



Clinuvel Pharmaceuticals Ltd

ANNUAL REPORT **2010**

CLINICAL SUMMARY

Clinuvel is currently evaluating SCENESSE® (afamelanotide) in four medical indications in clinical trials:

ERYTHROPOIETIC PROTOPORPHYRIA (EPP)

Phase III trial (Europe & Australia) complete. Phase II (US) and Phase III (Europe) confirmatory trials underway

EPP is a rare genetic disease found mainly in people with fair skin. It is characterised by severe phototoxicity (or intolerance to light) of the skin resulting in intolerable pain, swelling, and scarring, usually of the exposed areas such as the face, hands and feet. The pain experienced and expressed by EPP patients when their skin is exposed to light is reported as intolerable. EPP patients are often forced to remain indoors, severely affecting their quality of life.

NONSEGMENTAL VITILIGO (NSV)

Phase II trial (US & Europe) pending regulatory approval

Vitiligo is a common skin disorder in which the pigment producing cells of the skin (melanocytes) are absent or demonstrate lack of activity. As a result, lighter depigmented patches of skin (target lesions) appear in different parts of the body due the lack of melanin (pigment). The exact cause of vitiligo is unknown, but it is generally recognised as an autoimmune disease. Between 0.1-2% of the global population is affected by vitiligo, affecting all races. Vitiligo causes significant psychological and emotional distress.

Vitiligo is traditionally separated into two clinical forms: nonsegmental, or generalised, vitiligo (NSV) and segmental vitiligo (SV), which present with distinctive clinical features and natural histories.

NSV is the most common form of the disease, accounting for 72-95% of the cases. The vitiliginous lesions are usually symmetrically distributed and new patches may appear throughout the patient's life. The disease is progressive with flare-ups. NSV is frequently associated with personal or family history of auto-immunity.

ACTINIC KERATOSIS (AK) AND SQUAMOUS CELL CARCINOMA (SCC) SKIN CANCER

Phase II trial (Europe & Australia) underway

AKs are precancerous skin lesions; collections of abnormal skin cells (keratinocytes) found in the upper layers of skin (epidermis) that develop after prolonged exposure to UVR. AKs form discrete, dry, rough adherent or scaly lesions, usually caused by sun exposure. The major clinical consequences of 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 UVR. 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 is thought to be a determining factor 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, due to the necessary use of immune suppressive medications. It has been found that OTRs are up to 65 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)

Phase III trial (Europe) underway

PLE is the most common recurrent photodermatosis causing sensitivity and, after sunburn (solar erythema), is the most common sun-related problem seen by physicians. PLE is a distressing seasonal skin condition with episodes typically beginning in spring and resolving by late-summer or autumn, and symptoms include non-scarring, burning red papules, vesicles or plaques which appear on sun-exposed skin 30 minutes to several hours following exposure to sunlight.

For more details on Clinuvel's clinical program with SCENESSE®, log onto <http://www.clinuvel.com>.

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BACKGROUND OF PHOTOPROTECTIVE THERAPY



Clinuvel worked on developing trial protocols which would enable the company to present data that definitively showed regulators both the safety and efficacy of the drug when used in a range of patients.

In 2005 Clinuvel established a strategy to take a first-in-class molecule to market as the world's first systemic photoprotective drug. It was clear that the scientific basis of the molecule supported the use of the drug – known generically as afamelanotide – as the world's first systemically administered photoprotectant (protectant of skin from UV and visible light). Afamelanotide worked by mimicking the body's natural defense mechanism to UV light, activating melanin in skin which in turn would reflect and refract photons and protect the skin cells underneath. The drug had shown a good safety and tolerability record in early clinical trials in the USA and Australia, and promise as a potent activator of dermal melanin in vivo and in vitro. The main problem for Clinuvel, however, was determining how best to pursue the technology such that it could become a viable medicinal product which would be proven safe and effective.

The answer took time, but focused around one key ingredient: light. By understanding how skin, and select diseases, interacted with light, the Clinuvel team was able to identify possible applications of the drug where protection from light was essential.

Three indications – erythropoietic protoporphyria (EPP), polymorphous light eruption (PLE) and precancerous and cancerous lesions (AK/SCC) – were shortly pursued in initial trials. It became apparent from early clinical feedback that EPP showed the greatest promise. EPP is a rare disease, affecting approximately 8,000-10,000 individuals globally. A metabolic disorder which disrupts the pathway to synthesise haem in the body, EPP causes the accumulation of a chemical in the skin called protoporphyrin IX (PPIX) which, when exposed to light and blue light in particular, causes phototoxic reactions. In short, individuals

with EPP experience excruciating burning reactions on their skin whenever it is exposed, even briefly, to levels of light others would find inconsequential. Early clinical anecdotes suggested that afamelanotide, administered as a controlled release implant, could transform the lives of individuals with EPP and allow them to expose their skin to the outside world for the first time. Clinical evidence soon followed and the program for EPP was accelerated to late stage Phase III trials.

Meanwhile, the Clinuvel team continued to explore other applications of the drug, gaining a deeper understanding of how light and skin interacted. Two pilot studies suggested afamelanotide could be of clinical benefit as an adjunct therapy in a cancer treatment known as photodynamic therapy (PDT) as well as in a rare sunlight allergy called solar urticaria (SU). Trials for PLE and skin cancer also progressed, with the latter focusing on patients who had received organ transplants yet whose reliance on immunosuppressive drugs made them significantly prone to sun induced malignancies.

As the trials progressed, Clinuvel began to crystallise its program to make the drug 'evaluable' by regulators to obtain marketing approval. As a first-in-class drug, afamelanotide had no peer program against which it could be evaluated, nor a predecessor drug which had been presented to regulatory agencies, such as the FDA or European Medicines Agency (EMA). Working closely with these agencies, and others, the Clinuvel team finalised the drug's formulation: a controlled release 16mg injectable implant, easily administrable by a physician in a controlled clinical setting once every two months. The dose was finely tuned such that it produced the optimal photoprotective response in patients, while minimising exposure to the drug substance. A suitable manufacturer for the product has recently been settled, enabling the company to supply the drug on a scale necessary for clinical trials and commercial supply. This year, the company revealed the product's approved trade name: SCENESSE®.

Concurrently, Clinuvel worked on developing trial protocols which would enable the company to present data that definitively showed regulators both the safety and efficacy of the drug when used in a range of patients. Working with a novel drug in diseases which had not been studied in controlled trials continues to prove a challenge, yet the company relied upon internal knowledge, as well as that of a large number of global experts, to establish a unique clinical program for the drug. For EPP in particular, great progress was made in the clinic. As with the earlier study, anecdotal evidence mounted for the drug's use in the EPP

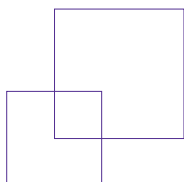
population during a Phase III trial and, with the encouragement of physicians and patients, the company sponsored ongoing use of the drug in a large number of European and Australian EPP trial participants under compassionate use protocols. In Italy, the community support for the drug's use in EPP eventuated in a world first: a pre-approval for the drug's supply for Italian EPP patients and reimbursement to Clinuvel for this supply. For the first time, SCENESSE® would begin to generate revenues, a key milestone in the life of a drug product.

Yet, as one chapter of the Clinuvel story draws to a close, several more are about to be written. As the company has worked more closely with leaders in the fields of photobiology, dermatology and melanocortins, new opportunities have arisen. It is from this work that two new programs have been announced in recent months and which prove most exciting for the company.

Pending regulatory approval SCENESSE® will, for the first time, commence clinical trials as a repigmentation therapy before the end of 2010 in the most common form of the pigmentary disorder vitiligo. This subclassification, known as nonsegmental or generalised vitiligo, affects over 45 million individuals globally. Again, it was by looking at how light and skin interact that the Clinuvel team began to realise the potential of the drug to assist patients. By using SCENESSE® as an adjunct to a common light therapy (known as NB-UVB) it is hoped that the drug may accelerate the repigmentation process and reduce the burden of treatment for individuals with nonsegmental vitiligo.

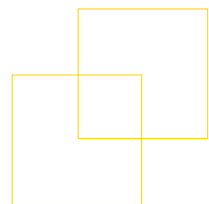
Finally, Clinuvel announced that it had the proprietary rights to a new molecule; a new melanocortin known as CUV9900. Based on preclinical evidence to date, the company believes that CUV9900 may prove a potent skin protectant and form the basis for a product to compliment SCENESSE®.

There is still much for Clinuvel to achieve, but since its early development and strategy the company has proven its ability to progress novel drugs from concepts through the clinic. By understanding UV, light, melanin and skin, and learning from those around it, Clinuvel is well positioned to succeed in a business where so many have failed.





CHAIR'S LETTER



Dear Shareholders,

As the newly elected Chair of Clinuvel, in the first instance I would like to thank the retiring Chair, Mrs Brenda Shanahan, for her leadership of the company over the past two years. During that period there has been considerable progress made on clinical, regulatory and commercial fronts as SCENESSE® (afamelanotide) moves towards global approval and marketing.

During a long career in pharmaceutical development and commercialisation I have witnessed a few outstanding successes, and also some dismal failures. Seeking regulatory approval and registration of a new chemical entity is a long, precise process. It requires an effective and safe product and tremendous rigour, co-ordination and a degree of creativity in developing the appropriate clinical strategy to achieve a positive outcome. It is my belief that we have an outstanding, dedicated team of professionals progressing the program, but the company is bound by the speed of responses by the regulatory authorities in both the US and Europe.

When this current management started five years ago, there was no formulation other than a surgically implantable polymer which was not commercially viable. There was no corporate direction, and no clinical and regulatory strategy. Most of all, there was no funding in place to even contemplate a mature development plan. With the appointment of Drs Wolgen and Agersborg the company took off; a new formulation was developed into a preferred dissolvable injectable product, and a new clinical and regulatory direction was found. The management team under Philippe Wolgen succeeded in securing AUD\$68M in funding in two rounds,

sufficient to establish the company as it exists today. At the top of the markets, new investors were found, and the decline in share price started when many of the interested funds were required to redeem their portfolios. This process has had a major impact on CUV's stock performance, despite the internal performance of the team. Here a value gap has started to open, namely between the intrinsic value of the company and the enterprise value as shown on the ASX on a daily basis.

Management is following a prudent financial strategy where cash preservation is demonstrated. Our initial three year projection has surpassed the Board's expectation thus far, and with current cash it is expected that the company has approximately another two years in funding.

Given its focus and commitment, the team is well within the realm of drug development which normally takes 9-11 years to bring a product to market. Here, management has done well to post first revenues within five years.

Clinuvel was awarded orphan drug designation by EMA and FDA for developing SCENESSE® in Europe and the US for erythropoietic protoporphyria (EPP). The initial results have been very good, and both patients and physicians unanimously support the drug in the use of EPP, as exemplified in the high retention rate in the trials as well as the high demand for the drug after completion of the trials. It is a major testimony of our management to gain worldwide acceptance of SCENESSE®.

The major leading academics and physicians have now joined with Clinuvel to develop the drug in vitiligo.

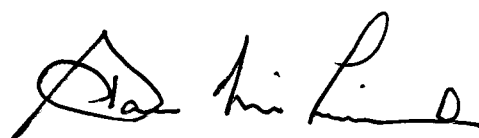
The most recent application, the use of SCENESSE® in vitiligo, is notable. I believe it is necessary to reflect on this historical event and direction. An abundance of requests have come over the years to Clinuvel to test SCENESSE® in vitiligo, the auto-immune disease causing depigmentation of the skin. Recent scientific breakthrough in the use of phototherapy demonstrated how stem cell stimulation leads to repigmentation efforts in vitiligo, which can be further boosted to accelerate the pigmentary response by SCENESSE®. The clinical and commercial implications are potentially enormous. The overwhelming response we have seen the past weeks is testimony to this potential. The major leading academics and physicians have now joined with Clinuvel to develop the drug in vitiligo. Your Board looks forward to the start of trials and first clinical results.

When management first proposed at the end of 2008 that it would develop a program in several individual European countries in order to obtain first registration for SCENESSE®, some skepticism was heard in the Board room, as no other drug or company had obtained such an approval ahead of the European agency EMA. Last May, we were shown collectively that one can be an exception to the rule if patient and physician demand for a drug is high. Eighteen months of dialogue with the Italian regulatory agency (AIFA) resulted in SCENESSE® being included in the list of reimbursable drugs, whereby the company is now posting its first revenues from distribution to Italian patients.

The European EPP program has also enabled Clinuvel to expand its program into the US, with a Phase II confirmatory trial underway across the country. Pending data from this trial, along with that from a confirmatory Phase III trial in Europe, Clinuvel should be in a position to present compelling evidence to European, and possibly US, regulators to approve SCENESSE® for EPP. Here management is following a strict and prudent path: it will only file if all data are convincing and have a chance to stand up to regulatory scrutiny. The company has only one chance to obtain regulatory approval. Given the track record of this team the past five years, I am comfortable and convinced that this company will deliver further.

Finally, after years of internal research, we now have a second molecule (CUV9900) which will complement SCENESSE® for further indications, translating into larger markets. Further announcements will be made on CUV9900's progress in due course.

I am sure that shareholders who are investing in biotechnology development for the first time would agree that it is a long, slow process. I thank you for your patience and look forward to your continuing support as we move inexorably towards registration and commercial approval of SCENESSE® (afamelanotide) in EPP, vitiligo and other appropriate dermatological applications.



Stan McLiesh, Chairman



MANAGING DIRECTOR'S REPORT

Dear Shareholders,

Amidst all the uncertainty in the markets and discussions of shareholder value, I did not lose sight of the most important premise in healthcare: fill an unmet clinical need. In developing afamelanotide, my major focus has been to manage uncertainty in terms of clinical results, drug development and delivery, and the creation of shareholder value.

As time has passed, any uncertainty surrounding the need for Clinuvel's lead product SCENESSE® (afamelanotide) has been reduced. The risk that we will not be able to do that which is required for development has been essentially eliminated. The risk that we will not be able to meet regulatory requirements has been significantly reduced. Therefore, the Clinuvel team will maintain its focus, dedication and tenacity, and my expectation is that the company will be successful in delivering a beneficial product to a global market.

The unique objective in new drug development is to provide a new pharmaceutical solution for patients requiring treatment. After nearly five years at the helm of Clinuvel, I am convinced that the common feedback from physicians and patients stems from a genuine medicinal benefit they received after the administration of SCENESSE®. 'Doing good' by developing a novel drug for erythropoietic protoporphyria (EPP) patients meets this sole objective.

In this review, I will take the opportunity to look back at key events of past 12 months and to assess the company's position and current status of development. I shall also provide an outlook on how I intend to build further value in the company. It has been clear to the Board and all involved that the Clinuvel business model is different from other pharmaceutical entities; this realisation has assisted the Board in making choices and defining options.

In 2005, at the start of the restructuring and redirecting of Clinuvel, the clear mandate of the Board and shareholders was to explore the viability of afamelanotide as a medicinal product for the European and US markets. The ultimate goal was to find a venue which would optimise the commercial potential of the drug.

The significant events of 2010 have given us confidence that these goals can be achieved and that Clinuvel will belong to the select group of life sciences companies which succeed in developing a successful first-in-class drug.

REVIEW 2010

A breakthrough event in March was Clinuvel's start of the US trial in EPP (CUV030).

