Equity | Australia | Pharma & Biotech

4 February 2010

Produced by: RBS Equities (Australia) Limited

Clinuvel Pharmaceuticals

Analysis of CUV's opportunities

In our view, CUV is moving ever closer to final approval of its drug, afamelanotide. We have analysed the company's target markets and have developed a scenario analysis based on the potential market opportunities we see in the US and the EU. We value these at A$1.56 per share. Buy.

Buy

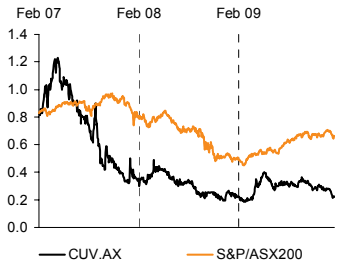
Target price
A$0.78

Price
A$0.225

Short term (0-60 days)
n/a

Price performance

	(1M)	(3M)	(12M)
Price (A$)	0.27	0.31	0.24
Absolute (%)	-16.7	-28.6	-6.3
Rel market (%)	-12.7	-30.4	-29.2
Rel sector (%)	-19.0	-31.9	-11.6



Market capitalisation
A$66.69m (US$59.18m)

Average (12M) daily turnover
A$0.09m (US$0.08m)

Sector: BBG AP Pharm & Biotech
Part of: n/a
RIC: CUV.AX, CUV AU
Priced A$0.22 at close 3 Feb 2010.
Source: Bloomberg

Key forecasts

	FY08A	FY09A	FY10F	FY11F	FY12F
EBITDA (A$m)	-17.1	-17.4	-17.9	-9.01	0.68
Reported net profit (A$m)	-14.7	-15.6	-14.3	-6.46	2.31
Normalised net profit (A$m)[1]	-13.6	-15.6	-14.3	-6.46	2.31
Normalised EPS (c)[1]	-4.51	-5.15	-4.7	-2.13	0.76
Normalised EPS growth (%)	21.9	14.3	-8.68	-54.7	n/a
Dividend per share (c)	0	0	0	0	0
Dividend yield (%)	0	0	0	0	0
Normalised PE (x)	n/m	n/m	n/m	n/m	28.8
EV/EBITDA (x)	n/m	n/m	n/m	n/m	84.7
Price/net oper. CF (x)	-9.26	-6.07	-4.85	-11.3	8.67
ROIC (%)	-39.8	-49.1	-82.2	-42.4	2.83

1. Pre non-recurring items and post preference dividends — year to Jun, fully diluted
Accounting standard: IFRS
Source: Company data, RBS forecasts

CUV's afamelanotide increases natural melanin production for two months

Afamelanotide is a synthetic analogue of a natural hormone called alpha-melanocyte-stimulating hormone, or alpha-MSH. This hormone is released when ultraviolet (UV) radiation from the sun penetrates the upper layers of the skin and damages it. It stimulates melanin production in the skin. A single subcutaneous injection of a slow-release, grain-of-rice-sized, dissolving implant containing afamelanotide provides two months of increased photo-protection via increased melanin density in the skin.

CUV moving ever closer to market approval, in our view

As the volume of clinical data grows showing afamelanotide's safety and efficacy in treating a number of conditions, we believe the potential for its market approval increases. CUV is undertaking trials in erythropoietic protoporphyria, solar urticaria, photodynamic therapy, squamous-cell carcinoma/actinic keratosis in transplant recipients, and polymorphous light eruption. We believe approval for its use to treat any of these conditions would result in its subsequent use in most of the others because the safety profile implied by positive regulatory approval generally applies to other diseases.

Scenario analysis suggests potential NPV of A$1.56 per share for CUV

We have analysed CUV's target markets and have developed a scenario analysis based on the company's potential market opportunity in the US and the EU. We assume CUV will garner a 20% share of revenue from sales made through its distribution partners, with an NPAT margin of 25% and a per-injection price of €1,500. On this basis we calculate a total potential NPV of A$1.56 for CUV's opportunities in the US and the EU.

Target price A$0.78, Buy recommendation maintained

As a result of this analysis, we maintain our Buy call and A$0.78 target price. This analysis reaffirms our belief that there is considerable upside potential in this stock and that CUV is an opportunity for investors with a higher risk appetite.

Important disclosures can be found in the Disclosures Appendix.

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Scenario analysis of CUV's opportunities

As clinical evidence grows regarding the efficacy of afamelanotide in treating serious photosensitive conditions, the product's approval becomes more likely. Approval for the use of afamelanotide to treat any condition would create the opportunity for its off-label cosmetic application, and this seems increasingly likely, in our view, if the price is right. We see significant long-term upside potential if afamelanotide is approved for use in any one of the following conditions:

- polymorphous light eruption;
- erythropoietic protoporphyria;
- solar urticaria;
- photodynamic therapy; and
- squamous-cell carcinoma/actinic keratosis in transplant recipients.

In this report we:

- analyse the markets that CUV has targeted and then establish a scenario based on the apparent market opportunity; and
- summarise the potential upside for CUV.

Summary

In valuing these markets we assume CUV will get its product to market within the timeframes listed below, with the initial approval for EPP stimulating its earlier use in the other markets. We further assume the company will take 20% of revenues generated through distribution partnerships.

