



# Annual Report 2008

# Contents

## **Clinuvel Pharmaceuticals Limited & Controlled Entities Annual Report**

Year Ended 30 June 2008  
ABN 88 089 644 119  
Level 11, 330 Collins Street,  
Melbourne, Vic 3000 Australia  
Telephone +61 3 9660 4900  
Facsimile +61 3 9660 4999  
mail@clinuve.com  
investorrelations@clinuve.com  
www.clinuve.com

Company Profile	2
Chair's Letter	3
Managing Director's Report	4
Value Drivers For Clinuvel Pharmaceuticals	7
Clinuvel's Photoprotective Afamelanotide	8
Indications For Afamelanotide	9
Communicating Photoprotection	14
Clinical Trial Summary	15
Clinuvel Analyst Reports And Media Coverage	16
Corporate Governance Statement	18
Directors' Report	23
Consolidated Income Statement	35
Consolidated Balance Sheet	36
Consolidated Statement Of Cash Flows	37
Consolidated Changes In Equity	38
Notes To Financial Statements	39
Directors' Declaration	69
Independent Audit Report	70
Independent Audit Declaration	73
Additional Information	74
Corporate Directory	77
Glossary	78

# Clinuvel: Developing A World First Photoprotective Drug

Clinuvel Pharmaceuticals Limited (Clinuvel) is an Australian biopharmaceutical company developing a first-in-class photoprotective drug afamelanotide\* (CUV1647) for use in a range of UV and light related skin disorders.

Afamelanotide provides skin protection against UV radiation (UVR) as it stimulates the body's natural ability to produce eumelanin, the dark pigment of the skin which is known to have photoprotective properties.

Increased pigmentation of the skin appears a few days after administration of afamelanotide and lasts up to two months. Afamelanotide is administered underneath the skin as a biodegradable implant approximately the size of a grain of rice.

Afamelanotide is being developed as a preventative for UV related skin disorders. Some people are more at risk from UVR than others. Many of these disorders have no current preventative treatment and medication offers only symptomatic relief. Clinuvel has progressed significantly in its five clinical applications and aims to have afamelanotide in the market by 2010.

*We all need light in the form of sun and ultraviolet radiation.*

*We know light is required for our biological production of Vitamin D and folic acid.*

*Too little leads to Vitamin D deficiency and attendant diseases.*

*Too much is a threat to our existence.*

*We need to find a balance to allow us to embrace life.*

*Our product afamelanotide is a natural photoprotective that helps to control the effects of UV on our skin.*

## Afamelanotide is aimed at the clinical demands of these patients

Indication	Description
Erythropoietic Protoporphyrria (EPP) or absolute sun intolerance	A rare genetic porphyrin metabolism disorder. When skin is exposed to UVR a chemical reaction results in severe pain, swelling and scarring.
Polymorphic Light Eruption (PLE/PMLE) or sun poisoning	A recurrent skin disorder characterised by the appearance of a severe red rash, papules, vesicles, pruritus and burning sensation after exposure to UV.
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTR)	AK, a skin cancer precursor. SCC a non-melanoma skin cancer. OTRs are extraordinarily prone to develop AKs and skin cancers.
Solar Urticaria (SU) or acute anaphylactic reaction to the sun	Acute anaphylactic reaction to sun which may develop a burning redness on exposed skin and include headache, nausea, difficulty breathing.
Photodynamic Therapy (PDT) Phototoxicity associated with this cancer treatment	Phototoxicity associated with cancer treatment (e.g. gastro-intestinal, oesophagus, gall bladder).

\* the World Health Organisation generic name for [Nle4, D-Phe7]  $\alpha$ -MSH.

# Leadership In Light Related Skin Disorders

Dear Shareholder,

This has been a momentous year for Clinuvel Pharmaceuticals Limited in which we have relentlessly pursued our vision of bringing to market the world's first natural photoprotective afamelanotide, and commercializing its benefits.

For the leadership position in photoprotection that Clinuvel has achieved, the management and staff led by the CEO, Dr. Philippe Wolgen, are to be congratulated. It has been a year of outstanding progress. The effort required from such a small team is testimony to their dedication to sustained quality output.

It has been a very challenging year for equity markets. Clinuvel stands out among those biotechnology companies recognized as well funded, in a late stage of development and with genuine value drivers.

The capital raising program of 2007 laid the foundation for the clinical and operational growth that has occurred over 2008 and which has brought much closer the commercialization of afamelanotide.

I am very pleased to report to you that Clinuvel has completed a year of significant milestones on its pathway to commercialization, as we are currently conducting clinical trials in Europe, the UK and Australia.

Our two Phase III trials have advanced one year. With one of these we aim to file for registration late in 2009. Three new Phase II trials began. These build on the diversification of applications for which Clinuvel can advance afamelanotide.

The company has expanded its personnel to bring to the company the skill sets required as we move from clinical trial scale toward commercialization.

I am delighted to welcome Jack Wood to the Board. His world class international experience will be invaluable in a host of fields for the company in the years ahead.

On behalf of all shareholders I would like to congratulate Dr. Wolgen and his entire team at Clinuvel for achieving three orphan drug designations from three globally recognized regulatory bodies, the EMEA in Europe, Swissmedic in Switzerland, and the FDA in the USA.

The company's focus on photoprotection is world leading. We are now even more confident of a successful clinical application for afamelanotide.

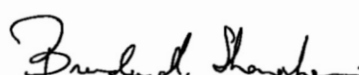
Clinuvel is fortunate to have a management that raised funds when times were favourable in 2007 and does not need to come to market for its clinical program which is fully funded and will see our first filing for registration.

Our achievements take us closer to a new era. We have expanded and consolidated our activities on three continents. This alone warrants acknowledgement for the outstanding efforts of the Clinuvel team to run in-house such a diverse operation in so few hands.

We are well connected globally with the clinical experts. Being an Australian company providing a solution to a global problem it only seems natural that we lead the field in photoprotection.

We remain focused strategically and operationally on the achievement of our commercial milestones.

Your Board is very optimistic about Clinuvel's future. The strategic goals and plans for Clinuvel are set to deliver over the next two years.



Brenda Shanahan

Chair



# Managing Director's Report

Dear Shareholder,

## Annual review

Clinuvel's team has completed a memorable year in the development of its photoprotective drug afamelanotide (CUV1647).

However, contextual thinking is needed to come to appreciate the disparity between value and progress of the company. The past 12 months, the chaos in capital markets worldwide has overshadowed our sector, and the advancement by Clinuvel has been largely undetected by the markets. Nevertheless, shareholders' support for the company has remained strong as exemplified by a broad group of investors who decided to purchase the majority stake in Clinuvel of shareholder hedge fund Absolute Capital Management Holdings in September 2008.

Keeping perspective of Clinuvel's core undertakings, it has been my primary objective to develop a solution for specific diseases in a group of patients who could not find relief thus far. In the domain of light and UV related skin disorders, we focused on a class of relatively unattended disorders. To illustrate, only recently has the medical community started paying attention to the specific clinical problems seen in organ transplant recipients, who have been proven over the years to be at highest risk of contracting skin cancers. Generally, a recent shift has been seen in media reporting on the phenomenon of light and UV exposure as a significant risk factor to skin, whereas traditionally an outdoors life would have been associated with health, affluence and indulgence.

Anecdotal reports throughout the year from patients expressing their gratitude for making afamelanotide available in clinical trials forms by no means evidence of drug efficacy. However, these messages certainly affirm why Clinuvel is in this business. These reports alone make it worthwhile to persist in the treacherous field of drug development.

The novelty of Clinuvel's development program comes with its drug afamelanotide. Several challenges have been overcome, the drug is innovative and relatively unknown, its targeted diseases are not well understood and often not acknowledged by those who are unable to imagine the effects of light and UV on fair skin. We are thankful for the many experts, patients and investors who share the common vision that a preventative photoprotective agent may one day become commercially available to reduce the number and severity of phototoxic symptoms suffered by so many globally.

Important metrics this year have been provided by the positive news emanating from regulatory agencies EMEA, Swissmedic and FDA. After months of preparation, for the first time in the company's history, Clinuvel obtained orphan drug designation (ODD) for the severe metabolic disorders erythropoietic porphyria (EPP and CEP). Clinuvel now has a clear route to market, pending ongoing safety and efficacy of afamelanotide. Importantly, the ODD status offers Clinuvel tax relief and exemption from high filing fees. Strategically, the orphan drug status offers Clinuvel 7 years of market exclusivity for afamelanotide in the US and 10 years protection in the European markets.

## A word on those sufferers of skin related light disorders

To highlight the ordeal of EPP patients who lead a sheltered existence deprived of a normalized social existence, as they are incapacitated by ambient light, UV and sun. For the unaffected like you and I, it is difficult to conceive what a lifelong captivity indoors would constitute. We take for granted that we need to cross a parking lot to go to a supermarket, however for an EPP patient the gait to the supermarket equals 2 minutes of UV exposure and the risk of burn and blister formation and of intolerable pain for days. To be able to contribute here is rewarding.

By the end of 2008, 42 centers worldwide will be using afamelanotide. Acknowledgement amongst physicians has gradually grown that Clinuvel possesses leading technology offering medicinal benefit, prevention in skin diseases caused by light and UV. The recognition is reflected in the increase of our clinical activities globally. We have increased to five the number of clinical applications for afamelanotide. Our fifth, the use of afamelanotide as adjunct therapy in oncology treatment to improve the quality of life began in September 2008.

The introduction of afamelanotide as a New Molecular Entity (NME) poses strict requirements by regulatory agencies on safety and efficacy. The safety profile is excellent for the drug, but we remain vigilant throughout the entire development process.

### Value drivers

Clinuvel's next US regulatory step is to obtain the much desired status of Investigational New Drug (IND). This will mark the entrance to US clinics and will confirm the regulatory acknowledgement of our program. Pending a positive outcome, we intend to start our US program by the first half of 2009.

The company has increased the value of its program in achieving a number of well recognized equity drivers in biopharmaceutical development including:

- Advancing two Phase III clinical trials, with interim results to be analyzed by December 2008 for EPP and in the March quarter 2009 for Polymorphic Light Eruption (PLE);
- Expanding the number of indications in the clinic from 2 to 5, adding the application in organ transplant recipients (OTR) and Solar Urticaria (SU) and Photodynamic Therapy (PDT)

With the regulatory progress to date, we are coming to a point where choices are to be made on the scale up of manufacturing. The company will need to estimate and project commercial production of its final product. To this extent we have developed in partnership with our manufacturers over the past 3 years a controlled-release implant technology which elutes afamelanotide in the desired pico-quantities to achieve the biological effect of photoprotection of the skin for the duration of 60 days.

### Operational activities, communication

Melbourne constitutes the center of Clinuvel's activities, implying that regulatory strategy and further commercial decisions are all made out of our headquarters in Australia.

With the increase of clinical activities, the Zürich office has become the operational hub where clinical trials are being coordinated. By the end of 2008, we aim to have between 7 and 10 people on the ground to manage 37 centers in Europe. We are planning several other Phase II and III trials in Europe in 2009, most likely exceeding 50 in number.

Reliable data remain the oxygen of any pharmaceutical company, and contemporary collection of data greatly assists the physicians managing the trials. New ways of collecting data aids drug developers to evaluate and assess the safety and efficacy of the drug.

Critical to Clinuvel's success in recruiting and retaining patients in its clinical trials has been the introduction of electronic technology to retrieve patients' data.

We closely monitored a changed behaviour in our patients and online users. The change prompted us to launch novel online facilities at [clinuvel.com](http://clinuvel.com), where we set ourselves the objective to become leaders in the fields of photoprotection by 2009.

The online **Xptise** section deserves special mention where web interaction deepens the understanding of skin, environment and related topics. A prominent thought leader series will provide instant feedback online. In this respect, the growing number of visitors to [clinuvel.com](http://clinuvel.com) bodes well for the interest in the novel drug afamelanotide.

We welcome the progress of the advanced studies in EPP and PLE. In the northern hemisphere in PLE, the first season has been completed and a second season is planned to commence early 2009.

In EPP, the placebo controlled trial is being conducted in 14 different sites in Europe and Australia. We are planning further registration studies in the rest of the world as part of our pre-emptive regulatory strategy (PRS). More updates will be provided over the course of the first quarter of 2009.

The commencement in October 2007 of the Phase II trial focused on immune compromised OTR aiming to reduce the development of skin cancers. This 24-month trial is the longest of all our clinical tests and we eagerly await the first results.

The Solar Urticaria Phase II trial is a short 6 month trial with a small number of therapy resistant patients (6) aimed at demonstrating proof of concept.



The Phase II trial to treat phototoxicity associated with the use of Photodynamic Therapy (PDT) in oncology has started in one French center, where the first patients have received afamelanotide. Patient recruitment in other centers is well advanced and anticipated to start in December 2008. In PDT, the phototoxicity seen in patients follows the biochemical pathways seen in EPP. We will expect to see the first results in the first quarter of 2009.

### Market dynamics

We remain aware of our unique position as an entity focused on the commercial development of a single molecule within the broader pharmaceutical landscape. In this respect, the decision to focus the company on the development of one drug has paid off. The past 3 years of progress would not have taken place without the strong commitment and resources spent on the development of afamelanotide.

### Finance

The reserves of the company currently stand at \$47m and provide sufficient resources for completion of the current clinical trial program and corporate development through to 2010. It is anticipated that the cash burn will increase from the current average of under \$1m per month to \$1.7m per month by the latter stages of 2009, reflecting the increase in operational activities.

### Corporate objectives

With clinical trials well advanced in Phase II and III, Clinuvel continues to strengthen a dossier to be able to meet regulatory standards when filing for marketing authorization (MAA) in the various jurisdictions.

As the company progresses in developing afamelanotide with the ultimate goal of commercializing the drug, so is the Board of Clinuvel developing. Most recently, the appointment of Jack Wood underwrote our objective to add international industry experience to the Board.

I would like to thank Dr. Roger Aston for his service as Chair of Clinuvel during 2006 and 2007 and his support to refocus Clinuvel. Roger continues to be a pivotal member as a Non-Executive Director.

The progress of Clinuvel is a function of the continuous pool of talent that we are able to retain and attract. Execution is key in the company, and the way we approach the business is said to be focused and characterized with relentless persistence.

Acknowledgement is due to Dr. Hank Agersborg, Board member and much valued as Chief Scientific Officer of the company. The contributions made by Hank and his boundless energy to the program serve as example to all of us. Under his guidance, together with the direction provided by Drs. D. Wright and N. Muner, the regulatory and clinical sections of the company have developed to maturity. Special mention must go to Mr D. Keamy and C. Mackie for leading the business during the year. Without doing injustice to any of the team members, the entire team of Clinuvel - spread over 3 continents - is to be commended for their performance the past 12 months: the real assets of Clinuvel lie in the skills currently in the team, my gratitude for the daily commitment shown.

Equally, I am aware of the privilege to enjoy continued support of investors, existing and new, who endure difficult times in global equity markets. If we continue to execute in the same fashion, I am certain that we will return value to our shareholders in the near future.



Dr. Philippe Wolgen, MBA MD

Managing Director



# Value Drivers For Clinuvel Pharmaceuticals

Value Drivers 2006	Value Drivers 2007	Value Drivers 2008
Pathway to regulation established		Orphan Drug Designation: EMA, Swissmedic, US FDA
Clinical pathway commenced	Clinical pathway progression	Clinical pathway progression
Indications identified	Clinical indications expanded	
Phase II commenced, x2 (PLE, EPP)	Phase II positive, x2 (PLE, EPP)	
	Phase III commenced, x2 (PLE, EPP)	Phase III midway, x2 (PLE, EPP)
		Phase II commenced, x2 (AK/SCC, SU)
		Pharmacokinetic studies validate safety
		Selection of final dosage for development
Available funds of \$10m	Available funds of \$62m	Available funds of \$47m
Raised \$31m	Raised \$36m	
New Management team	Management team evolution	Board and Management expand inline with activities
IP	IP - new patents / fortify portfolio	



# Our Photoprotective Afamelanotide

*Photoprotection (n) - protection from ultraviolet radiation and light of other wavelengths*

## Our lead product

Afamelanotide\* stimulates the body's natural ability to produce eumelanin, the dark pigment of the skin which is known to offer photoprotective properties.

Afamelanotide, an agonist of the melanocortin 1 receptor (MC1R), is described as an analogue of the naturally occurring hormone,  $\alpha$ -MSH and has a linear configuration as a peptide of thirteen amino acids.

Compared to the natural peptide, afamelanotide has a significantly longer half life and a efficacy that is 10 to 1,000 times greater.

The development of afamelanotide began in the mid 1980s by scientists at the University of Arizona. In 1999, Clinuvel (formerly Epitan) licensed the exclusive worldwide rights to develop and commercialise afamelanotide for the purpose of melanogenesis (natural stimulation of melanin). Since then, Clinuvel identified five light and UV-related skin disorders which would benefit from treatment with afamelanotide. All five disorders are expected to be in clinical trials by the end of 2008.

Clinuvel has determined the optimal dosage and delivery vehicle (a bioabsorbable controlled release implant formulation) for afamelanotide in the current development program.

Afamelanotide is a first-in-class drug. There are no other similar compounds being tested in clinical trials in the area of melanogenesis (melanin stimulation) of the skin.

We hold the view that afamelanotide has the potential to improve the quality of life of patients and change behavior of people worldwide.

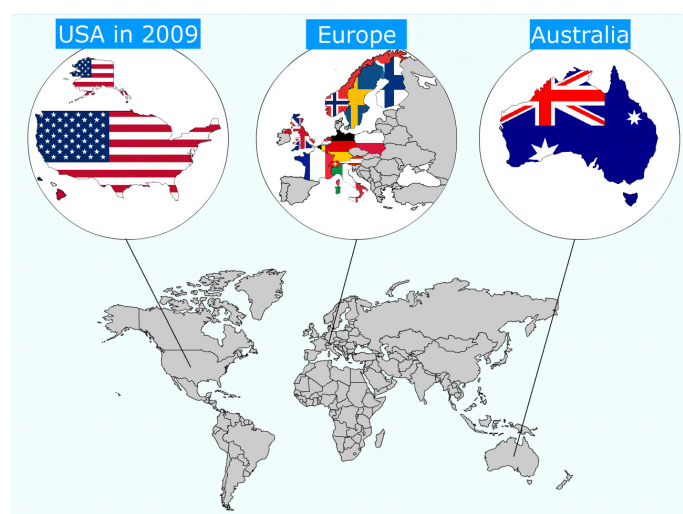
## Afamelanotide administration

Afamelanotide is delivered via a subcutaneous (under the skin) injection of the bioabsorbable implant (smaller than a grain of rice), which slowly releases afamelanotide over ten days and subsequently activates the production of the skin's pigment, melanin, for up to sixty days.

## Dosage

In the current five targeted clinical applications, the optimal dosage (via the implant) has been determined to be 16mg afamelanotide.

An Australian solution to a global problem



Clinuvel is trialing afamelanotide in 42 centres across Europe and Australia with plans to expand to the USA in 2009.

\* the World Health Organisation generic name for [Nle4, D-Phe7]  $\alpha$ -MSH.

# Indications For Afamelanotide

## 1. Erythropoietic Protoporphyria (EPP)

Also known as EPP, Erythropoietic Protoporphyria is a rare inherited metabolic disorder of the heme pathway, which results from a dysfunction of specific enzymes involved in the haem biosynthesis. Haem serves many essential functions in the body, one of which is oxygen transport via haemoglobin. The main feature of EPP is 'burning or prickling' pain when exposed to sunlight.

Its incidence is low; studies include incidence in the range of 1:200,000.

This disorder causes a chemical known as protoporphyrin IX to accumulate in the skin. When the skin is exposed to the sun, these molecules undergo a chemical reaction that results in swelling, severe and intolerable pain and scarring, a condition known as phototoxicity.

Symptoms of EPP are usually with patients for life. Typically, the disease begins in childhood and is characterized by episodes of phototoxicity.

The main symptoms are pain, which is often described as heat, prickling, toxicity of skin exposed to light. The pain is sometimes described as like having hot needles stuck into the skin. The pain is often very severe, and swelling and blistering of the skin may result. Skin lesions resolve slowly often leaving waxy or pitted scars. Repeated exposure leads to scarring and waxy thickening of the skin on the backs of the knuckles and nose. Liver failure occurs in 5% of EPP patients; this is thought to be related to the increased work of the liver to clear the excessive intermediate by-products from the defective haem pathway. If liver failure occurs it can be fatal.

The lifelong pain experienced by these patients, typically forces them to become socially isolated due to their need to continuously avoid sunlight and the lack of an efficacious treatment.