Another highlight came in May 2010, when the Italian regulatory agency, AIFA, included SCENESSE® in its list of reimbursable drugs. SCENESSE® is now available to Italian patients diagnosed with EPP (absolute light intolerance). This was significant in more than one aspect. First, it marked the product's entry into European markets, and second, it indicated a European regulatory agency's willingness to accept afamelanotide as a treatment for diseased patients. The company will soon post its first revenues from these patients. This historical event confirmed our ability to commercialise afamelanotide.

In July, we posted the results from the first placebo-controlled 12-month trial in EPP (CUV017). These results indicated that patients who went outside during active drug treatment received treatment benefit. Our teams also learned that patients who had been on the drug expressed the wish to remain on drug after completion of the clinical trials under compassionate use protocols.

With Clinuvel's entry in the US in 2009, and first trials in 2010, strict protection of our technology is required to maintain market leadership.

These observations bode well for the future of the drug, but ultimately we will all need to await the final regulatory outcomes. We also recently announced the development of Clinuvel's second molecule, CUV9900. We project that by the end of 2011, the Company will have one or two new formulations for use in complementary applications in dermatology.

UNIQUE CHALLENGES

A set of challenges came with Clinuvel's program:

- a new, untested molecule (first-in-class);
- a new formulation; and
- a treatment for a relatively unknown disease in an orphan (small) population of patients for whom no previous treatment existed

Various additional challenges are posed to our teams during the development process. Convincing physicians, ethics committees and individual regulatory agencies in more than twenty individual countries that our drug merited development was the initial hurdle. The attraction and retention of an adequate number of patients into our trials proved a further hurdle. Drop-out rates in most trials range from 20-30%. We managed to keep the drop-out rate in all our trials under 10%. The final restriction posed by the unique photoprotective characteristics of afamelanotide was the organisation of our global trials such that we cleared all regulatory agencies in time to be able to conduct the trials when UV and light intensity provokes and aggravates diseases symptoms, from March to October in the Northern hemisphere.

Our teams met the clinical criteria this past year. As I write, there are 77 patients enrolled in the confirmatory US EPP trial (CUV030) and 76 in the European EPP trial (CUV029). In 2011, we will learn how these patients have responded to the treatment.

INTELLECTUAL PROPERTY

In June we announced the grant of the US patent for the exclusive use of SCENESSE®, and any molecule belonging to the family of melanocortins, for UV-protection of individuals who have any genetic defect in the melanocortin-1 receptor (patent #7,745,408). The portfolio of patents granted and filed is a fundamental part of the company's position in terms of ability to successfully commercialise and defend its markets. The company is actively managing the lifecycle of its patents throughout US, Europe, Asia Pacific and Africa.

As scientific and clinical progress has been made the past years a number of new patents have been filed to protect the data generated by our innovative teams. Additionally, know how and specific trade secrets are guarded by our team to enable and to stabilise and defend our IP position. Yet, a middle ground is to be found between private rights and public interest in Clinuvel's technology. Clinuvel's innovation and novel steps into photoprotective therapy (of the skin) needs to be placed in the context of the Henry-Waxman Act passed in 1984 by the US Congress, whereby the House is empowered to promote 'the Progress of Science and useful Arts'. At the same time, inventors in life sciences retain their exclusive rights to their respective 'Writings and Discoveries'. With Clinuvel's entry in the US in 2009, and first trials in 2010, strict protection of our technology is required to maintain market leadership.

The European, Swiss and US orphan drug designations for EPP are an integral component of the roll out of our clinical program, while shielding the company from competitive pressure (Figure 1). Approval will provide SCENESSE® seven years market exclusivity in the US and an additional six months of market exclusivity following paediatric development approval by the FDA.

SCENESSE® IN EPP			
EUROPE	US	SWITZERLAND	REST OF THE WORLD
10 years market exclusivity (ODD)	7 years market exclusivity (ODD)	7 years market exclusivity (ODD)	N/A
Paediatric development ongoing	Paediatric development ongoing	Paediatric development ongoing	Paediatric development ongoing
Patent coverage	Patent coverage	Patent coverage	Patent coverage
Specific know how	Specific know how	Specific know how	Specific know how

SCENESSE® IN VITILIGO, POLYMORPHOUS LIGHT ERUPTION, SKIN CANCER (AK/SCC)			
EUROPE	US	SWITZERLAND	REST OF THE WORLD
Patent coverage	Patent coverage	Patent coverage	Patent coverage
Specific know how	Specific know how	Specific know how	Specific know how

Figure 1. IP protection – patents, orphan drug designations (ODD) and internal expertise

FINANCE

In 2006 and 2007, we were able to attract substantial funding for the company. This enabled us to execute the current program. We expected strict regulatory review processes in both US and Europe. We anticipated a lengthy development effort starting virtually from a zero base. We adopted a business model of self-sufficiency rather than relying only on consultation with third parties. We were able to extend the company's runway by two years; originally management had projected a total of three years worth of funding. However, strict and disciplined financial management provided us the funding to develop the drug to market. The annual expenditure rates on the afamelanotide program for the years ending 30 June were: 2006 A\$9.9m; 2007 A\$8.89m; 2008 A\$11.1m; 2009 A\$13.9m; and 2010 A\$13.2m. It is anticipated that for 2011 the company will spend A\$17.2m on the overall program. With A\$27 million remaining in funding (July 1, 2010), it is anticipated that funding is sufficient to obtain registration for SCENESSE® in Europe, and possibly in the US. The latter is dependent on the duration of the FDA approval process.

The share performance of the company has been affected by market conditions, despite the technological progress of the company. Risk aversion is seen in many of the institutional investors who review their investment mandates and portfolios. In general, biotechnology development companies have suffered from a lack of strong investment. I strongly believe that value will be realised when we continue to produce results and the safety and effectiveness of SCENESSE® is demonstrated to the satisfaction of the regulatory authorities.

Given the final stage of product development, and the volatility of the Clinuvel share price the past years, stock consolidation will be proposed to our shareholders at November's AGM. With the progress of the company in the US, Clinuvel is in a much better position to present its case to US institutional investors. In some cases, the legitimate argument is that some funds are restricted from investing in stocks with a nominal value below one US dollar. This investment restriction will be addressed by Clinuvel's proposed common share consolidation of 1:10.

For us it is fundamental to establish value by demonstrating a sustainable market in EPP and a second broader indication to allow strategic options.

BUSINESS MODEL

In evaluating the company over years, value creation followed the stage of development – or, differently phrased – intrinsic value is a function of product development. Here, successful development hinges on four factors:

1. positive clinical data;
2. positive regulatory feedback;
3. product acceptance by the medical community; and
4. patients' acceptance of treatment.

These factors very much determine the Board's and management's strategic choices.

Given the lengthy history and early choices made by the company, the commercial pathway is clear.

This year's review by the Italian regulatory agency AIFA acknowledged the complex but correct strategy of the company.

The field of orphan diseases has attracted much attention in pharmaceuticals, as demonstrated by the recent 'novel' focus on orphan diseases by the larger global pharmaceutical companies. In some instances, a product finds multiple applications once on the market, necessitating label expansion, in other cases the orphan indications are sufficient to provide shareholder return. At Clinuvel we are in the position to have identified both a viable global orphan market for SCENESSE® and application in larger markets such as polymorphous light eruption (PLE) and vitiligo.

In many ways the clinical response and indication indirectly dictate the strategic choices of a company. For us it is fundamental to establish value by demonstrating a sustainable market in EPP and a second broader indication to allow strategic options. Either direct distribution by Clinuvel or partnering with a larger distributor are pathways which may lie ahead. In Italy, the company has started its own distribution.

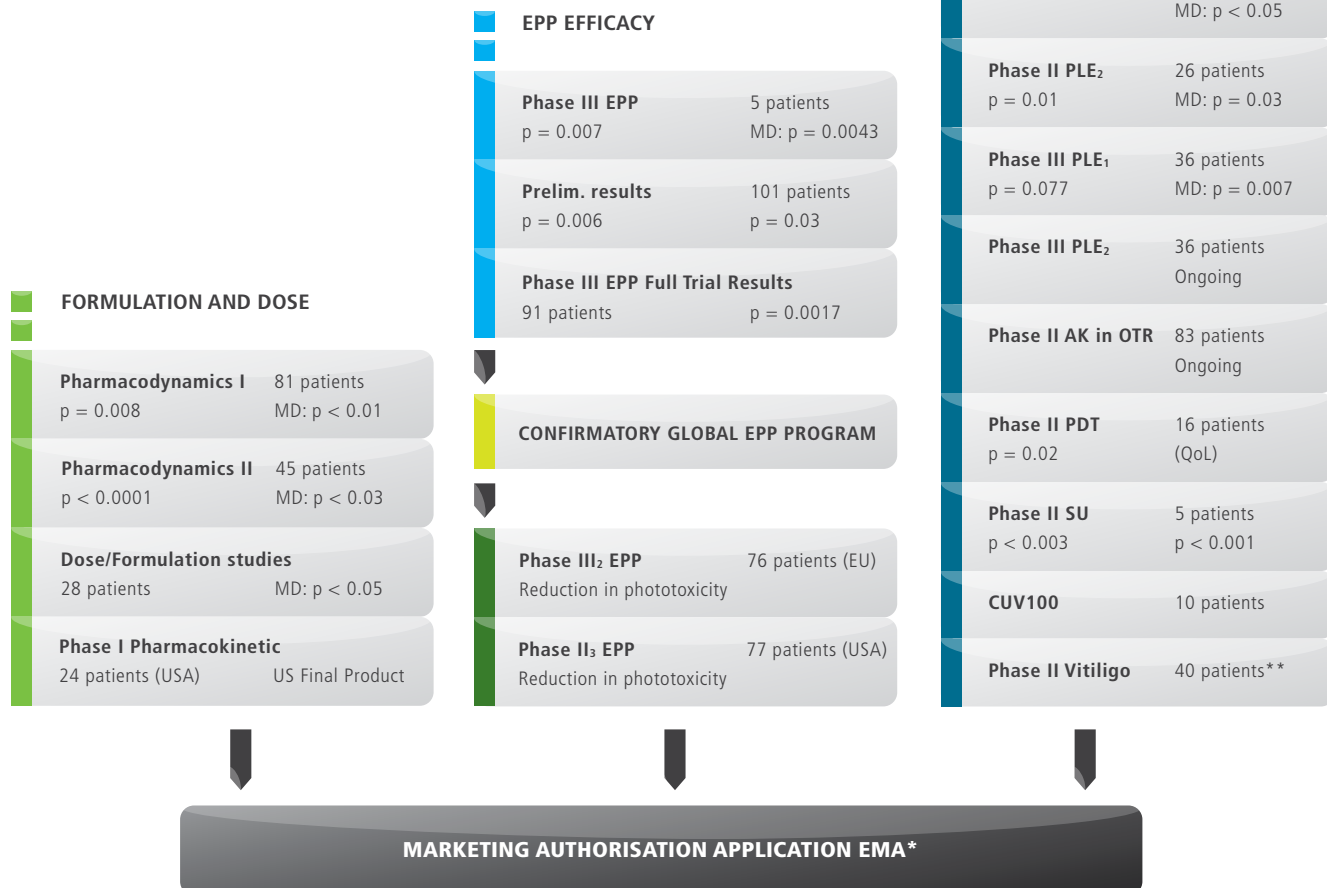
Many people are working and supporting the Company behind the scenes, and my gratitude goes out to all patients who participate in the clinical studies, especially those who remain in the trials despite receiving placebo treatment. My thanks and my team's appreciation goes out to all those who never receive recognition but make this project possible.

It is a privilege to serve this company and the patients worldwide.



Philippe Wolgen, Managing Director

CLINUVEL'S DEVELOPMENT PROGRAM



* Final Results from at least one confirmatory trial to be included in final MAA

** Pending regulatory approval

Clinuvel's clinical program is designed to address the strict regulatory requirements of safety. In modern drug development, preclinical and clinical safety data generated over a sufficient period gives more longitudinal certainty whether a drug might give rise to unexpected or undesired side effects. In essence, it is in the interest of the public, company, and shareholders to see this period through by working in close cooperation with the regulatory agencies worldwide.

In the figure above the middle column illustrates the EPP clinical program to establish efficacy of treatment of cutaneous symptoms.

Given the absolute low number of patients (Orphan Drug Designation) worldwide diagnosed with the disease, safety data are generated through the trials in PLE. PLE has a prevalence of 10-15% and hence there are more patients available for clinical testing, whereby the effectiveness of SCENESSE® is evaluated in spring and summer months. The other indications found in the right column also provide more data on both the ability to reduce and prevent diseases symptoms, as well as long-term safety.

In the left column, the 178 patients tested provided Clinuvel with data over the years to determine preferred human dose, release profile of the formulation, biological response and further effects of the drug. The recent addition of vitiligo as a promising indication for SCENESSE® is novel in more than one way. Most notably, whereas in the other indications SCENESSE® is used as a photoprotective preventative agent, in vitiligo an analysis will be made on the drug's ability to repigment vitiliginous (depigmented) skin lesions. Much scientific evidence exists to support the clinical and academic excitement worldwide surrounding the use of the drug in vitiligo.

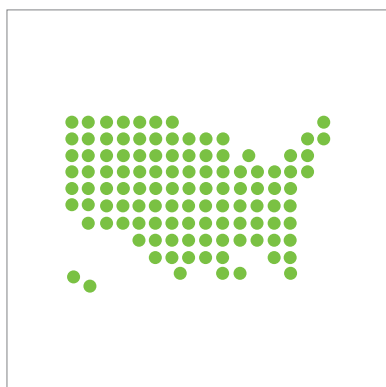
The entire program will result in a comprehensive dossier to be submitted to the EMA and FDA to obtain marketing authorisation, pending ongoing safety of SCENESSE®.

PATIENTS TO DATE

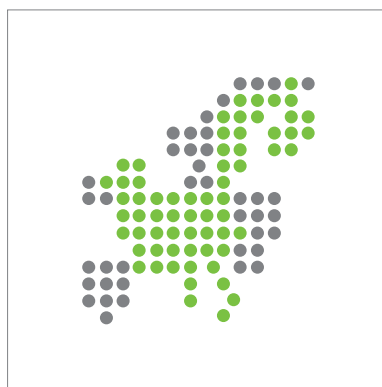
Aqueous solution: Approximately 1,700 doses in 137 patients
Resorbable implant: Approximately 1,340 doses in over 411 patients
Currently: 138 patients on trial



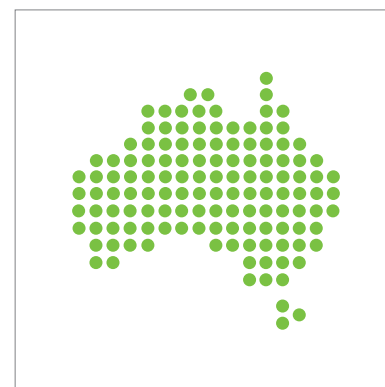
CLINICAL TRIAL LOCATIONS



UNITED STATES OF AMERICA



EUROPE



AUSTRALIA

CLINUVEL'S CLINICAL PROGRESS

INDICATION	DESCRIPTION	CLINICAL TRIAL STATUS
Erythropoietic Protoporphria (EPP)	Absolute sun/UV intolerance	Phase III trial full results reported July 2010 Confirmatory Phase II (US) and III (Europe) trials underway
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trial started October 2007
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trial preliminary results reported December 2009
Nonsegmental Vitiligo (NSV)	Pigmentary disorder	Phase II pilot trial to commence in 2010

Phase I and II human clinical trials using SCENESSE® have demonstrated that the drug is well tolerated and no significant safety concerns have been identified to date. Following successful conclusion of the development program, Clinuvel will work closely with global regulators to facilitate marketing approval of SCENESSE®. See the inside front cover for more information on the clinical indications.

