

Clinuvel: experts in the interaction of light and skin

Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing drugs for the treatment of a range of severe skin disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified three groups of patients with a clinical need for photoprotection and another group with a need for repigmentation. These patient groups range in size from 10,000 to 45 million.

Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg implant), is a first-in-class drug targeting the "orphan" disease erythropoietic protoporphyria (EPP) and the pigmentary disorder vitiligo. Clinuvel has completed Phase II and III trials in the US and Europe for EPP and in February 2012 SCENESSE® was filed for review by the European Medicines Agency. A confirmatory six month Phase III US EPP trial commenced in May 2012. Presently, there is no known effective treatment for EPP and SCENESSE® was granted orphan drug status in Europe, the US and Australia. Based in Melbourne, Australia, Clinuvel has operations in Europe, the US and Asia, with over 40 part- and full-time employees and a number of external service providers worldwide.

Interactions of light and human skin

Alpha-Melanocyte Stimulating Hormone (α -MSH) is a naturally occurring hormone released by skin cells in response to ultraviolet radiation (UVR) following exposure to sunlight or artificial sources of UV. Alpha-MSH activates melanin, a natural brown pigment which provides skin with colour and protection from UV and visible light (photoprotection).

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

Skin cancer in Organ Transplant Recipients

About SCENESSE®

SCENESSE® is a first-in-class dermatological drug being developed solely by Clinuvel. The active ingredient in SCENESSE® is afamelanotide, a chemical analogue of $\alpha\textsc{-MSH}$ which activates melanin in the skin. The process of melanin activation mimics the skin's natural protective umbrella against UVR and sunlight. SCENESSE® is delivered as a subcutaneous, dissolving implant approximately the size of a rice grain. Increased pigmentation of the skin appears two days after drug administration and lasts up to two months.

About EPP

Erythropoietic protoporphyria (EPP) is a rare life-long genetic disease found mainly in fair-skinned people. It is characterised by severe phototoxicity (intolerance of light) of the skin resulting in intolerable pain, swelling and scarring, usually of exposed areas such as the face, hands and feet. Reactions can vary from mild to extreme with hospitalisation and powerful pain killers required in the worst cases. Children and adults living with EPP must avoid sunlight and even reflected light for life, often staying indoors or wearing protective clothing. Conventional sunscreens have little to no effect. Approximately 10,000 people globally are affected by EPP.

Clinuvel's Pipeline for SCENESSE®

We are using our expertise in understanding light and skin to conduct clinical trials in a number of different severe skin disorders with SCENESSE*:

Indication	Phase II	Phase III	Marketing
Erythropoietic protoporphyria (EPP), EU			
Erythropoietic protoporphyria (EPP), USA			
Generalised vitiligo, USA/EU/Asia			
A depigmentation disorder			

Contents

SCENESSE* (afamelanotide 16mg) Development Program	2
Erythropoietic Protoporphyria	4
Target Indications	5
The Melanocyte - The Primary Target Cell	6
Academic and Press Coverage	7
Chair's Letter	8
Managing Director's Report	9
Financials Content	11
Shareholder Information as at 26 September 2013	66
Market Performance	68
Glossary	69

SCENESSE® (afamelanotide 16mg) Development Program

Clinuvel's Business Model - Single Product Development

SELECTION NEW MOLECULAR ENTITY
IN VITRO TESTING
FIRST PROOF OF CONCEPT IN NONCLINICAL STUDIES
NONCLINICAL DOSE RANGE STUDIES first toxicology, efficacy
REGULATORY SUBMISSION FIRST RESULTS DOSE RANGE STUDIES
FIRST STAGE FORMULATION DEVELOPMENT
FIRST HUMAN PHARMACOKINETIC STUDY healthy volunteers, single dose
SECOND STAGE FORMULATION DEVELOPMENT
SECOND HUMAN PHARMACOKINETIC STUDY 12 healthy volunteers, single dose
FINAL HUMAN PHARMACOKINETIC STUDY 12 healthy volunteers, single dose
FIRST PROOF OF CONCEPT STUDY regulatory submissions, ethics submissions, clinical trial agreements, safety/efficacy
REGULATORY EVALUATION AND PROTOCOL ASSESSMENT – SCIENTIFIC ADVICE regulatory discussions
PHASE IIA STUDY IN FIRST INDICATION single or multiple dosing, safety/efficacy
REGULATORY EVALUATIONS safety/efficacy
FINAL STAGE FORMULATION DEVELOPMENT
PHASE IIB STUDY IN FIRST INDICATION multiple dosing, safety/efficacy
1st PHASE III STUDY IN FIRST INDICATION multiple dosing, safety/efficacy
2nd PHASE III STUDY IN FIRST INDICATION multiple dosing, safety/efficacy
1st REGULATORY SUBMISSION benefit-risk assessment

lored to the specific characteristics of what later became the final trolled by the manufacturer of the implant. product, the 16 mg controlled-release formulation implant SCE-NESSE® (afamelanotide 16mg).

therapeutic window.

human physiologic response in animals.

velopment process, it is unfortunate that many of these process- all stakeholders owe much to them. es are organised in a serial, rather than parallel, manner. In the pharmaceutical development process one's goal is, ultimately, to At the end of five clinical trials in EPP Clinuvel administered 729 develop a novel but safe drug for human administration.

Specific to the SCENESSE® model has been the uniquely designed formulation, a novelty in pharmaceutical skin care and a global first. The implant was designed to release afamelanotide in a specific quantity, in a preferred interval and at a specific dose, while the implant was required to be absorbed by the body (bio-

In the development process of SCENESSE* in erythropoietic absorbable), meaning obviating the need for a physician to remove protoporphyria (EPP) Clinuvel has chartered a course through the implant at a later stage. The novelty of this delivery vehicle a labyrinth of steps to arrive at a safe and clinically effective took many years and multimillion dollars in R&D whereby both drug. Without claiming that this was the only route available to Clinuvel's scientific teams and our contract manufacturer were inthe promised land, this development program - conducted over tensely involved. At the end of the process Clinuvel was required to nearly two decades under three management teams - was tai- demonstrate a validated commercial manufacturing process con-

Eight years after the start of the first EPP trial in humans, Clinuvel looks back on five trials conducted in 351 EPP patients. Given that Introducing afamelanotide clinically as a new molecular enti- EPP is an ultra-rare disorder ("orphan disease"), it is remarkable ty has required much more work than, for instance, would be that so many patients have been recruited and have been willing the case for known chemical entities, derivatives, related active to participate in Clinuvel's clinical studies. While patients are despharmaceutical ingredients or generics. The novel pharmacolo- perate to alleviate their disease symptoms and gain a freedom to gy required testing in several trials in healthy volunteers. These live, it is not always the case that they are so invested in a new, studies taught us the melanogenic effects of the drug as well as previously untested product. Patients took the time to travel from the plasma levels at various time points in healthy individuals. long distances to attend the clinical procedures dictated by a study Together with the extensive animal studies, Clinuvel's team grad- protocol to be conducted at each visit of the trial. Clinical studies ually understood the bioavailability of SCENESSE* as well as the required more than 10 visits in a window of six to nine months. To shed more light on patients' burden in these clinical experiments, they had to maintain a daily diary (initially electronically, Animal studies have traditionally been the foundation for drug later written) to record their minutes of light exposure outdoors, companies to proceed to human studies. Although no other their level of pain and phototoxicity (pain following light), fill in a model has yet been designed and accepted by regulatory authori- weekly quality of life questionnaire and attend a weekly phone call ties (whose primary task it is to safeguard the general public from with a call center. Being part of these trials is hard work for patients health hazards that may arise from the use of new drugs), ani- and places an additional burden on individuals who are already mal data are not always comparable to the human as we possess a struggling to manage their health. Above all, it needs recognition unique physiology. For example, in most mammals the hormone that half of the patients never obtained the real drug (verum), but alpha-MSH (closely related to afamelanotide) is centrally secret- a placebo. As three trials were placebo controlled and randomised, ed by cerebral tissue, in humans 99% of this endocrine substance patients only discovered during the trial whether they had received is released by skin cells. Hence it is not always possible to simulate the real or placebo implant. Despite the early realisation that they may not have had the real drug, patients were prepared to continue their long journey to the trial centers and continue the study to The flow diagram (left) illustrates the sequential steps one has to the very end. This frustration was understandable but in current go through to gain confidence of previous data in order to be al- pharmaceutical development not avoidable. This persistence is lowed to proceed to the next. Here there are seldom shortcuts commendable and sometimes hardly imaginable: persisting with available or allowed, since the entire process is subject to national a disease in a clinical trial while knowing that one has not and regulatory bodies, ethics committees, scientific review commit- will not receive the real drug or its benefits demonstrates quite a tees, data safety monitoring boards and individual physicians tenacity and willingness to sacrifice one's self for the sake of others. casting an eye on protocols, data and results. In modeling the de- These EPP patients are the true heroes of Clinuvel's program, and

> SCENESSE® implants in 351 patients providing 43,740 patient days of treatment to photoprotect their skin.

Target Indications

Erythropoietic protoporphyria (EPP) is a rare metabolic disorder which causes acute phototoxicity – patients suffer severe burning attacks for several days following exposure to light. EPP patients have a defect in the haem biosynthesis pathway leading to an accumulation of the phototoxic chemical protoporphyrin IX (PPIX) in their skin and liver. When PPIX is exposed to light in the Soret band (visible blue light peaking at 408nm), it reacts, creating free radicals under the skin. For an EPP patient, this causes an intolerable burn and damage underneath the skin, which can take several days to heal. Patients liken an attack to having boiling water or searing hot needles under the skin. Traditional pain medicines – including opiates – provide no relief. EPP patients recognise their main symptomatic trigger, sunlight, and most alter their lifestyles by adulthood to avoid the exposure that causes an attack.



The SCENESSE® EPP program

Since 2006, Clinuvel has been trialing SCENESSE® (afamelanotide 16mg) in EPP patients to determine whether the activation of melanin in skin can provide a biological barrier, protecting EPP patients' skin from harmful wavelengths of light. In 2012 Clinuvel filed a marketing authorisation application (MAA) with the European Medicines Agency for EPP. Pending results from a US confirmatory Phase III study (CUV039), Clinuvel intends to file a new drug application (NDA) with the US FDA in the coming year.

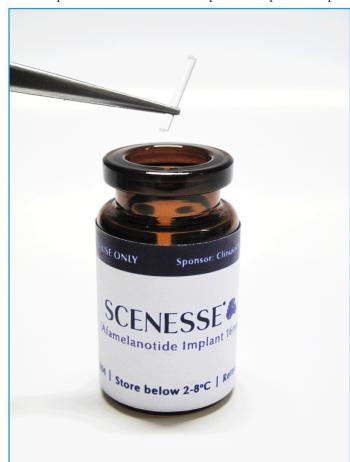
Phase II EU (CUV010)

Phase III EU/AU (CUV017)

Confirmatory program EU (CUV029)

Confirmatory program US (CUV030, CUV039)

19 expert treatment centres: (photo)dermatology, gastro-enterology, hematology, photobiology 351 EPP patients, 729 SCENESSE* implants, 709 placebo implants, 43,740 days of photoprotection



Compassionate use program

Due to the rarity of EPP, and the lack of effective treatments, a number of national regulatory authorities approved the use of SCENESSE* under compassionate circumstances, enabling Clinuvel to supply the drug at the conclusion of clinical trials.

8 expert treatment centres,

131 EPP patients, 620 SCENESSE* implants, 37,200 days of photoprotection

Early access programs

In 2010 the Italian regulatory authority (AIFA) allowed the prescription and reimbursement of SCENESSE* for EPP under law 648/96, recognising the need for EPP patients to have access to therapy. In 2012, Swiss authorities agreed to allow SCENESSE's use in EPP patients, with most insurance companies agreeing to reimburse the drug. A small number of patients from other European countries have also been able to access the drug through these programs, indicating high demand for the product, particularly in Spring and Summer.

>90 EPP patients, >400 SCENESSE* implants,

>24,000 days of photoprotection

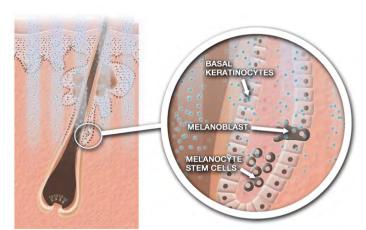
Safety profile - SCENESSE® in EPP

To date, no serious drug related safety issues have been identified with the use of SCENESSE* in EPP. Clinuvel, in co-operation of leading EPP experts, continues to closely monitor all EPP patients who receive the drug.

Vitiligo is a pigmentary skin disorder which causes the skin to lose colour in patches across the body. While its exact causes are unknown, it is believed that vitiligo is the result of an auto-immune disorder where the body's own immune system attacks and kills melanocytes, the cells responsible for producing pigment in the skin. It is estimated that at least 45 million people worldwide suffer from vitiligo. Many treatments have been proposed to halt the spread of vitiligo and repigment skin which has lost its colour and pigment, but, to date, none has proven totally effective and relapse of depigmentation is very common.

Right: depigmentation caused by vitiligo. Image taken prior to therapy in CUV102 study

Below: a cross-section of vitiliginous skin showing melanocyte stem cells in the 'niche' region of the hair follicle. It is believed that afamelanotide awakens and speeds up the process of stem cells migrating from the niche to the top layer of the skin activated by NB-UVB, thus repigmenting vitiligo lesions faster.





Using SCENESSE® to repigment skin in vitiligo

In 2010, Clinuvel announced that it would commence studies of SCENESSE* (afamelanotide 16mg) in vitiligo, using the drug as an adjunct to narrowband ultraviolet B (NB-UVB) phototherapy. NB-UVB works by stimulating melanocyte stem cells in hair follicles, encouraging their migration back to the skin as fully functioning melanocytes. To date, however, patients have been required to attend clinics 2-3 times weekly for up to 18 months before some satisfactory level of repigmentation was achieved. Relapse with NB-UVB therapy is also common.

It was believed that SCENESSE® would hasten repigmentation caused by NB-UVB, helping expedite the repigmentation process.

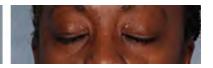
Clinical trials of SCENESSE® in vitiligo

A six month Phase IIa study of SCENESSE* used as an adjunct to NB-UVB in vitiligo was completed with treatment analyses and five-month follow-up results showing that the drug is safe, accelerates the repigmentation process and maintains the newly formed pigmentation. The results were most promising in darker skin types (Fitzpatrick IV-VI) where vitiliginous lesions are most prominent and the disease often has the greatest impact on patient quality of life.









Above: treatment results from Clinuvel's Phase IIa US study in vitiligo showing repigmentation following SCENESSE* and NB-UVB therapy. From left to right: baseline; day 35 after 15 NB-UVB sessions and 1 SCENESSE* implant; day 66 after 29 NB-UVB sessions and 2 implants; and day 171 after 62 NB-UVB sessions and 4 implants.

Vitiligo program expansion

Clinuvel now plans to conduct a Phase IIb vitiligo study in Singapore (CUV103), due to start in late 2013, where the drug will be tested in a larger number of patients in a proposed placebo controlled study. If successful, the Company expects that at least two Phase III multi-centre studies of the drug will be required for marketing applications to regulatory authorities.

Phase IIa EU/USA (CUV101/102) Phase IIb Singapore (CUV103) Phase III (1) EU/USA/Asia

Phase III (2) EU/USA/Asia

Above: the proposed clinical pathway for SCENESSE® in vitiligo.

The Melanocyte - The Primary Target Cell

Physiological regulation MC1R and (eu)melanin production

Melanin is the pigment which provides skin with colour and, in the correct circumstances, protection from radiation and light. Pigment production of the skin is a multistep process following distinct pathways whereby an early cellular 'choice' is made:

- either the cell produces the right pigmentation (eumelanin), initiated by correct and adequate binding of alpha-melanocyte stimulating hormone (alpha-MSH) to the melanocortin 1-receptor (MC1R), or
- the cell produces photoreactive and inferior quality of melanin (pheomelanin).

Biologically this process is activated by exposure to ultraviolet light as a protective, defensive response by the skin to repair UV damage and prevent further future damage.

Clinuvel's scientific teams have successfully simulated the biological process of "UV response" by developing a potent agonist of MC1R, which upregulates the melanin production by melanosomes, cell organelles, "the factory hall" of pigment production.

The main agonist afamelanotide binds for longer to the MC1R than the physiologic alpha-MSH. The drug is also connected for a longer period to the cell (dissociation) than the natural alpha-MSH. These two factors provide a better and more efficient photoprotective effect, activating the darker eumelanin.

Looking down the chain of cellular events, one of the key enzymes in this process is tyrosinase. This pathway eventually converges to regulate MITF levels, the master keyboard of the melanocyte function, and transcriptional activity, ultimately leading to increased expression of melanogenic enzymes and stimulation of eumelanin (the good pigment) synthesis.

The effectiveness of melanin to shield human skin from undesired radiation effects is well described. The standard measure of skin protection against light of various wavelengths is looking at absorption spectrum. Many chromophores have been tested, whereby eumelanin appears to be most effective in 300 to 700 band of wavelengths (figure 2).

Based on years of phototesting and photoprovocation in humans, we have understood the effectiveness of afamelanotide 16mg controlled-release implant formulation (SCENESSE*) as a therapy for a number of light related disorders. The choice to treat erythropoietic protoporphyria (EPP) is based on the need to treat patients, since an effective treatment is lacking. The scientific basis for treating EPP patients is found in the excitation spectrum of protoporphyrin IX (with a main peak at 408nm and excitement range up to 650nm), the main molecule causing the debilitating symptoms in EPP patients. The ability of eumelanin to absorb these wavelengths of light in skin makes EPP an obvious treatment target for SCENESSE*.

