



Investment Memo

Clinuvel Pharmaceuticals Ltd

20/11/07

Executive Summary

Key points

- Clinuvel Pharmaceuticals Limited (ASX:CUV, XETRA/DAX:UR9, ADR:CLVLY) is an Australian biopharmaceutical company developing its photo-protective drug CUV1647 as a **preventative treatment** for a range of UV-related skin disorders as well as in cancer related treatments.
- CUV1647 is injected as a deposit under the skin slowly releasing a peptide that activates the production of the skin's pigment, melanin. Essentially, melanin throughout biology has been shown to increase protection from the sun (photoprotection) and decrease the ageing effects of the sun (photoageing).
- During the fiscal year 2006/07 a total of A\$ 67 m was raised from the issue of ordinary shares (net of A\$ 1,8 m in issue expenses). As of 30.6.2007 the consolidated entity's cash and short term financial assets resources totaled A\$ 62,3 m. This should be sufficient to finance the entire development program until first registration.
- In 2008, the management of Clinuvel will establish an office in Europe. As a result we expect an increased attention from investors.
- We have calculated a **fair value range of A\$ 1,63 - 2,13 per share**, representing an **upside potential of 287% - 407%** to the current stock price level.
- The sharp decrease in the share price in the last 6 months stands in contrast to the development of the company's fundamentals.
- Skin damage resulting from UV exposure and subsequent risk of skin cancer will touch most of the people. There is a great need to develop a preventive protection against UV and the sun, especially in the changing environment of recent years. This should open Clinuvel's photo-protective drug a huge worldwide market.
- A further upside potential resulting of a potential off-label cosmetic market for CUV1647 is not reflected in our valuation.

SWOT Analysis

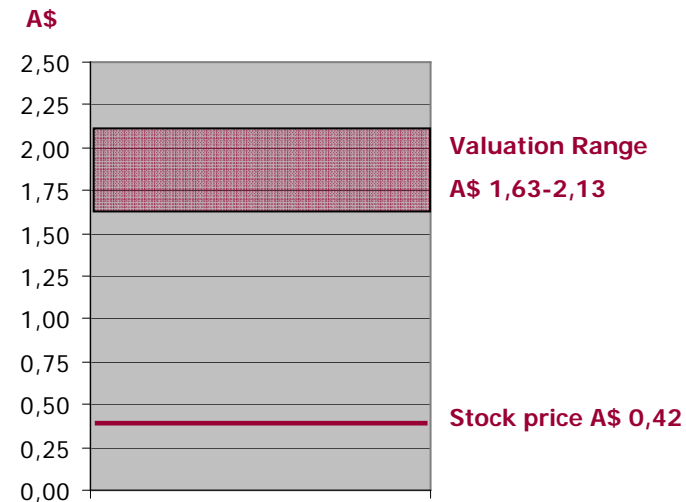
Strength/Opportunities

- 2 Phase III candidates
- Strong Management with Big Pharma expertise
- Comfortable cash position
- First mover in its markets
- Partnering with Big Pharma in 2008
- First registration in 2009 expected
- Off-label marketing potential

Weaknesses/Threats

- Difficulties or delays in the conduct of Clinuvel's clinical trial program
- Delays or failure to obtain regulatory approval for a product
- Uncertainties regarding the major shareholder Absolute Capital Management

Fair Value



Management Board

Management Board (Executive Members)

Dr Roger Aston BSc, PhD
Executive Chairman

Dr Aston has more than 20 years experience in the pharmaceutical and biotechnology industries and has been closely involved in organisational re-structuring of companies and in improving effectiveness and productivity.

Dr Philippe Wolgen MBA, MD
Chief Executive Officer, Director

Since holding office as CEO as of November 2005, Dr Wolgen has repositioned Clinuvel and its corporate strategy. Managed to attract 67 m\$ in past eighteen month. Having been recognised for his strategic mindset and meticulous execution in business, Dr Wolgen brought to the company his international finance experience and access to European capital markets, combined with in-depth analysis and expertise of the pharmaceutical and medical world. He has had vast exposure to equity research in the bio-medical industry.

Dr Helmer P.K. Agersborg BSc PhD
Chief Scientific Officer, Director

Dr Agersborg is director of Virxsys Corporation, a gene therapy corporation. He was formerly President of Wyeth-Ayerst Research. During his distinguished 45 years in the pharmaceutical industry, companies under his direction had more than 50 new drug applications approved in the US, countless marketing applications were approved outside the US and innumerable INDs were accepted.

