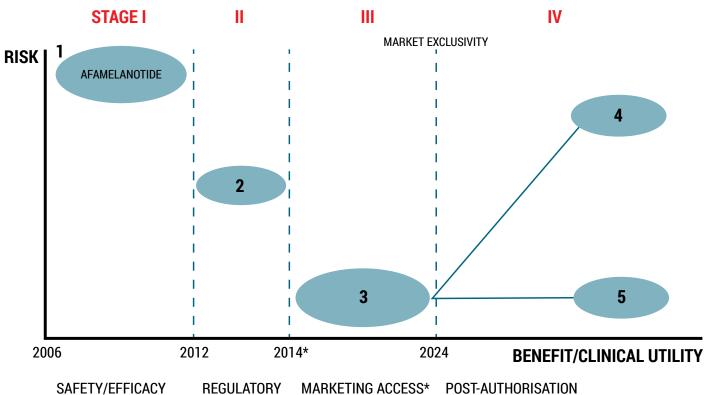


# CLINUVEL PHARMACEUTICALS ANNUAL REPORT 2014

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\*SUBJECT TO EMA REGULATORY APPROVAL OF SCENESSE® TO BE USED COMMERCIALLY

FIGURE 1: FOUR STAGE MODEL FROM DEVELOPMENT TO COMMERCIALISATION OF SCENESSE®

# STAGES AND MANAGEMENT OF SCENESSE®

In pharmaceutical planning discussions, lifecycle management is often seen as vital to retaining and enhancing product value. Managing product value, ranging from data to IP, must be emphasised early in the development lifecycle. Early on Clinuvel assessed its program, based on its data and published literature, and modelled various hypothetical outcomes of influence on the further stages in the lifecycle. It identified four stages and five steps, depicted in Figure 1. These stages and steps were laid out to represent realistic progress under the assumption that SCENESSE® (afamelanotide 16mg) could be made available for more than one clinical indication, and that value would be identified in the use of the family of melanocortins for other medical applications.

For the purpose of this explanation the medical use of melanocortins was presumed to be beneficial for patients. In Figure 1 the Company followed the regulatory rationale of assessing new therapies along a risk-benefit axis. It was essential to maintain a rational sequence of development in the process: new data had a marked influence on decisions to move through stages. Importantly, and unique to SCENESSE®, there was little flexibility to change decision nodes. The rigidity of the chronological decisions to be made primarily hinged on further data or new outcomes. Furthermore, the innovation needed to arrive at a first-in-class therapy for an untested disorder in a novel formulation posed additional stumbling blocks to the development program. Simultaneously, risks needed to be consistently low to meet the highest probability of regulatory success.

Given the inherent risk associated and perceived by the medical community (including the pharmaceutical regulators), the Company chose to model safety over efficacy of SCENESSE® as a key factor in reviewing development decisions. In working with patients, Clinuvel has been confident of the drug's safety profile, but also remained realistic that future safety concerns might arise. The management of risk is summarised in 'pharmacovigilance', activities to follow up and monitor patients post-marketing authorisation (stage IV).

Based on Clinuvel's early experiences and the vast evidence from experimental studies in published literature, the Company hypothesised in 2006 that follow-on products could be developed once the safety and efficacy of SCENESSE® had been established: 1) in sufficient patients and healthy volunteers and; 2) with longer term use. Based on longer term safety data, the Company has now arrived at the following conclusions: the initial plan had been validated and; the development of a further product is justified (step 4). In terms of risk, the translational use of SCENESSE® in further indications was estimated to be low (step 5). In the post-marketing authorisation stage, management of the second product will follow a similar program to SCENESSE®. During all research and development stages of SCENESSE® the trade-offs between risk and clinical utility were adapted continuously.

Clinical utility is not exclusively shown from efficacy data collected in the post-marketing authorisation stages. Rather it is also seen in the prescription patterns of treating physicians and the treatment compliance of patients. In Clinuvel's plans the post-marketing authorisation follow up of EPP patients is mandatory to assess the clinical utility and anticipated low treatment risk. The two dynamic factors of risk and benefit consistently determine the value of SCENESSE® and the potential for further development.

# **CHAIR'S LETTER**



Dear Shareholders,

#### **FINANCIAL YEAR 2014**

Clinuvel has ended the financial year of 2013/2014 strongly with new investors who participated in the May placement and those who invested in past years showing full support of the

Company's strategy. The main goal is to ensure that our stated direction remains clear and consistent. While the funding of the Company is secure, a targeted clinical and regulatory program continues. The programs in Italy and Switzerland provide us not only fees for treatment, but most of all an indication of the continuous care programs developed with SCENESSE® (afamelanotide 16mg).

#### **CLINICAL PROGRAM**

During the past year the Board has made it a priority to put all resources towards obtaining results from those clinical programs which most directly meet the requirements of the EMA's regulatory review. We commissioned and oversaw analyses on CUV039 the US phase III study in EPP and reanalysed the CUV102 data for assessment of safety follow up of the US vitiligo patients. We have performed an initial safety analysis of all patients in the CUV011 trial looking at the effect of SCENESSE® in immunecompromised patients; more efficacy analyses will follow.

Our team made an important first step in deploying the lead drug in a rare disorder Hailey-Hailey Disease (HHD) in a physician sponsored program in Italy. Recently SCENESSE® obtained the desired orphan drug status in Europe and the US for HHD.

To our delight, we read the first full vitiligo study CUV102 published in *JAMA Dermatology*. The US vitiligo experts are now preparing for the second study in vitiligo, and we are developing a refined protocol to better understand SCENESSE's effects in darker skin types. We saw the best initial responses as part of the UV combination therapy in patients of darker skin type and this program has now expanded into Asia to further evaluate the drug's effects. We have seen a sharp increase in the clinical demand for the drug from both patients and physicians. It is thus important for us to closely monitor this program; we are committed and owe it to those vitiligo patients to find a treatment.

