nd generation CUV1647 will provide more detail in 2008.

Intellectual Property & Patents:

Clinuvel owns the worldwide license to intellectual property covering analogues of natural hormones (α -MSH), there are 34 patents in the license's schedule. **The firm's principal barrier to entry involves the "Sustained Release Formulations" patent which measures the drug blood stream levels comprising all delivery methods.**

Clinuvel IP Portfolio – CUV1647	Description	Expired / Expiring to
Under License CTI	composition of matter	2014
Sustained Release Formulations*	plasma levels full range*	2025*
MC1R Allele Variations	melanogenesis in all variations leading to melano-incompetence	2024
Topical Formulations	melanogenesis & protection	2024
Photodermatoses	methods of use - EPP, PLE, SU etc.	2027
Skin Cancer	methods of use - immunocompromised	2027
PDT	methods of use - systemic and topical	2028

(Source: Company website)

Under the Patent Cooperation Treaty (PCT) a grant approval can take up to five years in each country. Originator pharma companies are protected from generics by a period of marketing exclusivity for 5-7 years following approval in the US, Australia and New Zealand. In Europe the exclusivity period extends for 6-10 years (plus a further 1 to 3 years for the generic registration process) irrespective of the originator pharmaceutical company's patent position. Clinuvel has filed patent applications for CUV1647 and other related compounds for patients undergoing PDT (Photodynamic Therapy) treatment as well as several related patents licensed from Competitive Technologies, Inc.

It's anticipated Clinuvel will gain marketing exclusivity due to its advanced development status, current IP position and aggressive clinical trial program posing a formidable commercial barrier to competitors and generics. Details of the patent applications as follows:

Patent Application	Country	Number	Filed	Status
Method for treatment of photodermatoses	Australia	Provisional Patent Application No. 2006904745	31-Aug-06	International (PCT) application filed 31 August 2006
Method for reducing incidence or rate of development of skin cancers and related conditions	Australia	Provisional Patent Application No. 2006904672	28-Aug-06	International PCT application filed 28 August 2006
Compositions and methods for inducing melanogenesis in a subject by topical application	Australia	PCT/AU2005/001552	7-Oct-05	Entered the national/regional phase 8 April 2007
Methods of inducing melanogenesis in a subject	Australia	PCT/AU2005/000181	11-Feb-05	Entered the national/regional phase 4 February 2007
Method of inducing melanogenesis in humans with MC1R variant alleles	Australia Canada Europe Japan New Zealand South Africa USA	PCT/AU2004/001630 PCT/AU2004/001630 PCT/AU2004/001630 PCT/AU2004/001630 PCT/AU2004/001630 PCT/AU2004/001630 PCT/AU2004/001630	23-Nov-04	Pending Pending Pending Pending Pending Pending Pending

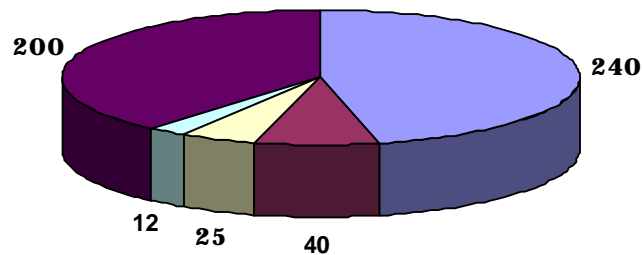
(Source: Company Prospectus 2006)

Markets:

U.S. incidence rates of melanoma in white males amounts to 25:100,000 vs 1.4:100,000 for black males. For white females the incidence rate is approximately 17.9:100,000 vs. black females at 1.1:100,000. In Australia, the melanoma death toll is more than 1000 people annually. Given the existing sun avoidance treatment CUV stands to dominate its key target markets in terms of clinical indications. Additionally, the market in off-label applications for cosmetic treatment could potentially outstrip clinical indications as Clinuvel would be the only firm offering clinical and cosmetic applications in the UV-related drugs category, enhancing credibility among consumers and posing a barrier to entry for competitors.

