Clinuvel Photoprotection

Annual Report 2009

Glossary

Albedo
Reflectance of solar radiation by the surroundings. This applies to the full integrated spectrum; the reflectance may depend strongly on the spectral region.

Action spectrum
Efficiency of monochromatic radiations for producing a specified actinic event in a specified system. For instance, specific wavelength and intensity of light causing acute dermal reactions in solar urticaria (SU).

α-MSH
Alpha-Melanocyte Stimulating Hormone is a peptide hormone which stimulates the production of (eu)melanin in the skin (melanogenesis).

Direct solar radiation
The part of extraterrestrial solar radiation which, as a collimated beam, reaches the earth's surface after selective attenuation by the atmosphere.

EMEA
The European Medicines Evaluation Agency is a decentralised body of the European Union regulating medical drugs and devices.

Erythema (actinic-solar)
Reddening of the dermis (the top layer of skin), with or without inflammatory component, caused by the actinic effect of solar radiation or wavelengths of light by artificial optical radiation (source).

Eumelanin
A black or brown pigment mainly concerned with the protection of the skin by absorbing incoming UV radiation. This protective ability warrants melanin to be termed a photoprotectant (a substance capable of providing protection against radiation from the sun). α-MSH acts specifically to stimulate (eu)melanin synthesis.

FDA
Food and Drug Administration, the USA's regulatory agency for food, medical drugs and devices.

Fitzpatrick Scale
A numerical classification schema that classifies the response of different types of skin to UV light.

Fitzpatrick type I - white unpigmented skin, always burns;
Fitzpatrick type II - white unpigmented skin, usually burns;
Fitzpatrick type III - olive pigmented skin, sometimes mild burns;
Fitzpatrick type IV - brown pigmented skin, rarely burns;
Fitzpatrick type V - dark brown pigmented skin, seldom burns;
Fitzpatrick type VI - black pigmented skin, never burns.

Immunocompromised
Having an immune system that has been impaired by disease or treatment, such as immunosuppressive drugs used to prevent organ rejection in transplant patients.

Immunomodulatory
Changes to the level of a person's immunity.

IPD or Immediate Pigmenting Dose
The amount of UV required to stimulate immediate pigmentation change.

Melanin
The dark pigment synthesised by melanocytes; responsible for skin pigmentation.

Melanocytes
The cells in the skin that produce melanin.

Melanogenesis
The process whereby melanin is produced in the body.

Minimum Erythema Dose (MED)
The actinic dose that produces a just noticeable erythema on normal, non-exposed, "fair" skin. The quantity usually corresponds to a radiant exposure of monochromatic (=1 wavelength) radiation at the maximum spectral efficiency (λ=295 nm) of approximately 100 J/m^2.

PBS
Australian Pharmaceutical Benefits Scheme.

Pheomelanin
A reddish pigment, a very weak absorptive of UV radiation. It also acts as a photosensitiser (makes your skin sensitive to light), where it increases sun sensitivity and skin ageing.

Phase I
The first trials of a new drug candidate in humans, Phase I trials are designed to evaluate how a new drug candidate should be administered, to identify the highest tolerable dose and to evaluate the way the body absorbs, metabolises and eliminates the drug.

Phase II
A Phase II trial is designed to continue to test the safety of the drug candidate, and begins to evaluate whether, and how well, the new drug candidate works (efficacy). Phase II trials often involve larger numbers of patients.

Phase III
An advanced-stage clinical trial that should conclusively demonstrate how well a therapy based on a drug candidate works. Phase III trials can be longer and typically much larger than Phase II trials, and frequently involve multiple test sites. The goal is statistically determining whether a therapy clinically improves the health of patients undergoing treatment.

Pharmacodynamics
The study of the time course of a drug's actions in the body.

Photodermatoses
Skin diseases caused by exposure to sunlight and UV.

Photoprotection
Protection from light and ultraviolet radiation. Melanin provides natural photoprotection to skin, whilst sunscreens provide artificial photoprotection.

Pharmacokinetics
The part of pharmacology that studies the release and availability of a molecule and drug in the human body.

Subcutaneous
Underneath the skin.

Sustained release
Process whereby a drug is released from a formulation over a period of time.

Thymine dimers
DNA changes which are characteristic of UV damage.

TGA
Therapeutic Goods Administration, Australia's regulatory agency for medicinal products and devices.

Topical
Cream, gel or spray applied to the skin.

Transdermal
Through the unbroken skin. Medications applied directly to the skin (creams, ointments or sprays) or in release forms (patches) with the aim to cause the active agent to be absorbed. Also known as transdermic, percutaneous or transcutaneous.

UV
Part of the electromagnetic spectrum at wavelengths below 400 nanometers, also called the invisible portion of light.
There are three sub-types of UV:
UVC <280 nm; UVB 280 – 320 nm; UVA 320 – 400 nm.

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Clinuvel: Australia's Photoprotective Company

The relationship between human health and ultraviolet (UV) radiation is paradoxical: we need UV to survive, but too little or too much has an adverse effect on our health and wellbeing.

The debate about vitamin D and sun exposure has played out in academic and mainstream press in recent years as we openly discuss the benefits of light exposure. Vitamin D levels are essential for maintenance of healthy bone structure and, more recently, deficiency of vitamin D has been linked with various cancers and seasonal affective disorder (SAD). To synthesise vitamin D humans need to expose themselves to light; more specifically UVB and UVA.

The question of how much UV one should receive has led to studies in UV dose and intensity to human skin. It is well known that insufficient constitutive pigmentation of the skin makes one more prone to damage from UVB and UVA, causing short-term sunburn and a long-term increase in the risk of skin cancer and skin disorders. We also now recognise that sunburn at a young age increases the probability of melanoma and non-melanoma skin cancers, Squamous Cell Carcinoma (SCC) and Basal Cell Carcinoma (BCC).

More recently, both UVA (emitted light at wavelengths between 320-400nm) and UVB (emitted light between 280-320nm), which constitute 95% of the UV radiation affecting life, have been identified as possible direct contributors to SCC, BCC and melanoma skin cancer. This link has led the World Health Organisation (WHO) to classify UV radiation as "carcinogenic to humans".[1]

In Australia, the relationship between the light and life is better understood than anywhere. UV conditions in Australia are amongst the harshest in the world: we regularly see the UV index reach 'extreme' levels in the summer months, even in cooler, southern cities such as Melbourne and Hobart.

"2 in 3 Australians will be diagnosed with skin cancer by the age of 70"

Yet Australians lead outdoor lifestyles, enjoying the benefits of a life in the sun whilst exposing us to this unforgiving environment in the summer months. While the clichéd bronzed Australian life saver on Bondi may no longer be the Australian ideal, it is common for our beaches and sporting fields to be busy on sunny summer days.

As a result, 2 in 3 Australians will be diagnosed with skin cancer by the age of 70[2]; over 1,600 Australians die from skin cancer annually (causing around 1% of all deaths).[3] Melanoma has been dubbed "our national cancer" by government organisations established to increase awareness of the risks of UV and reduce the incidence of skin cancer in the population.

Collectively, Australia has responded to environmental risks posed by UV. Each year, federal and state

governments and not-for-profit cancer councils spend millions of dollars re-enforcing the Sunsmart message and encouraging Australians to respect the threat posed by the sun. From childhood, Australians have been taught the message of "slip on a shirt, slop on some sunscreen and slap on a hat" and, recently, these messages have been expanded to include "seek out shade and slide on some sunglasses".

"Slip slop slap" has had an effect. Most primary school children (aged 5-12) are not permitted outside, even in the middle of winter, without wearing wide brimmed protective hats. Sunscreen is a permanent fixture in classrooms and workplaces. Solariums, recently declared carcinogenic by the WHO, have been regulated in most parts of the country in attempts to curb skin cancer rates, particularly in young women.

"To date, approximately 500 patients have been safely administered afamelanotide..."

Nowhere else in the world is the need for protection from UV and light, in other words medicinal photoprotection, so acute. In Australia, we understand, appreciate and respect light and UV.

For more than a decade, Clinuvel has been developing its photoprotective first-in-class drug, afamelanotide, in Australia.

The drug product has been refined and the safest, most effective formulation – a subcutaneous, controlled release implant – has been developed and tested. To date, approximately 500 patients have been safely administered afamelanotide, a safety profile we aim to maintain throughout our program.

Our research to date has shown that afamelanotide provides medicinal photoprotection to patients who are most severely affected by light and UV; patients who lack natural photoprotection from skin pigment (melanin) and effective treatment options.

Clinuvel aims to prove that afamelanotide can assist these patients by providing a biological barrier between skin and light; a layer of melanin which can reflect, refract and absorb light before it causes damage.

The global team at Clinuvel has worked to identify leaders in the fields of photodermatology, photobiology, haematology, oncology and beyond to partner in our trials, while adhering to the stringent guidelines of regulators worldwide.

In the next 12 months the Clinuvel team aims to finalise the first regulatory dossier on afamelanotide to be presented to the European Medicines Agency (EMEA). The filing will mark a major achievement for Australia's photoprotective company.

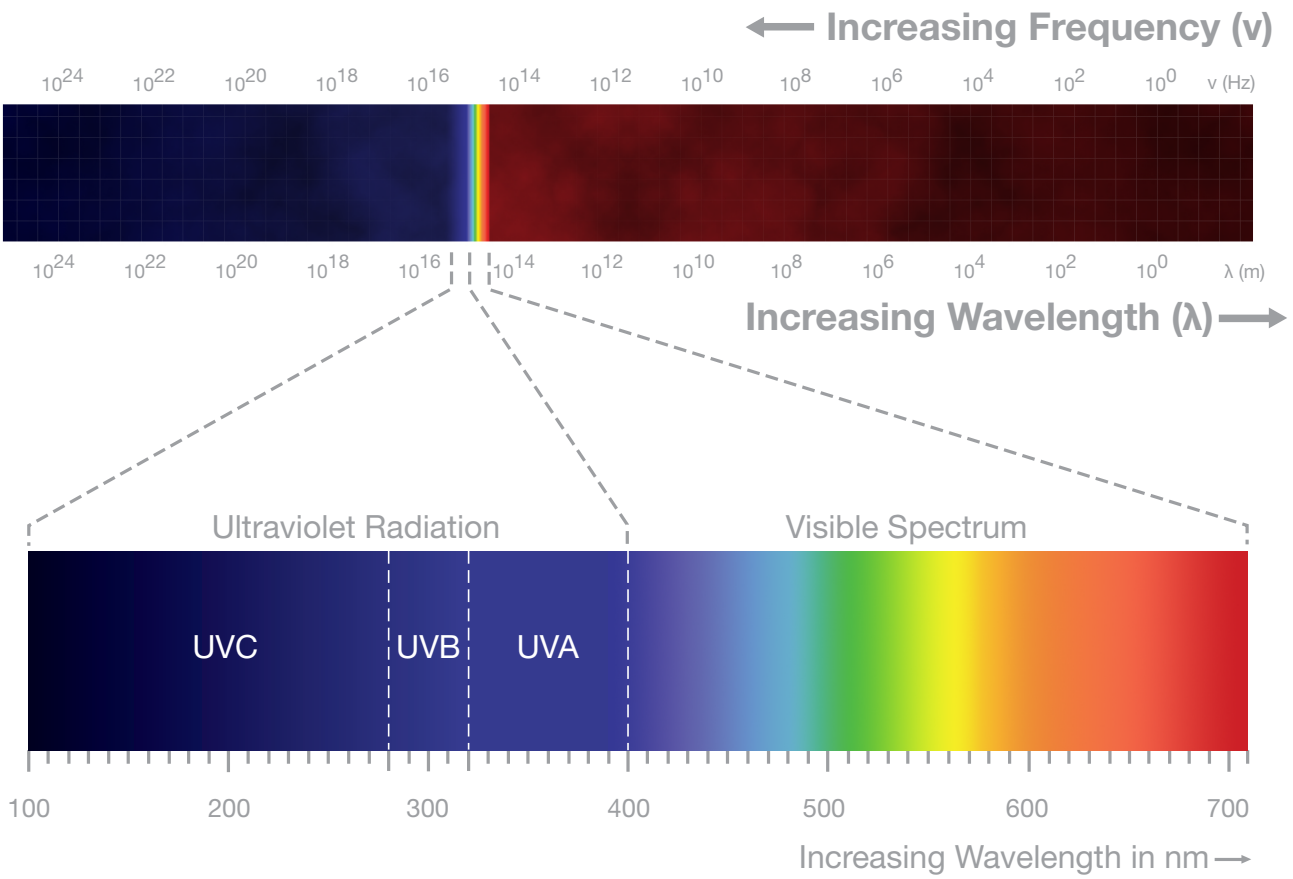
[1] El Ghissassi, F, et al (2009). "A review of human carcinogens—Part D: radiation." *The Lancet Oncology*; 10:8, 751-752.

[2] Staples, M, et al (2006). "Non-melanoma skin cancer in Australia: the 2002 national survey and trends since 1985." *Medical Journal of Australia*; 184, 6-10.

[3] Australian Institute of Health and Welfare (2005). *States & territories GRIM (General Record of Incidence of Mortality) Books*. Canberra: AIHW.

Stochastic Effects Of UV And Light

UV And Visible Light In The Electromagnetic Spectrum



The debate about thinning of the ozone layer and environmental factors threatening human existence was sparked in 1968 by Aurelio Pecci, the founder of the Club of Rome. He pointed at the dangers of environmental changes and their effects long-term to human health. Since then, the accords of Montreal and Kyoto led to the curbing of the use of chlorofluorocarbons, with an eye to improve the ozone status. However the discussion on ozone and global warming have far from subsided. The real question remains the immediate or long-term effect of ozone and global warming on human biology.

Clinuvel's global scientific team focuses on these effects and works to mitigate and reduce the effects of UV and visible light on human skin.

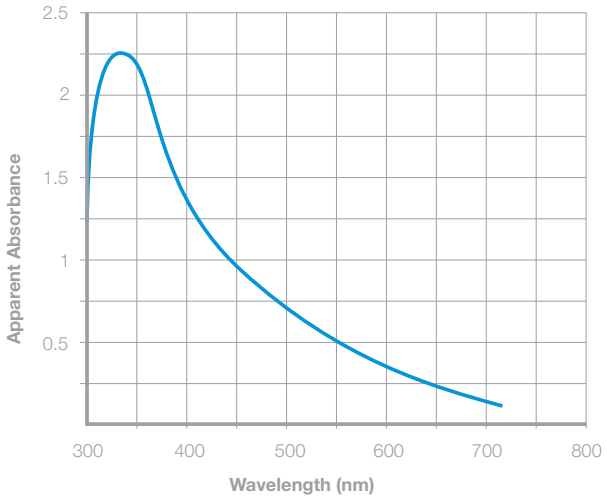
The spectrum of radiation affecting life depends on the content of water, CO_2, oxygen in air and stratospheric ozone. Diffuse and scattered (Rayleigh and Mie) radiation from the sun and indirect ground reflection determine terrestrial irradiation. The relevance of data are frequently related to geography and latitude. As a percentage of the radiation travelling through the atmosphere is expressed in air mass, standardisation often occurs in modelling the effects of radiation: on a clear day in January in Melbourne (Australia) at zero zenith angle, the global radiation is set at 1120 W/m^2 at ground level. The radiation reaching Melbourne (sea level) on this day is reflected in the Air Mass 1 Direct (AM 1D). Tolerated dose is then a function of length of time, intensity and biological response mechanism. The

Clinuvel teams works towards quantification of dose and response in human skin affected by, and most at risk to, UV damage.

The stochastic effects (probability assessments of skin diseases and cancer) of long-term exposure to UVA and UVB at different latitudes are being evaluated in the context of Clinuvel's development of the photoprotective drug, afamelanotide. Where in vivo studies dosing of 0.01 to 0.105 mJ/cm^2 is used, in phototesting of human skin a range from 0.0018 to 113 J/cm^2 is being used under polychromatic conditions to provoke similar symptoms as patients experience under ambient conditions. Phototesting of human skin is being used under polychromatic conditions to provoke symptoms similar to those patients experience under ambient conditions.

Absorbance of UV and visible light by tissue (skin) is measured following activation of melanin by Clinuvel's proprietary drug afamelanotide. The biological response to UV is modelled and simulated through administration of physiological doses of afamelanotide. Under conditions approximating ambient exposure, dose response curves define the time to first symptoms in patients with various skin disorders and at high risk of photo carcinogenesis.