CORPORATE MILESTONES

COMPANY MILESTONES SINCE DECEMBER 2005

DEC'05	JUN'06	DEC'06	JUN'07	DEC'07
<ul style="list-style-type: none"> ■ New management installed ■ Private placement A\$5m 	<ul style="list-style-type: none"> ■ Positive Phase II PLE trial results ■ Private placement A\$5m ■ Positive Phase II photoprotection trial results ■ Positive Phase II PLE trial results ■ Patent application for AK/SCC in OTR patients ■ Patent application for EPP and SU ■ Commenced Phase II EPP trial ■ Rights issue and private placement A\$35.2m 	<ul style="list-style-type: none"> ■ Positive Phase II EPP trial results ■ Patent application for PDT ■ Private placement A\$26m ■ Commenced Phase III PLE trial ■ Commenced Phase III EPP trial ■ Commenced Phase II AK/SCC in OTR patients trial 	<ul style="list-style-type: none"> ■ EMA granted ODD for EPP ■ Positive Phase I pharmacokinetic trial results ■ Swissmedic granted ODD for EPP 	

The progress of Clinuvel is highlighted in milestone table above. A continuous and systematic approach to the preclinical and clinical program is meant to lead to a robust dossier to be submitted to the regulatory authorities. By the frequent and multiple submissions to conduct clinical trials in a variety of European countries and the US, the company has already received an indication of the strength of its data. At each individual ethics and regulatory filing per country, the study protocols and available data are being assessed. Since 2005, the development program of Clinuvel has been successfully assessed and approved by more than 40 committees, Institutional Review Boards (IRBs) and regulatory agencies (FDA, EMA, TGA and SwissMedic).

Characteristic to Clinuvel's current development and business conduct is an aversion to risk. Regulatory review of a first-in-class pharmaceutical product is going to be subject to draconian criteria. In anticipation of this review Clinuvel has implemented a preemptive regulatory strategy, whereby a maximum number of patients diagnosed with the orphan disease (limited population) are being evaluated during administration of SCENESSE® as a preventative drug. Therefore, multiple trials are being conducted

using various protocols to be able to capture all possible clinical data. This approach requires detailed planning to be able to conduct trials in 2 hemispheres in spring and summer.

The upcoming clinical and regulatory events demonstrate that the two confirmatory EPP trials are being completed early 2011. Additionally, the program in polymorphic light eruption (PLE), and pilot study in vitiligo will be finalised and analysed.

The complexity of the pharmaceutical development of SCENESSE® has been significantly reduced in the clinical and regulatory design, whereby chemistry, formulation, preventative and symptomatic treatment of various diseases receive specific attention from the scientific teams within, and external to, the company.

The ultimate objective is filing for marketing authorisation to gain approval to market SCENESSE® in Europe (EMA) and in the US (FDA). This process is critical and requires coordination with all trial centres, suppliers, manufacturers and regulatory agencies. Pending safety of the drug, Clinuvel intends to file in 2011 to gain approval to commercialise SCENESSE®.

JUN'08	DEC'08	JUN'09	DEC'09	JUN'10	DEC'10
--------	--------	--------	--------	--------	--------

- | | | | | | |
|--|---|--|---|--|--|
| <ul style="list-style-type: none"> Commenced Phase II SU trial Generic name afamelanotide assigned by WHO FDA granted ODD for EPP | <ul style="list-style-type: none"> Commenced Phase II PDT trial Positive Phase III EPP trial Switzerland 12 months results FDA granted IND | <ul style="list-style-type: none"> Commenced confirmatory Phase III EPP trial Granted SME status by EMA Positive Phase II PDT trial results Positive preliminary Phase III PLE trial results Positive preliminary Phase III EPP trial results EMA granted ODD for SU Positive Phase II SU trial results | <ul style="list-style-type: none"> First manufacturer signed for SCENESSE® Positive full Phase III EPP trial results Commenced vitiligo program Second molecule, CUV9900, revealed Commenced confirmatory Phase II EPP trial, USA AIFA allows supply, reimbursement of SCENESSE® in Italy for EPP EMA approved SCENESSE® brand name revealed | | |
|--|---|--|---|--|--|

AK/SCC: Actinic Keratosis/Squamous Cell Carcinoma in Organ Transplant Recipients (OTRs) – Skin cancer in transplant patients

EPP: Erythropoietic Protoporphyrria – Absolute sun/UV intolerance

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

Note: See the inside front cover for full details of Clinuvel's current clinical indications.

UPCOMING CLINICAL AND REGULATORY MILESTONES

Q4'10

Q1'11

Q2'11

Q3'11

Q4'11

- | | | | | |
|--|---|---|--|---|
| | <ul style="list-style-type: none"> Confirmatory Phase II EPP trial results USA | <ul style="list-style-type: none"> Phase III PLE trial results Start confirmatory EPP trial USA* Confirmatory Phase III EPP trial results Europe MAA filing - EMA** | <ul style="list-style-type: none"> Phase II vitiligo trial results*** | |
| | | | | <ul style="list-style-type: none"> Phase II AK/SCC trial interim results |

* Confirmatory program being prepared pending FDA filing discussions

** Pending confirmatory trial results and regulatory feedback

*** Pending EU & US regulatory approval

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

PRESS, LITERATURE AND NEW MEDIA

Clinuvel's bright future

After making some tough decisions early in the year, 2010 should be a pivotal year for Clinuvel, which is on the verge of bringing its new photoprotective drug, afamelanotide, to market.



Australia's first photoprotective drug to begin US patent trials



Drug implant blocks skin cancer

Clinuvel Pharmaceuticals Ltd.: Italianische Patienten fordern UV-Medikament: Afamelanotid für seltene Sonnenerkrankung zugelassen

Italy approves Aussie Drug



Ray of Hope For Children of the Moon

FDA Gives Clinuvel Approval for Phase 2 Trial Drug Discovering & Development

Clinuvel announces strategic focus of final regulatory program



All that Twitters turns to gold

IRV Press: Clinuvel Pharma: Clinuvel Pharmaceuticals Ltd.: Italian Patients Request UV-Drug: Afamelanotide Available For Rare Sun Disorder

Clinuvel to commence trial of afamelanotide in the US

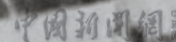
Drug companies target trial recruits on Twitter

Clinuvel's afamelanotide classified as reimbursable in Italy

SCENESSE®



紫外线疫苗"即将面世"可助日光过敏者防晒



San Gallicano, nuova terapia efficace per la Protoporfiria Eritropoietica

Hope for new skin-disorder drug

Clinuvel Shines Under Pressure

Clinuvel Pharmaceuticals Ltd.: Italian patients request UV-drug: afamelanotide available for rare sun disorder

Clinuvel Pharma UV-drug

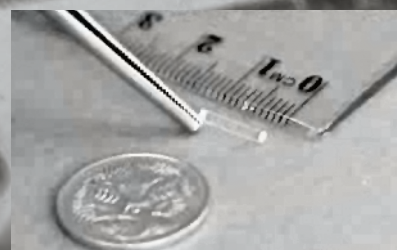
Afamelanotide Wins Italian Approval

Nuova terapia efficace per la protoporfiria eritropoierica

FDA grants Clinuvel an additional orphan drug designation

FARMACI: OK IN ITALIA A PRODOTTO SPERIMENTALE PER RARA FORMA FOTOSENSIBILITA'

LifeScientist



Brighter shade of pale

CLINICAL progress and corporate dramas dominate *BTN*'s list of top stories of last year, as the sector sped to a strong recovery after the 2008 *annus horribilus*.

Clinuvel's drug improves quality of life in cancer patients

아파메라노타이드, 광선 광선 피부발진 피부발진 희귀약 희귀약 지정지정
유럽의약청서 유럽의약청서 광선 광선 피부발진에 피부발진에 허가된
허가된 후후 FDA가 추가 추가 승인승인

Salute: Nasce Terapia Per Protoporfiria,
Malattia Rara 'Nemica' Del Sole

Positive results for Clinuvel drug trial



Clinuvel Pharmaceuticals SCENESSE® approved in EU
Australian company develops "UV Vaccine" treatment for skin disorder

Anti-sunburn drug protects fair
skinned people from UV rays

Clinuvel appoints ex-CSL
exec as chairman

**Clinuvel Pharmaceuticals Ltd.: Clinuvel unveils
SCENESSE® following European brand approval**

Clinuvel Success!

Clinuvel: positive results in Solar Urticaria study

Clinuvel changes management team to improve Scenesse commercialization

Dall'eccellenza della clinica e della ricerca una nuova
opportunità per la qualità di vita dei pazienti



Clinuvel shifts trial strategy on EMEA advice

Clinuvel Pharmaceuticals SCENESSE® approved in EU

FDA genehmigt klinische Studien zur Anwendung von Afamelanotid
bei EPP in den USA **Clinuvel gets pre-approval win in Italy**

FDA 肯定日光性蕁麻疹防治薬 Afamelanotide Promising drug results

Clinuvel Pharmaceuticals
Gets FDA Approval For Light
Intolerance Drug Trial

Breaking the rules.

BioSpectrum

One life-saving Tweet at a time

BUSINESS MODEL CLINUVEL

Clinuvel's SCENESSE® is already being tested in multiple indications as there is widespread belief that the clinical effectiveness can be expected in other photodermatoses and pigmentary disorders.

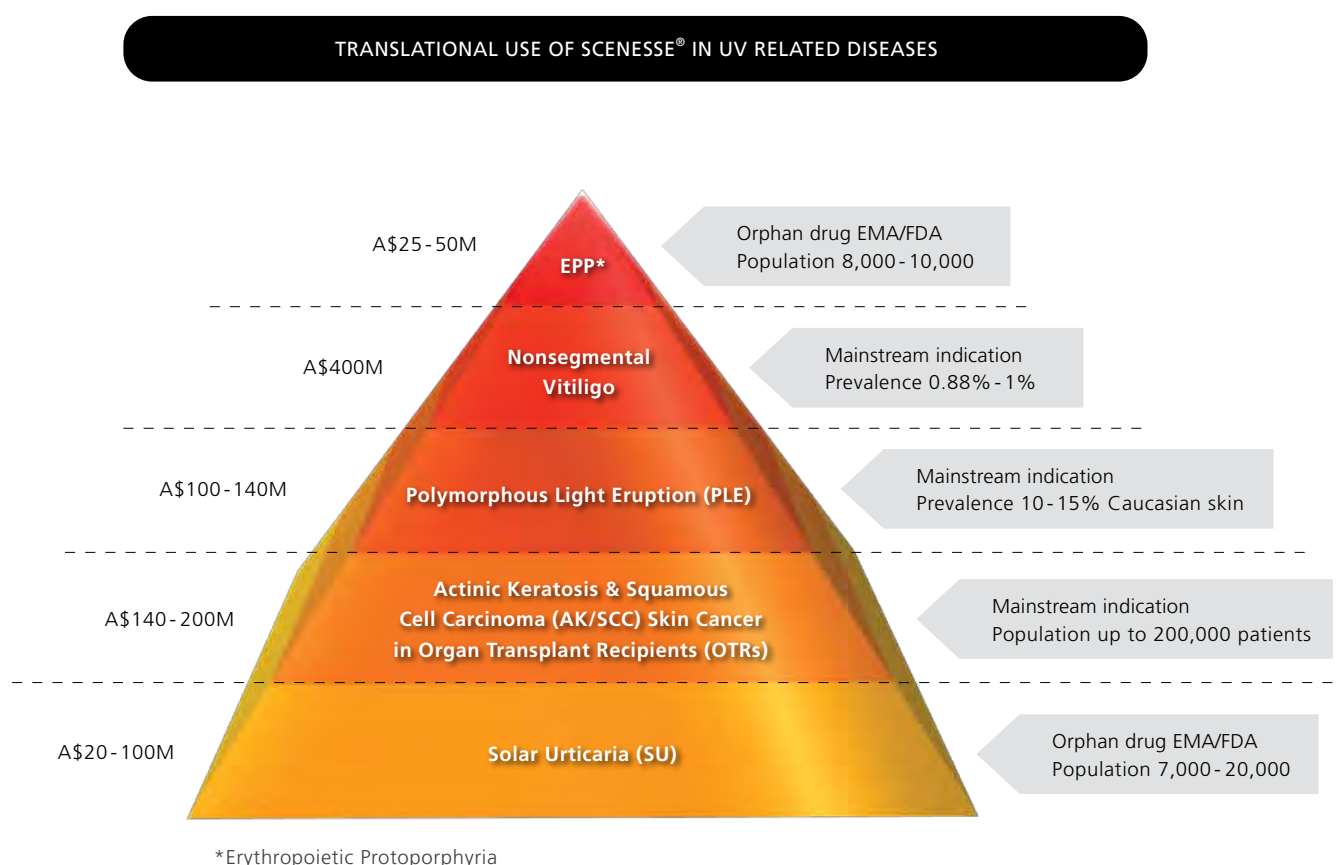


Figure 1. Translational Use of SCENESSE® in UV Related Diseases



In selecting and deciding the appropriate business model, the Clinuvel Board considered various factors which are unique to the company. The novelty of introducing SCENESSE® (afamelanotide) as a photoprotective drug called for a different business approach to peer pharmaceutical companies.

The utility of the afamelanotide molecule necessitated a different development program. The molecular characteristics, coupled with final product specifications, very much determines the roll out of applications. Here the sequence of our program – **see Figure 1** – is dictated by medical need; the clinically expressed need for actual treatment.

Various factors are considered, but most prominent is the identified lack of existing **effective** therapies in erythropoietic protoporphyria (EPP) and vitiligo, followed by the **severity of disease**, another important feature of Clinuvel's development program. In the genetic and metabolic disease EPP, the enzymatic deficiency causes a dermal phototoxicity which is known to require treatment, yet patients have no pharmaceutical solution to date. Living indoors is a sufficiently serious consequence of the disease to warrant development of a drug. A third consideration is posed by **the economics of lack of available treatment**, the cost to the healthcare systems worldwide. Relevant to EPP, an attempt is being made to review how much of a burden the disease is to insurers, and to national health systems in Europe and Medicare programs in the US and Australia.

The final related factor in arriving at a viable program is **a quality assessment** of the patients' life. Although EPP and vitiligo are not life-threatening diseases, the disease burden is significant as frequently described by physicians and in peer reviewed publications.

Without prejudice in our choices, we look at the product roll out and execution of the program accordingly. However, a written business plan and practical roll out differ and the execution is

complex. Conversely, is it this complexity which provides the company a lead time over any competitor which may emerge. Thus far, Clinuvel is the only company known to be developing a systemic photoprotectant for UV and light related diseases. When descending the illustrated pyramid in Figure 1, one is following a development path of clinical need, much in line with how regulatory agencies worldwide are seeking to address medical conditions for which new drugs are needed. In selecting EPP as a lead indication, we obtained – two years after starting the clinical trials – the much coveted orphan drug designation with many added benefits. The company is well under way in this program. In various drug development programs, translational use of a product becomes manifest. This implies that the molecule or drug product finds more than one application, again dictated by its clinical demand for the drug. The translation in other patient groups opens the way for further regulatory submissions. Clinuvel's SCENESSE® is already being tested in multiple indications as there is widespread belief that the clinical effectiveness can be expected in other photodermatoses and pigmentary disorders.