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Market size by indication (USD Millions)



■ SCC and AK ■ PLE / PMLE □ EPP □ SU ■ Other

Indication	Comment
SCC and AK (non-melanoma skin cancer)	<ul style="list-style-type: none"> 19.3% (58 M) of the US population in 2004 suffered from AK (26 M > 64 Years old) with up to 25% (11.25M) classified as severe, in particular those receiving (donor) organ transplants. In 2006 28,923 organ transplant operations were performed in the US and 3,074 transplants in the UK 2006/07 [UK Transplant (UKT)]. 6% of transplant recipients die from SCC directly attributable to the formation of AK; <u>there are currently no prophylactic treatments available other than sun protection creams / clothing or sun avoidance.</u> Conservative estimates between 35 - 70% of all transplant recipients develop some form of skin cancer (usually SCC and basal cell carcinomas but also melanoma) within 20 years of transplantation.
PLE / PMLE	<ul style="list-style-type: none"> 10% of the US population (30M) suffers from PLE and 10% (3M) of these patients can be classified as severe. Additionally 5% (1M) of the Australian population suffers whereas 15% (9M) of the UK and 15 - 20% in the most northerly latitudes of Europe. <u>There's currently no prophylactic drug available for PLE aside from sun avoidance or protection.</u>
EPP	<ul style="list-style-type: none"> EPP affects 1: 200,000 - 750,000 people with fair-skinned complexion characterized by intolerable severe light-toxicity (extreme photo-sensitivity) of the skin. <u>This is a lifelong disease requiring treatment with analgesics. EPP patients are often forced to remain indoors affecting their (quality of) life. Parents are often desperate following years of delayed diagnosis of their child's symptoms, which are often misinterpreted and misunderstood.</u>

(Source: IMS Primary Market Research 2006; "The Burden of Skin Diseases", The Lewin Group 2005)

Financial Health:

In April 2007 Clinuvel announced a private placement of 24,339,054 shares at A\$1.07 to several well-known Australian and European institutions for A\$26M; the funds will be applied toward European PLE and EPP Phase III clinical trials with registration expected by 2009. Including the recent placement and investment reserves totaling A\$65.3M, Clinuvel is well positioned to promote CUV1647's commercialization across one or more indications. Expenses through December 2009 are forecast at US\$53.9M / A\$64.1M with a current burn rate of currently under A\$1.0M per month increasing to A\$1.7M when CUV1647 is applied in all indications. Management expects to develop all 5 indications and gain market approval with current funds.

CUV Funding since 2001		
Event	Net proceeds raised	Share-capital
Pre-Money V	A\$15 M (USD\$11.7M)	52M
IPO	A\$2.4 M (USD\$1.9M)	60M
SPP/PP	A\$34.6M (USD\$27M)	186M
RI +PP Oct'06	A\$35.2M	277M
SPP/PP Apr'07	A\$26M	24.3M
Total current assets (June 2007)	A\$65.3M	
Current burn rate: A\$1.0 p/m		

Total projected expenses until end-2009	USD / AUD
Estimated clinical trial costs	
• Program for PLE Phase II/ III, AK Phase II, EPP Phase II / III	
• Program for continuous product development	
• Program - Other clinical	
SUB-TOTAL	\$34.9M / A\$41.5M
Estimated operational costs	
• Regulatory & Filing Fees	
• Staff and Payroll Costs	
• General Operations (including travel and marketing costs)	
• Legal fees, intellectual property maintenance & other	
SUB-TOTAL	\$19M / A\$22.6
TOTAL	\$53.9M / A\$64.1M

(* Spot AUD/ USD 0.8414 June 12, 2007)

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Valuation

	Potential Peak Sales (\$ M)	Probability	Probability Weighted Sales	NPV*
Phase III				
PLE	40 M	50%	20	
EPP	25 M	50%	12.5	
Phase II				
SCC/AK	240 M	30%	72	
SU	12 M	30%	3.6	
Other	200 M	15%	30	
TOTAL	517 M		138.1	68.7
COGS				10.3
SG&A				17.7
EBIT				46.6
Tax (35%)				16.3
Net				30.3
EPS				0.1
P/E				9.1
Industry P/E (BBG World Biotech Index)				45.05