Dr Dennis Wright BPharm MSc PhD
Manager, Clinical Development & Regulatory Affairs

Dr Wright has a broad range of experience in the pharmaceutical industry spanning 25 years. He spent more than 17 years at CSL working predominantly in regulatory affairs with nearly a decade as Regulatory Affairs Manager.

Darren Keamy B Com CPA
Chief Financial Officer

Mr Keamy is a qualified CPA who joined CUV in November 2005 after working in key management accounting and commercial roles in Amcor Limited over a period of 9 years.

Colin Mackie BA Dip Ed
Head of Corporate Development

Colin brings 15 years of experience in corporate investment management to Clinuvel. In his recent position at Tolhurst, Colin was the research analyst for the healthcare sector in Asia/Pacific.



Management Board (Non Executive Members)

Mr Stanley McLiesh BEd
Non-Executive Director

Mr McLiesh has extensive experience in commercialising pharmaceutical products internationally. Formerly General Manager, Pharmaceuticals at CSL Limited, he was closely involved in the transition of CSL from government ownership through corporatisation to a highly successful listed company. While at CSL, Mr McLiesh brokered numerous in-licensing agreements with international companies enabling CSL to expand into new markets profitably. He has also been closely involved in a number of merger and acquisition negotiations, the establishment of partnerships and collaborative relationships and the negotiation of supply agreements for CSL's export products to international markets.

Ms Brenda Shanahan BEc, BCom.
Non-Executive Director

Ms Shanahan has a research background in finance in Australian and overseas economies and share markets. She is currently Chair of both St Vincent's Health and St Vincent's Medical Research Institute in Melbourne. She is a non-executive Director of JM Financial Group Ltd and Challenger Financial Services Group Ltd, and a Director of Loop Ltd, a Melbourne-based public/investor relations company.

Fair Value

Valuation-Model		Scenario I	Scenario II
Market size	mUSD	1.300	1.700
Royalties		20%	20%
Recurring sales	mUSD	260	340
Net profit margin		30%	30%
Net profit	mUSD	78,0	102,0
# of shares		302,2	302,2
EPS	USD	0,26	0,34
Timeline	years	5	5
P/E		25	25
Discount rate	%	35%	35%
Fair value per share	AUD	1,63	2,13
Fair value per share	EUR	1,02	1,33
Fair value per share	USD	1,44	1,88

Key points

- As of 30.6.2007 a total of 302,2 m shares are outstanding. A further 34,2 m share options were issued, with a volume weighted exercise price of A\$ 0,85, well above current share price levels. Given the strike prices and expiring dates of the stock options a potential dilution effect would only be of minor influence (<8%).
- Due to the comfortable cash position of Clinuvel, we do not expect a further dilution effect resulting of a share issue.
- The estimated market size of Clinuvel's products for the current indications amounts to USD 1,3 bn to 1,7 bn.
- We expect a partnering for the major indications, which should lead to annual royalties of appx 20%. These royalties/sales levels should be reachable for Clinuvel within 5 years. We assume a net profit margin of 30% as a reasonable estimate.
- Taking into account that profitable biotech companies with a focus on drug development currently have P/E values of around 25x-40x. We believe that Clinuvel should have a P/E of at least 25x reflecting on one hand that the company is not profitable yet but also taking into account that the company until now has reported positive safety and efficacy data.
- We assign Clinuvel a discount rate of 35%, which is typical for a biotech company focused on drug development following a novel approach. In contrast we would give profitable biotech companies with established products risk factors of around 20%-25%.
- Based on this assumptions we calculate a **fair value range of A\$ 1,63 – 2,13 per share**, representing an **upside potential of 287% - 407%** to the current stock price level (as of Nov 19th 2007).
- The calculated fair value only reflects the current stage of Clinuvel's medical program, taking into account the industry inherit risk factors. As the research program advances Clinuvel's risk premium will further decrease, thus driving its fair value.
- Our estimates are based on clinical and technical information obtained from management or derived from discussions with management of Clinuvel or from industry specialists.