## References

- Marko P B et al., (2007). "Erythropoietic protoporphyria patients in Slovenia", *Acta Dermatoven.* Vol 16 (3), pp99-104.
- Murphy, G M, (2003). "Diagnosis and Management of the Erythropoietic Porphyrrias", *Dermatologic Therapy.* Vol 16, pp57-64.
- Schneider-Yin et al., (2000). "New insights into the pathogenesis of erythropoietic protoporphyria and their impact on patient care", *European Journal of Pediatrics.* Vol 125, pp 719-725.
- Thunell, S, Harper, P & Brun, A, (2000). "Porphyrins, Porphyrin Metabolism and Porphyrrias, IV, Pathophysiology of Erythropoietic Protoporphyria - Diagnosis, Care and Monitoring of the Patient", *Scandinavian Journal of Clinical and Laboratory Investigation.* Vol 60, pp581-604.
- Todd, D J, (1998). "Clinical Implications of the Molecular Biology of Erythropoietic Protoporphyria", *Journal of European Academy of Dermatology Venereology.* Vol 11, pp207-213.

## 2. Polymorphous Light Eruption (PLE)

PLE is an annually recurring skin reaction to sunlight or UV light sources, and can also be seen on areas of the skin not directly exposed.

There are many morphological variants including papular, vesicular, papulovesicular, plaque, erythema multiforme-like, insect bite-like, purpuric and sine eruptione.

PLE is very common worldwide with the incidence reported in literature to be 5% in Australia, 10% in the US, 15% in the UK and 15-20% in most northerly latitudes of Europe. It has only rarely been reported in Asian and African countries. Its prevalence decreases with decreasing latitude.

PLE occurs in all skin types and racial groups, but is more common in Caucasian individuals.

PLE usually starts before the age of 30 and is much more common in females than males.

PLE eruption typically occurs after the first substantial UV radiation exposure and is common in spring and early summer. It has also been reported to occur after solarium use and, rarely, to visible radiation. Continued exposure

often leads to abatement of symptoms - the 'hardening phenomenon', and so PLE is often less troublesome towards the end of summer than in spring.

Individual susceptibility differs, and the period of continuous exposure needed to trigger the eruption varies from 30 minutes to several hours. The delay after exposure is usually several hours to days, however there is an early onset PLE variant with symptoms as soon as 30 minutes after first exposure. The eruption always occurs on an exposed, but typically not regularly exposed site of the body and is intensely itchy, the itch sometimes preceding development of the rash. PLE outbreaks always tend to recur at the same site within an individual and are usually symmetrical. Symptoms usually resolve within a few days to 2 weeks of onset and with subsequent light avoidance.

PLE has many possible morphologic forms as suggested by the name (polymorphic). Papular and vesicular morphologies are most common, followed by plaque and papular subtypes. PLE often looks similar each time it occurs within an individual (monomorphic), however some patients do have different morphologies on different sites, for example plaques on the face and a papular eruption on the forearms.

The aetiology (origin) of PLE is unknown. It is believed to be a delayed type hypersensitivity response to an ultraviolet-induced allergen (photoallergen). The clinical observation that a first time eruption occurs after particularly intense ultraviolet exposure (deliberate sunbathing or solarium use) could indicate that such an exposure leads to the development of autosensitization thus lending support to an autoimmune role in the development of this disease.

Sun avoidance and protective measures alone are sufficient for most mild/moderately affected people and are the mainstays of treatment in those severely affected. Avoiding unnecessary environmental exposure, such as beach holidays, wearing appropriate clothing with tightly woven fabrics, using broad spectrum high factor sunscreens applied thickly and frequently, and avoiding the midday sun are integral. For those more severely affected, the use of UV absorbing film, and shielding from glass (car and house windows) is often appropriate.

Patients who experience PLE infrequently usually respond to short courses of oral corticosteroids. Topical steroids may also be useful. There is evidence for the use of topical steroids applied prophylactically immediately after exposure and this can also be helpful preventing flares during desensitisation.

For those more severely affected, prophylactic photochemotherapy with narrow-band UVB or PUVA given in spring serves to desensitise the skin and is beneficial in the majority of patients. Such therapy can in itself induce a reaction. Various other therapies have also been tried but appear largely ineffective. These include hydroxychloroquine,  $\beta$ -carotene, nicotinamide, omega-3-polyunsaturated fatty acids. Oral immunosuppressive therapy with Azathioprine or Cyclosporin has been shown to be effective for severe cases.

### References

- Hawk, J & Ferguson, J (2008). "Abnormal Responses to Ultraviolet Radiation: Idiopathic, Probably Immunologic and Photoexacerbated", in Fitzpatrick's Dermatology in General Medicine 7th Edition. Ch 90, pp816-818.
- Ferguson, J, (2006). "Polymorphic light eruption", in Introduction to Photodermatology Photodynamic therapy and laser therapy, Ninewells Hospital and Medical School, Dundee.
- Hasan, T et al., (1998). "Disease associations in polymorphous light eruption. A long-term follow up study of 94 patients", Archives of Dermatology. Vol 134, pp1081-1085.
- Ferguson, J, (1996). "The management of the photodermatoses with phototherapy" in Honigsmann, H, Jori G & Young, A R (eds) The fundamental bases of phototherapy. OEMF spa, Milan, Italy, pp 171-179.
- Gonzalez-Amaro, R et al., (1991). "Immune sensitization against epidermal antigens in polymorphous light eruption", Journal of American Academic Dermatology. Vol 24, pp70-73.
- Frain-Bell, W, (1985). "The idiopathic dermatoses", in Cutaneous photobiology. Oxford University Press, Oxford. pp24-59.

### 3. Actinic Keratosis (AK)

Actinic Keratoses (AKs) are collections of altered keratinocytes confined to the upper epidermis of the skin that develop in response to prolonged ultraviolet light exposure. Actinic Keratoses are described in-situ cancerous lesions and are the initial lesions in a disease continuum that may progress to invasive Squamous Cell Carcinoma (SCC), may develop into invasive SCC. AKs are a very good indicators of significant past sun exposure, and are the strongest predictor that an individual may subsequently develop non-melanoma skin cancer (SCC or Basal Cell Carcinoma, BCC).

Actinic Keratoses are very common. The two major risk factors are cumulative lifetime sun exposure and individual susceptibility. In Europe, Actinic Keratoses occur in up to 25% of adults. In Australia 50% of adults are expected to have one or more Actinic Keratosis in their lifetime.

Age is another important risk factor; Actinic Keratosis occurs in up to 80% of fair-skinned adults aged 60-69

but in less than 10% of fair-skinned adults 20-29 years. Males have a higher tendency towards developing Actinic Keratosis than females, however this is likely the result of higher cumulative lifetime sun exposure in males than females.

Other risk factors include fair skin that easily burns and does not tan, blue or light coloured eyes and blond or red hair.

Organ transplant recipients (OTRs) are much more vulnerable to developing Actinic Keratosis and SCC, in part due to the immunosuppressive drugs they must take to prevent transplant rejection. OTRs are up to 250 times more likely to develop skin cancer than those who have not had an organ transplant.

A typical Actinic Keratosis lesion presents as a red, flat, rough or scaly papule, 2-6mm in size however some AKs can reach several centimetres. Many AKs may convalesce together giving the appearance of a rash. They are commonly found on a background of photodamaged (sun damaged) skin with dyspigmentation (loss of pigmentation), ephelides (freckles), telangiectases (dilated superficial blood vessels), and solar elastosis (decreased skin elasticity as a result of photodamage). 80% of AKs occur in sun exposed sites and are particularly common on the back of hands, arms and scalp.

Hypertrophic keratoses are a subtype of Actinic Keratoses and manifest as thicker, scaly, rough plaques. A cutaneous horn is a conical protuberance and is often a further extension of the hypertrophic keratosis, however it can also represent an outgrowth of many other lesions including SCC. A biopsy of the skin should always confirm the nature of an underlying lesion.

Itching, burning, stinging, bleeding and crusting are frequently associated with Actinic Keratosis. Increasing thickness, pain and ulceration are the main signs that an Actinic Keratosis may be transforming to a SCC and in this case a biopsy should be taken at the earliest time possible.

Cumulative lifetime sun exposure is the most important contributing factor to the development of Actinic Keratosis and eventually Squamous Cell Carcinomas. UV radiation may cause mutations in cellular DNA that, when un-repaired, may lead to uncontrolled cell growth and proliferation and eventually tumour formation. Also, UV radiation causes immunosuppression which impairs the cells capacity to repair the damaged DNA. This allows for the DNA mutations to persist and subsequently tumour rejection may not occur.

DNA is the main chromophore for UVB radiation. When photons of UVB light are absorbed by the DNA, damage is caused to the DNA helix, often resulting in C-T single mutations or CC-TT tandem mutations (cyclobutane pyrimidine dimers - CPD). These are commonly called 'signature mutations' and are indicative of photodamage due to UVB light. The photodamage caused by UVA light is less understood, but is likely to play a role in the transformation from normal to abnormal cells.

These 'signature' mutations are nearly always found in the p53 tumour suppressor gene (p53 is responsible for ensuring all DNA is repaired before allowing the cell to recommence cell division) which is found in the early developmental stages of Actinic Keratosis and SCC.

Multiple UV radiation induced-insults to the skin result in a pathway that begins with photodamaged skin, progresses to Actinic Keratosis and eventually, if left unchecked may lead, to an invasive SCC. Actinic Keratoses are expanded clones of genetically abnormal cells that have escaped the normal DNA repair mechanisms and apoptosis (programmed cell death) to proliferate into what can be seen as an in-situ cancer of the skin.

Avoiding UV sun exposure is the most effective measure to decrease the risk of skin damage. Studies have shown that the critical time, the time of most sensitivity, is in childhood; education of young people is particularly important.

Complete avoidance of the sun is obviously not practical, but the next best thing - *so far* - is to avoid the strong midday sun between 10am and 4pm. Also consistent application and reapplication of a broad-spectrum sunscreen and UV protective clothing, hats and sunglasses should always be worn.

Actinic Keratoses are pre-malignant lesions and so should therefore be treated to prevent transformation into malignant tumours of the skin. The type of treatment will depend on the size, location and number of lesions but include cryotherapy, curettage, and shave excision. Topical therapies include the chemotherapeutic agent 5-FU, 5% Imiquimod, and Diclofenac 3% gel, a non-steroidal anti-inflammatory drug.

## References

- Kyle, J W et al., (2008). "Economic Evaluation of the US Environmental Protection Agency's SunWise Program: Sun Protection Education for Young Children", *Pediatrics*. Vol 121 (5), pp e1074-e1084.
- Euvrard, S et al., (2006) "Subsequent Skin Cancers in Kidney and Heart Transplant Recipients after the First Squamous Cell Carcinoma", *Transplantation*. Vol 81 (8), pp1093-1100.



Tsai, T, Vu, C and Henson, D E, (2005). "Cutaneous, ocular and visceral melanoma in African Americans and Caucasians", *Melanoma Research*. Vol 15, pp213-217.

Anwar, J, Wrone, D A, Kimyai-Asadi, A & Alam, M, (2004). "The Development of Actinic Keratosis into Invasive Squamous Cell Carcinoma: Evidence and Evolving Classification Schemes", *Clinics in Dermatology*. Vol 22, pp189-196.

Oppel, T & Korting, H C, (2004) "Actinic Keratosis: The Key Event in the Evolution from Photoaged Skin to Squamous Cell Carcinoma", *Skin Pharmacology and Physiology*. Vol 17 (2), pp67-76.

Dwyer et al., (2002). "Cutaneous Melanin Density of Caucasians measured by spectrophotometry and risk of malignant melanoma, basal cell carcinoma and squamous cell carcinoma of the skin", *American Journal of Epidemiology*. Vol 155, pp614-621.

Hoffman et al., (2002). "Malignant melanoma in Cape Town, South Africa", *British Journal of Dermatology*. Vol 138, pp998-1002.

Carter, R, Marks, R & Hill D, (1999). "Could a national skin cancer primary prevention campaign in Australia be worthwhile?: an economic perspective", *Health Promotion International*. Vol 14 (1), pp73-82.

#### 4. Solar Urticaria (SU)

SU is a rare, sunlight induced hypersensitivity (allergic) reaction that causes wheals (raised red skin welts) very soon after or during sun or light exposure. In Solar Urticaria, the reaction is triggered by exposure to UV or visible light. It may be severely disabling and can even be life threatening.

An estimated 3.1 per 100,000 people are affected by SU and it is believed to occur worldwide. There is a higher preponderance in females than males.

Solar Urticaria may arise at any age, with the episode occurring after marked sunlight exposure. Initial presentation has also been reported after first solarium use. Symptoms usually develop within 5 minutes of sun exposure and often develop from an unpleasant sensation to itching, redness and swelling, followed by localized or widespread development of wheals (an urticarial flare). Gradual resolution then follows over 1-2 hours.

Rarely, a more prolonged exposure may be required for symptoms to develop, or the onset of symptoms may be delayed for several hours. With extensive whealing some patients also experience headache, nausea, bronchospasm (asthma-type respiratory symptoms) and syncope (dizziness) which may become life threatening (although this is rare).

Sun exposed areas are most commonly affected, although occasionally reactions are seen in dermal areas that are not exposed to the sun.

Primary Solar Urticaria is an immediate Type 1 hypersensitivity response (IgE mediated allergic reaction) towards a photoallergen which is a compound produced in the body when UV light is absorbed by a cellular precursor. Mast cell degranulation and histamine release are important factors in SU but many other inflammatory cells, particularly neutrophils and eosinophils are involved in amplifying the whealing response.

Many light wavelengths may trigger the production of different photoallergens but SU is most commonly caused by UVA or visible light. There appears to be no genetic basis for this condition. Very rarely, secondary SU occurs in association with drug photosensitivity, cutaneous porphyria or lupus.

Phototesting confirms the diagnosis and reveals the wavelengths responsible for inducing an urticarial response.

The mainstay of treatment is behavioural change, avoidance of sunlight, photoprotective clothing and broad-spectrum sunscreens, however this may not always be useful in cases of visible light being responsible for the Solar Urticaria.

High doses of H1-antihistamines taken an hour before sun exposure are very effective in one third of patients and give another third partial relief. Desensitization with phototherapy may be useful for some patients, however therapy generally needs to be continued to maintain its benefit and so consequently carries a risk of long-term risks such as skin cancers. In severely affected individuals, this treatment also carries the risk of anaphylaxis (severe, often life threatening allergic reaction) and so should be undertaken with extreme caution. Immunosuppressant medications such as Cyclosporin or plasmapheresis may need to be considered in the most severe cases.

#### References

Dice, J P, (2004). "Physical Urticaria", *Immunology and Allergy Clinics of North America*. 24, pp225-246.

Beattie, P E, Dawe, R S, Ibbotson, S H, & Ferguson, J, (2003). "Characteristics and prognosis of idiopathic solar urticaria: A cohort of 87 cases", *Archives of Dermatology*. 139 (9), pp1149-1154.

Buxton, P K, (2003). "ABC of Dermatology", London: BMJ Publishing Group Ltd.

Roelandts, R, (2003). "Diagnosis and treatment of solar urticaria", *Dermatologic Therapy*. pp52-56.

Ng, J H C, Foley, P A, Crouch, R B, & Baker, C S, (2002). "Changes of Photosensitivity and Action Spectrum with Time in Solar Urticaria", *Photodermatology, Photoimmunology & Photomedicine*. Vol 18, pp191-195.

## 5. Photodynamic Therapy

Photodynamic Therapy (PDT) is a systemic treatment used in oncology by a variety of specialist to eradicate premalignant and early-stage cancer and reduce the tumour size in end-stage cancers. Applied PDT in dermatology is a localized procedure used to treat skin cancers and some other benign skin conditions.

PDT combines the intravenous administration of a photosensitizer (porfimer sodium) with targeted illumination using a focal light source to activate photochemical tissue reactions. This combination proves highly selective in cancer treatment.

Photosensitising agents are drugs that become active when light of a certain wavelength is directed onto the anatomical area where they are concentrated. The photosensitizing agent is preferentially taken up, into, and by cancer cells.

PDT is a treatment mainly used in oncology (gastro-enterology) to endoscopically eradicate incipient pre-malignant lesions of the esophagus ('Barrett's esophagus') and as a palliative treatment in bile duct cancer (choleangio-carcinoma), and a variety of other cancers.

A consistent side effect and significant clinical disadvantage to the use of porfimer sodium as a photosensitizer is the associated phototoxicity of the skin experienced for up to 3 months following treatment. Consequently, PDT patients are obliged to observe continuous precautions to avoid exposure to light and UV. Exposure to UV results in erythema, acute blistering and severe burns of the skin, causing intense pain and skin damage. Conventional UV sunscreens are of no value in protecting against phototoxic reactions following PDT, and patients are forced to stay indoors over a three months period.

## References

- Goldberg, J (2008). "Laser Dermatology". Blackwell Publishing, Oxford.
- Sakamoto, F H, Wall, T, Avram, M M & Anderson, R R, (2008). "Lasers and Flashlamps in Dermatology", In: Wolff, K, Goldsmith, L A, Katz, S I, Gilchrist, B A, Paller, A S & Leffell, D J (2008). Fitzpatrick's Dermatology in General Medicine, McGraw-Hill.
- Kendall, C A & Morton, C A, (2003). "Photodynamic Therapy for the Treatment of Skin Disease", Technology in Cancer Research & Treatment. Vol 2 (4), pp283-288.
- Altshuler, G B et al., (2001). "Extended theory of selective photothermolysis", Laser surg Med. Vol 29 (5), pp416-432.
- Zenzie, H H et al., (2000). "Evaluation of cooling methods for laser dermatology", Lasers Surg Med. Vol 26 (2), pp130-144.
- Fritsch, C, Goerz, G & Ruzicka, T, (1998). "Photodynamic Therapy in Dermatology", Archives of Dermatology. Vol 134, pp207-214.
- Sripachya-Anunt, S et al., (1997). "Infections complicating pulsed carbon dioxide laser resurfacing for photoaged skin", Dermatol Surg. Vol 23 (7), pp527-535.
- Burkhardt, B R & Maw, R, (1997). "Are more passes better: Safety versus efficacy with the pulsed CO2 laser", Plast Reconstr Surg. Vol 100 (6), pp1531-1534.



# Communicating Photoprotection

Clinuvel is being innovative in building awareness for photoprotection.

## Clinuvel.com

Through our novel development of a next generation website at [clinuvel.com](http://clinuvel.com) and [Xptise.com](http://Xptise.com), all stakeholders and those with an interest in the field of photoprotection are now able to interact amongst each other online, and access specialists and experts in associated fields of medicine, skin cancer and physics.

We believe that enabling patients, consumers, physicians and industry experts to interact with one another will enhance the understanding and importance of photoprotection and the diagnosis and management of light related skin disorders.

Users can engage in online discussions and Q&As with experts. Clinuvel is providing a first model of information in 4 dimensions.

With novel navigation and variable levels of content, anyone can quickly identify the related topic desired, and the depth of information to delve into, from a brief overview through to 'peer reviewed' research.

The website and our other initiatives are part of our company's steady clinical progress and move towards commercialization. It has become clear to us that we have a growing audience, and we want to provide the loyal online users with valuable information.

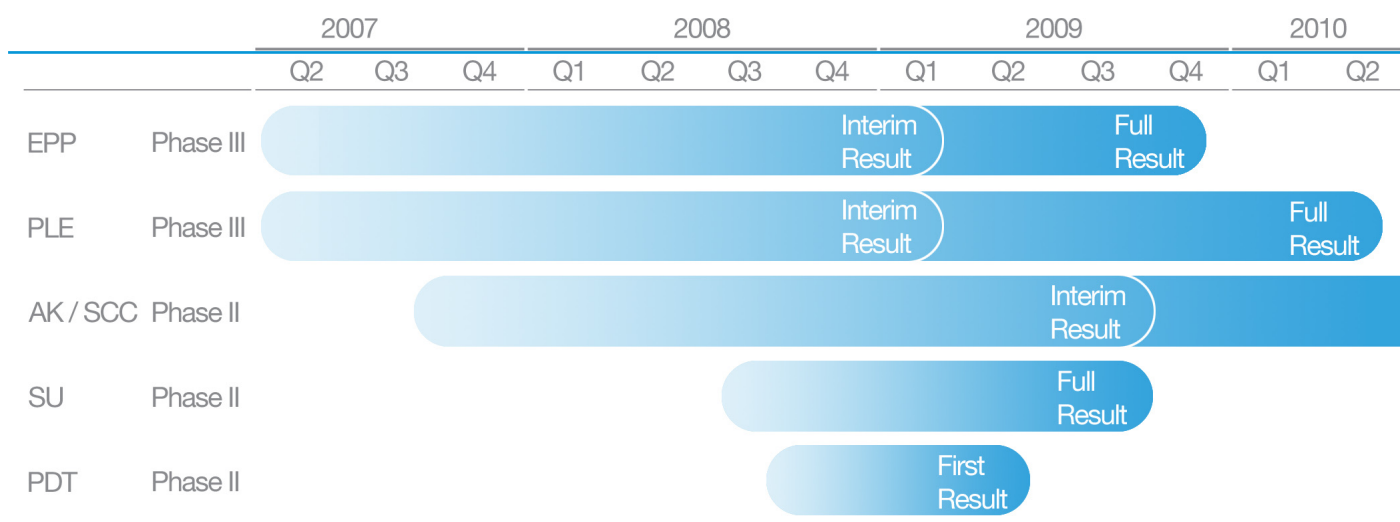


## E-Diary technology

Clinuvel has adopted cutting edge diary technology for 2 studies throughout Australia and Europe, replacing paper diary systems with e-diaries. Patients record and transmit relevant clinical data electronically, which can be accessed by investigating physicians and CRAs immediately. The Tungsten TX e-diary has been programmed into 7 languages, and streamlines data access and analysis via a secure, central web based platform, allowing study results to be compiled and released quickly and accurately.