#### **STRATEGY**

Clinuvel's current position is the result of careful execution and regular Board review of the direction given in respect of scientific knowledge, safety data obtained, feedback from the academic community, global risk in capital markets and funding requirements. The Board reviews the carousel of internal and external input continuously and, more common than expected, we change parts of our program to be able to arrive at a viable treatment and obtain regulatory approval in the EU and US.

The company has developed a work ethic led by the indefatigable Dr Wolgen. Neither shareholders nor I as Chairman could ask for greater dedication and it is clear that we are building towards Clinuvel establishing a significant presence in pharmaceuticals. The industry heads communicate to me their eagerness to learn whether the Clinuvel model of total focus on a new molecular entity will eventually be successful in terms of regulatory acceptance.

#### **FUTURE OF CLINUVEL**

Much lies ahead for Clinuvel's team. Regardless of the EMA's decision, they will need to adapt to tackle new challenges and capitalise on the progress that has been made. Dr Wolgen has spoken about the potential EMA outcomes throughout the year, and I encourage you to review these communications as the EMA's decision approaches. It is abundantly clear to me, however, that this team has done all that is possible to make SCENESSE® available as the first effective therapy for erythropoietic protoporphyria (EPP) in Europe.

Clinuvel has designed and executed a unique strategy for the release of SCENESSE® to EPP patients. By the time you read this we shall know whether the regulatory effort has been successful or whether further work is needed to obtain approval for SCENESSE®. The Board remains steadfast despite the many bouts of frustration over the past years. The value of the Company will be realised and I take this opportunity to thank our shareholders and investors for their strong support over the past twelve months.

Stan McLiesh Chairman

Sa Lilo

# MANAGING DIRECTOR'S REPORT



Dear Shareholders,

With great sadness we unexpectedly lost our most esteemed Board member Jack Wood only months before the long-awaited European regulatory outcome. He has been a remarkable professional with a strong vision of Clinuvel's longevity.

Jack's industry knowledge and his ever-present calmness have been great assets to our Board. We attribute much of Clinuvel's status to Jack, but also to the late Hank Agersborg. Both travelled with us along this complex but unique journey. I have had the indelible privilege to have worked closely with both of them.

For almost a decade now Clinuvel has focused on the development of SCENESSE® (afamelanotide 16mg) for an uncommon debilitating light affliction disorder, erythropoietic protoporphyria (EPP). By virtue of being the first inter pares in the pharmaceutical sector, Clinuvel has specialised in disorders afflicted by light. The research on the impact of environmental, ambient and artificial light has become part of what we do, our field of expertise. This novel domain of medicine led us to investigate the restrictions for patients who cannot expose themselves to light at the risk of debilitating pain.

Our teams have delved into an area of medicine which thus far had been underexplored to innovate and deliver a new therapy. Whereas we know the impact of light deprivation on flora, photosynthesis in man is not yet fully acknowledged other than through the psychiatric condition known as seasonal affective disorder (SAD).

In EPP one cannot scientifically claim that all patients have a depressive predisposition and reach a state of SAD, but is obvious from decades of clinical expertise gained that these patients are gravely affected by their inability to lead a normal life.

In SCENESSE® we developed a therapy which enables patients to assume a normal life for the first time in their existence. Our teams are continuously expanding clinical data to quantify and better understand the impact of deprivation of normal life and the value of providing a full existence. One tends to forget that this is a right for all. The invisible nature of the disorder does conceal the severity of

the impact, in more than one way a double handicap for EPP patients.

By the time this document goes to print we expect the European Medicines Agency will have made its first regulatory decision on SCENESSE®. On the basis of nine years of patients' and physicians' experiences, I have no doubts that SCENESSE® will – if not already by now – soon become the main preventative therapy for adult EPP patients, and in the future for children.

#### ONGOING DEVELOPMENT

In considering the further development of SCENESSE®, and in compliance with the stipulations from the EMA, we have for some time been reviewing options to develop a specific formulation suitable for paediatric use. Recently, we were excited to announce the formation of a partnership with Biotech Laboratories Singapore (BLS), a joint venture under the name VALLAURIX PTELTD to spread the financial risk, and benefit from both partners' knowledge and experience. Funding development requirements, risk, property and possible future competition have been some of the factors which led us to enter into the Singaporean partnership. BLS acts as the bridge to Asia for Clinuvel and has the local knowledge to assist us to arrive at the satisfactory endgame: being able to commercialise a suite of products.

Modelling Clinuvel against other pharmaceutical companies we find ourselves once again as the first to enter a relatively unknown field in medicine. We will excel in the required R&D where others have thus far failed in developing specialised melanocortin products for patients with unmet needs. The first task will be to accelerate the development a dose to be used in paediatric EPP patients. The development program will be far from simple, however the clinical programs in adult EPP patients the past nine years have seen Clinuvel build sufficient in-house knowhow to succeed with younger patients too. Our teams are confident that we will succeed in this mission and will keep you updated on the development progress.

Equally, we are finalising the development program for CUV9900, which has progressed to a stage where we can speak about the follow-on and complementary product for SCENESSE®.

#### INTELLECTUAL PROPERTY, KNOWHOW AND EXPERTISE

Inherently connected to the discussion of corporate

value is the question of IP. As stated in public, Clinuvel builds its IP position carefully and protects it with rigour. Clinuvel has increased its IP position each year as patents are being granted in strategic jurisdictions. Value is indirectly being recognised by some groups and companies who have tried to file their early staged research projects for a number of the same indications we target. We remain vigilant of the potential competition that emerge and act to stay steps ahead.