Table 1 : Summary of market opportunities

Market opportunity	Estimated year of market entry	NPV per share (A$)
EPP	2011	0.14
SU	2012	0.13
PDT	2012	0.09
SCC and AK	2012	0.09
PLE	2012	1.09
	Total value	**1.56**

Source: RBS estimates

What is afamelanotide?

Afamelanotide is a synthetic analogue of a natural hormone called alpha-melanocyte-stimulating hormone, or alpha-MSH. This hormone is released when ultraviolet (UV) radiation from the sun penetrates the upper layers of the skin and damages it. It stimulates specialised melanin producing cells called melanocytes, which in turn produce the tanning molecule melanin. Melanin production takes several days and is transferred in packets to the major constituent cells of the skin, called keratinocytes. These cells slowly move to the skin surface and ultimately give it its 'tanned' look.

Afamelanotide is the synthetic recreation of Alpha-MSH molecules in a more stable and potent form. The problem with directly injecting alpha-MSH molecules to induce a sunless tan is that their small half life (only a few seconds) means they break down before being able to stimulate enough of the body area. Afamelanotide has a half life of a few minutes, allowing for greater stimulation of more skin.

Clinuvel intends to develop and distribute afamelanotide as a commercial drug to aid in the treatment of patients susceptible to phototoxicity and photosensitivity of the skin caused by UV, sun and light. Its focus is on the most severe and rare conditions.

Delivery through slow-release, dissolving implant

Clinuvel's chosen method for delivery of afamelanotide is through subcutaneous (ie, the layer of skin just below the dermis and epidermis) injection of a rice-sized, dissolving implant that allows for the peptide's slow release. This method demonstrated greater melanin production for longer periods of time compared to daily intravenous injections. A single implant creates a full-body tan that lasts as long as two months.

Assumption of distribution partnership

In delivering its product to market, we believe CUV will have to take on one or more distribution partners. We expect these partners to take most of the sales revenue; we assume CUV will be left with 20% of total sales revenue.

We will analyse briefly each applicable condition, the medical application of afamelanotide and, finally, the potential market size.

1. Erythropoietic protoporphyria (EPP)

EPP is a rare and severe genetic disorder causing absolute UV and light intolerance in the skin. It occurs as a result of an enzyme deficiency that allows for an abnormal build up of protoporphyrin, a molecule toxic to the body that transforms into excited states on absorption of light energy causing photo oxidative damage to the skin. This is manifested through various symptoms such as tingling, stinging, or burning and may accompany the appearance of a rash or blisters. Protoporphyrin build up also causes general tissue nerve damage that can result in abdomen pain, stomach reflux or, in extreme cases, temporary psychosis. In dealing with the excess protoporphyrin there is also a high potential for liver damage over time.

The photosensitive effects of EPP can be extremely painful and uncomfortable, often unbearably so. As such, the effect on a patient's lifestyle is normally dramatic. Most patients spend a considerable amount of time and effort avoiding excessive light sources and employing almost complete clothing coverage when possible. Since the photosensitivity results from light in the visual spectrum as well as UV, most sunscreens offer little protection and severe cases may even struggle to find comfort indoors. Ultimately there is no cure for EPP and limiting light exposure remains the best current treatment option.

Clinuvel application

Clinuvel believes that increases in skin melanin production through the application of afamelanotide will greatly improve EPP sufferers' total life quality by limiting the skin's light absorption. CUV has received FDA Orphan drug designation (ODD), allowing for an accelerated review process and certain associated privileges. Currently in Phase III trials, recent four-month results showed an overall reduction in the average number of phototoxic reactions for patients treated with afamelanotide compared to placebo, especially in patients usually reporting more severe pain. While quality-of-life data is not yet complete, all eight physicians involved in this trial reported a dramatic improvement in the patients' ability to engage in outdoor activities, the major restricting factor of EPP.

Market opportunity

With no real treatment options for EPP sufferers beyond limiting light exposure, Clinuvel's afamelanotide therapy may prove efficacious. The disease is rare, affecting around one in 60,000-200,000 people worldwide according to PubMed, although accurate statistics are hard to find. We estimate there are between 7,000 and 14,000 EPP sufferers across the US and Europe. Afamelanotide appears to be one of the few viable treatment options for EPP and if it proves efficacious, we believe it should be approved. The product is at the end of Phase III trials with early results indicating strong efficacy, and we believe the chances of approval are high.

Valuation and assumptions

Market entry: 2011
NPV per share: A$0.14

In valuing this opportunity we assume CUV will treat 80% of the c10,000 EPP sufferers across the US and Europe. We assume a market growth rate of 4.5% pa, in line with industry averages, and that CUV will receive 20% of the revenues generated through distributors. Given the small patient population, we believe CUV can charge a significant premium and we assume a price of €7,500 per year per patient (an average of five injections at €1,500 each) at an NPAT margin of 25%. This is in line with other orphan drug designation (ODD) products. Reflecting the progress of clinical trials, we assume market entry in 2011. This generates an NPV per share of A$0.14 for CUV.