# Clinical Trial Summary 2008

## Communicating Signposts



\*timelines may be subject to change, pending various clinical and regulatory approval processes worldwide

## Clinical trial summary 2008

Indication	Description	Trial status
Erythropoietic Protoporphyrria (EPP)	Absolute sun intolerance	Phase III started April 2007
Polymorphic Light Eruption (PLE / PMLE)	Sun poisoning	Phase III started May 2007
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTR)	Precursor to skin cancer/non-melanoma skin cancer	Phase II started October 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun	Phase II approved June 2008
Phototoxicity associated with Photodynamic Therapy (PDT)	Photosensitivity following cancer treatment	Phase II started September 2008

# Analyst Reports And Media Coverage

## Analyst Reports

09/09/08	RRS Capital Strategies Services	update (German only)
29/08/08	ABN AMRO	update
11/06/08	ABN AMRO	update
21/04/08	Intersuisse	update
14/03/08	ABN AMRO	update
11/02/08	Louis Capital	update
31/01/08	ABN AMRO	update
20/11/07	RRS Capital Strategies Services	initiation of coverage
01/11/07	ABN AMRO	update
03/09/07	Intersuisse	update
29/08/07	ABN AMRO	update
02/08/07	ABN AMRO	initiation of coverage

## Clinuvel In The Media

12/06/08	BioTechnology News	Ethics approval for sun drug in sunny Manchester
23/04/08	Business Spectator	Clinuvel skin treatment dosages safe
18/04/08	MoneyTV (Germany)	MoneyTV - Interview with Dr. Philippe Wolgen
17/04/08	Euro am Sonntag (Germany)	Clinuvel steuert 2009 Zulassung für Hautpräparat
08/04/08	BioSpectrum - Asia Edition	EMA grants two orphan drug designations
17/03/08	TradeCentre Börsenbrief (Germany)	TradeCentre Ticker
14/03/08	Bioshares	Clinuvel Pharmaceuticals Successfully Changes Course With Regulators
13/03/08	The Australian	Biotech corner
13/03/08	Herald Sun	Drug shines on a range of problems
09/03/08	Cash Daily (Switzerland)	Web TV
01/03/08	Vogue (Germany)	Sonnige Aussichten
08/02/08	The Australian	New drug may lead to a safer golden glow
06/02/08	The Australian	No magic bullet for biotech aspirants
17/12/07	MXNews	I've got you under my skin
06/11/07	FDANews	Clinuvel Starts Skin Cancer Trials
02/11/07	Bioshares	Clinuvel: "An excellent buying opportunity."
02/11/07	Pharmaceutical Business Review	Clinuvel initiates Phase II skin cancer trials
01/11/07	Herald Sun	Tan pill hope for cancer fight

# Financials' Contents

Corporate Governance Statement	18
Director's Report (including Remuneration Report)	23
Consolidated Income Statements	35
Consolidated Balance Sheets	36
Consolidated Cash Flow Statement	37
Consolidated Statement Of Changes In Equity	38
Notes To The Financial Statements	39

# Corporate Governance Statement

## Overview

Corporate governance is the system by which the company is directed and managed. It is the framework within which:

- the Clinuvel Pharmaceuticals Ltd Board of Directors is accountable to shareholders for the performance of the company;
- the company's strategic direction is set;
- the risks of business are identified and managed;
- Clinuvel Pharmaceuticals Ltd's values and behaviour underpin the way it does business.

This statement outlines the main corporate governance principles and practices of Clinuvel Pharmaceuticals Ltd and is organised under headings based on the Australian Stock Exchange Corporate Governance Council's (ASXCGC) Revised Corporate Governance Principles and Recommendations, dated 2 August 2007. The company's charters and policies were comprehensively reviewed and updated in April 2005.

Charters and policies referred to are available on Clinuvel Pharmaceuticals Ltd's internet site ([www.clinuvel.com](http://www.clinuvel.com)).

The Board is accountable to shareholders for the performance of Clinuvel Pharmaceuticals Ltd.

Clinuvel Pharmaceuticals Ltd's shareholders appoint the company's Directors and hold them accountable for the performance of the company.

## **The Board prescribes the respective roles and responsibilities of Board and management (ASXCGC principle 1)**

The Board strives to create shareholder value and ensure that shareholders' funds are prudently safeguarded. The Board's functions are summarised in the Board Charter.

The Board delegates to the Managing Director the authority to manage the company and its businesses within levels of authority specified by the Board from time to time.

The responsibilities and terms of employment, including termination entitlements, for the Managing Director and senior Executives are set out in a formal letter of appointment.

Letters of employment are also prepared for Non-Executive Directors, covering duties, time commitments, induction and the corporate governance framework described on the company's internet site.

At a minimum, the performances of each senior Executive is appraised by the Managing Director annually against agreed targets, set either upon appointment or at the time of prior performance evaluation. Performance targets for senior Executives are reviewed by the Remuneration and Nomination Committee.

For the reporting period, the performances of the company's senior Executives were evaluated in accordance to the above.

## **Clinuvel Pharmaceuticals Ltd has a Board of effective composition, size and commitment to discharge its responsibilities and duties (ASXCGC principle 2)**

The Clinuvel Pharmaceuticals Ltd Board Charter prescribes the structure of the Board and its committees, the framework for independence and some obligations of Directors.

## **Size and composition of the Board**

The Board comprises four Non-Executive Directors and two Executive Directors – the Managing Director and the Chief Scientific Officer. Information about Directors, including their skills, experience, expertise and length of service can be found in pages 23 and 24.

The Board keeps under review the balance of skills and experience of its members, their independence and access to advice and information.

## **Directors' independence and dealing with conflict of interest**

Clinuvel Pharmaceuticals Ltd has four Non-Executive Directors (including the Chair) considered independent of the company and its management, having no business or other relationships that could materially compromise their autonomy as a Director (Dr. Aston, Mr. McLiesh, Mrs. Shanahan and Mr. Wood). The Board's framework for determining Director independence and the company's materiality thresholds is included in the Board Charter. Mrs. Shanahan is a Director of a professional adviser not considered material to the company according to its materiality thresholds. The impact of any past or present relationship with the company on a Director's ability to exercise independent judgment is carefully assessed.

The Board currently does not have a majority of independent Non-Executive Directors on the Board, but an equal number of independent and non-independent Directors. Due to the company size and developing status it would be considered detrimental to shareholders interests to construct a Board to satisfy this requirement at additional cost and/or ignoring the skill and expertise of Directors with who have made substantial contributions to the business. Accordingly, it considers its current Board size and composition to be appropriate under current circumstances. In addition, it is expected that all Directors will bring their independent views and judgment to the Board.

If a potential conflict of interest arises, the Director concerned does not receive the relevant Board papers and leaves the Board meeting while the matter is considered. Directors must advise the Board immediately of any interests that could potentially conflict with those of Clinuvel Pharmaceuticals Ltd.

Directors may obtain independent professional advice at Clinuvel Pharmaceuticals Ltd's expense on matters arising in the course of their Board and committee duties, after obtaining the Chair's approval. The Board Charter requires all Directors to be provided with a copy of such advice and to be notified if the Chair's approval is withheld.

## **Remuneration and Nomination Committee - Nomination**

To increase its effectiveness, the Board has a Remuneration and Nomination Committee. The Remuneration and Nomination Committee comprises at least three Directors (two voting and one non-voting) and is chaired by Mr. McLiesh. The Managing Director attends Remuneration and Nomination Committee meetings by invitation. He is not present if this could

compromise the objectivity of proceedings. The membership and number of meetings held, along with each Director's attendance record last year, is shown on page 24. A committee charter can be found on the company's website.

The Remuneration and Nomination Committee makes recommendations to the Board on the appointment of new Directors and criteria for new appointees, focusing on the particular skills and experience most appropriate to the company's business and objectives.

The company aims to have on its Board individuals with sound commercial judgment and inquiring minds, able to work cohesively with other Directors. Clinuvel Pharmaceuticals Ltd seeks a combination of Executives experienced in finance, the law and, ideally, the pharmaceutical industry in which Clinuvel Pharmaceuticals Ltd participates.

The reputation and ethical standards of appointees must be beyond question. Prospective Directors confirm that they will have sufficient time to meet their obligations and that they will keep the company informed of their other commitments.

Non-Executive Directors are subject to re-election by rotation at least every three years, under the company's constitution. Newly appointed Directors must seek re-election at the first general meeting of shareholders following their appointment.

## **The work of Directors**

In addition to attending Board and committee meetings, Non-Executive Directors allocate time for strategy and budget sessions and preparation for meetings.

The Chair commits additional time and meets regularly with the Managing Director to review and business and strategic issues and to agree Board meeting agendas, over and above his Executive duties.

The Board strives to ensure that Directors and key Executives have the knowledge and information to operate effectively. The performance of the Board is regularly reviewed.

## **Performance review**

The Remuneration and Nomination Committee regularly reviews the composition and performance of the Board and its committees. The process to evaluate the Board and the company's key Executives can be found in the Remuneration and Nomination Committee charter and



section 1 of the Corporate Governance Protocol on the Clinuvel website.

During the year a performance review of the Board and committees was made by the Remuneration and Nomination Committee in accordance with the process disclosed in the Committee Charter.

#### Access to information

Directors receive a comprehensive performance report from the Managing Director each Board meeting and have unrestricted access to company records and information.

All Directors have direct access to the Company Secretary who is accountable to the Managing Director and, through the Chair, the Board on all corporate governance matters.

#### **Clinuvel Pharmaceuticals Ltd actively promotes ethical and responsible decision making (ASXCGC principle 3)**

Ethical behaviour is required of Directors, Executives and all other employees.

#### Code of business conduct and ethics

The Board has endorsed a Code of Business Conduct and Ethics (found in the Corporate Governance Protocol on the company's website) that formalises the long standing obligation of all Clinuvel Pharmaceuticals Ltd people including Directors to behave ethically, act within the law, avoid conflicts of interest and act honestly in all business activities. Clinuvel Pharmaceuticals Ltd's Code of Business Conduct and Ethics reinforces the company's commitment to giving proper regard to the interests of people and organisations dealing with the company. Each Clinuvel Pharmaceuticals Ltd person is required to respect and abide by the company's obligations to fellow employees, shareholders, customers, suppliers and communities in which we operate.

#### Trading in shares

Directors' shareholdings at 30 June 2008 are shown on pages 23 and 24. The company has a strict share trading policy in place, details of which are included in the Corporate Governance Policy available on the company's internet site. Directors and employees may only buy or sell Clinuvel Pharmaceuticals Ltd shares during specified periods. Also, they are prohibited from buying or selling Clinuvel Pharmaceuticals Ltd shares at any time if they are aware of any price sensitive

information that has not been made public. All Clinuvel Pharmaceuticals Ltd share dealings by Directors are promptly notified to ASX.

#### **Clinuvel Pharmaceuticals Ltd has a structure to independently verify and safeguard the integrity of the company's financial reporting (ASXCGC principle 4)**

Clinuvel Pharmaceuticals Ltd's governance structure is designed to ensure that risks of conducting business are properly managed.

#### Audit and Risk Committee

To increase its effectiveness, the Board has an Audit and Risk Committee. The Audit and Risk Committee comprises at least three Directors (two voting and one non-voting) and is chaired by Dr. Aston who is a voting, non-independent and Non-Executive Director. The remaining voting committee member is independent and Non-Executive. The ASXCGC revised Corporate Governance Principles and Recommendations requires audit committees to be chaired by an independent Director. While the Board has regard to this requirement, it considers the skills and experience of Dr. Aston to best serve this position, taking into account current Board composition. It is expected each committee member will bring their independent view and judgment to Committee proceedings and put aside any conflicts, business or other relationship that could materially interfere with – or could reasonably be perceived to interfere with – the exercise of their unfettered and independent judgement.

The Managing Director attends Audit and Risk Committee meetings by invitation. He is not present if this could compromise the objectivity of proceedings. The membership and number of meetings held, along with each Director's attendance record last year, is shown on page 24. A committee charter can be found on the company's website.

The committee advises the Board on all aspects of audit, the adequacy of accounting and risk management procedures, systems, controls and financial reporting.

Specific responsibilities include advising the Board on the appointment of external auditors (following the procedure in the committee's charter), the yearly audit plan, and the yearly and half yearly financial reports.

The external audit firm partner in charge of the Clinuvel Pharmaceuticals Ltd audit attends committee meetings by invitation. The committee seeks to ensure the independence of the external auditor. Non-audit services are performed by other firms. The committee's charter

requires that individuals playing a significant role in the Clinuvel Pharmaceuticals Ltd audit be rotated every five years. The auditor annually confirms its independence within the meaning of applicable legislation and professional standards.

**Clinuvel Pharmaceuticals Ltd promotes timely and balanced disclosure of all material matters concerning the company (ASXCGC principle 5)**

**Continuous disclosure**

Clinuvel Pharmaceuticals Ltd has a practice of providing relevant and timely information to shareholders, supported by its share market disclosure policy (located in the Corporate Governance Protocol on the company's website) which details comprehensive procedures to ensure compliance with all legal obligations. The policy limits external briefings in the periods between the end of a financial year or half year and the release to the Australian Stock Exchange (ASX) of the relevant results. The Managing Director is responsible for communications with ASX.

Clinuvel Pharmaceuticals Ltd provides a review of operations and a financial review in this annual report. All announcements to the ASX are made available on the company's internet site.

**Clinuvel Pharmaceuticals Ltd respects the rights of shareholders and facilitates the effective exercise of those rights (ASXCGC principle 6)**

Clinuvel Pharmaceuticals Ltd strives to communicate effectively with shareholders about the company's performance, presenting the Annual Report and other corporate information in clear language, supported where appropriate by descriptive graphs, tables and medical glossaries. Where practicable, the company uses the latest widely available electronic technology to communicate openly and continually with shareholders – and the stock market in general. Announcements to ASX, significant briefings, notices of meetings, annual reports and speeches at Annual General Meetings are promptly posted on the company's internet site and emailed to shareholders and other interested parties. Proxies can be lodged electronically for the Annual General Meeting. Also, the external audit firm partner in charge of the Clinuvel Pharmaceuticals Ltd audit is available to answer shareholder questions at the company's Annual General Meeting.

**Clinuvel Pharmaceuticals Ltd has a sound system of risk oversight and management and internal control (ASXCGC principle 7)**

Clinuvel Pharmaceuticals Ltd identifies the risks facing its business, assesses the balance of risks and rewards to deliver shareholder value. The Directors seek to minimize the impact of risk factors commensurate with the industry sector in which it operates. The risk framework comprises:

**a) Business risks**

The Board regularly reviews Clinuvel Pharmaceuticals Ltd's businesses to identify and quantify business risks. Risk management is a key element of Clinuvel Pharmaceuticals Ltd's strategic planning, decision making and execution of strategies. The Group's business exposes it to potential risks which are inherent in the R&D, pre-clinical studies, clinical trials, manufacturing, marketing and use of human therapeutic products.

**b) Financial risks**

The Board has approved principles and policies to manage financial risks of exposures to foreign currencies, and interest rates. Clinuvel Pharmaceuticals Ltd's policies prohibit speculative transactions. The policies specify who may authorise transactions and segregates duties of those carrying them out. The company requires access to additional funding periodically to fund development programs. If the company fails to obtain such funding, it may need to delay or scale back the development and commercialization of its products or R&D programs. The funds that the company may need will be determined by numerous factors, some of which are beyond the company's control. Additionally, funds may be necessary due to a number of factors including the following:

- progress of research activities;
- the number and scope of research programs;
- the progress of pre-clinical and clinical development activities;
- the company's ability to establish and maintain current and new R&D and licensing arrangements;
- the company's ability to achieve (or delays in achieving the sales giving rise to) royalty and milestone payments under licensing arrangements;
- the costs involved in enforcing patent claims and other intellectual property rights; and

- the cost requirements and timing of regulatory approvals.

If the company is unable to obtain additional funds on satisfactory terms, it may be required to cease or reduce its operating activities. If the company raises additional funds by selling additional shares, the ownership interests of existing shareholders may be materially diluted. There is no assurance that additional funding will be available to Clinuvel Pharmaceuticals Ltd in the future or be secured on acceptable terms.

- Financial integrity risks  
Management has put into practice policies, procedures and controls to ensure the integrity of its accounting and financial reporting to stakeholders.

The Board oversees and reviews the effectiveness of the risk management systems implemented by management. The Board has assigned responsibility to:

- Audit and Risk Committee  
Reviews and reports to the Board in relation to the company's financial reporting, internal control structure, risk management systems, and the external audit functions.
- Management  
Manages and reports to the Board on business and financial risks and compliance with other legal obligations.

An independent external audit is performed on the annual financial report of Clinuvel Pharmaceuticals Ltd.

### **Risk management & Financial Report accountability**

As part of the process of approving the financial statements, the Managing Director provides statements in writing to the Board on the quality and effectiveness of the company's risk management and internal compliance and control systems.

Clinuvel Pharmaceuticals Ltd's process for approval of financial statements has a long standing requirement that authorisations be given by various levels of management. Clinuvel Pharmaceuticals Ltd's Managing Director and Chief Financial Officer are required to state to the Board, in writing, that the company's financial report states a true and fair view, in all material respects, of the company's financial condition and operational results and are in accordance with relevant accounting standards (of which they have done for the current reporting period).

**Clinuvel Pharmaceuticals Ltd ensures that the level and composition of remuneration is sufficient and reasonable and that its relationship to corporate and individual performance is defined (ASXCGC principle 8)**

### **Remuneration and Nomination Committee - Remuneration**

As previously stated, Clinuvel Pharmaceuticals Ltd has appointed a Remuneration and Nomination Committee, comprising two voting, independent Non-Executive Directors, chaired by Mr. McLiesh. The Managing Director attends Remuneration and Nomination Committee meetings by invitation. He is not present if this could compromise the objectivity of proceedings. The membership and number of meetings held, along with each Director's attendance record last year, is shown on page 24. A committee charter can be found on the company's website.

Together with an overview of people issues, particularly succession and development planning, the Committee advises the Board on remuneration policies and practices, evaluates the performance of the Managing Director against pre-agreed goals and makes recommendations to the Board on remuneration for the Managing Director and managers reporting to him. The Committee considers independent advice on policies and practices to attract, motivate, reward and retain strong performers.

The Committee also considers the Board's size and composition, criteria for membership, candidates to fill vacancies and the terms and conditions of their appointment.

Clinuvel Pharmaceuticals Ltd's policy is to reward Executive Directors and senior Executives with a combination of fixed remuneration and short and long-term incentives structured to drive improvements in shareholder value. Employees cannot approve their own remuneration, nor that of their direct subordinates.

Non-Executive Directors are remunerated by way of fees, and unlisted options (conditional upon shareholder approval). The Board considers the granting of options to Non-Executive Directors as appropriate policy and reflects their significantly greater roles in the management and business of the company. All perform Executive functions to varying degrees and as a result the company is able to conduct its business with a far smaller senior management team than its peers. They receive no other incentive payments

# Directors' Report

The Directors of the Board present their report on the company and its controlled entity for the financial year ended 30 June 2008 and the independent Audit Report thereon.

## Directors

The names of Directors in office at any time during or since the end of the year are set out below.

- Dr. H.P.K. Agersborg (Deputy Chair, Chief Scientific Officer)
- Mr. S.R. McLiesh (Non-Executive)
- Dr. R. Aston (Executive Chair to 6 December 2007, Non-Executive thereafter)
- Dr. P.J. Wolgen (Managing Director, Chief Executive Officer)
- Mrs. B.M. Shanahan (Non-Executive to 6 December 2007, Non-Executive Chair thereafter)
- Mr. L.J. Wood (Non-Executive, joined company 11 July 2008)

Directors have been in office since the start of the financial year to the date of this report unless otherwise stated.

## Information On Directors

### Dr. Roger Aston (joined Board 2005)

Executive Chair to 6 December 2007, Non-Executive Director thereafter  
Chairman of the Audit and Risk Committee  
Qualifications: BSc (Hons) PhD  
Shares in Clinuvel: 108,224  
Options over shares in Clinuvel: 2,450,000

While enjoying over 20 years experience in the sector, in the past 3 years Dr. Aston served as director of pSivida Ltd (ASX:PVA; 2000-2005 and 2006-2007), and Avantogen Limited (ASX:ACU; 2001-2005). Since 2008, Dr. Aston has been appointed director of Ascent Pharmahealth Limited (ASX:APH) and since 2007

managing director of Halcygen Pharmaceuticals Ltd (ASX:HGN). Dr. Aston is a member of the Biological Committee of the Industry Research and Development Board.