* NPV is total probability weighted sales discounted to present at 15% discount rate assuming peak sales are reached in 5 years



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Biotechnology companies are typically uncorrelated to the global economy and widely regarded as a safe-haven during market volatility. On a relative P/E basis the firm trades at a discount to the BBG World Biotech Index, however, recent corporate advances in Phase III trials have not been reflected in the share price. This disconnect has been associated with distressed shareholder's activity which is wholly unrelated to CUV's clinical trial progress. The share price is currently supported around the A\$0.40 level creating a bargain opportunity. Events such as filing IND in the United States or starting SU, and interim phase III results should all boost share price in 2008, with the firm well supported financially to complete Phase III trials for PLE and EPP in Europe there's significant upside to this stock.

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Competitive Landscape (Mar 2007)			
Development Stage	Competitor	Description	Cash
Idea generation/ hypothesis	<ul style="list-style-type: none"> • U Cinn • UVa 	<ul style="list-style-type: none"> • Topical / Systemic • Incubator-Formulation 	<ul style="list-style-type: none"> • \$1M grant • N/A
Proof of Concept	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> •
Toxicology + Carcinogenicity	<ul style="list-style-type: none"> • PE • Boston 	<ul style="list-style-type: none"> • Herbal / Topical • Topical / Forskolin-Topical 	<ul style="list-style-type: none"> • \$15M • N/A
First in man studies			
Phase I			
Phase II			
Phase III	<ul style="list-style-type: none"> • Clinuvel 	<ul style="list-style-type: none"> • SRI / IP 5 	<ul style="list-style-type: none"> • A\$63.5M
Market Approval			
Registration			

(Source: Clinuvel Strategic Update to Investors: Apr 2, 2007)

The key difference in Clinuvel's approach to UV-related skin disorders is subcutaneous (under the skin) delivery with an emphasis on efficacy, safety and clinical applications. Primary competitors include a cluster of university research departments focused on topical and systemic delivery which are inherently difficult to control in terms of release/penetration. Subcutaneous delivery is easier for health providers to safely administer with potentially fewer side effects, a key point in advancing through regulatory trials and preventing recall. Palatin Technologies Inc, a NASDAQ listed company developing a drug active on the central nervous system has recently delayed plans for the initiation of Phase III clinical trials with bremelanotide, a first in class melanocortin (MC) agonist candidate for male erectile dysfunction (ED), after U.S. health regulators raised safety concerns about the efficacy of the results in early- and mid-stage trials. Bremelanotide was deemed effective at enhancing melanin pigmentation of the skin as a faint byproduct as well as regulating erectile function.

Management:

Clinuvel's management assets include seasoned professionals with broad experience in the drug's target markets. CEO Philippe Wolgen (MBA, MD) and CSO Helmer Agersborg (Msc, PhD) have refocused the Company's strategy to testing CUV1647 for the 5 current clinical indications. Since new management formed in December 2005, Clinuvel has steadily advanced the clinical program towards registration in multiple markets while developing a new dosage form.

Former Executive Chairman Dr. Roger Aston has recently stepped aside but remains on the board as a Non-Executive Director, he brings more than 20 years experience in the pharmaceutical industry. Recently appointed Non-executive Chair, Ms. Brenda Shanahan, brings more than 20 years of financial knowledge and expertise in institutional healthcare and Mr. Stanley McLiesh, former general manager of CSL, provides background in commercializing pharmaceutical products globally.

Through their guidance CUV has steadily advanced to Phase III trials for two clinical indications.

Going Forward in 2008:

- Clinuvel is partnering with global firms to develop delivery platforms containing CUV1647 for use in the final trials.
- Clinuvel has begun important Phase II trials in Europe and Australia for both AK/SCC (skin cancer) in 2007.
- The firm intends to lodge an IND with the FDA early in 2008 to start US trials. In 2006 CUV opened a San Francisco branch to facilitate and secure the participation of several leading clinicians from research hospitals to conduct trials with the Zurich office opened in November 2007.

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