Table 2 : EPP – distribution revenue share sensitivity

Revenue share percentage	10%	20%	30%	40%
NPV per share (A$)	0.07	0.14	0.22	0.29

Source: RBS estimates

2. Solar urticaria (SU)

SU is a rare condition in which UV, or even visible light exposure causes an acute allergic response in the form of a local outbreak of urticaria (hives). SU may also induce breathing difficulty, nausea and headaches. The primary cause is a hypersensitive immune response to an antigen induced by UV or visible radiation. Each patient usually reacts to a relatively small wavelength band compared to the total spectra covered by the condition. The hypersensitivity can either be inherent to the individual or induced only after exposure to some other agent such as tar, dyes or pitch. SU is a rare condition; the number of reported cases is in the low hundreds since its first diagnosis in 1916. It is statistically said to account for 4-5% of all patients with photodermatosis disorders, or three or four of every 100,000 people.

Treatment is usually through antihistamines and/or skin desensitisation (gradually increasing exposure to the detrimental radiation), with immunosuppression considered only in more extreme cases.

Clinuvel application

Clinuvel believes the subcutaneous administration of afamelanotide and its subsequent photo-protective effects will help to reduce skin and anaphylactic reactions in SU patients. Phase II trial results from July 2009 demonstrated a significant reduction in skin reactions at both 30 and 60 days following afamelanotide administration, and an increase in the minimal urticarial dose (the minimum radiation intensity required to induce hives). Given these results, Clinuvel intends to accelerate its SU program and has applied for permission to start Phase III confirmatory-controlled trials. Considering the small patient population, Clinuvel received orphan drug status for afamelanotide application to SU from the EMEA in June 2009 and from the FDA in December 2009, garnering an accelerated approval process and varying other benefits.

Market opportunity

The market size for SU is fairly small. We estimate there are around 9,000 sufferers in the US and another 25,000 across Europe. We expect that, if offered as a treatment option, afamelanotide would certainly have a large appeal and would likely be used by a significant portion of this market.

Valuation and assumptions

Market entry: 2012
NPV per share: A$0.13

In valuing this opportunity we assume CUV will treat 40% of the c34,000 SU sufferers across the US and Europe. We assume a market growth rate of 4.5% in line with industry averages. Given the small patient population we believe CUV can charge a significant premium and we assume a price of €6,000 per year per patient (an average of four injections at €1,500 each) at an NPAT margin of 25%. This is in line with other ODD products. Reflecting the progress of clinical trials, we assume market entry in 2012 and that CUV will receive 20% of the revenues generated through distributors. This results in an NPV per share of A$0.13 for CUV.

Table 3 : SU – distribution revenue share sensitivity

Revenue share percentage	10%	20%	30%	40%
NPV per share (A$)	0.07	0.13	0.20	0.26

Source: RBS estimates

3. Photodynamic therapy (PDT)

PDT is a treatment method for cancer involving the stimulation of a photo-sensitive drug (photofrin) at the tumour site via laser beam. On stimulation, photofrin is absorbed by the cancerous tissue, which is subsequently destroyed. Photofrin can be used to treat a number of cancer types, but its intravenous application is most common in cancer of the oesophagus, some lung cancers, Barrett's oesophagus (disorder of oesophagus lining), some gastro-intestinal cancer, a particular form of bladder cancer and age-related macular degeneration. One of the main and consistent side effects of using photofrin is in the associated phototoxicity of the skin

and eyes experienced for up to three months following treatment. It is advised that patients limit exposure of the eyes and skin to direct sunlight for at least 30 days after treatment, and this creates a significant lifestyle restriction for the patient.

Clinuvel application

Clinuvel hopes the application of afamelanotide in patients undergoing PDT will greatly reduce the severity and longevity of the phototoxic after-effects. The company is awaiting Phase II trial results; we expect these to be positive.

Market potential

PDT is a fairly common procedure that has found a stable market since the late '90s. PDT's greater uptake has been limited by the associated phototoxic side effects. In FY07, sales of photofrin reached US$5.9m, up 7% over FY06 but down 23% relative to FY05, indicating a fairly stagnant growth rate. We believe PDT could see significant growth if the associated phototoxic effects can be limited or eliminated. Certainly we expect sales of Clinuvel's afamelanotide would mirror photofrin's if CUV's product is proven efficacious in this application given the obvious benefits to the procedure after-effects. We estimate the total potential patient population for this market at about 250,000 across the US and Europe, based on the relevant disease prevalence and percentage use of PDT.

Valuation and assumptions

Market entry: 2012
NPV per share: A$0.09

In valuing this opportunity we assume 10% of the potential c250,000 patients will undertake PDT and require afamelanotide in any given year at a price of €1,500 per treatment. We assume a market growth rate of 4.5% in line with the industry average despite stagnant growth for photofrin given the greater treatment appeal, and an NPAT margin of 30% in line with other ODD applications. Reflecting the progress of clinical trials, we assume market entry in late 2012 and that CUV will receive 20% of the revenue generated through distributors. This generates an NPV per share A$0.09 for CUV .