### Dr. Philippe J. Wolgen (joined Board 2005)

Managing Director and Chief Executive Officer since December 2005

Non-voting member of the Audit and Risk committee and the Remuneration and Nomination committee

Qualifications: MBA, MD

Shares in Clinuvel: 95,000

Options over shares in Clinuvel: 9,250,000

Trained as cranio-facial surgeon, Dr. Wolgen has been involved in bringing medical devices to market. He holds several awards in medical sciences and in business administration. He founded a not-for profit organization to promote the exchange of academic and surgical skills between Indonesia and the Netherlands. He was appointed managing director of medical centres in England and Israel. He has vast experience in licensing generic pharmaceuticals for the EU markets. He holds a background in European capital markets, international finance and life sciences equity research. No other directorships.

### Mrs. Brenda M. Shanahan (joined Board 2007)

Non-Executive Director to 6 December 2007, Non-Executive Chair thereafter

Member of the Remuneration and Nomination Committee

Qualifications: BComm, FAICD, ASIA

Shares in Clinuvel: 420,071

Options over shares in Clinuvel: 850,000

Chair of both St Vincent's Health and St Vincent's Medical Research Institute in Melbourne, Mrs Shanahan has a background in finance in Australian and overseas equity markets. In the past 3 years Mrs. Shanahan was a director of Challenger Financial Services Group Ltd (ASX:CGF; 2003-2007), and from 2007 as current Chair

of Challenger Listed Investments Limited. Mrs. Shanahan is also non-executive Director of JM Financial Group Ltd.

#### **Dr. Helmer P.K. Agersborg (joined Board 2001)**

Executive Director, Chief Scientific Officer since December 2005

Qualifications: BSc PhD

Shares in Clinuvel: 921,105

Options over shares in Clinuvel: 2,000,000

Joining the Board of Clinuvel Pharmaceuticals soon after inception, Dr. Agersborg has 45 years experience in the pharmaceutical industry and has been involved in the approval of 50 new drug applications in the USA. Former President of Wyeth Ayerst Research. Dr. Agersborg is a current director of Virxsys Corporation.

#### **Mr. Stanley R. McLiesh (joined Board 2002)**

Non-Executive Director

Chair of the Remuneration and Nomination Committee, member of the Audit and Risk Committee

Qualifications: BEd

Shares in Clinuvel: 760,000

Options over shares in Clinuvel: 650,000

Formerly General Manager, Pharmaceuticals at CSL Limited, Mr. McLiesh was closely involved in the transition of CSL from government ownership to a successful listed company. No other Directorships.

#### **Mr. Lawrence John (Jack) Wood (joined Board 2008)**

Non-Executive Director (joined company 11 July 2008)

Qualifications: BComm

Shares in Clinuvel: 0

Options over shares in Clinuvel: 0

Mr Wood has 45 years experience in the health care industry in Australia, North America and Europe. He has held various Executive positions with CSL Limited (1992-2000). Mr Wood has held Directorships with QLT Inc since 2001, a biopharmaceutical company listed in the USA and Canada.

#### **Information On Company Secretary**

##### **Mr. Darren M. Keamy**

Company Secretary, Chief Financial Officer

Qualifications: BComm, CPA

Certified Practicing Accountant, joined Clinuvel Pharmaceuticals Limited November 2005 and became Chief Financial Officer of the Company in 2006.

#### **Meeting Of Directors**

The following table summarises the number of and attendance at all meetings of Directors during the financial year.

Director	Board		Audit & Risk Committee		Remuneration & Nomination Committee	
	A	B	A	B	A	B
Dr. R. Aston	*7	*7	2	2	-	-
Dr. H.P.K. Agersborg	7	6	2	2	-	-
Mrs. B.M. Shanahan	**7	**7	-	-	4	4
Mr. S.R. McLiesh	7	7	-	-	4	4
Dr. P.J. Wolgen	7	7	2	2	2	2

Column A indicates the number of meetings held during the period the Director was a member of the Board and/or Board Committee.

Column B indicates the number of meetings attended during the period the Director was a member of the Board and/or Board Committee

\*4 meetings as Chair

\*\* 3 meetings as Chair

#### **Principal Activities**

The principal activities of the consolidated entity during the financial year were to develop its leading drug candidate afamelanotide (CUV1647) for a range of UV and light related skin disorders. Clinuvel's pioneering

work aims at preventing the symptoms of skin diseases related to the exposure to harmful UV radiation. There was no significant change in the nature of activities during the financial year.



## Operating Results

The consolidated loss of the consolidated entity after providing for income tax amounted to \$14,655,791 (2007 – loss of \$9,176,123).

## Dividends Paid Or Recommended

No dividends were paid or declared during the financial year.

## Review Of Operations

A review of operations is set out in the Managing Director's Report, commencing on page 4 of this Annual Report.

## Highlights For The Year

### Financial

Expenditures on the consolidated entity's research and development program for afamelanotide totalled \$8,416,207 (2007: \$4,469,391) that were non-capital in nature and included payments for drug supply, development of delivery formulations (principally the sustained release implant) and clinical trials conducted in Australia and Europe. Expensing of the peptide is deferred until used in the clinical trial program, these costs are retained in the balance sheet and amounted to \$1,390,730 (2007: \$1,780,581).

At the beginning of the year the consolidated entity's cash resources totalled \$33,841,849. Investments in income securities totalled \$25,048,387. At the end of the year the consolidated entity's cash resources totalled \$25,752,193 and investments in income securities totalled \$25,048,387.

Basic earnings per share was -\$0.048 per share (2007: -\$0.037).

A full commentary of the results is attached.

## Significant Changes In The State Of Affairs

The Directors are not aware of any matter or circumstance not otherwise dealt with in this report that has significantly or may significantly affect the operations of Clinuvel Pharmaceuticals Ltd.

## Significant Events After The Balance Date

There has not been any matters, other than reference to the financial statements that has arisen since the end of the financial year, that has affected or could significantly affect, the operations of the consolidated entity, except that:

On 29 July 2008 Clinuvel announced that its photoprotective drug afamelanotide (CUV1647) has been granted orphan drug designation by the US Food and Drug Administration (FDA) for the management of erythropoietic porphyrias.

## Likely Developments And Expected Results

Information on the expected results of operations and research and development has not been included in this report because the Directors believe it would be unreasonable and speculative to do so.

## Environmental Regulation And Performance

The consolidated entity's operations are not regulated by any significant environmental regulation under a law of the Commonwealth or of a State or Territory.

## Indemnification And Insurance Of Directors And Officers

During or since the end of the financial year the company has given an indemnity or entered an agreement to indemnify, or paid or agreed to pay insurance premiums as follows.

The company has paid premiums to insure each of the Directors against liabilities for costs and expenses incurred by them in defending any legal proceedings arising of their conduct while acting in the capacity of Director of the company, other than conduct involving wilful breach of duty in relation to the company.

## Directors' Benefits and Interest In Contracts

Since the end of the previous financial year no Director has received or become entitled to receive a benefit (other than a benefit included in the total amount of emoluments received or due and receivable by Directors shown in the financial statements and the remuneration report), because of a contract that the Director or a firm of which the Director is a member, or an entity in which the Director has a substantial interest has made with Clinuvel Pharmaceuticals Limited or a controlled entity.

Further information on these contracts is included in Note 20 to the financial statements.



# Remuneration Report

## Principles Used To Determine The Nature And Amount Of Remuneration

The Board has overseen a reward framework:

- to ensure the most qualified and experienced Directors and Executives are attracted and retained, both domestically and internationally, at internationally competitive rates;
- to align management interest with that of the company's shareholders;
- to support the achievement of the company's strategic objectives.

The reward framework provides a mix of fixed and variable pay, structured to incentivize over the long-term and short-term.

- Short-term (generally cash payment in the form of performance-based bonuses at a fixed amount or as a percentage of base salary).
- Long-term (generally based upon the issue of options to acquire shares in the Company. Options are currently issued under the company's Share Option Plan approved by shareholders 25 January 2007 and the vesting conditions can be either time and/or performance milestone-based).

The Board has provided a mandate to the Remuneration and Nomination Committee to provide advice on salaries and fees, short and long-term incentives and employment terms and conditions for Directors and Executives. The Remuneration and Nomination Committee obtains independent data to assess the appropriateness of remuneration packages, given trends in comparative companies.

The Committee reviews the remuneration and incentive levels for Directors and specified Executives annually.

The Corporate Governance Statement provides further information on the role of the Committee.

## Non-Executive remuneration

Under the company's Constitution, the maximum aggregate remuneration available for division among the Non-Executive Directors is to be determined by the shareholders in a General Meeting. The maximum aggregate is currently fixed at \$400,000. This amount (or some part of it) is to be divided among the Non-Executive Directors as determined by the Board. Non-Executive Directors' base fees are presently \$50,000 per annum. The Chair receives \$80,000 per annum when in a Non-Executive capacity. The Chair's role is for a 12 month term, whereby the Company reserves the right to extend the term for another 12 month period. The Heads of the Audit and the Remuneration and Nomination Committees receive \$65,000 per annum when in a Non-Executive capacity. Director's fees are considered appropriate given their skills, qualifications and experience comparative to the external market.

Non-Executive Directors are also issued options under the company's Share Option Plan. Non-Executive Directors are issued options to align their interests with that of shareholders and to reflect their greater role in the management of the company comparative to peer companies (and reflected in a smaller management team). The number of options and nature of vesting is determined upon the Director's appointment and is subject to shareholder approval.

## Executive remuneration

Remuneration packages for Executives include:

- Base pay and benefits (including statutory benefits);
- Long-term incentive payments through the achievement of pre-specified performance-based targets;
- Participation in Clinuvel's Employee Share Option Plan.

Base pay, including superannuation, is reviewed annually by the Remuneration and Nomination Committee to ensure the Executive's pay is competitive in international markets. There are no guaranteed base pay increases

in any Executives' contracts. Health insurance benefits and living away from home allowances are offered to Executives under specific circumstances.

The CEO and CSO have their own individual short-term incentive component to their Executive remuneration. Appropriate targets are set by the Remuneration and Nomination Committee. The targets can relate to either the clinical and regulatory development program or to corporate and associated activities and are evaluated for achievement, reviewed and reset (if required) annually. Payment of short-term incentives is made in the financial year following the year of achievement. The methods used by the Remuneration and Nomination Committee to assess Board performance is disclosed in the Corporate Governance Protocol. The remaining Executives, excluding the Head of Corporate Development who has his own short-term incentive scheme as part of his remuneration package, share in a team-based incentive pool along with the Company's employees. These incentives are paid out each quarter and are directly linked to the successful progression of the clinical development program.

The long-term incentives are provided to Executive Directors and certain employees via the Clinuvel Employee Share Option Plan. See page 31 for further information.

### Details Of Remuneration

The key management personnel of Clinuvel Pharmaceuticals Ltd are those Executives Directors disclosed in pages 23 and 24 of this Annual Report and the following specified Executives:

#### Dr. D.J. Wright

Vice President, Scientific Affairs

#### Mr. D.M. Keamy

Chief Financial Officer and Company Secretary

#### Mr. C.H. Mackie

Head of Corporate Development (commenced employment 15 August 2007)

### Remuneration Of The Directors Of The Company For The Year Ended 30 June 2008

Director	Short-term employment benefits				Post employment benefits	Share based payments	Total
	Salary	Cash Bonus	Allowance	Consult Fees	Superannuation Contributions	Options	
	\$	\$	\$	\$	\$	\$	\$
Dr. H.P.K. Agersborg	275,159	56,136	-	-	-	87,177	418,472
Mr. S.R. McLiesh	59,633	-	-	-	5,367	28,627	93,627
Dr. R. Aston*	29,816	-	-	50,000	2,684	100,648	183,148
Dr. P.J. Wolgen	434,872	150,000	114,727	-	13,092	323,539	1,036,229
Mrs. B.M. Shanahan	60,762	-	-	-	5,469	37,294	103,524
<b>Total</b>	<b>860,242</b>	<b>206,136</b>	<b>114,727</b>	<b>50,000</b>	<b>26,611</b>	<b>577,285</b>	<b>1,835,000</b>

\* Dr. Aston provided Executive consultancy services to the company in his capacity as Executive Chair until 6 December 2007. In doing so, no Non-Executive Director fees were paid in addition to the consultancy service payments during this period.

**Remuneration of the specified Executives of the company for the year ended 30 June 2008**

	Short-term employment benefits			Post-employment benefits		Share based payments	Total
	Salary	Cash Bonus	Allowance	Superannuation Contributions	Other	Options	
	\$	\$	\$	\$	\$	\$	\$
Dr. D.J. Wright	149,796	-	-	12,926	-	73,929	236,651
Mr. D.M. Keamy	143,137	-	-	12,740	-	33,718	189,594
Mr. C.H. Mackie	169,603	-	-	11,730	-	-	181,333
<b>Total</b>	<b>462,535</b>	<b>-</b>	<b>-</b>	<b>37,396</b>	<b>-</b>	<b>107,647</b>	<b>607,578</b>

**Remuneration of the Directors of the company for the year ended 30 June 2007**

	Short-term employment benefits			Post-employment benefits		Share based payments	Total
	Salary	Cash Bonus	Allowance	Consult Fees	Superannuation Contributions	Options	
	\$	\$	\$	\$	\$	\$	\$
Dr. W.A. Millen	19,113	-	-	100,000	1,720	-	120,833
Dr. H.P.K. Agersborg	298,129	-	-	-	-	47,590	345,719
Dr. T.E. Winters	75,000	50,325	-	33,333	-	24,398	183,056
Mr. S.R. McLiesh	45,872	-	-	-	4,128	19,874	69,874
Dr. R. Aston*	-	-	-	165,404	-	90,147	255,551
Dr. P.J. Wolgen	383,333	252,391	49,410	-	12,686	211,925	909,745
Mrs. B.M. Shanahan	18,349	-	-	-	1,651	14,367	34,367
<b>Total</b>	<b>839,796</b>	<b>302,716</b>	<b>49,410</b>	<b>298,737</b>	<b>20,185</b>	<b>408,301</b>	<b>1,919,145</b>

\*Dr. Aston provides Executive consultancy services to the company in his capacity as Executive Chair. In doing so he forgoes Non-Executive Director fees for 2006/07.

**Remuneration of the specified Executives of the company for the year ended 30 June 2007**

	Short-term employment benefits			Post-employment benefits		Share based payments	Total
	Salary	Cash Bonus	Allowance	Superannuation Contributions	Other	Options	
	\$	\$	\$	\$	\$	\$	\$
Dr. D.J. Wright	137,151	4,180	-	12,198	-	85,364	238,893
Mr. D.M. Keamy	116,415	15,000	-	10,431	-	14,710	156,555
<b>Total</b>	<b>253,566</b>	<b>19,180</b>	<b>-</b>	<b>22,629</b>	<b>-</b>	<b>100,074</b>	<b>395,448</b>

### The relative proportions of remuneration between fixed and based on performance for the year ending 30 June 2008

	2008		2007	
	Fixed Remuneration	Performance Based	Fixed Remuneration	Performance Based
Dr. P.J. Wolgen	73%	27%	66%	34%
Dr. H.P.K. Agersborg	76%	24%	95%	5%
Dr. D.J. Wright	92%	8%	92%	8%
Mr. D.M. Keamy	95%	5%	88%	12%
Mr. C.H. Mackie	100%	0%	N/A	N/A

### Service Agreements

On appointment to the Board, all Non-Executive Directors enter into a service agreement with the company in the form of a letter of appointment. The letter summarises the Board's policies, the Director's responsibilities and compensation for holding office.

Remuneration and other terms of employment for the Chief Executive Officer and Chief Scientific Officer are formalised by service agreements determined by the Remuneration and Nomination Committee. The agreements provide for base salary, bonuses, other benefits and participation, when eligible, in the Clinuvel Employee Share Option Plan. The Managing Director, in consultation with the Remuneration and Nomination Committee, oversees the service agreements entered into with company Executives, providing for base salary, bonuses, other benefits and participation, when eligible, in the Clinuvel Employee Share Option Plan.

The details of the service agreements to Executive Directors and key management personnel are:

- Dr. Wolgen's (Managing Director and Chief Executive Officer) term of employment is 2 years from 19 May 2008 and his base salary inclusive of superannuation for the year to 30 June 2008 is \$447,964. Termination payment is set at 6 months of base salary provided the termination is not for a material breach of the agreement. Dr. Wolgen requires to provide 6 month's notice.
- Dr. Agersborg (Director & Chief Scientific Officer) is on a 12 month rolling contract and his base salary inclusive of superannuation for the year ending 30 June 2008 is \$275,159. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Dr. Agersborg does not require providing notice.

- Dr. Aston's (Executive Chair until 6 December 2007) management company, Newtonmore Biosciences Pty Ltd, was paid an Executive consultancy fee of \$8,333 per month, the length of term being 12 months which expired 31 December 2007.

- Dr. Wright's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2008 is \$162,722. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Dr. Wright requires providing 3 month's notice.

- Mr. Keamy's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2008 is \$155,877. Termination payments are set at 1 month of base salary provided the termination is not for a material breach of the agreement. Mr. Keamy requires providing 1 month's notice.

- Mr. Mackie's term of employment commenced 15 August 2007 and is on-going. His base salary inclusive of superannuation for the period from commencement of employment to 30 June 2008 is \$181,333. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Mr. Mackie requires providing 3 month's notice.

### Share-Based Remuneration

The consolidated entity has ownership based scheme for Directors, key management personnel and select consultants of the company and are designed to provide long-term incentives for Directors and Executives to deliver long-term shareholder value. Options issued prior to 25 January 2007 were issued in accordance with The Corporations Act. Options issued after this date fall under the Clinuvel Employee Share Option Plan, approved by shareholders at a shareholder meeting on 25 January 2007. All share options issued prior or after 25 January 2007 converts to one ordinary share of the consolidated entity. All options are issued for nil

consideration, there are no voting rights attached to the option and they can be exercised any time from the date of vesting to the date of expiry. They are non-transferable and not listed on the ASX. For those options issued prior to 25 January 2007 the exercise price is based on the weighted average price at which the company's shares were traded on the ASX during the week up to and including the date of grant. For those options issued after 25 January 2007 the exercise price is based on the weighted average price at which the company's shares were traded on the ASX 20 business days leading up to the date of grant, plus 10%.

The number of options granted is subject to approval by the Remuneration and Nomination Committee and by shareholders at General Meetings. Options currently issued have specific terms and conditions, from 12 month restriction periods for the number of options to vest, to monthly restriction periods over 48 months, and to the satisfaction of performance objectives set by the Directors of the consolidated entity.

#### Terms and conditions of each grant of options affecting remuneration in the current or future reporting periods

Entity	Number of Shares under Options	Exercise Price	Value per Option on Grant Date	Class	Grant Date	Vested & Exercisable Dates	Expiry Date
Clinuvel	300,000	\$0.87	\$0.53	Ordinary	19/04/2004	19/04/2005	18/04/2009
Clinuvel		\$0.87	\$0.57			19/04/2006	
Clinuvel		\$0.87	\$0.60			19/04/2007	
Clinuvel	1,500,000	\$0.34	\$0.17	Ordinary	31/10/2005	31/10/2006	01/11/2009
Clinuvel		\$0.34	\$0.19			31/10/2007	
Clinuvel		\$0.34	\$0.22			31/10/2008	
Clinuvel	500,000	\$0.75	\$0.46	Ordinary	01/03/2005	01/03/2006	28/02/2010
Clinuvel		\$0.75	\$0.54			01/03/2007	
Clinuvel		\$0.75	\$0.57			01/03/2008	
Clinuvel	1,500,000	\$0.50	\$0.01	Ordinary	23/02/2006	23/02/2007	03/03/2010
Clinuvel		\$0.50	\$0.01			24/08/2007	
Clinuvel		\$0.50	\$0.01			23/02/2008	
Clinuvel	15,660,000	\$0.86	\$0.25	Ordinary	09/02/2007	monthly over 48 periods	09/02/2012
Clinuvel		\$0.86	\$0.22			31/12/2007	
Clinuvel		\$0.86	\$0.23			09/02/2008	
Clinuvel		\$0.86	\$0.26			31/12/2009	
Clinuvel		\$0.86	\$0.24			09/02/2009	
Clinuvel	110,000	\$0.86	\$0.21	Ordinary	03/08/2007	31/12/2007	03/08/2012

No options were issued to Directors or key management personnel during 2007/08.

The Board is currently considering a new issue of options to:

(a) existing and new employees, and consultants, of the Company including its Australian, US and European operations; and

(b) existing and new directors, subject to shareholder approval.

It is anticipated that any new issue of options to directors would include a component which would vest only upon the achievement of milestones.

The Board recognises that the options granted under the company's Employee Share Option Plan approved by shareholders 25 January 2007 are unlikely to be exercised by the optionholder in the current market and are considering the proposal to make a new issue of options in order to provide a realistic long term incentive to directors, employees and select consultants.

