



Clinuvel Pharmaceuticals Ltd

ANNUAL REPORT 2011

CLINICAL SUMMARY

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), a first-in-class drug targeting erythropoietic protoporphyria (EPP), is in Phase II and III trials in the US and Europe, and is expected to be filed before the end of 2011 for review by the European Medicines Agency. Presently, there is no known effective treatment for EPP and SCENESSE® has been granted orphan drug status. Based in Melbourne, Australia, Clinuvel has operations in Europe and in the US, with 30 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/light (photoprotection).

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 α -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 ERYTHROPOIETIC PROTOPORPHYRIA (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. Approximately 10,000 people globally are affected by EPP.

CLINUVEL'S PIPELINE

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 | PATIENT POPULATION | CLINICAL STATUS | RESULTS EXPECTED |
|--|-----------------------------|-----------------|-------------------|
| Erythropoietic protoporphyria (EPP) | 10,000 | Phase II US | Q4 2011 |
| Absolute light intolerance | | Phase III EU | Q4 2011 |
| Nonsegmental vitiligo (NSV) A common depigmentation disorder | >45 million | Phase II US/EU | Q1 2012 |
| Actinic Keratosis (AK) & Squamous Cell Carcinoma (SCC) Skin cancer in Organ Transplant Recipients | Up to 200,000 | Phase II EU/Au | Q4 2011 (interim) |
| Polymorphic Light Eruption (PLE/PMLE) Severe UV/Sun Poisoning | 10-15% Caucasian population | Phase III EU | Q4 2011 |

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CLINUVEL ARE EXPERTS IN THE INTERACTION OF LIGHT AND HUMAN SKIN

Our focus is to develop and make commercially available drugs which provide medicinal photoprotection and repigmentation to the skin. Since the structural changes made to the company in December 2005, management has concentrated its efforts to become a global leader in the fields of photoprotection and dermal pigmentation.

PHOTOPROTECTION

Photoprotection is defined as the protection of skin from non-ionising radiation emitted from the sun or artificial light sources. Clinuvel's SCENESSE® (afamelanotide 16mg) provides exogenous (individually administered) photoprotection to the entire skin of patients diagnosed with ultraviolet radiation (UV) related skin disorders. This pharmacological process simulates the biological function endogenous to the skin, whereby photoprotection is provided when pigmentation (eumelanin) is activated when one exposes him or herself to sun or UV sources.

PIGMENTATION AND REPIGMENTATION

Pigmentation and repigmentation is defined as the activation or stimulation of pigment producing cells (melanocytes) in the skin exclusively, required to overcome medical deficiencies causing depigmentation. Clinuvel's SCENESSE® (afamelanotide 16mg) is used in the main depigmentation disorder (vitiligo), most prominent in darker skin types (phototypes III-VI). The pharmacological process aims to stimulate differentiating precursor cells (melanoblasts) to mature melanocytes able to generate effective pigment (eumelanin).



INDICATIONS OF USE

Clinuvel's lead product SCENESSE® is being used in a number of skin disorders to prevent symptoms.

| NAME DISEASE | SYMPTOMS | PHOTOTYPE | PREVALENCE | SPECIALIST |
|--|---|-----------------------------------|-------------------------------|--|
| Erythropoietic protoporphyria (EPP) | Absolute light intolerance | Most common in I-II | Approximately 10,000 patients | Dermatologist, Haematologist, Gastroenterologist, Photobiologist |
| Nonsegmental vitiligo (NSV) | A common depigmentation disorder | All, but more prominent in III-VI | >45 million patients | Dermatologist |
| Actinic Keratosis (AK) & Squamous Cell Carcinoma (SCC) | Skin cancer in Organ Transplant Recipients (OTRs) | Most common in I-II | Up to 200,000 patients | Dermatologist Transplant surgeon |
| Polymorphic Light Eruption (PLE/PMLE) | Severe UV/Sun Poisoning | Most common in I-II | Up to 200,000 patients | Dermatologist |

SKIN CANCER

SCENESSE® (afamelanotide 16mg) and CUV9900 are foreseen as preventatives in patients diagnosed with skin cancer (actinic keratosis (AK), squamous cell carcinoma (SCC)). The highest risk categories for skin cancer are fair-skinned patients (with deficient pigmentation) and organ transplant recipients (OTRs). Clinuvel is currently testing SCENESSE® in OTRs who have had at least one carcinoma of their skin previously, results thus far are encouraging. In 1991, the National Institute of Health in the US assisted the early scientists financially to find melanoma prevention strategies. Analogues of alpha-melanocyte stimulating hormone were patented and developed for further clinical use. Clinuvel has further developed the chemistry and formulation of one of these potent molecules, and two decades later the use of SCENESSE® is indeed to find a pharmacological answer to decrease the rate of skin cancer in OTRs.

The prevalence of skin cancer globally is increasing due to a number of factors, such as continuous risky behaviour - exposing to ambient sun at midday and solarium use - medical adjunct treatment (immunosuppressive drugs) and/or lack of an effective genetically programmed pigmentary system (mostly red hair, blue eyes, freckled individuals).

NON-MELANOMA SKIN CANCER (NMSC) MOST RECENT INCIDENCE ESTIMATES

| REGION | YEAR | NMSC PATIENTS | % OF POPULATION |
|--------------------------|------|---------------|-----------------|
| USA ¹ | 2006 | 2,152,500 | 0.7% |
| UK ² | 2008 | 98,800 | 0.2% |
| Australia ³ | 2007 | 434,000 | 2% |
| New Zealand ⁴ | 2008 | 67,000 | 1.6% |

1 Rogers, HW et al (2010). "Incidence Estimate of Nonmelanoma Skin Cancer in the United States, 2006", Arch Dermatol. 146(3):283-287.

2 Cancer Research UK (2009). "Skin Cancer - Facts About the Different Types of Skin Cancer", online [http://www.sunsmart.org.uk/skin-cancer-facts/about-skin-cancer/]. Accessed 12/9/11.

3 Cancer Council Australia (2011). "Skin cancer facts and figures", online [http://www.cancer.org.au/cancersmartlifestyle/SunSmart/Skin-cancerfactsandfigures.htm] Accessed 12/9/11.

4 Cancer Society NZ (2011). "Skin Cancer Facts and Figures", online [http://www.cancernz.org.nz/reducing-your-cancer-risk/sunsmart/about-skin-cancer/skin-cancer-facts-and-figures/] Accessed 12/9/11.

ERYTHROPOIETIC PROTOPORPHYRIA (EPP)

EPP IS THE LEAD INDICATION FOR CLINUVEL'S FIRST-IN-CLASS DRUG SCENESSE® (AFAMELANOTIDE)

| | |
|-----------------------------------|--|
| Description | Absolute skin intolerance to UV and light. |
| ICD-10 | E80.0 |
| Prevalence | Up to 10,000 |
| Prognosis | Lifelong genetic disease. |
| Treatments | None approved by EMA/FDA. |
| SCENESSE® clinical trial progress | Phase III complete (CUV029, EU); Phase II complete (CUV030, US), results expected Q4 2011. |

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.

EPP has a dramatic impact on quality of life with patients reporting high levels of unemployment and severe mental health issues as a result of their restricted lifestyles.



A phototoxic EPP reaction in a young patient

EPP burns are inevitable, and we just have to accept a life of pain and hopelessness

US EPP patient

CLINICAL RESULTS TO DATE

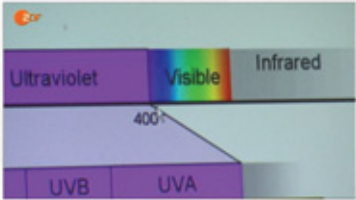
Clinuvel has conducted four clinical studies of SCENESSE® (afamelanotide) in adult patients diagnosed with EPP in Europe, Australia and the US. Treatment with SCENESSE® has, to date, been shown in Phase II and III clinical trials to reduce the frequency and severity of phototoxic reactions in EPP patients. The drug has been well tolerated across these studies with no serious adverse events identified to date, including in patients exposed to the drug for up to 24 months (12 months study and 12 months treatment under compassionate use protocols). Results from the CUV029 and CUV030 studies are being analysed to determine the drug's safety and efficacy profile in a larger number of EPP patients.

In this study on the efficacy of afamelanotide in EPP patients, an improved tolerance to artificial and natural light was found in all patients.

Harms JH, et al (2009). "Mitigating Photosensitivity of Erythropoietic Protoporphyria Patients by an Agonistic Analog of α -Melanocyte Stimulating Hormone". Photochem, Photobiol 85(6): 1434-9.

EPP IN POPULAR PRESS

Girl, 6, loves the rainy weather... because her incurable skin condition means sun's rays leave her in agony




EVERY TIME JAMES WENT IN THE SUN, HE'D START CRYING
“The pain is like having 200 needles stuck in your skin but about a hundred times worse”
For the past 24 years daytrips and family holidays have been a nightmare for her and her worried family

“All I can remember of my childhood is pain”
“He was just screaming for no apparent reason; he just wanted to pull his skin off”

For Robert Saupe, there was never any such thing as fun in the sun. He has a condition called erythropoietic protoporphyria, or EPP, a rare disease that causes extreme sensitivity to sunlight and certain types of artificial light.

EPP CENTRES OF EXCELLENCE



| REGION | EPP PATIENT ESTIMATES* |
|---------------|------------------------|
| Europe | ~4000 |
| MEA | ~700 |
| North America | ~4000 |
| Australasia | ~400 |
| South America | ~2000 |

*Estimates based on patient registries and information from expert centres

NONSEGMENTAL VITILIGO (NSV)

VITILIGO IS A NOVEL APPLICATION OF CLINUVEL'S SCENESSE® (AFAMELANOTIDE)

| | |
|-----------------------------------|---|
| Description | Common depigmentation disorder |
| ICD-10 | L80.0 |
| Prevalence | >45 million |
| Prognosis | Disease may arrest or resume spreading without warning, treatment relapse is common. |
| Treatments | No pharmaceutical therapy approved. Phototherapy medical devices approved by EMA/FDA. |
| SCENESSE® clinical trial progress | Phase II underway (CUV101 EU & CUV102 US), results expected 1H 2012. |

Vitiligo is a common skin disorder in which the pigment producing cells of the skin (melanocytes) are absent or dysfunctional. As a result, lighter depigmented patches of skin (lesions) appear in different parts of the body due to the lack of melanin (pigment). The exact cause of vitiligo is unknown, but it is generally recognised that an autoimmune component plays a part in this disease. Vitiligo causes significant psychological and emotional distress and can have a severe impact on patient quality of life.

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

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

Vitiligo therapy is intended to arrest depigmentation or provide repigmentation of depigmented lesions. Many treatment options exist (many of which are 'off-label' therapies) but many clinical challenges persist. Not all patients respond to available therapies and relapse is common.



Vitiligo lesion

Nonsegmental vitiligo (NSV) is historically the sixth indication to be clinically evaluated by Clinuvel for the novel drug SCENESSE®, but it takes a prominent place in the development program of the company. Two trials (CUV101 in Europe and CUV102 in the US) are currently evaluating SCENESSE's ability to repigment vitiligo lesions with the use of narrowband ultraviolet B (NB-UVB) phototherapy.

Phototherapy, mainly narrowband UVB (NB-UVB), has emerged as a mainstay of repigmentation treatment in individuals affected by vitiligo. NB-UVB, an approved therapy, utilises a localised light source to activate melanin in vitiliginous lesions of the skin. This therapy is known to effectively suppress the local immune response and accelerate the maturity of melanocytes in the area around hair follicles, which act as melanocyte reservoirs. This process leads to activation of melanin (pigment). Patients are required to attend clinics 2-3 times per week for up to 18 months to achieve repigmentation of lesions.

It is believed that SCENESSE®, when used in conjunction with NB-UVB, could accelerate the repigmentation process, reducing the treatment and cost burden on patients and health care providers. Data from this pilot study will give Clinuvel insight into whether the two treatments provide a superior clinical result than NB-UVB alone.



Facial vitiligo. Image courtesy of Pearl E Grimes MD



ura di una malattia rara, la **Protoporfiria Eritropoietica**
cui sintomi limitano l'esposizione al sole

FierceBiotech
THE BIOTECH INDUSTRY'S DAILY MONITOR

Modics drug **delivery** tech has **day in the sun** with Clinuvel: **US patent** to assist drug as potential **skin cancer preventative** in red heads

Bloomberg Clinuvel Drug Offers **Relief** for Rare **Light Sensitivity** Malady, Study Shows
Clinuvel identifies **potential** Clinuvel CEO has **high hopes** for long-awaited melanin activator

EMA acknowledges Clinuvel's novel drug
ling in Europe in 2011

Philippe Wolgen
Company CEO

Are sufferers of erythropoietic protoporphyria now free to leave the shadows?

SCENESSE®  **THE US FDA**

Media Coverage 2010 - 2011 has provided **positive** guidance on the development of Clinuvel Pharmaceuticals' lead asset **SCENESSE** (afamelanotide)

Clinuvel records first **A\$1million** in sales
Clinuvel Pharmaceuticals had its drug **cleared for use** in **Italy in 2010**, and in the second half of 2011 it expects to file the compound for wider approval in Europe.

Clinuvel **completes phase** **SCENESSE** study
FDA allows world **first vitiligo** drug trial
Clinuvel **granted** Australian **formulation patent**

LIGHT-protection drug developer Clinuvel Pharmaceuticals has received its first revenues from **SCENESSE** (afamelanotide) and expects to update the **Read more at Clinuvel.com** **INSPIRE** phase study of vitiligo patients within six weeks.

CLINUVEL BUSINESS MODEL

EXECUTING A GLOBAL DRUG DEVELOPMENT STRATEGY

The current macro-economic conditions have urged management teams worldwide to rethink the adagium to form global businesses. Market conditions have dictated our ambitions by accepting that it may be better to become a leader locally before thinking globally. It is not say that global ideas have become extinct in our adopted thinking, but financial constraints on forward planning have had an impact on managements' risk appetite for early entry to new territories. In essence, local markets have become a proof of concept before cross-border expansion of the venture in question.

In early 2006 Clinuvel deliberated on the benefits of developing SCENESSE® (afamelanotide 16mg) for local markets first and establishing home-grown demand state by state before seeking further application for the drug elsewhere. Demographically, we could make a sound case of restricting our clinical, regulatory and financial efforts to Australia and New Zealand. However, over the Australian autumn of 2006, we decided again this and – contrary to the aforementioned dictum – management and Board voted to develop the drug in all major markets at the same time, with an initial focus on Europe.

To contextualise the implications of this decision, a flow-diagram of the activities is presented in Figure 1. Equipped with all conceivable information, the decision was taken to develop SCENESSE® in four global markets at the same time; for this enterprise to succeed, a concise and expert team of 25-30 professionals was recruited, operating the first four years out of Australia and the past two out of Switzerland. Along the route of development, this single decision to globalise proved to be one of the better one taken by Clinuvel.



**CLINUVEL'S
SCENESSE® (AFAMELANOTIDE 16MG) IMPLANT**



Figure 1: Clinuvel's decision process

CORPORATE MILESTONES

2011

AUGUST 2011 PRE-CLINICAL PROGRAM FOR SCENESSE® COMPLETED

JUNE 2011 FIRST A\$1M SALES OF SCENESSE® RECORDED

MAY 2011 EMA PRE-SUBMISSION MEETING COMPLETED

MARCH 2011 FDA ALLOWED FIRST VITILIGO TRIAL OF SCENESSE®

2010

NOVEMBER 2010 FDA PROVIDED POSITIVE GUIDANCE ON EPP PROGRAM
TGA GRANTED ODD FOR EPP

AUGUST 2010 COMMENCED VITILIGO PROGRAM & SECOND MOLECULE CUV9900, REVEALED

JULY 2010 FIRST MANUFACTURER SIGNED FOR SCENESSE®

POSITIVE FULL PHASE III EPP TRIAL RESULTS

MAY 2010 AIFA ALLOWS SUPPLY, REIMBURSEMENT OF SCENESSE® IN ITALY FOR EPP

EMA APPROVED SCENESSE® BRAND NAME REVEALED

MARCH 2010 COMMENCED CONFIRMATORY PHASE II EPP TRIAL USA

2009

DECEMBER 2009 POSITIVE PHASE II PDT, PRELIMINARY PHASE III PLE & PRELIMINARY PHASE III EPP TRIAL RESULTS

NOVEMBER 2009 GRANTED SME STATUS BY EMA

AUGUST 2009 COMMENCED PHASE III EPP CONFIRMATORY TRIAL EUROPE

JULY 2009 POSITIVE PHASE II SU RESULTS

JUNE 2009 EMA GRANTED ODD FOR SU

2008

JANUARY 2009 POSITIVE PHASE III EPP SWITZERLAND 12 MONTHS RESULTS & FDA GRANTED IND

DECEMBER 2008 FDA IND SUBMISSION

SEPTEMBER 2008 COMMENCED PHASE II PDT TRIAL

JULY 2008 FDA GRANTED ODD FOR EPP

JUNE 2008 COMMENCED PHASE II SU TRIAL

GENERIC NAME AFAMELANOTIDE ASSIGNED BY WHO

APRIL 2008 POSITIVE PHASE I PHARMACOKINETIC TRIALS RESULTS & SWISSMEDIC GRANTED ODD FOR EPP

MARCH 2008 EMA GRANTED ODD FOR EPP

2007

OCTOBER 2007 COMMENCED PHASE II AK/SCC IN OTR PATIENTS TRIAL

JULY 2007 FINAL DOSAGE SELECTION FOR AFAMELANOTIDE

JUNE 2007 COMMENCED PHASE III EPP TRIAL

MAY 2007 COMMENCED PHASE III PLE TRIAL

APRIL 2007 PRIVATE PLACEMENT A\$26M

FEBRUARY 2007 POSITIVE PHASE II EPP RESULTS

2006

NOVEMBER 2006 RIGHTS ISSUE AND PRIVATE PLACEMENT A\$35.2M

SEPTEMBER 2006 COMMENCED PHASE II EPP TRIAL

AUGUST 2006 POSITIVE PHASE II PLE RESULTS

JUNE 2006 POSITIVE PHASE II PHOTOPROTECTION TRIAL RESULTS

MAY 2006 PRIVATE PLACEMENT A\$5M

APRIL 2006 POSITIVE PHASE II PLE RESULTS

2005

DECEMBER 2005 NEW MANAGEMENT INSTALLED (IS CURRENT MANAGEMENT)

COMPANY MILESTONES SINCE DECEMBER 2005

** In this overview the numerous discussion with regulatory authorities are not listed,
but full details can be found on www.clinuvel.com

UPCOMING CLINICAL AND REGULATORY MILESTONES

| Q4 2011 | Q1 2012 | Q2 2012 | Q3 2012 |
|---|--|---------|--|
| Final Results US EPP Phase II study (CUV030) Final Results EU EPP Phase III study (CUV029) Final Results EU PLE Phase III study (CUV032) Interim Results EU/Au OTR Phase II study (CUV011) MAA Filing EU EPP* | Interim Results EU/US vitiligo Phase II INSPIRE studies (CUV101/CUV102) Commence US Phase III EPP study** | | MAA Decision EU EPP* Full Results EU/US vitiligo Phase II INSPIRE studies (CUV101/CUV102) |

* Results CUV030/CUV029 will dictate timing of EMA filing

** Pending discussions with FDA

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

CLINUVEL'S DRUG DEVELOPMENT

Over the past five years Clinuvel has focused on the development of SCENESSE® (afamelanotide) as a first-in-class drug for patients diagnosed with severe skin disorders.