Absorption spectrum by melanin polymer in human skin

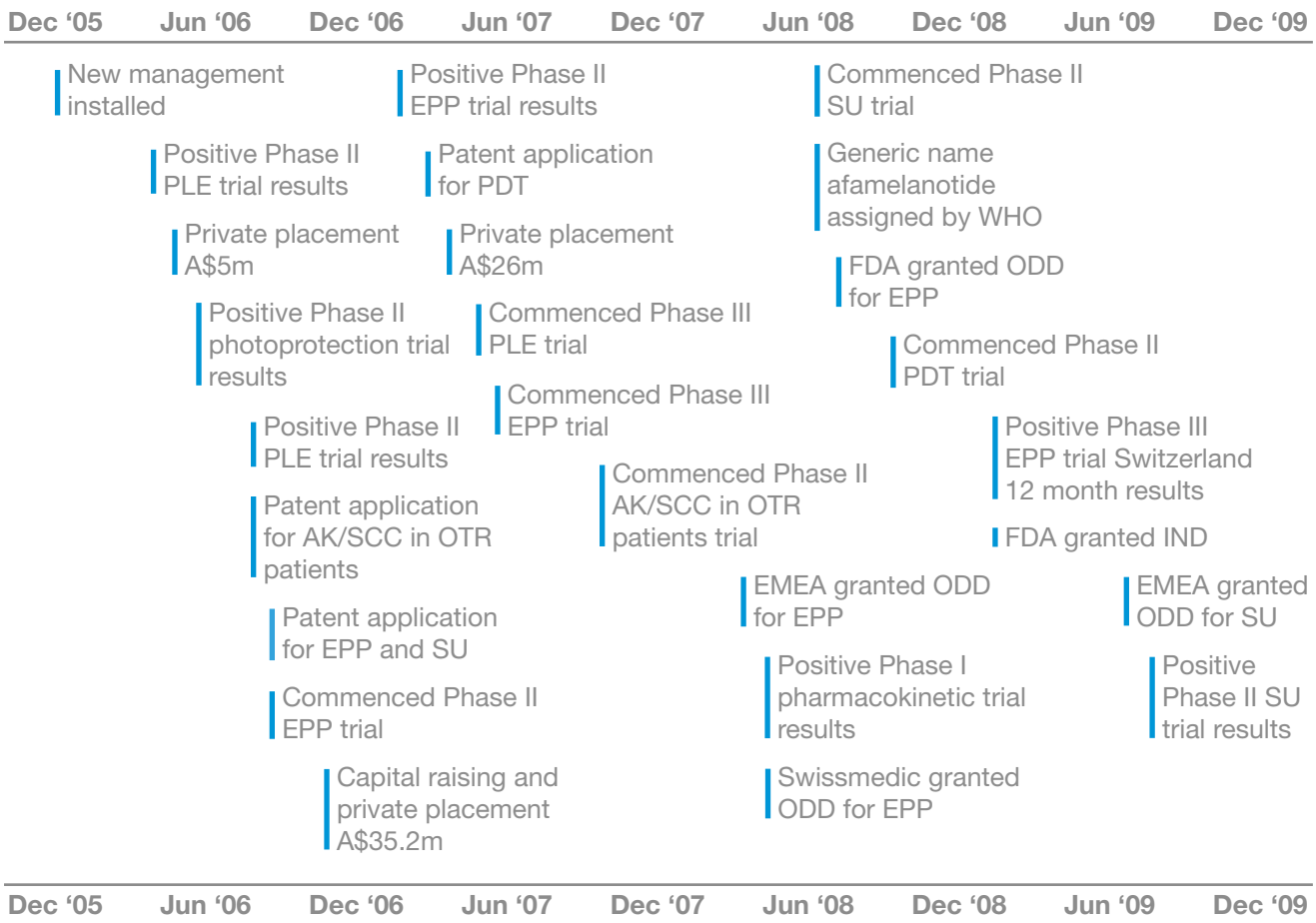


Kollas, N, (1995). "The spectroscopy of human melanin pigmentation". From Melanin: Its Role in Human Photoprotection. Overland Park: Valdenmar Publishing Co., pp31 - 38.

Recent quantitative data have consistently demonstrated the effective bands of photoprotection by afamelanotide specified per disease. The progress in quantifying dermal protection will be coupled to exposure time and risk profile per patient, and this will have substantial influence on product claims of afamelanotide.

Corporate Milestones

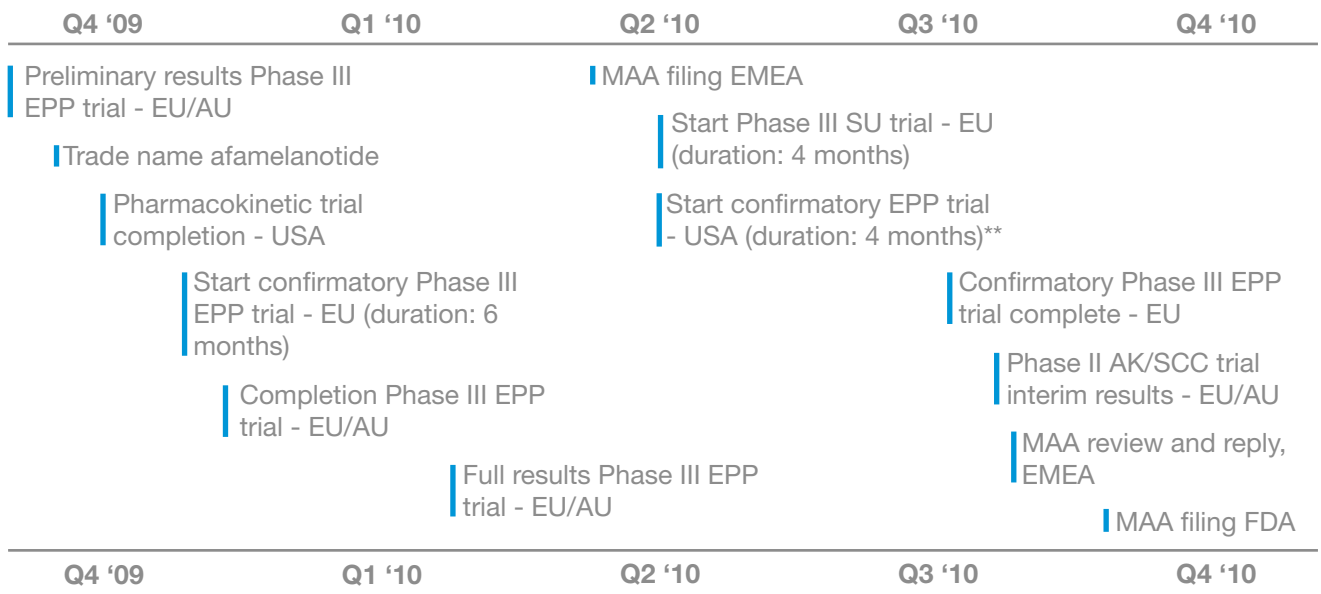
Company Milestones Since December 2005



AK/SCC:	Actinic Keratosis/Squamous Cell Carcinoma in Organ Transplant Recipients (OTRs) - Skin cancer in transplant patients
EMEA:	European Medicines Agency
EPP:	Erythropoietic Protoporphyria - Absolute sun/UV intolerance
FDA:	US Food and Drug Administration
MAA:	Marketing Authorisation Application
ODD:	Orphan Drug Designation
PLE:	Polymorphic Light Eruption - Severe sun/UV poisoning
PDT:	Photodynamic Therapy - Phototoxicity following cancer treatment
SU:	Solar Urticaria - Acute anaphylactic reaction to sun/UV
WHO:	World Health Organisation

*See p80 for full details of Clinuvel's current clinical indications.

Upcoming Regulatory And Clinical Milestones



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

**Pending FDA approval

Commercialising Afamelanotide

Commercialisation Overview

Afamelanotide is a synthetic analogue of the human hormone alpha-Melanocyte Stimulating Hormone. A proprietary drug to Clinuvel, afamelanotide is a first-in-class medicine. With the novelty of developing this drug comes a substantial corporate challenge: no other company worldwide has endeavoured to develop a drug to provide medicinal photoprotection to the skin aimed at patients who are deficient in their pigmentary response to UV and light. Clinuvel is breaking new ground and is gradually demonstrating in patients tested worldwide that this peptide may deserve a place in the clinic. As exemplified by the results, much progress has been made over the past four years and physicians and patients have responded well.

Since January 2006, Clinuvel has been able to identify six medical applications for afamelanotide, with a focus on developing the drug in the most severe indications. Exceptionally, the company is currently providing afamelanotide to clinics for the treatment of congenital erythropoietic porphyria (CEP) under 'compassionate use'.

During years of global pre-clinical and clinical development, the Clinuvel team has learned that afamelanotide could well serve a sizable population of patients who are most at risk of developing severe disease symptoms in spring and summer.

With strong regulatory support globally (multiple Orphan Drug Designations) Clinuvel's strategy is aimed at commercialising afamelanotide for those patients with the most acute clinical need to provide skin protection: erythropoietic protoporphyria (EPP), solar urticaria (SU) and - pending positive results - photodynamic therapy (PDT) are the priorities in development.

Depending on the final results from the Australian and European Phase III clinical trial in EPP (CUV017), Clinuvel aims to file afamelanotide for its first Marketing Authorisation Approval in Europe in early 2010.

As shown by the challenging deadlines imposed by the company, it is anticipated that sufficient data will be generated to demonstrate to pharmaceutical regulators that afamelanotide is safe, and of substantial clinical benefit. From patients' and physicians' response to date, a clear need for the drug has been identified.

Clinuvel's Clinical Development: Acute Need For Medicinal Photoprotection

Our belief is that the starting point in drug development ought to be to focus on the most acute disease(s) that a drug may address, in other words the most acute therapeutic need. Secondly, when starting a new development, one must find an answer to whether the proposed therapy has significant benefits over existing lines of treatment.

Once these questions were answered favourably, the Clinuvel team initiated the clinical and regulatory development of afamelanotide. Two patient groups most acutely affected by UV and light exposure to skin were identified. For these patients, suffering from porphyria (EPP) and solar urticaria (SU), an effective prophylactic drug would be of substantial clinical benefit.

EPP is characterised by a phototoxicity caused by the accumulation of a chemical substance in the skin, protoporphyrin IX (PPIX). When the skin is exposed to sun or light – specifically light at 408nm – PPIX is provoked and causes a chemical reaction resulting in internal skin damage and intolerable pain. Eventually, when light exposure is prolonged over minutes, these patients develop mutilating lesions and scarring, mainly on the face and hands. In EPP, afamelanotide offers the potential to reduce maximum severity of phototoxic reactions and reduce the total severity of phototoxic reactions during spring and summer months (Phase III Swiss 12-month results, January 2009). Thus far patient response has been positive, and upon completion of the Phase III trial in December, analysis of final results will provide us with the answer of safety and efficacy in this debilitating condition.

SU is a skin disorder marked by an acute allergic response following UV or sun exposure. Symptoms can be systemic, such as anaphylaxis, breathing difficulty, nausea and headaches. Immediate localised reactions vary from characteristic 'wheal' (angioedema) formation and erupting flares (diffuse erythema) on exposed skin sites, to swelling of soft tissues. In SU, the tolerance of the skin to light of

various wavelengths and intensities has been shown to increase following administration of afamelanotide (Phase II results, July 2009).

Regulatory Path-To-Market: Orphan Drug Designations

Over 5,000 rare diseases have been identified which have a severe impact upon the quality of life of patients. Legislation has been developed in various jurisdictions to provide incentives to pharmaceutical companies to develop products to address the clinical needs of patients suffering from these rare and severe diseases. This legislation has led to the development path of new drugs under the status of Orphan Drug Designation (ODD). The advantages of ODD vary according to jurisdiction, however the designation commonly provides financial and regulatory incentives for drug developers and, importantly, market exclusivity.

Clinuvel received orphan drug designation (ODD) in Europe, Switzerland and the US for EPP; and most recently was granted ODD in Europe by the European Medicines Agency (EMEA) for SU. The results and clinical feedback in combination with the lack of current therapies have led us to make EPP and SU our priority towards obtaining regulatory approval.

Milestones To Market

Clinuvel's lead Phase III trial for EPP will complete in the fourth quarter of 2009. Clinuvel intends to file afamelanotide for its first Marketing Authorisation Approval (MAA) in Europe shortly after the analysis of the results and, naturally, pending positive results on the safety and efficacy of afamelanotide.

The company will announce further commercial steps including a drug trade name, final drug pricing and distribution plans in the coming months.

Orphan Drugs

Various companies have concentrated their resources on the development of drugs for rare disorders. In this specific development many factors play a role in the ultimate commercial success achieved, while the primary pharmaceutical objective should never be kept out of sight: "doing good" for patients who have not found medicinal relief for their disease and symptoms. When this objective is kept in sight at all times, the course of development will have the highest chance of reward.

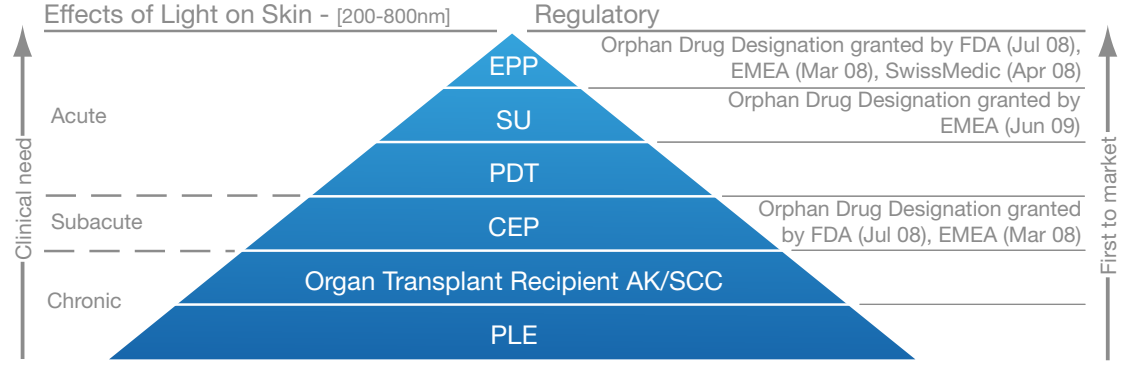
An understanding of the medical communities and current treatment modalities (however deficient) for these patients is key to successful development and distribution of orphan drugs. From a commercial point of view, development costs ought to be reflected in the ultimate price of the new proposed treatment: payors, regulators, patient associations and drug developers all have a role to play in the determination of the price. However, from a payor's point of view, reimbursement of the new drug is partially influenced by the consideration of severity of disease, burden to the patient and eventual cost to payors, significant factors in reaching a price for the new drug.

Some recent enzymatic therapies designated as orphan drugs are illustrating the clinical need versus size of population per disease.

In Gaucher's disease, a prevalence of 5,000 patients worldwide is reported. The 1st-in-line drug addresses the enzymatic deficiency in this severe liver disease. Similar cases can be made for new drugs in smaller indications.

When pharmaceutical companies decide to address severe diseases for a limited population of patients, the challenge is to show significant relief and reduction of symptoms and above all improved quality of life. This is the domain on which the Clinuvel team has focused. When all pieces of the puzzle come together, and when afamelanotide remains safe and effective, commercialisation will follow.

Clinuvel has chosen to focus on diseases for which no effective and preventative therapy is available. A host of factors determine the commercial choices for product distribution following regulatory approval. Clinuvel's business strategy logically and closely follows the clinical development of afamelanotide.



Chair's Letter

Dear shareholders, supporters of the company,

The 2009 financial year has been another momentous year for Clinuvel with outstanding progress toward commercialisation being achieved.

Clinuvel has continued on its path to bring to market the world's first medicinal photoprotective, afamelanotide. As part of our commercial objectives, the company has relentlessly pursued its educational role in its field, both through professionals and in all forms of global media.

One of the highlights has been the first Investigational New Drug (IND) granted to the company after 10 years of development in Europe and Australia and allowing the team to commence US trials.

In looking back on the year, some of the significant company milestones have included:

1. The FDA granted afamelanotide an Orphan Drug Designation (ODD) for EPP – the first regulatory recognition for Clinuvel in the US. Our success in the US was further reinforced when the FDA allowed IND status for afamelanotide;

2. Positive Phase III interim results in our lead indication EPP, showing that afamelanotide has the ability to reduce the maximum severity of reactions in EPP patients;

3. The EMEA granted an ODD for Solar Urticaria (SU), the second ODD for afamelanotide in Europe, firming our focus on orphan indications in the near term; and

4. The commencement of Phase II trials for Photodynamic Therapy (PDT) in France, the results of which are due shortly.

Since the close of the financial year we have announced positive Phase II results from our SU trial and are looking at the possibility to conduct further confirmatory Phase III trials for EPP in Europe. Here the company has adopted a progressive regulatory strategy, and the belief is that it will eventually be of benefit to the company to test the drug on a maximum number of EPP patients worldwide.

Final results from the lead Phase III study are expected in the coming months. These results from trials based on two continents, Europe and Australia, and our clinical program planned from March 2010 in the US, imply that Clinuvel is approaching the end stages of development for the lead orphan indication EPP.

The company has been meticulous in building a high level of competence in clinical and regulatory matters and as commercialisation nears we are addressing manufacturing and distribution, as well as the positioning and branding of the drug and company.

As you are well aware 2008-2009 has been a very difficult year in financial markets. Clinuvel is fortunate in its sector that, due to past capital raisings, it has sufficient funds to complete its clinical trial program. I stress my gratitude to all shareholders for their continued support.

I also thank our Managing Director, Dr Philippe Wolgen and his staff for their total focus on achieving a successful outcome and the Board for the major support they provide.

Brenda Shanahan
Chair

Managing Director's Report

Dear shareholders,

It has been four turbulent but exciting years since we started restructuring the company.

In drug development, the challenge is to lower the individual R&D risks inherent in the chosen model as the business progresses and matures. In Clinuvel's case, we identified a variety of risks early on, such as chemistry, formulation, clinical application, finances, managerial know-how and regulatory acceptance.