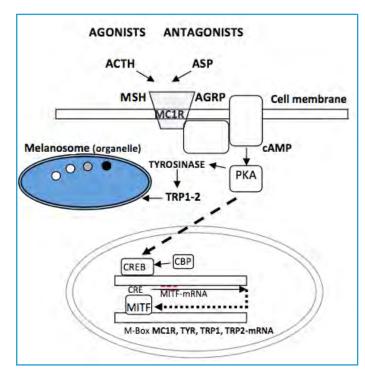


Figure 1: the melanin production pathway illustrated inside the melanocyte

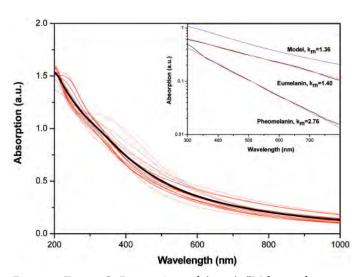


Figure 2: Zonios G. Dimou A. et al (2008). "Melanin absorption spectroscopy: new method for noninvasive skin investigation and melanoma detection". J Biomed Opt. 13(1). The broad spectrum of absorption up to the infrared wavelengths distinguishes epidermal melanin from most biological chromophores.

Academic and Press Coverage

Clinuvel Pharmaceuticals heads to market

Afamelanotide and Narrow-Band Ultraviolet B (NB-UVB) Light in the Treatment of Nonsegmental Vitiligo (NSV) (CUV102) (March 2013)





A review and update on melanocyte stimulating hormone therapy: afamelanotide. (J Drugs Dermatol., July 2013)

JAMA Dermatology

Ein Leben im Schatten (Tages Anzeiger February 2013)

Healthcare: Big pharma, big data

(Financial Times, April 2013)



Afamelanotide for the treatment of erythropoietic protoporphyria (informa healthcare, April 2013)







Wenn Licht wehtut

(Tages Anzeiger May 2013)

Clinuvel posts follow-up data from vitiligo trial (Life Scientist, September 2013)



A bioassay for the detection of neutralizing antibodies against the α-melanocyte stimulating hormone analog afamelanotide in patients with erythropoietic protoporphyria. (J Pharm Biomed Anal., March 2013)

The efficacy of afamelanotide and narrowband UV-B phototherapy for repigmentation of vitiligo.

Chair's Letter

programs. The success rate in the industry is no surprise to me. of the vitiligo program in Singapore towards the end of 2013. Many years ago when I joined the Board of Clinuvel's predecessor stark, with limited funding, limited resources, no or limited rev- Hank Agersborg. enue stream and shareprice driven by a speculative market based on an expectation of swift delivery by the company.

troducing a completely new untested chemical entity - is one for your continuing support. of years of sacrifice, hard slog, incredible attention to detail and elapsed time in meeting all the required stringent testing, therapeutic and safety standards.

Reality holds that less than 5% of New Chemical Entities which commence clinical development reach Phase II or Phase III trial status, let alone submission for marketing approval. Bringing afa- Stan McLiesh melanotide (SCENESSE*) to a point where it is now being considered for marketing approval by one of the two major authorities worldwide has been a herculean task, made all the more difficult by an initial therapeutic application in the treatment of erythropoietic protoporphyria (EPP) where therapeutic effectiveness is extremely difficult to confirm because of the nature of the condition and the self-protective measures patients have put in place to avoid severe symptoms.

Now, looking at the position Clinuvel is in, I oversee a Company which is on the verge of releasing a new promising drug, which moves through regulatory hurdles to obtain marketing approval and general re-imbursement.

Remarkably SCENESSE® has been approved for use in the treatment of EPP in two major European Markets over the past few years prior to a formal approval by the European Medicines Agency. All patients have continued on the program because of the significant improvement to their quality of life. At the time of writing, we also eagerly await results from our final US study, which – hopefully – will enable the drug's first filing in the USA.

More recently, the Company's decision to pursue research and development in vitiligo - a condition which leaves patients in a truly deplorable state - is showing what one can achieve when thoroughness and attention to detail are prioritised. Through significant advancement in research, we finally found a way to assist patients in regaining their pigmentation and colour. Surrounded by the global experts in the field, and leveraging the internal knowledge on stem cell differentiation, we received the first positive results from 60 patients in the trial CUV102. These results have received much acclaim among the academic circles, pressing the company to make the drug available in vitiligo. I remain

In my position as Chairman, I oversee the functioning of Board amazed by how much scientific demand exists for SCENESSE*, to and management, and remain in touch with multiple other bio- a point that our two programs seem to have become driven by the technology and pharmaceutical companies. Clinuvel is a talking clinical demand and necessity to serve unmet diseases. In my expepoint of the industry, as it attempts to succeed in an area where rience, the academic demand puts Clinuvel in a different position many, through sheer necessity, have been forced to abandon their to most other companies. We eagerly await the planned expansion

company, my colleague and former CEO of CSL Limited, Austra- Our small but dedicated clinical and regulatory management team lia's most successful pharmaceutical, intimated that I would find and staff continue to work assiduously towards our goal of first the world of biotechnology vastly different to the many years that marketing approval. They are capably led by our CEO Dr. Philippe I had spent in the mainstream of the pharmaceutical industry. He Wolgen and Dr. Dennis Wright who have also filled the void left proved certainly correct in that advice. The differences are quite by the loss of fellow Board member and Chief Scientific Officer Dr.

Once again I thank the Clinuvel Staff for their dedication in progressing SCENESSE® toward registration and eventual marketing Reality in the biotechnology industry - particularly if one is in- approval. To our resilient and dedicated shareholders my thanks

Managing Director's Report

Dear shareholders, patients,

our vitiligo (disorder of loss of pigmentation) research. Clinu- newly presented mode of action. vel's special access programs making SCENESSE® (afamelanotide and feedback remains consistently positive.

valuation, and with an eye to protecting the existing holders of place. Clinuvel's stock. In aiming to build a diversified share register, the Board looks to encourage a diversified share register to protect STRATEGY all investors from unexpected market conditions and shielding on FYE 2012, this was largely due to the decreased costs in final and resources for the European and US market.

Company has, over the years, been able to attract a unique mix of shareholders willing and able to support our long term strategy.

CLINUVEL'S OPERATIONS

ing some key findings in a new field of science, keeping in mind development beyond the research phase. that no other 'systemic' drug has been tested to treat generalised vitiligo in patients. We find ourselves surrounded by the world In SCENESSE's case, we obtained a reasonably accurate assessthese trials are designed in such a manner that maximum inforenthusiasm for this drug in North America.

REGULATORY PATHWAY

Together with our Board of Directors I look back on a success- Following eight years of R&D on SCENESSE* and a sole focus on ful financial year, whereby the capital raise in May 2013 of A\$6.3 proving the safety and benefit of the drug in patients, our teams million confirmed the interest in the Company and in our chosen await the final European regulatory (EMA) outcome. The lengthy specialty of photodermatology. The funding provided Clinuvel review takes into account the complexity of Clinuvel's dossier: a more time to focus on the regulatory review process and expand novel drug, a novel formulation, an untested indication, and a

16mg) available in Italy and Switzerland continue strongly with The process of obtaining marketing authorisation (MAA/NDA) in sales of A\$1.7M for the year. Entering the fifth financial year of Europe or the US is far from simple when it concerns previously supply in Italy, and third year in Switzerland, our teams are learn- untested, innovative products in relatively unknown diseases, such ing about the clinical use for the product and patients' yearly dease rythropoietic protoporphyria (EPP), and, in some respects, vitmand. Porphyria physicians play a pivotal role in the prescription iligo. Despite the lengthy European review our teams are confident that Clinuvel will launch its groundbreaking product in Europe. This confidence stems from the genuine clinical demand for the Clinuvel's decision to proceed with an issuance of 11% of its out-product by physicians, experts in their field, and patients worldstanding capital raised at 4.3% premium to 20 day VWAP befits wide. In essence it is this demand and annual testimonies of effecthe objective of minimising dilution at a relatively low enterprise tiveness which have driven Clinuvel's advanced trials in the first

all from unforeseen redemptions and selling of stock. While an- The excitement of developing SCENESSE* is nearing a zenith, and nual losses have been curbed to A\$6.803 million, a 30% decrease while we managed a program of uncertainty, the majority of identified risks have been solved and answered. In disruptive technoloproduct development as we have maintained our regulatory focus gy lies the risk of not knowing what lies ahead, not having certainty about the long term effects on human health, and not being able to initially assess the demand for the product or anticipate pro-Given the innovative development program, a number of in- fessional reaction from the medical community. At the end of a ternational institutions are monitoring Clinuvel's advancement. pharmaceutical development cycle, companies are entirely at the Our eventual success will indicate a landmark in pharmaceutical mercy of physicians and a positive academic opinion to prescribe development: the first medicinal photoprotective drug in a spe- a product. Drilling down to the heart of the matter, prescription cialised segment of dermatology. It is of little surprise that the of a new product is a process which requires an instantaneous decision from a physician to provide medical remedy during a faceto-face consultation with a patient. These decisions seal the fate of a product, and the physician's choice for a product - crucial to value creation for any pharmaceutical company – rightfully occurs behind closed doors. In other words, the administration of a novel The recent addition of a Singapore office is the first step to give product is not only dictated by patients' clinical demand and need Clinuvel access to the Asian market. We believe that SCENESSE* or the availability of alternatives to treat the disease. It is foremost will benefit select groups of patients prevalent in Asia. Our next the decision taken by a physician to prescribe or not. I view this vitiligo trial (CUV103) is being finalised and will commence in process of particular importance since the experts' use of a product Singapore before the end of 2013. Following the indicative results needs to be one free of conflicts of interests and free of commercial found in the US Phase IIa trial (CUV102), the clinical response interests. We have spent much time subjecting SCENESSE® to the from patients, and feedback from the leading academics in vitili- litmus test, assessing whether the product would actually have a go, we will further evaluate SCENESSE* in darker skinned vitiligo place in the market and armamentarium of EPP specialists, and patients. In this domain we are innovating once again and adopt- this evaluation dictated our decision to continue the commercial

experts in the field of dermatology and other specialties to ensure ment of the professional willingness to prescribe the drug on various continents. Additional data came from our compassionmation can be expected from testing patients. I am very pleased ate programs when we supplied the drug free of charge following that the US FDA and American academics have been very sup- completion of the clinical trials. From 2010 onwards we started to portive of the initiative to treat vitiligo, and we anticipate much grasp the repetitive demand expressed by patients and physicians during the special access programs in Italy and Switzerland. In both countries Clinuvel has commercially supplied SCENESSE®,

in Europe and the US.

the main development process, in our case our work on afamela- evolving world, patents and physicians will have the final word. notide 16mg controlled-release formulation. Clinuvel's Board has opposed the use of long term debt or notes to finance its R&D and stuck to the mantra of equity funding. I ultimately stand by our collective conservative approach and believe that Clinuvel would not have progressed to this stage if our teams had taken on more.

CLINUVEL'S OUTLOOK

Drug development is a process which one experiences intensely on a daily basis, and from a distance it is difficult to comprehend the uncertainties and risk factors. After two decades, I have reduced the process to a simplicity which bears relevance to the Philippe Wolgen capital markets.

Adhering to the benefit versus risk assessment of new drugs, a development team continuously evaluates the risk of making a treatment available to patients. This risk defines the long term utility of the medical technology, the willingness of academics and expert physicians to prescribe the treatment, and the acceptance by patients. Even after trials, risk continues to be assessed through so called 'risk mitigation plans' and pharmacosurveillance measures. At any given time, one can reassess that a treatment is not warranted to patients as the health risk is being reassessed of being too high. In so many words, the health risk is captured in safety, or simpler terms short-, mid- and long-term "side effects". In my view a drug's safety is the single most important factor in contemporary drug development, and attention and concern to safety overshadows any public board's decision to be taken.

On the other hand one routinely monitors the effectiveness or medical usefulness of a newly introduced treatment; this benefit needs to be clinically significant, to impact patients' health and wellbeing positively and, preferably nowadays, to have a positive effect on the "quality of life" of patients, expressed as patients reported outcomes. In some instances, a medication's effect provides a better existence and enables patients to engage in normal activities; this is applicable to SCENESSE® in EPP.

In a scientific review by regulators - let's speak about EMA and FDA specifically in this context – a newly developed drug (NME) is assessed on this axis of "benefit versus risk". The global regulators have the task of coming to an objective assessment of safety versus clinical significant effectiveness. How they arrive at this assessment is partially dictated by the quality of a scientific dossier, the intentions of the scientific team developing the drug, the ability to compare the science presented academically against agency precedents and, preferably, physicians and patients' input. In Clinuvel's case, the EMA's regulatory review is ongoing.

Naturally, the benefit-risk axis is of clinical and commercial significance. My experience, however, has taught me one essential lesson in contemporary pharmaceuticals: one may recover in time from lack of evidence on efficacy, but one may never recover from lack of compelling evidence on drug's safety.

and from the data of approximately 150 EPP patients on active I believe after closely reviewing two decades of data on the clinidrug we now have a solid understanding of the utility of SCE- cal use of afamelanotide in various chemical processes, numerous NESSE*. These market data are incorporated in our business plan, formulations, alternate doses, different regimens in non-human and form the basis of our continuous development of SCENESSE* models, healthy volunteers and patients with co-morbidity (sickness), immunosuppression and immunocompetence that we have arrived at a safe drug for clinical use. This removes one important From a business perspective, one always weighs up the pros of component and concern out of the dichotomous regulatory assessdiversifying a company's portfolio against the cons of sticking to ment. Clinical efficacy is the one remaining and, in this modern





Financials Content

Directors' Report (including Remuneration Report)					
Remuneration Report	18				
Corporate Governance Statement	28				
Consolidated Statement of Profit or Loss and Other Comprehensive Income	33				
Consolidated Statement of Financial Position	34				
Consolidated Statement of Cash Flows	35				
Consolidated Statement of Changes in Equity	36				
Notes To The Financial Statements	37				
Directors' Declaration	61				
Independent Auditor's Report	62				
Auditor's Independence Declaration	65				

Directors' Report

The Directors of the Board present their report on the Com-June 2013 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.

- Mr. S.R. McLiesh (Non-Executive Chair)
- Dr. P.J. Wolgen (Managing Director, Chief Executive Officer)
- Dr. H.P.K. Agersborg (Deputy Chair, Chief Scientific Officer – ceased Directorship 26 September 2012)
- Mrs. B.M. Shanahan (Non-Executive)
- Mr. L.J. Wood (Non-Executive)
- Mr E. Ishag (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

Mr. Stanley R. McLiesh (joined Board 2002)

Non-Executive Chair

Member of the Remuneration and Nomination Committee.

Member of the Audit and Risk Committee

Qualifications: BEd Shares in Clinuvel: 76,000

Conditional Performance Rights over shares in Clinuvel: 80,000

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. Mc-Liesh is involved in formulating the commercial phase of Clinuvel.

Dr. Philippe J. Wolgen (joined Board 2005)

Managing Director and Chief Executive Officer since December

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

Qualifications: MBA, MD Shares in Clinuvel: 577,334

Conditional Performance Rights to shares: 391,666

Having been recognised for his strategic mindset and metic-

ulous business execution, Dr. Wolgen has brought to the Company his international finance experience and professional contacts to European capital markets. As a former equity analyst, his in-depth analysis and expertise of the life science sector has pany and its controlled entities for the financial year ended 30 been an asset to Clinuvel. He held positions in private pharmaceutical companies in Europe, as MD of two medical centres in the UK and Israel, and consulted medical device companies. He has been instrumental in raising \$79 million since 2006 for the funding of the current development program of SCENESSE*.

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

Dr. Helmer P.K. Agersborg (to 26 September 2012)

Executive Director, Chief Scientific Officer from December 2005 to September 2012

Member of the Remuneration and Nomination Committee (to September 2012)

Qualifications: BSc PhD Shares in Clinuvel: 242,111

Conditional Performance Rights to shares: 57,500

Dr Agersborg was a 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 $were \, approved \, outside \, the \, US \, and \, in numerable \, INDs \, were \, accepted.$

Dr. Agersborg contributed 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 served as Chief Scientific Officer. His experience as a toxicologist and understanding of regulatory requirements was fundamental in the repositioning of the Company.

Mrs. Brenda M. Shanahan (joined Board 2007)

Non-Executive Director

Chair of the Audit and Risk Committee Qualifications: BComm, FAICD, ASIA

Shares in Clinuvel: 42,007

Conditional Performance Rights over shares in Clinuvel: 50,000

Mrs. Shanahan has a longstanding background in finance in Australian and overseas' economies and share markets and is a Fellow of the Institute of Directors. She is currently Chair of St Vincent's Medical Research Institute in Melbourne, and is a serving Non-Executive Director of Challenger Limited (ASX:CGF) since 2011 and Bell Financial Group (ASX:BFG) since 2012. Mrs Shanahan is also a Non-Executive Director of DMP Asset Management and a Director of the not-for-profit Kimberley Foundation Australia. Mrs. Shanahan is the former 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. Mrs. Shanahan was Non-Executive Chair of the Clinuvel Board from late 2007 until July 2010.