Drug development is not a linear process and the company's milestones to date reflects the balancing of a diverse development program with commercial, regulatory and clinical realities. The company has focused on two distinct applications of SCENESSE® – the protection of skin from light and UV (photoprotection) and the repigmentation of skin – identifying a number of clinical indications where the drug may safely provide significant therapeutic benefit.

The initial application of the drug as a novel photoprotective agent has been encouraging to date, with the lead program for the indication erythropoietic protoporphyria (EPP) completing late stage clinical trials. Ongoing discussions with regulatory agencies have lead to the formal recognition of SCENESSE's potential to treat EPP, with the designation of orphan drug status by European, US and Australian regulatory authorities.

A special listing in Italy has allowed physicians to prescribe SCENESSE® to EPP patients since May 2010. This program has also enabled the company to evaluate commercial and distribution needs for this orphan indication in a smaller market prior to a commercial launch while generating A\$1million in sales to June 30, 2011. Further commercial developments throughout 2010-2011 have helped the team prepare SCENESSE® for distribution.

By September 1, 2011, SCENESSE® had been tested in over 600 patients – including 250 EPP patients – with no serious drug-related adverse events identified. In coming months, pending clinical results from studies conducted in the US and Europe between 2010-2011, Clinuvel intends to file SCENESSE® with the European Medicines Agency (EMA) for marketing authorisation approval (MAA) for EPP. Beyond the filing, the company expects results from the first patients ever treated with SCENESSE® for vitiligo, with decisions on the direction of the program to be taken in early 2012.

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

EPP: Erythropoietic Protoporphyria – Absolute sun/UV intolerance

EMA: European Medicines Agency

MAA: Marketing Authorisation Application

ODD: Orphan Drug Designation

PLE: Polymorphic Light Eruption – Severe sun/UV poisoning

PDT: Photodynamic Therapy – Phototoxicity following cancer treatment

SU: Solar Urticaria – Acute anaphylactic reaction to sun/UV

WHO: World Health Organisation

Note: See the inside front cover for a summary of Clinuvel's current clinical progress.

CHAIR'S LETTER



Dear Shareholders,

During the past twelve months there have been significant events in global financial markets which have in no small way affected all market segments and certainly those which are seen to be of a more speculative nature, such as biotechnology in general and Clinuvel in particular.

Despite the market uncertainties we have relentlessly pursued a strategy of focussing our efforts on development of afamelanotide to a point where we can submit a dossier to mainstream regulatory bodies with a strong chance of achieving registration and marketing approval. Significant progress has been achieved in this challenge and we believe we are well placed to meet the rigours of regulatory requirements set by the European, US and Australia authorities (EMA, FDA and TGA, respectively). The challenge over the past five years has been to develop a range of data which will give regulatory authorities a better understanding of the patient benefits that can result from the application of SCENESSE® (afamelanotide) in a number of indications where there is a clinical need for

photoprotection through the activation of the body's own defence mechanisms.

Over that period we have put together a clinical and regulatory team of professionals which is at least the equal to any Australian group and could certainly be compared favourably on the international stage. Because afamelanotide is a new chemical entity (NCE) and is being used to treat a condition where there has been no effective treatment in the past, it has been necessary to prove the safety and clinical relevance of our drug beyond doubt and develop unique measuring techniques which prove efficacy of the product. There are strong indications that SCENESSE® does meet the critical essence of pharmaceutical development in that it confers positive benefits to patients who have suffered from erythropoietic protoporphyria (EPP) over a span of many years. This has been confirmed by the use of SCENESSE® to serve a well defined "orphan" program for EPP patients in Italy at a re-imbursement price which is appropriate an NCE.

“*There are strong indications that SCENESSE® does meet the critical essence of pharmaceutical development in that it confers positive benefits to patients who have suffered from erythropoietic protoporphyria (EPP) over a span of many years.*

”

In addition there are already positive signs that afamelanotide will be a useful adjunct in the treatment of nonsegmental vitiligo, a disease which affects an estimated 45 million people worldwide including around three million in the US alone. The FDA welcomed Clinuvel's efforts to develop a therapy for nonsegmental vitiligo, a condition which has quite an impact on an individual's quality of life and for which there is no effective therapy.

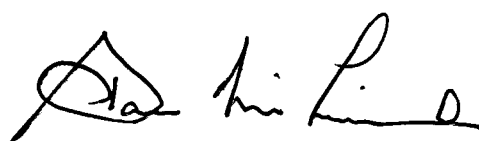
Clinuvel's business is in the field of pigmentation and its value is enhanced by the intangible asset of knowledge it has acquired in genetics, melanoma, melanocyte signalling and biochemistry specific to a field not previously explored in pharmaceutical development. This has led to the identification of three other groups of patients with a clinical need for photoprotection where afamelanotide may well be an effective therapeutic agent.

Over the past five years we have carefully pursued a clinical program which we believe will lead to a submission of a dossier for Marketing Authorisation Approval (MAA) in Europe later this calendar year. This submission requires the completion and evaluation of our two confirmatory EPP studies, the Phase II trial (CUV030) in the US and the Phase III trial (CUV029) in Europe. We have also developed a Paediatric Implementation Plan (PIP) which is central to our submission for MAA in Europe.

At Board level through both the Commercial Management Committee and the full Board there has been a clear awareness of the need for a well-developed Business Plan as well as the focus on the pharmaceutical development strategy. Distribution will become

a key issue the moment the company has released its final EPP results. Agreements are in place that guarantee appropriate supplies of both raw material and finished implants. Sales in excess of A\$1 million have been recorded since the listing of afamelanotide under law 648/96 in Italy which allows doctors to prescribe SCENESSE® for EPP patients. Business plans are well advanced for the marketing of SCENESSE® in both a restricted "orphan" drug market, in addition to an expanded global market for an indication such as nonsegmental vitiligo.

My thanks go to a Board of Directors who are all frequently required to be involved in many of the day-to-day activities of the company in a manner not seen as a requirement in larger pharmaceutical companies. We thank Shareholders for their patience and understanding in this most difficult undertaking: bringing a completely new therapeutic substance to global markets. We believe Shareholder value will be greatly enhanced on the completion of the EPP program and submission of the MAA in Europe.



Stan McLiesh
Chairman



MANAGING DIRECTOR'S REPORT

Dear shareholders, friends

In review of this past year, I would like to take a moment to elaborate, once again, on the essence of Clinuvel and why our program is unique in comparison to most biopharmaceutical or biotechnology companies. The year 2011 has been marked by substantial internal progress in developing SCENESSE® (afamelanotide) to market. Given the utmost complexity of the clinical and regulatory process, the technological progress is not always understandable for the individual shareholder. It is anticipated that after reading the annual review, most readers will then be better informed of the strides we have taken in making the drug available.

INNOVATION

Innovation in pharmaceutical development is complex and fraught with failure, to which even the large pharmaceutical companies can testify. Many industry analysts report how the established pharma R&D model has reached the end of the road, partially owing to companies' inability to successfully develop new drugs and partially due to consistent negative returns from lengthy programs. Two dominant factors, one internal and one external, decide the fate of these R&D teams: lack of focus and an inability to demonstrate a positive 'risk-benefit' ratio to Regulatory Authorities. In recent times, we have witnessed what one would have once said to be inconceivable: R&D facilities and laboratories – the so-called engine room of the pharmaceutical industry – of dominant players (read Pfizer, Astra Zeneca, GSK) have been down sized or shut down. These leading pharmaceutical companies decided to no longer rely on organic growth but instead to restructure their business model and to focus on product distribution and growth through M&A.

Yet at Clinuvel we hold the view that innovation is the long-term key success factor to differentiating one's pharmaceutical business. With the rise of generics, the powerlessness to enforce patents in emerging markets and the staving off of counterfeit producers, pharmaceutical development by larger established companies came under review. At the same time, once-thought larger markets in metabolic and cardiovascular diseases have come under pressure from local authorities and payers, seeking ways

of curtailing the purchase of branded costly pharmaceuticals. In other medical domains, orphan diseases and where treatment for medical conditions is lacking ('unmet medical need'), the need for innovated competence is critical for survival. Traditionally, pharmaceutical innovation was led by the US, EU and Switzerland. Now the playing field seems to be levelling out.

HISTORICAL PERSPECTIVE

The Clinuvel Board and management deliberated long during the Northern winter of 2005-2006 and we reached the conclusion that innovation in our case – despite the hazards and pitfalls – was nevertheless worth the effort and risk. We clearly saw an advantage of being a small but nimble organisation, not hampered by the hierarchical layers seen in larger pharmaceutical conglomerates. One may legitimately ask whether we were too confident in our abilities or too biased towards the properties of the melanocortin drug. To mitigate both risks, we obtained third party expert advice and engaged with the Regulatory Authorities in discussions to gauge the interest in melanocortins as a medical solution for a number of photo reactive skin diseases. Once the feedback proved positive, we set out to address the very two shortcomings identified in many other R&D teams: the lack of focus and inability to generate returns on investment. Let me expand on both in a more extensive and technical fashion.

The plan was well defined and current management raised A\$68M from October 2006 to March 2007, involving a number of European and Australian shareholders in support of this mono-focal approach. The mandate was to successfully develop a new class of drug, the linear melanocortin afamelanotide, or SCENESSE®. Fast-tracking forward to mid 2006, we managed to match the pharmaceutical characteristics of the drug to the clinical spectrum and biological profile of diseases and identified the highest clinical need for patients.

FOCUS ON KNOWLEDGE

The quality of technological advancement depends principally on the calibre of the professional team and aptitude of the collective group of professionals. Clinuvel formed a team of six Board members – whereby Directors were expected to perform hands-

on duties – attracted seven managers and a very select pool of staff with diverse knowledge. Charging all with specific tasks and evaluating progress, initially monthly, we built a core know-how around skin, pigmentation and pharmaceutical development, while financial discipline became central to our operational activities.

We paid particular attention to drug safety (short-term and long-term), regulatory requirements, end-user requirements, and risk management plans (RMP) to deal with unforeseen events. Drug safety requires much thinking, planning and follow up. Safety of pharmaceuticals is unlike general health and safety issues applicable in consumables. Hence, the 'safety' aspect of SCENESSE® received our daily attention. Issues such as pharmacovigilance (monitoring side effects and clinical reports), frequency of dosing, proper administration of the drug, interaction with other drugs, patient consent and information on the expected pharmacological aspects of the drug were only some of the issues which came with innovation.

REGULATORY ACTIVITIES

When it came to drug development, we anticipated from the outset that the European Medicines Agency (EMA) and Food and Drug Administration (FDA) would look much more closely at SCENESSE® than other drugs, given its status as a novel chemical entity (NCE). In Clinuvel's program, novelty came in five forms:

- a new operational team;
- a new drug;
- a new formulation;
- a new way of administration through a subcutaneous injection; and
- a 'new' community of physicians unfamiliar with the drug to be administered to untreated patients, those who had not found previous medical relief for their symptoms.

In discussion with the EMA and FDA, we developed a strategy which is now coming to its final phase in Europe, culminating in Clinuvel's first EMA filing of SCENESSE® for the treatment of erythropoietic protoporphyria (EPP).

When I assumed the role of CEO in December 2005, I knew that profound knowledge and unique expertise, together with sufficient data, would be expected from Clinuvel's groundbreaking program. With innovation came the responsibility of demonstrating not only that the drug would provide benefit to those thousands of patients, but also that the drug would not provoke undesired side effects. We have spent the past six years de-risking Clinuvel's development program on all fronts and, after years of treating patients and reviewing two decades of preclinical and clinical data, my Chief Scientific Officer and I are confident that SCENESSE® is a safe drug for human use. From repetitive animal models and human trials in more than 600 patients, as well as continuous long-term drug use (up to three years in some EPP patient populations), there is ample indication and compelling evidence that SCENESSE® activates the melanocyte in a controlled and safe manner to provide clinical photoprotection against UV and the visible spectrum of light. Additionally, we now see the first signs that SCENESSE® reduces the skin damage which patients have incurred from UV exposure (photodamage).

Those insightful shareholders who consciously chose to invest in Clinuvel to help develop a drug for select patient populations have borne patience whilst realising that there would be no short-cut or accelerated development times due to the innovative and unique properties of SCENESSE®. Slowly but surely we have seen adoption and acknowledgement of the Clinuvel program by the various Regulatory Agencies over the years. We remained alert, however, to the fact that acceptance of a concept was one positive thing, but ultimately quantitative proof of efficacy, alongside unambiguous demonstration of drug's safety, would be the two most decisive factors to obtain marketing approval (MAA or NDA). However, Clinuvel's lengthy development is benefiting all stakeholders; patients, physicians, Regulatory Authorities and the investment community. Clinuvel's teams find themselves at present at a penultimate point: we have completed the EPP program in Europe and Asia-Pacific, while we are in final preparation to present the scientific dossier in five modules to the EMA through a formal submission for MAA.

MARKET RISK

In part guided by my professional experience as a former surgeon and pharmaceutical professional, and in part dictated by business nous, I asked our team in 2006 to fulfil the most ambitious clinical goal conceivable: to gain global academic and clinical support from the very best physicians known in the fields of dermatology, gastro-enterology and internal medicine, the three areas of clinical focus relevant to the use of SCENESSE®. Although this ambition seemed somewhat obvious and theoretically simple, it hadn't been done before on such a scale.

In order to obtain the most valuable feedback on a novel program, and engage the best minds in these three fields of use, we selectively approached the heads of academia and research centres in 90 renowned hospitals, academic clinics and precincts globally. The feedback of the 'Ivy-League' academics would give the Clinuvel team a reasonable sense of the level of interest in this pharmaceutical product (ahead of market entry), as well as an inkling of the scientific critique to be expected from regulatory bodies. I can easily summarise the six years of intense dialogue and cooperation with these academics: initial scepticism and hesitation to consider a new product soon turned into positive opinion and, the past two years, into overwhelming support for the drug in erythropoietic protoporphyria (EPP, light disorder) and more recently into demand for the use of the drug in vitiligo (NSV, depigmentation disorder).

It has been an enormous undertaking to maintain a continuous dialogue, both in terms of high level scientific knowledge and engagement and in terms of coordinating the sheer number of expert centres worldwide. We needed to ensure that all critique was duly considered, verified, debated, substantiated and taken onboard or justifiably dismissed. Numerous global scientific and protocol meetings were organised in various continents, as well as frequent on-site visits and telephone-calls with the dozens of leading experts in Europe, US and Asia Pacific. Our undertakings resulted in a high recognition among the academic community of

our work and efforts to develop a photoprotective drug. Our annual scientific meetings (ASCEM), the global dermatology conferences where reference is made to afamelanotide or SCENESSE®, the Photodermatology meeting in Geneva in September and the first symposium on alpha-MSH during the European Association of Dermatology and Venereology (EADV) meeting in Lisbon in October are good examples of the level of interest in the product and Clinuvel's work.

Led by our Chief Scientific Officer, Dr Hank Agersborg, our scientific and regulatory team ventured out to three continents to learn, in depth, the patients' medical needs and visited patient associations and conferences globally to gain valuable feedback. Similar to physicians, the initial stance by patients and their support groups was one of scepticism but this changed and has grown into widespread support, starting from the first clinical data in 2008 in EPP as the results became known within the patient community. Better put, the most convincing support for a novel pharmaceutical product comes primarily from patients who have been repetitively exposed to the drug. The word spread fast, and we learned early on through the physician and patient experiences in the EPP program that the decision to develop SCENESSE® for the smaller ('orphan') disorder EPP had been justified from a clinical perspective.

We looked ahead to identify and address the market risk to which the Company could become exposed post-approval in Europe. We sought to establish an efficient way to gauge the most effective and easiest penetration route for the product. Significant barriers to entry in this sector would include uptake by physicians, national reimbursement and patient acceptance. To pre-empt and counteract these obstacles ahead of time, we asked for feedback from leading clinical experts, patient groups and insurers worldwide. This strategy played out well and assessment of the market uptake was the so-called 'compassionate program' whereby Clinuvel had agreed with Regulatory Authorities and clinical centres to make the drug available free of charge for one year after the EPP trials. Consequently, the percentage uptake by

clinical trial participants, patients, gave us a precise indication over the past 24 months of the expected demand for the drug. This has led to Clinuvel obtaining valuable market information on the product such as patient compliance, dose frequency, patient visits and feedback longer term on drug use.

From here we can further extrapolate accurate market information on clinical demand and use for SCENESSE® from the EPP community of physicians and patients. This is now being repeated with the vitiligo population worldwide. For a Company of the size of Clinuvel it has not been a negligible undertaking and we are proud of our achievement thus far in minimising market risk post-approval.

ANNUAL REVIEW AND PREVIEW

Clinuvel's Board welcomed Mr Elie Ishag earlier this year as its latest member, and all members have worked, at times intensely, to support management in daily tasks. I thank them for all the time devoted to the Company.

At the time of writing the results of CUV030 (US EPP trial) and CUV029 (EU EPP Trial) are being processed. The lengthy analyses are pivotal for Clinuvel's first-ever regulatory dossier to obtain European marketing authorisation, the right to distribute the drug in EU. The work behind the scenes has been impressive, and I look with astonishment and pride to my teams.