As some of the long-term shareholders may start to recognise a pattern in my conservative outlook, rather than starting with the upside and chances of success, I first wish to address the remaining risks in our model. Some analysts may find this a rather grim and less flamboyant perspective given the progress Clinuvel has made, however I believe it will keep us within Clinuvel wary of (too) early claims of success and focused until the last day of regulatory review.

Four years on, many of the development issues have been resolved while a lesser number remain. Clinical safety of afamelanotide is linked to the regulatory acceptance of the development program, and will receive our continuous attention. Since in global drug development, safety or perceived lack of safety is sufficient to put a program to a halt, we continue to focus on the clinical and regulatory aspects of this program. The confidence of patients and physicians in the safety of afamelanotide is growing steadily as global regulators review the dossier positively. Physicians and patients are consistently reporting good safety following long-term administration of afamelanotide. I am optimistic but always careful and vigilant about early claims.

This sense of realism is somewhat in contrast to the real clinical and regulatory progress towards the end of development and the start of commercialisation. The excitement in and around the company has increased, as witnessed by the number of online visitors, investor interest, and physicians' request for afamelanotide. In summary, we are confident enough to look at each single step ahead, but not beyond. This approach has served the managerial teams well, and we have to continue operating in this manner.

Review

In the past year, a few events stand out for Clinuvel and its shareholders. It has been a year in which the 14 months of intense work to file the company's first IND came to a successful end. The time and manpower which have been allocated to meet this objective is hard to describe in this short review. Set back by a failed filing in the US in 2004, the challenge of my management team had been clear from the start. With a new approach, diligence, expertise, new data and meticulous planning formed the key ingredients of this year's successful FDA filing. As a most welcome side effect, the US achievement has given our global teams an invaluable boost for the remainder of the program.

Positive clinical results from the porphyria (EPP) trial in Switzerland have given further support to the allocation of resources towards the orphan program. Clinical response and feedback from physicians has served as pivotal input to our regulatory strategy. The severity of disease symptoms in EPP patients has once again come to our attention the past twelve months, and to be able to provide preventative treatment is truly a rewarding cause.

An important but somewhat unexpected recent event has been the EMEA's grant of the second orphan designation for solar urticaria (SU). This year's results from the UK Phase II trials on SU bode well for the use of the drug in this incapacitating disease. Although this was a pilot trial using photoprovocation as an endpoint, the benefit to patients was evident.

The year has been marked by clinical expansion and statistical analyses of the Swiss EPP cohort of patients, while delay has been incurred in the PLE trial analysis due to some sites ending later in the trial. In contemplating the year, I realise how much work has been achieved in our path to innovate and develop a medicinal therapy as a photoprotective.

As part of our objectives to answer the queries on afamelanotide and related issues, such as environmental factors, skin disorders, skin cancer and UV damage and pigmentation, we have expanded our online presence. Communication is essential to reach a global audience, and I am most pleased with our progressive efforts on this front.

The introduction of novel technology almost logically demands communication with new audiences, hence Clinuvel's Xptise channels and forums online. So far the feedback has been very positive.

Biomimicry By Afamelanotide

When fair-skinned individuals are exposed to light and UV, their skin's inability to respond appropriately to damage poses a risk of increasing the incidence of a number of diseases including skin cancer. Common to these patients is that they either have an acute or long-term response to UV and may have trouble conducting a normal life.

We believe we have developed a successful injectable controlled-release formulation which mitigates against the effects of non-ionizing radiation in the spectrum up to 700 nm. In some ways afamelanotide supplements the activation of the skin's pigmentation. The scientific community has known for some time about the potent effect of melanin (pigmentation) as a shield against sun. We are commercialising applied knowledge in our medicinal therapy.

To receive the worldwide clinical anecdotes from patients who are able – following administration of afamelanotide – to lead a life which was previously impossible is rewarding for our entire team. The concept of biomimicry holds true for these patients who seem to respond to the treatment, but before the analyses conclusively demonstrate efficacy it still is too early to deduce any conclusions from the clinical testimonies.

Business Model Clinuvel

The challenge to our management team is to turn project development into a viable and valuable business. Although financial returns are expected I am well aware that shareholders have given us the mandate to develop afamelanotide for those severely affected patients. The preclinical and clinical data, together with the recent approvals by regulators, have a profound influence on management's decisions to focus the company on the current technological development. With this decision, we anticipate that both patients and shareholders will be rewarded.

In the business model to date, the Board has chosen to dedicate all resources to the marketability of afamelanotide. Naturally we are evaluating other opportunities, as is our fiduciary duty, but after a decade of development afamelanotide continues to have our priority. Nearing the final phase of development and looking at the commercial aspects of afamelanotide, we have come to an important junction. Expansion of the business and retaining staff and management is essential to enhance further value.

In 2006, I set the managerial target to identify the most proficient and qualified scientists, experts and physicians in the fields of our focus. The second challenge was to approach and gauge their interest in working with afamelanotide, at the time a novel and unproven drug for any disease. We identified the top 100 specialists, physicians and scientists in the fields of photoprotection, photophysics, dermatology and skin cancer. We succeeded in involving these individuals in working with and testing afamelanotide in six categories of patients. We remained conscious of the risks to this approach. If the drug had failed to provide clinical effect in the hands of these renowned physicians, the academic fall-out could have been disastrous to Clinuvel's development. However, this is where much gain has been made the past four years. We can now pride ourselves that most heads of academia have adopted the initiative and merits of afamelanotide for the preventative treatment of light-affected patients.

Most physicians and many EPP and PLE patients have now experienced the effects of afamelanotide. The demand for afamelanotide is being established as we proceed in the clinic.

A sobering note is that pharmaceutical development of successful drugs is not based on physicians' and patients' global assessments, but on the statistical outcome of placebo-controlled randomised trials. We confidently anticipate the analyses of the trial ending December 2009, against a background of positive clinical observations worldwide. However new businesses need to remain realistic in proving and introducing new technologies. I am optimistic that, with the team, value will emerge in the not-too-distant future.

Outlook

In light of our clinical and regulatory progress, we should evaluate the optimum commercial distribution of afamelanotide. Various options are available to Clinuvel. The so-called go-alone route to market or partnership with established distributors or pharmaceutical companies.

The Clinuvel Board is reviewing all these options. Shareholder value remains a significant factor in the commercial deliberations. Arguments in favor of Clinuvel's path to distribute the final product itself are based on the in-house expertise built over the years and size of the orphan market. In many ways Clinuvel has succeeded in developing its own market. Arguments can be put forward that the company

does not require a strong partnership to distribute its drug to the eligible patients with porphyria (EPP) and solar urticaria (SU).

On the other hand, a strong licensing partner may well be more efficient in its capacity to reach all patients in the smaller disease categories. Evidently, the commercial terms to obtain the rights to distribute and sell Clinuvel's proprietary drug will be a key determinant in the Board's decisions during the next year.

In the next months, we expect further analyses on the additional pharmaceutical properties of afamelanotide. As the company progresses, more knowledge is being generated on afamelanotide and its beneficial effects on biology. We aim to utilise this new insight to enhance the value of the drug.

On the regulatory front, in meetings with the FDA and EMEA, we expect to further discuss filing requirements and outcome of the trials. These formal meetings also serve to exchange with the agencies Clinuvel's distribution plans and pricing strategies. Health economics nowadays are a necessary ingredient of obtaining marketing authorisation.

With much anticipation, our team is working on obtaining the green light to conduct placebo-controlled randomised trials in EPP in the US. The organisation and logistics involved in running trials in rare disorders poses a new set of challenges to Clinuvel. Yet, the team has excelled in its organisation of the EPP trials in Europe, and I am certain that we will relish the US challenge too, of course pending regulatory approval.

In the meantime the Phase II trials in the prevention of actinic keratosis and squamous cell carcinoma in Europe and Australia continue.

Results of the trial in photodynamic therapy (PDT, an oncology treatment using a photosensitising agent and LASER) are imminent at the time of this report. PDT is a promising treatment to extend the life-expectancy of patients diagnosed with cholangio-carcinoma; significant benefit in survival and quality of life has been demonstrated, and it is anticipated that afamelanotide may provide photoprotection to these patients. This would add to these patients' quality of life by reducing the necessity to stay indoors after treatment. This is a revolutionary way of treating these patients. We are once again breaking new ground.

Over the past year in Australia we witnessed the global financial crisis and were reasonably spared from the fall out. In Clinuvel, we directly experienced how global redemptions had an immediate effect on our shareholders' ability to maintain their positions. The contagion by cross-border funds did not leave Clinuvel unaffected. As the equity markets worldwide experienced lows and deep corrections, we remained focused on the R&D while keeping in contact with our shareholders. More importantly, we communicated more frequently in these times of depressed markets.

At times, we witnessed that volatility of the CUV stock reduced, while market performance remained depressed for the majority of the year. As the efficient market theory was no longer deemed applicable, Clinuvel too saw a disconnect between internal performance and stock price.

All in all, we sailed through these rougher times while maintaining the belief that the company would maintain its attraction to capital markets, as long as internal progress was demonstrated.

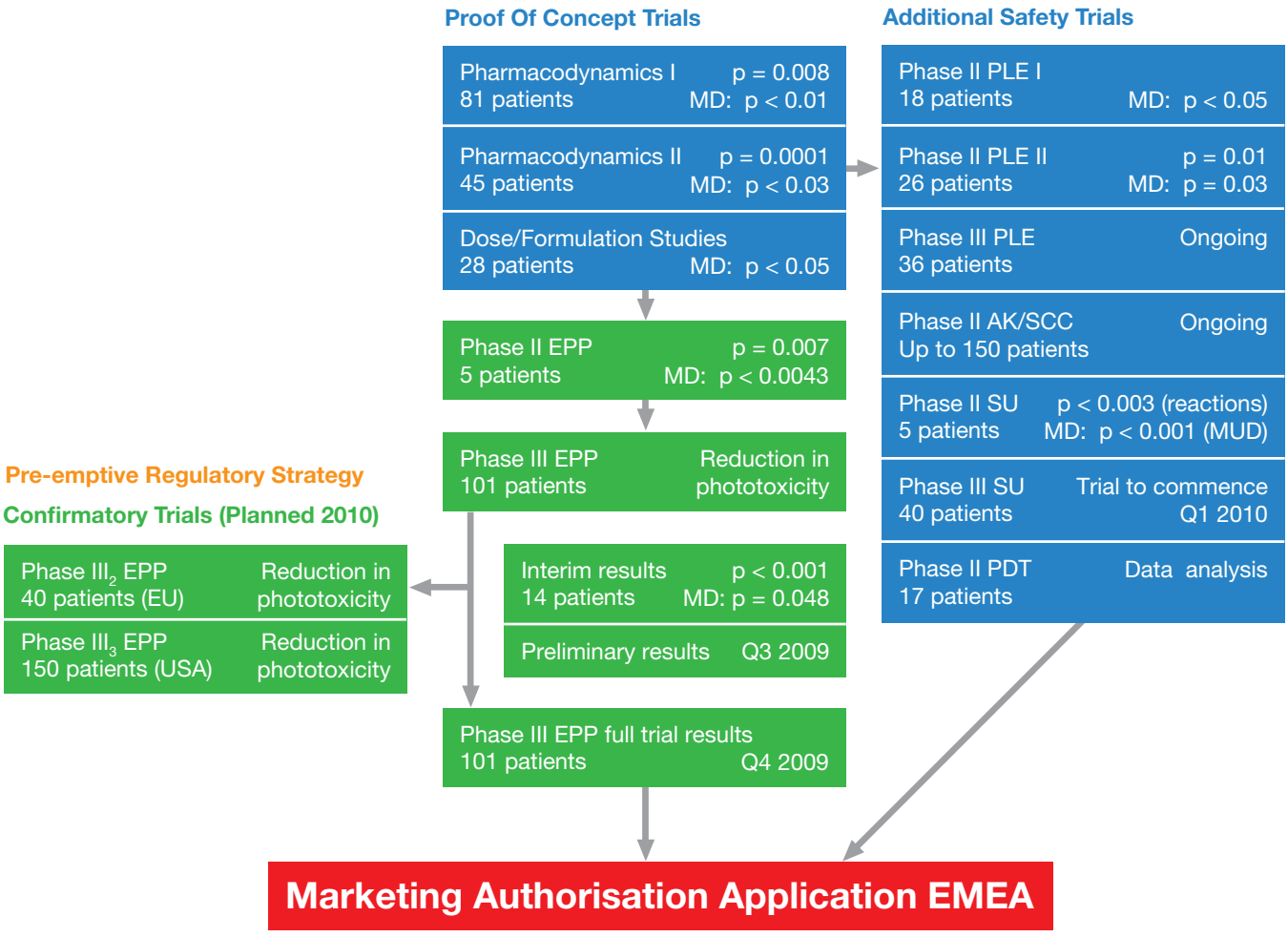
I seize the opportunity to thank all shareholders for their belief and support in our team, and all patients worldwide for their continued participation. Your participation is greatly valued and is the basis of our success to date.

Sincerely

Philippe Wolgen

Clinuvel's Development Program

Registration Strategy - EPP



Clinuvel is now entering the final stages of development for afamelanotide. The company has planned a clinical and regulatory strategy which focuses on providing photoprotection to patients who are yet to receive adequate medicinal therapy.

The registration strategy flow chart (above) outlines the progress to date and planned first path to market for afamelanotide, for the orphan disease erythropoietic protoporphyria (EPP). Results for this trial are anticipated in Q4 of 2009.

The left column illustrates Clinuvel's pro-active regulatory strategy whereby, in anticipation of regulatory reviews, the company will undertake two additional, confirmatory trials for EPP. This strategy is unique to Clinuvel.

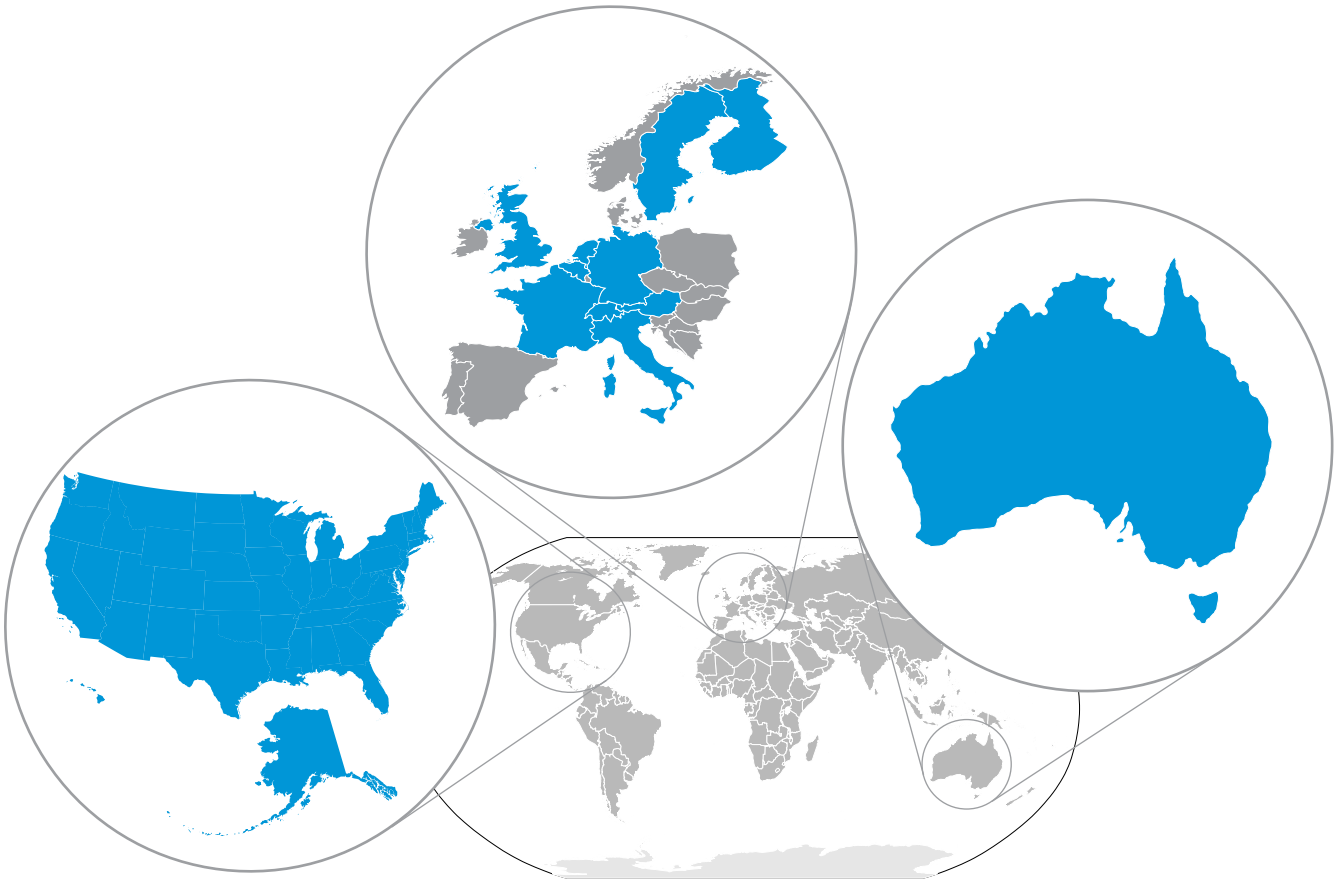
In addition to EPP, Clinuvel is trialing afamelanotide for four further indications in Phase II and III trials in Europe, illustrated in the right column above. Safety data from these trials will assist in forming the registration dossier for afamelanotide and, pending trial results, the company intends to pursue registration for these indications.