The Board recognises that the purpose of issuing options is to provide a long term incentive within the Company's remuneration framework to link the achievement of performance benchmarks, encourage direct involvement and interest in the performance of the Company, and enable the acquisition of a long term equity interest by its directors, employees and select consultants.

#### Further Information – share-based compensation

	A	B	C	D
	% of Remuneration consisting of Options	Value at Grant Date	Value at Exercise Date	Value at Lapse Date
Dr. H.P.K. Agersborg	20.8%	-	-	8,600
Dr. R. Aston	55.0%	-	-	5,160
Mr. S.R. McLiesh	30.6%	-	-	3,440
Dr. P.J. Wolgen	31.2%	-	-	34,402
Mrs. B.M. Shanahan	36.0%	-	-	0
Dr. D.J. Wright	31.2%	-	-	3,440
Mr. D.M. Keamy	17.8%	-	-	1,720
Mr. C.H. Mackie	0.0%	-	-	0

A The percentage of the value of remuneration consisting of options, based on the value of the options expensed during the year.

B The value at grant date calculated in accordance with AASB 2 Share Based Payments of options granted during the year as part of remuneration.

C The value at exercise date of options that were granted as part of remuneration and were exercised during the year, being the intrinsic value of the options at that date.

D The value at lapse date of options that were granted as part of remuneration and that lapsed during the year because a vesting condition was not satisfied. The value is determined at the time of lapsing but assuming the condition was satisfied.

Options were priced using the Black Scholes Binominal option pricing model. The expected life used in the model is assumed to be the midpoint between the vesting date and exercise date. Expected volatility of each share option is based on the historical share price for the same length of time for the expected life of the options. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the option pricing model is assumed to be the zero coupon interest rate on valuation date.

#### Additional information on options issued to Directors and key management personnel

	Options Vested During the Year – 2008	Options Granted During the Year - 2008	Options Granted During the Year – 2007
Dr. H.P.K. Agersborg	750,000	-	2,500,000
Dr. R. Aston	500,000	-	2,000,000
Mr. S.R. McLiesh	125,000	-	850,000
Dr. P.J. Wolgen	3,375,000	-	9,000,000
Mrs. B.M. Shanahan	283,333	-	850,000
Dr. D.J. Wright	341,667	-	1,300,000
Mr. D.M. Keamy	125,000	-	800,000
Mr. C.H. Mackie	-	-	N/A



### Additional Information - Remuneration

For each cash bonus and option granted, the percentage of the available grant or bonus that was paid or vested in the financial year, and the percentage forfeited due to unmet milestones (including service length), is set out below. Bonuses are paid in the year following the period of performance.

#### Remuneration details of cash bonuses and options

	Bonus						Options	
	Paid	Forfeited	Year Granted	Vested	Forfeited	Year of Vesting	Minimum grant value yet to Vest(\$)	Maximum grant value yet to Vest (\$)
Dr. H.P.K. Agersborg	33%	67%	2006/07	50%	50%	2009/10	-	132,100
Dr. R. Aston	0%	0%	2005/06	100%	0%	2008/09	-	54,986
			2006/07	63%	37%	2009/10	-	105,680
Mr. S.R. McLiesh	0%	0%	2006/07	38%	62%	2009/10	-	52,840
Dr. P.J. Wolgen	75%	25%	2005/06	100%	0%	2008/09	-	54,986
			2006/07	67%	33%	2009/10	-	264,200
Mrs. B.M. Shanahan	0%	0%	2006/07	100%	0%	2009/10	-	68,383
Dr. D.J. Wright	0%	0%	2006/07	68%	32%	2008/09	-	41,912
						2009/10	-	98,905
						2010/11	-	33,571
Mr. D.M. Keamy	0%	0%	2006/07	56%	44%	2009/10	-	29,937
								59,324
								23,979
Mr. C.H. Mackie	0%	0%	-	0%	0%	-	-	-

The exercise price for those options granted in 2006/07 is \$0.86. The exercise price for those options granted to in 2005/06 to Dr. Aston is \$0.34 and to Dr. Wolgen is \$0.34 and \$0.50.

## Performance of Clinuvel Pharmaceuticals Ltd and Controlled Entities

The consolidated entity is solely dedicated to the research and development of unique and medically beneficial technology with the aim of future commercialization once testing and development is complete. It is anticipated the consolidated entity will not derive profit and pay a dividend until commercialization of the drug under research and development occurs. With very few peer competitors developing drugs in the field of photoprotection, shareholder interest is promoted through the company successfully completing regulatory

milestones and clinical trials. The table below shows the progress made in moving through the clinical pathway, reflecting the performance of the Executive team.

The remuneration and incentive framework, which has been put in place by the Board, has ensured the Executives are focussed on both maximising short-term operating performance and long-term strategic growth. This has been an important factor in the consolidated entity moving closer to commercialization of its drug under research and development.

Year ending 30 June 2005	Year ending 30 June 2006	Year ending 30 June 2007	Year ending 30 June 2008
Phase II Photoprotective effectiveness study commenced	Phase II Photoprotective effectiveness study completed	Phase II Study commenced & completed (EPP)	Phase II Study commenced (AK)
	Phase II Study commenced (PLE)	Phase II Study completed (PLE)	Phase II Study commenced (SU)
		Phase III Study commenced x 2 (EPP & PLE)	Orphan-drug designation (EPP)

## Shares Provided On Exercise Of Options

### Details of shares issued during the financial year as a result of exercise of options

Entity	Number of Shares Issued	Amount paid for shares	Class
Clinuvel Pharmaceuticals	500,000	\$0.16	Ordinary
Clinuvel Pharmaceuticals	500,000	\$0.29	Ordinary

These shares were issued to former Directors and former key management personnel no longer employed by the consolidated entity. No shares were provided upon exercise of options to Directors or key management personnel during the years ending 30 June 2008 and 30 June 2007.

## Shares Under Option

### Details of unissued shares or interests under options

Entity	Number of Shares under Options	Exercise Price	Class	Expiry Date
Clinuvel Pharmaceuticals	300,000	\$0.87	Ordinary	18/04/2009
Clinuvel Pharmaceuticals	1,500,000	\$0.34	Ordinary	01/11/2009
Clinuvel Pharmaceuticals	500,000	\$0.75	Ordinary	28/02/2010
Clinuvel Pharmaceuticals	1,500,000	\$0.50	Ordinary	31/03/2010
Clinuvel Pharmaceuticals	15,660,000	\$0.86	Ordinary	09/02/2012
Clinuvel Pharmaceuticals	110,000	\$0.86	Ordinary	03/08/2012

## Loans To Directors And Executives

No loans were granted to Directors or Executives for the years ending 30 June 2008 and 30 June 2007.

### Non-Audit Services

Grant Thornton did not provide services other than audit related for the years ending 30 June 2008 and 30 June 2007.

### Auditors' Independence Declaration

The auditor's independence declaration is included in the Financial Report.

### Proceedings On Behalf Of The Company

No person has applied for leave of Court to bring proceedings on behalf of the company or intervene in any proceedings to which the company is party for the purpose of taking responsibility on behalf of the company for all or any part of those proceedings.

The company was not party to any such proceedings during the year.

Signed in accordance with a resolution of the Board of Directors pursuant to s.298(2) of The Corporations Act 2001.



Dr. Philippe Wolgen MBA MD  
Director

Dated this 16<sup>th</sup> day of September, 2008

# Consolidated Income Statements For The Year Ended 30 June 2008

		Consolidated		Clinuvel Pharmaceuticals Ltd	
	Note	2008	2007	2008	2007
		\$	\$	\$	\$
Revenues	2	4,297,103	2,553,901	4,296,376	2,237,822
Total expenses	2	(18,952,894)	(11,730,024)	(18,941,444)	(11,410,952)
<b>Profit (Loss) before income tax expense</b>		<b>(14,655,791)</b>	<b>(9,176,123)</b>	<b>(14,645,068)</b>	<b>(9,173,130)</b>
Income tax expense (benefit)	3	-	-	-	-
<b>Profit (Loss) after income tax expense</b>		<b>(14,655,791)</b>	<b>(9,176,123)</b>	<b>(14,645,068)</b>	<b>(9,173,130)</b>
<b>Net Profit (Loss) for the year</b>		<b>(14,655,791)</b>	<b>(9,176,123)</b>	<b>(14,645,068)</b>	<b>(9,173,130)</b>
Basic earnings per share - cents per share	16	(4.8)	(3.7)		

The accompanying notes form part of these financial statements.

# Consolidated Balance Sheets As At 30 June 2008

		Consolidated		Clinuvel Pharmaceuticals Ltd	
	Note	2008	2007	2008	2007
		\$	\$	\$	\$
<b>Current Assets</b>					
Cash and cash equivalents	17(a)	25,752,193	33,841,849	25,569,158	33,685,891
Other Financial Assets	8	25,048,387	28,511,650	25,048,387	28,511,650
Receivables	4	616,136	241,493	616,136	239,621
Other	5	1,703,396	2,721,627	1,674,347	2,713,557
<b>Total Current Assets</b>		<b>53,120,112</b>	<b>65,316,619</b>	<b>52,908,028</b>	<b>65,150,719</b>
<b>Non Current Assets</b>					
Receivables	4	-	-	1,390,272	2,244,415
Property, plant and equipment	6	431,034	332,015	372,208	316,094
Intangible assets	7	1,419,612	2,176,111	45,999	55,199
Other financial assets	8	-	-	102,286	172
<b>Total Non Current Assets</b>		<b>1,850,646</b>	<b>2,508,126</b>	<b>1,910,765</b>	<b>2,615,880</b>
<b>Total Assets</b>		<b>54,970,758</b>	<b>67,824,745</b>	<b>54,818,793</b>	<b>67,766,599</b>
<b>Current Liabilities</b>					
Payables	10	2,968,356	2,315,298	2,896,556	2,262,079
Provisions	11	178,576	112,890	168,959	111,126
<b>Total Current Liabilities</b>		<b>3,146,932</b>	<b>2,428,188</b>	<b>3,065,515</b>	<b>2,373,205</b>
<b>Non Current Liabilities</b>					
Provisions	11	9,310	4,741	9,310	4,741
<b>Total Non Current Liabilities</b>		<b>9,310</b>	<b>4,741</b>	<b>9,310</b>	<b>4,741</b>
<b>Total Liabilities</b>		<b>3,156,242</b>	<b>2,432,929</b>	<b>3,074,825</b>	<b>2,377,946</b>
<b>Net Assets</b>		<b>51,814,516</b>	<b>65,391,816</b>	<b>51,743,968</b>	<b>65,388,653</b>
<b>Equity</b>					
Contributed equity	12	113,222,456	112,813,470	113,222,456	112,813,470
Reserves	13	1,763,836	1,644,837	1,679,400	1,638,509
Accumulated losses	14	(63,171,776)	(49,066,491)	(63,157,888)	(49,063,326)
<b>Total Equity</b>		<b>51,814,516</b>	<b>65,391,816</b>	<b>51,743,968</b>	<b>65,388,653</b>

The accompanying notes form part of these financial statements.

# Consolidated Cash Flows Statements For The Year Ended 30 June 2008

		Consolidated		Clinuvel Pharmaceuticals Ltd	
	Note	2008	2007	2008	2007
		\$	\$	\$	\$
<b>Cash Flows From Operating Activities</b>					
Refund from ATO		298,507	375,282	298,007	379,131
Receipt from customers		-	407,826	-	-
Interest received		3,979,879	2,006,309	3,979,514	2,005,612
Payments to suppliers and employees		(11,459,719)	(10,968,231)	(10,565,944)	(9,793,039)
<b>Net cash provided by (used in) operating activities</b>	<b>17(b)</b>	<b>(7,181,333)</b>	<b>(8,178,814)</b>	<b>(6,288,423)</b>	<b>(7,408,296)</b>
<b>Cash Flows From Investing Activities</b>					
Payments for property, plant and equipment		(221,106)	(181,108)	(171,489)	(164,121)
Payments for investment securities		(21,965,276)	(26,484,370)	(21,965,276)	(26,484,370)
Payments for subsidiaries		-	-	(102,113)	-
Payments for patents & trademarks		-	-	-	-
Payments for product distribution rights		-	(259,390)	-	-
Funds received for transfer of product distribution rights		-	450,000	-	-
Proceeds from investment securities		21,444,811	-	21,444,811	-
<b>Net cash provided by (used in) investing activities</b>		<b>(741,571)</b>	<b>(26,474,868)</b>	<b>(794,067)</b>	<b>(26,648,491)</b>
<b>Cash Flows From Financing Activities</b>					
Loans to related parties				(867,491)	(677,301)
Proceeds from issue of ordinary shares		80,000	61,792,528	80,000	61,792,528
Payment of share issue costs		(78,950)	(1,768,669)	(78,950)	(1,768,669)
<b>Net cash provided by (used in) financing activities</b>		<b>1,050</b>	<b>60,023,859</b>	<b>(866,441)</b>	<b>59,346,558</b>
<b>Net Increase/(Decrease) In Cash Held</b>		<b>(7,921,854)</b>	<b>25,370,177</b>	<b>(7,948,931)</b>	<b>25,289,774</b>
Cash at beginning of the year		33,841,849	8,605,814	33,685,891	8,530,259
Effects of exchange rate changes on foreign currency held		(167,802)	(134,142)	(167,802)	(134,142)
<b>Cash At End Of The Year</b>	<b>17(a)</b>	<b>25,752,193</b>	<b>33,841,849</b>	<b>25,569,158</b>	<b>33,685,891</b>

The accompanying notes form part of these financial statements.



# Consolidated Statement Of Changes In Equity For The Year Ended 30 June 2008

		Consolidated	
	Note	2008	2007
		\$	\$
<b>Retained Earnings</b>			
Retained earnings at the beginning of period		(49,066,491)	(39,890,368)
Transfer from Share Option Reserve		550,506	-
Net profit/(loss) attributable to members of Clinuvel Pharmaceuticals Ltd		(14,655,791)	(9,176,123)
<b>Retained Earnings At The End Of Period</b>	<b>14</b>	<b>(63,171,776)</b>	<b>(49,066,491)</b>
<b>Reserves</b>			
Reserves at the beginning of period		1,644,837	1,153,193
Exchange difference on translating foreign operations		78,108	6,328
Movement in share option reserve		40,891	485,316
<b>Reserves At The End Of Period</b>	<b>13</b>	<b>1,763,836</b>	<b>1,644,837</b>
<b>Share Capital</b>			
Share capital at the beginning of period		112,813,470	52,726,007
302,148,665 fully paid shares (1 July 2006: 184,979,305)			
Issue of shares via investor share purchase plan			403,916
Issue of shares through institutional placement			30,696,904
Issue of shares via rights issue			30,529,834
Share options exercised and value of exercised options transferred from Share Option Reserve		410,186	225,458
Capital raising costs		(1,200)	(1,768,649)
<b>Share capital at the end of period: 303,148,665 fully paid shares</b>	<b>12(b)</b>	<b>113,222,456</b>	<b>112,813,470</b>

# Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2008

## 1. Summary Of Significant Accounting Policies

The financial report is a general purpose financial report that has been prepared in accordance with Australian Accounting Standards, Urgent Issues Group Interpretations, other authoritative pronouncements of the Australian Accounting Standards Board and the Corporations Act 2001. Accounting Standards include Australian equivalents to International Financial Reporting Standards ('A-IFRS'). Compliance with the A-IFRS ensures that the consolidated financial statements and notes of the consolidated entity comply with International Financial Reporting Standards ('IFRS'). The financial report has been prepared on an accruals basis and is based on historical costs and does not take into account changing money values or, except where stated, current valuations of non current assets. Cost is based on the fair values of the consideration given in exchange for assets. The accounting policies have been consistently applied, unless otherwise stated.

The following is a summary of the significant accounting policies adopted by the consolidated entity in the preparation of the financial report.

### a) Basis of Accounting

The financial report has been prepared in accordance with the historical cost convention.

The financial statements of the consolidated entity have been prepared on a going concern basis. The consolidated entity's operations are subject to major risks due primarily to the nature of research development and the commercialization to be undertaken. The risk factors set out may materially impact the financial performance and position of the consolidated entity.

In applying A-IFRS management must make judgement regarding carrying values of assets and liabilities that are not readily apparent from other sources. Assumptions and estimates are based on historical experience and any other factor that are believed reasonable in light of the relevant circumstances. These estimates are

reviewed on an ongoing basis and revised in those periods to which the revision directly affects.

All accounting policies are chosen to ensure the resulting financial information satisfies the concepts of relevance and reliability.

The going concern basis assumes that, if required, future capital raisings will be available to enable the consolidated entity to undertake the research, development and commercialization of its projects and that the subsequent commercialization of products will be successful. The financial statements take no account of the consequences, if any, of the inability of the consolidated entity to obtain adequate funding or of the effects of unsuccessful research, development and commercialization of the consolidated entity projects. The consolidated entity has successfully raised additional working capital in past years and as such the Directors do not envisage the need to raise additional capital in the coming financial year.

### b) Principles of Consolidation

The consolidated financial statements are prepared by combining the financial statements of all the entities that comprise the consolidated entity, being the company (the parent entity) and its subsidiaries as defined in Accounting Standard AASB 127 Consolidated and Separate Financial Statements. Consistent accounting policies are employed in the preparation and presentation of the consolidated financial statements.

The consolidated financial statements include the information and results of each subsidiary from the date on which the company obtains control and until such time as the company ceases to control such entity. In preparing the consolidated financial statements, all intercompany balances and transactions, and unrealised profits arising within the consolidated entity are eliminated in full.

A list of controlled entities is contained further to the Note 9 of the Financial Statements.

### **c) Income Tax**

At present it is uncertain that tax losses can be utilised. Once a position becomes known, tax losses will be brought to account.

#### **Current Tax**

Current tax is calculated by reference to the amount of income tax payable or recoverable in respect of the taxable profit or loss for the period. It is calculated using tax rates and tax laws that have been enacted or substantially enacted by reporting date. Current tax for current and prior periods is recognized as a liability (or asset) to the extent it is unpaid (or refundable).

#### **Deferred Tax**

Deferred tax is accounted for using the comprehensive balance sheet liability method in respect of temporary differences arising from differences between the carrying amount of assets and liabilities in the financial statements and in corresponding tax base of those items.

In principle, deferred tax liabilities are recognized on all taxable differences. Deferred tax assets are recognized for deductible temporary differences and unused tax losses to the extent that it is probable that sufficient unused tax losses and tax offsets can be utilised by future taxable profits. However, deferred tax assets and liabilities are not recognized if the temporary differences given rise to them arise from the initial recognition of assets and liabilities (other than as a result of a business combination) which affect neither taxable income nor accounting profit. Furthermore, a deferred tax liability is not recognized in relation to taxable temporary differences arising from goodwill.

Deferred tax liabilities are recognized for taxable temporary differences arising on investments in subsidiaries, except where the consolidated entity is able to control the reversal of the temporary differences and it is probable that the temporary differences will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with these investments and interests are only recognized to the extent that it is probable that there will be sufficient taxable profits against which to utilise the benefits of the temporary differences and they are expected to reverse in the foreseeable future.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period(s) when the asset and liability giving rise to them are realised or settled, based on tax rates (and tax laws) that have been enacted or substantially enacted by reporting date. The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the consolidated entity expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets and liabilities are offset when they relate to income taxes levied by the same taxation authority and the company/consolidated entity intends to settle its current tax assets and liabilities on a net basis.

#### **Tax Consolidation**

The company and its wholly-owned Australian entities are part of a tax-consolidation group under Australian Taxation law. Clinuvel Pharmaceuticals Ltd is the head entity of the tax-consolidation group.

#### **Current And Deferred Tax For The Period**

Current and deferred tax is recognized as an expense or income in the income statement, except when it relates to items credited or debited directly to equity, in which case the deferred tax is also recognized directly in equity, or where it arises from the initial accounting for a business combination, in which case it is taken into account in the determination of goodwill or excess.

### **d) Cash And Cash Equivalents**

Cash and cash equivalents comprise of cash on hand, at call deposits with banks or financial institutions, bank bills and investments in money market instruments.

### **e) Property, Plant And Equipment**

Plant and equipment are stated at cost less accumulated depreciation and impairment. Cost includes expenditure that is directly attributable to the acquisition of the item. In the event that settlement of all or part of the purchase consideration is deferred, cost is determined by discounting the amounts payable in the future to their present value as at the date of acquisition.

Depreciation is calculated on diminishing value so as to write off the net cost of each asset over its expected useful life to its estimated residual value. The estimated useful lives, residual values and depreciation method are reviewed at the end of each annual reporting period and adjusted if appropriate. An assets carrying amount is written off immediately to its recoverable amount if

the assets carrying amount is greater than its estimated recoverable amount.

The following diminishing value percentages are used in the calculation of depreciation:

- Computers and software 40%
- All other assets 20%

Gains and losses on disposal of assets are determined by comparing proceeds upon disposal with the asset's carrying amount. These are included in the income statement.