One often doesn't give sufficient credit to the knowledge and knowhow built in a company. At Clinuvel we boast a knowledge base of work on the family of melanocortins going back as far as 30 years, and a decade of specific intellectual expertise on product development for animal and human applications. This should be sufficient to retain a competitive advantage in the next two decades. As stated, the market exclusivity granted by EMA and FDA will shield Clinuvel further from any third party contemplating entering 'our domain'.

Corporate value extends much further than that found in data and patents. We view the goodwill built and maintained with the leading researchers, physicians, hospitals and insurers as an intrinsic part of Clinuvel's value proposition. The key element in building value for patients and shareholders is summarised in one word: consistency. For ongoing success, we need to remain consistent in the way we approach our business, in our intentions and in our dialogue with the global pharmaceutical regulators, and equally with government payor and insurance bodies.

#### REGULATORY REVIEW OF SCENESSE®

Since my original investigation into alpha-MSH technology, I fully understood that the pathway required to register the first melanocortin would be perhaps unorthodox. Most of all, I knew it would be complex. Clinuvel has pursued the only feasible program, driven by a mantra of 'safetyfirst' and designed in collaboration with the leading academic and clinical centres globally. In hindsight, the scientific dialogue and exchange over the past decade has been riveting at times. In some encounters academics and Clinuvel sat on opposite sides of the table, challenging each other on the clinical relevance of treatment. Since the clinical question of developing a therapy for EPP patients had never been relevant for most physicians, Clinuvel found itself in position where it needed to deepen the question of clinical relevance of the newly proposed treatment. In 2011, this question was finally agreed by all porphyria experts worldwide. The consensus was integrated in Clinuvel's clinical programs.

I can reflect on the complex process of developing a new therapy in an unchartered field of science, however at each stage we asked ourselves how we could turn it into both a meaningful therapy for patients, and a commercially viable business model. This thought process resulted in frequent self-evaluation and adaptation of plans. At this juncture, I now am convinced that Clinuvel will succeed in its commercialisation plans for SCENESSE®.

We now know that the perception of the drug's safety is a factor during development, but also long-term when the development phase has been completed. Total dedication to ensure safety is the number one criterion of Board and management, it is the foundation of our house.

An associated factor, and one well and truly exhausted with EMA, is that of control of the product's distribution, which is vital to maintaining the product's ongoing safety profile. The question was often posed – internally and externally – as to whether a commercial partner was better placed than Clinuvel to distribute our drug. More than four years of experience in Italy and Switzerland has shown us that it is efficient to manage distribution in-house and it is through the same network of expert physicians who helped develop the EPP program that Clinuvel intends to ensure patient drug access. Control of distribution provides the Company – as well as regulators – with the assurance that we can continue to monitor safety and efficacy under conditions of use.

We are transitioning from a complex R&D operation to a commercial one, and many decisions will be made from now on. We all hope and anticipate that first major regulatory approval from the EMA will put Clinuvel among the very few who have succeeded in taking a new therapy to market. As I stated in the early years, this turning point will affect the value of Clinuvel.



Philippe Wolgen

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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 2014 and the Auditor's Independence Declaration thereon.

#### DIRECTORS

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

- Mr. S.R. McLiesh (Non-Executive Chair)
- Dr. P.J. Wolgen (Managing Director, Chief Executive Officer)
- · Mrs. B.M. Shanahan (Non-Executive)
- Mr. L.J. Wood (Non-Executive ceased Directorship 27 July 2014)
- Mr E. Ishag (Non-Executive)

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

#### INFORMATION ON DIRECTORS

MR. STANLEY R. MCLIESH (JOINED BOARD 2002) Non-Executive Chair

Member of the Remuneration and Nomination Committee, Member of the Audit and Risk Committee

Qualifications: BEd

Shares in Clinuvel: 76,000

Conditional Performance Rights over shares in Clinuvel: 80,000

Mr McLiesh has vast experience in commercialising pharmaceutical products internationally. As the former General Manager, Pharmaceuticals at CSL Limited, he was closely involved in the transition of CSL from government ownership through corporatisation to a highly successful listed company. While at CSL, Mr McLiesh

brokered numerous in-licensing agreements with international companies enabling CSL to expand into new markets profitably.

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

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

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: 577,334

Conditional Performance Rights to shares: 391,666

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 \$86 million since 2006 for the funding of the current development program of SCENESSE®.

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

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

Conditional Performance Rights over shares in Clinuvel: 50,000

Mrs Shanahan has a longstanding background in finance in Australian and overseas' economies and share markets and is a Fellow of the Institute of Directors. She is currently Chair of St Vincent's Medical Research Institute in Melbourne, and is a serving non-Executive Director of Challenger Limited (ASX: CGF) since 2011 and Bell Financial Group (ASX: BFG) since 2012. Mrs Shanahan is also a non-Executive Director of DMP Asset Management and a Director of the not-for-profit Kimberley Foundation Australia. Mrs Shanahan is the former Chair of Challenger Listed Investments Ltd, the reporting entity for Challenger Infrastructure Fund (ASX: CIF), Challenger Diversified Property Group (ASX: CDI) and Challenger Wine Trust (ASX: CWT).

She is a former member of the Australian Stock Exchange and former executive director of a stockbroking firm, a fund management company and an actuarial company. Mrs Shanahan is well known in the business and financial community; her insights add significant value to the current Board and the Company. Mrs Shanahan was Non-Executive Chair of the Clinuvel Board from late 2007 until July 2010.