We look back on a very successful year where we distributed SCENESSE® in Italy, and the Company generated its first US\$1,000,000 in sales. Many stakeholders would have deemed this unthinkable one year ago.

Looking ahead, after our European submission, the time will come for the Clinuvel Board to address the commercial distribution of the drug. All conceivable distribution options remain open, and I am confident that for both patients and Clinuvel's shareholders an optimum distribution strategy will be adopted. Despite the uncertainty in global markets, our challenge is to continue positioning Clinuvel as a Company which will have delivered on its results. Since we have not taken any shortcuts in the development of the drug SCENESSE® and genuine benefits have been delivered to patients, value creation will flow from the authenticity of the drug.

Thank you for your support,



Philippe Wolgen
Managing Director

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DIRECTORS' REPORT

The Directors of the Board present their report on the company and its controlled entities for the financial year ended 30 June 2011 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. H.P.K. Agersborg (Deputy Chair, Chief Scientific Officer)
- Dr. P.J. Wolgen (Managing Director, Chief Executive Officer)
- Mrs. B.M. Shanahan (Non-Executive)
- Dr. R. Aston (Non-Executive, resigned September 1 2010)
- Mr. L.J. Wood (Non-Executive)
- Mr. E. Ishag (Non-Executive, joined Board February 1, 2011)

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

INFORMATION ON DIRECTORS

DR. ROGER ASTON (TO SEPTEMBER 1 2010)

Non-Executive Director

Chairman of the Audit and Risk Committee

Qualifications: BSc (Hons) PhD

Shares in Clinuvel: 10,823

Dr Aston has more than 20 years experience in the pharmaceutical and biotechnology industries and has been closely involved in organisational restructuring of companies and in improving effectiveness and productivity. In the past three years Dr Aston has served as Chair of Ascent Pharmahealth Limited (ASX:APH, 2008-2010) and is also serving CEO of Mayne Pharma Group Limited (formerly Halcyon Pharmaceuticals Ltd) (ASX: MYX, 2007-current).

His previous positions include director of pSivida Ltd, Cambridge Antibody Technology Limited (UK), Chairman of Cambridge Drug Discovery Limited (UK) (now BioFocus plc), founder and CEO of Biokine Technology Ltd (UK) prior to its acquisition by the Peptech Group as well as CEO of Peptech Limited, founder and CEO of UK-based pSiMedica Limited, CEO of pSiOncology, Dr Aston was Executive Chairman of Clinuvel until late 2007.

DR. PHILIPPE J. WOLGEN (JOINED BOARD 2005)

Managing Director and Chief Executive Officer since December 2005
Non-voting member of the Audit and Risk committee and the Remuneration and Nomination committee

Qualifications: MBA, MD

Shares in Clinuvel: 9,500

Options over shares in Clinuvel: 600,000

Conditional Performance Rights to shares: 900,000

Having been recognised for his strategic mindset and meticulous business execution, Dr Wolgen has brought to the company his international finance experience and professional contacts to European capital markets. As a former equity analyst, his in-depth analysis and expertise of the life science sector has 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 A\$68 million in 2006-2007 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 surgeon, Dr Wolgen holds an MD from the University of Utrecht, the Netherlands.

MRS. BRENDA M. SHANAHAN (JOINED BOARD 2007)

Non-Executive Director

Chair of the Audit and Risk Committee (since September 1, 2010)

Qualifications: BComm, FAICD, ASIA

Shares in Clinuvel: 42,007

Options over shares in Clinuvel: 85,000

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, a non-Executive Director of DMP Asset Management, a non-Executive Director of Challenger Limited (ASX:CGF) and a Director of the Kimberley Foundation of 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.

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

Executive Director, Chief Scientific Officer since December 2005

Member of the Remuneration and Nomination Committee (since March 2011)

Qualifications: BSc, PhD

Shares in Clinuvel: 92,111

Options over shares in Clinuvel: 150,000

Conditional Performance Rights to shares: 450,000

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

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

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

Options over shares in Clinuvel: 45,000

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 final stages of the development program Mr McLiesh is involved in formulating the commercial phase of Clinuvel.

MR. LAWRENCE JOHN (JACK) WOOD (JOINED BOARD 2008)

Non-Executive Director

Chair of the Remuneration and Nomination Committee

Qualifications: BComm

Shares in Clinuvel: 40,000

Options over shares in Clinuvel: 35,000

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

Positions held by Mr Wood during his career include Chairman of EnGene Corporation 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

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 Practising Accountant. Joined Clinuvel Pharmaceuticals Limited November 2005 and became Chief Financial Officer of the Company in 2006.

MEETING OF DIRECTORS

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

| DIRECTOR | BOARD | | AUDIT & RISK COMMITTEE | | REMUNERATION & NOMINATION COMMITTEE | |
|----------------------|-------|---|------------------------|---|-------------------------------------|---|
| | A | B | A | B | A | B |
| Dr. R. Aston | 2 | 1 | 1 | 1 | - | - |
| Dr. H.P.K. Agersborg | 6 | 6 | - | - | 1 | 1 |
| Mrs. B.M. Shanahan | 6 | 6 | 1 | 1 | - | - |
| Mr. S.R. McLiesh | 6 | 6 | 2 | 2 | 3 | 3 |
| Dr. P.J. Wolgen | 6 | 6 | 2 | 0 | 3 | 1 |
| Mr. L.J. Wood | 6 | 6 | - | - | 3 | 3 |
| Mr. E. Ishag | 2 | 2 | - | - | - | - |

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

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

PRINCIPAL ACTIVITIES

The principal activities of the consolidated entity during the financial year were to develop its leading drug candidate SCENESSE® (afamelanotide) for the treatment of a range of severe skin disorders. Clinuvel's pioneering work aims at preventing the 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

No dividends were paid or declared during the financial year.

REVIEW OF OPERATIONS

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

| CONSOLIDATED | 2011 | 2010 | CHANGE |
|--|----------------|----------------|--------|
| Revenues | \$2,276,064 | \$1,845,720 | 23% |
| Net (Loss) before income tax expense | (\$11,409,089) | (\$11,521,040) | 1% |
| Profit (Loss) after income tax expense | (\$11,409,089) | (\$11,521,040) | 1% |
| Basic earnings per share - cents per share | (37.6) | (38.0) | 1% |
| Net tangible assets backing per ordinary share | \$0.54 | \$1.00 | (46%) |
| Dividends | Nil | Nil | Nil |

Note: Clinuvel does not operate individual segments.

The group result for the year ending 30 June 2011 was an \$11.409 million loss, compared to a \$11.521 million loss for the prior financial year, a decrease in the loss of 1%. The group comprises a balance sheet of \$16.408 million in net assets at 30 June 2011 compared to \$26.426 million at 30 June 2010. Current liabilities increased 22 % to \$3.716 million. Monthly average cash spend was \$0.929 million for the year compared to \$1.114 million for the 2009/10 year.

Research and development accounted for 58% of the group's total expense result for 2010/11, compared to 63% for the 2009/10 year. Research and development expenditures, comprising clinical study costs, drug delivery research and manufacture, toxicity studies, regulatory fees and research and development-specific overheads such as personnel, were \$7.987 million in 2011 compared to \$8.380 million in 2010. Clinical study costs remained relatively unchanged from \$2.553 million in 2010 to \$2.560 million in 2011, reflecting the continuing efforts in completing the global trials in EPP and the ongoing Phase II trial in AK. Expenditures from the drug delivery program decreased 15% from \$2.981 million in 2010 to \$2.520 million in 2011. 2011 was a period whereby further process improvement and qualification continued but with a lower drug product supply requirements to meet ongoing clinical trial supply when compared to the 2010 year. More R&D-specific personnel were engaged during 2010/11 to service the expanding research and development programs resulting in a 12% increase in research and development overheads from \$1.888 million in 2010 to \$2.109 million in 2011. The completion of long term toxicity studies into the safety profile of SCENESSE® to support regulatory filings in 2011 has resulted in a 17% decrease in toxicity and regulatory costs, from \$0.958 million to \$0.797 million.

Marketing activities in the company decreased by \$0.07 million to \$0.63 million in 2011 (10% decrease) primarily due to the completion of a comprehensive market pricing study in 2010.

The result from general operations was \$4.918 million in 2011 compared to \$4.384 million in 2010, a 12% increase. General operations comprised 36% of the group's total expense result for 2011 compared to 33% in 2010. The main difference year-on-year is the valuation of share based payments issued to executive directors during the year, contributing to a \$0.561 million increase when compared to 2010. For 2011, a gain of \$1.016 million has been recorded in revaluing financial assets held at fair value compared to a gain of \$2.295 million for the same period last year. The gain reflects the improvement in values of income securities investments held but at a lower rate of improvement to 2010. In contrast, the liquidation of certain income securities has shown a loss of \$0.683 million (2010: \$1.047 million).

Interest received on cash and financial assets held decreased by 20% from \$1.474 million in 2010 to \$1.184 million in 2011. The drop in revenues is a result of the gradual decline in cash reserves and financial assets for working capital deployment. Sales receipts from the supply of SCENESSE® implants to EPP patients in Italy under a special access scheme resulted in revenues of \$1.041 million during 2011 (2010: \$0). For the 2010/11 year the group started with \$27.003 million in cash and financial assets and finished with \$17.499 million. In contrast the group started the 2009/10 year with \$37.754 million. Additionally, increased expenditures in currencies other than the Australian dollar resulted in currency gains of \$0.05 million (2010: \$0.372 million) and is reflected as revenue.

At 30 June 2011 basic earnings per share were -\$0.376 on 30,381,706 issued ordinary shares. This is compared to basic earnings per share of -\$0.38 as at 30 June 2010 on 30,318,867 issued ordinary shares (restated to a post consolidated basis to reflect the 10:1 share consolidation of the company's issued ordinary shares, approved by Shareholders at the company's Annual General Meeting in November 2010).

The advancement in the group's clinical and regulatory activities in preceding years to commercialise SCENESSE® was matched by a number of significant achievements in 2010/11. The major highlights include:

- The granting of US patent 7,745,408 which recognises the potential for drugs called melanocortins – including Clinuvel's drug SCENESSE® (afamelanotide) – to protect fair skinned individuals from ultraviolet (UV) if they possess a genetic variation in the melanocortin-1 receptor (MC1R).
- Entering an agreement with SurModics Inc, a US-based leading provider of drug delivery technologies to the healthcare industry, for the manufacture of the novel SCENESSE® formulation. Under this exclusive arrangement, SurModics will commercially manufacture and supply Clinuvel with the unique product for an indefinite period.
- The announcement of positive results from a 12 month, multicenter, randomised, double-blind, placebo-controlled Phase III crossover study of SCENESSE® (CUV017) in patients diagnosed with erythropoietic protoporphyria (EPP). In one Australian and seven European centres (n=91), SCENESSE® was evaluated for its ability to provide preventative pharmaceutical therapy in EPP patients who are known to suffer from phototoxic reactions following exposure to sun and light (>400 nanometres wavelength). In an analysis of the total number of days (frequency distribution) on which patients experienced pain in the specific pain severity categories (severe, moderate, mild and none), a significant reduction of frequency was observed in patients on active drug [$p=0.0023$]. Characteristic to EPP, the majority of phototoxic reactions occurred during spring and summer.
In analysing the average pain severity experienced by the total number of patients, the assessment of all individual daily pain scores was significantly lower in patients receiving SCENESSE® compared to those receiving placebo [$p=0.0017$].
- The announcement and subsequent commencement of the International SCENESSE® Pilot Repigmentation Evaluation (INSPIRE) program. SCENESSE® is being evaluated as a combination therapy with narrowband UVB light therapy in two clinical studies (CUV101 in Europe and CUV102 in the US) in patients with nonsegmental vitiligo, a common pigmentary disorder affecting over 45 million individuals globally. The FDA gave approval for trials to commence in March 2011.
- Provision of positive guidance by the US Food and Drug Administration (FDA) on Clinuvel's program for EPP following a meeting with the FDA's Division of Dermatology and Dental Products (DDDP). In the meeting, held in October 2010, the FDA provided clear guidance on the data package required to file a New Drug Application (NDA) for SCENESSE®. Based on the preclinical and clinical results presented at the meeting, the FDA did not raise any safety concerns for afamelanotide. An approved NDA allows sponsoring companies to market drugs in the US.
- Granting of orphan drug designation (ODD) to SCENESSE® by Australia's Therapeutic Goods Administration (TGA) for erythropoietic porphyrias (EPP and CEP), two rare genetic diseases causing skin intolerance to light. The Australian ODD provides Clinuvel with a waiver of all registration fees for SCENESSE® in the orphan indications in Australia. ODD status also enables priority evaluation for the registration of SCENESSE® with the TGA, thus expediting the approval process. The TGA is the fourth global regulator to grant SCENESSE® ODD status after similar recognition from the European Medicines Agency, SwissMedic and the US FDA in 2008.
- Completion of a 10:1 consolidation of the company's ordinary shares (ASX:CUV) approved by shareholders at the 2010 Annual General Meeting on 10th November.
- Hosting the company's third Annual Scientific & Clinical Excellence Meeting (ASCEM III) in Switzerland in January. The nine ASCEM III invitees and delegates – global leaders and experts in photomedicine, dermatology and molecular biology – convened in Luzern during a two-day seminar to present and discuss the advances in their field of expertise.
- The appointment of Mr Elie Ishag as a Non-Executive Director to the Board of Directors. Mr Ishag is a London based entrepreneur with over 40 years' commercial experience.
- The announcement that the company held a constructive Pre-Submission Meeting with the European Medicines Agency (EMA) on May 5 at which the EMA agreed with Clinuvel's tentative dossier submission period of the last quarter of 2011 for the orphan designated disease erythropoietic protoporphyria (EPP). After reviewing the proposed content of the registration dossier for afamelanotide (SCENESSE®), the EMA acknowledged that Clinuvel would meet all filing requirements to file SCENESSE® under the EMA's centralised procedure (CP). EMA's approval through the CP would allow Clinuvel to market afamelanotide under the brand name SCENESSE® in all 27 European Union member states as well as Norway, Iceland and Liechtenstein.

- The granting of Australian patent 2005269244 for the exclusive use and manufacture of formulations of alpha melanocyte stimulating hormone (alpha-MSH) analogues until early 2025. Patent 2005269244 covers the use of alpha-MSH analogue formulations to induce melanogenesis and prevent UV radiation induced damage in humans, as well as the manufacture of medicaments and the use of pharmaceutical compositions containing alpha-MSH analogues for these purposes.
- The announcement that the company had recorded its first \$1 million in sales of SCENESSE® from the Italian 648/96 program for erythropoietic protoporphyria. Since commencing a special access 648/96 scheme SCENESSE® has been distributed to approximately 47 patients in Italy to treat EPP, a severe genetic disorder designated as an 'orphan' disease. Throughout the treatment period all patients have been followed up by EPP specialists and, significantly, no serious drug-related adverse events have been recorded.

2011/12 will see the company continue to focus on announcing final study results to its trials into EPP and to generate the optimal data required to complete an application for marketing authorisation to submit to the EMA in late 2011.

The outlook for 2011/12 includes additional research activities on SCENESSE® in areas of acute medical need as the scientific community continues to gather knowledge on molecular biology, UV and pigmentation. Of particular relevance is Clinuvel's INSPIRE program for vitiligo, the first results from which are expected in 2011/12.

The company has maintained a consistent and better than anticipated cash burn over the 2010/11 period. With the anticipated filing of SCENESSE® with the EMA, dossier preparation and commercialisation initiatives, there will be ongoing further pressure on cash burn. The company will continually monitor the situation moving forward to ensure the availability of necessary financial resources.

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 & EXPECTED RESULTS

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

ENVIRONMENTAL REGULATION & PERFORMANCE

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

INDEMNIFICATION & INSURANCE OF DIRECTORS & OFFICERS

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

The company has paid premiums to insure each of the Directors against liabilities for costs and expenses incurred by them in defending any legal proceedings arising of their conduct while acting in the capacity of Director of the company, other than conduct involving wilful breach of duty in relation to the company. The cost of the aforementioned insurance premium was \$56,690 (2010: \$54,064. The premium for 2011 is 14 months duration compared to 12 months duration for 2010.).

DIRECTORS' BENEFITS AND INTEREST IN CONTRACTS

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

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

REMUNERATION REPORT

EXPLANATORY NOTE TO PAGE 27 TO 28 SHARE BASED PAYMENT REMUNERATION

On pages 27 to 28, an accounting calculation to value share based payments is disclosed in the remuneration tables of the company's Directors and specified Executives for the years ended 30 June 2011 and 30 June 2010. As these values are accounting values the Directors and specified Executives may not derive a financial benefit from these amounts.

Whilst the options held by Directors and specified Executives have an exercise price of \$8.60 and an expiry date of 9 February 2012 (excepting Mr. L.J. Wood whose options expire 18 November 2013 at an exercise price of \$2.75) no Director received a benefit during the current or previous financial year.

Of the performance rights, the only benefit derived by the Executive Directors and specified Executives during the current or previous financial year were those performance rights which vested at nil exercise price and disclosed on page 32. The value of all performance rights and options granted, exercised and lapsed during the financial year is detailed in pages 29 to 31.

PRINCIPLES USED TO DETERMINE THE NATURE AND AMOUNT OF REMUNERATION

The Board has overseen a reward framework:

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

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

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

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

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

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

NON-EXECUTIVE REMUNERATION

Under the company's Constitution, the maximum aggregate remuneration available for division among the Non-Executive Directors is to be determined by the shareholders in a General Meeting. The maximum aggregate is currently fixed at \$400,000. This amount (or some part of it) is to be divided among the Non-Executive Directors as determined by the Board. Non-Executive Directors' base fees are presently \$50,000 per annum 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. Director's 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. Certain Non-Executive Directors were previously issued options under the Company's Share Option Plan.

There are no further retirement benefits, other than statutory superannuation entitlements, offered to Non-Executive Directors.

EXECUTIVE REMUNERATION

Remuneration packages for Executives include:

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

Base pay, including superannuation, is reviewed annually by the Remuneration and Nomination Committee to ensure the Executive's pay is competitive in international markets. There are no guaranteed base pay increases in any Executives' contracts. Health insurance benefits and living away from home allowances are offered to Executives under specific circumstances.