Table 4 : PDT – distribution revenue sensitivity

Revenue share percentage	10%	20%	30%	40%
NPV per share (A$)	0.04	0.09	0.13	0.17

Source: RBS estimates

4. Squamous-cell carcinoma (SCC) and actinic keratosis (AK) in transplant patients

SCC is a malignant form of cancer that can affect the skin, lips, mouth, oesophagus, urinary bladder, prostate, lungs, vagina and cervix. It is the second-most-common cancer of the skin and is caused primarily by prolonged and detrimental UV exposure. It is a dangerous form of skin cancer if left untreated, resulting in a risk of metastasis (spreading to other organs). It is characterised by a growing bump that may have rough, scaly and flat reddish patches. A sore that does not heal or any change in an existing wart, mole or skin lesion may be a sign of SCC. SCC has a high cure rate if caught and treated early.

AK is the most common precursor to SCC, characterised by thick, scaly or crusty patches of skin. It is associated with frequent sun exposure and fair skin, and carries a high progression rate to SCC if left untreated. Treatment of either SCC or AK usually involves their total removal from the skin.

SCC and its precursor, AK, are a significant health issue for organ-transplant recipients. Their long-term immunosuppression significantly reduces their bodies' ability to repair UV-damaged cells, resulting in more rapid and degenerative development into cancer. Organ-transplant recipients are 40-250 times more likely to develop SCC then the general population and in a much more aggressive form. The increased development of AK legions is also a common and continuous reminder of the SCC threat. As such, transplant recipients must go to considerable effort to avoid prolonged sun exposure.

Clinuvel application

Clinuvel believes the photo-protective effects of afamelanotide will help to significantly reduce the onset of SCC, AK and other skin cancers in organ-transplant recipients. CUV is in Phase II trials for this application, as of October 2007**.** Given the nature of the cancer onset (over many years), the trial will need to be significantly long to provide meaningful data and so far no preliminary results have been released.

Market opportunity

The increased risk of SCC and other skin cancers is a real and serious issue for transplant recipients. We believe a product that would significantly reduce SCC incidence would certainly have a strong appeal to the market, especially in hotter climates. Around 45% of transplant recipients in Australia develop SCC within 11 years and 70% within 20 years. In colder climates such as the Netherlands, the numbers are closer to 10% and 40%, respectively. In FY09, about 56,000 organ transplants were undertaken in the US and EU collectively. If patients chose to use afamelanotide, it would require continued use throughout the course of immunosuppression, implying a number of years of treatment. Hence if efficacious, this market could provide a consistent and growing revenue line to CUV. The rate of organ transplants has seen no real growth since FY06 in the US.

Valuation and assumptions

Market entry: 2012
NPV per share: A$0.09

In valuing this opportunity we assume CUV will treat 5% of the c56,000 new transplant recipients across the US and Europe each year, and that the treatment will last five years at a declining ongoing patient rate of 20% per year. We assume a market growth rate of 4.5% in line with industry averages and that CUV will receive 20% of sales revenue through distribution. Given the small patient population we believe CUV can charge a premium and we assume a price of €4,500 per year per patient (an average of three injections at €1,500 each) at an NPAT margin of 25%. In line with EPP approval, we assume off-label market entry in late 2012. This generates an NPV per share of A$0.09 for CUV.

Table 5 : SCC and AK – distribution revenue share sensitivity

Revenue share percentage	10%	20%	30%	40%
NPV per share (A$)	0.05	0.09	0.14	0.19

Source: RBS estimates

5. Polymorphous light eruption (PLE)

PLE is a common skin condition characterised by recurrent, aggravated skin lesions forming as a delayed reaction to sunlight 30 minutes to several hours after sun exposure. It affects between 10% and 20% of the European and US populations, and its effects can last for up to seven days. It is usually a seasonal issue, occurring predominantly between spring and autumn, and it naturally resolves over the winter or with proper sun-protection measures. Its cause is not completely understood, but it is predominantly associated with an immune reaction to a skin compound that is altered on UV exposure. Further connections have been made to a female hormone that prevents suppression of this hypersensitivity response and may explain the higher PLE risk in females compared to males.

PLE can affect all races but is found predominantly in fair-skinned individuals. While ultimately having no long-term serious health implications, its adverse affects on lifestyle and physical comfort create a treatment need for many patients.

Clinuvel application/efficacy

Clinuvel believes the use of afamelanotide to increase the melanin count in patients suffering from PLE will help reduce symptoms and improve quality of life. Preliminary results from the Phase III trial released in December 2009 showed a total trend toward reduced PLE symptoms and increased melanin density for patients injected with 20mg of afamelanotide compared to the placebo controls. Positive reports from leading academic dermatologists in the trial form the basis for further testing on 40-50 Caucasian patients using 16mg of afamelanotide in Europe from March to October 2010 as an intended final commercial product.

Market opportunity

PLE affects around 10% of the US population, 18% of Europeans, 4% of Australians and around 0.7% of the Chinese. This equates to more than 100m sufferers in the US and the EU alone. We estimate around 6% of PLE sufferers seek GP treatment advice. There is a range of current therapies, from topical anti-inflammatories, antihistamines, prophylactic phototherapy and intravenous steroids to immunosuppressive drugs. Considering the range of drugs available we believe there is no gold standard of treatment and that avoiding significant sun exposure on the sensitive area is probably still the preferred therapy in most cases. The development of new sunscreen formulas whose inclusions of anti-oxidants have shown clinical effectiveness in reducing PLE symptoms could be a simple treatment preference for mild cases. We believe

afamelanotide would be an appealing treatment option for a number of PLE patients if it proves efficacious.