# MR. LAWRENCE JOHN (JACK) WOOD (JOINED BOARD 2008 – TO 27 JULY 2014)

Non-Executive Director

Chair of the Remuneration and Nomination Committee

Qualifications: BComm

Shares in Clinuvel: 100,000

Mr Wood had an extensive background in international marketing and manufacture of pharmaceutical products. He lived in Germany, England, Australia, USA and Canada and overseen pharmaceutical operations throughout Europe, Asia and North America. He was 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 included Chairman of EnGene Corporation, director of QLT Inc. (until 2011), and also Executive Vice President CSL Limited Australia, where he coordinated the Company's worldwide expansion in the plasma products industry. President and CEO Exogene Corporation, Senior Vice President BioResponse Corporation both biotechnology companies sold to Baxter Healthcare Corporation. Mr Wood was also formerly Vice President Bayer Corporation Pharmaceutical division responsible for operations in Europe and Japan.

Mr Wood spent over seventeen years with Baxter Healthcare Corporation holding a series of operating and general management positions in North America, Europe, Asia and Australia.

#### MR ELIE ISHAG (JOINED BOARD 2011)

Non-Executive Director

Shares in Clinuvel: 72,733

Conditional Performance Rights over shares in Clinuvel: 50,000

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

#### INFORMATION ON COMPANY SECRETARY

MR. DARREN M. KEAMY

Company Secretary, Chief Financial Officer

Qualifications: BComm, CPA

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

#### **MEETING OF DIRECTORS**

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

DIRECTOR		BOARD	AUDIT & RISK COI	MMITTEE	REMUNER NOMINATION COM	
	A	В	A	В	Α	В
Mrs. B.M. Shanahan	7	7	2	2	-	-
Mr. S.R. McLiesh	7	7	2	2	4	4
Dr. P.J. Wolgen	7	7	2	-	4	4
Mr. L.J. Wood	7	7	-	-	4	4
Mr. E. Ishag	7	7	-	-	-	-
Column A indicates the number of mee Director was a member of the Board an		Column B indicates the n		•	period the	

#### PRINCIPAL ACTIVITIES

The principal activities of the consolidated entity during the financial year were to develop its leading drug candidate SCENESSE® (afamelanotide 16mg) 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.

#### REVIEW OF OPERATIONS

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

#### **DIVIDENDS PAID OR RECOMMENDED**

No dividends were paid or declared during the financial year or after reporting date.

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

CONSOLIDATED	2014	2013	CHANGE
	\$	\$	%
Revenues	2,526,561	1,963,462	29%
Net Loss before income tax expense	(5,525,889)	(6,802,823)	19%
Loss after income tax expense	(5,525,889)	(6,802,823)	19%
Basic earnings per share - cents per share	(14.3)	(19.3)	26%
Net tangible assets backing per ordinary share	\$0.36	\$0.36	Nil %
Dividends	Nil	Nil	Nil %
Note: Clinuvel does not operate individual segmen	nts.		

The distribution of SCENESSE® continued in Italy and Switzerland where reimbursement is received for the supply of the drug to provide a preventative treatment for the rare disease erythropoietic protoporphyria (EPP) patients. These revenues increased 42% to \$2.200 million for the 2013-14 year compared to \$1.554 million for the 2012-13 year. More patients in Italy and Switzerland have sought treatment whilst the demand for SCENESSE® from the existing patient base continues. Other revenues from ordinary activities include interest received from surplus funds held in bank accounts and term deposits, from \$0.410 million to \$0.326 million, a 20% decrease. The decrease reflects a combination of lower average interest rates year-on-year along with more workling capital held in non-Australian currencies when compared to the previous year.

The group's balance sheet has \$15.428 million in net assets at 30 June 2014 compared to \$13.839 million at 30 June 2013. Current liabilities decreased 12% to \$1.718 million. Monthly average cash spend was \$0.675 million for the year compared to \$0.785 million for the 2012-2013 year.

Excluding the government research and development (R&D) refundable tax incentives, R&D accounted for 38% of the group's total expense result for 2013/14, compared to 46% for the 2012/13 year. R&D expenditures, comprising clinical study costs, drug delivery research and manufacture, toxicity studies, regulatory fees and research and development-specific overheads such as personnel, were \$3.258 million in 2014 compared to \$4.490 million in 2013. The government refundable tax incentive gain of \$0.463 million is a result of the Australian government implementing a broadbased, market driven program allowing eligible R&D entities to receive a refundable 45% tax offset on certain qualifying R&D expenditures if their aggregate turnover is less than \$20 million per annum. The 2012-13 result for the consolidated entity includes the 2012-13 and 2011-12 income tax years compared to the 2013-14 year which only accounts for the expected refund from eligible qualifying expenditures incurred in the most recent 12 month period. Clinical study costs improved 50% from \$1.414 million in 2013 to \$0.708 million in 2014. The reduction in expenditures on clinical study costs reflects the continuing refinement of the Company's late stage clinical program in EPP, its careful progression into vitiligo and its focus on the EMA regulatory review. The majority of clinical development expenses in 2013-14 relate to the completion of its Phase II EPP study in the USA (CUV039) and the latter stages of the Phase II clinical study in actinic keratosis in organ transplant receipients (CUV011).

The expenses towards the drug delivery program further improved year-on-year, from \$0.913 million in 2013 to \$0.563 million in 2014, a 38% improvement. Implant manufacturing costs were incurred prior to the 2013-14 year but the drug delivery program

result included the expensing of prepaid supplies not utilised in the manufacturing development process. The head count of R&D personnel employed to oversee and monitor the clinical, regulatory and manufacturing programs was relatively stable over the course of 2013-14, resulting in a modest 1% improvement in R&D overhead costs (from \$1.694 million in 2013 to \$1.673 million in 2014). Toxicity study costs and regulatory affairs related fees also decreased year on year, from \$0.468 million in 2013 to \$0.313 million in 2014, a 33% reduction year-on-year.