The CEO and CSO have their own individual short-term incentive component to their Executive remuneration. Appropriate targets are set by the Remuneration and Nomination Committee. The targets can relate to either the clinical and regulatory development program or to corporate and associated activities and are generally, but not always, evaluated for achievement, reviewed and reset (if required) annually. Payment of short-term incentives is made in the financial year following the year of achievement. The methods used by the Remuneration and Nomination Committee to assess Board performance is disclosed in the Corporate Governance Protocol. The remaining Executives receive discretionary short term incentives, evaluated annually against targets set at each performance review.

SERVICE AGREEMENTS

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

Remuneration and other terms of employment for the Chief Executive Officer and Chief Scientific Officer are formalised by service agreements determined by the Remuneration and Nomination Committee. The agreements provide for base salary, 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 Executive Directors and key management personnel are:

- Dr. Wolgen's (Managing Director and Chief Executive Officer) term of employment is 3 years from 18 May 2010, his base salary exclusive of retirement benefits for the year to 30 June

2011 is \$597,770 and his service agreement is with the wholly-owned Swiss subsidiary entity. Notice of termination to be provided by the company is set at 12 months of base salary provided the termination is not for a material breach of the agreement. Dr. Wolgen is required to provide 6 month's notice.

- Dr. Agersborg (Director & Chief Scientific Officer) is on a 12 month rolling contract and his base salary inclusive of superannuation for the year ending 30 June 2011 is \$304,888. Notice of termination to be provided by the company is set at 3 months of base salary provided the termination is not for a material breach of the agreement. Dr. Agersborg does not require providing a specified notice period.
- Dr. Wright's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2011 is \$206,059. Notice of termination to be provided by the company is set at 3 months of base salary provided the termination is not for a material breach of the agreement. Dr. Wright requires providing 3 month's notice.
- Mr. Keamy's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2011 is \$174,920. Notice of termination to be provided by the company is set at 1 month of base salary provided the termination is not for a material breach of the agreement. Mr. Keamy requires providing 1 month's notice.

SHARE-BASED REMUNERATION

The consolidated entity has an ownership based scheme for Directors, 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.

SHARE OPTIONS

Options issued prior to 25 January 2007 were issued in accordance with the Corporations Act. Options issued after this date fall under the Clinuvel Employee Share Option Plan, approved by Shareholders at a Shareholder meeting on 25 January 2007. All share options issued prior or after 25 January 2007 converts to one ordinary share of the consolidated entity. All options are issued for nil consideration, there are no voting rights attached to the option and they can be exercised any time from the date of vesting to the date of expiry. They are non-transferable and not listed on the ASX.

For those options issued prior to 25 January 2007 the exercise price is based on the weighted average price at which the company's shares were traded on the ASX during the week up to and including the date of grant. For those options issued after 25 January 2007 the exercise price is based on the weighted average price at which the company's shares were traded on the ASX 20 business days leading up to the date of grant, plus 10%.

The number of options granted is subject to approval by the Remuneration and Nomination Committee and by Shareholders at General Meetings. Options currently issued have specific terms and conditions, from 12 month restriction periods for the number of options to vest, to monthly restriction periods over 48 months, and to the satisfaction of performance objectives set by the Directors of the consolidated entity. The Company does not intend to issue further share options under this Plan.

The long-term incentives are provided to Executive Directors and certain employees via the Clinuvel Employee Share Option Plan (no further issues of options to be made under this Plan) and the Clinuvel Conditional Rights Plan. See page 15 for further information.

DETAILS OF REMUNERATION

The key management personnel of Clinuvel Pharmaceuticals Ltd are those Executive Directors disclosed in the Information of Directors section to this report and the following specified Executives:

DR. D.J. WRIGHT

Vice President, Scientific Affairs

MR. D.M. KEAMY

Chief Financial Officer and Company Secretary

REMUNERATION OF THE DIRECTORS OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2011

| Director | SHORT-TERM EMPLOYMENT BENEFITS | | | POST EMPLOYMENT BENEFITS | SHARE BASED PAYMENTS ² (ACCOUNTING CHARGE ONLY) | | Total |
|----------------------|--------------------------------|------------|--------------------|--------------------------|--|------------------|--------------------|
| | Salary | Cash Bonus | Other ¹ | | Perf Rights | Options | |
| Dr. H.P.K. Agersborg | \$304,388 | - | - | - | \$254,545 | \$60,534 | \$619,467 |
| Mr. S.R. McLiesh | \$73,395 | - | - | \$6,605 | - | \$17,987 | \$97,987 |
| Dr. R. Aston | \$9,939 | - | - | \$895 | - | \$35,283 | \$46,117 |
| Dr. P.J. Wolgen | \$597,770 | - | \$65,618 | \$7,347 | \$494,715 | \$242,134 | \$1,407,584 |
| Mrs. B.M. Shanahan | \$57,339 | - | - | \$5,161 | - | \$37,192 | \$99,692 |
| Mr. L.J. Wood | \$58,750 | - | - | - | - | \$3,364 | \$62,114 |
| Mr. E. Ishag | \$20,833 | - | - | - | - | - | \$20,833 |
| Total | \$1,122,414 | - | \$65,618 | \$20,008 | \$749,260 | \$396,494 | \$2,353,794 |

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

² As these values are accounting values the Director may not derive any financial benefit from these amounts. Whilst the options held by Directors have an exercise price of \$8.60 and an expiry date of 9 February 2012 (excepting Mr. L.J. Wood whose options expire 18 November 2013 at an exercise price of \$2.75), no Director received a benefit during the current or previous financial year.

Of the performance rights, the only benefit derived by the Executive Directors during the current or previous financial year were those performance rights which vested at nil exercise price and disclosed on page 32. The value of all performance rights and options granted, exercised and lapsed during the financial year is detailed in pages 29 to 31.

REMUNERATION OF THE SPECIFIED EXECUTIVES OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2011

| | SHORT-TERM EMPLOYMENT BENEFITS | | | POST EMPLOYMENT BENEFITS | SHARE BASED PAYMENTS ⁴ (ACCOUNTING CHARGE ONLY) | | Total |
|-----------------|--------------------------------|-----------------|--------------------|------------------------------|---|-----------------|------------------|
| | Salary | Cash Bonus | Other ³ | Superannuation Contributions | Perf Rights | Options | |
| Dr. D.J. Wright | \$190,860 | \$22,427 | \$16,471 | \$15,199 | \$64,926 | \$41,965 | \$351,848 |
| Mr. D.M. Keamy | \$160,542 | \$22,427 | \$38,610 | \$14,378 | \$26,045 | \$28,345 | \$290,347 |
| Total | \$351,402 | \$44,854 | \$55,081 | \$29,577 | \$90,971 | \$70,310 | \$642,195 |

³ 'Other' includes health insurance, housing and other allowances to facilitate relocation of specified Executives.

⁴ As these values are accounting values the specified Executive may not derive any financial benefit from these amounts.

Whilst the options held by the specified Executives have an exercise price of \$8.60 and an expiry date of 9 February 2012, no specified Executive received a benefit during the current or previous financial year. Of the performance rights, the only benefit derived by the specified Executives during the current or previous financial year were those performance rights which vested at nil exercise price and disclosed on page 32. The value of all performance rights and options granted, exercised and lapsed during the financial year is detailed in pages 29 to 31.

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

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

⁵ 'Other' includes health insurance and other allowances subject to fringe benefits tax.

⁶ 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.

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

| | SHORT-TERM EMPLOYMENT BENEFITS | | | POST EMPLOYMENT BENEFITS | SHARE BASED PAYMENTS ⁷ (ACCOUNTING CHARGE ONLY) | | Total |
|-----------------|--------------------------------|-----------------|-----------|------------------------------|---|-----------------|------------------|
| | Salary | Cash Bonus | Allowance | Superannuation Contributions | Perf Rights | Options | |
| Dr. D.J. Wright | \$182,800 | \$20,000 | - | \$14,461 | \$72,232 | \$41,965 | \$331,458 |
| Mr. D.M. Keamy | \$154,350 | \$20,000 | - | \$13,939 | \$36,656 | \$28,345 | \$253,290 |
| Total | \$337,150 | \$40,000 | - | \$28,400 | \$108,888 | \$70,310 | \$584,748 |

⁷ As these values are accounting values, the specified Executives 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 YEAR ENDED 30 JUNE 2011**

| | 2011 | | 2010 | |
|----------------------|-------|-------------|-------|-------------|
| | Fixed | Performance | Fixed | Performance |
| Dr. P.J. Wolgen | 87% | 13% | 75% | 25% |
| Dr. H.P.K. Agersborg | 84% | 16% | 84% | 16% |
| Dr. D.J. Wright | 75% | 25% | 70% | 30% |
| Mr. D.M. Keamy | 83% | 17% | 76% | 24% |

CONDITIONAL PERFORMANCE RIGHTS

All performance rights issued fall under the Clinuvel Conditional Rights Plan, available to eligible employees of the company. Any issue of rights to executive and Non-Executive Directors requires shareholder approval in accordance with ASX Listing Rules.

All rights converts to one ordinary share of the consolidated entity, are issued for nil consideration, have no voting rights, are non-transferable and are not listed on the ASX. They can be converted to ordinary shares at any time once the vesting conditions attached to the rights have been achieved, whereby they will be held by a Scheme Trustee on behalf of the eligible employee

for up to 7 years. The eligible employee can request for shares to be transferred from the Scheme Trust after 7 years or at an earlier date if the eligible employee is no longer employed by the company or all transfer restrictions are satisfied or waived by the Board in its discretion.

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

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

| ENTITY | NUMBER OF SHARES UNDER OPTIONS* | EXERCISE PRICE | VALUE PER OPTION ON GRANT DATE | CLASS | GRANT DATE | VESTED & EXERCISABLE DATES | EXPIRY DATE |
|----------|---------------------------------------|-------------------|--------------------------------------|----------|---------------|-------------------------------|-------------|
| Clinuvel | 1,136,000 | \$8.60 | \$2.46 | Ordinary | 09/02/2007 | monthly over 48 periods | 09/02/2012 |
| | | \$8.60 | \$2.20 | | | 31/12/2007 | |
| | | \$8.60 | \$2.30 | | | 09/02/2008 | |
| | | \$8.60 | \$2.60 | | | 31/12/2009 | |
| | | \$ 8.60 | \$2.40 | | | 09/02/2009 | |
| Clinuvel | 35,000 | \$2.75 | \$0.40 | Ordinary | 18/11/2008 | 18/11/2008 | 18/11/2013 |
| | | \$2.75 | \$0.50 | | | 18/11/2009 | |
| | | \$2.75 | \$0.50 | | | 18/11/2010 | |

* Restated to post-consolidation amounts (10:1 share consolidation approved at November 2010 AGM)

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

| ENTITY | NUMBER OF RIGHTS* | TRANCHE NO | VALUE PER RIGHT ON GRANT DATE | CLASS | GRANT DATE | VESTED & EXERCISABLE DATES |
|----------|-------------------|------------|-------------------------------|----------|------------|----------------------------|
| Clinuvel | 10,000 | 1 | \$2.00 | Ordinary | 16/10/2009 | 17/12/2009 |
| Clinuvel | 9,750 | 2 | \$2.00 | Ordinary | 16/10/2009 | 13/7/2010 |
| Clinuvel | 9,500 | 2 | \$1.70 | Ordinary | 07/01/2010 | 13/7/2010 |
| Clinuvel | 27,500 | 3 | \$2.00 | Ordinary | 16/10/2009 | - |
| Clinuvel | 17,750 | 4 | \$2.00 | Ordinary | 16/10/2009 | - |
| Clinuvel | 750 | 4 | \$1.70 | Ordinary | 07/01/2010 | - |
| Clinuvel | 39,000 | 5 | \$2.00 | Ordinary | 16/10/2009 | - |
| Clinuvel | 2,250 | 5 | \$1.70 | Ordinary | 07/01/2010 | - |
| Clinuvel | 118,250 | 6 | \$2.00 | Ordinary | 16/10/2009 | - |
| Clinuvel | 3,750 | 6 | \$1.70 | Ordinary | 07/01/2010 | - |
| Clinuvel | 10,000 | 8 | \$1.70 | Ordinary | 07/01/2010 | 07/04/2010 |
| Clinuvel | 450,000 | 9 | \$1.04 | Ordinary | 25/11/2010 | 24/05/2011 |
| Clinuvel | 186,667 | 10 | \$1.04 | Ordinary | 25/11/2010 | - |
| Clinuvel | 149,167 | 11 | \$1.04 | Ordinary | 25/11/2010 | - |
| Clinuvel | 149,167 | 12 | \$1.04 | Ordinary | 25/11/2010 | - |
| Clinuvel | 149,167 | 13 | \$1.04 | Ordinary | 25/11/2010 | - |
| Clinuvel | 149,167 | 14 | \$1.04 | Ordinary | 25/11/2010 | - |
| Clinuvel | 116,665 | 15 | \$1.04 | Ordinary | 25/11/2010 | - |

* Restated to post-consolidation amounts (10:1 share consolidation approved at November 2010 AGM)

**SHARES PROVIDED UPON EXERCISE OF OPTIONS AND RIGHTS
DETAILS OF SHARES ISSUED DURING THE FINANCIAL YEAR AS A RESULT OF EXERCISE OF RIGHTS**

| ENTITY | NUMBER OF SHARES ISSUED* | AMOUNT PAID FOR SHARES | CLASS |
|----------|--------------------------|------------------------|----------|
| Clinuvel | 62,250 | Nil\$ | Ordinary |

* Restated to post-consolidated amounts

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 2011 and 30 June 2010.

FURTHER INFORMATION - SHARE-BASED COMPENSATION

| | A | B | C | D |
|----------------------|--|---------------------|------------------------|---------------------|
| | % of Remuneration consisting of Options and Rights | Value at Grant Date | Value at Exercise Date | Value at Lapse Date |
| Dr. H.P.K. Agersborg | 50.9% | 254,545 | - | - |
| Dr. R. Aston | 76.5% | - | - | 214,647 |
| Mr. S.R. McLiesh | 18.4% | - | - | - |
| Dr. P.J. Wolgen | 52.3% | 494,715 | - | - |
| Mrs. B.M. Shanahan | 37.3% | - | - | - |
| Mr. L. J. Wood | 5.4% | - | - | - |
| Mr. E. Ishag | - | - | - | - |
| Dr. D.J. Wright | 11.9% | - | - | - |
| Mr. D.M. Keamy | 9.8% | - | - | - |

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

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

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

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

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

Performance Rights were priced using a binomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the pricing model is assumed to be the yield on 2 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

ADDITIONAL INFORMATION ON OPTIONS ISSUED TO DIRECTORS AND KEY MANAGEMENT PERSONNEL

* ALL OPTIONS AND CONDITIONAL RIGHTS RESTATED TO A POST-CONSOLIDATED BASIS

| | OPTIONS VESTED DURING THE YEAR – 2011 | OPTIONS VESTED DURING THE YEAR – 2010 | OPTIONS GRANTED DURING THE YEAR - 2011 | OPTIONS GRANTED DURING THE YEAR - 2010 | RIGHTS VESTED DURING THE YEAR – 2011 | RIGHTS VESTED DURING THE YEAR – 2010 | RIGHTS GRANTED DURING THE YEAR - 2011 | RIGHTS GRANTED DURING THE YEAR - 2010 |
|----------------------|---|---|--|--|--|--|---|---|
| Dr. H.P.K. Agersborg | - | - | - | - | 150,000 | - | 450,000 | - |
| Dr. R. Aston | - | - | - | - | - | - | - | - |
| Mr. S.R. McLiesh | - | - | - | - | - | - | - | - |
| Dr. P.J. Wolgen | - | - | - | - | 300,000 | - | 900,000 | - |
| Mrs. B.M. Shanahan | - | - | - | - | - | - | - | - |
| Mr. L.J. Wood | 11,667 | 11,667 | - | - | - | - | - | - |
| Mr. E. Ishag | - | - | - | - | - | - | - | - |
| Dr. D.J. Wright | 10,208 | 17,500 | - | - | 5,000 | 5,000 | - | 87,500 |
| Mr. D.M. Keamy | 7,292 | 12,500 | - | - | 4,000 | 4,000 | - | 40,000 |

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 / RIGHTS | | | | | | |
|----------------------|-------|-----------|------------------|---------|--------|-----------|-----------------|--|--|
| | Paid | Forfeited | Year Granted | Type | 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 | 100% | 0% | 2010/11 | - | - |
| | | | 2010/11 | Rights | 0% | 0% | No limitation | - | \$312,000 |
| Dr. P.J. Wolgen | 0% | 0% | 2010/11 | Rights | 100% | 0% | 2010/11 | - | - |
| | | | 2010/11 | Rights | 0% | 0% | No limitation | - | \$624,000 |
| Mr. L.J. Wood | 0% | 0% | 2008/09 | Options | 100% | 0% | 2010/11 | - | - |
| Dr. D.J. Wright | 0% | 0% | 2006/07 | Options | 100% | 0% | 2010/11 | - | - |
| | | | 2009/10 | Rights | 100% | 0% | No limitation | - | \$155,000 |
| Mr. D.M. Keamy | 0% | 0% | 2006/07 | Options | 100% | 0% | 2010/11 | - | - |
| | | | 2009/10 | Rights | 100% | 0% | No limitation | - | \$64,000 |

The exercise price for those options granted in 2006/07 is \$8.60. The exercise price for those options granted to Mr. Wood in 2008/09 is \$2.75. The exercise price for those rights granted in 2009/10 and 2010/11 was \$Nil. The exercise prices are restated to a post-consolidated basis.

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 photo protection 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.



SHARES UNDER OPTION*** ALL OPTIONS AND CONDITIONAL RIGHTS RESTATED TO A POST-CONSOLIDATED BASIS**

| DETAILS OF UNISSUED SHARES OR INTERESTS UNDER OPTIONS | | | | | |
|---|--------------------------------|-------------------------------|----------------|----------|--|
| Entity | Number of Shares under Options | Number of Shares under Rights | Exercise Price | Class | Expiry Date |
| Clinuvel Pharmaceuticals | 1,136,000 | - | \$8.60 | Ordinary | 09/02/2012 |
| Clinuvel Pharmaceuticals | 35,000 | - | \$2.75 | Ordinary | 18/11/2013 |
| Clinuvel Pharmaceuticals | - | 1,598,500 | \$Nil | Ordinary | Upon achievement of specific performance and time-based milestones |

LOANS TO DIRECTORS AND EXECUTIVES

No loans were granted to Directors or Executives for the years ending 30 June 2011 and 30 June 2010.