Market size is indicated on the left column of **Figure 1**, with the number of known patients diagnosed with the disease on the right. These numbers do not take into account whether patients are actually seeking treatment for their condition. Again, the severity of the disorder will dictate the necessity to seek treatment, much in line with Clinuvel's leitmotiv.

During the lengthy development process of the product, the Clinuvel team has obtained support from the leading academics in relevant fields, whereby each disease treated has its own subset of medical and clinical experts. Broad academic support is pivotal in Clinuvel's long-term plans to develop SCENESSE® successfully. In summary, it is read from the pyramid in Figure 1 that value will be created towards the base following first approval of the product in EPP.



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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 and November 2009.

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 website.

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 in pages 24 to 25.

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 three Non-Executive Directors (including Mr. McLiesh, the Chair) who 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 an officer of a former professional advisor 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.

As of September 1, 2010, the Board has a majority of independent Non-Executive Directors on the Board. Accordingly, it considers its current Board size and composition to be appropriate under current circumstances. 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. Mr. Wood 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 26. A committee charter can be found on the company's website.

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

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

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

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

THE WORK OF DIRECTORS

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

The Chair commits additional time and meets regularly with the Managing Director to review 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 Clinuvel website.

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

ACCESS TO INFORMATION

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

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

CLINUVEL PHARMACEUTICALS LTD ACTIVELY PROMOTES ETHICAL AND RESPONSIBLE DECISION MAKING (ASXCGC PRINCIPLE 3)

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

CODE OF BUSINESS CONDUCT AND ETHICS

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

TRADING IN SHARES

Directors' shareholdings at 30 June 2010 are shown on pages 24 and 25. 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. 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 was a voting, non-independent and Non-Executive Director. From September 1 2010, the Audit and Risk Committee has been chaired by Mrs. Shanahan who is a voting, independent, 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 view and judgment to Committee proceedings and put aside any conflicts, business or other relationship that could materially interfere with – or could reasonably be perceived to interfere with – the exercise of their unfettered and independent judgment.

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 26. A Committee charter can be found on the company's website.

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

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

The external audit firm partner in charge of the Clinuvel Pharmaceuticals Ltd audit attends committee meetings by invitation. The Committee seeks to ensure the independence of the external auditor. Non-audit services are performed by other firms. The Committee's charter requires that individuals playing a significant role in the Clinuvel Pharmaceuticals Ltd audit be rotated every five years. The auditor annually confirms its independence within the meaning of applicable legislation and professional standards.

CLINUVEL PHARMACEUTICALS LTD PROMOTES TIMELY AND BALANCED DISCLOSURE OF ALL MATERIAL MATTERS CONCERNING THE COMPANY (ASXCGC PRINCIPLE 5)

CONTINUOUS DISCLOSURE

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

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

CLINUVEL PHARMACEUTICALS LTD RESPECTS THE RIGHTS OF SHAREHOLDERS AND FACILITATES THE EFFECTIVE EXERCISE OF THOSE RIGHTS (ASXCGC PRINCIPLE 6)

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

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 Group's business exposes it to potential risks which are inherent in the R&D, pre-clinical studies, clinical trials, manufacturing, marketing and use of human therapeutic products.

B. FINANCIAL RISKS

The Board has approved principles and policies to manage financial risks of exposures to foreign currencies, and interest rates. Clinuvel Pharmaceuticals Ltd's policies prohibit speculative transactions.

The policies specify who may authorise transactions and segregates duties of those carrying them out. The company requires access to additional funding periodically to fund development programs. If the company fails to obtain such funding, it may need to delay or scale back the development and 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**

Reports to the Board on the effectiveness of its management of business and financial risks and compliance with other legal obligations.

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

RISK MANAGEMENT & FINANCIAL REPORT ACCOUNTABILITY

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

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

CLINUVEL PHARMACEUTICALS LTD ENSURES THAT THE LEVEL AND COMPOSITION OF REMUNERATION IS SUFFICIENT AND REASONABLE AND THAT ITS RELATIONSHIP TO CORPORATE AND INDIVIDUAL PERFORMANCE IS DEFINED (ASXCGC PRINCIPLE 8)

REMUNERATION AND NOMINATION COMMITTEE – REMUNERATION

As previously stated, Clinuvel Pharmaceuticals Ltd has appointed a Remuneration and Nomination Committee, comprising two voting, independent Non-Executive Directors, chaired by Mr. McLiesh. The Managing Director attends Remuneration and Nomination Committee meetings by invitation. He is not present if this could compromise the objectivity of proceedings. The membership and number of meetings held, along with each Director's attendance record last year, is shown on page 26. A committee charter can be found on the company's website.

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

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

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

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

DIRECTORS' REPORT

The Directors of the Board present their report on the company and its controlled entities for the financial year ended 30 June 2010 and the Auditor's 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), resigned September 1 2010
- Mr. L.J. Wood (Non-Executive)

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 to July 1 2010, Non-Executive Director thereafter, Member of the Remuneration and Nomination Committee to July 1 2010, Chair of the Audit and Risk Committee from September 1 2010
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, Mrs. Shanahan is current Chair of Challenger Listed Investments Ltd, the reporting entity for Challenger Infrastructure Fund (ASX:CIF), Challenger Diversified Property Group (ASX: CDI) and Challenger Wine Trust (ASX:CWT).

She 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.

DR. HELMER P.K. AGERSBORG (JOINED BOARD 2001)

Executive Director, Chief Scientific Officer since December 2005
Qualifications: BSc, PhD
Shares in Clinuvel: 921,105
Options over shares in Clinuvel: 1,500,000

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: 6,000,000

Having been recognised for his strategic mindset and meticulous business execution, Dr. Wolgen lead the company in attracting A\$68M in funding to execute on the current pharmaceutical development program of SCENESSE®. Dr. Wolgen has brought to the company his international finance experience and professional contacts to European capital markets. As a former healthcare analyst and manager of general medical centers in UK and Israel, his in-depth analysis and expertise of the lifescience sector has been an asset to Clinuvel.

Dr. Wolgen is recognised for his energetic management style and has been able to attract and retain key managerial talent to develop Clinuvel's novel program.

MR. STANLEY R. MCLIESH (JOINED BOARD 2002)

Non-Executive Director to July 1 2010, Non-Executive Chair thereafter, Chair of the Remuneration and Nomination Committee Member of the Audit and Risk Committee

Qualifications: BEd

Shares in Clinuvel: 760,000

Options over shares in Clinuvel: 450,000

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, RESIGNED SEPTEMBER 1, 2010)

Non-Executive Director, Chairman of the Audit and Risk Committee to August 31 2010

Qualifications: BSc (Hons), PhD

Shares in Clinuvel: 108,224

Options over shares in Clinuvel: 1,300,000

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. In the past 3 years Dr. Aston has served as Chair of Ascent Pharmahealth Limited (ASX:APH, 2008-current) and is also serving Chair/CEO of Halcyon Pharmaceuticals Ltd (ASX:HGN, 2007-current).

His previous positions include Director of pSivida Ltd, 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.

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 prospectus 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, Member of the Remuneration and Nomination Committee from July 1 2010

Qualifications: BComm

Shares in Clinuvel: 400,000

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 currently is 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.

INFORMATION ON COMPANY SECRETARY**MR. DARREN M. KEAMY**

Company Secretary, Chief Financial Officer

Qualifications: BComm, CPA

Certified Practising 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	5	5	2	2	—	—
Dr. H.P.K. Agersborg	5	5	—	—	—	—
Mrs. B.M. Shanahan	5	5	—	—	2	2
Mr. S.R. McLiesh	5	5	2	2	2	2
Dr. P.J. Wolgen	5	5	2	—	2	2
Mr. L.J. Wood	5	5	—	—	—	—

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 SCENESSE® (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

A summary of Clinuvel's financial result is presented in the following table:

CONSOLIDATED	2010	2009	CHANGE
Revenues	\$1,845,720	\$2,904,917	-36%
Net (Loss) before income tax expense	(\$11,521,040)	(\$15,372,907)	25%
Profit (Loss) after income tax expense	(\$11,521,040)	(\$15,372,907)	25%
Basic earnings per share - cents per share	(\$3.8)	(\$5.1)	25%
Net tangible assets backing per ordinary share	0.10	0.12	-17%
Dividends	Nil	Nil	Nil

Note: Clinuvel does not operate individual segments.

The group result for the year ended 30 June 2010 was a \$11.521 million loss, compared to a \$15.373 million loss for the prior financial year, a decrease in the loss of 25%. The group continues to display a strong balance sheet, with \$26.426 million in net assets at 30 June 2010 compared to \$37.051 million at 30 June 2009. Current liabilities decreased 33% to \$3.040 million. The improvement in payables is a result of the completing of the scale-up activities in the R&D drug delivery formulation program in the first half of the financial year. Monthly average cash spend was \$1.114 million for the year compared to \$1.175 million for the 2008/09 year.

Research and development accounted for 63% of the group's total expense result for 2009/10, compared to 56% for the 2008/09 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 \$8.380 million in 2010 compared to \$8.429 million in 2009. Clinical study costs increased 12% from \$2.281 million in 2009 to \$2.553 million in 2010, reflecting the progress made in completing the Phase III trial in Europe, the start of further trials in Europe and the USA and the multi-year study in AK in organ transplant recipients. Expenditures from the drug delivery program decreased 52% from \$6.176 million in 2009 to \$2.981 million in 2010. The validation of the production process to meet commercial manufacturing scale was primarily incurred in the previous financial year. More R&D specific personnel were engaged during 2009/10 to service the expanding research and development programs resulting in a 23% increase in research and development overheads from \$1.535 million in 2009 to \$1.888 million in 2010. The commencement of long term toxicity studies into the safety profile of SCENESSE® to support regulatory filings in early 2010 has resulted in a 206% increase in toxicity and regulatory costs, from \$0.313 million to \$0.958 million.

Marketing activities in the company decreased by \$0.142 million to \$0.704 million in 2010 (17%). The reduction in expenditures is primarily due to staff reductions and further reduced dependence in public marketing agencies to support roadshow and general marketing initiatives.

Excluding the revaluation of financial assets, the result from general operations was \$5.832 million in 2010 compared to \$4.389 million in 2009. General operations comprised 44% of the groups total expense result for 2010 compared to 24% in 2009. The main difference year-on-year is the restatement of foreign currency creditor balances and currencies held resulted in a \$0.604 million gain in 2009, compared to a \$0.405 million loss in 2010. For 2010, a gain of \$2.295 million has been recorded in revaluing financial assets held at fair value compared to a loss of \$1.821 million for the same period last

year. The gain reflects the improvement in investment values in the past 18 months.

Interest received on cash and financial assets held decreased by 45% from \$2.668 million in 2009 to \$1.474 million in 2010. The drop in revenues is a result of the gradual decline in cash reserves and financial assets for working capital deployment. For the 2009/10 year the group started with \$37.754 million in cash and financial assets and finished with \$27.003 million. In contrast the group started the 2008/09 year with \$50.800 million. Additionally, increased expenditures in currencies other than the Australian dollar resulted in currency gains of \$0.372 million (2009: \$0.237 million) and is reflected as revenue.

At 30 June 2010 basic earnings per share were -\$0.038 on 303,188,665 issued ordinary shares. This is compared to basic earnings per share of -\$0.051 as at 30 June 2009 on 303,148,665 issued ordinary shares.

The advancement in the group's clinical and regulatory activities in preceding years to commercialise SCENESSE® (afamelanotide) was matched by a number of significant achievements in 2009/10, highlighted as follows:

- The announcement of positive results from the open-label five patient pilot Phase II study (CUV016) in the severe skin disorder Solar Urticaria (SU) conducted at Manchester Hope Hospital UK. The tolerance of the skin to light of various wavelengths and intensities was increased following administration of SCENESSE®.
- The approval by European regulatory authorities to proceed with a confirmatory Phase III clinical trial of SCENESSE® in Erythropoietic Protoporphyrria (EPP). The trial of approximately 40 patients, in 8 centres, aims to evaluate SCENESSE's ability to reduce the severity and frequency of phototoxic reactions in EPP patients. The trial commenced during the year. The results from this trial (CUV029) are intended to support the clinical data generated from the Phase III study in EPP (CUV017), the results of which were announced in July 2010.
- The announcement of positive results from the experimental randomised placebo-controlled Phase II trial (CUV025) in 16 patients undergoing systemic Photodynamic Therapy (PDT). PDT is a cancer treatment, causing phototoxicity of the skin as a side effect for up to 90 days following treatment. Post-operative analysis at 7 and 12 days revealed a positive trend to tolerate ambient light at standardised exposure by 7 out of 9 patients receiving SCENESSE®. Importantly, a significant improvement in quality of life was demonstrated after 60 days of treatment with SCENESSE®.

- Attaining small and medium enterprise (SME) status from the European Medicines Agency (EMA). The status provides incentives to Clinuvel during the preparation for its filing and commercialisation of SCENESSE® in Europe. SME status is granted by the EMA to assist eligible companies during the pre-marketing authorisation period.
- The US Food and Drug Administration (FDA) granted Clinuvel an Orphan Drug Designation (ODD) for the management of Solar Urticaria (SU), in addition to having been granted an ODD for the management of Erythropoietic Protoporphyrria (EPP) in 2008. The status is reserved for new drugs being developed to treat rare diseases or conditions that affect smaller 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 US upon receiving marketing authorisation, tax benefits and exemptions from user fees.
- The announcement of preliminary results from the multicenter, randomised, double-blind, placebo controlled Phase III study (CUV015) in Polymorphic Light Eruption (PLE) evaluating the safety and efficacy of SCENESSE® in 20mg implants. The study into PLE, a recurrent seasonal UV-related skin disorder seen mostly in fair-skinned patients, revealed a trend toward reduction of characteristic dermal symptoms.
- Preliminary results from the Phase III study in EPP (CUV017), a multicentre randomised double-blind placebo controlled study, showing an overall reduction in the average number of phototoxic reactions. The interim analysis also showed pain severity to be positively correlated with treatment.
- Approval by the US FDA to commence a Phase II clinical trial (CUV030) to evaluate SCENESSE® in patients diagnosed with EPP in the United States. The trial will be conducted in six centres (Alabama, California, New York, North Carolina, Texas and Utah). The objectives of the trial are to further evaluate SCENESSE's effect on the severity of phototoxic reactions and the protocol used under CUV030 will be identical to the one used in the confirmatory European Phase III EPP trial (CUV029).
- SCENESSE® being included in the list of drugs reimbursable by the Italian National Health System (Sistema Sanitario Nazionale, SSN) for the treatment of EPP. SCENESSE® can now be prescribed as a photoprotective drug for Italian patients diagnosed with EPP under Law 648/96, prior to the drug's formal approval in Europe. Clinuvel will be fully reimbursed by the SSN for all prescribed units of SCENESSE®. It is estimated that approximately 60 patients will initially benefit from this treatment.
- The approval by EMA Name Review Group (NRG) and the Agency's Committee for Human Medicinal Products (CHMP) for the company's proposed trade name – SCENESSE® – for its proprietary first-in-class medicinal photoprotective drug (afamelanotide).

2010/11 will see the company continue to focus on treating acute medical need and to generate the optimal data required to complete an application for marketing authorisation in Europe.