More information on Clinuvel's clinical indications can be found on page 80 of this report.

Patients To Date

Liquid	Approximately 1,700 doses in 137 patients
Implant	Approximately 800 doses in over 300 patients
Currently	Over 150 patients on trial

Clinical Trial Locations



Clinuvel's Clinical Progress

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyria (EPP)	Absolute sun/UV intolerance	Phase III trials started April 2007
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trials started May 2007
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trials started October 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun/UV	Phase II trials reported July 2009
Photodynamic Therapy (PDT) - systemic	Phototoxicity following cancer treatment	Phase II trials started September 2008

Financials' Contents

Contents

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).

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, posted on the company's internet site.

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 performance 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 on pages 22 to 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 Mrs Shanahan, the Chair) of which three are considered independent of the company and its management, having no current or previous business or other relationships that could materially compromise their autonomy as a Director (Mr McLiesh, Mrs Shanahan and Mr Wood). The CEO of the company is Dr Wolgen who is not the Chair. 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 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. Mrs Shanahan is the other voting member. 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 internet site.

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 business and strategic issues and to agree Board meeting agendas.

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, along with the Board's policy for nomination and appointment of Directors, can be found in the Remuneration and Nomination

Committee charter and section 1 of the Corporate Governance Protocol on the company's internet site.

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 internet site) 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 2009 are shown on pages 22 and 23. The company has a share trading policy in place, details of which are included in the Corporate Governance Protocol available on the company's internet site. Directors and employees may only buy or sell Clinuvel Pharmaceuticals Ltd shares during specified periods; however Mr Wood was granted permission by the Board to purchase shares outside a recent specified period. 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 the 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, Mr McLiesh, 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 views 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 internet site.

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 internet site) 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. A copy of the company's communications policy can be found in the Corporate Governance Protocol on the company's internet site.

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 minimise 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 consolidated entity'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 commercialisation 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).

In 2009/10 the Board will review its published risk management policies in the Audit Committee charter.

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 internet site.

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 entities for the financial year ended 30 June 2009 and the Auditors' Independence Declaration thereon.

Directors

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

- Mrs. B.M. Shanahan (Non-Executive Chair)
- Dr. H.P.K. Agersborg (Deputy Chair, Chief Scientific Officer)
- Dr. P.J. Wolgen (Managing Director, Chief Executive Officer)
- Mr. S.R. McLiesh (Non-Executive)
- Dr. R. Aston (Non-Executive)
- 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

Mrs. Brenda M. Shanahan (joined Board 2007)
Non-Executive Chair
Member of the Remuneration and Nomination Committee
Qualifications: BComm, FAICD, ASIA
Shares in Clinuvel: 420,071
Options over shares in Clinuvel: 850,000

Mrs Shanahan has a longstanding background in finance in Australian and overseas economies and share markets. She is currently Chair of St Vincent's Medical Research Institute in Melbourne and is a non-executive Director of JM Financial Group Ltd. Formerly a Director of Challenger Financial Services Group Ltd (2003-2007 - ASX:CGF), Mrs Shanahan is current Chair of Challenger Listed Investments Ltd, the reporting entity for Challenger Kenedix Japan Trust (ASX:CKT), Challenger Infrastructure Fund (ASX:CIF), Challenger Diversified Property Group (ASX:CDI) and Challenger Wine Trust (ASX:CWT).

Mrs Shanahan is a former member of the Australian Stock Exchange and former executive director of a stockbroking firm, a fund management company and an actuarial company. Mrs Shanahan is well known in the business and financial community; her insights add significant value to the current Board and the company. Mrs Shanahan was appointed Non-Executive Chair of the Board in late 2007.

Dr. Helmer P.K. Agersborg (joined Board 2001)
Executive Director, Deputy Chair and Chief Scientific Officer since December 2005
Qualifications: BSc, PhD
Shares in Clinuvel: 921,105
Options over shares in Clinuvel: 2,000,000

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

Dr Agersborg contributes broad international pharmaceutical development experience at the highest level to the company. Since the change of management in the company in November 2005, Dr Agersborg has served as Chief Scientific Officer. His experience as a toxicologist and understanding of regulatory requirements has been fundamental in the repositioning of the company.

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

Since holding office as CEO as of November 2005, Dr Wolgen has repositioned Clinuvel and its corporate strategy. His leadership has been instrumental in capitalising the current program in two rounds of funding, totaling AUD$70M Under Dr Wolgen's management the company has attracted

international institutions and the support of the global scientific community was gained for the use of the novel drug product afamelanotide.

Having been recognised for his strategic mindset and meticulous business execution, Dr Wolgen has brought to the company his international finance experience and professional contacts to European capital markets. As a former equity analyst, his in-depth analysis and expertise of the lifescience sector has been an asset to Clinuvel. He has held positions in private pharmaceutical companies in Europe, as MD of two medical centres in the UK and Israel, and consulted for medical device companies. He is a Board-member and founder of WOKO Indonesia: a charity exchange program for surgical professionals between Europe and Indonesia to treat paediatric craniofacial anomalies.

Dr Wolgen holds an MBA from Columbia University NY and the London Business School. Trained as a surgeon, Dr Wolgen holds an MD from the University of Utrecht, the Netherlands.

Mr. Stanley R. McLiesh (joined Board 2002)
Non-Executive Director
Chair of the Remuneration and Nomination Committee and member of the Audit and Risk Committee
Qualifications: BEd
Shares in Clinuvel: 760,000
Options over shares in Clinuvel: 650,000

Mr McLiesh has vast experience in commercialising pharmaceutical products internationally. As the former General Manager, Pharmaceuticals at CSL Limited, he was closely involved in the transition of CSL from government ownership through corporatisation to a highly successful listed company. While at CSL, Mr McLiesh brokered numerous in-licensing agreements with international companies enabling CSL to expand into new markets profitably.

He has also been closely involved in a number of M&A transactions, the establishment of partnerships and collaborative relationships while he was the key professional to negotiate supply agreements for CSL's export products to international markets.

Mr McLiesh was formerly a Non-Executive Director of Unilife Medical Solutions Ltd. His considerable experience in the international pharmaceutical industry benefits Clinuvel's international strategies. In the latter stages of the development program Mr McLiesh is involved in formulating the commercial phase of Clinuvel.

Dr. Roger Aston (joined Board 2005)
Non-Executive Director
Chairman of the Audit and Risk Committee
Qualifications: BSc (Hons), PhD
Shares in Clinuvel: 108,224
Options over shares in Clinuvel: 2,450,000

Dr Aston has more than 20 years experience in the pharmaceutical and biotechnology industries and has been closely involved in organisational restructuring of companies and in improving effectiveness and productivity. Dr Aston is CEO and Chair of Halcygen Pharmaceuticals Ltd (ASX:HGN) and Chair of Ascent Pharmahealth Ltd (ASX:APH).

His previous positions include director of Cambridge Antibody Technology Limited (UK), Chairman of Cambridge Drug Discovery Limited (UK) (now BioFocus plc), founder and CEO of Biokine Technology Ltd (UK) prior to its acquisition by the Peptech Group as well as CEO of Peptech Limited, founder and CEO of UK-based pSiMedica Limited, CEO of pSiOncology, Dr Aston was Executive Chairman of Clinuvel Limited until late 2007 and consults for BIO-IB Inc. He was previously a director of pSivida Ltd (ASX:PVA 2000-2005, 2006-2007).

Aspects of his experience include FDA registration and CTX and CTN submissions to European and Australian authorities, clinical trials, global licensing agreements, fundraising through private placements, preparation of prospects for a public offering, and a network of contacts within the pharmaceutical, banking and stock broking sectors.

Mr. Lawrence John (Jack) Wood (joined Board 2008)
Non-Executive Director (joined company 11 July 2008)
Qualifications: BComm
Shares in Clinuvel: 100,000
Options over shares in Clinuvel: 350,000

Mr Wood has an extensive background in international marketing and manufacture of pharmaceutical products. He has lived in Germany, England, Australia, USA and Canada and overseen pharmaceutical operations throughout Europe, Asia and North America. He is currently Chairman of EnGene Corporation and a Director of QLT; both are companies engaged in biotechnology and headquartered in Vancouver Canada. He is an active member of several civic boards and organisations in Vancouver, Canada. Prior to joining the pharmaceutical industry, Mr Wood served in the Canadian Armed Forces retiring with the rank of Lt. Col.

Positions held by Mr Wood during his career include: Executive Vice President CSL Limited

Australia, where he coordinated the company's world wide expansion in the plasma products industry; President and CEO Exogene corporation; Senior Vice President BioResponse Corporation both biotechnology companies sold to Baxter Healthcare Corporation; Vice President Bayer Corporation Pharmaceutical division responsible for operations in Europe and Japan. Mr Wood spent over seventeen years with Baxter Healthcare Corporation holding a series of operating and general management positions in North America, Europe, Asia and Australia. Mr Wood was invited to join the Clinuvel board in July 2008, and since has been involved in the commercial decisions to bring afamelanotide to market.

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	6	2	2	-	-
Dr. H.P.K. Agersborg	7	7	-	-	-	-
Mrs. B.M. Shanahan	7	7	-	-	4	4
Mr. S.R. McLiesh	7	7	2	2	4	4
Dr. P.J. Wolgen	7	7	2	2	2	2
Mr. L.J. Wood	6	6	-	-	-	-

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.

Principal Activities

The principal activities of the consolidated entity during the financial year were to develop its leading drug candidate afamelanotide 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.

Dividends Paid Or Recommended

No dividends were paid or declared during the financial year.

Review Of Operations

The following table presents a summary of Clinuvel's financial result:

Consolidated	2009	2008	Change
	$	$	%
Revenues	2,904,917	4,297,103	-32%
Net (loss) before income tax expense	(15,372,907)	(14,655,791)	-5%
Profit (loss) after income tax expense	(15,372,907)	(14,655,791)	-5%
Basic earnings per share - cents per share	(5.1)	(4.8)	-6%
Net tangible assets backing per ordinary share	0.12	0.17	-29%
Dividends	Nil	Nil	Nil

Note: Clinuvel does not operate individual segments.

The group result for the year ending 30 June 2009 was a $15.372 million loss, compared to a $14.656 million loss for the prior financial year, a loss increase of 4.9%. The group continues to display a strong balance sheet, with $37.051 million in net assets at 30 June 2009 compared to $51.814 million at 30 June 2008. Current liabilities increased 44% to $4.544 million primarily due to increased R&D in Clinuvel's final formulation and drug delivery development activities year-on-year. Monthly average cash spend was $1.175 million for the year compared to $0.95 million for the 2007/08 year.

Research and development accounted for 46% of the group's total expense result for 2008/09, compared to 34% for the 2007/08 year. Research and development expenditures, comprising clinical study costs, drug delivery research and manufacture, toxicity studies, regulatory fees and research and development-specific overheads such as personnel, were $8.429 million in 2009 compared to $6.455 million in 2008. Clinical study costs increased 55% from $1.475 million in 2008 to $2.281 million in 2009, reflecting the increase in, and progress made of, the number of centres participating in the company's various studies, the number of patients enrolled and the data generated from each study. Expenditures from the drug delivery program increased 24% from $4.986 million in 2008 to $6.176 million in 2009. Production of implants to supply the clinical study activities, the validation of the production process to meet commercial manufacturing scale and regulatory compliance were primary reasons for the increase in spend. More personnel to service the expanded research and development programs as they move into Phase III resulted in an increase in research and development overheads to $1.535 million in 2009 from $1.126 million in 2008, up 36%. The completion of further animal studies at the start of the financial year resulted in a decrease in toxicity study and regulatory costs from $0.828 million to $0.313 million, down 62%.

Marketing activities in the company decreased by $0.567 million to $0.846 million in 2009. The reduction in expenditures year on year is attributed to a reduced dependence on public marketing agencies, replaced by in-house expertise to support the group's IT and marketing initiatives whilst the company focuses on its end stage research and development. European-based marketing personnel numbers were reduced year-on-year and set-up expenditures incurred by the company on its novel online facilities in 2008 contributed a $0.140 million reduction in the 2009 result.

The result from general operations was $6.210 million in 2009 compared to $8.176 million in 2008. General operations comprised 34% of the group's total expense result for 2009 compared to 43% in 2008. A contributing factor in the result was an improvement of $1.533 million in the mark-to-market charge and realised losses from investments in 2009 compared to 2008. Restating foreign currency creditor balances and currencies held resulted in a $0.604 million gain in 2009. The costs of the group's Zürich operations established part way through 2008 was included for the twelve months in 2009.

Interest received on cash and financial assets held decreased by 38% from $4.297 million in 2008 to $2.668 million in 2009. The drop in revenues is a result of the gradual decline in cash reserves and financial assets for working capital deployment combined with reduced returns from the decline in prevailing interest rates. For the 2008/09 year the group started with $50.800 million in cash and financial assets and finished with $37.754 million. In contrast the group started the 2007/08 year with $62.353 million. Additionally, increased expenditures in currencies other than the Australian dollar in the second half of the 2008-09 resulted in currency gains of $0.236 million and is reflected as revenue.

At 30 June 2009 basic earnings per share were -$0.051 on 303,148,665 issued ordinary shares. This is compared to basic earnings per share of -$0.048 as at 30 June 2008 on the equivalent number of issued ordinary shares.

The advancement in the group's clinical and regulatory activities in the 2007/08 year to commercialise afamelanotide was matched by a number of significant achievements in 2008/09. These achievements, highlighted below, further strengthen the preparation of a dossier to meet the required regulatory standards to successfully file for marketing authorisation:

- The US Food and Drug Administration (FDA) granted Clinuvel Orphan Drug Designation (ODD) for the management of Erythropoietic Porphyrias (EPP). The status is reserved for new drugs being developed to treat rare diseases or conditions that affect US populations, for whom there is no effective medical therapy. The ODD allows an accelerated review process by the FDA, seven year market exclusivity in the USA upon receiving marketing authorisation, tax benefits and exemptions from user fees. Additionally, the EMEA also granted Clinuvel Orphan Drug Designations in March 2008 and Swissmedic followed suit in April 2008 for the treatment of EPP and CEP, a related porphyria.

- A Phase II trial commenced in September 2008 to test afamelanotide for patients undergoing Photodynamic Therapy (PDT). Final results are expected in the second half of the 2009 calendar year. PDT is a cancer treatment, which causes phototoxicity of the skin as a side-effect up to 90 days following treatment. The purpose of the trial is to demonstrate whether afamelanotide can be used as an effective adjunct therapy to PDT to reduce phototoxicity in these patients.

- In December 2008 the company submitted an Investigational New Drug (IND) application to the FDA to conduct clinical trials in the US. The FDA granted Clinuvel its first privilege to conduct trials in the US in the following month.

- On the basis of 14 EPP patients in Switzerland who had successfully completed a 12 month Phase III study, positive preliminary results were announced to the market in January 2009. The severity of phototoxicity was significantly reduced by afamelanotide treatment in comparison to placebo treatment.

- In June 2009, the EMEA granted afamelanotide an ODD for the treatment for Solar Urticaria (SU). SU is a skin disorder marked by allergic responses to UV or sun exposure.

During the year, the company appointed Mr Jack Wood as a Non-Executive Director. Mr Wood has brought to the company a wealth of experience gained from working in various operational and marketing roles within the global pharmaceutical sector. The company's share register was further diversified in September 2008 following the transfer of 20% common stock by a key institutional investor to existing and new Australian and overseas institutions.

2009/10 sees the company entering the end stage of its product development. With two recently granted Orphan Designations for EPP and SU (light/UV related skin disorders), the company has focused on treating acute medical need. Currently, the company is involved in the treatment of 6 diseases through the use of its principal drug, afamelanotide.

As an overview, the current Phase III trials in EPP and PLE will complete within twelve months.

The next year will see an expansion to the current clinical trial program. Most importantly, the scientific team is planning to generate more data to give optimal chance for afamelanotide to gain a place as a new photoprotective drug. The company will follow up on its positive results in SU and start Phase III trials, pending sufficient number of patients and regulatory approval. The next few months, the results in PDT will dictate whether the company will pursue this indication in Phase III trials, the same assessment will be made for the other two indications, actinic keratosis and polymorphic light eruption.

The outlook for 2009/10 includes additional research activities on afamelanotide as the scientific community continues to gather knowledge on molecular biology, UV and pigmentation. The company believes further opportunities may come to light as scientific information is generated from the ongoing basic research. Any opportunities may bring further value to the company and add to the potential of afamelanotide as a key photoprotective.

The need to support the expansion of the company's clinical research and development activities will require additional quality key management personnel. The company intends to secure senior scientific staff prior to the start of the planned additional trials to complement and add to the existing in-house expertise and intellectual knowledge base.

With the expected completion and positive results of the aforementioned clinical studies, the next twelve months will see key commercial decisions made. The execution of existing activities combined with the expected progress will further support the company's positioning as a leader in a relatively new field of medicinal photoprotection. Monthly cash burn will increase from 2008/09 levels and cash reserves will decrease accordingly. The existing cash and financial asset reserves is considered sufficient to cover the current development program. The decision to remain a single-drug company or to expand will dictate any further activities.