NON-AUDIT SERVICES

For the years ending 30 June 2011 and 30 June 2010 Grant Thornton only provided audit services to the company.

AUDITOR'S INDEPENDENCE DECLARATION

The Auditor's Independence Declaration as required by s.307C of the Corporations Act 2001 is included and forms part of this Directors' Report.

PROCEEDINGS ON BEHALF OF THE COMPANY

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

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

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



Dr. Philippe Wolgen, MBA, MD
Director

Dated this 25th day of August, 2011

CORPORATE GOVERNANCE STATEMENT

OVERVIEW

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

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

This statement outlines the main corporate governance principles and practices of Clinuvel Pharmaceuticals Ltd and is organised under headings based on the Australian Stock Exchange Corporate Governance Council's (ASXCGC) Revised Corporate Governance Principles and Recommendations, dated 2 August 2007. The company's charters and policies were comprehensively reviewed and updated in April 2005 and November 2009.

Charters and policies referred to are available on Clinuvel Pharmaceuticals Ltd's website (www.clinuvel.com).

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

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

THE BOARD PRESCRIBES THE RESPECTIVE ROLES AND RESPONSIBILITIES OF BOARD AND MANAGEMENT (ASXCGC PRINCIPLE 1)

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

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

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

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

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

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

CLINUVEL PHARMACEUTICALS LTD HAS A BOARD OF EFFECTIVE COMPOSITION, SIZE AND COMMITMENT TO DISCHARGE ITS RESPONSIBILITIES AND DUTIES (ASXCGC PRINCIPLE 2)

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

SIZE AND COMPOSITION OF THE BOARD

The Board comprises four Non-Executive Directors and two Executive Directors – the Managing Director and the Chief Scientific Officer. Information about Directors, including their skills, experience, expertise and length of service can be found in pages 19 to 20.

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

DIRECTORS' INDEPENDENCE

AND DEALING WITH CONFLICT OF INTEREST

Clinuvel Pharmaceuticals Ltd has four Non-Executive Directors (including Mr McLiesh, the Chair) considered independent of the company and its management, having no current or previous business or other relationships that could materially compromise their autonomy as a Director (Mr McLiesh, Mrs Shanahan, Mr Wood and Mr Ishag). The CEO of the company is Dr Wolgen who is not the Chair. The Board's framework for determining Director independence and the company's materiality thresholds is included in the Board Charter. Mrs Shanahan is no longer an officer of a former substantial shareholder and the relationship is not considered material to the company according to its materiality thresholds. The contractual relationship between Mr Ishag and the company within the three years prior to his appointment is not considered material. The impact of any past or present relationship with the company on a Director's ability to exercise independent judgment has been carefully assessed. With Dr Aston's resignation and Mr Ishag's appointment during 2010/11, the Board currently has a majority of independent Non-Executive Directors.

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

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

REMUNERATION AND NOMINATION COMMITTEE - NOMINATION

To increase its effectiveness, the Board has a Remuneration and Nomination Committee. The Remuneration and Nomination Committee comprises at least four Directors (three voting and one non-voting) and is chaired by Mr. Wood. Mr McLiesh and Dr Agersborg is the other voting members and the committee comprises a majority of voting independent directors. The Managing Director attends Remuneration and Nomination Committee meetings by invitation. He, along with Dr Agersborg 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 21. A committee charter can be found on the company's website.

The Remuneration and Nomination Committee makes recommendations to the Board on the appointment of new Directors and criteria for new appointees, focusing on the particular 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 Executives experienced in finance, the law and, ideally, the pharmaceutical industry in which Clinuvel Pharmaceuticals Ltd participates.

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

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

THE WORK OF DIRECTORS

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

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

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

PERFORMANCE REVIEW

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

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

ACCESS TO INFORMATION

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

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

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

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

CODE OF BUSINESS CONDUCT AND ETHICS

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

TRADING IN SHARES

Directors' shareholdings at 30 June 2011 are shown on pages 19-20. 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.

The key elements to the diversity policy are:

- To maintain an equal gender diversity representation at across the entire company,
- For the remuneration and nomination committee to annually assess the gender diversity objectives and the performance against those objectives.

The company's performance against the diversity policy objectives as at 30 June 2011 are:

| GENDER REPRESENTATION | FEMALE % | MALE % |
|---------------------------|----------|--------|
| BOARD | 17% | 83% |
| TOP 7 SALARIED EMPLOYEES* | 43% | 57% |
| CONSOLIDATED ENTITY | 57% | 43% |

*excludes executive Directors

CLINUVEL PHARMACEUTICALS LTD HAS A STRUCTURE TO INDEPENDENTLY VERIFY AND SAFEGUARD THE INTEGRITY OF THE COMPANY'S FINANCIAL REPORTING (ASXCGC PRINCIPLE 4)

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

AUDIT AND RISK COMMITTEE

To increase its effectiveness, the Board has an Audit and Risk Committee. The Audit and Risk Committee comprises at least three Directors (two voting and one non-voting) and is chaired by Mrs Shanahan who is a voting, independent and Non-Executive Director. The remaining voting committee member, Mr McLiesh, is also independent and Non-Executive.

The Managing Director attends Audit and Risk Committee meetings by invitation. He is not present if this could compromise the objectivity of proceedings. The membership and number of meetings held, along with each Director's attendance record last year, is shown on page 21. A committee charter can be found on the company's website.

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

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

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

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

CONTINUOUS DISCLOSURE

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

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

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

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

CLINUVEL PHARMACEUTICALS LTD HAS A SOUND SYSTEM OF RISK OVERSIGHT AND MANAGEMENT AND INTERNAL CONTROL (ASXCGC PRINCIPLE 7)

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

A. BUSINESS RISKS

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

B. FINANCIAL RISKS

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

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

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

- **FINANCIAL INTEGRITY RISKS**

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

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

- **AUDIT AND RISK COMMITTEE**

Reviews and reports to the Board in relation to the company's financial reporting, internal control structure, risk management systems, and the external audit functions.

- **MANAGEMENT**

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

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

RISK MANAGEMENT & FINANCIAL REPORT ACCOUNTABILITY

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

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

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

REMUNERATION AND NOMINATION COMMITTEE

– REMUNERATION

As previously stated, Clinuvel Pharmaceuticals Ltd has appointed a Remuneration and Nomination Committee, comprising three voting members, being two voting, independent Non-Executive Directors, chaired by Mr Wood and a voting, non-independent Executive Director (Dr Agersborg). 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 21. A committee charter can be found on the company's website.

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

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

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

Non-Executive Directors are remunerated by way of fees, and unlisted 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 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 COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2011

| | | CONSOLIDATED | |
|--|----------|-----------------------|------------------------|
| | | 2011 | 2010 |
| Revenues | | | |
| Total Revenues | 2 | \$2,276,064 | \$1,845,720 |
| Total Expenses | 2 | (\$13,685,153) | (\$13,366,760) |
| Profit (Loss) before income tax expense | | (\$11,409,089) | (\$11,521,040) |
| Income tax expense (benefit) | 3 | - | - |
| Profit (Loss) after income tax expense | | (\$11,409,089) | (\$11,521,040) |
| Net Profit (Loss) for the year | | (\$11,409,089) | (\$11,521,040) |
| Other Comprehensive Income | | | |
| Exchange differences of foreign exchange translation of foreign operations | | \$38,788 | (\$29,573) |
| Income tax (expense) benefit on items of other comprehensive income | | - | - |
| Other comprehensive income (loss) for the period, net of income tax | | \$38,788 | (\$29,573) |
| Total Comprehensive Income for the period | | (\$11,370,301) | (\$11, 550,613) |
| Basic earnings per share – cents per share | 16 | (37.6) | (38.0) |

The accompanying notes form part of these financial statements.

STATEMENT OF FINANCIAL POSITION

AS AT 30 JUNE 2011

| | | CONSOLIDATED | |
|--------------------------------------|-------|---------------------|---------------------|
| Current Assets | Note | 2011 | 2010 |
| Cash and cash equivalents | 17(a) | \$12,178,030 | \$19,414,846 |
| Other financial assets | 8 | \$5,321,057 | \$7,588,331 |
| Receivables | 4 | \$973,610 | \$362,970 |
| Other | 5 | \$1,459,566 | \$1,791,371 |
| Total Current Assets | | \$19,932,263 | \$29,157,518 |
| Non Current Assets | | | |
| Property, plant and equipment | 6 | \$214,794 | \$321,665 |
| Intangible assets | 7 | \$18,400 | \$27,600 |
| Total Non Current Assets | | \$233,194 | \$349,265 |
| Total Assets | | \$20,165,457 | \$29,506,783 |
| Current Liabilities | | | |
| Trade and other payables | 10 | \$3,435,627 | \$2,802,936 |
| Provisions | 11 | \$281,325 | \$237,046 |
| Total Current Liabilities | | \$3,716,952 | \$3,039,982 |
| Non Current Liabilities | | | |
| Provisions | 11 | \$40,404 | \$40,638 |
| Total Non Current Liabilities | | \$40,404 | \$40,638 |
| Total Liabilities | | \$3,757,356 | \$3,080,620 |
| Net Assets | | \$16,408,101 | \$26,426,163 |
| Equity | | | |
| Issued capital equity | 12 | \$113,388,940 | \$113,227,565 |
| Reserves | 13 | \$3,214,412 | \$2,169,316 |
| Accumulated losses | 14 | (\$100,145,251) | (\$88,970,718) |
| Total Equity | | \$16,408,101 | \$26,426,163 |

The accompanying notes form part of these financial statements.

STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 30 JUNE 2011

| | | CONSOLIDATED | |
|---|-------|----------------|----------------|
| Cash Flows From Operating Activities | Note | 2011 | 2010 |
| Refund from ATO | | \$100,890 | \$151,284 |
| Receipts from customers | | \$171,055 | - |
| Interest received | | \$1,322,027 | \$1,430,728 |
| Payments to suppliers and employees | | (\$11,080,829) | (\$13,364,757) |
| Net Cash provided by (used in) operating activities | 17(b) | (\$9,486,857) | (\$11,782,745) |
| Cash Flows From Investing Activities | | | |
| Payments for property, plant and equipment | | (\$69,535) | (\$45,162) |
| Proceeds from investment securities | | \$2,615,441 | \$9,687,758 |
| Net Cash provided by (used in) investing activities | | \$2,545,906 | \$9,642,596 |
| Cash Flows From Financing Activities | | | |
| Payment of share issue costs | | - | (\$1,500) |
| Net Cash provided by (used in) financing activities | | - | (\$1,500) |
| Net increase (decrease) in cash and cash equivalents held | | (\$6,940,951) | (\$2,141,649) |
| Cash and cash equivalents at beginning of the year | | \$19,414,846 | \$21,710,643 |
| Effects of exchange rate changes on foreign currency held | | (\$295,865) | (\$154,148) |
| Cash and cash equivalents at end of the year | 17(a) | \$12,178,030 | \$19,414,846 |

The accompanying notes form part of these financial statements.

STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 30 JUNE 2011

| | SHARE CAPITAL | SHARE OPTION RESERVE | PERFORMANCE RIGHTS RESERVE | FOREIGN CURRENCY TRANSLATION RESERVE | RETAINED EARNINGS | TOTAL EQUITY |
|--|----------------------|-------------------------|----------------------------------|---|------------------------|-----------------------|
| Balance at 1 July 2009 | \$113,221,065 | \$2,150,416 | - | \$17,030 | (\$78,337,327) | \$37,051,184 |
| Issue of Share Capital under share-based payment | \$8,000 | - | - | - | - | \$8,000 |
| Employee share-based payment options | - | (\$356,581) | \$328,878 | - | \$887,649 | \$859,946 |
| Capital Raising Costs | (\$1,500) | - | - | - | - | (\$1,500) |
| Transactions with Owners | \$113,227,565 | \$1,793,835 | \$328,878 | \$17,030 | (\$77,449,678) | \$37,917,630 |
| Profit (Loss) for the year | | | | | (\$11,521,040) | (\$11,521,040) |
| Other Comprehensive Income: | | | | | | |
| Exchange differences of foreign exchange translation of foreign operations | - | - | - | \$29,573 | - | \$29,573 |
| Balance at 30 June 2010 | \$113,227,565 | \$1,793,835 | \$328,878 | \$46,603 | (\$88,970,718) | \$26,426,163 |
| Issue of Share Capital under share-based payment | \$111,375 | - | - | - | - | \$111,375 |
| Employee share-based payment options | - | \$279,660 | \$804,224 | - | \$234,556 | \$1,318,440 |
| Capital Raising Costs | - | - | - | - | - | - |
| Transactions with owners | \$113,338,940 | \$2,073,495 | \$1,133,102 | \$46,603 | (\$88,736,162) | \$27,855,978 |
| Profit (Loss) for the year | | | | | (\$11,409,089) | (\$11,409,089) |
| Other Comprehensive Income: | | | | | | |
| Exchange differences of foreign exchange translation of foreign operations | - | - | - | (\$38,788) | - | (\$38,788) |
| Balance at 30 June 2011 | \$113,338,940 | \$2,073,495 | \$1,133,102 | \$7,815 | (\$100,145,251) | \$16,408,101 |

The accompanying notes form part of these financial statements.

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED **30 JUNE 2011**

1. BASIS OF PREPARATION

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

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 translated to Australian dollars for presentation in the Clinuvel Pharmaceuticals Ltd financial report.

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

In applying Australian Accounting Standards management must make judgment regarding carrying values of assets and liabilities that are not readily apparent from other sources. Assumptions and estimates are based on historical experience and any other factor that are believed reasonable in light of the relevant circumstances. These estimates are reviewed on an ongoing basis and revised in those periods to which the revision directly affects.

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

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

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

A) PRINCIPLES OF CONSOLIDATION

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

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

A list of controlled entities is found in Note 9 of the Financial Statements.

B) INCOME TAX

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

Current Tax

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

Deferred Tax

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

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

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

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

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

Tax Consolidation

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

Current And Deferred Tax For The Period

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

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 attributable to the acquisition of the item. In the event that settlement of all or part of the purchase consideration is deferred, cost is determined by discounting the amounts payable in the future to their present value as at the date of acquisition.

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

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

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

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

E) INVESTMENTS AND OTHER FINANCIAL ASSETS

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

F) RESEARCH AND DEVELOPMENT EXPENDITURE

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

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

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

At 30 June 2011 the consolidated entity has yet to demonstrate the satisfaction of all the above criteria to recognise and generate an intangible asset from its development activities. The inherent risks in pharmaceutical development are such that the criterion to recognise an intangible asset is not met until regulatory approval to market the drug has been granted.

G) INTANGIBLE ASSETS

Trademarks, Patents and Sub-Licence

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

Sub-licence

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

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

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

Amortisation Of Sub-licence

The sub-licence to develop and commercialise SCENESSE® has been amortised on a straight-line basis over 10 years. The Sub-licence had been fully amortised.

H) PAYABLES

Trade payables and other accounts payable are recognised when the consolidated entity becomes obliged to make future payments resulting from the purchase of goods and services, incurred prior to the end of the financial year.

I) EMPLOYEE BENEFITS

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

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

Provisions made in respect of employee benefits which are not expected to be settled within 12 months are measured as the present value of the estimated future cash outflows to be made by the consolidated entity in respect of services provided by employees up to reporting date. The discount rate used to estimate future cash flows is the 5 year Treasury bond yield published by the Reserve Bank of Australia at reporting date.

J) DIRECTORS' REMUNERATION - SHARE BASED PAYMENTS

Under AASB 2 Share Based Payments, the consolidated entity must determine the fair value of options and conditional performance rights issued to employees as remuneration and recognise an expense in the Statement of Comprehensive Income. This standard is not limited to options and to conditional performance rights. It also extends to other forms of equity based remuneration. The fair value of options is measured by the use of the Black Scholes binominal model. The fair value of conditional performance rights is measured by a binomial model. It is determined at grant date and expensed on a straight- line basis over the vesting period. For the full year reporting period ending 30 June 2011 the fair value of options and conditional performance rights is required to be shown as an expense to the entity together with comparative information for the same period in the preceding reporting period. For the 2010/11 year \$500,249 (2009/10: \$531,068) for options and \$929,566 (2009/10: \$336,878) for conditional performance rights was recognised as an employment benefit expense. The fair value for options was largely attributable to the issue of new options to Directors and Executives as approved by shareholders in an Extraordinary General Meeting held 25 January 2007. The fair value of conditional performance rights was attributable to the issue of rights to eligible employees as approved by the Board during 2009/10 and 2010/11

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

K) REVENUE

Interest

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

Sale Of Goods

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

L) SHARE CAPITAL

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

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

M) EARNINGS PER SHARE

Basic Earnings Per Share

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

Diluted Earnings Per Share

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

N) GOODS AND SERVICES TAX/ VALUE ADDED TAX (GST)

Revenues, expenses and assets are recognised net of the amount of 'goods and services tax' or 'valued added tax' as it is known in 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.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables. Cash flows are included in the Statement of Cash Flow on a gross basis. The GST component of cash flows arising from investing and financing activities which is recoverable from, or payable to, the taxation authority is classified as operating cash flows.

O) IMPAIRMENT OF ASSETS

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

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

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

P) LEASES

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

Q) COMPARATIVES

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

R) PROVISIONS

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

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

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

S) OTHER CURRENT ASSETS

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

T) FOREIGN CURRENCY TRANSACTIONS AND BALANCES

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

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

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

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

U) SHARE-BASED PAYMENT TRANSACTIONS

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 transactions'). The plan currently in place to provide these benefits is the Employee Share Option Plan (ESOP), which provides benefits to senior executives.

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 a Black-Scholes 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').

The cost of equity-settled transactions is recognised, together with a corresponding increase in equity, over the period in which the performance conditions are fulfilled, ending on the date on which the relevant employees become fully entitled to the award ('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 of awards that, in the opinion of the directors of the group, will ultimately vest. This opinion is formed based on the best available information at balance date. No adjustment is made for the likelihood of market performance conditions being met as the 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

The Directors evaluate estimates and judgments incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the Group.