Valuation and assumptions

Market entry: 2012
NPV per share: A$1.10

In valuing this opportunity we assume CUV will treat 5% of the c7m PLE sufferers across the US and Europe seeking treatment. We assume a market growth rate of 4.5% in line with industry averages and that CUV will receive 20% of the revenue made through distributors. We assume a price of €1,500 per year per patient (an average of one injection at €1,500 each) at an NPAT margin of 25% in line with other applications. In line with EPP approval, we assume off-label market entry in late 2012. This generates an NPV per share of A$1.10 for CUV.

Table 6 : PLE – distribution revenue share sensitivity

Revenue share percentage	10%	20%	30%	40%
NPV per share (A$)	0.55	1.10	1.65	2.20

Source: RBS estimates

7. Summary of opportunities

On the basis of the individual scenario analysis, we believe the NPV of the potential opportunities developed by CUV is A$1.56. We provide a full summary of the per-market NPV with other relevant assumptions in the table that follows.

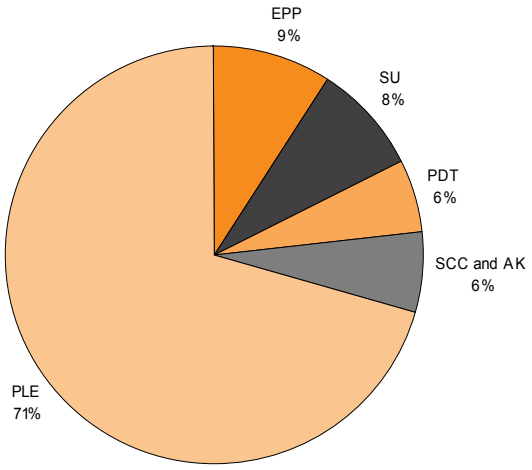
Table 7 : Summary of opportunities

Market opportunity	Estimated year of market entry	NPV per share (A$)
EPP	2011	0.14
SU	2012	0.13
PDT	2012	0.09
SCC and AK	2012	0.09
PLE	2012	1.10
	Total value	**1.56**

Source: RBS estimates

The distribution of NPVs for CUV's opportunities is shown in the chart that follows. We believe PLE represents the largest opportunity for CUV.

Chart 1 : Opportunity distribution



Source: RBS estimates

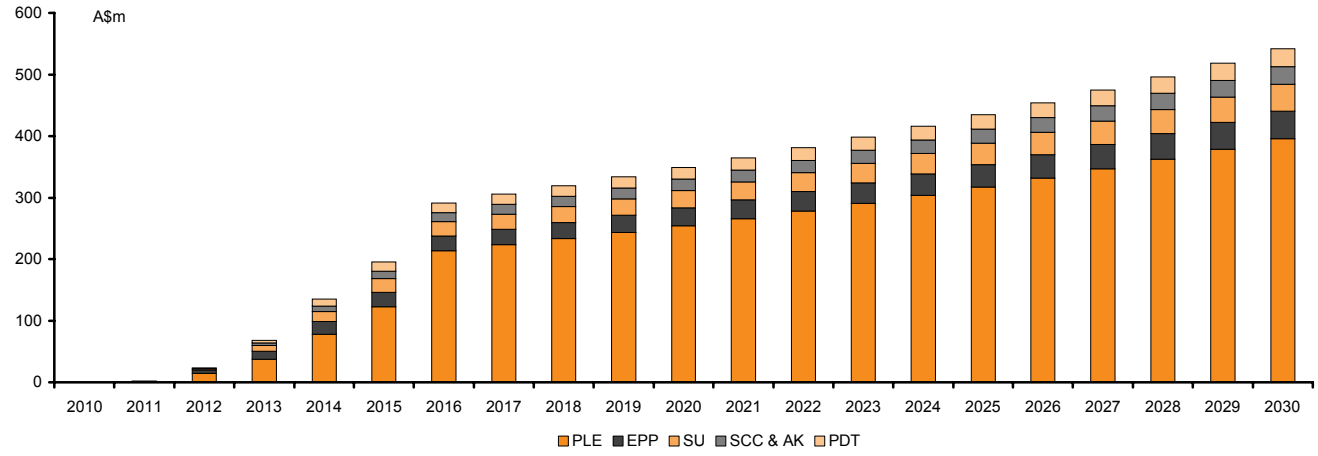
We value the total opportunity without PLE application at an NPV per share of A$0.45.

Clinuvel has a number of potential market opportunities. If afamelanotide is approved for PLE then the upside will be large, in our view. We believe the chance of Clinuvel getting afamelanotide to market to treat EPP is high, with Phase III trials coming to an end and a serious need for viable treatment options for EPP sufferers. We expect the approval of afamelanotide in this application would further accelerate opportunities to market the product for treating other conditions.