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.

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 or of any other jurisdiction.

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. The cost of the aforementioned insurance premium was $46,725 (2008: $54,345).

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; and
- to align management interest with that of the company's shareholders; and
- to support the achievement of the company's strategic objectives.

The reward framework provides a mix of fixed and variable pay, structured to incentivise 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); and
- long-term incentive payments through the achievement of pre-specified performance-based targets; and
- 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 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 the Information of Directors section to this 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 (agreement terminated 15 March 2009)

Remuneration Of The Directors Of The Company For The Year Ended 30 June 2009

	Short-term Employment Benefits				Post Employment Benefits	Share Based Payments	
Director	Salary	Cash Bonus	Other	Consult Fees	Superannuation Contributions	Options	Total
	$	$	$	$	$	$	$
Dr. H.P.K. Agersborg	408,596	-	-	-	-	86,939	495,535
Mr. S.R. McLiesh	59,633	-	-	-	5,367	28,549	93,549
Dr. R. Aston	59,633	-	-	-	5,367	80,225	145,225
Dr. P.J. Wolgen	611,981	175,000	3,220	-	13,694	301,122	1,105,016
Mrs. B.M. Shanahan	73,395	-	-	-	6,606	37,192	117,192
Mr. L.J. Wood	47,917	-	-	-	-	2,065	49,981
Total	**1,261,154**	**175,000**	**3,220**	**-**	**31,033**	**536,091**	**2,006,498**

Remuneration Of The Specified Executives Of The Company For The Year Ended 30 June 2009

	Short-term Employment Benefits			Post Employment Benefits		Share Based Payments	
Director	Salary	Cash Bonus	Allowance	Superannuation Contributions	Other	Options	Total
	$	$	$	$	$	$	$
Dr. D.J. Wright	175,471	17,000	-	13,694	-	52,527	258,692
Mr. D.M. Keamy	147,001	10,000	-	13,265	-	33,626	203,891
Mr. C.H. Mackie *	158,562	10,000	-	9,892	51,250	-	229,705
Total	**481,034**	**37,000**	**-**	**36,851**	**51,250**	**86,153**	**692,287**

* terminated 15 March 2009

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

	Short-term Employment Benefits				Post Employment Benefits	Share Based Payments	
Director	Salary	Cash Bonus	Allowance	Consult Fees	Superannuation Contributions	Options	Total
	$	$	$	$	$	$	$
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
Total	**860,242**	**206,136**	**114,727**	**50,000**	**26,612**	**577,285**	**1,835,000**

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	
Director	Salary	Cash Bonus	Allowance	Superannuation Contributions	Other	Options	Total
	$	$	$	$		$	$
Dr. D.J. Wright	149,796	-	-	12,926	-	73,929	236,651
Mr. D.M. Keamy	143,137	-	-	12,740	-	33,718	189,595
Mr. C.H. Mackie	169,603	-	-	11,730	-	-	181,333
Total	**462,536**	**-**	**-**	**37,396**	**-**	**107,647**	**607,579**

The Relative Proportions Of Remuneration Between Fixed And Based On Performance For The Year Ending 30 June 2009

	2009		2008	
	Fixed Remuneration	Performance Based	Fixed Remuneration	Performance Based
Dr. P.J. Wolgen	72%	28%	73%	27%
Dr. H.P.K. Agersborg	91%	9%	76%	24%
Dr. D.J. Wright	86%	14%	92%	8%
Mr. D.M. Keamy	91%	9%	95%	5%
Mr. C.H. Mackie*	96%	4%	100%	0%

* terminated 15 March 2009

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 2009 is $625,675. Termination payment is set at 6 months of base salary provided the termination is not for a material breach of the agreement. Dr Wolgen is required to provide 6 month's notice.

- Dr Agersborg (Director and Chief Scientific Officer) is on a 12 month rolling contract and his base salary inclusive of superannuation for the year ending 30 June 2009 is $408,596. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Dr Agersborg is not required to provide a specified notice period.

- Dr Wright's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2009 is $189,165. 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 2009 is $160,266. 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 agreement was terminated 15 March 2009. His base salary inclusive of superannuation for 1 July 2008 to 15 March 2009 is $168,454. The amount of termination payment was 3 months of base salary exclusive of superannuation.

Share-Based Remuneration

The consolidated entity has an ownership based scheme for Directors, key management personnel and select consultants of the company which is designed to provide long-term incentives to deliver 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	1,500,000	$0.34	$0.17	Ordinary	31/10/2005	31/10/2006	01/11/2009
		$0.34	$0.19			31/10/2007	
		$0.34	$0.22			31/10/2008	
Clinuvel	500,000	$0.75	$0.46	Ordinary	01/03/2005	01/03/2006	28/02/2010
		$0.75	$0.54			01/03/2007	
		$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
		$0.50	$0.01			24/08/2007	
		$0.50	$0.01			23/02/2008	
Clinuvel	15,340,000	$0.86	$0.25	Ordinary	09/02/2007	monthly over 48 periods	09/02/2012
		$0.86	$0.22			31/12/2007	
		$0.86	$0.23			09/02/2008	
		$0.86	$0.26			31/12/2009	
		$0.86	$0.24			09/02/2009	
Clinuvel	350,000	$0.275	$0.04	Ordinary	18/11/2008	18/11/2008	18/11/2013
		$0.275	$0.05			18/11/2009	
		$0.275	$0.05			18/11/2010	

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	17.5%	-	-	-
Dr. R. Aston	55.2%	-	-	-
Mr. S.R. McLiesh	30.5%	-	-	-
Dr. P.J. Wolgen	27.3%	-	-	-
Mrs. B.M. Shanahan	31.7%	-	-	-
Mr. L.J. Wood	4.1%	2,065	-	-
Dr. D.J. Wright	20.3%	-	-	-
Mr. D.M. Keamy	16.5%	-	-	-
Mr. C.H. Mackie	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 – 2009	Options Vested During The Year – 2008	Options Granted During The Year - 2009	Options Granted During The Year - 2008
Dr. H.P.K. Agersborg	-	750,000	-	-
Dr. R. Aston	250,000	500,000	-	-
Mr. S.R. McLiesh	-	125,000	-	-
Dr. P.J. Wolgen	250,000	3,375,000	-	-
Mrs. B.M. Shanahan	283,333	283,333	-	-
Mr. L.J. Wood	116,667	-	350,000	-
Dr. D.J. Wright	175,000	341,667	-	-
Mr. D.M. Keamy	125,000	125,000	-	-
Mr. C.H. Mackie	-	-	-	-

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	0%	0%	2006/07	0%	0%	2009/10	-	132,100
Dr. R. Aston	0%	0%	2005/06	100%	0%	2008/09	-	-
			2006/07	0%	0%	2009/10	-	105,680
Mr. S.R. McLiesh	0%	0%	2006/07	0%	0%	2009/10	-	52,840
Dr. P.J. Wolgen	61%	39%	2005/06	0%	0%	2008/09	-	-
			2006/07	0%	0%	2009/10	-	264,200
Mrs. B.M. Shanahan	0%	0%	2006/07	100%	0%	2008/09	-	-
Mr. L.J. Wood	0%	0%	2008/09	100%	0%	2010/11		11,739
Dr. D.J. Wright	0%	0%	2006/07	100%	0%	2008/09	-	-
				100%	0%	2009/10	-	98,905
				100%	0%	2010/11	-	33,571
Mr. D.M. Keamy	0%	0%	2006/07	100%	0%	2009/10	-	59,324
				100%	0%	2010/11	-	23,979
Mr. C.H. Mackie	27%%	73%	-	0%	0%	-	-	-

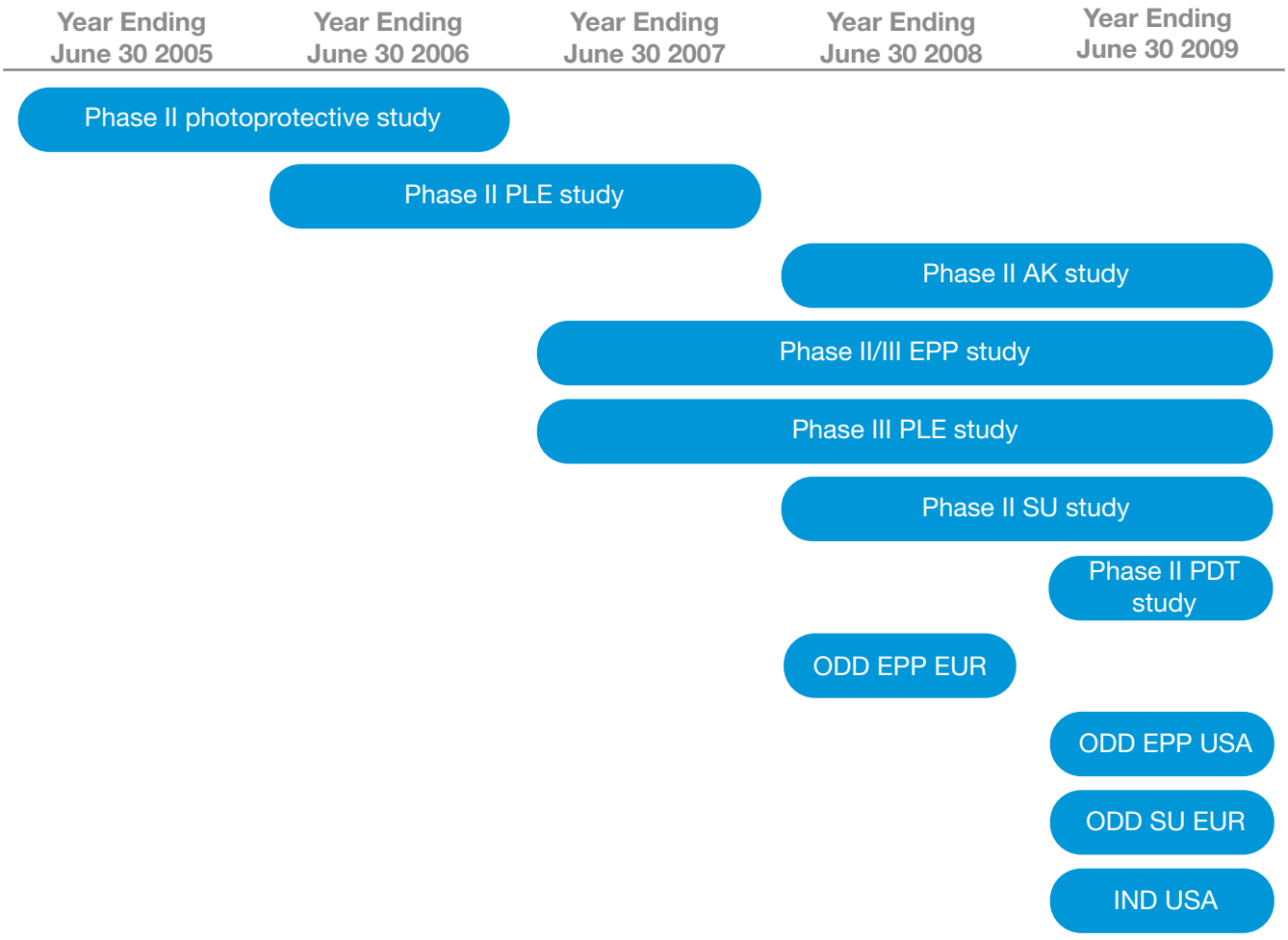
The exercise price for those options granted in 2006/07 is $0.86. The exercise price for those options granted to in 2005/06 to Dr Aston is $0.34 and to Dr Wolgen is $0.34 and $0.50. The exercise price for those options granted to Mr Wood in 2008/09 is $0.275.

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 commercialisation once testing and development is complete. It is anticipated the consolidated entity will not derive profit and pay a dividend until commercialisation 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 commercialisation of its drug under research and development.

Regulatory and Clinical Milestones



Shares Provided On Exercise Of Options

No shares were issued during the financial year as a result of exercise of options. No shares were provided upon exercise of options to Directors or key management personnel during the years ending 30 June 2009 and 30 June 2008.

Shares Under Option

Details Of Unissued Shares Or Interests Under Options

Entity	Number Of Shares Under Options	Exercise Price	Class	Expiry Date
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	15,340,000	$0.86	Ordinary	09/02/2012
Clinuvel Pharmaceuticals	350,000	$0.275	Ordinary	18/11/2013

Loans To Directors And Executives

No loans were granted to Directors or Executives for the years ending 30 June 2009 and 30 June 2008.

Non-Audit Services

For the years ending 30 June 2009 and 30 June 2008 Grant Thornton only provided audit services to the company.

Auditors' Independence Declaration

The auditors' independence declaration as required by s.307C of the Corporations Act 2001 is included and forms part of this Director's 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 J. Wolgen
Director

Dated this 27th day of August, 2009

Consolidated Income Statement For The Year Ended 30 June 2009

		Consolidated		Clinuvel Pharmaceuticals Ltd	
	Note	2009	2008	2009	2008
		$	$	$	$
Revenues	2	2,904,917	4,297,103	2,904,789	4,296,376
Total expenses	2	(18,277,824)	(18,952,894)	(18,271,166)	(18,941,444)
Profit (Loss) Before Income Tax Expense		**(15,372,907)**	**(14,655,791)**	**(15,366,377)**	**(14,645,068)**
Income tax expense (benefit)	3	-	-	-	-
Profit (Loss) After Income Tax Expense		**(15,372,907)**	**(14,655,791)**	**(15,366,377)**	**(14,645,068)**
Net Profit (Loss) For The Year		**(15,372,907)**	**(14,655,791)**	**(15,366,377)**	**(14,645,068)**
Basic earnings per share - cents per share	16	(5.1)	(4.8)	-	-

The accompanying notes form part of these financial statements.

Consolidated Balance Sheets As At 30 June 2009

		Consolidated		Clinuvel Pharmaceuticals Ltd	
	Note	2009	2008	2009	2008
		$	$	$	$
Current Assets:					
Cash and cash equivalents	17(a)	21,710,643	25,752,193	21,490,824	25,569,158
Other financial assets	8	16,043,498	25,048,387	16,043,498	25,048,387
Receivables	4	211,787	616,136	211,787	616,136
Other	5	2,627,585	1,703,396	2,599,256	1,674,347
Total Current Assets		**40,593,513**	**53,120,112**	**40,345,365**	**52,908,028**
Non Current Assets:					
Receivables	4	-	-	712,600	1,390,272
Property, plant and equipment	6	357,135	431,034	305,362	372,208
Intangible assets	7	663,114	1,419,612	36,799	45,999
Other financial assets	8	-	-	114,080	102,286
Total Non Current Assets		**1,020,249**	**1,850,646**	**1,168,841**	**1,910,765**
Total Assets		**41,613,762**	**54,970,758**	**41,514,206**	**54,818,793**
Current Liabilities:					
Payables	10	4,369,406	2,968,356	4,283,012	2,896,556
Provisions	11	174,646	178,576	158,096	168,959
Total Current Liabilities		**4,544,052**	**3,146,932**	**4,441,108**	**3,065,515**
Non Current Liabilities:					
Provisions	11	18,526	9,310	18,526	9,310
Total Non Current Liabilities		**18,526**	**9,310**	**18,526**	**9,310**
Total Liabilities		**4,562,578**	**3,156,242**	**4,459,634**	**3,074,825**
Net Assets		**37,051,184**	**51,814,516**	**37,054,572**	**51,743,968**
Equity:					
Contributed equity	12	113,221,065	113,222,456	113,221,065	113,222,456
Reserves	13	2,167,446	1,763,836	2,150,416	1,679,400
Accumulated losses	14	(78,337,327)	(63,171,776)	(78,316,909)	(63,157,888)
Total Equity		**37,051,184**	**51,814,516**	**37,054,572**	**51,743,968**

The accompanying notes form part of these financial statements.

Consolidated Cash Flows Statements For The Year Ended 30 June 2009

		Consolidated		Clinuvel Pharmaceuticals Ltd	
	Note	2009	2008	2009	2008
		$	$	$	$
Cash Flows From Operating Activities:					
Refund from ATO		196,452	298,507	194,791	298,007
Receipt from customers		-	-	-	-
Interest received		2,927,278	3,979,879	2,926,908	3,979,514
Payments to suppliers and employees		(14,109,276)	(11,459,719)	(12,316,065)	(10,565,944)
Net Cash Provided By (Used In) Operating Activities	17(b)	**(10,985,544)**	**(7,181,333)**	**(9,194,364)**	**(6,288,423)**
Cash Flows From Investing Activities:					
Payments for property, plant and equipment		(32,454)	(221,106)	(9,744)	(171,489)
Payments for investment securities		-	(21,965,276)	-	(21,965,276)
Payments for subsidiaries		-	-	-	(102,113)
Payments for patents and trademarks		-	-	-	-
Payments for product distribution rights		-	-	-	-
Funds received for transfer of product distribution rights		-	-	-	-
Proceeds from investment securities		6,554,630	21,444,811	6,554,630	21,444,811
Net Cash Provided By (Used In) Investing Activities		**6,522,176**	**(741,571)**	**6,544,886**	**(794,067)**
Cash Flows From Financing Activities:					
Loans to related parties		-	-	(1,850,674)	(867,491)
Proceeds from issue of ordinary shares		143,606	80,000	143,606	80,000
Payment of share issue costs		-	(78,950)	-	(78,950)
Net Cash Provided By (Used In) Financing Activities		**143,606**	**1,050**	**(1,707,068)**	**(866,441)**
Net Increase/(Decrease) In Cash Held:		**(4,319,762)**	**(7,921,854)**	**(4,356,546)**	**(7,948,931)**
Cash And Cash Equivalents At Beginning Of The Year		**25,752,193**	**33,841,849**	**25,569,158**	**33,685,891**
Effects of exchange rate changes on foreign currency held		278,212	(167,802)	278,212	(167,802)
Cash And Cash Equivalents At End Of The Year	17(a)	**21,710,643**	**25,752,193**	**21,490,824**	**25,569,158**

The accompanying notes form part of these financial statements.