Key estimates – share-based payments transactions

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined using a Black-Scholes 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.

W) NEW ACCOUNTING STANDARDS AND INTERPRETATIONS

In the current year, the Group has adopted all of the new and revised Standards and Interpretations issued by the Australian Accounting Standards Board that are relevant to its operations and effective for the current annual reporting period. The 2010 comparatives contained in these financial statements therefore differ from those published in the financial statements for the year ended 30 June 2010 as described below.

Certain new accounting standards and UIG interpretations have been published that are not mandatory for the 30 June 2011 reporting period. The Company's assessment indicates that there is no new Australian Accounting Standards or interpretations that have been issued but are not yet effective that are expected to have a material impact on the Company's financial report in the period of initial application.

X) NEW AUSTRALIAN ACCOUNTING STANDARDS ISSUED BUT NOT YET EFFECTIVE

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

Y) SEGMENT REPORTING

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

2. PROFIT/(LOSS) FROM CONTINUING OPERATIONS

| | CONSOLIDATED | |
|--|---------------------|---------------------|
| | 2011 | 2010 |
| (a) Revenues | | |
| Interest revenue – other persons | \$1,184,148 | \$1,473,664 |
| Sales Reimbursements – Law 648/96 | \$1,041,021 | - |
| Realised Net Gain (Loss) on currency gain on transactions | \$50,895 | \$372,056 |
| Total Revenues | \$2,276,064 | \$1,845,720 |
| (b) Expenses | | |
| Clinical development costs | \$2,560,558 | \$2,553,354 |
| Drug delivery research costs | \$2,520,012 | \$2,981,322 |
| Regulatory and toxicity studies | \$797,499 | \$957,588 |
| Research & development overheads | \$2,109,535 | \$1,887,799 |
| Business marketing & listing | \$626,389 | \$704,143 |
| Licenses patents and trademarks | \$148,513 | \$745,970 |
| General operations (incl. Board) | \$4,917,552 | \$4,383,393 |
| Net Loss on disposal of financial assets held at fair value through profit and loss | \$683,525 | \$1,046,848 |
| Unrealised Net (Gain) Loss on revaluation of financial assets held at fair value through profit and loss | (\$1,015,937) | (\$2,295,212) |
| Loss on restating foreign currency creditors and currencies held | \$337,507 | \$401,055 |
| Total Expenses | \$13,685,153 | \$13,366,760 |
| (c) Profit (Loss) before income tax includes the following specific expenses | | |
| Depreciation | \$82,700 | \$80,633 |
| Amortisation of patents, trademarks & sub-licence | \$9,200 | \$635,515 |
| Loss on sale of property, plant and equipment | \$93,706 | - |
| Share Based Payments | \$1,429,815 | \$867,946 |
| Operating Lease Expense – minimum lease payments | \$494,489 | \$280,309 |

3. INCOME TAX EXPENSE

| | CONSOLIDATED | |
|---|---------------------|---------------------|
| | 2011 | 2010 |
| (a) The prima facie tax on profit (loss) is reconciled to the income tax expense (benefit) as follows: | | |
| Prima facie tax payable on profit (loss) from ordinary activities before income tax at 30% (2010: 30%) | (\$3,422,727) | (\$3,456,312) |
| Add: Tax effect of | | |
| Non deductible amortisation | \$2,760 | \$2,760 |
| Capital raising costs | - | (\$450) |
| Non deductible legal fees | \$2,458 | \$24,348 |
| Share based payments | \$325,165 | (\$8,311) |
| Research & development deduction | (\$55,881) | (\$81,003) |
| (Over) Under provision of income tax in previous years | - | \$1,499,641 |
| Net (Gain) on revaluation of financial assets at fair value through profit and loss | (\$304,781) | (\$688,563) |
| Unrealised foreign exchange losses | \$101,252 | \$135,524 |
| Deferred tax assets not brought to account | \$3,351,754 | \$2,572,366 |
| (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 | \$29,733,301 | \$26,471,013 |
| Net temporary differences | \$1,484,179 | \$1,394,713 |
| Total | \$31,217,480 | \$27,865,726 |

The tax rate used in this report is the corporate tax rate of 30%.

There has been no change in the corporate tax rate when compared with the previous reporting period.

4. RECEIVABLES

| | CONSOLIDATED | |
|----------------------|------------------|------------------|
| | 2011 | 2010 |
| Current | | |
| Trade debtors | \$834,714 | - |
| Accrued income | \$107,310 | \$245,189 |
| Sundry debtors | \$31,586 | \$117,781 |
| Total Current | \$973,610 | \$362,970 |

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

| | CONSOLIDATED | |
|---------------------|--------------------|--------------------|
| | 2011 | 2010 |
| Current Prepayments | | |
| Peptide | \$1,277,604 | \$1,609,295 |
| Other | \$181,962 | \$182,076 |
| Total | \$1,459,566 | \$1,791,371 |

6. PROPERTY, PLANT AND EQUIPMENT

| | CONSOLIDATED | |
|--|------------------|------------------|
| | 2011 | 2010 |
| Plant and Equipment | | |
| At cost | \$472,254 | \$630,189 |
| Less: accumulated depreciation | (\$308,635) | (\$379,408) |
| Sub-total | \$163,619 | \$250,781 |
| Furniture and Fittings | | |
| At cost | \$79,653 | \$118,637 |
| Less: accumulated depreciation | (\$28,478) | (\$47,753) |
| Sub-total | \$51,175 | \$70,884 |
| Total Property, Plant and Equipment | \$214,794 | \$321,665 |

MOVEMENTS IN CARRYING AMOUNTS - PROPERTY, PLANT AND EQUIPMENT

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

| CONSOLIDATED ENTITY | PLANT AND EQUIPMENT | FURNITURE AND FITTINGS | TOTAL |
|---------------------------------------|---------------------|------------------------|------------------|
| Carrying amount at 30 June 2009 | \$272,495 | \$84,640 | \$357,135 |
| Additions | \$43,283 | \$1,681 | \$44,964 |
| Disposals | - | - | - |
| Depreciation written back on disposal | - | - | - |
| Depreciations expense | (\$65,500) | (\$15,470) | (\$80,970) |
| Exchange differences | \$503 | \$33 | \$536 |
| Carrying amount at 30 June 2010 | \$250,781 | \$70,884 | \$321,665 |
| Additions | \$41,396 | \$28,139 | \$69,535 |
| Disposals | (\$199,331) | (\$67,123) | (\$266,454) |
| Depreciation written back on disposal | \$136,446 | \$36,302 | \$172,748 |
| Depreciations expense | (\$65,673) | (\$17,027) | (\$82,700) |
| Exchange differences | - | - | - |
| Carrying amount at 30 June 2011 | \$163,619 | \$51,175 | \$214,794 |

7. INTANGIBLE ASSETS

| | CONSOLIDATED | |
|--|-----------------|-----------------|
| | 2011 | 2010 |
| Sub-licence to develop and commercialise Afamelanotide | | |
| 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 | (\$54,625) | (\$47,797) |
| Sub-total | \$13,656 | \$20,484 |
| Patents | | |
| At cost | \$23,718 | \$23,718 |
| Less: Accumulated amortisation of Patents | (\$18,974) | (\$16,602) |
| Sub-total | \$4,744 | \$7,116 |
| Total | \$18,400 | \$27,600 |

MOVEMENTS IN CARRYING AMOUNTS – INTANGIBLE ASSETS

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

| CONSOLIDATED ENTITY | SUB-LICENCE | TRADEMARKS AND PATENTS | TOTAL |
|---------------------------------|------------------|------------------------|------------------|
| Carrying amount at 30 June 2009 | \$626,315 | \$36,800 | \$663,115 |
| Additions | - | - | - |
| Impairment | - | - | - |
| Amortisation expense | (\$626,315) | (\$9,200) | (\$635,515) |
| Carrying amount at 30 June 2010 | - | \$27,600 | \$27,600 |
| Additions | - | - | - |
| Impairment | - | - | - |
| Amortisation expense | - | (\$9,200) | (\$9,200) |
| Carrying amount at 30 June 2011 | - | \$18,400 | \$18,400 |

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

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

8. OTHER FINANCIAL ASSETS

| | CONSOLIDATED | |
|--|--------------|-------------|
| | 2011 | 2010 |
| (Current) Investments Comprise | | |
| Income Securities (at fair value through profit and loss)* | \$5,321,057 | \$7,588,331 |

* The consolidated entity holds listed perpetual floating rate notes (income securities) returning 1.25% above the 90 day bank bill rate with interest paid out quarterly and senior debt securities returning 0.25% to 0.37%, above the 90 day bank bill rate with interest paid out quarterly and maturity dates ranging up to 7 months from reporting date.

9. INTERESTS IN SUBSIDIARIES

| NAME OF ENTITY | COUNTRY OF INCORPORATION | OWNERSHIP INTEREST | |
|------------------------------|--------------------------|--------------------|------|
| Parent Entity | | 2011 | 2010 |
| Clinuvel Pharmaceuticals Ltd | Australia | - | - |
| Controlled Entities | | | |
| A.C.N. 089 584 467 Pty Ltd | Australia | 100% | 100% |
| A.C.N. 108 768 896 Pty Ltd | Australia | 100% | 100% |
| Clinuvel (UK) Ltd | United Kingdom | 100% | 100% |
| Clinuvel, Inc. | United States | 100% | 100% |
| Clinuvel AG | Switzerland | 100% | 100% |

10. PAYABLES

| | CONSOLIDATED | |
|---|--------------------|--------------------|
| Current | 2011 | 2010 |
| Unsecured trade payables | \$1,697,355 | \$569,192 |
| Sundry payables and accrued expenses | \$1,738,272 | \$2,233,744 |
| | \$3,435,627 | \$2,802,936 |
| (a) Aggregate amounts payable to: | | |
| Directors and Director-related entities | - | - |
| (b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in trade and sundry creditors: | | |
| US dollars | \$468,786 | - |
| Euro | \$313,806 | - |
| British pounds | \$166,828 | \$173,068 |
| Other | \$393,574 | \$104,999 |
| | \$1,342,994 | \$278,067 |

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

(c) Terms and conditions:

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

11. PROVISIONS

| | CONSOLIDATED | |
|-------------------|--------------|-----------|
| Current: | 2011 | 2010 |
| Employee benefits | \$281,325 | \$237,046 |
| Non Current: | | |
| Employee benefits | \$40,404 | \$40,638 |

12. CONTRIBUTED EQUITY

| (a) Issued and Paid Up Capital | | |
|--------------------------------|--------------|------|
| | CONSOLIDATED | |
| | 2011 | 2010 |

30,381,706 fully paid ordinary shares \$113,338,940 \$113,227,565
 (2010: 30,318,867 on a post-consolidated basis)

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 | | |
| | 2011 | 2010 | |

| | No. | \$ | No. | \$ |
|---|-------------------|--------------------|--------------------|--------------------|
| At the beginning of the financial year | 303,188,665 | 113,227,565 | 303,148,665 | 113,221,065 |
| Issued during the year | | | | |
| Options exercised and valuation transferred from Share Option Reserve | | | - | - |
| Rights exercised and valuation transferred from Conditional Rights Reserve | 255,000 | 48,375 | 40,000 | 8,000 |
| 10:1 Share Consolidation (November 2010) | (273,099,299) | - | - | - |
| Adjustments for fractional entitlements upon 10:1 Share Consolidation | 590 | - | - | - |
| Conditional rights issues and transferred from conditional rights reserve (post 10:1 Share Consolidation) | 36,750 | 63,000 | - | - |
| Less: transaction costs | - | - | - | (1,500) |
| Balance at the end of the financial year | 30,381,706 | 113,338,940 | 303,188,665 | 113,227,565 |

12. CONTRIBUTED EQUITY (CONT'D)

(c) Share Options (restated at a post-share consolidated basis)

As at 30 June 2011 the following share options existed which if exercised, would result in the issue of fully paid ordinary shares

| Expiry Date | Exercise Price | Number of Options |
|------------------|----------------|-------------------|
| 9 February 2012 | \$8.60/share | 1,136,000 |
| 18 November 2013 | \$2.75/share | 35,000 |
| Total | | 1,171,000 |

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 (restated at a post-share consolidated basis)

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 Options |
|--|----------------|-------------------|
| Upon achievement of various performance milestones | \$nil/share | 1,350,000 |
| Total | | 1,350,000 |

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 Options |
|--|----------------|-------------------|
| Upon achievement of various performance milestones | \$nil/share | 62,250 |
| Total | | 62,250 |

As at 30 June 2011 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 Options |
|--|----------------|-------------------|
| Upon achievement of various performance milestones | \$nil/share | 1,598,500 |
| Total | | 1,598,500 |

13. RESERVES

| | CONSOLIDATED | |
|---|--------------------|--------------------|
| | 2011 | 2010 |
| SHARE OPTION RESERVE | | |
| Balance at the beginning of period | \$1,793,835 | \$2,150,416 |
| Share based payment | \$500,249 | \$531,068 |
| Transfer to share capital | - | - |
| Lapsed options | (\$220,589) | (\$887,649) |
| Balance at the end of period | \$2,073,495 | \$1,793,835 |
| 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 | \$328,878 | - |
| Share based payment | \$929,566 | \$336,878 |
| Transfer to share capital | (\$111,375) | (\$8,000) |
| Lapsed Options | (\$13,967) | - |
| Balance at the end of period | \$1,133,102 | \$328,878 |
| The Conditional Performance Rights reserve arises on the grant of conditional performance rights to eligible employees under the Conditional Performance Rights Plan. Amounts are transferred out of the reserve and into issued capital when the rights are exercised and to retained earnings when rights lapse. | | |
| FOREIGN CURRENCY TRANSLATION RESERVE | | |
| Balance at the beginning of period | \$46,603 | \$17,030 |
| Translating foreign subsidiary to current rate at balance date | (\$38,788) | \$29,573 |
| Balance at the end of period | \$7,815 | \$46,603 |
| The consolidated entity has a foreign operation with a USD functional currency and another with a Swiss Franc functional currency. The assets and liabilities of these foreign operations are translated into the consolidated entity's presentation currency at exchange rates on reporting date. Items in the Statement of Comprehensive Income of the foreign operations are translated at average monthly exchange rates. Any exchange differences arising on translation are recognised in the foreign currency translation reserve. | | |
| Total Reserves | \$3,214,412 | \$2,169,316 |

14. ACCUMULATED LOSSES

| | CONSOLIDATED | |
|--|------------------------|-----------------------|
| | 2011 | 2010 |
| Accumulated losses at the beginning of the year | (\$88,970,718) | (\$78,337,327) |
| Transfer from share option reserve of lapsed & expired options | \$220,589 | \$887,649 |
| Transfer from Performance Rights reserve of lapsed & expired Rights | \$13,967 | - |
| Net loss attributable to the members of Clinuvel Pharmaceuticals Ltd | (\$11,409,089) | (\$11,521,040) |
| Accumulated losses at the end of the financial year | (\$100,145,251) | (\$88,970,718) |

15. LEASE COMMITMENTS

| | CONSOLIDATED | |
|--|------------------|------------------|
| | 2011 | 2010 |
| Operating lease commitments (Non-cancellable operating leases) | | |
| Contracted for, but not capitalised in, the accounts: | | |
| Payable not later than 1 year | \$237,468 | \$221,654 |
| Payable later than 1 year but not later than 5 years | \$26,639 | - |
| | \$264,107 | \$221,654 |

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

16. EARNINGS PER SHARE (EPS)

| | CONSOLIDATED | |
|--|----------------|----------------|
| | 2011 | 2010 |
| (a) Basic earnings per share – cents per share | (\$37.6) | (\$38.0) |
| (b) The weighted average number of ordinary shares (WANOS) used in the calculation of basic earnings per share | \$30,361,645 | \$30,316,434 |
| (c) The numerator used in the calculation of basic earnings per share | (\$11,409,089) | (\$11,521,040) |

As at 30 June 2011 the company had on issue 1,171,000 unlisted options and 1,598,500 unlisted performance rights over unissued capital. These options and rights are not considered dilutive as they do not increase the net loss per share.

Shares are shown on a post-consolidation basis.

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.