Various non-clinical analyses and external regulatory affairs advice to support the consolidated entity was at a slightly lower rate of activity through the ongoing regulatory review in the 2013-14 year compared to the period leading up to the commencement of review in February 2012 and in the earlier stages of the review process throughout 2012-13.

Marketing expenditures in the Company decreased by \$0.087 million to \$0.516 million in 2014 (14% decrease) primarily due using external consultants engaged to perform critically specific business and market development projects. The result from general operations was \$4.541 million in 2014 compared to \$4.516 million in 2013, a marginal 1% increase. General operations comprised 53% of the group's total expense result for 2014 compared to 47% in 2013. Combined managerial, administrative payroll and non-cash remuneration costs was slightly lower to previous year but overseas travel costs offset this trend. In 2012-13 the consolidated entity liquidated all income securities held.

For the 2013/14 year the group started with \$12.569 million in cash and financial assets and finished with \$14.626 million. In May 2014 the group raised \$6.92 million additional capital. For the reporting date of 30 June 2014, due to movements in the Australian dollar compared to other currencies used top meet working capital requirements, the consolidated entity reported a loss of \$0.023 million from holding foreign currencies and in holding trade creditors in non-Australian currency (a \$0.059 million gain for the same period last year).

At 30 June 2014 basic earnings per share were -\$0.143 on 42,391,435 issued ordinary shares. This is compared to basic earnings per share of -\$0.193 as at 30 June 2013 on 38,217,038 issued ordinary shares.

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 patients with a clinical need for photoprotection and another group with a need for repigmentation. These patient groups range in size

from approximately 10,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg), a first-in-class drug targeting erythropoietic protoporphyria (EPP), has completed Phase II and III trials in the US and Europe and has been filed for review by the European Medicines Agency (EMA).

There were a number of significant events in 2013/14. These events include:

- a) The finalising of study preparations and subsequent start of a Phase II Singaporean study (CUV103) of SCENESSE® in adult patients with vitiligo. Clinuvel co-designed the study with global vitiligo experts to focus on treating patients with darker skin complexion (Fitzpatrick skin types III, IV, V and VI). In this seven-month study, patients will be evaluated on the safety and efficacy of SCENESSE® in combination with narrowband ultraviolet B (NB-UVB) light.
- b) The announcement in November 2013 of results from a Phase III US study (CUV039) evaluating the administration of SCENESSE® to patients diagnosed with erythropoietic protoporphyria (EPP), which showed the drug had shown a clinically meaningful treatment effect and was well tolerated. The primary objective of evaluating SCENESSE® in EPP patients was to determine whether the prophylactic use of the drug would provide a clinically relevant benefit. The primary endpoint was to establish the extent to which patients exposed themselves to direct sunlight between 10:00 and 18:00 as recorded daily in patient diaries. A strong statistical trend towards greater direct sunlight exposure was seen in the active group compared to placebo recipients. In total 93 patients were enrolled and 87 completed the study (93.5%), 45 on active treatment and 42 placebo recipients. Three from each group withdrew from the study due to reasons unrelated to drug administration.
- c) The publishing of results from a physician-led pilot study of SCENESSE® in the rare Hailey-Hailey Disease (HHD) in the journal *Clinical and Experimental Dermatology*. The pilot study, in two patients, indicated for the first time that afamelanotide may be of therapeutic benefit by offering long-term remission (disease free period). A physician-led study of SCENESSE® HHD patients commenced in Italy in February 2014. The open label study will enrol ten HHD patients to be treated with twelve doses of SCENESSE® during one year, with a three month clinical follow up period. Afamelanotide was granted orphan drug status for HHD by the EMA and US FDA in May 2014
- d) An announcement in August 2013 of an extension of the EMA's review period for SCENESSE® to January 2014, with another announcement in

January 2014 confirming a subsequent extension to mid-2014.

- e) The presentation of data from global clinical trials of SCENESSE® at the American Academy of Dermatology (AAD) Meeting and two specialist dermatology meetings in Denver, Colorado, in March 2014. Results from the CUV102 study of SCENESSE® in vitiligo, including long-term follow up data and published clinical observations, were presented across multiple sessions. Data from Clinuvel's global erythropoietic protoporphyria (EPP) program, evaluating SCENESSE® as a photoprotective, featured in AAD sessions on photomedicine and photoprotection.
- f) The announcement in May 2014 of a capital raise of A\$6.9million via a private placement ("Placement") to Asian and European institutional and professional investors. Subscriptions by the Board of Directors of Clinuvel for a further \$0.3 million at terms equivalent to those subscribed by all other participants to the Placement were received and are still subject to shareholder approval. Clinuvel earmarked the funds raised in the Placement to progress the development of SCENESSE® in the vitiligo program and further product development. The Company continues to look forward to securing a positive outcome to the EMA's review of the consolidated entity's scientific dossier into SCENESSE® in EPP. A positive outcome is a key strategic objective as this will largely determine its right to commercially market SCENESSE®. If successful, the consolidated entity will seek full or partial reimbursement from national insurers, payors and reimbursement agencies within the European Union to ensure that SCENESSE® can be distributed free of charge or as part of co-payment schemes to patients diagnosed with EPP.

# SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

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

# SIGNIFICANT EVENTS AFTER THE BALANCE DATE

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

a) On July 28th July, the consolidated entity announced it had received an unsolicited conditional proposal from Retrophin, Inc. (NASDAQ:

RTRX) on 17th July to acquire all of the ordinary shares in Clinuvel via scheme of arrangement.

b) On August 8th 2014, the consolidated entity announced its Board, in conjunction with its advisers, had evaluated the unsolicited proposal received from Retrophin, Inc., the subject of the July 28th announcement. The Board believed the proposal materially undervalued the consolidated entity and therefore declined the proposal.