#### **f) Investments And Other Financial Assets**

The consolidated entity classifies its financial assets into financial assets at fair value through profit and loss and loans and receivables. Financial assets at fair value through profit and loss are held for trading if the entity does not have a positive intention to hold its investment in the financial asset until maturity (if a fixed maturity) or if it intends to hold the financial asset for an undefined period. Loans and receivables are non-derivative financial assets with fixed payments that are not quoted in an active market. They are included in current assets, except those loans and receivables that are due more than 12 months from reporting date.

#### **g) Research And Development Expenditure**

Expenditure on research activities is recognized as an expense in the period in which it is incurred. Where no internally-generated intangible asset can be recognized, development expenditure is recognized as an expense in the period as incurred. An intangible asset arising from development (or from the development phase of an internal project) is recognized if, and only if, all of the following is demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probably future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

At 30 June 2008 Clinuvel Pharmaceuticals Ltd has yet to demonstrate the satisfaction of all the above criteria to recognise and internally generate an intangible asset from its development activities.

#### **h) Intangible Assets - Trademarks, Patents and Sub-Licence**

Trademarks, patents and licences have a finite useful life and are recorded at cost less accumulated amortisation and impairment losses. Amortisation is charged on a straight line basis over the shorter of the relevant agreement or useful life. The estimated useful life and amortisation method is reviewed at the end of each annual reporting period.

##### **Sub-licence**

The sub-licence to develop and commercialise afamelanotide has been recorded at cost. Cost is based on the fair value of the consideration given in exchange for the assets.

The consideration given for the acquisition of the sub-licence was the issue of 11,167,000 ordinary shares and attaching options in the company. Hence the cost of the sub-licence has been determined by assessing the fair value of net assets of the consolidated entity immediately after the sub-licence was acquired. For the purpose of valuing the assets of the company, an independent valuation of the sub-licence was performed. The valuation was based on discounted future cash flows expected to flow from the right to the sub-licence. The valuation was adjusted for the probability of successful commercial development as a pharmaceutical drug.

The Directors have determined that it is appropriate to record the sub-licence at cost rather than revalue to market value at this time.

##### **Amortisation Of Sub-licence**

The sub-licence to develop and commercialise afamelanotide is amortised on a straight-line basis over 10 years. The Directors have assessed this to be the period over which the future consolidated benefits of the sub-licence are expected to be realised. The period approximates the remaining life and likely extensions of the patents subject to the sub-licence.

#### **i) Payables**

Trade payables and other accounts payable are recognized when the consolidated entity becomes obliged to make future payments resulting from the

purchase of goods and services, incurred prior to the end of the financial year but remain unpaid.

#### **j) Employee Benefits**

Provision is made for benefits accruing to employees in respect of wages and salaries, annual leave and long service leave when it is probable that settlement will be required and they are capable of being measured reliably.

Provisions made in respect of employee benefits expected to be settled within 12 months, are measured at their nominal values using the remuneration rate expected to apply at the time of settlement.

Provisions made in respect of employee benefits which are not expected to be settled within 12 months are measured as the present value of the estimated future cash outflows to be made by the consolidated entity in respect of services provided by employees up to reporting date.

#### **k) Directors' Remuneration - Share Based Payments**

Under AASB 2 Share Based Payments, the consolidated entity must determine the fair value of options issued to employees as remuneration and recognise an expense in the Income Statement. This standard is not limited to options and also extends to other forms of equity based remuneration. The fair value of options is measured by the use of the Black Scholes binominal model. It is determined at grant date and expensed on a straight-line basis over the vesting period. For the full year reporting period ending 30 June 2008 the fair value options is required to be shown as an expense to the entity together with comparative information for the same period in the preceding reporting period. For the 2007/08 year \$776,582 (2007:\$548,917) was recognized as an employment benefit expense and was largely attributable to the issue of new options to Directors and Executives as approved by shareholders in an Extraordinary General Meeting, held 25 January 2007.

Further information can be found in Note 23 to the financial statements.

#### **l) Revenue**

##### **Interest**

Interest revenue is recognized on a proportional basis that takes into account the effective yield on the financial asset.

##### **Sale Of Goods**

Revenue from the sale of goods is recognized when the consolidated entity has transferred to the Buyer the significant risks and rewards of ownership of the goods.

#### **m) Share Capital**

Ordinary share capital is recognized at the fair value of the consideration received by the company.

Any transaction costs arising on the issue of ordinary shares are recognized directly in equity as a reduction of the shares proceeds received.

#### **n) Earnings Per Share**

##### **Basic Earnings Per Share**

Basic earnings per share is determined by dividing net profit after income tax attributable to members of the company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year.

##### **Diluted Earnings Per Share**

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares

#### **o) Goods And Services Tax (GST)**

Revenues, expenses and assets are recognized net of the amount of goods and services tax (GST), except:

- where the amount of GST incurred is not recoverable from the taxation authority, it is recognized as part of the costs of acquisition of an asset or as part of an item of expense; or
- for receivables and payables which are recognized inclusive of GST.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables.

Cash flows are included in the cash flow statement on a gross basis. The GST component of cash flows arising from investing and financing activities which is

recoverable from, or payable to, the taxation authority is classified as operating cash flows.

#### **p) Impairment Of Assets**

At each reporting date, the consolidated entity reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where the asset does not generate cash flows that are independent from other assets, the consolidated entity estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment annually and whenever there is an indication that the asset may be impaired. Recoverable amount is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risk specified to the asset for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognized in profit or loss immediately.

Where an impairment loss subsequently reverses, the carrying amount of the asset (cash-generating unit) is increased to the revised estimate of its recoverable amount, but only to the extent that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (cash-generating unit) in prior years. A reversal of an impairment loss is recognized in profit or loss immediately.

#### **q) Leases**

Lease payments for operating leases, where substantially all the risks and benefits remain with the lessors, are

charged as expenses in the periods in which they are incurred.

#### **r) Comparatives**

Where necessary, comparatives have been reclassified and repositioned for consistency with current year disclosure.

#### **s) Provisions**

Provisions are recognized when a present obligation to the future sacrifice of economic benefits becomes probable, and the amount of the provision can be measured reliably.

The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at reporting date, taking into account the risks and uncertainties surrounding the obligation. Where a provision is measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows.

When some or all of the economic benefits required to settle a provision are expected to be recovered from a third party, the receivable is recognized as an asset if it is virtually certain that recovery will be received and the amount of the receivable can be measured reliably.

#### **t) Other Current Assets**

Other current assets comprise prepayments of drug peptide yet to be used in Clinuvel Pharmaceuticals Ltd trial program, prepayments for feasibility study costs for drug delivery systems and prepayments for clinical trial insurances yet to expire, along with other general prepayments. The expenditures represent an unused expense and therefore a decrease in future economic benefit has yet to be incurred.

#### **u) Foreign Currency Transactions And Balances**

All foreign currency transactions during the financial year are brought to account using the exchange rate in effect at the date of the transaction. Foreign currency monetary items at reporting date are translated at the exchange rate existing at reporting date. Non-monetary assets and liabilities carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when the fair value was determined. Exchange differences are recognized in profit or loss in the period in which they arise as defined in AASB 121: The Effects of Changes in Foreign Exchange Rates.



#### **v) New Accounting Standards And Interpretations**

The following standards have been identified as those which may impact the consolidated entity in the first period of application. They are available for early adoption at 30 June 2008, but have not been adopted in preparing this financial report.

##### **Revised AASB101 Presentation Of Financial Statements**

This revised Standard introduces a new financial statement titled "Statement of Comprehensive Income". It will not change the recognition, measurement, or disclosure of transactions that are required by other Accounting Standards. The consolidated entity will need to conform to this standard for the reporting period ending 30 June 2010.

##### **AASB8 Operating Segments**

Application of this standard may result in different segments or segment results and different types of information reported in segment reporting, but it will not impact the results of the consolidated entity. The consolidated entity will need to conform to this standard for the reporting period ending 30 June 2010.

**2. Profit/(Loss) From Continuing Operations**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>(a) Revenues</b>				
Interest revenue – other persons	4,297,103	2,238,876	4,296,376	2,237,822
Sales revenue	-	283,308	-	-
Gain on disposal of A.C.N. 108 768 896 Pty Ltd assets after providing for impairment 30 June 2006	-	31,717	-	-
<b>Total revenues</b>	<b>4,297,103</b>	<b>2,553,901</b>	<b>4,296,376</b>	<b>2,237,822</b>
<b>(b) Expenses</b>				
Clinical Development costs	1,475,445	990,218	1,469,248	990,218
Drug Delivery Research costs	4,986,059	2,263,413	4,986,059	2,263,413
Toxicity Studies	828,646	464,610	828,646	464,610
R & D Overheads	1,126,057	751,150	700,399	693,304
Sales & Marketing costs	1,498	419,821	-	-
Business Marketing & Listing	1,413,358	1,235,658	1,413,358	1,198,825
Licenses Patents and Trademarks	945,443	957,166	139,359	209,868
General Operations (incl Board)	8,176,388	4,527,155	7,682,741	4,114,310
Doubtful Debt Provision	-	-	1,721,634	1,476,404
Impairment Loss	-	120,833	-	-
<b>Total expenses</b>	<b>18,952,894</b>	<b>11,730,024</b>	<b>18,941,444</b>	<b>11,410,952</b>
<b>(c) Profit/(loss) before income tax includes the following specific expenses</b>				
Depreciation	85,265	68,301	85,265	67,235
Amortisation of sub-licence	747,298	747,298	-	-
Amortisation of trademarks	9,200	8,414	9,200	8,414
Amortisation of product distribution rights	-	81,174	-	-
Research & Development costs	6,455,307	3,253,631	6,455,307	3,253,631
Doubtful Debts – wholly owned subsidiary	-	-	1,732,357	1,476,404
Loss on sale of property, plant and equipment	30,099	(373)	30,099	(373)
Impairment Loss - A.C.N. 108 768 896 Pty Ltd	-	120,833	-	-
Realised loss on disposal of financial assets at fair value through profit and loss	1,031,333	-	1,031,333	-
Net Loss on revaluation of financial assets held at fair value through profit & loss	2,952,395	3,280	2,952,395	3,280
Operating Lease Expense – minimum lease payments	379,467	797,120	243,609	421,227

**3. Income Tax Expense**

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2008	2007	2008	2007
	\$	\$	\$	\$
<b>(a) The prima facie tax on profit (loss) is reconciled to the income tax expense (benefit) as follows:</b>				
Prima facie tax payable on profit (loss) from ordinary activities before income tax at 30% (2007: 30%)	(4,396,737)	(2,752,837)	(4,393,520)	(2,751,939)
<b>Add:</b>				
<b>Tax effect of</b>				
non deductible amortisation	2,760	11,274	2,760	2,524
non deductible shareholder admin	-	(7,700)	0	(7,700)
capital raising costs	(360)	(530,594)	(360)	(530,594)
non deductible legal fees	-	(675)	-	-
Impairment Loss	-	36,250	-	-
Share Based payments	12,267	145,595	12,267	145,595
research and development deduction	(110,134)	(244,022)	(110,134)	(244,022)
(over)/under provision of income tax in previous years	135,397	(645,084)	135,397	(645,084)
<b>Deferred tax assets not brought to account</b>	<b>4,356,807</b>	<b>3,987,793</b>	<b>4,353,590</b>	<b>4,031,221</b>

**(b) Deferred tax assets arising from unconfirmed tax losses and net timing differences not brought to account at balance date as realisation of the benefit is not regarded as probable.**

**The benefits will only be obtained if the conditions set out in note 1(c) occur:**

Tax losses	19,228,663	14,880,457	18,497,106	14,152,116
Net temporary differences	1,181,248	1,172,647	1,608,334	1,599,733
	<b>20,409,911</b>	<b>16,053,104</b>	<b>20,105,440</b>	<b>15,751,849</b>

The tax rate used in this report is the corporate tax rate of 30%. There has been no change in the corporate tax rate when compared with the previous reporting period.

**4. Receivables**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Current</b>				
Trade debtors	-	1,535	-	-
Accrued income	459,286	188,244	459,286	188,244
Sundry debtors	156,850	51,714	156,850	51,377
<b>Total Current</b>	<b>616,136</b>	<b>241,493</b>	<b>616,136</b>	<b>239,621</b>
<b>Non Current</b>				
Receivable from wholly owned entity				
Melanotan (Australia) Pty Ltd	-	-	8,070,017	8,011,231
Provision for non-recovery	-	-	(6,696,404)	(5,890,320)
			<b>1,373,613</b>	<b>2,120,911</b>
A.C.N. 108 768 896 Pty Ltd	-	-	4,377,496	4,343,613
Provision for non-recovery	-	-	(4,370,868)	(4,343,613)
	-	-	<b>6,628</b>	-
Clinuvel, Inc	-	-	1,001,285	428,700
Provision for non-recovery (Clinuvel, Inc)	-	-	(1,001,285)	(305,197)
	-	-	-	<b>123,503</b>
Clinuvel AG	-	-	202,237	
Provision for non-recovery (Clinuvel AG)	-	-	(192,206)	
	-	-	<b>10,031</b>	
<b>Total Non Current</b>	<b>-</b>	<b>-</b>	<b>1,390,272</b>	<b>2,244,415</b>

There has been no bad debts written off during 2008 or 2007 against the provision for non-recovery.

The Group has recognized a loss of \$1,718,641 (2007: \$1,476,404) in respect of impaired related party receivables. This loss has been included in operating expenses in the income statement.

The carrying amount of receivables is a reasonable approximation of fair value.

**5. Other Assets**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Current Prepayments</b>				
Peptide	1,390,730	1,780,581	1,390,730	1,780,581
Other	312,666	941,046	283,617	932,976
<b>Total</b>	<b>1,703,396</b>	<b>2,721,627</b>	<b>1,674,347</b>	<b>2,713,557</b>

**6. Property, Plant And Equipment**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Plant and equipment</b>				
At cost	587,576	544,740	554,000	540,335
Less: accumulated depreciation	(258,469)	(241,282)	(254,102)	(240,843)
	<b>329,107</b>	<b>303,458</b>	<b>299,898</b>	<b>299,492</b>
<b>Furniture and fittings</b>				
At cost	117,888	57,858	84,860	45,275
Less: accumulated depreciation	(15,961)	(29,301)	(12,550)	(28,673)
	<b>101,927</b>	<b>28,557</b>	<b>72,310</b>	<b>16,602</b>
<b>Total property, plant and equipment</b>	<b>431,034</b>	<b>332,015</b>	<b>372,208</b>	<b>316,094</b>

**Movements in Carrying Amounts - Property, Plant And Equipment**

Movements in the carrying amounts for each class of property, plant and equipment between the beginning and the end of the financial year

	<b>Plant And Equipment</b>	<b>Furniture And Fittings</b>	<b>Total</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Consolidated Entity and Parent Entity</b>			
<b>Carrying Amount at 1 July 2006</b>	<b>201,860</b>	<b>20,382</b>	<b>222,242</b>
Additions	168,153	12,583	180,736
Disposals	(3,284)	(3,781)	(7,065)
Depreciation written back on disposal	623	-	623
Depreciation expense	(63,894)	(627)	(64,521)
<b>Carrying Amount at 1 July 2007</b>	<b>303,458</b>	<b>28,557</b>	<b>332,015</b>
Additions	118,388	106,795	225,183
Disposals	(75,031)	(45,275)	(120,306)
Depreciation written back on disposal	59,457	28,673	88,130
Depreciations expense	(77,165)	(16,823)	(93,988)
<b>Carrying Amount at 30 June 2008</b>	<b>329,107</b>	<b>101,927</b>	<b>431,034</b>
<b>Parent Entity</b>			
<b>Carrying Amount at 1 July 2006</b>	<b>201,860</b>	<b>20,383</b>	<b>222,243</b>
Additions	163,748	-	163,748
Disposals	(3,284)	-	(3,284)
Depreciation written back on disposal	622	-	622
Depreciation expense	(63,455)	(3,781)	(67,236)
<b>Carrying Amount at 1 July 2007</b>	<b>299,491</b>	<b>16,602</b>	<b>316,093</b>
Additions	88,696	84,860	173,556
Disposals	(75,031)	(45,275)	(120,306)
Depreciation written back on disposal	59,457	28,673	88,130
Depreciations expense	(72,715)	(12,550)	(85,265)
<b>Carrying Amount at 30 June 2008</b>	<b>299,898</b>	<b>72,310</b>	<b>372,208</b>



**7. Intangible Assets**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Sub-licence to develop and commercialise afamelanotide</b>				
At cost	7,472,983	7,472,983	-	-
Less: Accumulated amortisation	(6,099,370)	(5,352,072)	-	-
	<b>1,373,613</b>	<b>2,120,911</b>	<b>-</b>	<b>-</b>
<b>Trademarks</b>				
At cost	68,281	68,281	68,281	68,281
Less: Accumulated amortisation of Trademarks	(34,141)	(27,312)	(34,141)	(27,312)
<b>Patents</b>				
At cost	23,718	23,718	23,718	23,718
Less: Accumulated amortisation of Patents	(11,859)	(9,487)	(11,859)	(9,487)
	<b>45,999</b>	<b>55,200</b>	<b>45,999</b>	<b>55,200</b>
	<b>1,419,612</b>	<b>2,176,111</b>	<b>45,999</b>	<b>55,200</b>

**Movements in Carrying Amounts – Intangible Assets**

Movement in carrying amounts for each class of intangible asset between the beginning and end of the financial year

	Sub-Licence	Trademarks And Patents	Product Distribution Rights	Total
	\$	\$	\$	\$
<b>Consolidated Entity</b>				
<b>Carrying Amount at 1 July 2006</b>	<b>2,868,209</b>	<b>63,614</b>	<b>-</b>	<b>2,931,823</b>
Additions	-	-	150,000	150,000
Impairment charged to profit	-	-	(120,833)	(120,833)
Amortisation expense	(747,298)	(8,414)	(29,166)	(784,878)
<b>Carrying Amount at 1 July 2007</b>	<b>2,120,911</b>	<b>55,200</b>	<b>-</b>	<b>2,176,111</b>
Additions	-	-	-	-
Impairment charged to profit	-	-	-	-
Amortisation expense	(747,298)	(9,201)	-	(756,499)
<b>Carrying Amount at 30 June 2008</b>	<b>1,373,613</b>	<b>45,999</b>	<b>-</b>	<b>1,419,612</b>
<b>Parent Entity</b>				
<b>Carrying Amount at 1 July 2006</b>	<b>-</b>	<b>63,614</b>	<b>-</b>	<b>63,614</b>
Additions	-	-	-	-
Impairment charged to profit	-	-	-	-
Amortisation expense	-	(8,414)	-	(8,414)
<b>Carrying Amount at 1 July 2007</b>	<b>-</b>	<b>55,200</b>	<b>-</b>	<b>55,200</b>
Additions	-	-	-	-
Impairment charged to profit	-	-	-	-
Amortisation expense	-	(9,201)	-	(9,201)
<b>Carrying Amount at 30 June 2008</b>	<b>-</b>	<b>45,999</b>	<b>-</b>	<b>45,999</b>

Amortisation expense is included in the line item 'Total expenses' in the Consolidated Income Statement.

Please refer to the Summary of Significant Accounting Policies regarding significant intangible assets.

**8. Other Financial Assets**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Current</b>				
Investments comprise:				
Income Securities (at fair value through profit and loss)*	25,048,387	28,511,650	25,048,387	28,511,650

**Non Current**

Shares in unlisted controlled entities at cost	-	-	102,286	172
--	---	---	---------	-----

\* The consolidated entity holds listed perpetual floating rate notes (income securities) returning 0.75% - 2.20% above the 90 day bank bill rate with interest paid out quarterly and senior debt securities returning 0.25% to 0.37%, above the 90 day bank bill rate with interest paid out quarterly and maturity dates ranging from 20 to 43 months from reporting date.

**9. Interests In Subsidiaries**

Name of Entity	Country of incorporation	Ownership interest	
		2008	2007
Parent entity			
Clinuvel Pharmaceuticals Ltd	Australia	-	-
Controlled entities			
Melanotan (Australia) Pty Ltd	Australia	100%	100%
A.C.N. 108 768 896 Pty Ltd (formerly EpiPharm Pty Ltd)	Australia	100%	100%
EpiPharm (NZ) Ltd (dissolved)	New Zealand	0%	100%
Clinuvel (UK) Ltd	United Kingdom	100%	100%
Clinuvel, Inc	United States	100%	100%
Clinuvel AG (incorporated 3 March 2008)	Switzerland	100%	0%

**10. Payables**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Current</b>				
Unsecured Trade creditors	733,985	1,597,428	672,457	1,571,024
Sundry creditors and accrued expenses	2,234,371	717,870	2,224,099	691,055
	<b>2,968,356</b>	<b>2,315,298</b>	<b>2,896,556</b>	<b>2,262,079</b>
<b>(a) Aggregate amounts payable to:</b>				
Directors and Director-related entities	683	6,705	683	6,705
<b>(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade creditors:</b>				
US dollars	1,925,623	-	1,925,623	-
Euro	157,847	-	157,847	-
British pounds	110,544	28,151	110,544	28,151
Other	27,697	525	27,697	525
	<b>2,221,711</b>	<b>28,676</b>	<b>2,221,711</b>	<b>28,676</b>

For an analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 22.