Clinuvel focus on severe orphan drug indications

Clinuvel is focused on developing its product for the most severe treatment indications. This includes an order of focus starting with EPP, SU, PDT, organ transplant recipients and, finally, PLE. This is also the order we expect for market approval. We think this implies that initial price points could be high.

Chart 2 : CUV opportunities – projected revenue growth – NPAT margin 25%, distribution share 20%



Source: RBS estimates

We assume EPP approval will lead to earlier-than-expected adoption of afamelanotide to treat other conditions

In our analysis we assume approval for afamelanotide to treat EPP will result in earlier-than-expected approval of the product for use in the other applications. This is because we believe the product safety profile is equally applicable to each condition; so doctors should be comfortable prescribing the treatment off-label in cases where they believe there is a serious need for it. We assume late 2012 entry for all markets besides EPP. This gives a full year for EPP treatment to further establish a solid safety profile.

Price for afamelanotide

In valuing each market we assume a price of €1,500 per injection. We consider this viable for the orphan drug markets given their small size and serious need for viable treatment options. A high price point is also necessary for CUV to see any upside from them. As yet there have been few indications on actual price, so our assumption is a matter of uncertainty.

8. Further scenario analysis

To fully illustrate CUV's market potential we include further scenario analyses. Our base-case assumptions are shown in Table 8.

Table 8 : Assumptions for scenario analysis

Market opportunity	First year of revenue	Potential patient population
EPP	2011	10,000
SU	2012	34,000
PDT	2012	250,000
SCC and AK	2012	56,000
PLE	2012	7m
Market growth rate		4.50%
WACC		10%
EUR/AUD		0.64

Source: RBS estimates

Scenario 1

We show our analysis calculating NPV per share per market with varying percentage share of revenues generated through distributors. All other inputs remain the same. This analysis suggests that if CUV could keep 40% of revenue generated through distributors, then the implied NPV per share would be A$3.11.

Table 9 : NPV per share for varying distribution agreements

(A$)	Revenue percentage of total sales			
Market opportunity	**10%**	**20%**	**30%**	**40%**
EPP	0.07	0.14	0.22	0.29
SU	0.07	0.13	0.20	0.26
PDT	0.04	0.09	0.13	0.17
SCC and AK	0.05	0.09	0.14	0.19
PLE	0.55	1.10	1.65	2.20
Total	**0.78**	**1.56**	**2.33**	**3.11**

Source: RBS estimates

Scenario 2

We demonstrate our analysis calculating total per share NPVs for varying product price points and NPAT margins in Table 10. All other inputs remain the same, and we assume CUV revenue is 20% of total revenue from sales through distribution partners.

Table 10 : Total NPV per share (A$m) for varying price points and NPAT margins

	NPAT margin		
Price	**15%**	**25%**	**35%**
€100	A$0.06	A$0.10	A$0.15
€500	A$0.31	A$0.52	A$0.73
€1,000	A$0.62	A$1.04	A$1.45
€1,500	A$0.93	A$1.56	A$2.18
€2,000	A$1.24	A$2.07	A$2.90

Source: RBS estimates

This analysis suggests potential upside for CUV at any product price point of €500 or above and at an NPAT margin 15% or above. It also suggests that a 35% NPAT margin and €2,000 price would result in an NPV per share of A$2.90.

Buy recommendation and target price maintained

As a result of this analysis, we maintain our Buy call and target price of A$0.78. This analysis reaffirms our belief that there is considerable upside potential in this stock and that CUV is an opportunity for investors with a higher risk appetite.

CUV – financial summary

Year to 30 Jun (A$m)	AIFRS	AIFRS	AIFRS	AIFRS	AIFRS
Income statement	**2008A**	**2009A**	**2010F**	**2011F**	**2012F**
Divisional sales	0.0	0.0	0.0	13.2	27.1
Total revenue	0.0	0.0	0.0	13.2	27.1
EBITDA	-17.1	-17.4	-17.9	-9.0	0.7
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation/Amortisation	-0.8	-0.8	-0.1	-0.1	-0.1
EBITA	-17.9	-18.3	-18.0	-9.1	0.6
Goodwill Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-17.9	-18.3	-18.0	-9.1	0.6
EBIT(incl associate profit)	-17.9	-18.3	-18.0	-9.1	0.6
Net interest expense	4.3	2.7	3.8	2.6	2.7
Pre-tax profit	-13.6	-15.6	-14.3	-6.5	3.3
Income tax expense	0.0	0.0	0.0	0.0	-1.0
After-tax profit	-13.6	-15.6	-14.3	-6.5	2.3
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT pre significant items	-13.6	-15.6	-14.3	-6.5	2.3
Significant items	-1.0	0.0	0.0	0.0	0.0
Reported NPAT	-14.7	-15.6	-14.3	-6.5	2.3