# LIKELY DEVELOPMENTS AND EXPECTED RESULTS

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

## ENVIRONMENTAL REGULATION AND PERFORMANCE

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

## INDEMNIFICATION AND INSURANCE OF DIRECTORS AND OFFICERS

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

The Company has paid premiums to insure each of the Directors against liabilities for costs and expenses incurred by them in defending any legal proceedings arising of their conduct while acting in the capacity of Director of the Company, other than conduct involving wilful breach of duty in relation to the Company. The cost of the aforementioned insurance premium for 12 months was \$27,980 (2013: \$48,630).

### 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 19 to the financial statements.

# REMUNERATION REPORT

#### PRINCIPLE OBJECTIVE

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

# PRINCIPLES USED TO DETERMINE THE NATURE AND AMOUNT OF REMUNERATION

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

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

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

The policy has been adopted to cover the overall structure of remuneration for:

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

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

#### REMUNERATION POLICY

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

- a) Remuneration is structured to align with the Company's interests, taking account of the Company's strategies and risks.
- b) The level and composition of remuneration is reasonable, sufficient and provides competitive rewards that attract, retain and motivate people of high calibre to work towards the long-term growth and success of the Company.
- c) The role that total fixed remuneration and shortand long-term incentives play is clearly defined.
- d) The levels and structure of remuneration are benchmarked against relevant peers.
- e) There is a clear relationship between Company and individual performance and remuneration of key management personnel.
- f) The principles underlying the Company's remuneration structure are openly communicated and understood.
- g) The Company complies with applicable legal requirements and appropriate standards of governance.
- h) Remuneration policies and practices are evaluated over time, taking account of pay

outcomes and the relationship between pay and performance, and the results of any evaluations or review processes.

i) Remuneration is consistent regardless of gender.

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

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

The Company's reward framework provides a mix of fixed and variable pay, structured to incentivise short-term and long-term:

- Short-term (generally cash payment in the form of performance-based bonuses at a fixed amount or as a percentage of base salary).
- Long-term (generally based upon the issue of options and/or performance rights to acquire shares in the Company, along with other fixed amount cash bonuses). Performance rights are issued under the Company's Conditional Rights Plan, most recently approved by shareholders 12 November 2013 and is currently available to Executives and Directors, subject to shareholder approval. The vesting conditions can be either time and/or performance milestone-based. The Conditional Rights Plan was instituted to replace a former Share Option Plan, approved by shareholders 25 January 2007.

## REMUNERATION AND NOMINATION COMMITTEE

The Board has provided a mandate to the Remuneration and Nomination Committee to provide advice on salaries and fees, short and long-term incentives and employment terms and conditions for Directors, Executives and key management. The Remuneration and Nomination Committee obtains independent data to assess the appropriateness of remuneration packages, given trends in comparative companies, industry or related field of expertise. The Remuneration and Nomination Committee may consult with specialist remuneration consultants with experience in the healthcare industry as part of making and reviewing remuneration recommendations. For the year ended 30 June 2014, no remuneration recommendations were received from specialist remuneration consultants.

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

#### NON-EXECUTIVE REMUNERATION

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

Subject to shareholder approval, Non-Executive Directors can be issued performance rights under the Company's Conditional Rights Plan. Non-Executive Directors can be issued performance rights to align their interests with that of shareholders and to reflect their greater role in the management of the Company comparative to peer companies (and reflected in a smaller management team). The number of performance rights and nature of vesting is determined after the Director's appointment. One Non-Executive Director held unlisted share options which were previously issued under the Company's Share Option Plan. These share options expired during the year. This Plan is no longer used.

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

#### **EXECUTIVE REMUNERATION**

Remuneration packages for Executives may include:

- Base pay and benefits (including statutory benefits);
- Short-term incentive payments through the achievement of pre-specified performance-based targets;
- Longer-term business generation incentive payments through the achievement of prespecified performance-based targets;
- Discretionary payments for exceptional performance, innovation and/or expansion; and
- Long-term equity participation in Clinuvel's Conditional Rights Plan.

Base pay, including superannuation, is reviewed annually by the Remuneration and Nomination Committee to ensure the Executive's pay is competitive in international markets, industry and related fields of expertise. Some key managerial contracts contain guaranteed base pay increases linked to CPI data. Health insurance, accommodation benefits and living away from home allowances are offered to key management and Executives under specific circumstances.

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

For the 2013/14 financial year it was decided by the Remuneration and Nomination Committee to award the Managing Director a discretionary payment for achieving exceptional clinical, regulatory and revenue milestones

In the most recent Annual General Meeting (AGM), the Company obtained 96.67% of the proxy votes (including votes at the Board's discretion) in favour of adopting the 2013 remuneration report, and this resolution was passed on a show of hands at the meeting. The Company did not receive any further feedback at the AGM on its remuneration practices.

The methods used by the Remuneration and NominationCommitteetoassessBoardperformance is disclosed in the Corporate Governance Protocol. The remaining Executives receive discretionary short term incentives, generally evaluated annually against targets set at each performance review.

The long-term equity remuneration is provided to Directors and certain employees via the Clinuvel Conditional Rights Plan. See below for further information.

# COMPANY PERFORMANCE AND EXECUTIVE DIRECTOR REMUNERATION

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

The current Managing Director Remuneration structure is designed to maximise the motivation, retention and incentivisation of the Managing Director to advance the Company's program to its current stage of development, taking into account the complexity of the current development and business model. It is also designed to reflect the expertise, qualifications, seniority and achievements to date of the Managing Director since joining the Company in 2005.