17. CASH FLOW INFORMATION

| | CONSOLIDATED | |
|---|---------------------|---------------------|
| | 2011 | 2010 |
| (a) Reconciliation of cash | | |
| Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled to the related items in the Statement of Financial Position as follows: | | |
| Cash at bank | \$2,187,442 | \$2,482,165 |
| Cash on hand | \$782 | \$45 |
| Deposits on call | \$1,167,610 | \$4,894,433 |
| Term deposits (security bonds) | \$8,750,000 | \$12,000,000 |
| Security bonds | \$72,196 | \$38,203 |
| | \$12,178,030 | \$19,414,846 |

| | | |
|---|-----------------------|-----------------------|
| (b) Reconciliation of cash flows from operating activities with operating profit (loss) | | |
| Operating Profit (Loss) after income tax | (\$11,409,089) | (\$11,521,040) |
| Non cash flows in operating (loss) | | |
| Depreciation expense | \$82,700 | \$80,633 |
| Accrued income | \$137,879 | (\$44,264) |
| Exchange rate effect on foreign currencies held | \$295,865 | \$154,148 |
| Amortisation expense | \$9,200 | \$635,515 |
| Executive share option expense | \$1,429,815 | \$867,946 |
| Loss on Sale of non-current assets | \$93,706 | - |
| Realised gain on disposal of financial assets at fair value through profit and loss | \$683,525 | \$1,046,848 |
| Net Loss on revaluation of financial assets held at fair value | (\$1,015,937) | (\$2,295,212) |
| Unrealised loss foreign exchange translation | (\$38,788) | \$29,573 |
| Changes in assets and liabilities | | |
| (Increase) Decrease in receivables | (\$743,112) | (\$91,602) |
| (Increase) Decrease in prepayments | \$356,479 | \$836,214 |
| Increase (Decrease) in payables | \$586,856 | (\$1,566,016) |
| Increase (Decrease) in provisions | \$44,044 | \$84,512 |
| Net Cash used in operating activities | (\$9,486,857) | (\$11,782,745) |

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 5.95% (2010: 5.21%) these deposits have an average maturity date of 159 days (2010: 147 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)

Dr. R. Aston (Non-Executive, Resigned September 1 2010)

Mr. S.R. McLiesh (Non-Executive to July 1, 2010, Non-Executive Chair thereafter)

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

Dr. P.J. Wolgen (Managing Director)

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

Mr. E. Ishag (Non-Executive, Joined February 1, 2011)

THE SPECIFIED EXECUTIVES OF CLINUVEL PHARMACEUTICALS LIMITED DURING THE YEAR WERE:

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

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

KEY MANAGEMENT PERSONNEL COMPENSATION

| | CONSOLIDATED | |
|------------------------------|--------------------|--------------------|
| | 2011 | 2010 |
| Short-term employee benefits | \$1,639,369 | \$1,777,322 |
| Post-employment benefits | \$49,585 | \$60,201 |
| Long-term benefits | - | - |
| Termination benefits | - | - |
| Share-based payments | \$1,307,035 | \$593,334 |
| | \$2,995,989 | \$2,430,857 |

REMUNERATION OPTION HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2011

* ALL OPTIONS RESTATED TO A POST-CONSOLIDATED BASIS

| | 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 | 150,000 | - |
| R. Aston | 130,000 | - | - | (130,000) | - | - | - |
| E. Ishag | - | - | - | - | - | - | - |
| S.R. McLiesh | 45,000 | - | - | - | 45,000 | 45,000 | - |
| B.M. Shanahan | 85,000 | - | - | - | 85,000 | 85,000 | - |
| P.J. Wolgen | 600,000 | - | - | - | 600,000 | 600,000 | - |
| L.J. Wood | 35,000 | - | - | - | 35,000 | 35,000 | - |
| EXECUTIVES | | | | | | | |
| D.J. Wright | 140,000 | - | - | (50,000) | 90,000 | 90,000 | - |
| D.M. Keamy | 60,000 | - | - | - | 60,000 | 60,000 | - |

REMUNERATION CONDITIONAL PERFORMANCE RIGHTS HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2011

* ALL CONDITIONAL RIGHTS RESTATED TO A POST-CONSOLIDATED BASIS

| | 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 | - | - | 450,000 | 150,000 | 300,000 |
| R. Aston | - | - | - | - | - | - | - |
| E. Ishag | - | - | - | - | - | - | - |
| S.R. McLiesh | - | - | - | - | - | - | - |
| B.M. Shanahan | - | - | - | - | - | - | - |
| P.J. Wolgen | - | 900,000 | - | - | 900,000 | 300,000 | 600,000 |
| L.J. Wood | - | - | - | - | - | - | - |
| EXECUTIVES | | | | | | | |
| D.J. Wright | 87,500 | - | - | - | 87,500 | 10,000 | 77,500 |
| D.M. Keamy | 40,000 | - | (8,000) | - | 32,000 | - | 32,000 |

REMUNERATION OPTION HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2010

* ALL OPTIONS RESTATED TO A POST-CONSOLIDATED BASIS

| | BALANCE AT START OF YEAR | GRANTED AS COMPENSATION | EXERCISED | OTHER CHANGES | BALANCE AT END OF YEAR | VESTED AND EXERCISABLE | UNVESTED |
|-------------------|--------------------------------|----------------------------|-----------|------------------|------------------------------|---------------------------|----------|
| DIRECTORS | | | | | | | |
| H.P.K. Agersborg | 200,000 | - | - | (50,000) | 150,000 | 150,000 | - |
| R. Aston | 245,000 | - | - | (115,000) | 130,000 | 130,000 | - |
| E. Ishag | - | - | - | - | - | - | - |
| S.R. McLiesh | 65,000 | - | - | (20,000) | 45,000 | 45,000 | - |
| B.M. Shanahan | 85,000 | - | - | - | 85,000 | 85,000 | - |
| P.J. Wolgen | 925,000 | - | - | (325,000) | 600,000 | 600,000 | - |
| L.J. Wood | 35,000 | - | - | - | 35,000 | 23,333 | 11,667 |
| EXECUTIVES | | | | | | | |
| D.J. Wright | 160,000 | - | - | (20,000) | 140,000 | 129,792 | 10,208 |
| D.M. Keamy | 70,000 | - | - | (10,000) | 60,000 | 52,708 | 7,292 |

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

REMUNERATION CONDITIONAL PERFORMANCE RIGHTS HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2010

* ALL CONDITIONAL RIGHTS RESTATED TO A POST-CONSOLIDATED BASIS

| | BALANCE AT START OF YEAR | GRANTED AS COMPENSATION | EXERCISED | OTHER CHANGES | BALANCE AT END OF YEAR | VESTED AND EXERCISABLE | UNVESTED |
|-------------------|--------------------------------|----------------------------|-----------|------------------|------------------------------|---------------------------|----------|
| EXECUTIVES | | | | | | | |
| D.J. Wright | - | 87,500 | - | - | 87,500 | 5,000 | 82,500 |
| D.M. Keamy | - | 40,000 | - | - | 40,000 | 4,000 | 36,000 |

SHARE HOLDINGS OF KEY MANAGEMENT PERSONNEL

* ALL SHARES RESTATED TO A POST-CONSOLIDATED BASIS

| | ORDINARY SHARES – 2011 | | | | ORDINARY SHARES – 2010 | | | |
|-------------------|--------------------------------|-------------------------------------|-----------|------------------------------|--------------------------------|-------------------------------------|-----------|------------------------------|
| | BALANCE AT START OF YEAR | REC'D UPON OPTION EXERCISE | PURCHASES | BALANCE AT END OF YEAR | BALANCE AT START OF YEAR | REC'D UPON OPTION EXERCISE | PURCHASES | BALANCE AT END OF YEAR |
| DIRECTORS | | | | | | | | |
| H.P.K. Agersborg | 92,111 | - | - | 92,111 | 92,111 | - | - | 92,111 |
| S.R. McLiesh | 76,000 | - | - | 76,000 | 76,000 | - | - | 76,000 |
| R. Aston | 10,823 | - | - | 10,823 | 10,823 | - | - | 10,823 |
| E. Ishag | 72,733 | - | - | 72,733 | - | - | - | - |
| P.J. Wolgen | 9,500 | - | - | 9,500 | 9,500 | - | - | 9,500 |
| B.M. Shanahan | 42,007 | - | - | 42,007 | 42,007 | - | - | 42,007 |
| L.J. Wood | 40,000 | - | - | 40,000 | 10,000 | - | 30,000 | 40,000 |
| EXECUTIVES | | | | | | | | |
| D.J. Wright | - | - | - | - | - | - | - | - |
| D.M. Keamy | 160 | 8,000 | - | 9,600 | 160 | - | - | 160 |

19. AUDITORS' REMUNERATION

| | CONSOLIDATED | |
|---|-----------------|-----------------|
| | 2011 | 2010 |
| Amounts received or due and receivable by Grant Thornton for: | | |
| Audit services and review | \$60,000 | \$60,500 |
| Other services | - | - |
| Total | \$60,000 | \$60,500 |

20. RELATED PARTY DISCLOSURES

DIRECTORS

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

H.P.K. Agersborg, S.R. McLiesh, R. Aston, P.J. Wolgen, B.M. Shanahan, L.J. Wood, 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 commercialisation of the company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in A.C.N. 089 584 467 Pty Ltd.

The loan receivable by Clinuvel Pharmaceuticals Ltd from A.C.N. 108 768 896 Pty Ltd is non-interest bearing. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in A.C.N. 108 768 896 Pty Ltd. The loan to A.C.N. 108 768 896 Pty Ltd as at 30 June 2011 is \$4,370,640 (2010: \$4,370,640).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel, Inc is non-interest bearing. Repayment of the loan will commence upon commercialisation of the company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in Clinuvel, Inc. The loan to Clinuvel, Inc as at 30 June 2011 is \$4,022,820 (2010: \$2,893,576).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel AG is non-interest bearing. Repayment of the loan will commence upon commercialisation of the company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in Clinuvel AG. The loan to Clinuvel AG as at 30 June 2011 is \$5,421,381 (2010: \$2,740,069).

DIRECTOR RELATED AND KEY MANAGEMENT PERSONNEL TRANSACTIONS AND ENTITIES

There are no transactions and relationships in existence as at 30 June 2011 between Directors of the Company and their related entities.

21. SEGMENT INFORMATION

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

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.

22. FINANCIAL INSTRUMENTS

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

- Market Risk
- Credit Risk
- Liquidity Risk

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

MARKET RISK

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

FOREIGN CURRENCY RISK

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

The consolidated entity's policy of managing foreign currency risk is to purchase foreign currencies equivalent to the cash outflow projected over minimum 30 days by the placement of market orders or forward exchange contracts to achieve a target rate of exchange, with protection floors in the event of a depreciating Australian dollar exchange rate, to run for the time between recognising the exposure and the time of payment. In the event of an appreciating Australian dollar, the amount of foreign currency held is minimised at a level to only meet short term obligations in order to maximise gains in an appreciating Australian currency. Clinuvel does not engage in speculative transactions in its management of foreign currency risk. No forward exchange contracts had been entered into as at 30 June 2011 and as at 30 June 2010.

THE CONSOLIDATED ENTITIES EXPOSURE TO FOREIGN CURRENCY RISK AT 30 JUNE 2011

| | CONSOLIDATED | | | | CONSOLIDATED | | |
|-----|-------------------------|------------------------------|------------------------|--------------------|-------------------------|------------------------|-------------------|
| | 2011 | | | | 2010 | | |
| | Cash & cash equivalents | Trade Debtors & Other Assets | Trade & other payables | Total | Cash & cash equivalents | Trade & other payables | Total |
| USD | \$1,115,194 | - | (1,618,623) | (\$503,429) | \$1,240,196 | (\$1,042,362) | \$197,834 |
| EUR | \$339,831 | \$793,125 | (\$519,605) | \$613,351 | \$389,504 | (\$231,742) | \$157,762 |
| CHF | \$242,754 | - | (\$581,448) | (\$338,694) | \$200,545 | (\$284,988) | (\$84,443) |
| GBP | - | - | (\$111,224) | (\$111,224) | - | (\$98,060) | (\$98,060) |
| SEK | - | - | (\$92,736) | (\$92,736) | - | (\$89,132) | (\$89,132) |

SENSITIVITY ANALYSIS

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

For the consolidated entity, a 15% appreciation of the Australian dollar against the US currency would have increased profit and loss and equity by \$590,453 for the year ended 30 June 2011 (2010: \$731,753), on the basis that all other variables remain constant. 15% is considered representative of the market volatility in the Australian/US dollar rate for the period.

For the consolidated entity, a 15% depreciation of the Australian dollar against the US currency would have an equal but opposite effect to the above, on the basis that all other variables remain constant.

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

INTEREST RATE RISK

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

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

SENSITIVITY ANALYSIS

For the consolidated entity, at 30 June 2011, if interest rates had changed by +/- 50 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 \$105,865 higher/lower (2010: \$173,781 higher/lower) This analysis assumes all other variables are held constant.

PRICE RISK

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

SENSITIVITY ANALYSIS

At 30 June 2011, if the weighted average of the market-acknowledged benchmarks of the investments in income securities increased/decreased by 4.98% (2010: 3.4%) assuming all other variables constant and the investments in securities move in correlation with the indexes, the impact on profit and equity is:

| | CONSOLIDATED | |
|---|--------------|-----------|
| | 2011 | 2010 |
| Market-acknowledged weighted average benchmarks (+/- 4.98%) | \$66,320 | \$124,037 |

CREDIT RISK

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

Credit risk in relation to the consolidated entity is the cash and cash equivalents deposited with banks, trade and other receivables, and investments in securities. Exposure to credit risk in investments in securities is limited to the investing of surplus cash in a selection of senior debt securities and listed floating rate notes issued by counterparties deemed creditworthy by ratings agencies (A rated minimum). Portfolio managers engaged in the management of the investments in securities on behalf of Clinuvel continually assess the credit worthiness of the counterparties who report to Clinuvel of any change in credit risk. Exposure to credit risk in trade debtors is limited to the one counterparty, an Italian 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, investments in securities and foreign subsidiaries.

LIQUIDITY RISK

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

FAIR VALUE ESTIMATION

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

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

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

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

CAPITAL RISK MANAGEMENT

The consolidated entity's equity is limited to shareholder contributions. Its capital management objectives is limited to ensuring the equity available to the company will allow it to continue as a going concern and to realise adequate shareholder return by progressing in its developmental research of SCENESSE® and achieving eventual commercialisation.

CONTRACTUAL MATURITIES OF FINANCIAL ASSETS AS AT 30 JUNE 2011

| CONSOLIDATED | | |
|---|---------------------|---------------------|
| Cash and Cash Equivalents | 2011 | 2010 |
| Carrying amount | \$12,178,030 | \$19,414,846 |
| 6 months or less | \$12,133,359 | - |
| Greater than 6 months | \$44,671 | - |
| Total | \$12,178,030 | \$19,414,846 |
| Other Financial Assets (includes Trade and Other Receivables) | | |
| Carrying amount | \$6,294,667 | \$7,951,301 |
| 6 months or less | \$973,610 | \$362,970 |
| Greater than 6 months | \$5,321,057 | \$7,588,331 |
| Total | \$6,294,667 | \$7,951,301 |

CONTRACTUAL MATURITIES OF FINANCIAL LIABILITIES AS AT 30 JUNE 2011

| CONSOLIDATED | | |
|--------------------------|--------------------|--------------------|
| Trade and other payables | 2011 | 2010 |
| Carrying amount | \$3,435,627 | \$2,802,936 |
| 6 months or less | \$3,376,227 | \$2,598,829 |
| Greater than 6 months | \$59,400 | \$204,107 |
| Total | \$3,435,627 | \$2,802,936 |

23. EMPLOYEE BENEFITS

| CONSOLIDATED | | |
|---|------------------|------------------|
| The aggregate employee benefit liability is comprised of : | 2011 | 2010 |
| Provision for annual leave | \$270,470 | \$236,017 |
| Provision for long service leave | \$51,259 | \$41,667 |
| Accrued FBT, Superannuation, Pension Funds, Employee Insurances | \$350,442 | \$430,997 |
| Total | \$672,171 | \$708,681 |

A) SHARE BASED PAYMENTS

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

SHARE OPTION SCHEME

Each share option converts to one ordinary share of the consolidated entity. The options are issued for nil consideration. There are no voting rights attached to the option and they can be exercised any time from the date of vesting to the date of expiry. They are non-transferable and not listed on the ASX.

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

CONDITIONAL PERFORMANCE RIGHTS SCHEME

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

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

THE FOLLOWING SHARE BASED PAYMENT ARRANGEMENTS WERE IN EXISTENCE AT 30 JUNE 2011

* ALL SHARE OPTIONS AND CONDITIONAL RIGHTS RESTATED TO A POST-CONSOLIDATED BASIS

| OPTIONS SERIES | NUMBER | GRANT DATE | EXPIRY DATE | EXERCISE PRICE | FAIR VALUE AT GRANT DATE |
|---------------------------|-----------|------------|---|----------------|--------------------------|
| Issued 09/02/2007 | 1,136,000 | 09/02/2007 | 09/02/2012 | \$8.60 | \$2.20 |
| Issued 18/11/2008 | 35,000 | 18/11/2008 | 18/11/2013 | \$2.75 | \$0.50 |
| PERFORMANCE RIGHTS SERIES | NUMBER | GRANT DATE | EXPIRY DATE | EXERCISE PRICE | FAIR VALUE AT GRANT DATE |
| Issued 16/10/2009 | 222,250 | 16/10/2009 | Upon achievement of specific performance milestones | \$Nil | \$2.20 |
| Issued 07/01/2010 | 26,250 | 07/01/2010 | Upon achievement of specific performance milestones | \$Nil | \$0.50 |
| Issued 25/11/2010 | 1,350,000 | 25/11/2010 | Upon achievement of specific performance milestones | \$Nil | \$1.04 |

OPTION HOLDINGS OF ALL ISSUED OPTIONS – 2011

* ALL OPTIONS RESTATED TO A POST-CONSOLIDATED BASIS

| OPTIONS SERIES | BALANCE AT START OF YEAR | GRANTED AS COMPENSATION | EXERCISED | EXPIRED AND LAPSED | BALANCE AT END OF YEAR | VESTED AND EXERCISABLE | UNVESTED |
|------------------------------------|--------------------------------|----------------------------|-----------|--------------------------|---------------------------|---------------------------|----------|
| Issued 09/02/2007 | 1,276,000 | - | - | (140,000) | 1,136,000 | 1,136,000 | - |
| Issued 18/11/2008 | 35,000 | - | - | - | 35,000 | 35,000 | - |
| Total | 1,311,000 | - | - | - | 1,171,000 | 1,171,000 | - |
| Weighted Average Exercise Price | \$7.80 | - | - | \$8.60 | \$8.40 | \$8.50 | - |

The share options outstanding at the end of the financial year had an average remaining contractual life of 253 days (2010: 701 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 - 2011

* ALL CONDITIONAL RIGHTS RESTATED TO A POST-CONSOLIDATED BASIS

| 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 | 262,000 | - | (18,500) | (21,250) | 222,250 | 19,750 | 202,500 |
| Issued 07/01/2010 | 70,000 | - | (43,750) | - | 26,250 | 26,250 | - |
| Issued 25/11/2010 | - | 1,350,000 | - | - | 1,350,000 | 450,000 | 900,000 |
| Total | 332,000 | 1,350,000 | (62,250) | (21,250) | 1,598,500 | 496,000 | 1,102,500 |
| Weighted Average Exercise Price | \$Nil | \$Nil | \$Nil | \$Nil | \$Nil | \$Nil | \$Nil |

Performance Rights were priced using a binomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the pricing model is assumed to be the yield on 2 year Government bonds.