Consolidated Statement Of Changes In Equity For The Year Ended 30 June 2009

		Consolidated		Clinuvel Pharmaceuticals Ltd	
	Note	2009	2008	2009	2008
		$	$	$	$
Retained Earnings					
Retained earnings at the beginning of period		(63,171,776)	(49,066,491)	(63,157,888)	(49,063,326)
Transfer from Share Option Reserve		207,356	550,506	207,356	550,506
Net profit/(loss) attributable to members of Clinuvel Pharmaceuticals Ltd		(15,372,907)	(14,655,791)	(15,366,377)	(14,645,068)
Retained Earnings At The End Of Period	**14**	**(78,337,327)**	**(63,171,776)**	**(78,316,909)**	**(63,157,888)**
Reserves					
Reserves at the beginning of period		1,763,836	1,644,837	1,679,400	1,638,509
Exchange difference on translating foreign operations		(67,406)	78,108	-	-
Movement in Share Option Reserve		471,016	40,891	471,016	40,891
Reserves At The End Of Period	**13**	**2,167,446**	**1,763,836**	**2,150,416**	**1,679,400**
Share Capital					
Share capital at the beginning of period: 303,148,665 fully paid shares (1 July 2007: 302,148,665)		113,222,456	112,813,470	113,222,456	112,813,470
Share options exercised and value of exercised options transferred from Share Option Reserve		-	410,186	-	410,186
Capital raising costs		(1,391)	(1,200)	(1,391)	(1,200)
Share Capital At The End Of Period: 303,148,665 Fully Paid Shares	**12(b)**	**113,221,065**	**113,222,456**	**113,221,065**	**113,222,456**

The accompanying notes form part of these financial statements.

Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2009

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, other authoritative pronouncements of the Australian Accounting Standards Board and the Corporations Act 2001. Compliance ensures the consolidated financial statements and notes of the consolidated entity and parent complies 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 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 commercialisation to be undertaken. The risk factors set out may materially impact the financial performance and position of the consolidated entity.

In applying Australian Accounting Standards, management must make judgment 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 factors 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 commercialisation of its projects and that the subsequent commercialisation 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 commercialisation 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 found in 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 recognised 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 corresponding tax base of those items.

In principle, deferred tax liabilities are recognised on all taxable differences. Deferred tax assets are recognised 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 recognised 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 recognised in relation to taxable temporary differences arising from goodwill.

Deferred tax liabilities are recognised 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 recognised 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 recognised 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 recognised 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 discount on acquisition.

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 where it is easily convertible to a known amount of cash and subject to an insignificant risk of change in value.

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-derivate 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 recognised as an expense in the period in which it is incurred. Where no internally-generated intangible asset can be recognised, development expenditure is recognised as an expense in the period as incurred. An intangible asset arising from development (or from the development phase of an internal project) is recognised 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.

The consolidated entity uses its critical judgment in continually assessing whether development expenditures meet the recognition criteria of an intangible asset.

At 30 June 2009 Clinuvel Pharmaceuticals Ltd has yet to demonstrate the satisfaction of all the above criteria to recognise and generate an intangible asset from its development activities. The inherent risks in pharmaceutical development are such that the criterion to recognise an intangible asset is not met until regulatory approval to market the drug has been granted.

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 recognised 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.

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. The discount rate used to estimate future cash flows is the 5 year Treasury bond yield published by the Reserve Bank of Australia at 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 2009 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 2008/09 year $678,374 (2008: $776,582) was recognised 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 recognised 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 recognised 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 recognised at the fair value of the consideration received by the company.

Any transaction costs arising on the issue of ordinary shares are recognised 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 recognised 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 recognised 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 recognised 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 recognised 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 recognised for the asset (cash-generating unit) in prior years. A reversal of an impairment loss is recognised 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 recognised 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 recognised 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 recognised 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's 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 recognised in profit or loss in the period in which they arise as defined in AASB 121: The Effects of Changes in Foreign Exchange Rates.

Foreign subsidiaries that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- at the spot rate at reporting date for assets and liabilities; and
- at average monthly exchange rates for income and expenses.

Resulting differences are recognised within equity in a foreign currency translation reserve.

v) Critical Accounting Estimates And Judgment
The consolidated entity evaluates estimates and judgments incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data.

w) 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 were available for early adoption at 30 June 2008, but have not been adopted in preparing this financial report. All other newly issued standards (or standards yet to become effective) are not considered to have an impact on the consolidated entity.

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

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
(a) Revenues				
Interest revenue – other persons	2,667,920	4,297,103	2,667,792	4,296,376
Currency gain on transactions	236,997	-	236,997	-
Total Revenues	**2,904,917**	**4,297,103**	**2,904,789**	**4,296,376**
(b) Expenses				
Clinical development costs	2,280,762	1,475,445	2,252,265	1,469,248
Drug delivery research costs	6,176,670	4,986,059	6,176,670	4,986,059
Toxicity studies	312,877	828,646	312,877	828,646
Research & Development overheads	1,534,715	1,126,057	786,442	700,399
Business marketing & listing	845,904	1,414,856	822,627	1,413,358
Licenses patents and trademarks	916,535	945,443	145,957	139,359
General operations (incl Board)	6,210,361	8,176,388	5,245,981	7,682,741
Doubtful debt provision	-	-	2,528,347	1,721,634
Impairment loss	-	-	-	-
Total Expenses	**18,277,824**	**18,952,894**	**18,271,166**	**18,941,444**
(c) Profit/(Loss) Before Income Tax Includes The Following Specific Expenses				
Depreciation	74,061	85,265	74,061	85,265
Amortisation of sub-licence	747,298	747,298	-	-
Amortisation of trademarks	9,200	9,200	9,200	9,200
Amortisation of product distribution rights	-	-	-	-
Research & Development costs	8,428,935	6,455,307	8,428,935	6,455,307
Doubtful debts – wholly owned subsidiary	-	-	2,528,347	1,732,357
Loss on sale of property, plant and equipment	4,050	30,099	4,050	30,099
Impairment loss - A.C.N. 108 768 896 Pty Ltd	-	-	-	-
Realised loss on disposal of financial assets at fair value through profit and loss	628,844	1,031,333	628,844	1,031,333
Net loss on revaluation of financial assets held at fair value through profit & loss	1,821,414	2,952,395	1,821,414	2,952,395
Operating lease expense – minimum lease payments	311,391	379,467	194,154	243,609

3. Income Tax Expense

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
(a) The Prima Facie Tax On Profit (Loss) Is Reconciled To The Income Tax Expense (Benefit) As Follows:				
Prima facie tax payable on profit (loss) from ordinary activities before income tax at 30% (2008: 30%)	(4,611,872)	(4,396,737)	(4,609,913)	(4,393,520)
Add:				
Tax effect of				
Non deductible amortisation	2,760	2,760	2,760	2,760
Non deductible shareholder admin	-	-	-	-
Capital raising costs	(417)	(360)	(417)	(360)
Non deductible legal fees	-	-	-	-
Impairment loss	-	-	-	-
Share based payments	141,305	12,267	141,305	12,267
Research & Development deduction	(81,851)	(110,134)	(81,851)	(110,134)
(Over)/under provision of income tax in previous years	(333,374)	135,397	(333,374)	135,397
Deferred tax assets not brought to account	4,833,449	4,356,807	4,881,490	4,353,590

(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	23,942,623	19,228,663	23,209,107	18,497,106
Net temporary differences	1,350,737	1,181,248	1,777,823	1,608,334
	25,293,360	**20,409,911**	**24,986,930**	**20,105,440**

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

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Current				
Accrued income	200,925	459,286	200,925	459,286
Sundry debtors	10,862	156,850	10,862	156,850
Total Current	**211,787**	**616,136**	**211,787**	**616,136**
Non Current				
Receivable From Wholly Owned Entity:				
A.C.N. 089 584 467 Pty Ltd	-	-	8,093,297	8,070,017
Provision for non-recovery	-	-	(7,466,981)	(6,696,404)
			626,316	**1,373,613**
A.C.N. 108 768 896 Pty Ltd	-	-	4,370,640	4,377,496
Provision for non-recovery	-	-	(4,370,640)	(4,370,868)
	-	**-**	**-**	**6,628**
Clinuvel, Inc	-	-	1,804,088	1,001,285
Provision for non-recovery (Clinuvel, Inc)	-	-	(1,717,804)	(1,001,285)
	-	**-**	**86,284**	**-**
Clinuvel AG	-	-	1,233,684	202,237
Provision for non-recovery (Clinuvel AG)	-	-	(1,233,684)	(192,206)
	-	**-**	**-**	**10,031**
Total Non Current	**-**	**-**	**712,600**	**1,390,272**

There have been no bad debts written off during 2009 or 2008 against the provision for non-recovery.

The group has recognised a loss of $2,528,346 (2008: $1,721,633) 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.

Movement In The Provision Of Related Party Receivables

	Consolidated	Clinuvel Pharmaceuticals Ltd
Opening balance 1 July 2007	-	(10,539,130)
Charge for the year	-	(1,721,633)
Amount written off	-	-
Opening balance 30 June 2008	-	(12,260,763)
Charge for the year	-	(2,528,346)
Amount written off	-	-
Closing balance 30 June 2009	-	(14,789,109)

5. Other Assets

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Current prepayments				
Peptide	2,277,808	1,390,730	2,277,808	1,390,730
Other	349,777	312,666	321,448	283,617
Total	**2,627,585**	**1,703,396**	**2,599,256**	**1,674,347**

6. Property, Plant And Equipment

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Plant And Equipment				
At cost	586,638	587,576	542,650	554,000
Less: accumulated depreciation	(314,143)	(258,469)	(296,185)	(254,102)
	272,495	**329,107**	**246,465**	**299,898**
Furniture And Fittings				
At cost	117,025	117,888	84,860	84,860
Less: accumulated depreciation	(32,385)	(15,961)	(25,963)	(12,550)
	84,640	**101,927**	**58,897**	**72,310**
Total Property, Plant And Equipment	**357,135**	**431,034**	**305,362**	**372,208**

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.

	Plant And Equipment	Furniture And Fittings	Total
	$	$	$
Consolidated Entity			
Carrying Amount At 1 July 2007	**303,458**	**28,557**	**332,015**
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)
Carrying Amount At 30 June 2008	**329,107**	**101,927**	**431,034**
Additions	22,248	11,727	33,975
Disposals	(22,614)	(13,161)	(35,775)
Depreciation written back on disposal	18,564	4,133	22,697
Depreciations expense	(74,809)	(19,987)	(94,796)
Carrying Amount At 30 June 2009	**272,496**	**84,639**	**357,135**
Parent Entity			
Carrying Amount At 1 July 2007	**299,491**	**16,602**	**316,093**
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)
Carrying Amount At 30 June 2008	**299,898**	**72,310**	**372,208**
Additions	11,265	-	11,265
Disposals	(22,614)	-	(22,614)
Depreciation written back on disposal	18,564	-	18,564
Depreciations expense	(60,648)	(13,413)	(74,061)
Carrying Amount At 30 June 2009	**246,465**	**58,897**	**305,362**

7. Intangible Assets

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Sub-licence To Develop And Commercialise Afamelanotide				
At cost	7,472,983	7,472,983	-	-
Less: accumulated amortisation	(6,846,668)	(6,099,370)	-	-
Total Sub-licence	**626,315**	**1,373,613**	**-**	**-**
Trademarks				
At cost	68,281	68,281	68,281	68,281
Less: accumulated amortisation of trademarks	(40,969)	(34,141)	(40,969)	(34,141)
Patents				
At cost	23,718	23,718	23,718	23,718
Less: accumulated amortisation of patents	(14,231)	(11,859)	(14,231)	(11,859)
Total Trademarks And Patents	**36,799**	**45,999**	**36,799**	**45,999**
Total Intangible Assets	**663,114**	**1,419,612**	**36,799**	**45,999**

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	Total
	$	$	$
Consolidated Entity			
Carrying Amount At 1 July 2007	**2,120,911**	**55,200**	**2,176,111**
Additions	-	-	-
Impairment	-	-	-
Amortisation expense	(747,298)	(9,201)	(756,499)
Carrying Amount At 30 June 2008	**1,373,613**	**45,999**	**1,419,612**
Additions	-	-	-
Impairment	-	-	-
Amortisation expense	(747,298)	(9,200)	(756,498)
Carrying Amount At 30 June 2009	**626,315**	**36,799**	**663,114**
Parent Entity			
Carrying Amount At 1 July 2007	**-**	**55,200**	**55,200**
Additions	-	-	-
Impairment	-	-	-
Amortisation expense	-	(9,201)	(9,201)
Carrying Amount At 30 June 2008	**-**	**45,999**	**45,999**
Additions	-	-	-
Impairment	-	-	-
Amortisation expense	-	(9,200)	(9,200)
Carrying Amount At 30 June 2009	**-**	**36,799**	**36,799**

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

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Current				
Investments comprise:				
Income securities (at fair value through profit and loss)*	16,043,498	25,048,387	16, 043,498	25,048,387
Non Current				
Shares in unlisted controlled entities at cost	-	-	114,080	102,286

* 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 13 to 31 months from reporting date.

9. Interests In Subsidiaries

Name Of Entity	Country Of Incorporation	Ownership Interest	
		2009	2008
Parent Entity			
Clinuvel Pharmaceuticals Ltd	Australia	-	-
Controlled Entities			
A.C.N. 089 584 467 Pty Ltd (formerly Melanotan (Australia) Pty Ltd)	Australia	100%	100%
A.C.N. 108 768 896 Pty Ltd	Australia	100%	100%
Clinuvel (UK) Ltd	United Kingdom	100%	100%
Clinuvel, Inc	United States	100%	100%
Clinuvel AG	Switzerland	100%	100%

10. Payables

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Current				
Unsecured trade creditors	2,055,994	733,985	2,013,496	672,457
Sundry creditors and accrued expenses	2,313,412	2,234,371	2,269,516	2,224,099
Total	**4,369,406**	**2,968,356**	**4,283,012**	**2,896,556**
(a) Aggregate Amounts Payable To:				
Directors and Director-related entities	-	683	-	683
(b) Australian Dollar Equivalents Of Amounts Payable In Foreign Currencies Not Effectively Hedged And Included In Trade And Sundry Creditors:				
US dollars	1,688,947	1,925,623	1,751,000	1,925,623
Euro	456,784	157,847	456,784	157,847
British pounds	194,886	110,544	194,886	110,544
Other	74,758	27,697	139,264	27,697
Total	**2,415,375**	**2,221,711**	**2,541,934**	**2,221,711**

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

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Current				
Employee benefits	174,646	178,576	158,096	168,959
Non Current				
Employee benefits	18,526	9,310	18,526	9,310

12. Contributed Equity

(a) Issued And Paid Up Capital

303,148,665 fully paid ordinary shares (2008: 303,148,665)	113,221,065	113,222,456	113,221,065	113,222,456

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. The company does not have a limited amount of authorised capital and issued shares do not have a par value.

(b) Movements In Ordinary Share Capital:

	Clinuvel Pharmaceuticals Ltd			
		2009		2008
	No.	$	No.	$
At The Beginning Of The Financial Year	**303,148,665**	**113,222,456**	**302,148,665**	**112,813,470**
Issued during the year				
Options exercised and valuation transferred from Share Option Reserve	-	-	1,000,000	410,186
Rights issue	-	-	-	-
Share purchase plan	-	-	-	-
Private placement	-	-	-	-
Less: transaction costs	-	(1,391)	-	(1,200)
Balance At The End Of The Financial Year:	**303,148,665**	**113,221,065**	**303,148,665**	**113,222,456**

12. Contributed Equity (cont'd)

(c) Share Options

As at 30 June 2009 the following share options existed which if exercised, would result in the issue of fully paid ordinary shares:

Expiry Date	Exercise Price	Number Of Options
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	15,340,000
18 November 2013	$0.27/share	350,000
Total		**19,190,000**

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

18 November 2013	$0.27 /share	350,000
Total		**350,000**

During the year no share options issued in prior years were exercised, resulting in the issue of fully paid shares.

13. Reserves

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Share Option Reserve				
Balance At The Beginning Of Period	**1,679,400**	**1,638,509**	**1,679,400**	**1,638,509**
Share based payment	678,372	776,583	678,372	776,583
Transfer to share capital	-	(185,186)	-	(185,186)
Lapsed options	(207,356)	(550,506)	(207,356)	(550,506)
Balance At The End Of Period	**2,150,416**	**1,679,400**	**2,150,416**	**1,679,400**

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 and to retained earnings when options lapse.