The outlook for 2010/11 includes additional research activities on SCENESSE® as the scientific community continues to increase knowledge on molecular biology, UV and pigmentation. The company believes further opportunities may come to light as scientific information is being generated from the ongoing research. Any opportunities may bring further value to the company and add to the potential of SCENESSE® as a key photoprotective.

The company will continue to strengthen and expand its management teams to maximise progress through the end stage of product development and to explore further research opportunities. Clinical and regulatory activities within Europe and the USA will increase during 2010/11.

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 and 2009/10 levels and cash reserves will decrease accordingly. The existing cash and financial asset reserves is considered sufficient to cover the current development program.

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 & 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 & 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 & INSURANCE OF DIRECTORS & 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 \$54,064 (2009: \$46,725).

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 a controlled entity.

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

REMUNERATION REPORT

PRINCIPLES USED TO DETERMINE THE NATURE AND AMOUNT OF REMUNERATION

The Board has overseen a reward framework:

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

The reward framework provides a mix of fixed and variable pay, structured to 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 and/or performance rights 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. Performance rights are issued under the company's Conditional Performance Rights Plan and is currently available to Executives. The vesting conditions can be either time and/or performance milestone-based).

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

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

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

NON-EXECUTIVE REMUNERATION

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

external market.

Non-Executive Directors are also issued options under the Company's Share Option Plan. Non-Executive Directors are issued options to align their interests with that of shareholders and to reflect their greater role in the management of the Company comparative to peer companies (and reflected in a smaller management team).

The number of options and nature of vesting is determined upon the Director's appointment and is subject to shareholder approval.

EXECUTIVE REMUNERATION

Remuneration packages for Executives include:

- Base pay and benefits (including statutory benefits);
- Long-term incentive payments through the achievement of pre-specified performance-based targets;
- Participation in Clinuvel's Employee Share Option Plan;
- Participation in Clinuvel's Conditional Performance Rights 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 receive discretionary short term incentives, evaluated annually against targets set at each performance review. The Company's employees share in a team-based incentive pool. These incentives are paid out each quarter and are directly linked to the successful progression of the clinical development program.

The long-term incentives were previously provided to Executive Directors and certain employees via the Clinuvel Employee Share Option Plan. Since 2009, long term incentives are provided under the Clinuvel Conditional Rights Plan. See page 33 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

REMUNERATION OF THE DIRECTORS OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2010

Director	SHORT-TERM EMPLOYMENT BENEFITS			POST EMPLOYMENT BENEFITS	SHARE BASED PAYMENTS	Total
	Salary	Cash Bonus	Other	Superannuation Contributions	Options	
Dr. H.P.K. Agersborg	\$340,381	\$55,383	—	—	\$60,534	\$456,298
Mr. S.R. McLiesh	\$59,633	—	—	\$5,367	\$17,987	\$82,987
Dr. R. Aston	\$59,633	—	—	\$5,367	\$52,925	\$117,925
Dr. P.J. Wolgen	\$560,000	\$180,000	\$21,747	\$14,461	\$242,134	\$1,018,342
Mrs. B.M. Shanahan	\$73,395	—	—	\$6,606	\$37,192	\$117,193
Mr. L.J. Wood	\$50,000	—	—	—	\$3,364	\$53,364
Total	\$1,143,042	\$235,383	\$21,747	\$31,801	\$414,136	\$1,846,109

REMUNERATION OF THE SPECIFIED EXECUTIVES OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2010

	SHORT-TERM EMPLOYMENT BENEFITS			POST EMPLOYMENT BENEFITS		SHARE BASED PAYMENTS	Total
	Salary	Cash Bonus	Allowance	Superannuation Contributions	Other	Options & Rights	
Dr. D.J. Wright	\$182,800	\$20,000	—	\$14,461	—	\$114,197	\$331,458
Mr. D.M. Keamy	\$154,350	\$20,000	—	\$13,939	—	\$65,001	\$253,290
Total	\$337,150	\$40,000	—	\$28,400	—	\$179,198	\$584,748

REMUNERATION OF THE DIRECTORS OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2009

Director	SHORT-TERM EMPLOYMENT BENEFITS			POST EMPLOYMENT BENEFITS	SHARE BASED PAYMENTS	Total
	Salary	Cash Bonus	Allowance	Superannuation Contributions	Options	
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	\$49,982
Total	\$1,261,155	\$175,000	\$3,220	\$31,033	\$536,091	\$2,006,499

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	Total
	Salary	Cash Bonus	Allowance	Superannuation Contributions	Other	Options	
Dr. D.J. Wright	\$175,471	\$17,000	—	\$13,694	—	\$52,527	\$258,692
Mr. D.M. Keamy	\$147,000	\$10,000	—	\$13,265	—	\$33,626	\$203,891
Mr. C.H. Mackie*	\$158,562	\$10,000	—	\$9,892	\$51,250	—	\$229,704
Total	\$481,033	\$37,000	—	\$36,851	\$51,250	\$86,153	\$692,287

* Terminated 15 March 2009

THE RELATIVE PROPORTIONS OF REMUNERATION BETWEEN FIXED AND BASED ON PERFORMANCE FOR THE YEAR ENDED 30 JUNE 2010

	2010		2009	
	Fixed	Performance	Fixed	Performance
Dr. P.J. Wolgen	75%	25%	72%	28%
Dr. H.P.K. Agersborg	84%	16%	91%	9%
Dr. D.J. Wright	70%	30%	86%	14%
Mr. D.M. Keamy	76%	24%	91%	9%
Mr. C.H. Mackie*	n/a	n/a	96%	4%

* 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 and the Clinuvel Conditional Performance Rights 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 2010 and his base salary inclusive of superannuation for the year to 30 June 2010 is \$574,461. 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 & Chief Scientific Officer) is on a 12 month rolling contract and his base salary inclusive of superannuation for the year ended 30 June 2010 is \$340,381. 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 2010 is \$197,261. 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 2010 is \$168,289. 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.

SHARE-BASED REMUNERATION

The consolidated entity has ownership based scheme for Directors, key management personnel and select consultants of the Company and are designed to provide long-term incentives for Directors and Executives to deliver long-term shareholder value.

SHARE OPTIONS

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.

CONDITIONAL PERFORMANCE RIGHTS

All performance rights issued fall under the Clinuvel Conditional Performance Rights Plan, available to eligible employees of the Company. Any issue of rights to executive Directors requires shareholder approval in accordance with ASX Listing Rules. All rights converts to one ordinary share of the consolidated entity are issued for nil consideration, have no voting rights, are non-transferable and are not listed on the ASX. They can be converted to ordinary shares at any time once the vesting conditions attached to the rights have been achieved, whereby they will be held by a Scheme Trustee on behalf of the eligible employee for up to 7 years. The eligible employee can request for shares to be transferred from the Scheme Trust after 7 years or at an earlier date if the eligible employee is no longer employed by the Company or all transfer restrictions are satisfied or waived by the Board in its discretion.

The number of rights granted is subject to approval by the Remuneration and Nomination Committee.

Rights currently have specific terms and conditions, being the achievement of performance milestones 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	12,760,000	\$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	

**TERMS AND CONDITIONS OF EACH GRANT OF RIGHTS AFFECTING REMUNERATION
IN THE CURRENT OR FUTURE REPORTING PERIODS**

ENTITY	NUMBER OF RIGHTS	TRANCHE NO	VALUE PER RIGHT ON GRANT DATE	CLASS	GRANT DATE	VESTED & EXERCISABLE DATES
Clinuvel	177,500	1	\$0.20	Ordinary	16/10/2009	17/12/2009
Clinuvel	205,000	2	\$0.20	Ordinary	16/10/2009	13/07/2010
Clinuvel	182,500	2	\$0.17	Ordinary	07/01/2010	13/07/2010
Clinuvel	297,500	3	\$0.20	Ordinary	16/10/2009	—
Clinuvel	200,000	4	\$0.20	Ordinary	16/10/2009	—
Clinuvel	7,500	4	\$0.17	Ordinary	07/01/2010	—
Clinuvel	430,000	5	\$0.20	Ordinary	16/10/2009	—
Clinuvel	22,500	5	\$0.17	Ordinary	07/01/2010	—
Clinuvel	1,310,000	6	\$0.20	Ordinary	16/10/2009	—
Clinuvel	37,500	6	\$0.17	Ordinary	07/01/2010	—
Clinuvel	375,000	7	\$0.17	Ordinary	07/01/2010	07/04/2010
Clinuvel	75,000	8	\$0.17	Ordinary	07/01/2010	—

SHARES PROVIDED UPON EXERCISE OF OPTIONS AND RIGHTS

DETAILS OF SHARES ISSUED DURING THE FINANCIAL YEAR AS A RESULT OF EXERCISE OF RIGHTS

ENTITY	NUMBER OF SHARES ISSUED	AMOUNT PAID FOR SHARES	CLASS
Clinuvel	40,000	Nil\$	Ordinary

These shares were issued by the Scheme Trustee to departing employees who resigned from the consolidated entity during the year.

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 ended 30 June 2010 and 30 June 2009.

FURTHER INFORMATION – SHARE-BASED COMPENSATION

	A	B	C	D
	% of Remuneration consisting of Options and Rights	Value at Grant Date	Value at Exercise Date	Value at Lapse Date
Dr. H.P.K. Agersborg	13.3%	—	—	50,467
Dr. R. Aston	44.9%	—	—	50,467
Mr. S.R. McLiesh	21.7%	—	—	25,234
Dr. P.J. Wolgen	23.8%	—	—	126,168
Mrs. B.M. Shanahan	31.7%	—	—	—
Mr. L.J. Wood	6.3%	—	—	—
Dr. D.J. Wright	34.5%	72,232	—	25,234
Mr. D.M. Keamy	25.7%	36,656	—	12,617

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

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

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

D The value at lapse date of options and/or rights 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.

Performance Rights were priced using a binomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. 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 pricing model is assumed to be the yield on 2 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

ADDITIONAL INFORMATION ON OPTIONS ISSUED TO DIRECTORS AND KEY MANAGEMENT PERSONNEL

	OPTIONS VESTED DURING THE YEAR – 2010	OPTIONS VESTED DURING THE YEAR – 2009	OPTIONS GRANTED DURING THE YEAR – 2010	OPTIONS GRANTED DURING THE YEAR – 2009	RIGHTS VESTED DURING THE YEAR – 2010	RIGHTS VESTED DURING THE YEAR – 2009	RIGHTS GRANTED DURING THE YEAR – 2010	RIGHTS GRANTED DURING THE YEAR – 2009
Dr. H.P.K. Agersborg	–	–	–	–	–	–	–	–
Dr. R. Aston	–	250,000	–	–	–	–	–	–
Mr. S.R. McLiesh	–	–	–	–	–	–	–	–
Dr. P.J. Wolgen	–	250,000	–	–	–	–	–	–
Mrs. B.M. Shanahan	–	283,333	–	–	–	–	–	–
Mr. L.J. Wood	116,667	116,667	–	350,000	–	–	–	–
Dr. D.J. Wright	175,000	175,000	–	–	50,000	–	875,000	–
Mr. D.M. Keamy	125,000	125,000	–	–	40,000	–	400,000	–

ADDITIONAL INFORMATION – REMUNERATION

For each cash bonus and option and/or right 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 generally in the year following the period of performance.

REMUNERATION DETAILS OF CASH BONUSES AND OPTIONS/RIGHTS

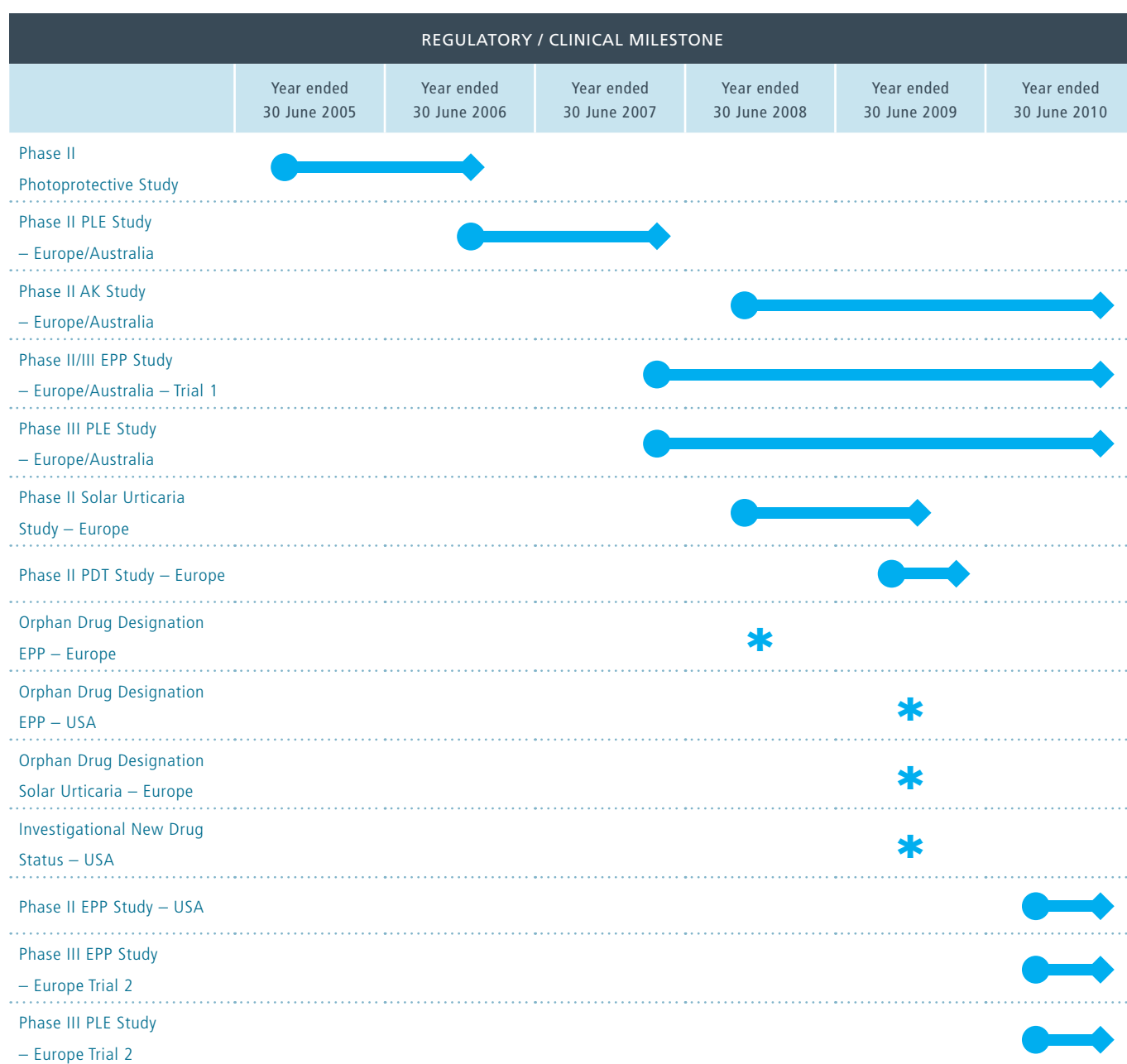
	BONUS		OPTIONS / RIGHTS					
	Paid	Forfeited	Year Granted	Vested	Forfeited	Year of Vesting	Minimum grant value yet to Vest	Maximum grant value yet to Vest
Dr. H.P.K. Agersborg	0%	0%	2006/07	0%	100%	2009/10	–	–
Dr. R. Aston	0%	0%	2005/06	0%	100%	2009/10	–	–
			2006/07	0%	100%	2009/10	–	–
Mr. S.R. McLiesh	0%	0%	2006/07	0%	100%	2009/10	–	–
Dr. P.J. Wolgen	75%	25%	2005/06	0%	100%	2009/10	–	–
			2006/07	0%	100%	2009/10	–	–
Mr. L.J. Wood	0%	0%	2008/09	100%	0%	2010/11	–	\$6,206
Dr. D.J. Wright	0%	0%	2006/07	47%	53%	2009/10	–	–
				0%	100%	2009/10	–	–
				0%	0%	2010/11	–	\$33,571
			2009/10	100%	0%	No limitation	–	\$62,232
Mr. D.M. Keamy	0%	0%	2006/07	56%	44%	2009/10	–	–
				0%	0%	2010/11	–	\$23,979
			2009/10	100%	0%	No limitation	–	\$28,656

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. The exercise price for those rights granted to Dr. Wright and Mr. Keamy in 2009/10 was \$Nil. Excluding the CEO, cash bonuses paid to Executives during 2009/10 were discretionary.