#### SERVICE AGREEMENTS

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

Remuneration and other terms of employment for the Managing Director is formalised by a service agreement determined by the Remuneration and Nomination Committee. The agreement provide for base salary, short- and long-term bonuses, other benefits and participation, when eligible, in the Clinuvel Conditional Rights Plan. The Managing Director, in consultation with the Remuneration and Nomination Committee, oversees the service agreements entered into with Company Executives, providing for base salary, bonuses, other benefits and participation, when eligible, in the Clinuvel Conditional Rights Plan.

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

 Dr. Wolgen's (Managing Director and Chief Executive Officer) term of employment is 3 years from 15 March 2013, his base salary exclusive of retirement benefits for the year to 30 June 2014 is \$781,626 and his service agreement is with the wholly-owned Swiss subsidiary entity. Termination payment is set at 12 months of base salary provided the termination is not for a material breach of the agreement. The base salary is CPI indexed. Dr. Wolgen is required to provide 12 months' notice.

- Dr. Wright's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2014 is \$246,756. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Dr. Wright is required to provide 3 months' notice.
- Mr. Keamy's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2014 is \$200,611. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Mr. Keamy is required to provide 3 months' 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.

#### 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 nontransferable 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 if all transfer restrictions are satisfied or waived by the Board in its discretion. The number of rights granted is subject to approval by the Remuneration and Nomination Committee. Rights currently have specific terms and conditions, being the achievement of performance milestones set by the Directors of the consolidated entity.

#### **SHARE OPTIONS:**

Only one Non-Executive Director (Mr Jack Wood) held unlisted share options in the 2013-14 financial year which were previously issued under the

Company's Share Option Plan. This Plan is no longer used. The unlisted share options held by Mr Wood expired 18 November 2013.

These share options were previously issued under the Clinuvel Employee Share Option Plan, the Plan approved by shareholders at a shareholder meeting on 25 January 2007. These share options converted to one ordinary share of the consolidated entity, were issued for nil consideration, have no voting rights attached to the option and could be exercised any time from the date of vesting to the date of expiry. They are non-transferable and not listed on the ASX. The exercise price was based on the weighted average price at which the Company's shares were traded on the ASX 20 business days leading up to the date of grant, plus 10%.

The Company does not intend to issue further share options under this Plan.

#### **DETAILS OF REMUNERATION**

Key management personnel include all Directors (including non-executive) and other key management personnel who together have the authority and responsibility for planning, directing and controlling the activities of the Group:

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

Dr P.J. Wolgen (Chief Executive Officer)

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

Mr L.J. Wood (Non-Executive Director) (Ceased directorship 27 Juy 2014)

Mr E. Ishaq (Non-Executive Director)

Dr H.P.K. Agersborg (Executive Director and Chief Scientific Officer) (Ceased directorship 26 September 2012)

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

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

All key management personnel have been appointed to the positions detailed above for the past two years unless specified otherwise.

#### REMUNERATION OF THE DIRECTORS OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2014

		SHORT-TERM EMPLOYMENT BENEFITS		POST EMPLOYMENT BENEFITS	ا ا	HARE BASED PAYMENTS <sup>2</sup> ING CHARGE ONLY)		
DIRECTOR	GROSS SALARY	SHORT TERM INCENTIVE	LOYALTY PAYMENT	OTHER <sup>1</sup>	SUPER- ANNUATION/ PENSION FUND	PERF RIGHTS <sup>3</sup>	OPTIONS <sup>4</sup>	TOTAL
	\$	\$	\$	\$	\$	\$	\$	\$
Mr. S.R. McLiesh	73,395	-	-		6,789			80,184
Dr. P.J. Wolgen	781,626	358,380	574,000	82,105	8,396	42,537	-	1,847,044
Mrs. B.M. Shanahan	59,633	-	-	-	5,516	-	-	65,149
Mr. L.J. Wood	65,000		-	-	_	-	1,300	66,300
Mr. E. Ishag	50,000	-	-	-	-	-	-	50,000
TOTAL	1,029,654	358,380	574,000	82,105	20,701	42,537	1,300	2,108,677

<sup>&</sup>lt;sup>1</sup>Other' includes health insurance, housing and other allowances that may be subject to fringe benefits tax to facilitate relocation to the European office.

<sup>&</sup>lt;sup>2</sup>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.

<sup>&</sup>lt;sup>3</sup>Performance rights with total accounting value of \$177,549 were expensed for the previous reporting period.

<sup>&</sup>lt;sup>4</sup>Unexercised share options originating from the 2007 Share Option Plan with total accounting value of \$3,364 were expensed for the previous reporting period.

#### REMUNERATION OF THE DIRECTORS OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2013

		POST   SHORT-TERM EMPLOYMENT   EMPLOYMENT   (ACCOUNTING CHARG		SHORT-TERM EMPLOYMENT BENEFITS		PAYMENTS <sup>2</sup>		
DIRECTOR	GROSS SALARY	SHORT TERM INCENTIVE RELATED TO CURRENT PERIODS	SHORT TERM INCENTIVE <sup>5</sup> RELATED TO PRIOR PERIODS	OTHER <sup>1</sup>	SUPER- ANNUATION/ PENSION FUND	PERF RIGHTS³	OPTIONS <sup>4</sup>	TOTAL
	\$	\$	\$	\$	\$	\$	\$	\$
Dr. H.P.K. Agersborg	72,215	_	-			19,683		91,898
Mr. S.R. McLiesh	73,395	-	-	-	6,605	23,898	-	103,898
Dr. P.J. Wolgen	736,971	337,841	455,398	98,649	7,229	89,160	-	1,725,248
Mrs. B.M. Shanahan	59,633	-	-	-	5,367	14,936	-	79,936
Mr. L.J. Wood	65,000	-	-	-	-	14,936	3,364	83,300
Mr. E. Ishag	50,000	-	-	-	-	14,936	-	64,936
TOTAL	1,057,214	337,841	455,398	98,649	19,201	177,549	3,364	2,149,216

<sup>1&#</sup>x27;Other' includes health insurance, housing and other allowances that may be subject to fringe benefits tax to facilitate relocation to the European office.