**(c) Terms and conditions:**

Trade and sundry creditors are non-interest bearing and normally settled on 30 day terms.

**11. Provisions**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Current</b>				
Employee benefits	178,576	112,890	168,959	111,126
<b>Non Current</b>				
Employee Benefits	9,310	4,741	9,310	4,741

**12 Contributed Equity****(a) Issued and Paid Up Capital**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
303,148,665 fully paid ordinary shares (2007: 302,148,665)	113,222,456	112,813,470	113,222,456	112,813,470

**(b) Movements in Ordinary Share Capital:**

	<b>Clinuvel Pharmaceuticals Ltd</b>			
	<b>2008</b>		<b>2007</b>	
	<b>No.</b>	<b>\$</b>	<b>No.</b>	<b>\$</b>
At the beginning of the financial year	302,148,665	112,813,470	184,979,305	52,726,007
<b>Issued during the year</b>				
options exercised and valuation transferred from Share Option Reserve	1,000,000	410,186	925,000	225,479
rights issue			79,298,274	30,529,836
share purchase plan			377,492	403,916
private placement			36,568,594	30,696,901
Less: transaction costs	-	(1,200)	-	(1,768,669)
<b>Balance at the end of the financial year:</b>	<b>303,148,665</b>	<b>113,222,456</b>	<b>302,148,665</b>	<b>112,813,470</b>

**12 Contributed Equity (cont'd)****(c) Share Options**

As at 30 June 2008 the following share options existed which if exercised, would result in the issue of fully paid ordinary shares

<b>Expiry Date</b>	<b>Exercise Price</b>	<b>Number of Options</b>
18 April 2009	\$0.87/share	300,000
1 November 2009	\$0.34/share	1,500,000
28 February 2010	\$0.75/share	500,000
31 March 2010	\$0.50/share	1,500,000
9 February 2012	\$0.86/share	15,660,000
3 August 2012	\$0.86/share	110,000
<b>Total</b>		<b>19,570,000</b>

During the year the following share options were issued which if exercised, would result in the issue of fully paid ordinary shares

9 February 2012	\$0.86 /share	110,000
<b>Total</b>		<b>110,000</b>

During the year the following share options issued in prior years were exercised, resulting in the issue of fully paid shares

2 February 2008	\$0.16 /share	500,000
13 June 2008	\$0.29 /share	500,000
<b>Total</b>		<b>1,000,000</b>

Ordinary shares have the right to receive dividends as declared and, in the event of winding up the company, to participate in the proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held. Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the company.



**13. Reserves**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Share Option reserve</b>				
Balance at the beginning of period	1,638,509	1,153,193	1,638,509	1,153,193
Share based payment	776,583	563,693	776,583	563,693
Transfer to share capital	(185,186)	(63,604)	(185,186)	(63,604)
Lapsed Options	(550,506)	(14,773)	(550,506)	(14,773)
<b>Reserves at the end of period</b>	<b>1,679,400</b>	<b>1,638,509</b>	<b>1,679,400</b>	<b>1,638,509</b>
The Executive share option reserve arises on the grant of share options to Executive and Directors under the Executive share option scheme. Amounts are transferred out of the reserve and into issued capital when the options are exercised.				
<b>Foreign currency translation reserve:</b>				
Balance at the beginning of period	-	-	-	-
Translating foreign subsidiary to current rate at Balance Date	84,436	6,328	-	-
<b>Balance at the end of period</b>	<b>84,436</b>	<b>6,328</b>	<b>-</b>	<b>-</b>
<b>Total Reserves</b>	<b>1,763,836</b>	<b>1,644,837</b>	<b>1,679,400</b>	<b>1,638,509</b>

**14. Accumulated Losses**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Accumulated losses at the beginning of the year	(49,066,491)	(39,890,368)	(49,063,326)	(39,890,196)
Transfer from Share Option reserve of lapsed & expired Options	550,506	-	550,506	-
Net loss attributable to the members of Clinuvel Pharmaceuticals Ltd	(14,655,791)	(9,176,123)	(14,645,068)	(9,173,130)
<b>Accumulated losses at the end of the financial year</b>	<b>(63,171,776)</b>	<b>(49,066,491)</b>	<b>(63,157,888)</b>	<b>(49,063,326)</b>

**15. Lease Commitments**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Operating lease commitments</b>				
Non-cancellable operating leases				
Contracted for but not capitalised in the accounts:				
Payable				
not later than 1 year	378,272	358,133	216,678	261,309
later than 1 year but not later than 5 years	449,959	661,955	404,032	596,510
	<b>828,231</b>	<b>1,020,088</b>	<b>620,710</b>	<b>857,819</b>

**16. Earnings Per Share (EPS)**

	<b>Consolidated</b>	
	<b>2008</b>	<b>2007</b>
(a) Basic earnings per share (cents per share)	(4.8)	(3.7)
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of Basic Earnings Per Share	302,380,172	248,219,988
(c) The numerator used in the calculation of Basic Earnings Per Share (\$)	(14,655,791)	(9,176,123)
(d) Potential Ordinary Shares not considered Dilutive	-	-

As at 30 June 2008 the company had on issue 19,570,000 unlisted options over unissued capital. These options are not considered dilutive as they do not increase the net loss per share.

**17. Cash Flow Information**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>(a) Reconciliation of Cash</b>				
Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled to the related items in the balance sheet as follows:				
Cash at bank	817,459	301,742	662,358	205,973
Cash on hand	300	300	300	300
Deposits on call	9,869,358	33,385,923	9,867,809	33,349,543
Term deposits (security bonds)	15,000,000	-	15,000,000	-
Security Bonds	65,076	153,884	38,691	130,075
	<b>25,752,193</b>	<b>33,841,849</b>	<b>25,569,158</b>	<b>33,685,891</b>
<b>(b) Reconciliation of cash flows from operating activities with operating profit (loss)</b>				
Operating profit (loss) after income tax	(14,655,791)	(9,176,123)	(14,645,068)	(9,173,130)
<b>Non cash flows in operating (loss):</b>				
Depreciation expense	91,978	68,301	85,266	67,325
Accrued income	(271,042)	(171,484)	(271,042)	(171,484)
Exchange Rate Effect on Foreign Currencies Held	167,802	134,142	167,802	134,142
Amortisation expense	756,499	836,886	9,201	8,414
Doubtful debt expense	-	-	1,721,633	1,476,405
Executive share option expense	776,582	548,917	776,582	548,917
WDV of non-current assets sold	30,099	2,662	30,099	2,662
Gain on sale of non-current asset	0	373	-	373
Realised loss on disposal of financial assets at fair value through profit and loss	1,031,333	-	1,031,333	-
Net Loss on revaluation of financial assets held at fair value	2,952,395	(3,280)	2,952,395	(3,280)
Unrealised Loss Foreign Exchange Translation	78,108	6,328	-	-
Loss on sale of product distribution licenses	-	701,623	-	-
Impairment Loss – product distribution license	-	120,833	-	-
July 1 Reversal of Impairment Loss A.C.N. 108768896 Pty Ltd	-	(1,228,615)	-	-
<b>Changes in assets and liabilities:</b>				
(Increase)/decrease in receivables	41,480	163,215	39,526	26,606
(Increase)/decrease in bonds & deposits	-	40,000	-	-
(Increase)/decrease in inventories	-	604,902	-	-
(Increase)/decrease in prepayments	1,018,242	(287,789)	1,039,215	(298,118)
Increase/(decrease) in payables	730,727	(568,636)	712,232	(93,182)
Increase/(decrease) in provisions	70,255	28,928	62,403	66,144
<b>Net cash used in operating activities</b>	<b>(7,181,333)</b>	<b>(8,178,814)</b>	<b>(6,288,423)</b>	<b>(7,408,296)</b>

## 18. Key Management Personnel Disclosures

### The specified Directors of Clinuvel Pharmaceuticals Limited during the year were:

Dr. H.P.K. Agersborg (Deputy Chair, Chief Scientific Officer)

Mr. S.R. McLiesh (Non-Executive)

Mrs. B.M. Shanahan (Non-Executive, Chair since 6 December 2007)

Dr. R. Aston (Executive Chair until 6 December 2007, Non-Executive Director thereafter)

Dr. P.J. Wolgen (Managing Director)

Mr. L.J. Wood (Non-Executive, joined Board 11 July 2008)

### The key management personnel of Clinuvel Pharmaceuticals Limited during the year were:

Dr. D. J. Wright (VP – Scientific Affairs)

Mr. C. H. Mackie (Head of Corporate Development)

Mr. D. M. Keamy (Chief Financial Officer, Company Secretary)

## Key Management Personnel Compensation

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2008	2007	2008	2007
	\$	\$	\$	\$
Short-term employee benefits:	1,543,428	1,546,738	1,543,428	1,546,738
Post-employment benefits	50,488	35,315	50,488	35,315
Long-term benefits	-	-	-	-
Termination benefits	-	33,333	-	33,333
Share-based payments	518,363	449,736	518,363	449,736
	<b>2,112,279</b>	<b>2,065,122</b>	<b>2,112,279</b>	<b>2,065,122</b>

## Remuneration Option holdings of Key Management Personnel – 2008

	Balance at Start of Year	Granted as Compensation	Exercised	Lapsed and Expired	Balance at End of Year	Vested and Exercisable	Unvested
<b>Directors</b>							
H.P.K. Agersborg	2,750,000	-	-	(750,000)	2,000,000	1,500,000	500,000
S.R. McLiesh	1,100,000	-	-	(450,000)	650,000	450,000	200,000
R. Aston	2,750,000	-	-	(300,000)	2,450,000	1,800,000	650,000
P.J. Wolgen	11,250,000	-	-	(2,000,000)	9,250,000	8,000,000	1,250,000
B. M. Shanahan	850,000	-	-	-	850,000	566,667	283,333
<b>Executives</b>							
D.J. Wright	1,800,000	-	-	(200,000)	1,600,000	947,911	652,089
D.M. Keamy	800,000	-	-	(100,000)	700,000	277,083	422,917
C.H. Mackie	-	-	-	-	-	-	-

**Remuneration Option Holdings of Key Management Personnel – 2007**

	Balance at Start of Year	Granted as Compensation	Exercised	Other Changes	Balance at End of Year	Vested and Exercisable	Unvested
<b>Directors</b>							
H.P.K. Agersborg	250,000	2,500,000	-	-	2,750,000	1,250,000	1,500,000
S.R. McLiesh	250,000	850,000	-	-	1,100,000	575,000	525,000
R. Aston	750,000	2,000,000	-	-	2,750,000	1,050,000	1,700,000
P.J. Wolgen	2,250,000	9,000,000	-	-	11,250,000	5,000,000	6,250,000
B. M. Shanahan	-	850,000	-	-	850,000	283,333	566,667
T.E. Winters	250,000	2,000,000	-	(800,000)	1,450,000	1,050,000	400,000

**Executives**

D.J. Wright	500,000	1,300,000	-	-	1,800,000	602,917	1,197,083
D.M. Keamy	-	800,000	-	-	800,000	152,083	647,916

All equity dealings with Directors have been entered into with terms and conditions no more favourable than those that the entity would have adopted if dealing at arm's length.

**Share Holdings of Key Management Personnel**

	Ordinary Shares – 2008				Ordinary Shares – 2007			
	Balance at Start of Year	Rec'd upon Option Exercise	Purchases	Balance at End of Year	Balance at Start of Year	Rec'd upon Option Exercise	Purchases	Balance at End of Year
<b>Directors</b>								
H.P.K. Agersborg	921,105	-	-	<b>921,105</b>	921,105	-	-	<b>921,105</b>
S.R. McLiesh	760,000	-	-	<b>760,000</b>	750,000	-	10,000	<b>760,000</b>
R. Aston	108,224	-	-	<b>108,224</b>	71,757	-	36,467	<b>108,224</b>
P.J. Wolgen	-	-	95,000	<b>95,000</b>	-	-	-	-
B. M. Shanahan	420,071	-	-	<b>420,071</b>	420,071	-	-	<b>420,071</b>
<b>Executives</b>								
D.J. Wright	-	-	-	-	-	-	-	-
D.M. Keamy	1,600	-	-	<b>1,600</b>	1,600	-	-	<b>1,600</b>
C.H. Mackie	-	-	-	-	-	-	-	-

**19. Auditors' Remuneration**

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2008	2007	2008	2007
	\$	\$	\$	\$
<b>Amounts received or due and receivable by Grant Thornton for:</b>				
audit services and review	44,818	43,450	44,818	43,450
other services	-	-	-	-
	<b>44,818</b>	<b>43,450</b>	<b>44,818</b>	<b>43,450</b>

## 20. Related Party Disclosures

### Directors

The Directors of Clinuvel Pharmaceuticals Ltd during the financial year were:

H.P.K. Agersborg, S.R. McLiesh, R. Aston, P.J. Wolgen, B.M. Shanahan

### Wholly-owned group transactions

#### Loans

The loan receivable by Clinuvel Pharmaceuticals Ltd from Melanotan (Australia) Pty Ltd is non-interest bearing. Repayment of the loan will commence upon commercialization of the company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in Melanotan (Australia) Pty Ltd.

The loan receivable by Clinuvel Pharmaceuticals Ltd from A.C.N. 108 768 896 Pty Ltd is non-interest bearing. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in A.C.N. 108 768 896 Pty Ltd. The loan to A.C.N. 108 768 896 Pty Ltd as at 30 June 2008 is \$4,377,496 (2007: \$4,343,613).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel, Inc is non-interest bearing. Repayment of the loan will commence upon commercialization of the company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in Clinuvel, Inc. The loan to Clinuvel, Inc as at 30 June 2008 is \$1,001,285 (2007: \$428,700).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel AG is non-interest bearing. Repayment of the loan will commence upon commercialization of the company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in Clinuvel AG. The loan to Clinuvel AG as at 30 June 2008 is \$202,237.

### Director related and key management personnel transactions and entities

The following transactions and relationships were in existence as at 30 June 2008 between Directors of the Company and their related entities.

#### Common Directors of the company and Melanotan Corporation (Inc)

A Director of the company, Dr. Helmer Agersborg, also holds a Directorship with Melanotan Corporation Inc. Melanotan Corporation Inc granted an exclusive sub-licence for the afamelanotide technology to Melanotan Australia Pty Ltd. One of the terms of this agreement is the payment of royalties to Melanotan Corporation Inc of 3.5% of the net selling price upon commercialization of the technology. Melanotan Corporation Inc is in the process of being dissolved.

#### Consultancy payments to Newtonmore Biosciences Pty Ltd

Under the terms of a consultancy agreement entered into between Dr. Aston and the consolidated entity, the consolidated entity paid Dr. Aston for the provision of consultancy services in lieu of Non-Executive Chair fees from July 1 to December 31 2007. The payments were made to Dr. Aston's management company Newtonmore Bioscience Pty Ltd with \$50,000 paid during 2007/08 (2006/07: \$165,404 [12 months]).



## 21. Segment Information

The consolidated entity operates in the biotechnology and in the pharmaceutical products industries. The consolidated entity operates predominantly in Australia.

	2008	2007	2008	2007	2008	2007
	Biotechnology		Pharmaceutical Products		Consolidated	
Segment Revenue And Results						
Revenues						
Interest Revenue (unallocated)	-	-	-	-	4,297,103	2,238,876
Sales	-	-	-	283,308	-	283,308
Gain on Business Disposal after Impairment	-	-	-	31,717	-	31,717
Total Revenue	-	-	-	315,025	4,297,103	2,553,901
Results	(14,628,536)	(8,444,024)	(27,255)	(732,099)	(14,655,791)	(9,176,123)

### Segment Assets And Liabilities

Current assets	52,986,541	65,277,634	11,401	38,984	52,997,942	65,316,619
Non-current assets	1,914,836	2,508,127	-	-	1,914,835	2,508,126
<b>Total Assets</b>	<b>54,901,377</b>	<b>67,785,761</b>	<b>11,401</b>	<b>38,984</b>	<b>54,912,777</b>	<b>67,824,745</b>

### Liabilities

Current Liabilities	3,085,434	2,389,204	4,773	38,984	3,090,207	2,428,188
Non-current liabilities						
Provisions	9,310	4,741	-	-	9,310	4,741
<b>Total Liabilities</b>	<b>3,094,744</b>	<b>2,393,945</b>	<b>4,773</b>	<b>38,984</b>	<b>3,099,517</b>	<b>2,432,929</b>

## 22. FINANCIAL INSTRUMENTS

Clinuvel Pharmaceuticals Ltd and consolidated entities have exposure to the following risks from its use in financial instruments:

- Market Risk
- Credit Risk
- Liquidity Risk

The Board of Directors oversees and reviews the effectiveness of the risk management systems implemented by management. The Board has assigned responsibility to the Audit and Risk committee to review and report back to the Board in relation to the company's risk management systems.

### Market Risk

Market risk is the risk of changes in market prices such as foreign exchange purchases, interest rates and equity prices will affect the value of the consolidated entity's financial instruments. The objective to manage market risk is to ensure exposures are contained within

acceptable parameters, to minimize costs and to stabilize existing assets.

### Foreign Currency risk

The consolidated entity is exposed to foreign currency risk on future commercial transactions and recognized assets and liabilities that are denominated in a currency other than the functional currency of each of the group's entities, primarily US dollars (USD), euros (EUR) and Swiss francs (CHF). The parent entity is exposed to the risk of its cash flows being adversely affected by movements in exchange rates that will increase the Australian dollar value of foreign currency payables.

The consolidated entity's policy of managing foreign currency risk is to purchase foreign currencies equivalent to the cash outflow projected over minimum 30 days by the placement of market orders or forward exchange contracts to achieve a target rate of exchange, with protection floors in the event of a depreciating Australian dollar exchange rate, to run for the time between

recognizing the exposure and the time of payment. In the event of an appreciating Australian dollar, the amount of foreign currency held is minimized at a level to only meet short term obligations in order to maximize gains in an appreciating Australian currency. Clinuvel does not

engage in speculative transactions in its management of foreign currency risk. No forward exchange contracts had been entered into as at 30 June 2008 and as at 30 June 2007.

#### The consolidated entities exposure to foreign currency risk at 30 June 2008

Consolidated				Consolidated		
2008				2007		
	Cash & Cash Equivalents	Trade & Other Payables	Total	Cash & Cash Equivalents	Trade & Other Payables	Total
USD	78,423	(1,548,046)	(1,469,623)	1,166,988	(1,121,282)	45,706
EUR	95,034	(239,821)	(144,787)	119,796	(75,763)	44,033
CHF	92,988	(67,806)	25,182		(2,615)	(2,615)
GBP		(53,382)	(53,382)		(11,925)	(11,925)
DKK		(1,943)	(1,943)		(659)	(659)
SEK		(24,000)	(24,000)			

Clinuvel Pharmaceuticals Ltd				Clinuvel Pharmaceuticals Ltd		
2008				2007		
	Cash & Cash Equivalents	Trade & Other Payables	Total	Cash & Cash Equivalents	Trade & Other Payables	Total
USD	30,086	(1,533,681)	(1,503,595)	1,083,790	(1,121,282)	(37,492)
EUR	95,034	(234,905)	(139,871)	119,796	(75,763)	44,033
CHF	0	(22,622)	(22,622)		(2,615)	(2,615)
GBP	0	(53,382)	(53,382)		(11,925)	(11,925)
DKK	0	(1,943)	(1,943)		(659)	(659)
SEK	0	(24,000)	(24,000)			

#### Sensitivity Analysis

During the financial year the company had a principal foreign currency transaction risk exposure to the US dollar. Assuming all other variables remain constant, an appreciation in the Australian dollar is advantageous to the consolidated entity as foreign currencies are required to be purchased from Australian dollars to pay for a key component of the clinical program.

For the consolidated entity, a 5% appreciation of the Australian dollar against the US currency would have increased profit and loss and equity by \$76,336 for the year ended 30 June 2008 (a loss of \$31,619 would have occurred for the corresponding period in the prior year), on the basis that all other variables remain constant. 5% is considered representative of the market volatility in the Australian/US dollar rate for the period.

For the consolidated entity, a 5% depreciation of the Australian dollar against the US currency would have an

equal but opposite effect to the above, on the basis that all other variables remain constant.

For Clinuvel Pharmaceuticals Ltd, a 5% appreciation of the Australian dollar against the US currency would have increased profit and loss and equity by \$78,101 for the year ended 30 June 2008 (a loss of \$26,718 would have occurred for the corresponding period in the prior year), on the basis that all other variables remain constant. 5% is considered a reflection of the market volatility in the Australian/US dollar rate for the period.

For Clinuvel Pharmaceuticals Ltd, a 5% depreciation of the Australian dollar against the US currency would have an equal but opposite effect to the above, on the basis that all other variables remain constant.

The Group's exposure to other foreign currency movements is not considered material.

### Interest Rate Risk

The consolidated entity holds floating interest bearing assets therefore exposure to interest rate risk exists. It does not hold interest bearing liabilities.