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.



SHARES UNDER OPTION

DETAILS OF UNISSUED SHARES OR INTERESTS UNDER OPTIONS					
Entity	Number of Shares under Options	Number of Shares under Rights	Exercise Price	Class	Expiry Date
Clinuvel Pharmaceuticals	12,760,000	—	\$0.86	Ordinary	09/02/2012
Clinuvel Pharmaceuticals	350,000	—	\$0.275	Ordinary	18/11/2013
Clinuvel Pharmaceuticals	—	3,320,000	\$Nil	Ordinary	Upon achievement of specific performance milestones

LOANS TO DIRECTORS AND EXECUTIVES

No loans were granted to Directors or Executives for the years ended 30 June 2010 and 30 June 2009.

NON-AUDIT SERVICES

For the years ended 30 June 2010 and 30 June 2009 Grant Thornton only provided audit services to the Company.

AUDITOR'S INDEPENDENCE DECLARATION

The auditor's independence declaration as required by s.307C of the Corporations Act 2001 is included and forms part of this Directors' 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(a) of The Corporations Act 2001.



Dr. Philippe Wolgen MBA, MD
Director

Dated this 27th day of August, 2010

STATEMENT OF COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2010

	Note	CONSOLIDATED	
		2010	2009
Revenues			
Interest received		\$1,473,664	\$2,667,920
Other income		\$372,056	\$236,997
Total Revenues	2	\$1,845,720	\$2,904,917
Total Expenses	2	(\$13,366,760)	(\$18,277,824)
Profit (Loss) before income tax expense		(\$11,521,040)	(\$15,372,907)
Income tax expense (benefit)	3	—	—
Profit (Loss) after income tax expense		(\$11,521,040)	(\$15,372,907)
Net Profit (Loss) for the year		(\$11, 521,040)	(\$15,372,907)
Other Comprehensive Income			
Exchange differences of foreign exchange translation of foreign operations		(\$29,573)	\$67,406
Income tax (expense) benefit on items of other comprehensive income		—	—
Other comprehensive income (loss) for the period, net of income tax		(\$29,573)	\$67,406
Total Comprehensive Income for the period		(\$11,550,613)	(\$15,305,501)
Basic earnings per share — cents per share	16	(\$3.8)	(\$5.1)
Diluted earnings per share — cents per share		(\$3.8)	(\$5.1)
The accompanying notes form part of these financial statements.			

STATEMENT OF FINANCIAL POSITION

AS AT 30 JUNE 2010

		CONSOLIDATED	
	Note	2010	2009
Current Assets			
Cash and cash equivalents	17(a)	\$ 19,414,846	\$21,710,643
Other financial assets	8	\$7,588,331	\$16,043,498
Receivables	4	\$362,970	\$211,787
Other	5	\$1,791,371	\$2,627,585
Total Current Assets		\$29,157,518	\$40,593,513
Non Current Assets			
Property, plant and equipment	6	\$321,665	\$357,135
Intangible assets	7	\$27,600	\$663,114
Total Non Current Assets		\$349,265	\$1,020,249
Total Assets		\$29,506,783	\$41,613,762
Current Liabilities			
Trade and other payables	10	\$2,802,936	\$4,369,406
Provisions	11	\$237,046	\$174,646
Total Current Liabilities		\$3,039,982	\$4,544,052
Non Current Liabilities			
Provisions	11	\$40,638	\$18,526
Total Non Current Liabilities		\$40,638	\$18,526
Total Liabilities		\$3,080,620	\$4,562,578
Net Assets		\$26,426,163	\$37,051,184
Equity			
Issued capital equity	12	\$113,227,565	\$113,221,065
Reserves	13	\$2,169,316	\$2,167,446
Accumulated losses	14	(\$88,970,718)	(\$78,337,327)
Total Equity		\$26,426,163	\$37,051,184

The accompanying notes form part of these financial statements.

STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 30 JUNE 2010

		CONSOLIDATED	
Cash Flows From Operating Activities	Note	2010	2009
Refund from ATO		\$151,284	\$196,452
Interest received		\$1,430,728	\$2,927,278
Payments to suppliers and employees		(\$13,364,757)	(\$14,109,276)
Net Cash provided by (used in) operating activities	17(b)	(\$11,782,745)	(\$10,985,546)
Cash Flows From Investing Activities			
Payments for property, plant and equipment		(\$45,162)	(\$32,454)
Proceeds from investment securities		\$9,687,758	\$6,554,632
Net Cash provided by (used in) investing activities		\$9,642,596	\$6,522,178
Cash Flows From Financing Activities			
Proceeds from issue of ordinary shares		—	\$143,606
Payment of share issue costs		(\$1,500)	—
Net Cash provided by (used in) financing activities		(\$1,500)	\$143,606
Net increase (decrease) in cash and cash equivalents held		(\$2,141,649)	(\$4,319,762)
Cash and cash equivalents at beginning of the year		\$21,710,643	\$25,752,193
Effects of exchange rate changes on foreign currency held		(\$154,148)	\$278,212
Cash and cash equivalents at end of the year	17(a)	\$19,414,846	\$21,710,643

The accompanying notes form part of these financial statements.

STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 30 JUNE 2010

	SHARE CAPITAL	SHARE OPTION RESERVE	PERFORMANCE RIGHTS RESERVE	FOREIGN CURRENCY TRANSLATION RESERVE	RETAINED EARNINGS	TOTAL EQUITY
Balance at 1 July 2008	\$113,222,456	\$1,679,400	–	\$84,436	(\$63,171,776)	\$51,814,516
Issue of Share Capital under share-based payment						–
Employee share-based payment options		\$471,016			\$207,356	\$678,372
Capital Raising Costs	(\$1,391)					(\$1,391)
Transactions with Owners	\$113,221,065	\$2,150,416	–	\$84,436	(\$62,964,420)	\$52,491,497
Profit (Loss) for the year					(\$15,372,907)	(\$15,372,907)
Other Comprehensive Income:						
Exchange differences of foreign exchange translation of foreign operations				(\$67,406)		(\$67,406)
Balance at 30 June 2009	\$113,221,065	\$2,150,416	–	\$17,030	(\$78,337,327)	\$37,051,184
Issue of Share Capital under share-based payment	\$8,000					\$8,000
Employee share-based payment options		(\$356,581)	\$328,878		\$887,649	\$859,946
Capital Raising Costs	(\$1,500)					(\$1,500)
Transactions with owners	\$113,227,565	\$1,793,835	\$328,878	\$17,030	(\$77,449,678)	\$37,917,630
Profit (Loss) for the year					(\$11,521,040)	(\$11,521,040)
Other Comprehensive Income:						
Exchange differences of foreign exchange translation of foreign operations				\$29,573		\$29,573
Balance at 30 June 2010	\$113,227,565	\$1,793,835	\$328,878	\$46,603	(\$88,970,718)	\$26,426,163

The accompanying notes form part of these financial statements.

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2010

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 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 factor that are believed reasonable in light of the relevant circumstances. These estimates are reviewed on an ongoing basis and revised in those periods to which the revision directly affects.

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

The going concern basis assumes that, if required, future capital raisings will be available to enable the consolidated entity to undertake the research, development and 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 Statement of Comprehensive Income, 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.

Taxation of Financial Arrangements (TOFA)

Legislation is in place which change the tax treatment of financial arrangements. The group is in the process of assessing the potential impact of these changes on the Group's tax position. At this stage no impact has been recognised and no adjustments have been made to the deferred tax and income tax balances at 30 June 2010 (2009: \$Nil).

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: 7.5% to 30%

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 Statement of Comprehensive Income.

F. INVESTMENTS AND OTHER FINANCIAL ASSETS

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

G. RESEARCH AND DEVELOPMENT EXPENDITURE

Expenditure on research activities is 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;
- 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 2010 the Consolidated entity 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 SCENESSE® has been amortised on a straight-line basis over 10 years. As at 30 June 2010, the sub-licence has been fully amortised.

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 and conditional performance rights issued to employees as remuneration and recognise an expense in the Statement of Comprehensive Income. This standard is not limited to options and to conditional performance rights. It 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. The fair value of conditional performance rights is measured by a binomial model. It is determined at grant date and expensed on a straight- line basis over the vesting period.

For the full year reporting period ended 30 June 2010 the fair value of options and conditional performance rights 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 2009/10 year \$531,068 (2009:\$678,374) for options and \$336,878 (2009:\$Nil) for conditional performance rights was recognised as an employment benefit expense. The fair value for options 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. The fair value of conditional performance rights was attributable to the issue of rights to eligible employees as approved by the Board during 2009/10.

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 Statement of Cash Flows 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 NON-FINANCIAL 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 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

In the current year, the Group has adopted all of the new and revised Standards and Interpretations issued by the Australian Accounting Standards Board that are relevant to its operations and effective for the current annual reporting period. The 2009 comparatives contained in these financial statements therefore differ from those published in the financial statements for the year ended 30 June 2009 as described below.

Adoption of AASB101 Presentation of Financial Statements

Clinuvel Pharmaceuticals Ltd and its controlled entities have adopted the revisions to *AASB 101 Presentation of Financial Statements* in these financial statements which has resulted in the introduction of the statement of comprehensive income, changes to the statement of changes in equity, and other terminology changes. It does not change the recognition, measurement, or disclosure of transactions that are required by other Accounting Standards.

Adoption of AASB 8 Operating Segments

AASB 8 replaced *AASB 114 Segment Reporting* which the Group also adopted from 1 July 2009. The new standard requires a “management approach”, under which segment information is presented on the same basis as that used for internal reporting purposes. Therefore, segments are now being reported in a manner that is consistent with the internal reporting provided to the Managing Director (as the Chief Operating Decision Maker). The Group concluded that the operating segments determined in accordance with AASB 8 are the same as the business segments previously identified under AASB 114.

X. NEW AUSTRALIAN ACCOUNTING STANDARDS ISSUED BY NOT YET EFFECTIVE

Australian Accounting Standards that have been recently issued or amended but are not yet effective have not been applied to the financial report. These amendments by the AASB to Australian Accounting Standards are not expected to have a material impact on the Group's financial position and performance, however increased disclosures will be required in the Group's financial statements.

Y. SEGMENT REPORTING

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.

2. PROFIT/(LOSS) FROM CONTINUING OPERATIONS

	CONSOLIDATED	
(a) Revenues	2010	2009
Interest revenue – other persons	\$1,473,664	\$2,667,920
Realised Net Gain (Loss) on currency gain on transactions	\$372,056	\$236,997
Total Revenues	\$1,845,720	\$2,904,917
(b) Expenses		
Clinical development costs	\$2,553,354	\$2,280,762
Drug delivery research costs	\$2,981,322	\$6,176,670
Regulatory and toxicity studies	\$957,588	\$312,877
Research & development overheads	\$1,887,799	\$1,534,715
Business marketing & listing	\$704,143	\$845,904
Licenses patents and trademarks	\$745,970	\$916,535
General operations (incl. Board)	\$5,831,796	\$4,388,947
Unrealised Net (Gain) Loss on revaluation of financial assets held at fair value through profit and loss	(\$2,295,212)	\$1,821,414
Total Expenses	\$13,366,760	\$18,277,824
(c) Profit (Loss) before income tax includes the following specific expenses		
Depreciation	\$80,633	\$94,794
Amortisation of sub-licence	\$626,315	\$747,298
Amortisation of trademarks	\$9,200	\$9,200
Research & development costs	\$5,534,676	\$8,428,935
Share-based payments	\$867,946	\$678,374
Loss on sale of property, plant and equipment	–	\$4,050
Realised loss on disposal of financial assets at fair value through profit and loss	\$1,046,848	\$628,844
Operating lease expense – minimum lease payments	\$280,309	\$311,391
(Gain) Loss on Restatement of foreign currency creditors and currencies held	\$401,055	(\$604,781)

3. INCOME TAX EXPENSE

	CONSOLIDATED	
	2010	2009
(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% (2009: 30%)	(\$3,456,312)	(\$4,611,872)
Add: Tax effect of		
Non deductible amortisation	\$2,760	\$2,760
Capital raising costs	(\$450)	(\$417)
Share based payments	(\$8,311)	\$141,305
Research & development deduction	(\$81,003)	(\$81,851)
(Over) Under provision of income tax in previous years	\$1,659,513	(\$333,374)
Net (Gain) on revaluation of financial assets at fair value through profit and loss	(\$688,563)	—
Deferred tax assets not brought to account	\$2,572,366	\$4,883,449
(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	\$26,471,013	\$23,942,623
Net temporary differences	\$1,394,713	\$1,350,737
Total	\$27,865,726	\$25,293,360

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	
	2010	2009
Current		
Accrued income	\$245,189	\$200,925
Sundry debtors	\$117,781	\$10,862
Total Current	\$362,970	\$211,787

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

5. OTHER ASSETS

	CONSOLIDATED	
	2010	2009
Current Prepayments		
Peptide	\$1,609,295	\$2,277,808
Other	\$182,076	\$349,777
Total	\$1,791,371	\$2,627,585

6. PROPERTY, PLANT AND EQUIPMENT

	CONSOLIDATED	
	2010	2009
Plant and Equipment		
At cost	\$630,189	\$586,638
Less: accumulated depreciation	(\$379,408)	(\$314,143)
Sub-total	\$250,781	\$272,495
Furniture and Fittings		
At cost	\$118,637	\$117,025
Less: accumulated depreciation	(\$47,753)	(\$32,385)
Sub-total	\$70,884	\$84,640
Total Property, Plant and Equipment	\$321,665	\$357,135

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.

CONSOLIDATED ENTITY	PLANT AND EQUIPMENT	FURNITURE AND FITTINGS	TOTAL
Carrying amount at 30 June 2008	\$329,107	\$101,927	\$431,034
Additions	\$22,247	\$11,728	\$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	\$272,495	\$84,640	\$357,135
Additions	\$43,283	\$1,681	\$44,964
Disposals	—	—	—
Depreciation written back on disposal	—	—	—
Depreciations expense	(\$65,500)	(\$15,470)	(\$80,970)
Exchange differences	\$503	\$33	\$536
Carrying amount at 30 June 2010	\$250,781	\$70,884	\$321,665

7. INTANGIBLE ASSETS

	CONSOLIDATED	
	2010	2009
Sub-licence to develop and commercialise afamelanotide		
At cost	\$7,472,983	\$7,472,983
Less: Accumulated amortisation	(\$7,472,983)	(\$6,846,668)
Sub-total	–	\$626,315
Trademarks		
At cost	\$68,281	\$68,281
Less: Accumulated amortisation of Trademarks	(\$47,797)	(\$40,969)
Sub-total	\$20,484	\$27,312
Patents		
At cost	\$23,718	\$23,718
Less: Accumulated amortisation of Patents	(\$16,602)	(\$14,231)
Sub-total	\$7,116	\$9,487
Total	\$27,600	\$663,114

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.