Pipeline

Indication	Description	Clinical Trial Status	Interim results	Final results
Erythropoietic Protoporphyrin (EPP)	Absolute sun intolerance	Phase III trials began June 2007	Q1 2008	Q3 2009
Polymorphic Light Eruption (PLE)	Sun poisoning	Phase III trials began May 2007	Q1 2009	Q4 2009
Solar Urticaria (SU)	Acute anaphylactic reaction to sun	Phase II trials planned to begin 2008	-	Q3 2008
Phototoxicity associated with Photodynamic Therapy (PDT)	Photo-sensitivity associated with cancer treatment	Phase II trials planned to begin 2008	-	Q4 2008
Squamous Cell Carcinoma (SCC) and Actinic Keratosis (AK) in organ transplant patients	Non-melanoma skin cancers/precursor to skin cancers	Phase II trials began November 2007	-	Q1 2010

Key points

- Phase I and II human clinical trials using CUV1647 have demonstrated that the drug is well tolerated and no significant safety concerns have been identified to date. Following successful conclusion of the development program, Clinuvel will work closely with global regulators to facilitate marketing approval of CUV1647.
- The main focus of Clinuvel's research remains on the safety and efficacy of the drug. The company is on target to file CUV1647 for registration by 2009. A detailed timeline will be announced at the AGM in November 2007.
- PLE has an incidence of 10% to 20% in the general population. EPP and SU are different propositions. They would fall under the orphan indication category. SCC and AK are growing markets. In the US over 900,000 patients are diagnosed with some form of skin cancer. Clinuvel addresses in its studies organ transplants recipients, a small and severely affected population of these overall sufferers.
- CUV1647 will be used as a **preventative treatment** for a range of UV-related skin disorders as well as in cancer related treatments. In May and June 2007 Clinuvel has started two trials in Phase III. The probability of bringing a product in Phase III to market is in the order of 70%. Further Phase II trials in the other indications are planned to begin in 2008.
- Over Fiscal Year 2007/08 Clinuvel's spend will be around A\$ 21 m spread across the five indications. The current cash burn rate is A\$ 0,9 m per month. With the increased activities in the last quarter of 2007 and 2008, it is projected that this cash burn will rise to A\$ 1,8 m per month.
- Besides the medical business there is a significant upside potential resulting of an off-label cosmetic market being developed for CUV1647. This is because one of the effects of CUV1647 treatment is the development of a suntan without being in the sun. In other words activation of one's skin pigmentation without actual sun damage.

Indications

Erythropoietic Protoporphyrin (EPP)

- EPP is a rare inherited porphyrin metabolism disorder that affects between one in 200,000 and one in 750,000 people. When the skin is exposed to the sun, it leads to a chemical reaction that results in swelling, intolerable pain and scarring.
- The lifelong pain experienced by these patients can be so severe that they require continuous treatment with analgesics and anti-inflammatory drugs to cope with the incessant pain.
- Since sun avoidance is recommended, patients lead lives where they are outdoors for very limited time. This prevents normal social activities and the intense pain that is experienced interferes with normal daily activities and prevents adequate sleep.
- It is hoped that with regular use of CUV1647, EPP patients will become more resistant to the effects of the sun in particular and be able to lead more normal lives.

Solar Urticaria

- SU is a rare and severe disorder occurring in less than 1% of the population. Following limited exposure to sunlight, sufferers may develop blistering and itchy or burning redness on exposed skin. More prolonged exposure can result in the development of "wheals" or round red raised areas on the skin. These symptoms can also be accompanied by headache, nausea, breathing difficulty or fainting. The symptoms usually develop soon after sun exposure and last anywhere from 30 minutes to 24 hours.
- Treatment is usually directed towards relief of symptoms. In some cases these patients need to be hospitalised to undergo plasmaphoresis (a procedure similar to dialysis where the plasma in their blood is removed and the blood cells are returned to the patient).
- With the use of CUV1647, it is aimed that in at risk patients the incidence and/or severity of attacks of SU will be significantly reduced.

Polymorphic Light Eruption (PLE)

- PLE is the most common photosensitivity and after sunburn is the most common sun-related problem seen by doctors. The incidence has been reported in literature to be approximately 5% in Australia, 10% in the United States, 15% in the United Kingdom and approximately 15% - 20% in the most northerly latitudes of Europe. While it occurs in people with all skin types, it is most common in fair-skinned individuals.
- Although the disease is regarded to be severely debilitating for patients who suffer from PLE there is a common understanding that only a fraction of patients present to dermatologists for treatment of their symptoms. The main reason for this is the current lack of available efficacious therapies.
- Treatment is aimed at either preventing or suppressing the disease. Sun and UV avoidance, the use of broad spectrum sunscreens and topical steroids are the first line of therapy used. PLE has a considerable impact on the quality of life for many people because of the need to avoid sun exposure during the spring and summer months.
- Through the EP005 and EP012 clinical studies, CUV1647 has been shown to offer protection against outbreaks of PLE. If used prophylactically during spring and summer, it should either prevent episodes of PLE or reduce the severity of symptoms experienced by patients

Indications

Squamous Cell Carcinoma (SCC) / Actinic Keratosis (AK)