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

Non-Executive Director

Chair of the Remuneration and Nomination Committee

Qualifications: BComm Shares in Clinuvel: 100,000

Options over shares in Clinuvel: 35,000

Conditional Performance Rights over shares in Clinuvel: 50,000

Mr. Wood has an extensive background in international marketing and manufacture of pharmaceutical products. He has lived in Germany, England, Australia, USA and Canada and overseen pharmaceutical operations throughout Europe, Asia and North America. He is 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 Chairman of EnGene Corporation, director of QLT Inc. (until 2011), and also Executive Vice President CSL Limited Australia, where he coordinated the company's worldwide expansion in the plasma products industry. President and CEO Exogene corporation, Senior Vice President BioResponse Corporation both biotechnology companies sold to Baxter Healthcare Corporation. Mr. Wood was also formerly Vice President Bayer Corporation Pharmaceutical division responsible for operations in Europe and Japan. Mr Wood spent over seventeen years with Baxter Healthcare Corporation holding a series of operating and general management positions in North America, Europe, Asia and Australia.

Mr Elie Ishag (joined Board 2011)

Non-Executive Director Shares in Clinuvel: 72,733

Conditional Performance Rights over shares in Clinuvel: 50,000

Mr. Ishag is a London based entrepreneur with over 40 years commercial experience. With a background in pharmaceutical chemistry, Mr. Ishag is active in European asset management, real estate development and IT. Mr. Ishag is currently the Chairman of European Investments & Developments Ltd, a privately held company with an investment mandate in defined asset classes, property development and cross-border commercial real estate. Mr. Ishag has been extensively involved in the commercial evolution and backing of various successful ventures including IT company Espotting Media.

Information On Company Secretary

Mr. Darren M. Keamy

Company Secretary, Chief Financial Officer Qualifications: BComm, CPA

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

Meeting of Directors

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

				U	U	/
Director	Boar	ď	Audit & Risk (Committee	Remuneration & Nom	ination Committee
	A	В	A	В	A	В
Dr. H.P.K. Agersborg	2	2	-	-	2	2
Mrs. B.M. Shanahan	6	6	2	2	-	-
Mr. S.R. McLiesh	6	6	2	2	4	4
Dr. P.J. Wolgen	6	6	2	-	4	3
Mr. L. J. Wood	6	5	-	-	4	4
Mr. E. Ishag	6	6	-	-	-	-

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

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 SCE-NESSE® (afamelanotide) for the treatment of a range of severe skin disorders. Clinuvel's pioneering work aims at preventing the No dividends were paid or declared during the financial year or symptoms of skin diseases related to the exposure to harmful UV radiation along with the need to repigment skin. There was no

significant change in the nature of activities during the financial year.

Dividends Paid Or Recommended

after reporting date

Review Of Operations

The consolidated entity's main strategic focus throughout the year was working through the European Medicine Agency's (EMA's) regulatory review process on its' submission to approve SCENESSE* for marketing authorisation. The R&D program in vitiligo and further melanocortin development continued at a lower intensity whilst all personnel focussed on the various aspects of the regulatory dossier during the ongoing review process.

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

7	O		
Consolidated	2013	2012	Change
	\$	\$	%
Revenues	1,963,462	1,294,041	52%
Net Loss before income tax expense	(6,802,823)	(9,767,228)	30%
Loss after income tax expense	(6,802,823)	(9,767,228)	30%
Basic earnings per share - cents per share	(19.3)	(31.8)	39%
Net tangible assets backing per ordinary share	\$0.36	\$0.39	(7%)
Dividends	Nil	Nil	Nil

Note: Clinuvel does not operate individual segments.

cial year, a decrease in the loss of 30%.

more at risk to exposure to light and UV.

The group result for the year ending 30 June 2013 was a \$6.803 sets at 30 June 2013 compared to \$13.637 million at 30 June 2012. million loss, compared to a \$9.767 million loss for the prior finan- Current liabilities decreased 17% to \$1.946 million. Monthly average cash spend was \$0.785 million for the year compared to \$0.971 million for the 2011/2012 year.

The distribution of SCENESSE* continued in Italy and Switzer- Excluding the government research and development (R&D) reland where reimbursement is received for the supply of the drug fundable tax incentives, R&D accounted for 46% of the group's toto provide a preventative treatment for the rare disease eryth- tal expense result for 2012/13, compared to 49% for the 2011/12 ropoietic protoporphyria (EPP). Patients with sales reimburse- year. R&D expenditures, comprising clinical study costs, drug dements increased 115% to \$1.553 million for the 2012/13 year livery research and manufacture, toxicity studies, regulatory fees compared to \$0.723 million for the 2011/12 year. In the weeks and research and development-specific overheads such as perfollowing 30 June 2013, orders were received for an additional 49 sonnel, were \$4.490 million in 2013 compared to \$5.389 million implants that will be reported in the 2013/14 financial year, indi- in 2012. The government refundable tax incentive gain of \$0.937 cating further patient demand to receive SCENESSE® deep into million is a result of the Australian government implementing a the summer in the northern hemisphere. Orders for SCENESSE* broad-based, market driven program allowing eligible R&D entitend to increase prior to spring and prior to patients becoming ties to receive a refundable 45% tax offset on certain qualifying R&D expenditures if their aggregate turnover is less than \$20 million per annum. The scheme replaced the R&D tax concession for The group comprises a balance sheet of \$13.839 million in net as-years of income beginning 1 July 2011. The 2012/13 result for the years.

the EMA regulatory review. The majority of clinical development at the same period last year. expenses in 2012/13 relate to the Phase III EPP study in the USA in 2012 to \$0.913 million in 2013, a 7% improvement. The costs ordinary shares. of replenishing implant supplies for the ongoing clinical trials and access schemes in Italy and Switzerland, along with ongoing Whilst the pace of advancement in the group's clinical and reguin 2011/12 year prior to submitting the scientific dossier to the 2012/13. These events include: EMA for marketing review.

The internal replacement of the Chief Scientific Officer, along with a minor reduction in head count of R&D personnel employed to oversee and monitor the clinical, regulatory and manufacturing programs resulted in a 19% improvement in R&D overhead costs (from \$2.102 million in 2012 to \$1.694 million in 2013). Toxicity study costs and regulatory affairs related fees also decreased year on year, from \$0.497 million in 2012 to \$0.468 million in 2013, a 6% reduction year-on-year. Various non-clinical analyses and external regulatory affairs advice was at a slightly lower rate of activity through the ongoing regulatory review in the 2012/13 year compared to the period leading up to the commencement of review in February 2012.

Marketing activities in the Company decreased by \$0.203 million to \$0.603 million in 2013 (25% decrease) primarily due to the reduction in use of external website development and global public relations consultants previously engaged to assist various communications, media and marketing strategies. The result from general operations was \$4.516 million in 2013 compared to \$4.657 million in 2012, a 3% decrease. Excluding the first-time benefit in the 2012/13 year of the R&D tax incentive, general operations comprised 47% of the group's total expense result for 2013 compared to 42% in 2012. There was a reduction of \$0.947 million from 2012 in the values of conditional performance rights granted to staff and directors but this was partially offset by increases to administrative and managerial personnel costs, overseas travel and general legal fees. For 2013, a gain of \$0.216 million has been recorded in revaluing financial assets held at fair value compared to a gain of \$0.164 million for the same period last year. The gain reflects the improvement in values of income securities investments held during the course of the 2012/13 year. In contrast, the liquidation of certain income securities has shown a loss of \$0.203 million (2012:\$ 0.233 million). As at 30 June 2013, the consolidated entity no longer holds income securities.

Interest received on cash and financial assets held decreased by 28% from \$0.571 million in 2012 to \$0.410 million in 2013. Whilst average cash balance holdings were reasonably comparable year-on-year, the drop in interest revenues is a result of the gradual decline in term deposit interest rates offered by banks and consequent to the Australian government reducing its cash rates during 2012/13.

For the 2012/13 year the group started with \$13.173 million in

consolidated entity includes the 2011/12 and 2012/13 income tax cash and financial assets and finished with \$12.569 million. In May 2013 the group raised \$6.37 million in additional capital. For the reporting date of 30 June 2013, due to a depreciating Australian Clinical study costs improved 22% from \$1.811 million in 2012 to dollar, the consolidated entity reported a gain of \$0.059 million \$1.414 million in 2013. The improvement reflects the late stage of from holding foreign currencies and in holding trade creditors in the consolidated entity's clinical program in EPP and its focus on non-Australian currency. This compares to a loss of \$0.026 million

(CUV039) and the Phase II clinical studies in vitiligo (CUV101 At 30 June 2013 basic earnings per share were -\$0.193 on and CUV102). Continuing the trend in recent years, expenses to- 38,217,038 issued ordinary shares. This is compared to basic earnwards the drug delivery program improved, from \$0.979 million ings per share of -\$0.318 as at 30 June 2012 on 34,651,874 issued

costs toward the development of the manufacturing processes, latory activities to commercialise SCENESSE® was greater in prewas less than the expenses incurred in the process improvement ceding years due to the focus on the EMA's regulatory review of and qualification of implant manufacturing program completed the drug in EPP, there were still a number of significant events in

- Confirmation was received during the EMA's continuing review of the marketing authorisation application (MAA) dossier that no major safety concerns regarding the use of SCE-NESSE® in EPP have been identified by either the Company or the Agency.
- The announcement of Dr. Dennis Wright to assume the role of Acting Chief Scientific Officer (CSO) after the untimely passing of the incumbent CSO, Dr. Helmer Agersborg, in September 2012.
- The announcement that preliminary observations from the consolidated entity's open label Phase IIa US pilot trial of SCENESSE® in four patients with vitiligo (CUV102) have been published in the international journal Archives of Dermatology. The authors concluded that the use of SCENESSE® as a combination therapy with narrowband ultraviolet B (NB-UVB) phototherapy appears to accelerate and achieve repigmentation in vitiligo, and that analyses of the entire study is needed to draw further conclusions.
- The preceding highlight was followed by an announcement in December 2012 of the successful, significant results from the US Phase IIa pilot study (CUV102) of SCENESSE® in the common pigmentation disorder vitiligo. The study showed that SCENESSE®, in combination with NB-UVB phototherapy, achieves better, faster repigmentation in vitiligo patients. The primary study objective was achieved in the extent of repigmentation in the SCENESSE® and NB-UVB combination was significantly greater than observed in patients who were administered NB-UVB without SCENESSE®. Patients with darker skin types responded best to the SCENESSE® combination treatment, the time to first repigmentation showed a strong favourable trend towards SCENESSE® treatment and no significant safety issues were reported.
- It was announced in February 2013 that the EMA successfully completed an audit of the manufacturing facilities for SCE-NESSE*, finding that the plant is compliant with current Good Manufacturing Practice (cGMP) regulations.

- Results and clinical observations from the Phase IIa study of SCENESSE® in vitiligo (CUV102) were presented at the Vitiligo Working Group meeting, accompanying the American Academy of Dermatology (AAD) meeting in Miami in March 2013. An abstract featuring the CUV102 study was also presented to the AAD Residents and Fellows Symposium at the main AAD meeting. Experiences of the use of SCENESSE® as a photoprotective in the rare disease EPP in Italy were also discussed at the San Gallicano Conference on rare diseases, where the presentation focussed on patient experiences with the drug in both clinical trials and in special access use in Italy.
- In May 2013, it was announced a capital raise of \$6.37 million via a private placement to international institutional and professional investors at a 4.3% premium to the 20 day volume weighted average price on April 29 2013 and 15.1% to the closing price on April 30 2013. The funds raised in the placement is to be used for an expanded global clinical trial program with SCENESSE* in patients with vitiligo, to support a filing for a New Drug Application for SCENESSE* with the US FDA, and to cover operating and commercialisation costs while the Company awaits a decision from the EMA on its application for marketing authorisation (MAA) for the orphan indication EPP.

Looking forward, in the coming months it is expected the results of the USA Phase III study in EPP (CUV039), data on the Phase II trial in actinic keratosis (CUV011) and commencement of a Phase IIb study in vitiligo (CUV103) will be announced. Securing a positive outcome to the EMA's review of the consolidated entity's scientific dossier into SCENESSE® in EPP is its key strategic objective as this will largely determine its' right to commercially market SCENESSE®. If successful, the consolidated entity will seek full or partial reimbursement from national insurers, payors and reimbursement agencies within the European Union to ensure that SCENESSE® can be distributed free of charge or as part of co-payment schemes to patients diagnosed with EPP.

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 the consolidated entity.

Significant Events After The Balance Date

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

Likely Developments And Expected Results

Information on likely developments and expected results of the research and development is included in the section titled Review of Operations to the extent it does not prejudice the interests of the consolidated entity.

Environmental Regulation And Performance

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

• Results and clinical observations from the Phase IIa study of **Indemnification And Insurance Of Directors And** SCENESSE* in vitiligo (CUV102) were presented at the Vit- **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 for 12 months was \$48,630 (2012: \$48,730).

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 are included in Note 20 to the financial statements.

Remuneration Report

Principle Objective

The Board's strategic objective that underpins its remuneration policy is to retain the Company's industry knowledge in relation to the development of SCENESSE® at a critical and pivotal stage of its development. The Board is aware that any disruption to the professional talent input would have a detrimental effect to the progress made in the EMA's review of Clinuvel's marketing authorisation application (MAA) in an environment where Clinuvel is the only pharmaceutical company active in this field of expertise. The Board wishes to secure staff and management critical to the development of a medicinal photoprotective drug.

Principles Used To Determine The Nature And Amount Of Remuneration

This Remuneration Policy has been adopted by the Board of the Company, to ensure that:

- The Company's remuneration policies and systems comply with the Corporations Act and ASX Listing Rules and support the Company's objectives as set by the Board from time to time.
- Remuneration of the Company's key management personnel is aligned to the interests of the Company and its shareholders within an appropriate control framework.
- The relationship between performance and remuneration of key management personnel is clear and transparent.
- The role of the Company's Remuneration and Nomination Committee in the remuneration processes of the Company is clearly defined.

For the purpose of this Policy, "key management personnel" has the meaning given in the ASX Listing Rules (which adopts the definition in Accounting Standard AASB 124, Related Party Disclosure). The definition catches those persons having authority and responsibility for planning, directing and controlling the activities of the Company, directly or indirectly, including any Director (whether Executive or otherwise) of the Company.

Therefore this Policy covers the overall structure of remuneration for:

- (a) The Managing Director and any other Executive Directors.
- (b) Non-Executive Directors, including the Company Chair.
- (c) Senior management.

This Policy does not cover people employed through another company such as third party contractors and secondees.

Remuneration Policy

The objectives of the Company's Remuneration Policy are to ensure that:

- (a) Remuneration is structured to align with the Company's interests, taking account of the Company's strategies and risks.
- (b) The level and composition of remuneration is reasonable,

- sufficient and provides competitive rewards that attract, retain and motivate people of high calibre to work towards the longterm growth and success of the Company.
- (c) The role that total fixed remuneration and short- and long-term incentives play is clearly defined.
- (d) The levels and structure of remuneration are bench marked against relevant peers.
- (e) There is a clear relationship between Company and individual performance and remuneration of key management personnel.
- (f) The principles underlying the Company's remuneration structure are openly communicated and understood.
- (g) The Company complies with applicable legal requirements and appropriate standards of governance.
- (h) Remuneration policies and practices are evaluated over time, taking account of pay outcomes and the relationship between pay and performance, and the results of any evaluations or review processes.
- (i) Remuneration is consistent regardless of gender.

There exist amongst the Managing Director and other key management personnel at least 42 collective years of industry knowledge and 38 collective years of tertiary level and specialist academic knowledge.

The Board is of the view that the current equity allocation to key Executives, when compared to the marketplace, has been lower than could be expected at this advanced stage of drug development, that key Executives have demonstrated long term loyalty and over time have absorbed extra workload as staffing levels have declined.

The total remuneration for each Executive is aimed to be market competitive in which the executive is placed, and to reflect performance and specific competencies.

The Company's reward framework provides a mix of fixed and variable pay, structured to incentivise short-term and long-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 theCompany). Performance Rights are issued under theCompany's Conditional Rights Plan approved by shareholders 18 November 2009 and is currently available to Executives and Directors, subject to shareholder approval. The vesting conditions can be either time and/or performance milestone-based. The Conditional Rights Plan was instituted to replace a former Share Option Plan, approved by shareholders 25 January 2007.

Remuneration And Nomination Committee

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, Executives and key management. The Remuneration and Nomination Committee obtains independent data to assess the appropriateness of remuneration packages, given trends in comparative companies, industry or related field of expertise. The Remuneration and Nomination Committee may consult with specialist remuneration consultants with experience in the healthcare industry as part of making and reviewing remuneration recommendations. For the year ended 30 June 2013, remuneration consultants.

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 inclusive of superannuation. The Chair receives \$80,000 per annum inclusive of superannuation 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 Risk and the Remuneration and Nomination Committees receive \$65,000 per annum inclusive of superannuation when in a Non-Executive capacity. Directors' fees are considered appropriate given their skills, qualifications and experience comparative to the external market.

Subject to shareholder approval, Non-Executive Directors can be issued performance rights under the Company's Conditional Rights Plan. Non-Executive Directors can be issued performance rights 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 performance rights and nature of vesting is determined after the Director's appointment. One Non-Executive Director holds unlisted share options which were previously issued under the Company's Share Option Plan and are unexpired. This Plan is no longer used.

There are no further retirement benefits, other than statutory superannuation entitlements, offered to Non-Executive Directors. From July 1 2012, as a means to restrict Company cash flow it was agreed for all Non-Executive Directors to defer their Director fees for a period of six months. At the end of the six months all outstanding Non-Executive Director's fees were paid and there were no extension to the deferral of Non-Executive Director fee payments.

Executive Remuneration

Remuneration packages for Executives may include:

- Base pay and benefits (including statutory benefits);
- pre-specified performance-based targets;
- •Longer-term business generation incentive payments through the achievement of pre-specified performance-based targets;

- Discretionary payments for exceptional performance, innovation and/or expansion;
- · Long-term equity participation in Clinuvel's Conditional Rights Plan.