Cash flow statement	**2008A**	**2009A**	**2010F**	**2011F**	**2012F**
EBITDA	-17.1	-17.4	-17.9	-9.0	0.7
Change in working capital	0.0	1.8	0.4	0.5	5.3
Net interest (pd)/rec	4.0	2.9	3.8	2.6	2.7
Taxes paid	0.3	0.2	0.0	0.0	-1.0
Other oper cash items	5.6	1.5	0.0	0.0	0.0
Cash flow from ops (1)	-7.2	-11.0	-13.8	-5.9	7.7
Capex (2)	-0.2	0.0	-0.2	-0.2	-0.2
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Cash flow from invest (3)	-0.2	0.0	-0.2	-0.2	-0.2
Incr/(decr) in equity	0.0	0.1	0.0	0.0	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	-0.5	6.6	0.0	0.0	0.0
Cash flow from fin (5)	-0.5	6.7	0.0	0.0	0.0
Forex and disc ops (6)	0.0	0.3	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	-7.9	-4.0	-13.9	-6.1	7.5
Equity FCF (1+2+4)	-7.4	-11.0	-13.9	-6.1	7.5

Balance sheet	**2008A**	**2009A**	**2010F**	**2011F**	**2012F**
Cash & deposits	25.8	21.7	7.8	1.7	9.2
Trade debtors	0.6	0.2	0.2	0.3	0.5
Inventory	0.0	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0
Other intangible assets	1.4	0.7	0.7	0.7	0.7
Fixed assets	0.4	0.4	0.4	0.5	0.6
Other assets	26.8	18.7	18.7	18.7	18.7
Total assets	55.0	41.6	27.8	21.8	29.7
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	3.0	4.4	4.8	5.3	10.9
Long-term borrowings	0.0	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.2	0.2	0.2	0.2	0.2
Total liabilities	3.2	4.6	5.0	5.5	11.0
Preference shares					
Hybrid equity					
Share capital	113.2	113.2	113.2	113.2	113.2
Other reserves	1.8	2.2	2.2	2.2	2.2
Retained earnings	-63.2	-78.3	-92.6	-99.1	-96.7
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	51.8	37.1	22.8	16.3	18.7
Minority interest	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	51.8	37.1	22.8	16.3	18.7
Total liabilities & SE	55.0	41.6	27.8	21.8	29.7

Closing price (A$)	**0.22**	**Price target (A$)**	**0.78**
Valuation metrics			
Preferred methodology	DCF	Val'n (A$)	$ 0.78
DCF valuation inputs			
Rf	6.50%	10-year rate	6.50%
Rm-Rf	4.50%	Margin	2.0%
Beta	1.50	Kd	8.50%
CAPM (Rf+Beta(Rm-Rf))	13.3%	Ke	13.2%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	214.7
Equity (E/EV)	100.0%	Minority interest (A$m)	0.0
Debt (D/EV)	0.0%	Net debt (A$m)	-21.7
Interest rate	8.50%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	236.5
WACC	13.2%	Diluted no. of shares (m)	303.1
		DCF valuation (A$)	**0.78**

Multiples	**2009A**	**2010F**	**2011F**	**2012F**
Enterprise value (A$m)	46.5	60.4	66.5	59.0
EV/Sales (x)			5.0	2.2
EV/EBITDA (x)	-2.7	-3.4	-7.4	87.0
EV/EBIT (x)	-2.5	-3.4	-7.3	99.6
PE (normalised) (x)	-4.4	-4.8	-10.6	29.5
PEG (normalised) (x)				

At target price	**2009A**	**2010F**	**2011F**	**2012F**
EV/EBITDA (x)	-12.3	-12.7	-26.1	335.1
PE (normalised) (x)	-15.1	-16.6	-36.6	102.2

Comparable company data (x)		**2010F**	**2011F**	**2012F**
Alchemia	EV/EBITDA	-22.6	8.8	3.9
Year to 30 Jun	EV/EBIT	-16.9	10.5	4.3
	PE	-20.0	11.1	5.9
	PEG	-5.7	3.2	1.7
Mesoblast	EV/EBITDA	-21.0	-18.1	146.7
Year to 30 Jun	EV/EBIT	-20.8	-18.1	731.8
	PE	-19.0	-19.0	-170.3
	PEG			

Per share data	**2009A**	**2010F**	**2011F**	**2012F**
No. shares	303.1	303.1	303.1	303.1
EPS (cps)	-5.1	-4.7	-2.1	0.8
EPS (normalised) (c)	-5.1	-4.7	-2.1	0.8
Dividend per share (c)	0.0	0.0	0.0	0.0
Dividend payout ratio (%)	0.0	0.0	0.0	0.0
Dividend yield (%)	0.0	0.0	0.0	0.0

Growth ratios	**2009A**	**2010F**	**2011F**	**2012F**
Sales growth	na	na	na	na
Operating cost growth	na	na	na	na
EBITDA growth	na	na	na	na
EBIT growth	na	na	na	na
Norm. NPAT growth	na	na	na	na
Norm. EPS growth	na	na	na	na

Operating performance	**2009A**	**2010F**	**2011F**	**2012F**
Asset turnover (%)	0.0	0.0	13.3	26.3
EBITDA margin (%)	na	na	-68.2	2.5
EBIT margin (%)	na	na	-68.8	2.2
Net profit margin (%)	na	na	-48.9	8.5
Return on net assets (%)	-49.3	-79.0	-55.6	3.2
Net debt (A$m)	-21.7	-7.8	-1.7	-9.2
Net debt/equity (%)	-58.6	-34.2	-10.5	-49.5
Net interest/EBIT cover (x)	6.9	4.8	3.5	-0.2
ROIC (%)	-49.1	-82.2	-42.4	2.8