CONSOLIDATED ENTITY	SUB-LICENCE	TRADEMARKS AND PATENTS	TOTAL
Carrying amount at 30 June 2008	\$1,373,613	\$46,000	\$1,419,613
Additions	–	–	–
Impairment	–	–	–
Amortisation expense	(\$747,298)	(\$9,200)	(\$756,498)
Carrying amount at 30 June 2009	\$626,315	\$36,800	\$663,115
Additions	–	–	–
Impairment	–	–	–
Amortisation expense	(\$626,315)	(\$9,200)	(\$635,515)
Carrying amount at 30 June 2010	–	\$27,600	\$27,600

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

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

8. OTHER FINANCIAL ASSETS

	CONSOLIDATED	
	2010	2009
(Current) Investments Comprise		
Income Securities (at fair value through profit and loss)*	\$7,588,331	\$16,043,498
Non Current		
Shares in unlisted controlled entities at cost	—	—

* The consolidated entity holds listed perpetual floating rate notes (income securities) returning 1.25% 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 up to 19 months from reporting date.

9. INTERESTS IN SUBSIDIARIES

NAME OF ENTITY	COUNTRY OF INCORPORATION	OWNERSHIP INTEREST	
Parent Entity		2010	2009
Clinuvel Pharmaceuticals Ltd	Australia	—	—
Controlled Entities			
A.C.N. 089 584 467 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	
Current	2010	2009
Unsecured trade payables	\$569,192	\$2,055,994
Sundry payables and accrued expenses	\$2,233,744	\$2,313,412
	\$2,802,936	\$4,369,406
(a) Aggregate amounts payable to:		
Directors and director-related entities	—	—
(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
Euro	—	\$456,784
British pounds	\$173,068	\$194,886
Other	\$104,999	\$74,758
	\$278,067	\$2,415,375

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	
Current	2010	2009
Employee benefits	\$237,046	\$174,646
Non Current		
Employee benefits	\$40,638	\$18,526

12. ISSUED CAPITAL EQUITY

(a) Issued and Paid Up Capital

	CONSOLIDATED	
	2010	2009

303,188,665 fully paid ordinary shares (Year 2009: 303,148,665) \$113,227,565 \$113,221,065

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			
	2010		2009	
	No.	\$	No.	\$
At the beginning of the financial year	303,148,665	113,221,065	303,148,665	113,222,456
Issued during the year				
Rights exercised and valuation transferred from Conditional Rights Reserve	40,000	8,000	—	—
Less: transaction costs	—	(1,500)	—	(1,391)
Balance at the end of financial year	303,188,665	113,227,565	303,148,665	113,221,065

12. ISSUED CAPITAL EQUITY (CONT'D)

(c) Share Options

As at 30 June 2010 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
9 February 2012	\$0.86/share	12,760,000
18 November 2013	\$0.27/share	350,000
Total		13,110,000

No share options issued in prior years were exercised, nor were share options issued during the year, resulting in the issue of fully paid shares.

(d) Conditional Performance Rights

During the year the following conditional performance rights were issued which if exercised, would result in the issue of fully paid ordinary shares

Expiry Date	Exercise Price	Number of Securities
Upon achievement of various performance milestones	\$nil/share	3,670,000
Total		3,670,000

During the year the following conditional performance rights were exercised, resulting in the issue of fully paid ordinary shares

Expiry Date	Exercise Price	Number of Securities
Upon achievement of various performance milestones	\$nil/share	40,000
Total		40,000

As at 30 June 2010 the following conditional performance rights existed which if exercised, would result in the issue of fully paid ordinary shares

Expiry Date	Exercise Price	Number of Securities
Upon achievement of various performance milestones	\$nil/share	3,320,000
Total		3,320,000

13. RESERVES

	CONSOLIDATED	
SHARE OPTION RESERVE	2010	2009
Balance at the beginning of period	\$2,150,416	\$1,679,400
Share based payment	\$531,068	\$678,372
Lapsed options	(\$887,649)	(\$207,356)
Balance at the end of period	\$1,793,835	\$2,150,416
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.		
CONDITIONAL PERFORMANCE RIGHTS RESERVE		
Balance at the beginning of period	—	—
Share based payment	\$336,878	—
Transfer to share capital	(\$8,000)	—
Balance at the end of period	\$328,878	—
The Conditional Performance Rights reserve arises on the grant of conditional performance rights to eligible employees under the Conditional Performance Rights Plan. Amounts are transferred out of the reserve and into issued capital when the rights are exercised and to retained earnings when rights lapse.		
FOREIGN CURRENCY TRANSLATION RESERVE		
Balance at the beginning of period	\$17,030	\$84,436
Translating foreign subsidiary to current rate at balance date	\$29,573	(\$67,406)
Balance at the end of period	\$46,603	\$17,030
The consolidated entity has a foreign operation with a USD functional currency and another with a Swiss franc functional currency. The assets and liabilities of these foreign operations are translated into the consolidated entity's presentation currency at exchange rates on reporting date. Items in the Statement of Comprehensive Income of the foreign operations are translated at average monthly exchange rates. Any exchange differences arising on translation are recognised in the foreign currency translation reserve.		
Total Reserves	\$2,169,316	\$2,167,446

14. ACCUMULATED LOSSES

	CONSOLIDATED	
	2010	2009
Accumulated losses at the beginning of the year	(\$78,337,327)	(\$63,171,776)
Transfer from share option reserve of lapsed & expired options	\$887,649	\$207,356
Net loss attributable to the members of Clinuvel Pharmaceuticals Ltd	(\$11,521,040)	(\$15,372,907)
Accumulated losses at the end of the financial year	(\$88,970,718)	(\$78,337,327)

15. LEASE COMMITMENTS

	CONSOLIDATED	
	2010	2009
Operating lease commitments (Non-cancellable operating leases)		
Contracted for, but not capitalised in, the accounts:		
Payable not later than 1 year	\$221,654	\$292,125
Payable later than 1 year but not later than 5 years	—	\$184,093
	\$221,654	\$476,218

Operating leases comprises commitments for office premises and miscellaneous equipment.

16. EARNINGS PER SHARE (EPS)

	CONSOLIDATED	
	2010	2009
(a) Basic earnings per share – cents per share	(3.8)	(5.1)
(b) The weighted average number of ordinary shares (WANOS) used in the calculation of basic earnings per share	303,164,336	303,148,665
(c) The numerator used in the calculation of basic earnings per share	(11,521,040)	(15,372,907)

As at 30 June 2010 the company had on issue 13,110,000 unlisted options and 3,320,000 unlisted performance rights over unissued capital. These options and rights are not considered dilutive as they do not increase the net loss per share.

17. CASH FLOW INFORMATION

	CONSOLIDATED	
(a) Reconciliation of cash	2010	2009

Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled to the related items in the Statement of Financial Position as follows:

Cash at bank	\$2,482,165	\$1,579,568
Cash on hand	\$45	\$728
Deposits on call	\$4,894,433	\$691,086
Term deposits (security bonds)	\$12,000,000	\$19,400,000
Security bonds	\$38,203	\$39,261
	\$19,414,846	\$21,710,643

The effective interest rate on short-term deposits was 5.21% (2009: 4.16%), these deposits have an average maturity date of 147 days.

(b) Reconciliation of cash flows from operating activities with operating profit (loss)		
Operating Profit (Loss) after income tax	(\$11,521,040)	(\$15,372,907)
Non cash flows in operating (loss)		
Depreciation expense	\$80,633	\$94,794
Accrued income	(\$44,264)	\$258,361
Exchange rate effect on foreign currencies held	\$154,148	(\$278,212)
Amortisation expense	\$635,515	\$756,498
Executive share option expense	\$867,946	\$678,374
WDV of non current assets sold	—	\$13,079
Realised gain on disposal of financial assets at fair value through profit and loss	\$1,046,848	\$628,844
Net Loss on revaluation of financial assets held at fair value	(\$2,295,212)	\$1,821,414
Unrealised loss foreign exchange translation	\$29,573	(\$67,406)
Changes in assets and liabilities		
(Increase) Decrease in receivables	(\$91,602)	\$907
(Increase) Decrease in prepayments	\$836,214	(\$924,187)
Increase (Decrease) in payables	(\$1,566,016)	\$1,399,611
Increase (Decrease) in provisions	\$84,512	\$5,286
Net Cash used in operating activities	(\$11,782,745)	(\$10,985,544)

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 to July 1 2010, Non-Executive Chair thereafter)

Mrs. B.M. Shanahan (Non-Executive Chair to July 1 2010, Non-Executive Director thereafter)

Dr. P.J. Wolgen (Managing Director)

Mr. L.J. Wood (Non-Executive)

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)

KEY MANAGEMENT PERSONNEL COMPENSATION

	CONSOLIDATED	
	2010	2009
Short-term employee benefits	\$1,777,322	\$1,957,408
Post-employment benefits	\$60,201	\$67,884
Long-term benefits	—	—
Termination benefits	—	—
Share-based payments	\$593,334	\$622,244
	\$2,430,857	\$2,647,536

REMUNERATION OPTION HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2010

	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	LAPSED AND EXPIRED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
DIRECTORS							
R. Aston	2,450,000	—	—	(1,150,000)	1,300,000	1,300,000	—
H.P.K. Agersborg	2,000,000	—	—	(500,000)	1,500,000	1,500,000	—
S.R. McLiesh	650,000	—	—	(200,000)	450,000	450,000	—
B.M. Shanahan	850,000	—	—	—	850,000	850,000	—
P.J. Wolgen	9,250,000	—	—	(3,250,000)	6,000,000	6,000,000	—
L.J. Wood	350,000	—	—	—	350,000	233,333	116,667
EXECUTIVES							
D.J. Wright	1,600,000	—	—	(200,000)	1,400,000	1,297,917	102,083
D.M. Keamy	700,000	—	—	(100,000)	600,000	527,083	72,917

REMUNERATION CONDITIONAL PERFORMANCE RIGHTS HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2010

	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	LAPSED AND EXPIRED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
EXECUTIVES							
D.J. Wright	–	875,000	–	–	875,000	50,000	825,000
D.M. Keamy	–	400,000	–	–	400,000	40,000	360,000

REMUNERATION OPTION HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2009

	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	2,000,000	–	–	–	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

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.

There were no conditional performance rights issued to Key Management Personnel in 2008/09.

SHARE HOLDINGS OF KEY MANAGEMENT PERSONNEL

	ORDINARY SHARES – 2010				ORDINARY SHARES – 2009			
	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	–	300,000	400,000	–	–	100,000	100,000
EXECUTIVES								
D.J. Wright	–	–	–	–	–	–	–	–
D.M. Keamy	1,600	–	–	1,600	1,600	–	–	1,600

19. AUDITORS' REMUNERATION

	CONSOLIDATED	
	2010	2009
Amounts received or due and receivable by Grant Thornton for:		
Audit services and review	\$60,500	\$50,682
Other services	–	–
Total	\$60,500	\$50,682

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 to A.C.N. 089 584 467 Pty Ltd as at 30 June 2010 is \$8,111,035 (2009: \$8,093,297).

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 2010 is \$4,370,640 (2009: \$4,370,640).

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 2010 is \$2,893,576 (2009: \$1,804,088).

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 2010 is \$2,740,069 (2009: \$1,233,684).

DIRECTOR RELATED AND KEY MANAGEMENT PERSONNEL TRANSACTIONS AND ENTITIES

The following transactions and relationships were in existence as at 30 June 2010 between Directors of the Company and their related entities.

COMMON DIRECTOR OF THE COMPANY AND SUB-LICENSOR

A Director of the company, Dr. Helmer Agersborg, also holds a Directorship with a company which 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 the sub-licensor of 3.5% of the net selling price upon commercialisation of the technology. This company has been dissolved.

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 2010 and as at 30 June 2009.

THE CONSOLIDATED ENTITIES EXPOSURE TO FOREIGN CURRENCY RISK AT 30 JUNE 2009

	CONSOLIDATED			CONSOLIDATED		
	2010			2009		
	Cash & cash equivalents	Trade & other payables	Total	Cash & cash equivalents	Trade & other payables	Total
USD	1,240,196	(1,042,362)	197,834	541,012	(1,911,425)	(1,370,413)
EUR	389,504	(231,742)	157,762	252,882	(515,362)	(262,480)
CHF	200,545	(284,988)	(84,443)	163,931	(65,415)	98,516
GBP	—	(98,060)	(98,060)	—	(96,748)	(96,748)
SEK	—	(89,132)	(89,132)	—	—	—

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 10% appreciation of the Australian dollar against the US currency would have increased profit and loss and equity by \$505,226 for the year ended 30 June 2010 (2009: \$437,187), on the basis that all other variables remain constant. 10% is considered representative of the market volatility in the Australian/US dollar rate for the period.

For the consolidated entity, a 10% depreciation of the Australian dollar against the US currency would have an equal but opposite effect to the above, on the basis that all other variables remain constant.

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

INTEREST RATE RISK

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

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

SENSITIVITY ANALYSIS

For the consolidated entity, at 30 June 2010, 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 \$343,119 higher/lower (2009: \$510,954 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 Statement of Financial Position 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 2010, if the weighted average of the market-acknowledged benchmarks of the investments in income securities increased/decreased by 5.3% (2009: 8.4%) assuming all other variables constant and the investments in securities move in correlation with the indexes, the impact on profit and equity is:

	CONSOLIDATED	
	2010	2009
Market-acknowledged weighted average benchmarks (+/- 5.3%)	\$398,734	\$1,479,609

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

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

The consolidated entity'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 ASSETS AS AT 30 JUNE 2010

CONSOLIDATED		
	2010	2009
Cash and Cash Equivalents		
Carrying amount	\$19,414,846	\$21,710,643
6 months or less	\$19,414,846	\$21,671,382
Greater than 6 months	—	\$39,261
Total	\$19,414,846	\$21,710,643
Other Financial Assets		
Carrying amount	\$7,588,331	\$16,043,498
6 months or less	—	—
Greater than 6 months	\$7,588,331	\$16,043,498
Total	\$7,588,331	\$16,043,498

CONTRACTUAL MATURITIES OF FINANCIAL LIABILITIES AS AT 30 JUNE 2010

CONSOLIDATED		
	2010	2009
Trade and other payables		
Carrying amount	\$2,802,936	\$4,369,406
6 months or less	\$2,598,829	\$4,369,406
Greater than 6 months	\$204,107	—
Total	\$2,802,936	\$4,369,406

23. EMPLOYEE BENEFITS

	CONSOLIDATED	
The aggregate employee benefit liability is comprised of:	2010	2009
Provision for annual leave	\$236,017	\$157,300
Provision for long service leave	\$41,667	\$18,526
Accrued FBT, Superannuation, Pension Funds, Employee Insurances	\$430,997	\$68,463
Total	\$708,681	\$244,289

A) SHARE BASED PAYMENTS

The consolidated entity has a share option scheme and a conditional performance rights scheme's which are ownership based for key management personnel and select consultants (including Executive Directors) of the company, .