Foreign Currency Translation Reserve:				
Balance At The Beginning Of Period	**84,436**	**-**	**-**	**-**
Translating foreign subsidiary to current rate at balance date	(67,406)	84,436	-	-
Balance At The End Of Period	**17,030**	**84,436**	**-**	**-**
Total Reserves	**2,167,446**	**1,763,836**	**2,150,416**	**1,679,400**

14. Accumulated Losses

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Accumulated Losses At The Beginning Of The Year	**(63,171,776)**	**(49,066,491)**	**(63,157,888)**	**(49,063,326)**
Transfer from Share Option Reserve of lapsed & expired options	207,356	550,506	207,356	550,506
Net loss attributable to the members of Clinuvel Pharmaceuticals Ltd	(15,372,907)	(14,655,791)	(15,366,377)	(14,645,068)
Accumulated Losses At The End Of The Financial Year	**(78,337,327)**	**(63,171,776)**	**(78,316,909)**	**(63,157,888)**

15. Lease Commitments

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Operating Lease Commitments (Non-Cancellable Leases)				
Contracted for, but not capitalised in, the accounts:				
Payable not later than 1 year	292,125	378,272	215,943	216,678
Payable later than 1 year but not later than 5 years	184,093	449,959	184,093	404,032
	476,218	**828,231**	**400,036**	**620,710**

Operating leases comprises commitments for office premises and miscellaneous equipment.

16. Earnings Per Share (EPS)

	Consolidated	
	2009	2008
(a) Basic Earnings Per Share (cents per share)	(5.1)	(4.8)
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of Basic Earnings Per Share	303,148,665	302,380,172
(c) The numerator used in the calculation of Basic Earnings Per Share ($)	(15,372,907)	(14,655,791)
(d) Potential Ordinary Shares not considered dilutive	-	-

As at 30 June 2009 the company had on issue 19,190,000 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

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
(a) Reconciliation Of Cash				
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	1,579,568	817,459	1,362,489	662,358
Cash on hand	728	300	258	300
Deposits on call	691,086	9,869,358	689,386	9,867,809
Term deposits (security bonds)	19,400,000	15,000,000	19,400,000	15,000,000
Security bonds	39,261	65,076	38,691	38,691
	21,710,643	**25,752,193**	**21,490,824**	**25,569,158**
(b) Reconciliation Of Cash Flows From Operating Activities With Operating Profit (Loss)				
Operating Profit (Loss) After Income Tax	**(15,372,907)**	**(14,655,791)**	**(15,366,377)**	**(14,645,068)**
Non cash flows in operating (loss):				
Depreciation expense	94,794	91,978	74,060	85,266
Accrued income	258,361	(271,042)	258,361	(271,042)
Exchange rate effect on foreign currencies held	(278,212)	167,802	(278,212)	167,802
Amortisation expense	756,498	756,499	9,200	9,201
Doubtful debt expense	-	-	2,528,346	1,721,633
Executive share option expense	678,374	776,582	678,374	776,582
WDV of non-current assets sold	13,079	30,099	4,050	30,099
Gain on sale of non-current asset	-	-	-	-
Realised loss on disposal of financial assets at fair value through profit and loss	628,844	1,031,333	628,844	1,031,333
Net loss on revaluation of financial assets held at fair value	1,821,414	2,952,395	1,821,414	2,952,395
Unrealised loss foreign exchange translation	(67,406)	78,108	-	-
Changes in assets and liabilities:				
(Increase)/decrease in receivables	907	41,480	988	39,526
(Increase)/decrease in bonds & deposits	-	-	-	-
(Increase)/decrease in inventories	-	-	-	-
(Increase)/decrease in prepayments	(924,187)	1,018,242	(924,907)	1,039,215
Increase/(decrease) in payables	1,399,611	730,727	1,373,142	712,232
Increase/(decrease) in provisions	5,286	70,255	(1,647)	62,403
Net Cash Used In Operating Activities	**(10,985,544)**	**(7,181,333)**	**(9,194,364)**	**(6,288,423)**

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)
Dr. R. Aston (Non-Executive)
Mr. S.R. McLiesh (Non-Executive)
Mrs. B.M. Shanahan (Non-Executive Chair)
Dr. P.J. Wolgen (Managing Director)
Mr. L.J. Wood (Non-Executive, joined Board 11 July 2008)
The Specified Executives Of Clinuvel Pharmaceuticals Limited During The Year Were:
Dr. D. J. Wright (VP – Scientific Affairs)
Mr. D. M. Keamy (Chief Financial Officer, Company Secretary)
Mr. C. H. Mackie (Head of Corporate Development, terminated 15 March 2009)

Key Management Personnel Compensation

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Short-term employee benefits	1,716,831	1,543,428	1,308,235	1,543,428
Post-employment benefits	50,544	50,488	50,544	50,488
Long-term benefits	-	-	-	-
Termination benefits	-	-	-	-
Share-based payments	474,214	518,363	474,214	518,363
	2,241,589	**2,112,279**	**1,832,993**	**2,112,279**

Remuneration Option Holdings Of Key Management Personnel – 2009

	Balance At Start Of Year	Granted As Compensation	Exercised	Lapsed And Expired	Balance At End Of Year	Vested And Exercisable	Unvested
Directors							
H.P.K. Agersborg	2,000,000	-	-	-	2,000,000	1,500,000	500,000
S.R. McLiesh	650,000	-	-	-	650,000	450,000	200,000
R. Aston	2,450,000	-	-	-	2,450,000	2,050,000	400,000
P.J. Wolgen	9,250,000	-	-	-	9,250,000	8,250,000	1,000,000
B.M. Shanahan	850,000	-	-	-	850,000	850,000	-
L.J. Wood	-	350,000	-	-	350,000	116,667	233,333
Executives							
D.J. Wright	1,600,000	-	-	-	1,600,000	1,122,917	477,083
D.M. Keamy	700,000	-	-	-	700,000	402,083	297,917
C.H. Mackie	-	-	-	-	-	-	-

Remuneration Option Holdings Of Key Management Personnel – 2008

	Balance At Start Of Year	Granted As Compensation	Exercised	Other Changes	Balance At End Of Year	Vested And Exercisable	Unvested
Directors							
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
Executives	**1,800,000**	**-**	**-**	**(200,000)**	**1,600,000**	**947,911**	**652,089**
D.J. Wright	800,000	-		(100,000)	700,000	277,083	422,917
D.M. Keamy	-	-	-	-	-	-	-

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 – 2009				Ordinary Shares – 2008			
	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
Directors								
H.P.K. Agersborg	921,105	-	-	921,105	921,105	-	-	921,105
S.R. McLiesh	760,000	-	-	760,000	760,000	-	-	760,000
R. Aston	108,224	-	-	108,224	108,224	-	-	108,224
P.J. Wolgen	95,000	-	-	95,000	-	-	95,000	95,000
B.M. Shanahan	420,071	-	-	420,071	420,071	-	-	420,071
L.J. Wood	-	-	100,000	100,000	-	-	-	-
Executives								
D.J. Wright	-	-	-	-	-	-	-	-
D.M. Keamy	1,600	-	-	1,600	1,600	-	-	1,600
C.H. Mackie	-	-	-	-	-	-	-	-

19. Auditors' Remuneration

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Amounts Received Or Due And Receivable By Grant Thornton For:				
Audit services and review	50,682	44,818	50,682	44,818
Other services	-	-	-	-
Total	**50,682**	**44,818**	**50,682**	**44,818**

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, L.J. Wood.

Wholly-owned Group Transactions

Loans

The loan receivable by Clinuvel Pharmaceuticals Ltd from A.C.N. 089 584 467 Pty Ltd is non-interest bearing. Repayment of the loan will commence upon commercialisation 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 A.C.N. 089 584 467 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 2009 is $4,370,640 (2007: $4,377,496).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel, Inc is non-interest bearing. Repayment of the loan will commence upon commercialisation 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 2009 is $1,804,088 (2008: $1,001,285).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel AG is non-interest bearing. Repayment of the loan will commence upon commercialisation 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 2009 is $1,233,684 (2008: $202,237).

Director Related And Key Management Personnel Transactions And Entities

The following transactions and relationships were in existence as at 30 June 2009 between Directors of the Company and their related entities.

Common Director 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 A.C.N. 089 584 467 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 commercialisation of the technology.

Consultancy Payments To Newtonmore Biosciences Pty Ltd

There was no consultancy payments made to Dr Aston's management company for 2008/09. 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 ($50,000).

21. Segment Information

A segment is a component of the consolidated entity that engages in business activities to provide products or services within a particular economic environment. The consolidated entity operates in one business segment, being the biopharmaceutical sector. It has established non-revenue generating entities in more than one geographical area, however the activities from these entities comparative to the consolidated entity are considered immaterial for the purposes of segment reporting. Furthermore,

although clinical trials are conducted in a number of countries, the core business functions supporting the trials are located in Australia.

In previous reporting periods, the consolidated entity reported a second business segment being Pharmaceuticals Products. This business segment relates to a non-strategic discontinued operation and is therefore no longer a business segment for the purposes of segment reporting.

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 to market prices of foreign exchange purchases, interest rates and equity prices resulting in a change in value of the financial instruments held by the consolidated entity. The objective to manage market risk is to ensure exposures are contained within acceptable parameters, to minimise costs and to stabilise existing assets.

Foreign Currency Risk

The consolidated entity is exposed to foreign currency risk on future commercial transactions and recognised 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 recognising the exposure and the time of payment. In the event of an appreciating Australian dollar, the amount of foreign currency held is minimised at a level to only meet short term obligations in order to maximise 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 2009 and as at 30 June 2008.

The Consolidated Entities Exposure To Foreign Currency Risk At 30 June 2009

	Consolidated			Consolidated		
	2009			2008		
	Cash & Cash Equivalents	Trade & Other Payables	Total	Cash & Cash Equivalents	Trade & Other Payables	Total
USD	541,012	(1,911,425)	(1,370,413)	78,423	(1,548,046)	(1,469,623)
EUR	252,882	(515,362)	(262,480)	95,034	(239,821)	(144,787)
CHF	163,931	(65,415)	98,516	92,988	(67,806)	25,182
GBP	-	(96,748)	(96,748)	-	(53,382)	(53,382)
DKK	-	-	-	-	(1,943)	(1,943)
SEK	-	-	-	-	(24,000)	(24,000)

The Consolidated Entities Exposure To Foreign Currency Risk At 30 June 2009						
	Clinuvel Pharmaceuticals Ltd			Clinuvel Pharmaceuticals Ltd		
			2009			2008
	Cash & Cash Equivalents	Trade & Other Payables	Total	Cash & Cash Equivalents	Trade & Other Payables	Total
USD	482,466	(1,903,228)	(1,420,762)	30,086	(1,533,681)	(1,503,595)
EUR	252,882	(515,362)	(262,480)	95,034	(234,905)	(139,871)
CHF	35,000	(23,308)	11,692	-	(22,622)	(22,622)
GBP	-	(96,748)	(96,748)	-	(53,382)	(53,382)
DKK	-	-	-	-	(1,943)	(1,943)
SEK	-	-	-	-	(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 25% appreciation of the Australian dollar against the US currency would have increased profit and loss and equity by $422,237 for the year ended 30 June 2009 (2008: $381,681), 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 25% 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 25% appreciation of the Australian dollar against the US currency would have increased profit and loss and equity by $437,750 for the year ended 30 June 2009 (2008: $390,504), on the basis that all other variables remain constant. 25% is considered a reflection of the market volatility in the Australian/US dollar rate for the period.

For Clinuvel Pharmaceuticals Ltd, a 25% 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 consolidated entity'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 2009, if interest rates had changed by +/- 100 basis points from the year-end rates (a movement considered reflective of the level of interest rate movements throughout the course of the financial year), with effect from the beginning of the year, profit and equity would be $510,954 higher/lower (2008: $592,704 higher/lower) This analysis assumes all other variables are held constant. For Clinuvel Pharmaceuticals Ltd, at 30 June 2009, if interest rates had changed by +/- 100 basis points from the year-end rates (a movement considered reflective of the level of interest rate movements throughout the course of the financial year), with effect from the beginning of the year, profit and equity would be $508,763 higher/lower (2008: $586,937 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 2009, if the weighted average of the market-acknowledged benchmarks of the investments in income securities increased/decreased by 8.4% (2008: 7.6%) assuming all other variables constant and the investments in securities move in correlation with the indexes, the impact on profit and equity is:

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Market-acknowledged weighted average benchmarks	1,479,609	2,369,982	1,479,609	2,369,982

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, investments in securities and foreign subsidiaries.

Liquidity Risk

Liquidity risk is the risk the consolidated entity will not be able to meets 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.

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 is assumed to approximate their fair values due to their short-term nature.

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.

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 commercialisation.

Contractual Maturities Of Financial Liabilities As At 30 June 2009

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
Trade And Other Payables				
Carrying amount	4,369,406	3,331,954	4,283,012	3,260,154
6 months or less	4,369,406	3,331,954	4,283,012	3,260,154
Greater than 6 months	-	-	-	-
Total	**4,369,406**	**3,331,954**	**4,283,012**	**3,260,154**

23. Employee Benefits

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
	$	$	$	$
The Aggregate Employee Benefit Liability Is Comprised Of :				
Provision for annual leave	157,300	178,576	157,300	168,959
Provision for long service leave	18,526	9,310	18,526	9,310
Accrued FBT & superannuation	68,463	24,756	36,386	32,561
Total	**244,289**	**212,642**	**212,212**	**210,830**

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 2009

Options Series		Number	Grant date	Expiry Date	Exercise Price	Fair Value At Grant Date
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
Issued	18/11/2008	350,000	18/11/2008	18/11/2013	$0.27	$0.05

Option Holdings Of All Issued Options - 2009

Options Series	Balance At Start Of Year	Granted As Compensation	Exercised	Expired And Lapsed	Balance At End Of Year	Vested And Exercisable	Unvested
Issued 19/04/2004	300,000	-	-	(300,000)	-	-	-
Issued 23/02/2006	1,500,000	-	-	-	1,500,000	1,500,000	-
Issued 01/03/2005	500,000	-	-	-	500,000	500,000	-
Issued 31/10/2005	1,500,000	-	-	-	1,500,000	1,500,000	-
Issued 09/02/2007	15,660,000	-	-	(320,000)	15,340,000	12,245,417	3,094,583
Issued 03/08/2007	110,000	-	-	(110,000)	-	-	-
Issued 18/11/2008	-	350,000	-	-	350,000	116,667	233,333
Total	**19,570,000**	**350,000**	**-**	**(730,000)**	**19,190,000**	**15,862,084**	**3,327,916**
Weighted Average Exercise Price	$0.79	$0.28	-	$0.86	$0.78	$0.60	-

The share options outstanding at the end of the financial year had an average remaining contractual life of 862 days (2008: 920 days).

The weighted average fair value of the options granted during the financial year was $0.05.

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.

Option Holdings Of All Issued Options - 2008

Options Series	Balance At Start Of Year	Granted As Compensation	Exercised	Expired And Lapsed	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	-	-	-	300,000	300,000	-
Issued 23/02/2006	1,500,000	-	-	-	1,500,000	750,000	750,000
Issued 01/03/2005	500,000	-	-	-	500,000	330,000	170,000-
Issued 31/10/2005	1,500,000	-	-	-	1,500,000	500,000	1,000,000
Issued 09/02/2007	19,210,000	-	-	(3,550,000)	15,660,000	8,446,458	7,213,542
Issued 03/08/2007		110,000	-	-	110,000	110,000	-
Total	**24,971,660**	**110,000**	**(1,000,000)**	**(4,461,660)**	**19,190,000**	**15,862,084**	**3,327,916**
Weighted Average Exercise Price	$0.78	$0.86	$0.23	$0.83	$0.79	$0.62	-

Black Scholes Binominal Model

Inputs	Options Issued & Granted 18 Nov 2008
Grant date share price	$0.25
Exercise price	$0.275
Grant date	18 November 2008
Expiry date	18 November 2013
Historical volatility (weighted average)	25.5%
Option life (weighted average)	3 years
Risk free interest rate	4.63%

24. Commitments Of Expenditure

	Consolidated		Clinuvel Pharmaceuticals Ltd	
	2009	2008	2009	2008
a) Research Commitments				
AU dollars	-	76,921	-	76,921
US dollars	226,460	363,599	226,460	363,599
Euro	51,009	1,230,315	51,009	1,230,315
Swiss francs	-	-	-	-
British pounds	40,080	24,535	40,080	24,535
Total	**317,549**	**1,695,370**	**317,549**	**1,695,370**
b) Other Expenditure Commitments				
AU dollars	30,000	30,000	30,000	30,000
US dollars	3,697	-	-	-
Euro	-	-	-	-
Swiss francs	6,834	-	-	-
British pounds	-	-	-	-
Total	**40,531**	**30,000**	**30,000**	**30,000**
Total Expenditure Commitments	**358,080**	**1,725,370**	**347,549**	**1,725,370**

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.