Base pay, including superannuation, is reviewed annually by the Remuneration and Nomination Committee to ensure the Execuno remuneration recommendations were received from specialist tive's pay is competitive in international markets, industry and related fields of expertise. There are no guaranteed base pay increases in any key manager's contracts. Health insurance, accommodation benefits and living away from home allowances are offered to key management and Executives under specific circumstances.

> The Managing Director has individual short-term and longer-term incentive components to his Executive remuneration. Longer term incentive components include business generation incentives, discretionary payments and equity participation through Clinuvel's Conditional Rights Plan. Appropriate targets are set by the Remuneration and Nomination Committee. The targets can relate to either the clinical, regulatory development program or to corporate, commercial and associated activities and are generally, but not always, evaluated for achievement, reviewed and reset (if required) annually. Generally, but not always, the quantifying of achievement of the Managing Director's short-term incentives for payment is assessed and made in the year following the year of achievement.

> For the financial year 2012/13 it was decided by the Remuneration and Nomination Committee upon renewal of the Managing Director's service agreement to evaluate and award the Managing Director's short-term incentive component on or around 30 June 2013 to bring the assessment and payment of incentives to current year. It was also agreed to no longer defer 100% of the short-term incentive payment that may be owed to the Managing Director, as disclosed in the 2012 Annual Report. The remuneration for the Managing Director for the 2012/13 year includes consideration for short term unpaid incentives relating to previous financial years.

> In the most recent Annual General Meeting (AGM), the Company obtained 93.78% of the proxy votes (including votes at the Chair's discretion) in favour of adopting the 2012 Remuneration Report, and this resolution was passed on a show of hands at the meeting. The Company did not receive any further feedback at the AGM on its remuneration practices.

> 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 long-term equity remuneration is provided to Executive Directors and certain employees via the Clinuvel Conditional Rights Plan. See page 19 for further information.

Company Performance And Executive Director Remuneration

• Short-term incentive payments through the achievement of Due to the inherent and specific risk in pharmaceutical development whereby the risks are exacerbated by the Company focusing on a novel, first-in-class drug, the Board has adopted a business model where most operational tasks are being retained in-house where possible, and most management responsibilities concentrated between the Managing Director (acting in a dual capacity as Chief Executive Officer and Chief Medical Officer) and the Acting Chief Scientific Officer. The Managing Director has the responsibility of guiding and overseeing the execution of global corporate strategy and has global responsibility for the safety aspects of the drug and pharmacovigilance. The Acting Chief Scientific Officer is responsible for pre-clinical programs and toxicology, the manufacturing of the drug delivery program, clinical program and setting the regulatory strategies in close coordination with Board of Directors. The Managing Director serves on the Commercial Management Committee, set up to oversee the best commercial options for SCENESSE®. As the business evolves and progresses through its development path, it is expected this centralised management model will also evolve and key management responsibilities will be shared across new and existing senior management.

The current Managing Director Remuneration structure is designed to maximise the motivation and incentivisation of the Managing Director to advance the Company's program to its current stage of development, taking into account the complexity of the current development and business model. It is also designed Share-Based Remuneration to reflect the expertise, qualifications, seniority and achievements The consolidated entity has an ownership based scheme for Di-2005.

From July 1 2012, as a means to restrict Company cash flow during the period of time needed for the EMA to evaluate the Conditional Performance Rights dossier to approve the marketing of SCENESSE® in Europe, it was payment that may be owed during this period (with their con-2012 it was agreed to pay all base salary owed to the Chief Scienmonth period.

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 Managing Director is formalised by a service agreement determined by the Remuneration and Nomination Committee. The agreement provide for base salary, short- and long-term bonuses, other benefits and participation, when eligible, in the Clinuvel Conditional Rights 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 Conditional Rights Plan.

The details of the service agreements to the Managing Director and key management personnel are:

• Dr. Wolgen's (Managing Director and Chief Executive Officer) term of employment is 3 years from 15 March 2013, his base salary exclusive of retirement benefits for the year to 30 June 2013 is \$736,971 and his service agreement is with the

wholly-owned Swiss subsidiary entity. Termination payment is set at 12 months of base salary provided the termination is not for a material breach of the agreement. The base salary is CPI indexed. Dr. Wolgen is required to provide 12 month's notice.

- Dr. Wright's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2013 is \$223,563. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Dr. Wright is required to provide 3 month's
- Mr. Keamy's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2013 is \$185,727. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Mr. Keamy is required to provide 3 month's

to date of the Managing Director since joining the Company in rectors, key management personnel and select consultants of the Company and is designed to provide long-term incentives for Directors and Executives to deliver long-term shareholder value.

All performance rights issued fall under the Clinuvel Conditional agreed in the July 2012 Directors' meeting for the Chief Scientific Rights Plan, available to eligible employees of the Company. Any Officer to defer 50% of his base salary for up to six months and for issue of rights to Executive and Non-Executive Directors requires the Managing Director to defer 100% of any short-term incentive shareholder approval in accordance with ASX Listing Rules. All rights convert to one ordinary share of the consolidated entity, are sent). Upon the death of the Chief Scientific Officer in September issued for nil consideration, have no voting rights, are non-transferable and are not listed on the ASX. They can be converted to tific Officer. At the end of the six months the short term incentive ordinary shares at any time once the vesting conditions attached agreed as owing to the Chief Executive Officer was paid. There to the rights have been achieved, whereby they will be held by a was no extension to the arrangement to defer short term incen- Scheme Trustee on behalf of the eligible employee for up to 7 years. tive payments to the Chief Executive Officer at the end of the six 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 if 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.

Share Options

At 30 June 2013, only one Non-Executive Director (Mr. Jack Wood) holds unlisted share options which were previously issued under the Company's Share Option Plan and remain unexpired. This Plan is no longer used. The unlisted share options held by Mr. Wood expire 18 November 2013.

These share options were previously issued under the Clinuvel Employee Share Option Plan, approved by shareholders at a shareholder meeting on 25 January 2007. These share options convert to one ordinary share of the consolidated entity, were issued for nil consideration, have no voting rights attached to the option and 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 exercise price was 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 was subject to approval by the Remuneration and Nomination Committee and (with respect to Directors) by shareholders at previous General Meetings. Options currently issued and unexpired at 30 June 30 2013 are fully vested. No options lapsed during the year. The Company does not intend to issue further share options under this Plan.

Details Of Remuneration

Key management personnel includes all Directors (including Non-Executive) and the following other key management personnel who together have the authority and responsibility for planning, directing and controlling the activities of the Group:

<u>Dr. D.J. Wright</u> Acting Chief Scientific Officer

Mr. D.M. Keamy
Chief Financial Officer and Company Secretary

Remuneration Of The Directors Of The Company For The Year Ended 30 June 2013

	Short-term	employment	benefits		Post em- ployment benefits	ployment (Accounting Charge Only)		
Director	Gross Salary	Short Term Incentive ⁶ Related to Current Period	Short Term Incentive ⁵ Related to Prior Periods	Other ¹	Superan- nuation/ Pension Fund	Performance Rights ³	Options ⁴	Total
	\$	\$	\$	\$	\$	\$	\$	\$
Dr. H.P.K. Agersborg	72,215	-	-	-	-	19,683	-	91,898
Mr. S.R. McLiesh	73,395	-	-	-	6,605	23,898	-	103,898
Dr. P.J. Wolgen	736,971	337,841	455,398	98,649	7,229	89,160	-	1,725,248
Mrs. B.M. Shanahan	59,633	-	-	-	5,367	14,936	-	79,936
Mr. L. J. Wood	65,000	-	-	-	-	14,936	3,364	83,300
Mr. E. Ishag	50,000	-	-	-	-	14,936	-	64,936
Total	1,057,214	337,841	455,398	98,649	19,201	177,549	3,364	2,149,216

¹ 'Other' includes health insurance, accommodation and other allowances that may be subject to fringe benefits tax to facilitate relocation to the European office.

Remuneration of the Other Key Management Personnel of the Company for the Year Ended 30 June 2013

	Short-term employment benefits			Post employ- ment benefits	Share based payments ² (Accounting Charge Only)		
	Salary Short Other ¹ Term Incentive		Superannuation Contributions	Performance Options Rights		Total	
	\$	\$	\$	\$	\$	\$	\$
Dr. D.J. Wright	207,093	11,824	51,802	16,470	66,723	-	353,912
Mr. D.M. Keamy	170,304	11,015	-	15,423	64,936	-	261,678
Total	377,397	22,839	51,802	31,893	131,659	-	615,590

¹ 'Other' includes health insurance, housing and other allowances to facilitate relocation of Key Management Personnel.

² As these values are accounting values the Director may not actually receive any benefit from these amounts, either in the current or future reporting periods. The value of all performance rights and share options granted, exercised and lapsed during the financial year is detailed in the following tables within the Remuneration Report.

³ Performance rights with total accounting value of \$471,155 were expensed for the previous reporting period 2011-2012.

⁴ Unexercised share options originating from the 2007 Share Option Plan was valued at \$222,983 for accounting purposes for the previous reporting period. All share options except \$3,373 lapsed 9 February 2012.

⁵ Short-term incentives related to performance and service in prior financial periods for the Chief Executive Officer and quantified for payment during the year amounted to \$455,398.

⁶ For the financial year 2012/13 it was decided by the Remuneration and Nomination Committee upon renewal of the Managing Director's service agreement to evaluate and award the Managing Director's short-term incentive component on or around 30 June 2013 to bring the assessment and payment of incentives to current year.

² As these values are accounting values, the Key Management Personnel may not actually receive any benefit from these amounts, either in the current or future reporting periods. The value of all performance rights and share options granted, exercised and lapsed during the financial year is detailed in the following tables within the Remuneration Report.

Remuneration Of The Directors Of The Company For The Year Ended 30 June 2012

	Post employment benefits	Share based ments ² (Accounting Only)						
Director	Gross Salary	Annual Leave Cashed Out ¹	Short Term Incentive	Other ²	Superannuation/ Pension Fund	Perfor- mance Rights	Options	Total
	\$	\$	\$	\$	\$	\$	\$	\$
Dr. H.P.K. Agersborg	290,890	-	-	-	-	132,291	37,149	460,330
Mr. S.R. McLiesh	73,395	-	-	-	6,606	29,483	11,038	120,522
Dr. P.J. Wolgen	608,172	152,026	309,111	88,992	7,540	254,100	148,598	1,568,539
Mrs. B.M. Shanahan	59,633	-	-	-	5,367	18,427	22,825	106,252
Mr. L. J. Wood	65,000	-	-	-	-	18,427	3,373	86,800
Mr. E. Ishag	50,000	-	-	-	-	18,427	-	68,427
Total	1,147,090	152,026	309,111	88,992	19,513	471,155	222,983	2,410,870

¹ Unused and accrued annual leave was paid out in lieu of taking such leave during the year, as permitted by law

Remuneration of the Other Key Management Personnel of the Company for the Year Ended 30 June 2012

	Short-term employment benefits			Post employ- ment benefits	Share based payr (Accounting Cha		
	Salary	Short Term Incentive	Other 1	Superannuation Contributions	Performance Rights	Options	Total
	\$	\$	\$	\$	\$	\$	\$
Dr. D.J. Wright	201,638	26,151	52,956	15,775	104,561	25,754	426,835
Mr. D.M. Keamy	173,978	19,534	39,736	14,881	91,435	17,395	356,959
Total	375,616	45,685	92,692	30,656	195,996	43,149	783,794

¹ 'Other' includes health insurance, housing and other allowances to facilitate relocation of other key management personnel.

² 'Other' includes health insurance, housing and other allowances subject to fringe benefits tax to facilitate relocation to the European office.

³ As these values are accounting values the Director may not actually receive any benefit from these amounts, either in the current or future reporting periods. The value of all performance rights and share options granted, exercised and lapsed during the financial year is detailed in the following tables within the Remuneration Report.

² As these values are accounting values, the other key management personnel may not actually receive any benefit from these amounts, either in the current or future reporting periods. The value of all performance rights and share options granted, exercised and lapsed during the financial year is detailed in the following tables within the Remuneration Report.

The relative proportions of remuneration between fixed and based on performance for the years ending 30 June 2013 and 30 June 2012

	201:	3	2012		
	Fixed	Performance	Fixed	Performance	
Dr. P.J. Wolgen	49%	51%	64%	36%	
Dr. H.P.K. Agersborg	79%	21%	71%	29%	
Dr. D.J. Wright	78%	22%	69%	31%	
Mr. D.M. Keamy	71%	29%	69%	31%	

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

Entity			Value per Option on Grant Date	Class	Grant Date	Vested & Exercisable Dates	Expiry Date
Clinuvel	35,000	\$2.75	\$0.40	Ordinary	18/11/2008	18/11/2008	18/11/2013
Clinuvel		\$2.75	\$0.40			18/11/2009	
Clinuvel		\$2.75	\$0.40			18/11/2010	

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

periods					
Entity	Number of Rights	Value per Right on Grant Date	Class	Grant Date	Vesting Date for Retention in Scheme Trust
Clinuvel	114,500	\$2.00	Ordinary	16/10/2009	
Clinuvel	3,750	\$1.70	Ordinary	13/01/2010	
Clinuvel	186,667	\$1.04	Ordinary	25/11/2010	19/12/2012
Clinuvel	149,167	\$1.04	Ordinary	25/11/2010	
Clinuvel	149,167	\$1.04	Ordinary	25/11/2010	
Clinuvel	149,167	\$1.04	Ordinary	25/11/2010	
Clinuvel	116,667	\$1.04	Ordinary	25/11/2010	
Clinuvel	75,000	\$0.72	Ordinary	16/09/2011	
Clinuvel	111,610	\$0.71	Ordinary	16/09/2011	19/12/2012
Clinuvel	156,197	\$0.55	Ordinary	16/09/2011	
Clinuvel	61,460	\$0.71	Ordinary	16/09/2011	
Clinuvel	112,155	\$0.72	Ordinary	16/09/2011	
Clinuvel	112,725	\$0.64	Ordinary	16/09/2011	
Clinuvel	115,000	\$0.67	Ordinary	16/11/2011	
Clinuvel	115,000	\$0.67	Ordinary	16/11/2011	
Clinuvel	75,000	\$1.19	Ordinary	14/01/2013	
Clinuvel	75,000	\$1.19	Ordinary	14/01/2013	
Clinuvel	75,000	\$1.19	Ordinary	14/01/2013	

Shares provided to departing employees upon exercise of options and rights

Entity	Number of Shares Issued	Amount Paid for Shares:	Class
Clinuvel	276,775	Nil\$	Ordinary

These shares were issued by the Scheme Trustee to departing employees who resigned from the consolidated entity during the year or had their transfer restrictions waived by the Board in their discretion.

No shares were issued during the financial year as a result of exercise of options. No shares were provided upon exercise of options to Directors or key management personnel during the years ending 30 June 2013 and 30 June 2012.

Further Information – share-based compensation

	A	В	С	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	21.4%		-	-
Mr. S.R. McLiesh	23.0%		-	-
Dr. P.J. Wolgen	5.2%		-	-
Mrs. B.M. Shanahan	18.7%		-	-
Mr. L. J. Wood	22.0%		-	-
Mr. E. Ishag	23.0%		-	-
Dr. D.J. Wright	18.8%	40,557	-	-
Mr. D.M. Keamy	24.8%	40,557	-	-

- 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 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 either a binomial or trinomial 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 either 1 year, 2 year, 3 year or 4 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 and rights issued to Directors and Key Management Personnel

* For Retention in the Scheme Trust - Transfer Restrictions Apply

	Options Vested During the Year – 2013	Options Vested During the Year – 2012	Options Granted During the Year - 2013	Options Granted During the Year - 2012	Rights Vested During the Year – 2013	Rights Vested During the Year – 2012	Rights Granted During the Year - 2013	Rights Granted During the Year - 2012
Dr. H.P.K. Agersborg	-	-	-	-	-	57,500	-	-
Mr. S.R. McLiesh	-	-	-	-	-	-	-	80,000
Dr. P.J. Wolgen	-	-	-	-	116,667	91,667	-	-
Mrs. B.M.	-	-	-	-	-	-	-	50,000
Mr. L. J. Wood	-	-	-	-	-	-	-	50,000
Mr. E. Ishag	-	-	-	-	-	-	-	50,000
Dr. D.J. Wright	-	-	-	-	40,208	92,917	75,000	162,500
Mr. D.M. Keamy	-	-	-	-	19,380	52,680	75,000	160,000

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 in the year following the period of performance.

Remuneration details of cash bonuses and options/rights

]	Bonus		Options and Rights			
	Paid	Forfeited	Year Granted	Туре	Vested	Forfeited	Year of Vesting	Minimum grant value yet to Vest	Maximum grant value yet to Vest
Dr. H.P.K. Agersborg	0%	0%					-	-	
			2010/11	Rights	0%	41%	No limitation	-	22,111
Dr. P.J. Wolgen	50%	50%						-	
			2010/11	Rights	13%	0%	No limitation	-	407,336
Mr. S.R. McLiesh	0%	0%						-	
			2011/12	Rights	0%	0%	No limitation	-	53,381
Mr. L. J. Wood	0%	0%	2008/09	Options	0%	0%	2010/11		-
			2011/12	Rights	0%	0%	No limitation	-	33,363
Mrs. B.M. Shanahan	0%	0%						-	-
			2011/12	Rights	0%	0%	No limitation	-	33,363
Mr. E. Ishag	0%	0%						-	-
			2011/12	Rights	0%	0%	No limitation	-	33,363
Dr. D.J. Wright	0%	0%						-	-
			2009/10	Rights	0%	0%	No limitation	-	87,500
			2011/12	Rights	36%	0%	No limitation	-	41,819
			2012/13	Rights	0%	0%	No limitation	-	89,100
Mr. D.M. Keamy	0%	0%						-	-
			2009/10	Rights	0%	0%	No limitation	-	40,000
			2011/12	Rights	12%	0%	No limitation	-	69,923
			2012/13	Rights	0%	0%	No limitation	-	89,100

The exercise price for those options granted to Mr. Wood in 2008/09 is \$2.75. The exercise price for those rights granted between 2009/10 and 2012/13 was \$Nil. Excluding the CEO, cash bonuses paid to Executives 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 and repigmentation, shareholder interest is promoted through the Company successfully completing regulatory milestones and clinical trials. The table below shows the progress made in moving through the clinical pathway, reflecting the performance of the Executive team.