SHARE OPTION SCHEME

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.

CONDITIONAL PERFORMANCE RIGHTS SCHEME

All performance rights issued fall under the Clinuvel Conditional Performance Rights Plan, available to eligible employees of the company. Any issue of rights to executive Directors requires shareholder approval in accordance with ASX Listing Rules. All rights converts to one ordinary share of the consolidated entity are issued for nil consideration, have no voting rights, are non-transferable and are not listed on the ASX. They can be converted to ordinary shares at any time once the vesting conditions attached to the rights have been achieved, whereby they will be held by a Scheme Trustee on behalf of the eligible employee for up to 7 years. The eligible employee can request for shares to be transferred from the Scheme Trust after 7 years or at an earlier date if the eligible employee is no longer employed by the company or all transfer restrictions are satisfied or waived by the Board in its discretion.

The number of rights granted is subject to approval by the Remuneration and Nomination Committee. Rights currently have specific terms and conditions, being the achievement of performance milestones set by the Directors of the consolidated entity.

THE FOLLOWING SHARE BASED PAYMENT ARRANGEMENTS WERE IN EXISTENCE AT 30 JUNE 2010

OPTIONS SERIES	NUMBER	GRANT DATE	EXPIRY DATE	EXERCISE PRICE	FAIR VALUE AT GRANT DATE
Issued 09/02/2007	12,760,000	09/02/2007	09/02/2012	\$0.86	\$0.22
Issued 18/11/2008	350,000	18/11/2008	18/11/2013	\$0.27	\$0.05
PERFORMANCE RIGHTS SERIES	NUMBER	GRANT DATE	EXPIRY DATE	EXERCISE PRICE	FAIR VALUE AT GRANT DATE
Issued 16/10/2009	2,620,000	16/10/2009	Upon achievement of specific performance milestones	\$Nil	\$0.20
Issued 07/01/2010	700,000	07/01/2010	Upon achievement of specific performance milestones	\$Nil	\$0.17

OPTION HOLDINGS OF ALL ISSUED OPTIONS - 2010

OPTIONS SERIES	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	EXPIRED AND LAPSED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
Issued 23/02/2006	1,500,000	–	–	(1,500,000)	–	–	–
Issued 01/03/2005	500,000	–	–	(500,000)	–	–	–
Issued 31/10/2005	1,500,000	–	–	(1,500,000)	–	–	–
Issued 09/02/2007	15,340,000	–	–	(2,580,000)	12,760,000	12,570,417	189,583
Issued 18/11/2008	350,000	–	–	–	350,000	233,333	116,667
Total	19,190,000	–	–	(6,080,000)	13,110,000	12,803,750	306,250
Weighted Average Exercise Price	\$0.78	–	–	\$0.77	\$0.78	\$0.77	–

The share options outstanding at the end of the financial year had an average remaining contractual life of 701 days (2009: 862 days).

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.

HOLDINGS OF ALL ISSUED CONDITIONAL PERFORMANCE RIGHTS - 2010

PERFORMANCE RIGHTS SERIES	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	EXPIRED AND LAPSED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
Issued 16/10/2009	–	2,970,000	(40,000)	(310,000)	2,620,000	177,500	2,442,500
Issued 07/01/2010	–	700,000	–	–	700,000	375,000	325,000
Total	–	3,670,000	(40,000)	(310,000)	3,320,000	552,500	2,767,500
Weighted Average Exercise Price	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	–

Performance Rights were priced using a binomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. 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 pricing model is assumed to be the yield on 2 year Government bonds.

The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

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	—

No conditional performance rights were granted during 2008/09.

PERFORMANCE RIGHTS - BINOMIAL PRICING MODEL

INPUTS		
Grant date share price	\$0.325	\$0.28
Exercise price	\$Nil	\$Nil
Grant date	16 October 2009	7 January 2010
Expiry date	Upon achievement of specific performance conditions	
Historical volatility (weighted average)	65%	65%
Expected life (weighted average)	18 months	18 months
Risk free interest rate	4.81%	4.50%

24. COMMITMENTS OF EXPENDITURE

	CONSOLIDATED	
	2010	2009
(a) Research Commitments		
US dollars	—	226,460
Euro	52,535	51,009
British pounds	74,430	40,080
Total	126,965	317,549
(b) Other Expenditure Commitments		
AU dollars	30,000	30,000
US dollars	3,520	3,697
Swiss francs	6,505	6,834
Total	40,025	40,531
Total Expenditure Commitments	166,990	358,080

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

25. CLINUVEL PHARMACEUTICALS LTD PARENT COMPANY INFORMATION

		CLINUVEL PHARMACEUTICALS LTD	
Assets	Note	2010	2009
Current Assets		\$28,383,497	\$40,345,365
Non Current Assets		\$639,688	\$1,168,841
Total Assets		\$29,023,185	\$41,514,206
Liabilities			
Current Liabilities		\$2,635,234	\$4,441,108
Non Current Liabilities		\$40,638	\$18,526
Total Liabilities		\$2,675,872	\$4,459,634
Equity			
Issued Equity		\$113,227,565	\$113,221,065
Reserves		\$2,122,713	\$2,150,416
Accumulated Losses		(\$89,002,965)	(\$78,316,909)
Total Equity		\$26,347,313	\$37,054,572
Financial Performance			
Net Profit (Loss) for the year		(\$11,553,460)	(\$15,366,377)
Other comprehensive income		—	—
Total Comprehensive Income		(\$11,553,460)	(\$15,366,377)

The accompanying notes form part of these financial statements.

26. 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.

27. ADDITIONAL COMPANY INFORMATION

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

THE REGISTERED OFFICE IS:

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E-mail: mail@clinuvel.com
 Website: www.clinuvel.com

DIRECTORS' DECLARATION

In the opinion of the Directors:

1. The financial statements and notes of the consolidated entity are in accordance with the Corporations Act 2001, including:
 - a. giving a true and fair view of the consolidated entity's financial position as at 30 June 2010 and of its performance for the year ended on that date; and
 - b. complying with Accounting Standards; and
 - c. complying with International financial Reporting Standards as disclosed in Note 1
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 Directors have been given the declarations by the Chief Executive Officer and Chief Financial Officer required by Section 295A of the Corporations Act 2001.

This declaration is made in accordance with a resolution of the Board of Directors.

A handwritten signature in black ink, appearing to read 'Philippe J. Wolgen', is written over a light grey rectangular background.

Dr. Philippe J. Wolgen
Director

Dated this 27th day of August, 2010



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Independent Auditor's Report To the Members of Clinuvel Pharmaceuticals Ltd

Report on the financial report

We have audited the accompanying financial report of Clinuvel Pharmaceuticals Ltd (the "Company"), which comprises the statement of financial position as at 30 June 2010, and the statement of comprehensive income, statement of changes in equity and statement of cash flows for the year ended on that date, a summary of significant accounting policies, other explanatory notes to the financial report 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 are 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. The directors also state, in the notes to the financial report, 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 which require us to 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 opinion.

Electronic presentation of audited financial report

This auditor's report relates to the financial report of Clinuvel Pharmaceuticals Ltd and controlled entities for the year ended 30 June 2010 included on Clinuvel Pharmaceuticals Ltd's web site. The Company's directors are responsible for the integrity of Clinuvel Pharmaceuticals Ltd's web site. We have not been engaged to report on the integrity of Clinuvel Pharmaceuticals Ltd'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 have complied with the independence requirements of the Corporations Act 2001.

Auditor's opinion

In our opinion,:

- a the financial report of Clinuvel Pharmaceuticals Ltd 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 2010 and of its 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 the notes to the financial statements..

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 2010. 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 on the remuneration report

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Ltd for the year ended 30 June 2010, complies with section 300A of the Corporations Act 2001.

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

David Ashmore
Director - Audit & Assurance Services

Melbourne, 27 August 2010



Grant Thornton Audit Pty Ltd
ACN 130 913 594

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**Auditor's Independence Declaration
To the Directors of Clinuvel Pharmaceuticals Ltd**

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of Clinuvel Pharmaceuticals Ltd for the year ended 30 June 2010, I declare that, to the best of my knowledge and belief, there have been:

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

A handwritten signature in black ink that reads "Grant Thornton".

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

A handwritten signature in black ink, appearing to read "David Ashmore".

David Ashmore
Director - Audit & Assurance

Melbourne, 27 August 2010

ADDITIONAL INFORMATION REQUIRED BY THE AUSTRALIAN SECURITIES EXCHANGE (ASX)

Additional information, as at 22 September 2010, 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	369
1,001 – 5,000	1,280
5,001 – 10,000	758
10,001 – 100,000	1,424
100,001 – 9,999,999,999	248
	4,079

b. The number of shareholdings held in less than marketable parcels is 862 for ordinary shares.

c. There are no substantial shareholders listed in the company's holding registry as at 22 September 2010.

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	JP MORGAN NOMINEES AUSTRALIA LIMITED <CASH INCOME A/C>	40,015,630	13.19%
2	ANZ NOMINEES LIMITED <CASH INCOME A/C>	32,312,519	10.65%
3	NATIONAL NOMINEES LIMITED	30,752,871	10.13%
4	CITICORP NOMINEES PTY LIMITED	19,053,445	6.28%
5	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	16,429,829	5.41%
6	SANDHURST TRUSTEES LTD <JMFG CONSOL A/C>	13,617,071	4.49%
7	BOODUP NOMINEES PTY LTD <OTTER SUPER FUND A/C>	6,666,426	2.20%
8	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	4,147,205	1.37%
9	J P MORGAN NOMINEES AUSTRALIA LIMITED	2,240,299	0.74%
10	HEADSTART GLOBAL HOLDINGS LTD	1,990,665	0.66%
11	ARMADA TRADING PTY LTD	1,817,744	0.60%
12	DR MICHAEL JAMES FISH	1,806,703	0.60%
13	UTOPIA LAND COMPANY PTY LTD	1,610,000	0.53%
14	ABN AMRO CLEARING SYDNEY NOMINEES PTY LTD <CUSTODIAN A/C>	1,576,305	0.52%
15	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED – A/C 2	1,557,557	0.51%
16	TERSTAN NOMINEES PTY LTD <MORROWS P/L SUPER FUND A/C>	1,555,222	0.51%
17	SWEET WATER PTY LTD <FARMOCEAN SUPER FUND>	1,400,000	0.46%
18	LIPPO SECURITIES NOMINEES (BVI) LTD <CLIENT A/C>	1,310,000	0.43%
19	MR DAVID JOHN LEWIS	1,272,932	0.42%
20	SANDHURST TRUSTEES LTD <JM MPS A/C>	1,210,099	0.40%
		182,342,522	60.09%

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
Facsimile: +61 3 9660 4999
Email: mail@clinuve.com
Website: http://www.clinuve.com

4. REGISTER OF SECURITIES

Computershare Investor Services Pty Ltd
Yarra Falls,
453 Johnson St
Abbotsford, VIC, 3067, Australia

5. AUSTRALIAN SECURITIES EXCHANGE LIMITED

Quotation has been granted for all the ordinary shares on all Member Exchanges of the Australian Securities Exchanged 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 (ADR) code: CLVLY

ADR Custodian: Bank of New York Mellon

6. RESTRICTED SECURITIES

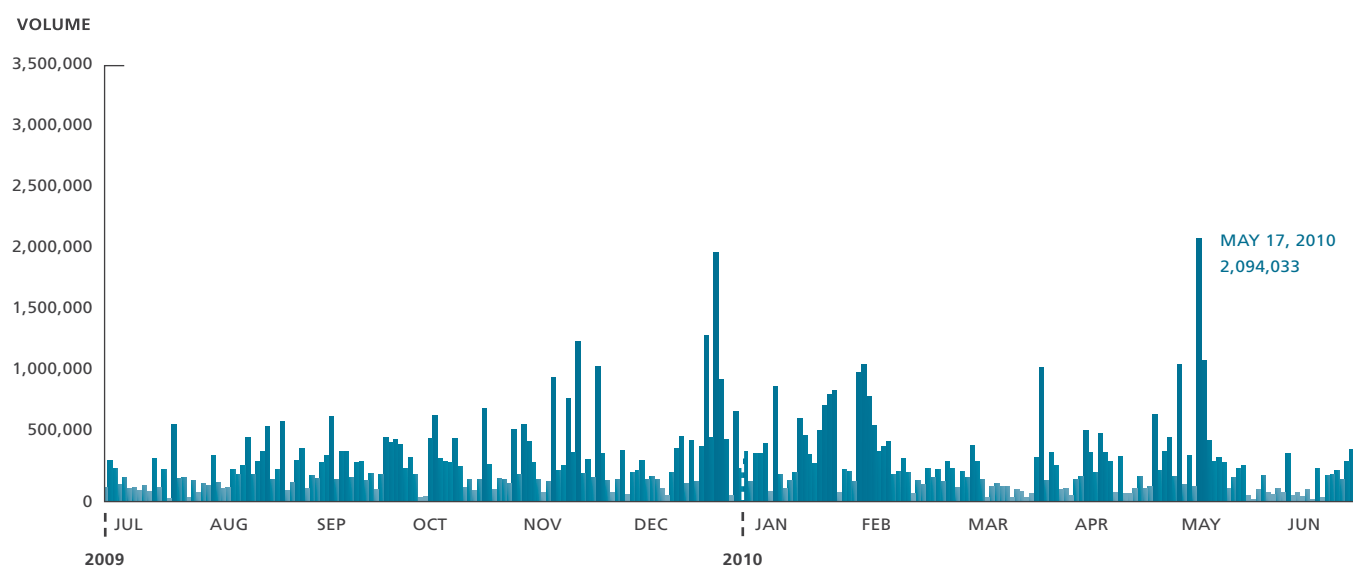
Restricted securities on issue at June 30 2010: Nil.

MARKET PERFORMANCE

ASX: CUV



DAILY TRADING VOLUME – ASX:CUV



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.

EMA

The European Medicines 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.

MARKETING AUTHORISATION APPLICATION (MAA)

A formal application to a regulatory agency to approve a drug product or medical device for sale.

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 ($\alpha=295$ nm) of approximately 100 J/m².

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.

THYMIN 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.

ULTRAVIOLET (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.

CORPORATE DIRECTORY

DIRECTORS AND EXECUTIVES

NON-EXECUTIVE CHAIR

Stanley McLiesh

NON-EXECUTIVE DIRECTORS

Brenda Shanahan, 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 INVESTOR SERVICES PTY LTD

Yarra Falls, 453 Johnston Street

Abbotsford, VIC 3067, Australia

Tel: +61 3 9415 4000

AUDITOR

GRANT THORNTON AUSTRALIA LIMITED

Level 2, 215 Spring Street

Melbourne, VIC 3000, Australia

BANKER

NATIONAL AUSTRALIAN BANK (NAB)

Western Branch, 460 Collins Street

Melbourne, VIC 3000, Australia

LEGAL COUNSEL

ALLENS ARTHUR ROBINSON

Level 27, 530 Collins Street

Melbourne, VIC 3000, Australia

ARNOLD BLOCH LEIBLER

Level 21, 333 Collins Street

Melbourne, VIC 3000, Australia

IP LAWYER

DIPL.-ING. PETER FARAGO

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Munchen 80469, Germany

SUSTAINABILITY

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