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

OPTION HOLDINGS OF ALL ISSUED OPTIONS - 2010

* ALL OPTIONS RESTATED TO A POST-CONSOLIDATED BASIS

| OPTIONS SERIES | BALANCE AT START OF YEAR | GRANTED AS COMPENSATION | EXERCISED | EXPIRED AND LAPSED | BALANCE AT END OF YEAR | VESTED AND EXERCISABLE | UNVESTED |
|---------------------------------|--------------------------|-------------------------|-----------|--------------------|------------------------|------------------------|---------------|
| Issued 23/02/2006 | 150,000 | - | - | (150,000) | - | - | - |
| Issued 01/03/2005 | 50,000 | - | - | (50,000) | - | - | - |
| Issued 31/10/2005 | 150,000 | - | - | (150,000) | - | - | - |
| Issued 09/02/2007 | 1,534,000 | - | - | (258,000) | 1,276,000 | 1,257,042 | 18,958 |
| Issued 18/11/2008 | 35,000 | - | - | - | 35,000 | 23,333 | 11,667 |
| Total | 1,919,000 | - | - | (608,000) | 1,311,000 | 1,280,375 | 30,625 |
| Weighted Average Exercise Price | \$7.80 | - | - | \$7.70 | \$7.80 | \$7.70 | - |

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

Performance Rights were priced using a binomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the pricing model is assumed to be the yield on 2 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

HOLDINGS OF ALL ISSUED CONDITIONAL PERFORMANCE RIGHTS - 2010

* ALL CONDITIONAL PERFORMANCE RIGHTS RESTATED TO A POST-CONSOLIDATED BASIS

| 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 | - | 297,000 | (4,000) | (31,000) | 262,000 | 17,750 | 244,250 |
| Issued 07/01/2010 | - | 70,000 | - | - | 70,000 | 37,500 | 32,500 |
| Total | - | 367,000 | (4,000) | (31,000) | 332,000 | 55,250 | 276,750 |
| Weighted Average Exercise Price | \$Nil | \$Nil | \$Nil | \$Nil | \$Nil | \$Nil | \$Nil |

Performance Rights were priced using a binomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the pricing model is assumed to be the yield on 2 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

PERFORMANCE RIGHTS - BINOMIAL PRICING MODEL

| INPUTS | |
|--|---|
| Grant date share price | \$1.73 |
| Exercise price | \$Nil |
| Grant date | 25 November 2010 |
| Expiry date | Upon achievement of specific performance conditions |
| Historical volatility (weighted average) | 60% |
| Expected life (weighted average) | 36 months |
| Risk free interest rate | 5.15% |

24. CLINUVEL PHARMACEUTICALS LTD PARENT COMPANY INFORMATION

| | | CLINUVEL PHARMACEUTICALS LTD | |
|-----------------------------------|------|------------------------------|-----------------------|
| Assets | Note | 2011 | 2010 |
| Current Assets | | \$18,092,766 | \$28,383,497 |
| Non Current Assets | | \$1,099,616 | \$639,688 |
| Total Assets | | \$19,192,382 | \$29,023,185 |
| Liabilities | | | |
| Current Liabilities | | \$2,716,513 | \$2,635,234 |
| Non Current Liabilities | | \$40,404 | \$40,638 |
| Total Liabilities | | \$2,756,917 | \$2,675,872 |
| Equity | | | |
| Issued Equity | | \$113,338,940 | \$113,227,565 |
| Reserves | | \$3,206,597 | \$2,122,713 |
| Accumulated Losses | | (\$100,110,072) | (\$89,002,965) |
| Total Equity | | \$16,435,465 | \$26,347,313 |
| Financial Performance | | | |
| Net Profit (Loss) for the year | | (\$11,374,096) | (\$11,553,460) |
| Other comprehensive income | | - | - |
| Total Comprehensive Income | | (\$11,374,096) | (\$11,553,460) |

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
Telephone: +61 3 9660 4900
Facsimilie: +61 3 9660 4999

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

DIRECTORS' DECLARATION

In the opinion of the Directors:

1. The financial statements and notes of the consolidated entity are in accordance with the Corporations Act 2001, including:
 - a. giving a true and fair view of the consolidated entity's financial position as at 30 June 2011 and of its performance for the year ended on that date; and
 - b. complying with Accounting Standards; and
 - c. complying with International financial Reporting Standards as disclosed in Note 1
2. There are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable; and
3. The Directors have been given the declarations by the Chief Executive Officer and Chief Financial Officer required by Section 295A of the Corporations Act 2001.

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



Dr. Philippe J. Wolgen
Director

Dated this 25th day of August, 2011



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

Report on the financial report

We have audited the accompanying financial report of Clinuvel Pharmaceuticals Limited (the "Company"), which comprises the consolidated statement of financial position as at 30 June 2011, the consolidated statement of 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 it controlled at the year's end or from time to time during the financial year.

Directors responsibility for the financial report

The Directors of the Company are responsible for the preparation of the financial report that gives a true and fair view of the financial report in accordance with Australian Accounting Standards and the Corporations Act 2001. This responsibility includes such internal controls as the Directors determine are necessary to enable the preparation of the financial report to be 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, that compliance with the Australian equivalents to International Financial Reporting Standards ensures that the financial report, comprising the financial statements and notes, complies with International Financial Reporting Standards.

Auditor's responsibility

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

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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 and fair presentation of the financial report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the 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.

Electronic presentation of audited financial report

This auditor's report relates to the financial report of Clinuvel Pharmaceuticals Limited and controlled entities for the year ended 30 June 2011 included on Clinuvel Pharmaceuticals Limited's web site. The Company's Directors are responsible for the integrity of Clinuvel Pharmaceuticals Limited's web site. We have not been engaged to report on the integrity of Clinuvel Pharmaceuticals Limited's web site. The auditor's report refers only to the statements named above. It does not provide an opinion on any other information which may have been hyperlinked to/from these statements. If users of this report are concerned with the inherent risks arising from electronic data communications they are advised to refer to the hard copy of the audited financial report to confirm the information included in the audited financial report presented on this web site.

Independence

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

Auditor's opinion

In our opinion:

- a the financial report of Clinuvel Pharmaceuticals Limited is in accordance with the Corporations Act 2001, including:
 - i giving a true and fair view of the consolidated entity's financial position as at 30 June 2011 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 12 to 21 of the directors' report for the year ended 30 June 2011. The Directors of the Company are responsible for the preparation and presentation of the remuneration report in accordance with section 300A of the Corporations Act 2001. Our responsibility is to express an opinion on the remuneration report, based on our audit conducted in accordance with Australian Auditing Standards.

Auditor's opinion on the remuneration report

In our opinion, the remuneration report of Clinuvel Pharmaceuticals Limited for the year ended 30 June 2011, complies with section 300A of the Corporations Act 2001.

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

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

A handwritten signature in blue ink, appearing to be "M.A. Cunningham".

M.A. Cunningham
Director - Audit & Assurance

Melbourne, 23 August 2011



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

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of Clinuvel Pharmaceuticals Limited for the year ended 30 June 2011, I declare that, to the best of my knowledge and belief, there have been:

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

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

GRANT THORNTON AUDIT PTY LTD
Chartered Accountants

A handwritten signature in blue ink, appearing to be "M.A. Cunningham".

M.A. Cunningham
Director – Audit & Assurance Services

Melbourne, 23 August 2011

ADDITIONAL INFORMATION REQUIRED BY THE AUSTRALIAN SECURITIES EXCHANGE (ASX)

Additional information, as at 27 September 2011, required by the ASX and not shown elsewhere in this report is as follows:

1. SHAREHOLDING

a. Distribution of Shareholders Numbers

| CATEGORY (SIZE OF HOLDING) | TOTAL HOLDERS |
|----------------------------|---------------|
| 1 – 1,000 | 2,185 |
| 1,001 – 5,000 | 1,064 |
| 5,001 – 10,000 | 214 |
| 10,001 – 100,000 | 233 |
| 100,001 – 9,999,999,999 | 21 |
| | 3,717 |

b. The number of shareholdings held in less than marketable parcels is 1,097 for ordinary shares.

c. There are no substantial Shareholders listed in the company's holding registry as at 27 September 2011.

d. Voting rights: ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the company.

e. 20 Largest Shareholders – Ordinary Shares

| POSITION | NAME | NUMBER OF ORDINARY FULLY PAID SHARES HELD | % HELD OF ISSUED ORDINARY CAPITAL |
|----------|---|---|-----------------------------------|
| 1 | JP MORGAN NOMINEES AUSTRALIA LIMITED <CASH INCOME A/C> | 7,525,303 | 24.76% |
| 2 | NATIONAL NOMINEES LIMITED | 4,065,143 | 13.37% |
| 3 | CITICORP NOMINEES PTY LIMITED | 1,751,991 | 5.76% |
| 4 | HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED | 1,709,641 | 5.62% |
| 5 | SANDHURST TRUSTEES LTD <JMFG CONSOL A/C> | 871,114 | 2.87% |
| 6 | BOODUP NOMINEES PTY LTD <OTTER SUPER FUND A/C> | 694,613 | 2.29% |
| 7 | DR MARK EDWIN BADCOCK | 369,534 | 1.22% |
| 8 | J P MORGAN NOMINEES AUSTRALIA LIMITED | 209,371 | 0.69% |
| 9 | ARMADA TRADING PTY LTD | 181,775 | 0.60% |
| 10 | DR MICHAEL JAMES FISH | 181,171 | 0.60% |
| 11 | UTOPIA LAND COMPANY PTY LTD | 161,000 | 0.53% |
| 12 | HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2 | 160,867 | 0.53% |
| 13 | TERSTAN NOMINEES PTY LTD <MORROWS P/L SUPER FUND A/C> | 155,523 | 0.51% |
| 14 | ABN AMRO CLEARING SYDNEY NOMINEES PTY LTD <CUSTODIAN A/C> | 139,557 | 0.46% |
| 15 | MR DAVID JOHN LEWIS | 127,294 | 0.42% |
| 16 | HEADSTART GLOBAL HOLDINGS LTD | 117,486 | 0.39% |
| 17 | SANDHURST TRUSTEES LTD <DMP ASSET MANAGEMENT A/C> | 108,000 | 0.36% |
| 18 | MR ROBERT THOMAS DORR | 106,987 | 0.35% |
| 19 | TERENA PTY LTD <SUPER FUND A/C> | 105,000 | 0.35% |
| 20 | MADGE PTY LTD <MORROWS EXECUTIVES S/F A/C> | 102,319 | 0.34% |
| | | 18,843,689 | 62.00% |

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

Facsimile: +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 Johnson St

Abbotsford, Vic 3067 Australia

5. AUSTRALIAN SECURITIES EXCHANGE LIMITED

Quotation has been granted for all the ordinary shares on all Member Exchanges of the Australian Securities 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

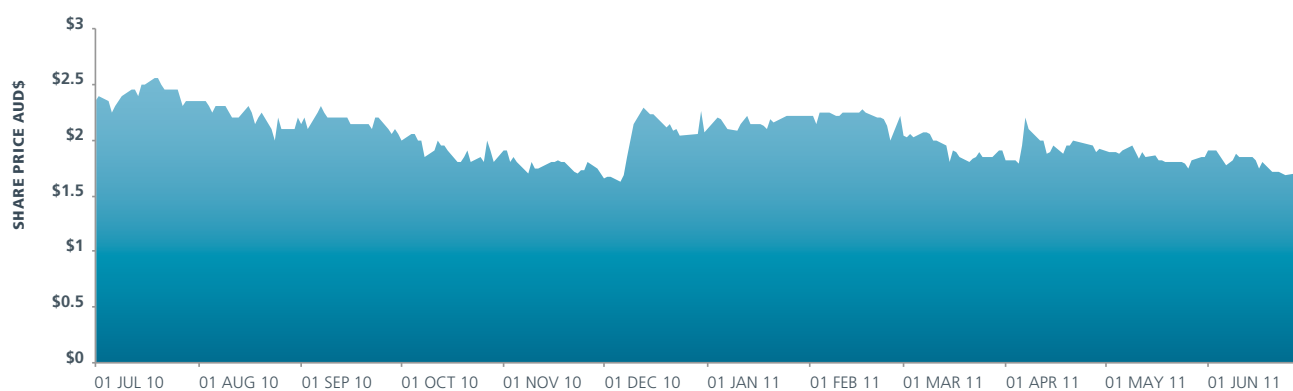
6. RESTRICTED SECURITIES

Restricted securities on issue at June 30 2011: Nil.

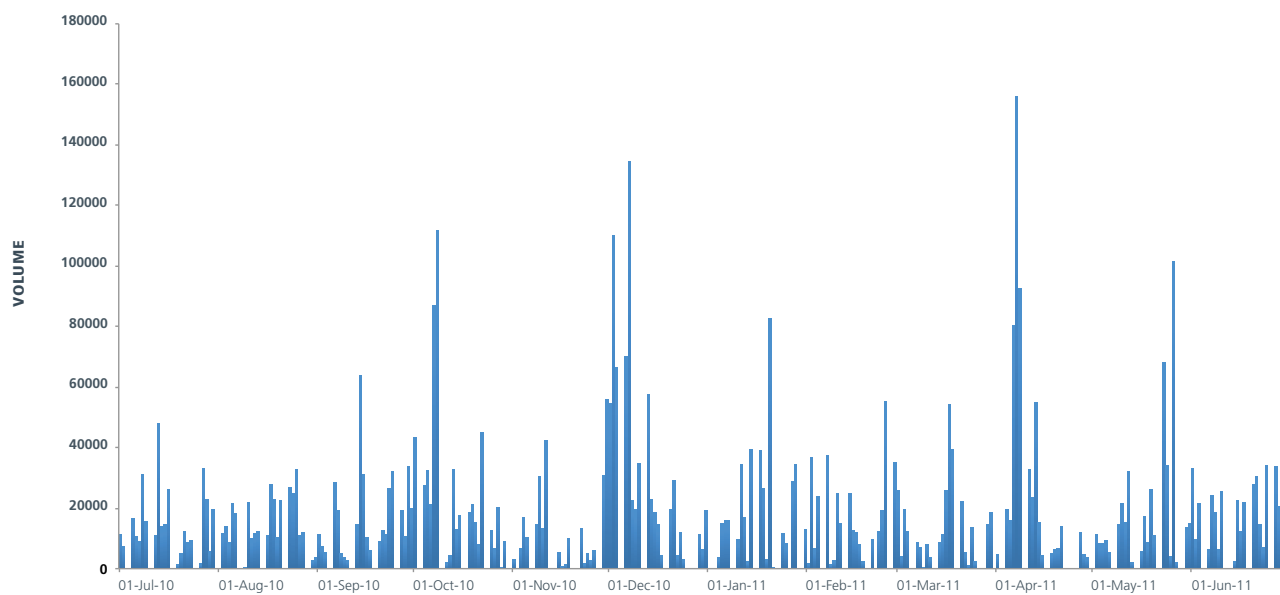
MARKET PERFORMANCE

ASX: CUV

SHARE PRICE AND TRADING VOLUME DATA PRIOR TO 25 NOVEMBER 2010
RESTATED ON A 10:1 POST CONSOLIDATION BASIS.



DAILY TRADING VOLUME – ASX:CUV



GLOSSARY

ACTION SPECTRUM

Efficiency of monochromatic radiations for producing a specified actinic event in a specified system. For instance, specific wavelength and intensity of light causing acute dermal reactions in polymorphous light eruption (PLE).

α-MSH

Alpha-Melanocyte Stimulating Hormone is a peptide hormone which activates or stimulates the production 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 atmosphere.

EMA

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

ERYTHEMA (ACTINIC-SOLAR)

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

EUMELANIN

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

FDA

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

FITZPATRICK SCALE

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

Fitzpatrick type I - white unpigmented skin, always burns;

Fitzpatrick type II - white unpigmented skin, usually burns;

Fitzpatrick type III - olive pigmented skin, sometimes mild burns;

Fitzpatrick type IV - brown pigmented skin, rarely burns;

Fitzpatrick type V - dark brown pigmented skin, seldom burns;

Fitzpatrick type VI - black pigmented skin, never burns.

IMMUNOCOMPROMISED

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

IMMUNOMODULATORY

Changes to the level of a person's immunity.

IPD OR IMMEDIATE PIGMENTING DOSE

The amount of UV required to stimulate immediate pigmentation change.

MARKETING AUTHORISATION APPLICATION (MAA)

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

MELANIN

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

MELANOCYTES

The cells in the skin that produce melanin.

MELANOGENESIS

The process whereby melanin is produced in the body.

MINIMUM ERYTHEMA DOSE (MED)

The actinic dose that produces a just noticeable erythema on normal, non-exposed, "fair" skin. The quantity usually corresponds to a radiant exposure of monochromatic (=1 wavelength) radiation at the maximum spectral efficiency (α=295 nm) of approximately 100 J/m².

PHEOMELANIN

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

PHASE I

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

PHASE II

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

PHASE II/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.

PHOTODERMATOSES

Skin diseases caused 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.

PHARMACOKINETICS

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

SUBCUTANEOUS

Underneath the skin.

SUSTAINED RELEASE/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.

TGA

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

TOPICAL

Cream, gel or spray applied to the skin.

TRANSDERMAL

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

ULTRAVIOLET (UV) 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.

CORPORATE DIRECTORY

DIRECTORS AND EXECUTIVES

NON-EXECUTIVE CHAIR

Stanley McLiesh

NON-EXECUTIVE DIRECTORS

Brenda Shanahan, Jack Wood, Elie Ishag

MANAGING DIRECTOR AND CHIEF EXECUTIVE OFFICER

Dr Philippe Wolgen

EXECUTIVE DIRECTOR AND CHIEF SCIENTIFIC OFFICER

Dr Helmer Agersborg

VICE PRESIDENT, SCIENTIFIC AFFAIRS

Dr Dennis Wright

CHIEF FINANCIAL OFFICER AND COMPANY SECRETARY

Darren Keamy

AUSTRALIAN STOCK EXCHANGE

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

The company's shares are also quoted on other international exchanges as follows:

Germany: Frankfurt and Xetra: UR9

USA: Level 1 American Depositary Receipt Code: CLVLY

ADR Custodian: Bank of New York Mellon

SHARE REGISTRY

COMPUTERSHARE INVESTOR SERVICES PTY LTD

Yarra Falls, 453 Johnston Street

Abbotsford, VIC 3067, Australia

Tel: +61 3 9415 4000

AUDITOR

GRANT THORNTON AUDIT PTY LTD

Level 2, 215 Spring Street

Melbourne, VIC 3000, Australia

BANKER

NATIONAL AUSTRALIAN BANK (NAB)

Western Branch, 460 Collins Street

Melbourne, VIC 3000, Australia

LEGAL COUNSEL

ALLENS ARTHUR ROBINSON

Level 27, 530 Collins Street

Melbourne, VIC 3000, Australia

IP LAWYER

DIPL.-ING. PETER FARAGO

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