Internal liquidity	**2009A**	**2010F**	**2011F**	**2012F**
Current ratio (x)	8.9	5.4	3.8	2.6
Receivables turnover (x)	na	0.0	54.0	69.3
Payables turnover (x)	na	3.9	4.4	3.3

Source: Company data, RBS forecasts

Recommendation structure

Absolute performance, short term (trading) recommendation: A Trading Buy recommendation implies upside of 5% or more and a Trading Sell indicates downside of 5% or more. The trading recommendation time horizon is 0-60 days. For Australian coverage, a Trading Buy recommendation implies upside of 5% or more from the suggested entry price range, and a Trading Sell recommendation implies downside of 5% or more from the suggested entry price range. The trading recommendation time horizon is 0-60 days.

Absolute performance, long term (fundamental) recommendation: The recommendation is based on implied upside/downside for the stock from the target price. A Buy/Sell implies upside/downside of 10% or more and a Hold less than 10%. For UK Mid/Small Cap Analysis a Buy/Sell implies upside/downside of 10% or more, an Add/Reduce 5-10% and a Hold less than 5%. For UK-based Investment Funds research the recommendation structure is not based on upside/downside to the target price. Rather it is the subjective view of the analyst based on an assessment of the resources and track record of the fund management company. For listed property trusts (LPT) or real estate investment trusts (REIT) the recommendation is based upon the target price plus the dividend yield, ie total return.

Performance parameters and horizon: Given the volatility of share prices and our pre-disposition not to change recommendations frequently, these performance parameters should be interpreted flexibly. Performance in this context only reflects capital appreciation and the horizon is 12 months.

Sector relative to market: The sector view relative to the market is the responsibility of the strategy team. Overweight/Underweight implies upside/downside of 10% or more and Neutral implies less than 10% upside/downside.

Target price: The target price is the level the stock should currently trade at if the market were to accept the analyst's view of the stock and if the necessary catalysts were in place to effect this change in perception within the performance horizon. In this way, therefore, the target price abstracts from the need to take a view on the market or sector. If it is felt that the catalysts are not fully in place to effect a re-rating of the stock to its warranted value, the target price will differ from 'fair' value.

Distribution of recommendations

The tables below show the distribution of recommendations (both long term and trading). The first column displays the distribution of recommendations globally and the second column shows the distribution for the region. Numbers in brackets show the percentage for each category where there is an investment banking relationship.

Long term recommendations (as at 04 Feb 2010)

	Global total (IB%)	Asia Pacific total (IB%)
Buy	655 (10)	434 (1)
Add	0 (0)	0 (0)
Hold	389 (4)	218 (0)
Reduce	0 (0)	0 (0)
Sell	98 (0)	58 (0)
Total (IB%)	1142 (7)	710 (0)

Source: ABN AMRO

Trading recommendations (as at 04 Feb 2010)

	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	2 (0)	2 (0)
Rec	00 (00)	00 (00)
Trading Sell	0 (0)	0 (0)
Total (IB%)	2 (0)	2 (0)

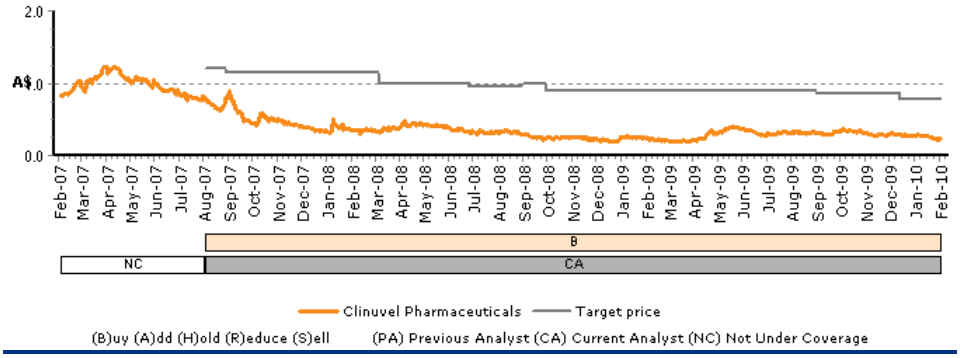
Source: ABN AMRO

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A$0.225, TP: A$0.78): Our valuation of CUV is based on a discounted cash flow model, from which we derive our target price. Upside risks include the faster-than-expected progression to production of CUV's photoprotective technology, while downside risks include any delay or failure to progress clinical trials.

Clinuvel Pharmaceuticals coverage data

Stock performance, recommendations and coverage (as at 3 Feb 2010)



Dr David Stanton started covering this stock on 2 Aug 07

Source: ABN AMRO

Trading recommendation history (as at 04 Feb 2010)

Date	Rec	Analyst
	n/a	

Source: ABN AMRO

Regulatory disclosures

An analyst or a member of any analyst's household who participated in the preparation of this report has a shareholding/financial interest in this company**: ACR.AX**

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