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

Regulatory / Clinical Milestone

Regulatory / Chinical Minestone									
	Year ending 30 June 2005	Year ending 30 June 2006	Year ending 30 June 2007	Year ending 30 June 2008	Year ending 30 June 2009	Year ending 30 June 2010	Year ending 30 June 2011	Year ending 30 June 2012	Year ending 30 June 2013
Phase II Photoprotective Study									
Phase II PLE Study – Europe/Australia									
Phase II AK Study - Europe/Australia									
Ph II/III EPP Study – Europe/Australia – Trial 1									
Phase III PLE Study – Europe/Australia									
Phase II Solar Urticaria Study - Europe									
Phase II PDT Study - Europe				-					
Orphan Drug Designation EPP - EUR				*					
Orphan Drug Designation EPP - USA					*				
Orphan Drug Designation SU – EUR					*				
Investigational New Drug Status - USA					*				
Phase II EPP Study - USA									
Ph III EPP Study – Europe Trial 2									
Ph III PLE Study – Europe Trial 2									
Ph II Vitiligo Studies – Europe/USA									
Orphan Drug Designation EPP – Australia							*		
Ph III EPP Study - USA									
Application for marketing authorisation submitted with EMA									

Shares Under Option

Details of unissued shares or interests under options or rights								
Entity	Number of Shares under Options	Number of Shares under Rights	Exercise Price	Class	Expiry Date			
Clinuvel Pharmaceuticals	35,000	-	\$2.75	Ordinary	18/11/2013			
Clinuvel Pharmaceuticals	-	1,528,616	\$Nil	Ordinary	Upon achievement of specific perfor- mance and time- based milestones			

Loans To Directors And Executives

No loans were granted to Directors or Executives for the years ending 30 June 2013 and 30 June 2012.

Non-Audit Services

For the years ending 30 June 2013 and 30 June 2012 Grant Thornton Australia only provided audit services to the Company.

Auditors' Independence Declaration

The auditors' independence declaration as required by s.307C of the Corporations Act 2001 is included and forms part of this 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(2) of The Corporations Act 2001.

Dr. Philippe Wolgen Managing Director

Dated this 28th day of August, 2013

Corporate Governance Statement

Overview

Corporate governance is the system by which Clinuvel Pharmaceuticals Ltd (or 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;
- the Company'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) Corporate Governance Principles and Recommendations with 2010 Amendments, 2nd Edition. The Company's Corporate Governance Protocol and Board charter was most recently comprehensively reviewed and updated in November 2009. The Committee charters were most recently reviewed and updated in August 2011.

Charters and policies referred to are available on the Company's The Board's framework for determining Director independence internet site (www.clinuvel.com).

and the Company's materiality thresholds is included in the Board.

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 shareholder funds are prudently safeguarded. The Board's functions are summarised in the Board Charter, posted on the Company's internet site.

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

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

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

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. The Board establishes performance criteria for the Managing Director and the Remuneration and Nomination Committee reviews the performance of the Managing Director against these targets.

For the reporting period, the performances of the Company's senior Executives, including the Managing Director, 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 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 one Executive Director (the Managing Director). Information about Directors, including their skills, experience, expertise and length of service can be found in pages 12 to 13.

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

and the Company's materiality thresholds is included in the Board Charter. The Company has four Non-Executive Directors 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 (Mrs. Shanahan, Mr. Wood, Mr. Ishag and Mr. McLiesh, who is the Chair). The Board has carefully assessed whether the impact of any past or present relationship with the Company, perceived or otherwise, materially interferes their ability to exercise independent judgment. The Board considers the contractual relationship between Mr. Ishag and the Company within the three years prior to his appointment is not material. Mr. McLiesh has served on the Board for more than nine years and the Board has determined his length of service does not materially interfere with his ability to act in the best interests of the Company. Thus the Board currently has a majority of independent Non-Executive Directors.

The Managing Director and Chief Executive Officer of the Company is Dr. Wolgen who is not the Chair.

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 Company'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 Access to information Nomination Committee. The Remuneration and Nomination Committee comprises at least three Directors (two voting and Directors receive a comprehensive performance report from the the other voting member and the committee is comprised of a cess to Company records and information. majority of voting independent Director. The Managing Director attends Remuneration and Nomination Committee meetings by All Directors have direct access to the Company Secretary who is tivity of proceedings. The membership and number of meetings held, along with each Director's attendance record last year, is shown on page 14. A Committee charter can be found on the Clinuvel Pharmaceuticals Ltd actively promotes Company's internet site.

The Remuneration and Nomination Committee makes recommendations to the Board on the appointment of new Directors and criteria for new appointees, focusing on the particular mix of skill, diversity 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 Directors experienced in finance, the law and, ideally, the pharmaceutical industry in which it participates.

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

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

The work of Directors

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

The Chair commits additional time and meets regularly with the Managing Director to review business and strategic issues and to agree Board meeting agendas.

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

Performance review

The Remuneration and Nomination Committee regularly reviews the composition and performance of the Board and its committees. The process to evaluate the Board and the Company's key Executives, along with the Board's policy for nomination and appointment of Directors, can be found in the Remuneration and Nomination Committee charter and section 1 of the Corporate Governance Protocol on the Company's internet site.

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 during the current year.

one non-voting) and is chaired by Mr. Wood. Mr. McLiesh is Managing Director each board meeting and have unrestricted ac-

invitation. He is not present if this could compromise the objec- accountable to the Managing Director and, through the Chair, the Board on all corporate governance matters.

ethical and responsible decision making (ASXCGC principle 3)

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

Code of business conduct and ethics

The Board has endorsed a Code of Business Conduct and Ethics (found in the Corporate Governance Protocol on the Company's internet site) that formalises the long standing obligation of all Clinuvel Pharmaceuticals Ltd people including Directors to behave ethically, act within the law, avoid conflicts of interest and act honestly in all business activities. The Company's Code of Business Conduct and Ethics reinforces its 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 2013 are shown on pages 12 to 13. 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.

Diversity Policy

The Company has a diversity policy in place, available for viewing in the Corporate Governance section to the Company's internet site. The Director's are committed to having an appropriate blend of gender, age, ethnic and cultural diversity amongst the Board and throughout all levels of the Company, taking into consideration the number of employees across its workforce.

The key elements to the diversity policy are:

- a) To maintain a reasonably balanced gender diversity representation across the entire Company,
- b) For the Remuneration and Nomination Committee to annu-

against those objectives.

The Company's performance against the diversity policy objectives as at 30 June 2013 and 30 June 2012 are:

Gender Rep- resentation		Female %	Male %				
Board	30 June 2013	20%		80%			
	30 June 2012	17%		83%			
Top 7 salaried	30 June 2013	57%		43%			
employees *	30 June 2012	43%		57%			
Consolidated	30 June 2013	63%		37%			
Entity	30 June 2012	57%		43%			
* excludes Execu	* excludes Executive Director						

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

Committee. The Audit and Risk Committee comprises at least tive Director. The remaining voting committee member, Mr. Mc-Liesh, is independent and Non-Executive.

The Managing Director attends Audit and Risk Committee meetthe Company's internet site.

The Committee advises the Board on all aspects of audit, the ad- nance Protocol on Clinuvel's website. equacy 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 financial audit attends committee meetings by invitation. The Committee seeks to ensure the independence of the external auditor. Non-audit services are generally 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.

ally assess the gender diversity objectives and the performance Clinuvel Pharmaceuticals Ltd promotes timely and balanced disclosure of all material matters concerning the Company (ASXCGC principle 5)

Continuous disclosure

Clinuvel Pharmaceuticals Ltd has a practice of providing relevant and timely information to shareholders, supported by its share market disclosure policy (located in the Corporate Governance Protocol on the Company's internet site) which details comprehensive procedures to ensure compliance with all legal obligations. The policy limits external briefings in the periods between the end of a financial year or half year and the release to the Australian Stock Exchange (ASX) of the relevant results. The Managing Director is responsible for overseeing and directing communications with the 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 To increase its effectiveness, the Board has an Audit and Risk the Annual Report and other corporate information in clear language, supported where appropriate by descriptive graphs, tables three Directors (two voting and one non-voting) and is chaired and medical glossaries. Where practicable, the Company uses by Mrs. Shanahan who is a voting, independent and Non-Execu- the latest widely available electronic technology to communicate openly and continually with shareholders - and the stock market in general. Announcements to the ASX, significant briefings, notices of meetings, annual reports and Annual General Meeting presentations are promptly posted on the Company's internet site ings by invitation. He is not present if this could compromise and emailed to shareholders and other interested parties. Proxies the objectivity of proceedings. The membership and number of can be lodged electronically for the Annual General Meeting. Also meetings held, along with each Director's attendance record last the external audit firm partner in charge of the Clinuvel Pharmayear, is shown on page 14. A Committee charter can be found on ceuticals 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 Gover-

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 the Company's businesses to identify and quantify business risks. Risk management is a key element of the Company's strategic planning, decision making and execution of strategies. The Company'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

transactions. The policies specify who may authorise transactions and internal compliance and control systems. and segregate duties of those carrying them out. The Company following:

- progress of research activities;
- the number and scope of research programs;
- the progress of pre-clinical and clinical development activ-
- 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 Together with an overview of people issues, particularly succession materially diluted. There is no assurance that additional funding 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

The Board has approved principles and policies to manage finan- As part of the process of approving the financial statements, the cial risks of exposures to foreign currencies, and interest rates. Managing Director provides statements in writing to the Board on Clinuvel Pharmaceuticals Ltd's policies prohibit speculative the quality and effectiveness of the Company's risk management

requires access to additional funding periodically to fund devel- Clinuvel Pharmaceuticals Ltd's process for approval of financial opment programs. If the Company fails to obtain such funding, statements has a long standing requirement that authorisations be it may need to delay or scale back the development and commer- given by various levels of management. The Company's Managcialisation of its products or R&D programs. The funds that the ing Director and Chief Financial Officer are required to state to Company may need will be determined by numerous factors, the Board, in writing, that the Company's financial report states a some of which are beyond the Company's control. Additionally, true and fair view in all material respects of the Company's finanfunds may be necessary due to a number of factors including the cial 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 members, being two voting, independent Non-Executive Directors, chaired by Mr. Wood. In addition, as a non-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 14. A Committee charter can be found on the Company's website.

and development planning, the Committee advises the Board on will be available to Clinuvel Pharmaceuticals Ltd in the future or 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. In reviewing and making recommendations to the Board, the Committee may take regard to employment market conditions and consult with specialist remuneration consultants with experience in the healthcare and biotechnology industries.

> 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, or that of their direct subordinates.

> Non-Executive Directors are remunerated by way of fees, and unlisted equity securities (conditional upon shareholder approval). The Board considers the granting of unlisted equity securities 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

Clinuvel Pharmaceuticals Ltd – Consolidated Entity - A.B.N 88 089 644 119

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.

Statement of Profit or Loss and Other Comprehensive Income For The Year Ended 30 June 2013

		Consolidated	l Entity
	Note	2013	2012
		\$	\$
Total Revenue	2	1,963,462	1,294,041
Other Income	2	937,026	-
Total Expenses	2	(9,703,311)	(11,061,269)
Profit (Loss) before income tax expense		(6,802,823)	(9,767,228)
Income tax expense (benefit)	3	-	-
Profit (Loss) after income tax expense		(6,802,823)	(9,767,228)
Net Profit (Loss) for the year		(6,802,823)	(9,767,228)
Other Comprehensive Income			
Items that will be re-reclassified subsequently to profit or loss			
Exchange differences of foreign exchange translation of foreign operations		(142,665)	96,879
Income tax (expense)/benefit on items of other comprehensive income		-	-
Other comprehensive income/(loss) for the period, net of income tax		(142,665)	96,879
Total comprehensive income for the period		(6,945,488)	(9,670,349)
Basic and diluted earnings per share -	16	(19.3)	(31.8)

The accompanying notes form part of these financial statements.

Statement of Financial Position For The Year Ended 30 June 2013

		Consolidated Enti	ty
	Note	2013	2012
		\$	\$
Current Assets			
Cash and cash equivalents	17(a)	12,568,839	12,719,025
Other Financial Assets	8	-	453,598
Trade and Other Receivables	4	1,742,870	1,007,207
Other Assets	5	1,356,685	1,627,247
Total Current Assets		15,668,394	15,807,077
Non Current Assets			
Property, plant and equipment	6	146,397	179,000
Intangible assets	7	-	9,200
Total Non Current Assets		146,397	188,200
Total Assets		15,814,791	15,995,277
Current Liabilities			
Trade and Other Payables	10	1,452,734	2,080,211
Provisions	11	493,530	258,732
Total Current Liabilities		1,946,264	2,338,943
Non Current Liabilities			
Provisions	11	29,237	18,998
Total Non Current Liabilities		29,237	18,998
Total Liabilities		1,975,501	2,357,941
Net Assets		13,839,290	13,637,336
Equity			
Contributed equity	12	126,710,267	119,323,391
Reserves	13	1,251,225	1,821,419
Accumulated losses	14	(114,112,202)	(107,507,474)
Total Equity		13,839,290	13,637,336

The accompanying notes form part of these financial statements.

Statement of Cash Flows For The Year Ended 30 June 2013

		Consolidated Entity	
N	lote	2013	2012
		\$	\$
Cash Flows From Operating Activities			
Refund for GST and VAT		123,019	134,449
Receipts from Customers		1,602,434	864,883
Interest received		419,594	623,300
Payments to suppliers and employees		(9,037,113)	(11,645,313)
Net cash provided by (used in) operating activities 1	7(b)	(6,892,066)	(10,022,681)
Cash Flows From Investing Activities			
Payments for property, plant and equipment		(30,849)	(4,504)
Proceeds from investment securities		467,458	4,798,711
Net cash provided by (used in) investing activities		436,609	4,794,207
Cash Flows From Financing Activities			
Proceeds from issue of ordinary		6,623,259	5,760,066
Payment of share issue costs		(348,413)	
Net cash provided by (used in) financing activities		6,274,846	5,760,066
Net Increase/(Decrease) In Cash Held		(180,611)	531,592
Cash and cash equivalents at beginning of the year		12,719,025	12,178,030
Effects of exchange rate changes on foreign currency held		30,425	9,403
Cash And Cash Equivalents At End Of The Year 1	7(a)	12,568,839	12,719,025

The accompanying notes form part of these financial statements.

Statement Of Changes In Equity For The Year Ended 30 June 2013

Consolidated Entity	Share Capital	Share Option Reserve	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
Balance at 30 June 2011	113,338,940	2,073,495	1,133,102	7,815	(100,145,251)	16,408,101
Issue of Share Capital under private placement	6,010,065	-	-	-	-	6,010,065
Issue of Share Capital under share-based payment	325,040	-	-	-	-	325,040
Employee share-based payment options	-	(2,061,329)	765,215		2,405,005	1,108,891
Capital Raising Costs	(350,654)					(350,654)
Transactions with Owners	119,323,391	12,166	1,898,317	7,815	(97,740,246)	23,501,444
Profit/(Loss) for the year					(9,767,228)	(9,767,228)
Other Comprehensive Income:						
Exchange differences of foreign exchange translation of foreign operations	-	-	-	(96,879)	-	(96,879)
Balance at 30 June 2012	119,323,391	12,166	1,898,317	(89,064)	(107,507,474)	13,637,336
Issue of Share Capital under private placement	6,373,245	-	-	-	-	6,373,245
Issue of Share Capital under share-based payment	1,011,391	-	-	-	-	1,011,391
Employee share-based payment options	-	3,364	(716,223)	-	188,095	(524,764)
Capital Raising Costs	2,240	-	-	-	-	2,240
Transactions with Owners	126,710,267	15,530	1,182,094	(89,064)	(107,319,379)	20,449,448
Profit / (Loss) for the year					(6,802,823)	(6,802,823)
Other Comprehensive Income:						
Exchange differences of foreign exchange translation of foreign operations	-	-	-	142,665	-	142,665
Balance at 30 June 2013	126,710,267	15,530	1,182,094	53,601	(114,122,202)	13,839,290

Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2013

1. Basis Of Preparation

entity with International Financial Reporting Standards ('IFRS'). consolidated financial statements. Clinuvel Pharmaceuticals Ltd is a for-profit entity for the purposes of reporting under Australian Accounting Standards.

based on historical costs and does not take into account changing money values or, except where stated, current valuations of financial 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.

Both the functional and presentation currency of the group and its Australian controlled entities is Australian dollars. The functional currency of certain non Australian controlled entities is not Australian dollars. As a result, the results of these entities are At present it is uncertain that tax losses can be utilised. Once a translated to Australian dollars for presentation in the Clinuvel position becomes known, tax losses will be brought to account. Pharmaceuticals Ltd financial report.

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 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 finan- Deferred Tax cial information satisfies the concepts of relevance and reliability.