26. 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
Telephone: +61 3 9660 4900
Facsimilie: +61 3 9660 4999
mail@clinuvel.com
www.clinuvel.com

Directors' Declaration

In the opinion of the Directors:

1. the financial statements and notes of the company and of the consolidated entity 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 2009 and of their performance for the year ended on that date; and

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

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; and

3. the remuneration disclosures set out in 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 J. Wolgen
Director

Dated this 27th day of August, 2009

Grant Thornton

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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 2009, 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 the Clinuvel Pharmaceuticals Limited Consolidated Entity for the year ended 30 June 2009 included on Clinuvel Pharmaceuticals' web site. The company's directors are responsible for the integrity of Clinuvel Pharmaceuticals' web site. We have not been engaged to report on the integrity of the Clinuvel Pharmaceuticals Limited Consolidated Entity'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 2009 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.

Grant Thornton

Report on the Remuneration Report

We have audited the Remuneration Report included in pages 11 to 19 of the directors' report for the year ended 30 June 2009. 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 2009, complies with section 300A of the Corporations Act 2001.

Grant Thornton.

GRANT THORNTON
Chartered Accountants

David Ashmore
Partner

Melbourne, Australia

Dated this 27th day of August 2009

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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 Clinuvel Pharmaceuticals Limited for the year ended 30 June 2009, 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.

Grant Thornton.

GRANT THORNTON
Chartered Accountants

David Ashmore
Partner

Melbourne, Australia

Dated this 27th day of August 2009

Additional Information Required By The Australian Stock Exchange (ASX)

Additional information, as at 22 September 2009, required by the ASX and not shown elsewhere in this report is as follows:

1. Shareholding

a) Distribution Of Shareholders Numbers

Category (Size Of Holding)	Total Holders
1 - 1,000	332
1,001 - 5,000	1,252
5,001 - 10,000	745
10,001 - 100,000	1,328
100,001 - 9,999,999,999	226
	3,883

b) The number of shareholdings held in less than marketable parcels is 554 for ordinary shares.

c) The names of the substantial shareholders listed in the holding company's register as at 22 September 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>	90,041,292	29.70
2.	CITICORP NOMINEES PTY LIMITED	20,026,510	6.61
3.	SANDHURST TRUSTEES LTD <JMFG CONSOL A/C>	17,190,438	5.67
4.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	14,976,215	4.94
5.	NATIONAL NOMINEES LIMITED	9,167,945	3.02
6.	LOUGHRAN & CO	6,936,336	2.29
7.	BOODUP NOMINEES PTY LTD <OTTER SUPER FUND A/C>	6,020,300	1.99
8.	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	3,679,686	1.21
9.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	3,579,358	1.18
10.	J P MORGAN NOMINEES AUSTRALIA LIMITED	3,533,147	1.17
11.	HEADSTART GLOBAL HOLDINGS LTD	2,733,553	0.90
12.	ARMADA TRADING PTY LTD	2,000,000	0.66
13.	UTOPIA LAND COMPANY PTY LTD	1,610,000	0.53
14.	DR MICHAEL JAMES FISH	1,602,310	0.53
15.	TERSTAN NOMINEES PTY LTD <MORROWS P/L SUPER FUND A/C>	1,555,222	0.51
16.	SANDHURST TRUSTEES LTD <JM MPS A/C>	1,530,000	0.50
17.	MR GREGORY MAXWELL WALLACE + MRS YVONNE EVELYN WALLACE	1,382,000	0.46
18.	HEADSTART GLOBAL AGGRESSIVE HOLDINGS LTD	1,266,447	0.42
19.	WEIGHTON PTY LTD	1,186,187	0.39
20.	FORTIS CLEARING NOMINEES P/L <SETTLEMENT A/C>	1,167,559	0.39
		191,184,505	**63.07**

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 st
Melbourne VIC 3000
Telephone: +61 3 9660 4900
Facsimilie: +61 3 9660 4999
mail@clinuvel.com
www.clinuvel.com

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).

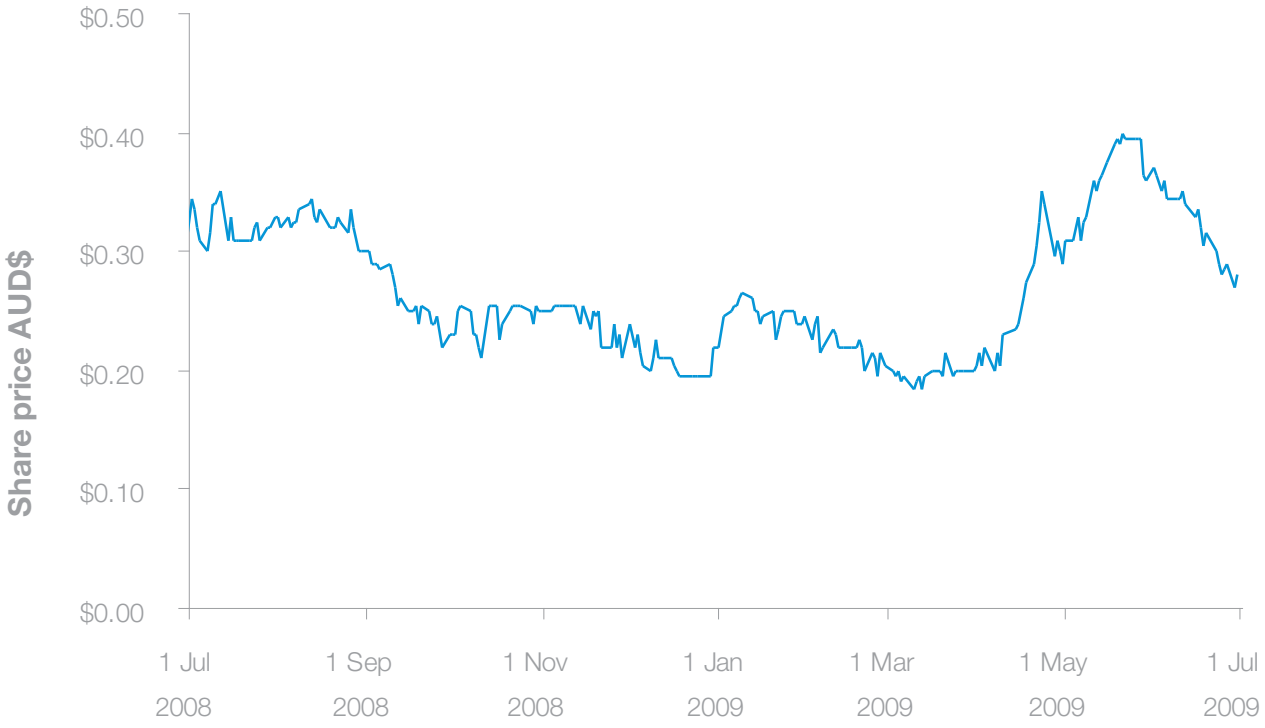
The company's shares are also quoted on other international exchanges as follows:
Germany: Frankfurt and Xetra: UR9
USA: Level 1 American Depositary Receipt Code: CLVLY
ADR Custodian: Bank of New York Mellon

6. Restricted Securities

Restricted securities on issue at 30 June 2009: Nil.

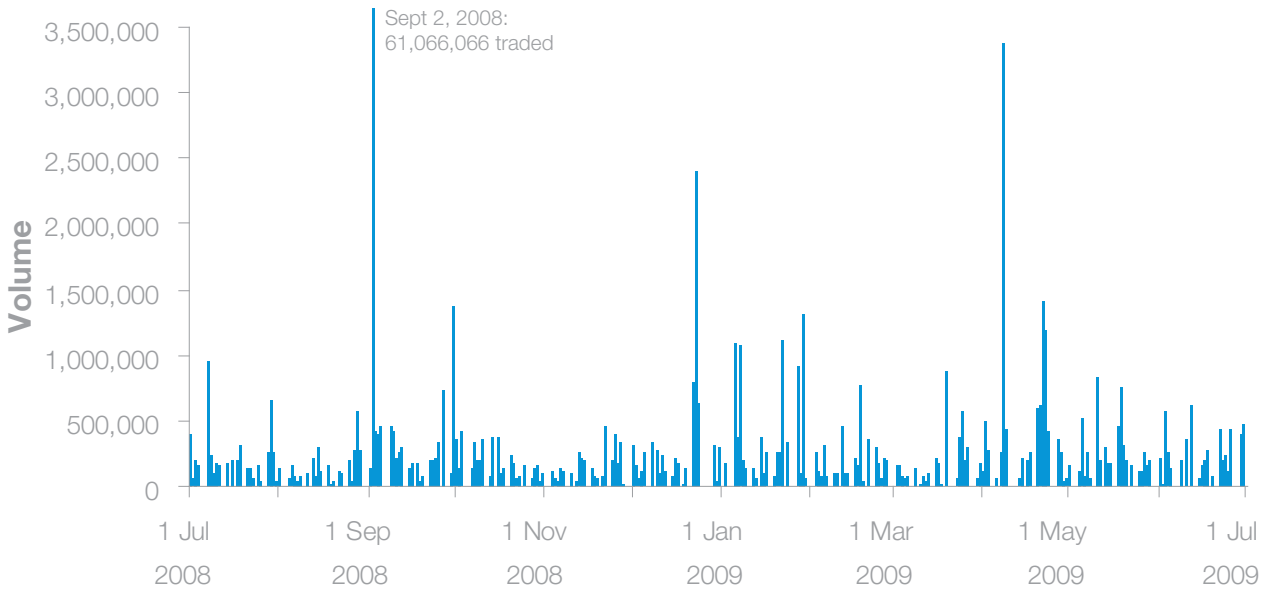
Market Performance

ASX: CUV



Daily Trading Volume ASX: CUV

Average daily trading volume 1/7/08-30/06/09: **509,243**



Press, Literature And New Media

Press Highlights

Article Title	Date	Outlet	Origin
Braune Haut per Spritze	04/07/2008	10vor10 - SF1	Switzerland
Marc Sinatra's Bioguide: Clinuvel	25/11/2008	Biotech Daily	Australia
Clinuvel: FDA Zulassung zum Greifen nah!	14/12/2008	Sunday-Market	Germany
Clinuvel announces positive Phase III interim results for EPP	21/01/2009	Biotech Intelligence	France
Clinuvel has skin treatment 'gateway to US'	29/01/2009	News Bites	Australia
FDA grants IND status to Clinuvel's photoprotective afamelanotide	30/01/2009	Fierce Biotech	USA
肌を黒くしたい人たちが乱用：「メラニンを増やす薬」が臨床試験へ	04/02/2009	Yahoo.jp	Japan
Clinuvel Pharmaceuticals – On Track for Market Launch in 2010	20/04/2009	Bioshares	Australia
Implant defence	16/05/2009	The Sun	UK
Clinuvel – Nur für starke Nerven	22/05/2009	Platow Emerging Markets	Austria
Clinuvel mulls Swiss listing in 2009	22/05/2009	Reuters	Switzerland
Clinuvel hopes to shine as photoprotective nears market	22/05/2009	Scrip	Online
Fool's Gold?	01/06/2009	Cosmopolitan	South Africa
EMEA grants Clinuvel new orphan drug designation	18/06/2009	PharmaLive	USA
Künstliche Bräune mit Nebenwirkungen	06/07/2009	BR-Online	Germany
Sun shines on Clinuvel trial	16/07/2009	BiotechnologyNews.net	Australia

Afamelanotide Academic Highlights

- Minder, E & Harms, J H (2009). "Nle-D-7Phe-α-Melanocyte-Stimulating Hormone (NDPMSH) to treat congenital erythropoietic porphyria (CEP) – an open label compassionate use application". *Poster: 67th Annual Meeting of the American Academy of Dermatology*. San Francisco: March.

- Neumann, N (2009). "Alpha-MSH-Analoga zur Behandlung von Photodermatosen". *Presentation: DGG-Tatung, ICC Dresden* [Annual Meeting of the German Dermatological Society]. Dresden: 29 April.

- Dunn, R et al, (2009). "Afamelanotide, an α-melanocyte stimulating hormone (MSH) agonist reduces phototoxicity in Erythropoietic Protoporphyria (EPP), as tested under laboratory conditions". *Australasian Journal of Dermatology*, 50 Suppl. 1:A12-A13, 13 May.

- Harms, J H, et al (2009). "Mitigating Photosensitivity of Erythropoietic Protoporphyria Patients by an Agonistic Analog of α-Melanocyte Stimulating Hormone". *Photochemistry and Photobiology*, ePub.

Analyst Coverage

David Stanton – ABN AMRO/RBS
Doy Gorton – Louis Capital
RRS Capital Strategic Services

Sun shines on Clinuvel trial
- BiotechnologyNews.net (Australia)

"An amazing new drug that protects fair-skinned people against skin cancer is set for launch next year."
- The Sun (UK)

"The safety aspect of the drug continues to be good."
- Bioshares (Australia)

Aiming to be photogenic
- Biocentury (USA)

"Clinuvel does not need more cash to bring its lead drug candidate to market,"
- Reuters (Switzerland)

Clinuvel Pharmaceuticals – On Track for Market Launch in 2010
- Bioshares (Australia)

"Selection of a niche indication is a valid approach for the company to get the drug on the market as quickly as possible"
- Bioshares (Australia)

Clinuvel hopes up
- The Age (Australia)

"Clinuvel has a quality board with experience covering each of the required areas."
- Biotech Daily (Australia)

Clinical Summary

Clinuvel is currently testing afamelanotide for five medical indications in clinical trials:

Erythropoietic Protoporphyria (EPP)

EPP is a rare genetic and metabolic disorder of heme synthesis which causes a chemical substance known as protoporphyrin IX to accumulate in the skin. When the skin is exposed to the sun, this substance is elicited by light, causing a chemical reaction that results in intolerable pain, skin damage and scarring: this phenomenon is known as phototoxicity.

Solar Urticaria (SU)

SU is a skin disorder marked by an acute allergic response following UV or sun exposure. Symptoms can be systemic, such as anaphylaxis, breathing difficulty, nausea and headaches. Immediate localised reactions vary from characteristic 'wheal' formation and erupting flares on exposed skin sites, to swelling of soft tissues. Current available treatment is only partially effective and consists of anti-histamines, immunotherapy and plasmapheresis (blood purification).

Photodynamic Therapy (PDT)

PDT is a specific cancer treatment globally. In PDT, a photosensitising agent is used as well as a specific light source and oxygen to selectively destroy cancer cells through a photodynamic reaction. Photosensitising agents are drugs that only become active when light sources of certain wavelength is directed onto the area where they are concentrated.

Photosensitising agents such as porfimer sodium make skin (and eyes) hyper sensitive to light for up to 90 days following treatment. Patients are strictly advised to avoid direct sunlight and bright indoor light. Patients suffer intense pain associated with this phototoxicity and are forced to avoid sunlight/ artificial light for up to 90 days following treatment.

Actinic Keratosis (AK) And Squamous Cell Carcinoma (SCC) Skin Cancer

AKs are precancerous skin lesions; collections of abnormally transformed skin cells (keratinocytes) found in the upper layers of skin (epidermis) that develop after prolonged exposure to UV. AKs form discrete, dry, rough adherent or scaly lesions, usually caused by sun exposure. The major clinical consequences of precancerous AKs are that these lesions may transition into skin cancer. AKs are also called Solar Keratoses (SKs).

SCC is a malignant tumour of the skin and the second most common form of skin cancer, caused by prolonged exposure to UV. Tumours are commonly found on sun exposed areas, such as the face, ears, neck, arms or hands, but can also form on areas which are rarely exposed to light. There has been a global increase in the incidence of SCC recorded in fair skinned people; their lack of skin pigmentation and sensitivity to UV is thought to be the two determining factors in developing SCC or skin tumours.

About Organ Transplant Recipients (OTRs) And Skin Cancer

There is a remarkably high incidence of skin cancer in organ transplant recipients (OTRs), due to the necessity to use immune suppressive medications. It has been found that OTRs are up to 65 to 250 times more likely to develop skin cancer than those who have not had an organ transplant. Non-melanoma skin cancers account for around 50% of malignancies in OTRs, with a mortality rate of OTR patients due to skin cancer believed to be 5-8%.

Polymorphic Light Eruption (PLE/PMLE)

PLE is the most common photosensitivity and, after sunburn, is the most common sun-related problem seen by doctors. A distressing seasonal skin condition with episodes most commonly beginning in spring and resolving by late-summer or autumn, symptoms include non-scarring, itchy or burning red papules, vesicles or plaques which appear on sun-exposed skin 30 minutes to several hours following exposure to sunlight.

Corporate Directory

Directors and Executives

Non-Executive Chair:
Brenda Shanahan

Non-Executive Directors:
Stanley McLiesh, Dr. Roger Aston, Jack Wood.

Managing Director and Chief Executive Officer:
Dr. Philippe Wolgen

Executive Director and Chief Scientific Officer:
Dr. Helmer Agersborg

Vice President, Scientific Affairs:
Dr. Dennis Wright

Chief Financial Officer and Company Secretary:
Darren Keamy

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
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Tel: +61 3 9415 4000

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Melbourne, Victoria 3000, Australia

Banker

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

Legal Counsel

Minter Ellison
Rialto Towers
Level 16/525 Collins Street
Melbourne, Victoria 3000, Australia

Allens Arthur Robinson
Level 27/530 Collins Street
Melbourne, Victoria 3000, Australia

IP Lawyer

Dipl.-Ing. Peter Farago
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