The consolidated entity currently finances its operations through reserves of cash and liquid resources and does not have a borrowing requirement. In order to be protected from, and to take advantage of, interest rate movements it is the consolidated entity's policy to place cash into deposits and other financial assets at both fixed and variable (floating) rates. The Board monitors the movements in interest rates in combination with current cash requirements to ensure the mix and level of fixed and floating returns is in the best interests of the consolidated entity.

### Sensitivity Analysis

For the consolidated entity, at 30 June 2008, if interest rates had changed by +/- 100 basis points from the year-end rates (a movement considered reflective of the level of recent interest rate movements), with effect from the beginning of the year, profit and equity would be \$592,772 higher/lower (2007: \$347,113 higher/lower) This analysis assumes all other variables are held constant.

For Clinuvel Pharmaceuticals Ltd, at 30 June 2008, if interest rates had changed by +/- 100 basis points from the year-end rates (a movement considered reflective of the level of recent interest rate movements), with effect from the beginning of the year, profit and equity would be \$587,137 higher/lower (2007: \$346,949 higher/lower) This analysis assumes all other variables are held constant.

### Price Risk

Clinuvel Pharmaceuticals Ltd and its consolidated entities are exposed to price risk in its investments in income securities classified in the balance sheet as held for trading. Diversification of its investments is used to manage price risk. Neither the consolidated entity nor the parent are exposed to commodity price risk

### Sensitivity Analysis

At 30 June 2008, if the weighted average of the market-acknowledged benchmarks of the investments in income securities increased/decreased by 7.6% assuming all other variables constant and the investments in securities moving in correlation with the indexes, the impact on profit and equity is:

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2008	2007	2008	2007
	\$	\$	\$	\$
Market-acknowledged weighted average benchmarks	2,369,982	1,548,121	2,369,982	1,548,121

The price risk for unlisted income securities is included in the sensitivity analysis due to higher than normal market volatility for most of the financial year.

### Credit Risk

Credit risk arises from the potential failure of counterparties to meet their contractual obligations, resulting in a loss to the consolidated entity.

Credit risk in relation to the consolidated entity is the cash and cash equivalents deposited with banks and investments in securities. Exposure to credit risk is limited to the investing of surplus cash in a range of senior debt securities and listed floating rate notes issued by counterparties deemed creditworthy by ratings

agencies (majority A rated minimum) and/or ASX Top 50. Portfolio managers engaged in the management of the investments in securities on behalf of Clinuvel continually assess the credit worthiness of the counterparties who report to Clinuvel of any change in credit risk.

The maximum credit exposure is the carrying value of the cash and cash equivalents deposited with banks and investments in securities.

## Liquidity Risk

Liquidity risk is the risk the consolidated entity will not be able to meet its financial obligations when they fall due. It is the policy of the consolidated entity to ensure there is sufficient liquidity to meet its liabilities when due without incurring unnecessary loss or damage. The consolidated entity holds cash and instruments in liquid markets. It does not hold financing facilities, overdrafts or borrowings.

The consolidated entity manages its liquidity needs by carefully identifying expected operational expenses by month and ensuring sufficient cash is on hand, across appropriate currencies, in the day-to-day bank accounts for a minimum 30 day period. When further liquidity is required the consolidated entity draws down on its cash under management and/or projects future liquidation of its investments in securities to service future liquidity needs.

## Contractual maturities of financial liabilities as at 30 June 2008

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2008	2007	2008	2007
	\$	\$	\$	\$
Trade and Other Payables				
Carrying Amount	3,331,954	2,315,298	3,260,154	2,262,080
6 months or less	3,331,954	2,315,298	3,260,154	2,262,080
Greater than 6 months	0	0	0	0
<b>Total</b>	<b>3,331,954</b>	<b>2,315,298</b>	<b>3,260,154</b>	<b>2,262,080</b>

## Fair Value Estimation

The fair value of financial assets and financial liabilities must be estimated for recognition and measurement for disclosure purposes.

The fair value of financial instruments traded in active markets is based on quoted market prices at reporting date. The quoted market price for the consolidated entity is the bid price. For longer term debt instruments held by the consolidated entity, dealer quotes are used to determine fair value.

The carrying value of trade payables are assumed to approximate their fair values due to their short-term nature.

## Capital Risk Management

Clinuvel Pharmaceuticals Ltd's equity is limited to shareholder contributions. Its capital management objectives is limited to ensuring the equity available to the company will allow it to continue as a going concern and to realise adequate shareholder return by progressing in its developmental research of afamelanotide and achieving eventual commercialization.

**23. Employee Benefits**

	<b>Consolidated</b>		<b>Clinuvel Pharamceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
The aggregate employee benefit liability is comprised of :				
Provision for annual leave	178,576	112,890	168,959	111,125
Provision for long service leave	9,310	4,741	9,310	4,741
Accrued FBT & Superannuation	24,756	45,415	32,561	45,415
	<b>222,642</b>	<b>163,046</b>	<b>210,830</b>	<b>161,281</b>

**a) Share Based Payments**

The consolidated entity has ownership based scheme for key management personnel and select consultants (including Executive Directors) of the company. Each share option converts to one ordinary share of the consolidated entity. The options are issued for nil consideration. There are no voting rights attached to the option and they can be exercised any time from the date of vesting to the date of expiry. They are non-transferable and not listed on the ASX.

The number of options granted is subject to approval by the Remuneration and Nomination Committee and by shareholders at general meetings. Each series of options have specific terms and conditions, from 12 month restriction periods for the number of options to vest, to monthly restriction periods over 48 months, and to the satisfaction of performance objectives set by the Directors of the consolidated entity.

**The following share based payment arrangements were in existence at 30 June 2008:**

<b>Options Series</b>	<b>Number</b>	<b>Grant date</b>	<b>Expiry Date</b>	<b>Exercise Price</b>	<b>Fair Value at Grant Date</b>
Issued 10/11/2003	750,000	10/11/2003	31/12/2007	\$0.74	\$0.51
Issued 01/01/2004	125,000	01/01/2004	01/01/2008	\$0.66	\$0.44
Issued 01/01/2005	86,660	01/01/2005	31/12/2007	\$0.90	\$0.58
Issued 13/03/2003	500,000	13/03/2003	02/02/2008	\$0.16	\$0.10
Issued 25/07/2003	500,000	25/07/2003	13/06/2008	\$0.29	\$0.27
Issued 19/04/2004	300,000	19/04/2004	18/04/2009	\$0.87	\$0.57
Issued 31/10/2005	1,500,000	31/10/2005	01/11/2009	\$0.34	\$0.19
Issued 01/03/2005	500,000	01/03/2005	28/02/2010	\$0.75	\$0.52
Issued 23/02/2006	1,500,000	23/02/2006	31/03/2010	\$0.50	\$0.01
Issued 09/02/2007	19,210,000	09/02/2007	09/02/2012	\$0.86	\$0.22
Issued 03/08/2007	110,000	03/08/2007	03/08/2012	\$0.86	\$0.21

**Option holdings of All Issued Options- 2008**

Options Series	Balance at Start of Year	Granted as Compensation	Exercised	Other Changes	Balance at End of Year	Vested and Exercisable	Unvested
Issued 10/11/2003	750,000	-	-	(750,000)	-	-	-
Issued 01/01/2004	125,000	-	-	(125,000)	-	-	-
Issued 01/01/2005	86,660	-	-	(86,660)	-	-	-
Issued 13/03/2003	500,000	-	(500,000)	-	-	-	-
Issued 25/07/2003	500,000	-	(500,000)	-	-	-	-
Issued 19/04/2004	300,000	-	-	-	<b>300,000</b>	300,000	-
Issued 23/02/2006	1,500,000	-	-	-	<b>1,500,000</b>	750,000	750,000
Issued 01/03/2005	500,000	-	-	-	<b>500,000</b>	330,000	170,000
Issued 31/10/2005	1,500,000	-	-	-	<b>1,500,000</b>	500,000	1,000,000
Issued 09/02/2007	19,210,000	-	-	(3,500,000)	<b>15,660,000</b>	8,446,458	7,213,542
Issued 03/08/2007	-	110,000	-	-	<b>110,000</b>	110,000	-

The weighted average fair value of the options granted during the financial year was \$0.35.

Options were priced using the Black Scholes Binominal option pricing model. The expected life used in the model is assumed to be the midpoint between the vesting date and exercise date. Expected volatility of each share option is based on the historical share price for the same length of time for the expected life of the options. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the option pricing model is assumed to be the zero coupon interest rate on valuation date.

**Black Scholes Binominal Model**

Inputs	Options Issued & granted 3 Aug 2007
Grant Date Share Price	\$0.79
Exercise Price	\$0.86
Grant Date	3 August 2007
Expiry Date	3 August 2012
Historical Volatility (weighted average)	24.7%
Option Life (weighted average)	2.7 years
Risk Free Interest Rate	6.40%

	2008		2007	
	Number of Options	Weighted average exercise price	Number of Options	Weighted average exercise price
Balance at beginning of year	4,821,660	\$0.71	2,886,660	\$0.41
granted	110,000	\$0.86	2,810,000	\$0.86
forfeited	(661,660)	\$0.85	-	-
exercised	(1,000,000)	\$0.23	(875,000)	\$0.18
Balance at end of year	3,270,000	\$0.79	4,821,660	\$0.71
Exercisable at end of year	1,826,458	\$0.78	2,458,327	\$0.58

The share options for Executives outstanding at the end of the financial year had an exercise price of \$0.79 and an average remaining contractual life of 920 days.

**24. Commitments Of Expenditure**

	<b>Consolidated</b>		<b>Clinuvel Pharmaceuticals Ltd</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
<b>a) Research commitments</b>				
AU Dollars	76,921	-	76,921	-
US Dollars	363,599	385,590	363,599	385,590
Euro	1,230,315	1,188,401	1,230,315	1,188,401
British Pounds	24,535	77,904	24,535	77,904
<b>Total</b>	<b>1,695,370</b>	<b>1,651,895</b>	<b>1,695,370</b>	<b>1,651,895</b>
<b>b) Other expenditure commitments</b>				
AU Dollars	30,000	49,500	30,000	49,500
US Dollars	-	-	-	-
Euro	-	-	-	-
British Pounds	-	-	-	-
<b>Total</b>	<b>30,000</b>	<b>49,500</b>	<b>30,000</b>	<b>49,500</b>
<b>Total</b>	<b>1,725,370</b>	<b>1,701,395</b>	<b>1,725,370</b>	<b>1,701,395</b>

Australian dollar equivalents of commitments for expenditure. Foreign currency amounts are unhedged.

**25. Subsequent Events**

There have not been any matters financial in nature, other than reference to the financial statements that has arisen since the end of the financial year that has affected or could significantly affect the operations of the consolidated entity.

**28. Additional Company Information**

Clinuvel Pharmaceuticals Ltd is a listed public company incorporated and operating in Australia.

**The Registered office is:**

Level 11,  
330 Collins Street  
Melbourne VIC 3000  
Ph: (03) 9660 4900



# Directors' Declaration

In the opinion of the Directors:

1. The financial statements and notes of the company and of the consolidated entity, set out in pages 23 to 68, are in accordance with the Corporations Act 2001, including:

a) giving a true and fair view of the company's and the consolidated entity's financial position as at 30 June 2008 and of their performance for the year ended on that date; and

b) complying with Accounting Standards and the Corporations Regulations 2001.

2. There are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

3. The remuneration disclosures set out in pages 26 to 34 of the Annual Report comply with Australian Accounting Standards 124 Related Party Disclosures and the Corporations Regulations 2001.

This declaration is made in accordance with a resolution of the Board of Directors. The Directors have been given the declarations by the Chief Executive Officer and Chief Financial Officer required by Section 295A of the Corporations Act 2001.



Dr. Philippe Wolgen MBA MD

Director

Dated this 16<sup>th</sup> day of September, 2008



Grant Thornton  
ABN 13 871 256 387

Level 2  
215 Spring Street  
Melbourne  
Victoria 3000  
GPO Box 4984WW  
Melbourne  
Victoria  
3001

**T** +61 3 8663 6000  
**F** +61 3 8663 6333  
**E** [info@grantthorntonvic.com.au](mailto:info@grantthorntonvic.com.au)  
**W** [www.grantthornton.com.au](http://www.grantthornton.com.au)

## **INDEPENDENT AUDITOR'S REPORT**

### **To the members of Clinuvel Pharmaceuticals Limited**

#### **Report on the Financial Report**

We have audited the accompanying financial report of Clinuvel Pharmaceuticals Limited, (the company) which comprises the balance sheet as at 30 June 2008, and the income statement, statement of changes in equity and cash flow statement for the year ended on that date, a summary of significant accounting policies, other explanatory notes and the directors' declaration of the consolidated entity comprising the company and the entities it controlled at the year's end or from time to time during the financial year.

#### **Directors' Responsibility for the Financial Report**

The directors of the company are responsible for the preparation and fair presentation of the financial report in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001*. This responsibility includes establishing and maintaining internal controls relevant to the preparation and fair presentation of the financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances. In Note 1, the directors also state, in accordance with Accounting Standard AASB 101 *Presentation of Financial Statements*, that compliance with the Australian equivalents to International Financial Reporting Standards ensures that the financial report, comprising the financial statements and notes, complies with International Financial Reporting Standards.

**Auditor's Responsibility**

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. These Auditing Standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions.

**Electronic Presentation of Audited Financial Report**

This auditor's report relates to the financial report of Clinuvel Pharmaceuticals Limited for the year ended 30 June 2008 included on Clinuvel Pharmaceuticals Limited's web site. The company's directors are responsible for the integrity of the Clinuvel Pharmaceuticals Limited's web site. We have not been engaged to report on the integrity of the Clinuvel Pharmaceuticals Limited's web site. The auditor's report refers only to the statements named above. It does not provide an opinion on any other information which may have been hyperlinked to/from these statements. If users of this report are concerned with the inherent risks arising from electronic data communications they are advised to refer to the hard copy of the audited financial report to confirm the information included in the audited financial report presented on this web site

**Independence**

In conducting our audit, we complied with applicable independence requirements of the *Corporations Act 2001*.

**Auditor's Opinion**

In our opinion:

- a the financial report of Clinuvel Pharmaceuticals Limited is in accordance with the *Corporations Act 2001*, including:
  - i giving a true and fair view of the company's and consolidated entity's financial position as at 30 June 2008 and of their performance for the year ended on that date; and
  - ii complying with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Regulations 2001*; and
- b the financial report also complies with International Financial Reporting Standards as disclosed in Note 1.

**Report on the Remuneration Report**

We have audited the Remuneration Report included in pages 26 to 33 of the directors' report for the year ended 30 June 2008. The directors of the company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

**Auditor's Opinion**

In our opinion the Remuneration Report of Clinuvel Pharmaceuticals Limited for the year ended 30 June 2008, complies with section 300A of the *Corporations Act 2001*.



GRANT THORNTON  
Chartered Accountants



D. A. Ashmore  
Partner

Melbourne, 18 September 2008



Grant Thornton  
ABN 13 871 256 387

Level 2  
215 Spring Street  
Melbourne  
Victoria 3000  
GPO Box 4984WW  
Melbourne  
Victoria  
3001

**T** +61 3 8663 6000  
**F** +61 3 8663 6333  
**E** [info@grantthorntonvic.com.au](mailto:info@grantthorntonvic.com.au)  
**W** [www.grantthornton.com.au](http://www.grantthornton.com.au)

**AUDITOR'S INDEPENDENCE DECLARATION  
TO THE DIRECTORS OF CLINUVEL PHARMACEUTICALS LIMITED**

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of Clinuvell Pharmaceuticals Limited for the year ended 30 June 2008, I declare that, to the best of my knowledge and belief, there have been:

- a No contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the audit; and
- b No contraventions of any applicable code of professional conduct in relation to the audit.

A stylized, handwritten signature in blue ink that reads "Grant Thornton".

GRANT THORNTON  
Chartered Accountants

A stylized, handwritten signature in blue ink, likely belonging to D. A. Ashmore.

D. A. Ashmore  
Partner

Melbourne, 18 September 2008

# Additional Information Required By The Australian Stock Exchange (ASX)

Additional information, as at 19 September 2008, required by the ASX and not shown elsewhere in this report is as follows:

## 1. Shareholding

<b>a) Distribution of Shareholders Numbers</b>	
<b>Category (size of holding)</b>	<b>Total Holders</b>
1 – 1,000	336
1,001 – 5,000	1,208
5,001 – 10,000	727
10,001 – 100,000	1,267
100,001 – 9,999,999,999	202
<b>Total</b>	<b>3,740</b>

b) The number of shareholdings held in less than marketable parcels is 586 For ordinary shares.

c) The names of the substantial shareholders listed in the holding company's register as at 19 September 2008 are:  
JM Financial Group Limited

d) Voting Rights

Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the company.

e) 20 Largest Shareholders – Ordinary Shares

Position	Name	Number of Ordinary Fully Paid Shares Held	% Held of Issued Ordinary capital
1	ANZ NOMINEES LIMITED CASH INCOME A/C	79,259,489	26.15
2	CITICORP NOMINEES PTY LIMITED	21,008,308	6.93
3	SANDHURST TRUSTEES LTD JMFG CONSOL A/C	17,177,133	5.67
4	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	14,009,881	4.62
5	NATIONAL NOMINEES LIMITED	10,225,482	3.37
6	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	8,651,742	2.85
7	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSI ECSA	7,329,115	2.42
8	LOUGHRAN & CO	6,936,336	2.29
9	BOODUP NOMINEES PTY LTD	5,720,300	1.89
10	UBS NOMINEES PTY LTD	4,738,500	1.56
11	J P MORGAN NOMINEES AUSTRALIA LIMITED	4,517,428	1.49
12	WEIGHTON PTY LTD	3,917,487	1.29
13	HEADSTART GLOBAL HOLDINGS LTD	2,733,553	0.90
14	SANDHURST TRUSTEES LTD JM ASSET MANAGEMENT A/C	2,255,210	0.74
15	ARMADA TRADING PTY LTD	2,000,000	0.66
16	JAGEN NOMINEES PTY LTD	2,000,000	0.66
17	BOURNE NOMINEES PTY LTD	1,850,000	0.61
18	UBS WEALTH MANAGEMENT AUSTRALIA NOMINEES PTY LTD	1,605,870	0.53
19	TERSTAN NOMINEES PTY LTD	1,555,222	0.51
20	SANDHURST TRUSTEES LTD JM MPS A/C	1,445,000	0.48
		<b>198,936,056</b>	<b>65.62</b>



## **2. Company Secretary**

The name of the company secretary is:  
Darren Keamy

## **3. Registered Office**

The address of the principal registered office in Australia is:

Level 11, 330 Collins Street,  
Melbourne, Victoria, 3000, Australia.  
Telephone (03) 9660 4900.

## **4. Register of Securities**

Computershare Investor Services Pty Ltd,  
Yarra Falls,  
453 Johnson Street  
Abbotsford, Victoria, 3000, Australia.

## **5. Stock Exchange Listing**

Quotation has been granted for all the ordinary shares of the company on all Member Exchanges of the Australian Stock Exchange Limited  
(ASX code: CUV).

## **6. Restricted Securities**

Restricted securities on issue at 30 June 2008:  
Nil

# Corporate Directory

## Directors and Executives

### Executive Chairman:

Brenda Shanahan

### Non-Executive Directors:

Stanley McLiesh, Dr. Roger Aston, Jack Wood.

### Managing Director and Chief Executive Officer:

Dr. Philippe Wolgen

### Chief Scientific Officer, Director:

Dr. Helmer Agersborg

### Manager Regulatory Affairs:

Dr. Dennis Wright

### Group Accountant and Company Secretary:

Darren Keamy

### Head of Corporate Development:

Colin Mackie

## Australian Stock Exchange

The company's shares are quoted on the official list of the Australian Stock Exchange:  
ASX Code: CUV

The company's shares are also quoted on other international exchanges as follows:  
Germany: Frankfurt and Xetra: UR9  
USA: Level 1 American Depositary Receipt Code: CLVLY  
ADR Custodian: Bank of New York Mellon

## Share Registry:

### Computershare

Yarra Falls, 452 Johnston Street  
Abbotsford, Victoria 3067, Australia  
Tel: +61 3 9415 4000

## Auditor

### Grant Thornton

Level 2, 215 Spring Street  
Melbourne, Victoria 3000, Australia

## Banker

### National Australia Bank

Western Branch, 460 Collins Street  
Melbourne, Victoria 3000, Australia

## Legal Counsel

### Australia – Arnold Bloch Leibler

Level 21, 333 Collins Street  
Melbourne, Victoria 3000, Australia

## IP Lawyer

### Dipl.-Ing. Peter Farago

Baadestr. 3  
Munich 80469  
Germany

# Clinuvel Photoprotection



Level 11 / 330 Collins Street  
Melbourne, Victoria 3000  
Telephone +61 3 9660 4900 Facsimilie +61 3 9660 4999  
[www.clinuvel.com](http://www.clinuvel.com)