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.

The going concern basis assumes that, if required, future capital raisings will be available to enable the consolidated entity to ed entity projects. The consolidated entity has successfully raised porary differences arising from goodwill. 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.

a) Principles of Consolidation

The financial report is a general purpose financial report that has The consolidated financial statements are prepared by combinbeen prepared in accordance with Australian Accounting Stan- ing the financial statements of all the entities that comprise the dards, other authoritative pronouncements of the Australian consolidated entity, being the Company (the parent entity) and its Accounting Standards Board and the Corporations Act 2001. subsidiaries as defined in Accounting Standard AASB 127 Consol-Compliance with Australian Accounting Standards ensures the idated and Separate Financial Statements. Consistent accounting consolidated financial statements and notes of the consolidated policies are employed in the preparation and presentation of the

The consolidated financial statements include the information and results of each subsidiary from the date on which the Company The financial report has been prepared on an accruals basis and is 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

b) Income Tax

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 and estimates are based on historical experience and any other 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 is accounted for using the comprehensive balance The financial statements of the consolidated entity have been pre-sheet liability method in respect of temporary differences arising pared on a going concern basis. The consolidated entity's oper- from differences between the carrying amount of assets and liaations are subject to major risks due primarily to the nature of bilities 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 undertake the research, development and commercialisation of utilised by future taxable profits. However, deferred tax assets and its projects and that the subsequent commercialisation of prod- liabilities are not recognised if the temporary differences given ucts will be successful. The financial statements take no account rise to them arise from the initial recognition of assets and liaof the consequences, if any, of the inability of the consolidated bilities (other than as a result of a business combination) which entity to obtain adequate funding or of the effects of unsuccessful affect neither taxable income nor accounting profit. Furthermore, research, development and commercialisation of the consolidat- a deferred tax liability is not recognised in relation to taxable tem-

> 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

vestments and interests are only recognised to the extent that it is lation of depreciation: 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.

bility giving rise to them are realised or settled, based on tax rates are included in the statement of comprehensive income. (and tax laws) that have been enacted or substantially enacted by reporting date. The measurement of deferred tax liabilities and e) Investments And Other Financial Assets assets reflects the tax consequences that would follow from the date, to recover or settle the carrying amount of its assets and liabilities.

liabilities on a net basis.

Tax Consolidation

The Company and its wholly-owned Australian entities are part f) Research And Development Expenditure of a tax-consolidation group under Australian Taxation law. Clinuvel Pharmaceuticals Ltd is the head entity of the tax-consoli- Expenditure on research activities is recognised as an expense in dation group.

Current And Deferred Tax For The Period

in the statement of comprehensive income, except when it relates is demonstrated: 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.

c) 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.

d) Property, Plant And Equipment

Plant and equipment are stated at cost less accumulated depreciation and impairment. Cost includes expenditure that is directly is determined by discounting the amounts payable in the future criteria of an intangible asset. to their present value as at the date of acquisition.

and depreciation method are reviewed at the end of each annual reporting period and adjusted if appropriate. An asset's carrying market the drug has been granted. amount is written off immediately to its recoverable amount if the assets carrying amount is greater than its estimated recoverable g) Intangible Assets - Trademarks, Patents And Sub-Licence amount.

from deductible temporary differences associated with these in- The following diminishing value percentages are used in the calcu-

- Computers and software 40%
- All other assets 7.5% to 20%

Deferred tax assets and liabilities are measured at the tax rates Gains and losses on disposal of assets are determined by comparthat are expected to apply to the period(s) when the asset and lia- ing proceeds upon disposal with the asset's carrying amount. These

manner in which the consolidated entity expects, at the reporting 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 Deferred tax assets and liabilities are offset when they relate to in- its investment in the financial asset until maturity (if a fixed matucome taxes levied by the same taxation authority and the compa-rity) or if it intends to hold the financial asset for an undefined peny/consolidated entity intends to settle its current tax assets and riod. Loans and receivables are non-derivate financial assets with fixed payments that are not quoted in an active market. They are included in current assets, except those loans and receivables that are due more than 12 months from reporting date.

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 Current and deferred tax is recognised as an expense or income an internal project) is recognised if, and only if, all of the following

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

attributable to the acquisition of the item. In the event that settle- The consolidated entity uses its critical judgment in continually ment of all or part of the purchase consideration is deferred, cost assessing whether development expenditures meet the recognition

At 30 June 2013 the consolidated entity has yet to demonstrate the Depreciation is calculated on diminishing value so as to write off satisfaction of all the above criteria to recognise and generate an the net cost of each asset over its expected useful life to its esti- intangible asset from its development activities. The inherent risks mated residual value. The estimated useful lives, residual values in pharmaceutical development are such that the criterion to recognise an intangible asset is not met until regulatory approval to

Trademarks, patents and licences have a finite useful life and are

annual reporting period.

Sub-licence

sideration given in exchange for the assets.

The consideration given for the acquisition of the sub-licence was k) Revenue And Other Income the issue of 11,167,000 ordinary shares and attaching options in the Company. Hence the cost of the sub-licence has been deter- Interest mined by assessing the fair value of net assets of the consolidated entity immediately after the sub-licence was acquired. For the Interest revenue is recognised on a proportional basis that takes purpose of valuing the assets of the Company, an independent into account the effective yield on the financial asset. valuation of the sub-licence was performed. The valuation was based on discounted future cash flows expected to flow from the Sale Reimbursements right to the sub-licence. The valuation was adjusted for the probability of successful commercial development as a pharmaceutical Revenue from reimbursement of implant sales from insurance

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

Amortisation Of Sub-licence

The sub-licence to develop and commercialise SCENESSE* has incentive can be reliably measured. been amortised on a straight-line basis over 10 years. The sub-license had been fully amortised.

h) Payables

Trade payables and other accounts payable are recognised when resulting from the purchase of goods and services, incurred prior to the end of the financial year.

i) Employee Benefits

Provision is made for benefits accruing to employees in respect of Basic Earnings Per Share wages and salaries, annual leave and long service leave when it is being measured reliably.

using the remuneration rate expected to apply at the time of set- issued during the year. tlement.

Provisions made in respect of employee benefits which are not expected to be settled within 12 months are measured as the pres- Diluted earnings per share adjusts the figures used in the detercash flows is the 5 year Treasury bond yield published by the Reserve Bank of Australia at reporting date.

j) Directors' Remuneration - Share Based Payments

recorded at cost less accumulated amortisation and impairment must determine the fair value of options and conditional perforlosses. Amortisation is charged on a straight line basis over the mance rights issued to employees as remuneration and recognise shorter of the relevant agreement or useful life. The estimated an expense in the Statement of Comprehensive Income. This stanuseful life and amortisation method is reviewed at the end of each dard 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 binominal options pricing model. The fair value of conditional performance rights is measured by either a binomial or a trinomial model. It The sub-licence to develop and commercialise SCENESSE* has is determined at grant date and expensed on a straight-line basis been recorded at cost. Cost is based on the fair value of the con- over the vesting period. The fair value of options and conditional performance rights is shown as an expense in profit or loss.

companies is recognised when the consolidated entity has transferred to the Buyer the significant risks and rewards of ownership

Government R&D tax incentive

Other income from the government R&D tax incentive program is recognised when it has been established that the conditions of the tax incentive have been met and that the expected amount of tax

1) Share Capital

Ordinary share capital is recognised at the fair value of the consideration received by the Company.

the consolidated entity becomes obliged to make future payments Any transaction costs arising on the issue of ordinary shares are recognised directly in equity as a reduction of the shares proceeds received.

m) Earnings Per Share

probable that settlement will be required and they are capable of 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 Provisions made in respect of employee benefits expected to be weighted average number of ordinary shares outstanding during settled within 12 months, are measured at their nominal values the financial year, adjusted for bonus elements in ordinary shares

Diluted Earnings Per Share

ent value of the estimated future cash outflows to be made by the mination of basic earnings per share to take into account the after consolidated entity in respect of services provided by employees income tax effect of interest and other financing costs associated up to reporting date. The discount rate used to estimate future 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.

n) Goods And Services Tax/Value Added Tax (GST)

Under AASB 2 Share Based Payments, the consolidated entity Revenues, expenses and assets are recognised net of the amount

of 'goods and services tax' or 'valued added tax' as it is known in r) Provisions certain jurisdictions (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.

flows are included in the Statement of Cash Flow on a gross basis. The GST component of cash flows arising from investing and taxation authority is classified as operating cash flows.

o) Impairment Of Assets

At each reporting date, the consolidated entity reviews the carrying amounts of its tangible and intangible assets to determine s) Other Current Assets whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable Other current assets comprise prepayments of drug peptide yet to unit to which the asset belongs.

Intangible assets with indefinite useful lives and intangible assets t) Foreign Currency Transactions And Balances not yet available for use are tested for impairment annually and estimates of future cash flows have not been adjusted.

is estimated to be less than its carrying amount, the carrying amount of the asset (cash-generating unit) is reduced to its rement of comprehensive income 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 the state- u) Share-based Payment Transactions ment of comprehensive income immediately.

p) Leases

Lease payments for operating leases, where substantially all the transactions'). risks and benefits remain with the lessors, are charged as expenses in the periods in which they are incurred.

q) Comparatives

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

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 net amount of GST recoverable from or payable to the taxa- the obligation. Where a provision is measured using the cash flows tion authority is included as part of receivables or payables. Cash estimated to settle the present obligation, its carrying amount is the present value of those cash flows.

financing activities which is recoverable from or payable to the 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.

amount of the asset is estimated in order to determine the extent be used in Clinuvel Pharmaceuticals Ltd trial program and prepayof the impairment loss (if any). Where the asset does not generate ments for certain insurances yet to expire, along with other general cash flows that are independent from other assets, the consolidat- prepayments. The expenditures represent an unused expense and ed entity estimates the recoverable amount of the cash-generating therefore a decrease in future economic benefit has yet to be in-

whenever there is an indication that the asset may be impaired. All foreign currency transactions during the financial year are Recoverable amount is the higher of fair value less costs to sell brought to account using the exchange rate in effect at the date and value in use. In assessing value in use, the estimated future of the transaction. Foreign currency monetary items at reporting cash flows are discounted to their present value using a pre-tax date are translated at the exchange rate existing at reporting date. discount rate that reflects current market assessments of the time Non-monetary assets and liabilities carried at fair value that are value of money and the risk specified to the asset for which the 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 If the recoverable amount of an asset (or cash-generating unit) they arise as defined in AASB 121: The Effects of Changes in Foreign Exchange Rates.

coverable amount. An impairment loss is recognised in the state- 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.

Benefits are provided to employees of the Group in the form of share-based payment transactions, whereby employees render services in exchange for shares or rights over shares ('equity-settled

The cost of these equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined using either a bionomial or a trinomial options pricing model. In valuing equity-settled transactions, no account is taken of any performance conditions, other than conditions linked to the price of the shares of Clinuvel Pharmaceuticals Limited ('market conditions').

which the relevant employees become fully entitled to the award comparatives presented in the financial statements. ('vesting date').

The cumulative expense recognised for equity-settled transactions at each reporting date until vesting date reflects (i) the extent to which the vesting period has expired and (ii) the number Certain new accounting standards and interpretations have been ultimately vest. This opinion is formed based on the best available information at reporting date. No adjustment is made for effect of these conditions is included in the determination of fair value at grant date.

No expense is recognised for awards that do not ultimately vest, except for awards where vesting is conditional upon a market condition.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified. In addition, an expense is recognised for any increase in the value of the transaction as a result of the modification, as measured at the date of modification. Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. However, if a new award is substituted for the cancelled award, and designated as a replacement award on the date that it is granted, the cancelled and new award are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share.

v) Critical Accounting Estimates And Judgment

economic data, obtained both externally and within the Group.

Key estimates – share-based payments transactions

at the date at which they are granted. The fair value is determined material for the purposes of segment reporting. using either a Black-Scholes, a binomial or a trinomial model, using the assumptions detailed in Note 23.

Key judgements - tax losses

Given the Company's and each individual entities' history of recent losses, the Group has not recognised a deferred tax asset with regard to unused tax losses and other temporary differences, as it has not been determined whether the Company or its subsidiaries will generate sufficient taxable income against which the unused tax losses and other temporary differences can be utilised. The value of tax losses not recognised is included in Note 3.

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

The cost of equity-settled transactions is recognised, together Accounting Standards Board that are relevant to its operations and with a corresponding increase in equity, over the period in which effective for the current annual reporting period. The adoption of the performance conditions are fulfilled, ending on the date on the new and revised standards did not result in any changes to the

x) New Australian Accounting Standards Issued But Not Yet Ef-

of awards that, in the opinion of the directors of the group, will published that are not mandatory for 30 June 2013 reporting periods, and have not yet been adopted by the Group.

the likelihood of market performance conditions being met as the The following new or amendments to existing standards have been published and are mandatory for accounting periods beginning on or after 1 January 2013 or later periods, but have not been adopted. They are expected to result in minimum or no impact to the Group's financial statements.

- AASB 9 Financial Instruments
- AASB 10 Consolidated Financial Statements;
- AASB 11 Joint Arrangements replaces AASB 131 Interests in Joint Ventures;
- AASB 12 Disclosure of Interests in Other Entities
- AASB 13 Fair Value Measurement and related AASB 2012-8 Amendments to Australian Accounting Standards arising from AASB 13
- AASB 119 Employee Benefits (2011), AASB 2012-10 Amendments to Australian Accounting Standards arising from AASB 119 (2011) and AASB 2012-11 Amendments to AASB 119 (September 2011) arising from Reduced Disclosure Requirements

y) Segment Reporting

The Directors evaluate estimates and judgments incorporated A segment is a component of the consolidated entity that earn revinto the financial report based on historical knowledge and best enues or incur expenses whose results are regularly reviewed by the available current information. Estimates assume a reasonable ex- chief operating decision makers and for which discrete financial pectation of future events and are based on current trends and information is prepared. The consolidated entity has one business segment, being the biopharmaceutical sector, and the majority of its activities is concentrated in researching and developing a sole asset, being its leading drug candidate. It has established entities in The Group measures the cost of equity-settled transactions with more than one geographical area, however the activities from these employees by reference to the fair value of the equity instruments entities comparative to the consolidated entity are considered im-

2. Profit/(Loss) From Continuing Operations

		Consolidate	ed
		2013	2012
		\$	\$
(a)	Revenues		
	Interest revenue – other persons	410,464	571,240
	Sales Reimbursements	1,552,998	722,801
Total	revenues	1,963,462	1,294,041
(b)	Other Income		
	Government R & D tax incentive	937,026	-
Total	other income	937,026	-
(c)	Expenses		
	Clinical Development costs	1,414,488	1,811,345
	Drug Delivery Research costs	913,451	978,860
	Regulatory and Toxicity Studies	467,936	497,269
	R & D Overheads	1,694,413	2,101,876
	Business Marketing & Listing	602,802	806,425
	Licenses Patents and Trademarks	166,451	114,061
	General Operations (incl Board)	4,516,150	4,656,598
	Net Loss on disposal of financial assets held at fair value through profit and loss	202,683	233,236
	Net gains on revaluation of financial assets held at fair value through profit and loss	(216,545)	(164,488)
	Gain on restating foreign currency creditors and currencies held	(58,518)	-
	Loss on restating foreign currency creditors and currencies held	-	26,087
Total	expenses	9,703,311	11,061,269
(d)	Profit/(loss) before income tax includes the following specific expenses		
	Employee benefits expense	4,834,921	4,595,960
	Depreciation	48,772	53,299
	Amortisation of patents, trademarks & sub-licence	9,200	9,200
	Loss on sale of property, plant and equipment	1,689	-
	Share Based Payments	486,627	1,433,931
	Operating Lease Expense – minimum lease payments	177,207	289,475

3. Income Tax Expense

	Consolidated	
	2013	2012
	\$	\$
(a) The prima facie tax on profit (loss) is reconciled to the income tax expense (benefit) as follows:	(2,040,847)	(2,930,169)
Prima facie tax payable on profit (loss) from ordinary activities before income tax at 30% (2012: 30%)		
Add:		
Tax effect of:		
non deductible entertainment	281	396
non deductible amortisation	2,760	-
Share Based payments	145,988	430,179
research and development deduction	319,988	-
(over)/under provision of income tax in previous years	753,741	(1,076,569)
Net (Gain) on revaluation of financial assets at fair value through profit and loss	(64,963)	(49,346)
Annual sub-license fees	4,585	(9,440)
Net loss on disposal of financial assets	60,805	69,971
Deferred tax assets not brought to account	817,662	3,564,978
(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	35,204,403	33,712,923
Net temporary differences	395,717	1,069,535
	35,600,120	34,782,458

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. Trade and Other Receivables

	Consoli	Consolidated	
	2013	2012	
	\$	\$	
Current			
Trade Debtors	734,848	660,895	
Accrued income	46,120	55,250	
Sundry debtors	961,902	291,062	
Total Current	1,742,870	1,007,207	

The carrying amount of receivables is a reasonable approximation of fair value. All of the Group's trade and other receivables have been reviewed for indicators of impairment. All receivables are non-interest bearing.