- In past decades AKs have been demonstrated to be an initial step in a continuum with squamous cell carcinomas (SCC) at the opposite end. SCC is the second most common form of skin cancer. SCC is caused by prolonged exposure to UV-radiation. There has been a global increase in the incidence of SCC recorded in fair skinned people; their lack of skin pigmentation is thought to be a determining factor in developing SCC or skin tumours.
- In the US, consultations for AKs are the second most common reason for patient visits to dermatologists and radical treatment of these lesions has become a major part of dermatology practice. The prevalence of AKs varies geographically with the incidence amongst Australians 40 years of age or older reported to be 40-60% compared with approximately 10-20% in the population in Europe and the US.
- There is a remarkably high incidence of skin cancer in organ transplant patients, due to the necessary use of immune suppressive drugs, to treat organ rejection by one's own immune surveillance. It has been found that organ transplant patients are up to 65 to 100 times more likely to develop skin cancer than those who have not had an organ transplant. There is a direct correlation between the incidence of skin cancer and the natural pigmentation of an individual's skin. Afro Americans who have undergone organ transplants have a lower incidence of skin cancer than Caucasian organ transplant patients, such findings add to the validation of our approach with CUV1647.

Photodynamic Therapy (PDT)

- It is anticipated that CUV1647 will be shown to prevent the phototoxicity associated with Photodynamic Therapy (PDT) in cancer therapy.
- The four most common cancer therapies are surgery, radiotherapy, chemotherapy and photodynamic therapy (PDT). PDT was first used as a cancer therapy over 100 years ago.
- PDT uses laser, or other light sources, combined with a light sensitive drug (called photosensitising agent) to destroy cancer cells. This treatment is used in many cases where surgery is neither possible nor preferred.
- One of the limiting factors and key side effects of PDT therapy is debilitating photosensitivity of skin and eyes to light (sunlight as well as artificial light). Patients suffer intense pain associated with this photosensitivity and are forced to avoid sunlight/artificial light for up to 90 days following treatment.

Shareholder structure

Facts

Reuters	CUV.AX			
Bloomberg	CUV AU			
Shares outstanding	m	302,2	m	302,2
Share price	AUD	0,42	EUR	0,26
High 12 Mo	AUD	1,40	EUR	0,77
Low 12 Mo	AUD	0,40	EUR	0,23
Market Cap	mAUD	126,9	mEUR	79,6

Source: Bloomberg 19/11/07

Top 5 Shareholders

	# shares mio	stake %
ANZ Nominees Limited A/C	87,7	29,0%
HSBC Custody Nominees A/C2	47,8	15,8%
Merrill Lynch Nominees PTY	27,4	9,1%
Citicorp Nominees PTY	16,01	5,3%
HSBC Custody Nominees GSI	13,29	4,4%

Source: Financial Report Year Ended 30.6.2007

Comments

- Absolute Capital Management (ABCAP) is the main shareholder in Clinuvel. Four of the investment funds (Absolute Octane Fund, Absolute Return Fund – Europe, Absolute Activist, Value Fund and European Catalyst Fund) are assumed to hold a total of appx 20% of the issued capital of the Company. The investment strategy of ABCAP is not transparent.
- The sharp decline in the share price over the last 6 months may be in connection with the uncertainties regarding the major shareholder (ABCAP).
- The Management is currently on a worldwide tour and visiting all major shareholder. There have been attempts to get non-core shareholders out of the stock, to stabilize the shareholder structure.

Chart 3 years



Source: Reuters 19/11/07

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Whichever valuation method is used there is a significant risk that the target price will not be achieved within the expected timeframe. Risk factors include unforeseen changes in competitive pressures or in the level of demand for the company's products. Such demand variations may result from changes in technology, in the overall level of economic activity or, in some cases, in fashion. Valuations may also be affected by changes in taxation, in exchange rates and, in certain industries, in regulations. Investment in overseas markets and instruments such as ADRs can result in increased risk from factors such as exchange rates, exchange controls, taxation, political and social conditions. This discussion of valuation methods and risk factors is not comprehensive – further information is available if required.

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Applicable specific disclosures: -

Terminology

Equity Value = Market Cap = Share price x Number of shares

Net debt = Financial debt – Cash & Equivalents

Net cash = Cash surplus over Financial debt

Enterprise Value (EV) = Market Cap + Net debt (- Net cash)

Earnings per share (EPS) = Net profit / Total shares outstanding

EV/Sales = Enterprise Value / Sales

EV/EBITDA = Enterprise Value / Earnings before interest, tax, depreciation and amortization

EV/EBIT = Enterprise Value / Earnings before interest and tax

P/E = Market Price per Share / Earnings per Share

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