5. Other Assets

	Consoli	dated
	2013	2012
	\$	\$
Current Prepayments		
Peptide	1,201,458	1,099,492
Other	155,227	527,755
Total	1,356,685	1,627,247

6. Property, Plant and Equipment

	Consoli	dated
	2013	2012
	\$	\$
Plant and equipment		
At cost	474,830	489,760
Less: accumulated depreciation	(363,291)	(352,521)
Sub-Total	112,539	137,239
Furniture and fittings		
At cost	79,653	79,653
Less: accumulated depreciation	(45,795)	(37,892)
Sub-Total Sub-Total	33,858	41,761
Total property, plant and equipment	146,397	179,000

Movements in Carrying Amounts - Property, Plant And Equipment

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

	Plant And Equipment	Furniture And Fittings	Total
	\$	\$	\$
Consolidated Entity			
Carrying Amount at 30 June 2011	163,619	51,175	214,794
Additions	17,540	-	17,540
Disposals	-	-	-
Depreciation written back on disposal	-	-	-
Depreciations expense	(43,665)	(9,227)	(52,892)
Exchange differences	(255)	(187)	(442)
Carrying Amount at 30 June 2012	137,239	41,761	179,000
Additions	19,770	-	19,770
Disposals	(32,779)	-	(32,779)
Depreciation written back on disposal	31,090	-	31,090
Depreciations expense	(40,859)	(7,903)	(48,772)
Exchange differences	(1,922)	10	(1,912)
Carrying Amount at 30 June 2013	112,539	33,858	146,397

7. Intangible Assets

	Consolid	ated
	2013	2012
	\$	\$
Sub-licence to develop and commercialise SCENESSE *		
At cost	7,472,983	7,472,983
Less: Accumulated amortisation	(7,472,983)	(7,472,983)
Sub-total	-	-
Trademarks		
At cost	68,281	68,281
Less: Accumulated amortisation of Trademarks	(68,281)	(61,453)
Sub-total	-	6,828
Patents		
At cost	23,718	23,718
Less: Accumulated amortisation of Patents	(23,718)	(21,346)
Sub-total	-	2,372
Total	-	9,200

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

7 0	U	0 0	,
		Trademarks And Patents	Total
		\$	\$
Carrying Amount at 30 June 2011		18,400	18,400
Additions		-	-
Impairment		-	-
Amortisation expense		(9,200)	(9,200)
Carrying Amount at 30 June 2012		9,200	9,200
Additions		-	-
Impairment		-	-
Amortisation expense		(9,200)	(9,200)
Carrying Amount at 30 June 2013		-	-

Amortisation expense is included in the line item 'Total expenses' in the consolidated statement of comprehensive income. Please refer to the Summary of Significant Accounting Policies regarding significant intangible assets.

8. Other Financial Assets

	Conso	lidated
	2013	2012
	\$	\$
Current		
Investments comprise:		
Income Securities (at fair value through profit and loss)*	-	453,598

^{*} The consolidated entity held listed perpetual floating rate notes (income securities) which returned 1.25% above the 90 day bank bill rate with interest paid out quarterly. The consolidated entity no longer holds income securities.

9. Interests in Subsidiaries

Name of Entity	Country of Incorporation		erest
		2013	2012
Parent entity			
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%
Clinuvel Singapore Pte Ltd	Singapore	100%	0%

10. Payables

Consolie		dated
	2013	2012
	\$	\$
Current		
Unsecured Trade creditors	184,016	838,928
Sundry creditors and accrued expenses	1,268,718	1,241,283
Total	1,452,734	2,080,211
a) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade and Sundry creditors:		
US dollars	-	-
Euro	-	-
British pounds	9,644	28,656
Swiss franc	665,379	158,323
Other	1,080	-
Total	676,103	186,979
For an analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 22.		
(b) Terms and conditions:		
Trade and sundry creditors are non-interest bearing and normally settled on 30 day terms.		

11. Provisions

	Consoli	Consolidated	
	2013	2012	
	\$	\$	
Current			
Employee benefits	493,530	258,732	
Non Current			
Employee Benefits	29,237	18,998	

12. Contributed Equity

(a) Issued and Paid Up Capital

	Consoli	Consolidated	
	2013	2012	
	\$	\$	
38,217,038 fully paid ordinary shares (2012: 34,651,874)	126,710,267	119,323,391	

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 and controlled entities			
	2013		2012	
	No.	\$	No.	\$
At the beginning of the financial year:	34,651,874	119,323,391	30,381,706	113,338,940
Issued during the year				
Private placement	2,983,726	6,373,245	3,434,323	6,010,065
Options exercised and valuation transferred from Share Option Reserve				
Conditional rights issues and transferred from conditional rights reserve	581,438	1,011,391	835,845	325,040
Less: transaction costs	-	2,240 ¹	-	(350,654)
Balance at the end of the financial year:	38,217,038	126,710,267	34,651,874	119,323,391

¹ Transaction costs for 2012/13 includes a reversal of amounts accrued in relation to the prior year capital raising. The reversal amounted to \$32,538.

(c) Share Options

As at 30 June 2013 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	
18 November 2013	\$2.75/share	35,000
Total		35,000

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 Conditional Rights
Upon achievement of various performance milestones	Nil\$	225,000

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 Conditional Rights	
Upon achievement of various performance milestones	Nil\$	835,845	
As at 30 June 2013 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 Conditional Rights
Upon achievement of various performance milestones	Nil\$	1 528 616

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.

Consolidated

Consolidated

13. Reserves

	Consol	Consolidated	
	2013	2012	
	\$	\$	
Share Option reserve			
Balance at the beginning of period	12,166	2,073,495	
Share based payment	3,364	300,240	
Lapsed, Forfeited Options	-	(2,361,569)	
Balance at the end of period	15,530	12,166	

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	1,898,317	1,133,102
Share based payment	483,263	1,133,691
Transfer to share capital	(1,011,391)	(325,040)
Lapsed, Forfeited Rights	(188,095)	(43,436)
Balance at the end of period	1,182,094	1,898,317

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	(89,064)	7,815
Translating foreign subsidiary to current rate at Balance Date	142,665	(96,879)
Balance at the end of period	53,601	(89,064)
Total Reserves	1,251,225	1,821,419

14. Accumulated Losses

	Consolidated	
	2013	2012
	\$	\$
Accumulated losses at the beginning of the year	(107,507,474)	(100,145,251)
Transfer from Share Option reserve of lapsed & expired Options	-	2,361,569
Transfer from Performance Rights reserve of lapsed & expired Rights	188,095	43,436
Net loss attributable to the members of Clinuvel Pharmaceuticals Ltd	(6,802,823)	(9,767,228)
Accumulated losses at the end of the financial year	(114,122,202)	(107,507,474)

15. Lease Commitments

	Consoli	dated
	2013	2012
	\$	\$
Operating lease commitments		
Non-cancellable operating leases		
Contracted for but not capitalised in the accounts:		
Payable		
not later than 1 year	203,526	137,994
later than 1 year but not later than 5 years	562	1,672
Total	204,088	139,666

Operating leases comprises commitments for office premises, accommodation for relocated employees and miscellaneous equipment.

No contingent rental clauses exist in lease agreements. Lease agreements range from 4 months to 13 months as from the reporting date and contain renewal options. Fixed increases are factored into agreements.

16. Earnings Per Share (EPS)

	Consoli	dated
	2013	2012
	\$	\$
(a) Basic earnings per share (cents per share)	(19.3)	(31.8)
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of Basic Earnings Per Share	35,295,370	30,760,172
(c) The numerator used in the calculation of Basic Earnings Per Share (\$)	(6,802,823)	(9,767,228)

As at 30 June 2013 the the Company had on issue unlisted options and unlisted performance rights over unissued capital. These options and rights are not considered dilutive as they do not increase the net loss per share.

There have been no other transactions involving ordinary shares or potential ordinary shares that would significantly change the number of ordinary shares outstanding between the reporting date and the date of the completion of this financial report.

As the group is in a loss situation all options are considered anti dilutive and have been excluded from the calculation of diluted earnings per share. Therefore basic and diluted earnings per share are the same. The number of options and performance rights that could potentially dilute earnings per share in the future is 1,563,616 (2012: 2,196,779).

17. Cash Flow Information

	Conso	Consolidated		
	2013	201		
	\$			
(a) Reconciliation of Cash Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled sheet as follows:	to the related items in	n the balance		
Cash at bank	1,274,559	1,555,00		
Cash on hand	1,491	5,615,80		
Deposits on call	1,224,026	459,33		
Term Deposits	10,000,000	5,038,14		
Security Bonds	68,763	50,74		
	12,568,839	12,719,02		
Operating profit (loss) after income tax Non cash flows in operating (loss):	(6,802,823)	(9,767,228		
Non cash flows in operating (loss):	(=)== ,= =,	(2)		
Depreciation expense	48,772	53,29		
Exchange Rate Effect on Foreign Currencies Held	(30,425)	(9,403		
Amortisation expense	9,200	9,20		
Executive share option expense	486,627	1,433,93		
Loss on Sale of non-current assets	1,689			
Realised loss on disposal of financial assets at fair value through profit and loss	202,683	233,23		
Net Loss on revaluation of financial assets held at fair value	(216,545)	(164,488		
Unrealised Loss Foreign Exchange Translation	142,686	150,69		
Changes in assets and liabilities:				
(Increase)/decrease in receivables	(985,663)	(21,715		
(Increase)/decrease in prepayments	270,562	(167,87)		
Increase/(decrease) in payables	(263,866)	(1,728,341		
Increase/(decrease) in provisions	245,037	(43,999		
Net cash used in operating activities	(6,892,066)			

Cash at bank earns floating rates based on daily bank deposit rates. The carrying amounts of cash and cash equivalents represent fair value.

The effective interest rate on short-term deposits was 4.43% (2012: 5.73%). These deposits have an average maturity date of 102 days (2012: 80 days).

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 - ceased Directorship 26 September 2012)

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

Mrs. B.M. Shanahan (Non-Executive Director)

Dr. P.J. Wolgen (Managing Director)

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

Mr. E. Ishag (Non Executive)

The other Key Management Personnel of Clinuvel Pharmaceuticals Limited during the year were:

Dr. D. J. Wright (Acting Chief Scientific Officer)

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

Please see the Remuneration Report on page 17 for further information.

Key Management Personnel Compensation

	Conso	Consolidated		
	2013	2012		
	\$	\$		
Short-term employee benefits:	2,401,140	2,211,212		
Post-employment benefits	51,094	50,169		
Long-term benefits	-			
Termination benefits	-	-		
Share-based payments	312,572	933,283		
	2,764,806	3,194,664		

Remuneration Option holdings of Key Management Personnel - 2013

	0						
	Balance at Start of Year	Granted as Compensation	Exercised	Lapsed and Expired	Balance at End of Year	Vested and Exercisable	Unvested
Directors							
H.P.K. Agersborg	-	-	-	-	-	-	-
E. Ishag	-	-	-	-	-	-	-
S.R. McLiesh	-	-	-	-	-	-	-
B. M. Shanahan	-	-	-	-	-	-	-
P.J. Wolgen	-	-	-	-	-	-	-
L. J. Wood	35,000	-	-	-	35,000	35,000	-
Executives							
D.J. Wright	-	-	-	-	-	-	-
D.M. Keamy	-	-	-	-	-	-	-

Remuneration Conditional Performance Rights holdings of Key Management Personnel - 2013

	Balance at Start of Year	Granted as Compensation	Exercised	Lapsed and Expired	Balance at End of Year	Vested and Exercisable	Unvested
Directors							
H.P.K. Agersborg	300,000	-	(57,500)	(185,000)	57,500	-	57,500
E. Ishag	50,000	-	-	-	50,000	-	50,000
S.R. McLiesh	80,000	-	-	-	80,000	-	80,000
B. M. Shanahan	50,000	-	-	-	50,000	-	50,000
P.J. Wolgen	600,000	-	(208,334)	-	391,666	-	391,666
L. J. Wood	50,000	-	-	-	50,000	-	50,000
Executives							
D.J. Wright	240,000	75,000	(133,125)	-	181,875	-	181,875
D.M. Keamy	139,320	75,000	(19,380)	-	194,940	-	194,940

Remuneration Option holdings of Key Management Personnel – 2012

	Balance at Start of Year	Granted as Compensation	Exercised	Lapsed and Expired	Balance at End of Year	Vested and Exercisable	Unvested
Directors							
H.P.K. Agersborg	150,000	-	-	(150,000)	-	-	-
E. Ishag	-	-	-	-	-	-	-
S.R. McLiesh	45,000	-	-	(45,000)	-	-	-
B. M. Shanahan	85,000	-	-	(85,000)	-	-	-
P.J. Wolgen	600,000	-	-	(600,000)	-	-	_
L. J. Wood	35,000	_	-		35,000	35,000	
Executives							
D.J. Wright	90,000	_	-	(90,000)	-	_	
D.M. Keamy	60,000	-	-	(60,000)	-	-	-

Remuneration Conditional Performance Rights holdings of Key Management Personnel – 2012

	Balance at Start of Year	Granted as Compensation	Exercised	Lapsed and Expired	Balance at End of Year	Vested and Exercisable	Unvested
Directors							
H.P.K. Agersborg	450,000	-	(150,000)	-	300,000	57,500	242,500
E. Ishag	-	50,000	-	-	50,000	-	50,000
S.R. McLiesh	-	80,000	-	-	80,000	-	80,000
B. M. Shanahan	-	50,000	-	-	50,000	-	50,000
P.J. Wolgen	900,000	-	(300,000)	-	600,000	91,667	508,333
L. J. Wood	-	50,000		-	50,000	-	50,000
Executives							
D.J. Wright	87,500	162,500	(10,000)	-	240,000	92,916	147,084
D.M. Keamy	32,500	160,000	(52,680)	-	139,820	-	139,820

19. Auditors' Remuneration

	Consc	lidated
	2013	2012
	\$	\$
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	63,014	61,415
Total	63,014	61,415

20. Related Party Disclosures

Directors

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

H.P.K. Agersborg, S.R. McLiesh, P.J. Wolgen, B.M. Shanahan, L.J. Wood, E Ishag

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 commercialization of the Company's 22. Financial Instruments drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a Clinuvel Pharmaceuticals Ltd and consolidated entities have exdeficiency in net assets exists in A.C.N. 089 584 467 Pty Ltd.

The loan receivable by Clinuvel Pharmaceuticals Ltd from A.C.N. 108 768 896 Pty Ltd is non-interest bearing. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in A.C.N. 108 768 896 Pty Ltd. The loan to A.C.N. 108 768 896 The Board of Directors oversees and reviews the effectiveness of Pty Ltd as at 30 June 2013 is \$4,370,640 (2012: \$4,370,640).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel, Inc is 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 2013 is \$6,549,360 (2012: \$5,562,409).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel AG is 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 2013 is \$10,709,418 (2012: \$8,417,857).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel Singapore Pte Ltd is 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 Singapore Pte Ltd. The loan to Clinuvel Singapore Pte Ltd as at 30 June 2013 is \$91,873 (2012: \$Nil).

Director related and key management personnel transactions and entities

There are no transactions and relationships in existence as at 30 June 2013 between Directors of the Company and their related entities.

21. Segment Information

A segment is a component of the consolidated entity that may earn revenues or incur expenses, whose operating results are

regularly reviewed by the chief operating decision makers and for which discrete financial information is available. The consolidated entity has one business segment, being the biopharmaceutical sector, and the majority of its activities is concentrated in researching and developing a sole asset, being its leading drug candidate. It has established 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.

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer.

posure to the following risks from its use in financial instruments:

- Market Risk
- Credit Risk
- Liquidity Risk

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/or 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 2013 and as at 30 June 2012.

Sensitivity Analysis

During the financial year the Company had a principal foreign the Australian/US dollar rate for the period. currency transaction risk exposure to the US dollar. Assuming all pay for a key component of the clinical program.

For the consolidated entity, a 10% appreciation of the Austra- The Group's exposure to other foreign currency movements is not lian dollar against the US currency would have increased profit considered material. and loss and equity by \$ 277,962 for the year ended 30 June 2013

(2012: \$229,886), on the basis that all other variables remain constant. 10% is considered representative of the market volatility in

other variables remain constant, an appreciation in the Australian For the consolidated entity, a depreciation of the Australian dollar dollar is advantageous to the consolidated entity as foreign cur- against the US currency would have an equal but opposite effect rencies are required to be purchased from Australian dollars to to the above, on the basis that all other variables remain constant.

The consolidated entities exposure to foreign currency risk at 30 June 2013

				•				
Consolidated						Consolidated		
				2013			2012	
	Cash & Cash Equivalents	Trade Debt- ors & Other Assets	Trade & Other Payables	Total	Cash & Cash Equivalents	Trade Debt- ors & Other Assets	Trade, Other Payables & Provisions	Total
USD	368,227	-	(166,729)	201,498	789,885	-	(764,207)	25,678
EUR	364,656	613,875	(121,127)	857,404	278,510	1,249,834	(259,948)	1,268,396
CHF	239,201	-	(821,674)	(582,473)	304,168	209,856	(458,090)	55,934
GBP	-	-	(5,856)	(5,856)	-	-	(19,105)	(19,105)
SEK	-	-	(7,418)	(7,418)	-	-	-	-
SGD	48,703	-	(5,107)	43,596	-	-	-	-

Interest Rate Risk

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

The consolidated entity currently finances its operations through solidated entity. reserves of cash and liquid resources and does not have a borrowing requirement. In order to be protected from, and to take Credit risk in relation to the consolidated entity is the cash and advantage of, interest rate movements it is the consolidated entity's policy to place cash into deposits and other financial assets 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 2013, 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 \$105,143 higher/lower (2012: \$107,585 higher/ lower) This analysis assumes all other variables are held constant.

Price Risk

Clinuvel Pharmaceuticals Ltd and its consolidated entities were Fair Value Estimation formerly exposed to price risk in its investments in income securities classified in the Statement of Financial Position as held for The fair value of financial assets and financial liabilities must be estrading. All income securities were liquidated during the course of the year and there are no future plans to invest in income securities. Neither the consolidated entity nor the parent is exposed

to commodity price risk.

Credit risk arises from the potential failure of counterparties to meet their contractual obligations, resulting in a loss to the con-

cash equivalents deposited with banks, trade and other receivables. Exposure to credit risk in trade debtors is limited to two counat both fixed and variable (floating) rates. The Board monitors terparties, being an Italian government funded medical institution and a Swiss government funded medical institution.

> The maximum credit exposure is the carrying value of the cash and cash equivalents deposited with banks, trade and other debtors and foreign, wholly-owned subsidiaries.

Liquidity Risk

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

timated 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 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 SCENESSE * and achieving eventual commercialisation.

Contractual Maturities of Financial Assets as at 30 June 2013

	Consolidated		
	2013	2012	
	\$	\$	
Cash and Cash Equivalents			
Carrying Amount	12,568,839	12,719,025	
6 months or less	12,539,218	12,719,025	
Greater than 6 months	29,621	-	
Total	12,568,839	12,719,025	
Other Financial Assets (includes Trade and Other Receivables)			
Carrying Amount	1,742,870	1,460,805	
6 months or less	1,742,870	1,460,805	
Greater than 6 months	-	-	
Total	1,742,870	1,460,805	

Contractual Maturities of Financial Liabilities as at 30 June 2013

	Consol	Consolidated		
	2013	2012		
	\$	\$		
Trade and Other Payables				
Carrying Amount	1,452,734	2,080,211		
6 months or less	1,452,734	1,757,294		
Greater than 6 months	-	322,917		
Total	1,452,734	2,080,211		

23. Employee Benefits

	Consoli	dated
	2013	2012
	\$	\$
The aggregate employee benefit liability is comprised of:		
Provision for annual leave	319,364	200,312
Provision for long service leave	203,403	77,418
Accrued FBT, Payroll, Superannuation, Pension Funds, Employee Insurances	810,198	260,459
Total	1,332,965	538,189

a) Share Based Payments

The consolidated entity has a share option scheme (which will no Conditional Performance Rights Scheme longer issue further share options under the scheme) and a con-Directors) of the Company.

Share Option Scheme

Each share option converts to one ordinary share of the consoliare no voting rights attached to the option and they can be exerare non-transferable and not listed on the ASX.

at general meetings. Each series of options had specific terms and conditions, from 12 month restriction periods for the number of The number of rights granted is subject to approval by the Remutors of the consolidated entity. Those options which are currently milestones set by the Directors of the consolidated entity. unexpired and held by only one Non-Executive Director are fully

ditional performance rights scheme which is ownership based for All performance rights issued fall under the Clinuvel Conditionkey management personnel and selected consultants (including al 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 convert 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 dated entity. The options were issued for nil consideration. There ordinary shares at any time once the vesting conditions attached to the rights have been achieved, whereby they will be held by a cised any time from the date of vesting to the date of expiry. They 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 The number of options granted was subject to approval by the employee is no longer employed by the Company or all transfer Remuneration and Nomination Committee and by shareholders restrictions are satisfied or waived by the Board in its discretion.

options to vest, to monthly restriction periods over 48 months, neration and Nomination Committee. Rights currently have speand to the satisfaction of performance objectives set by the Direccific terms and conditions, being the achievement of performance

The Following Share Based Payment Arrangements Were in Existence at 30 June 2013

Options	Series		Number	Grant date	Expiry Date	Exercise Price	Fair Value at Grant Date
Issued	18/11	/2008	35,000	18/11/2008	18/11/2013	\$2.75	\$0.50
Performa Series	ance Rights	Number	Grant date	Expiry Date		Exercise Price	Fair Value at Grant Date
Issued	16/10/2009	150,500	16/10/2009	Upon achievemore performance mi	•	\$Nil	\$2.20
Issued	07/01/2010	17,500	07/01/2010	Upon achievement of specific performance milestones		\$Nil	\$0.50
Issued	25/11/2010	900,000	25/11/2010		Upon achievement of specific performance milestones		\$1.04
Issued	16/09/2011	863,779	16/09/2011	Upon achievement of specific performance milestones		\$Nil	Between \$0.55 and \$0.72
Issued	16/11/2011	230,000	16/11/2011	Upon achievement of specific performance milestones		\$Nil	\$0.67
Issued	14/01/2013	225,000	14/01/2013	Upon achievement of specific performance milestones		\$Nil	\$1.19

Option Holdings of All Issued Options - 2013

Options Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired and Lapsed	Balance at End of Year		Unvested
Issued 18/11/2008	35,000	-	-	-	35,000	35,000	-
Total	35,000	-	-	-	35,000	35,000	-
Weighted Average Exercise Price	\$2.75	\$0.00	\$0.00	\$0.00	\$2.75	\$2.75	_

The share options outstanding at the end of the financial year had an average remaining contractual life of 141 days (2012: 506 days).

Options were priced using the Binomial 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 - 2013

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	150,500	-	(36,000)	-	114,500	-	114,500
Issued 07/01/2010	17,500	-	(3,750)	(3,750)	10,000	10,000	-
Issued 25/11/2010	900,000	-	(265,834)	(185,000)	449,166	-	449,166
Issued 16/09/2011	863,779	-	(275,854)	(87,975)	499,950	-	499,950
Issued 16/11/2011	230,000	-	-	-	230,000	-	230,000
Issued 14/01/2013	-	225,000	-	-	225,000	-	225,000
Total	2,161,779	225,000	(581,438)	(276,725)	1,528,616	10,000	1,518,616
Weighted Average Exercise Price	\$Nil						

Performance Rights were priced using either a binomial or trinomial 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 either the 1 year, 2 year, 3 year or 4 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 - 2012

Options Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired and Lapsed		Vested and Exercisable	Unvested
Issued 09/02/2007	1,136,000	-	-	(1,136,000)	-	-	-
Issued 18/11/2008	35,000	-	-	-	35,000	35,000	-
Total	1,171,000	-	-	(1,136,000)	35,000	35,000	-
Weighted Average Exercise Price	\$8.50	-	-	\$8.60	\$2.75	\$2.75	

The share options outstanding at the end of the financial year had an average remaining contractual life of 506 days (2011: 253 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 - 2012

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	222,250	-	(66,000)	(5,750)	150,500	36,000	114,500
Issued 07/01/2010	26,250	-	(8,750)		17,500	13,750	3,750
Issued 25/11/2010	1,350,000	-	(450,000)		900,000	149,167	750,833
Issued 16/09/2011	0	1,301,000	(311,095)	(126,126)	863,779	75,676	788,103
Issued 16/11/2011	0	230,000			230,000	0	230,000
Total	1,598,500	1,531,000	(835,845)	(131,876)	2,161,779	274,593	1,887,186
Weighted Average Exercise Price	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil

Performance Rights were priced using either a binomial or trinomial 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 either the 1 year, 2 year, 3 year or 4 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

Performance Rights - Binominal Pricing Model

Inputs	
Grant Date Share Price	\$1.98
Exercise Price	\$Nil
Grant Date	21 January 2013
Expiry Date	Undefined
Historical Volatility (weighted average)	52.5%
Expected Life (weighted average)	14 months
Hurdle Rate	\$Nil
Risk Free Interest Rate	2.79%

24. Clinuvel Pharmaceuticals Ltd Parent Company Information

	Clinuvel Pharma	ceuticals Ltd
	2013	2012
	\$	\$
Assets		
Current Assets	13,670,505	14,122,798
Non-Current Assets	1,038,350	767,111
Total Assets	14,708,855	14,889,909
Liabilities		
Current Liabilities	725,809	1,508,180
Non-Current Liabilities	29,237	18,998
Total Liabilities	755,046	1,527,178
Equity		
Issued equity	126,710,253	119,323,392
Share-based payments reserve	1,197,639	1,910,483
Accumulated losses	(113,954,083)	(107,871,144)
Total Equity	13,953,809	13,362,731
Financial Performance		
Net Profit (Loss) for the year	(5,894,843)	(10,131,092)
Other Comprehensive Income	-	-
Total Comprehensive Income	(5,894,843)	(10,131,092)

25. Subsequent Events

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

26. Additional Company Information

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

The Registered office is:

Level 14, 190 Queen Street Melbourne VIC 3000 Ph: (03) 9660 4900

Directors' Declaration

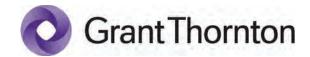
In the opinion of the Directors:

- 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 2013 and of their 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.
- 3. the remuneration disclosures set out in the Annual Report comply with Australian Accounting Standards 124 Related Party Disclosures and the Corporations Regulations 2001.

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

DR P.J. WOLGEN DIRECTOR

Dated this 28th day of August, 2013



Grant Thornton Audit Pty Ltd ACN 130 913 594

The Rialto, Level 30 525 Collins St Melbourne Victoria 3000 GPO Box 4736 Melbourne Victoria 3001

T +61 3 8320 2222 F +61 3 8320 2200 E info.vic@au.gt.com W www.grantthornton.com.au

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 consolidated statement of financial position as at 30 June 2013, the consolidated statement of profit and loss statement and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information and the directors' declaration of the consolidated entity comprising the Company and the entities that it controlled at 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 of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 The Directors' responsibility also includes such internal control as the Directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error. The Directors also state, in the notes to the financial report, in accordance with Accounting Standard AASB 101 Presentation of Financial Statements, the financial statements comply with International Financial Reporting Standards.

Auditor's responsibility

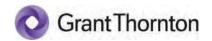
Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. Those standards require us to comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain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

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2



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 Company's preparation of the financial report that gives a true and fair view 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 Company'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.

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 consolidated entity's financial position as at 30 June 2013 and of its performance for the year ended on that date; and
 - ii complying with Australian Accounting Standards 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 25 to 35 of the directors' report for the year ended 30 June 2013. 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.

63



3

Auditor's opinion on the remuneration report

In our opinion the remuneration report of Clinuvel Pharmaceuticals Ltd for the year ended 30 June 2013, complies with section 300A of the Corporations Act 2001.

GRANT THORNTON AUDIT PTY LTD

anat Thompson

Chartered Accountants

M. A. Cunningham

Partner - Audit & Assurance

Melbourne, 28 August 2013



Grant Thornton Audit Pty Ltd ACN 130 913 594

The Rialto, Level 30 525 Collins St Melbourne Victoria 3000 GPO Box 4736 Melbourne Victoria 3001

T +61 3 8320 2222 F +61 3 8320 2200 E info.vic@au.gt.com W www.grantthornton.com.au

Auditor's Independence Declaration To the Directors of Clinuvel Pharmaceuticals Limited

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of Clinuvel Pharmaceuticals Limited for the year ended 30 June 2013, I declare that, to the best of my knowledge and belief, there have been:

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

GRANT THORNTON AUDIT PTY LTD

1 . A Thombon

Chartered Accountants

M. A. Cunningham

Partner - Audit & Assurance

Melbourne, 28 August 2013

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Shareholder Information as at 26 September 2013

ASX and not shown elsewhere in this report is as follows:

Additional information, as at 26 September 2013, required by the b. The number of shareholdings held in less than marketable parcels is 980 for ordinary shares.

1. Shareholding

a. Distribution of Shareholder Numbers

Category (Size of Holding)	Total Holders
1-1,000	1,954
1,001-5,000	890
5,001-10,000	198
10,001-100,000	208
100,001-999,999,999	29

- c. The names of the substantial shareholders listed in the holding company's register at 26 September are: Ender 1 LLC.
- 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

Position	Name	Number of Ordinary	% Held of Issued
		Full Paid Shares held	Ordinary Capital
1.	JP MORGAN NOMINEES AUSTRALIA LIMITED <cash a="" c="" income=""></cash>	8,003,857	20.94
2.	NATIONAL NOMINEES LIMITED	4,120,291	10.78
3.	CITICORP NOMINEES PTY LIMITED	3,125,860	8.18
4.	ENDER 1 LLC	2,340,824	6.13
5.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	2,065,029	5.40
6.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	1,214,200	3.18
7.	ACN 108 768 896 PTY LTD	1,113,133	2.91
8.	BOODUP NOMINEES PTY LTD <otter a="" c="" fund="" super=""></otter>	694,613	1.82
9.	J P MORGAN NOMINEES AUSTRALIA LIMITED	622,091	1.63
10.	SANDHURST TRUSTEES LTD < JMFG CONSOL A/C>	518,482	1.36
11.	M BADCOCK AND P CHU SUPERANNUATION FUND PTY LTD	500,000	1.31
12.	HEADSTART GLOBAL AGGRESSIVE HOLDINGS LTD	489,515	1.28
13.	HEADSTART GLOBAL HOLDINGS LTD	447,633	1.17
14.	MANHATTAN RUBY PTY LTD <shepherd a="" c="" f="" king="" s=""></shepherd>	355,063	0.93
15.	MS MARCELLA FELCHLIA AGERSBORG	299,611	0.78
16.	ABN AMRO CLEARING SYDNEY NOMINEES PTY LTD <custodian a="" c=""></custodian>	256,207	0.67
17.	DR MARK EDWIN BADCOCK	255,000	0.67
18.	SANDHURST TRUSTEES LTD < AUSTRALIAN NEW HORIZONS A/C>	213,586	0.56
19.	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	174,488	0.46
20.	DR MICHAEL JAMES FISH	174,361	0.46
Total		26,983,844	70.61

2. Company Secretary

The name of the Company Secretary is: Darren Keamy

3. Registered Office

The address of the principle registered office in Australia is: Level 14/190 Queen St

Melbourne, Vic 3000

Telephone: +61 3 9660 4900
Fax: +61 3 9660 4999
Email: mail@clinuvel.com
Website: http://www.clinuvel.com

4. Register of Securities

Computershare Investor Services Pty Ltd Yarra Falls, 453 Johnston St, Abbotsford, VIC 3067, Australia Tel: +61 3 9415 4000

5. Australian Securities Exchange Limited

Quotation has been granted for all the ordinary shares on all Member Exchanges of the Australian Securities Exchange Limited (ASX: 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 2013: Nil.

7. Directory

Non-Executive Chair

Stan McLiesh

Non-Executive Directors

Brenda Shanahan, Jack Wood, Elie Ishag

Managing Director and Chief Executive Officer

Dr Philippe Wolgen

Acting Chief Scientific Officer

Dr Dennis Wright

Chief Financial Officer and Company Secretary

Darren Keamy

Auditor

Grant Thornton Australia Limited The Rialto, Level 30, 525 Collins St, Melbourne, VIC 3000, Australia

Banker

National Australia Bank (NAB)

Western Branch, 460 Collins St, Melbourne, VIC 3000, Australia

Legal Counsel

Arnold Bloch Leibler

Level 21, 333 Collins St, Melbourne, VIC 3000, Australia

Bristows

100 Victoria Embankment, London EC4Y 0DH, United Kingdom

IP Lawyer

Dipl.-Ing Peter Farago

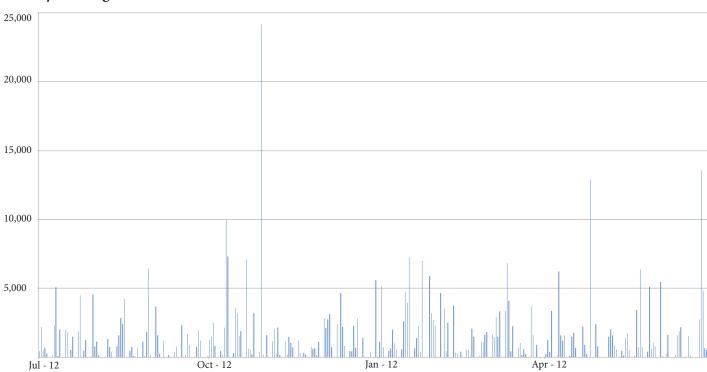
Baadestr 3, Munich 80, Germany

Market Performance

Share Price ASX:CUV



Daily Trading Volume



Glossary

Alpha-Melanocyte Stimulating Hormone (α-MSH)

A peptide hormone which activates or stimulates the production The cells in the skin that produce melanin. and release 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 Minimum Erythema Dose (MED) atmosphere.

European Medicines Agency (EMA)

The 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 Therapy which utilises an ultraviolet B light source to activate melinflammatory component, caused by the actinic effect of solar anin in vitiliginous lesions of the skin. 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 Pheomelanin ability warrants melanin to be termed a photoprotectant (a sub- A reddish pigment, a very weak absorptive of UV radiation. It also sun). α-MSH acts specifically to stimulate (eu)melanin synthesis. it increases sun sensitivity and skin ageing.

Food and Drug Administration (FDA)

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.

Marketing Authorisation Application (MAA)

A formal application to the EMA to approve a drug product or medical device for sale.

Melanin

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

Melanocytes

Melanogenesis

The process whereby melanin is produced in the body.

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 (α =295 nm) of approximately 100 J/m2.

Narrowband Ultraviolet B (NB-UVB) phototherapy

New Drug Application (NDA)

A formal application to the FDA to approve a drug product for

stance capable of providing protection against radiation from the acts as a photosensitiser (makes your skin sensitive to light), where

The USA's regulatory agency for food, tobacco, medicines and 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 IIb/Phase III

Advanced-stage clinical trials 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 while remaining safe and well tolerated.

Pharmacodynamics

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

Pharmacokinetics

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

Glossary

Photodermatoses

Skin diseases onset by exposure of skin to sunlight and UV.

Photoprotection

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

Subcutaneous

Underneath the skin.

Sustained release/controlled-release

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

Thymine dimers

DNA changes which are characteristic of UV damage.

Therapeutic Goods Administration (TGA)

Australia's regulatory agency for medicinal products and devices.

Ultraviolet (UV) radiation

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.

Notes