<sup>&</sup>lt;sup>2</sup>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.

<sup>&</sup>lt;sup>3</sup>Performance rights with total accounting value of \$471,155 were expensed for the previous reporting period.

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

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

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

## REMUNERATION OF THE OTHER KEY MANAGEMENT PERSONNEL OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2014

					SHARE BASE	D PAYMENTS	
	SHORT-TERM	M EMPLOYMENT	BENEFITS	POST EMPLOYMENT BENEFITS	(ACCOUNT	TING CHARGE   ONLY)	
DIRECTOR	SALARY	SHORT TERM INCENTIVES	OTHER <sup>1</sup>	SUPERANNUATION CONTRIBUTIONS	PERF RIGHTS <sup>3</sup>	OPTIONS <sup>4</sup>	TOTAL
	\$	\$	\$	\$	\$	\$	\$
Dr. D.J. Wright	228,981	13,355	16,516	17,775	47,464	-	324,091
Mr. D.M. Keamy	183,529	11,404	-	17,082	43,273	-	255,288
TOTAL	412,510	24,759	16,516	34,857	90,737	-	579,379

<sup>&#</sup>x27;Other' includes health insurance, housing and other allowances to facilitate relocation of other Key Management Personnel.

# REMUNERATION OF THE OTHER KEY MANAGEMENT PERSONNEL OF THE COMPANY FOR THE YEAR ENDED 30 JUNE 2013

JUNE 2013							
					SHARE BASE	D PAYMENTS	
	SHORT-TERM	M EMPLOYMENT	BENEFITS	POST EMPLOYMENT BENEFITS	(ACCOUNT	TING CHARGE ONLY)	
DIRECTOR	SALARY	SHORT TERM INCENTIVES	OTHER <sup>1</sup>	SUPERANNUATION CONTRIBUTIONS	PERF RIGHTS <sup>3</sup>	OPTIONS⁴	TOTAL
	\$	\$	\$	\$	\$	\$	\$
Dr. D.J. Wright	207,093	11,824	51,802	16,470	66,723	-	353,912
Mr. D.M. Keamy	170,304	11,015	0	15,423	64,936	-	261,678
TOTAL	377,397	22,839	51,802	31,893	131,659	-	615,590

<sup>&#</sup>x27;Other' includes health insurance, housing and other allowances to facilitate relocation of other Key Management Personnel.

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

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

## THE RELATIVE PROPORTIONS OF REMUNERATION BETWEEN FIXED AND BASED ON PERFORMANCE FOR THE YEARS ENDING 30 JUNE 2014 AND 30 JUNE 2013

		2014		2013
	FIXED REMUNERATION	PERFORMANCE BASED	FIXED REMUNERATION	PERFORMANCE BASED
Dr. P.J. Wolgen	47%	53%	49%	51%
Dr. H.P.K. Agersborg	n/a	n/a	79%	21%
Dr. D.J. Wright	81%	19%	78%	22%
Mr. D.M. Keamy	79%	21%	71%	29%

# 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	35,000	\$2.75	\$0.40	Ordinary	18/11/2008	18/11/2008	18/11/2013
Clinuvel		\$2.75	\$0.50			18/11/2009	
Clinuvel		\$2.75	\$0.50			18/11/2010	

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

ENTITY	NUMBER OF RIGHTS	VALUE PER RIGHT ON GRANT DATE	CLASS	GRANT DATE	VESTING DATE FOR RETENTION IN SCHEME TRUST
Clinuvel	114,500	\$2.00	Ordinary	16/10/2009	-
Clinuvel	149,167	\$1.04	Ordinary	25/11/2010	<u>-</u>
Clinuvel	91,667	\$1.04	Ordinary	25/11/2010	-
Clinuvel	91,667	\$1.04	Ordinary	25/11/2010	<u>-</u>
Clinuvel	116,667	\$1.04	Ordinary	25/11/2010	<u>-</u>
Clinuvel	97,625	\$0.64	Ordinary	16/09/2011	-
Clinuvel	75,000	\$1.19	Ordinary	14/01/2013	<u>-</u>
Clinuvel	75,000	\$1.19	Ordinary	14/01/2013	<u>-</u>
Clinuvel	75,000	\$1.19	Ordinary	14/01/2013	-

#### 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	81,867	Nil\$	Ordinary

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

No shares were issued during the financial year as a result of exercise of options. No shares were provided upon exercise of options to Directors or Key Management Personnel during the years ending 30 June 2014 and 30 June 2013.

#### FURTHER INFORMATION - SHARE-BASED COMPENSATION

	A	В	С	D			
	% OF REMUNERATION CONSISTING OF OPTIONS AND RIGHTS	VALUE AT GRANT DATE	VALUE AT EXERCISE DATE	VALUE AT LAPSE DATE			
Mr. S.R. McLiesh	Nil%	-	-				
Dr. P.J. Wolgen	2.3%	-	-	-			
Mrs. B.M. Shanahan	Nil %	-	-	-			
Mr. L.J. Wood	2.0%	-	-				
Mr. E. Ishag	Nil%	-	-	-			
Dr. D.J. Wright	14.6%	-	-	-			
Mr. D.M. Keamy	17.0%	-	-	-			
A The percentage the year.	of the value of remuneration consisti	ng of options and/or rights, bas	ed on the value of the options a	and/or rights expensed during			
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.							
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.							
The value at lapse date of options and/or rights that were granted as part of remuneration and that lapsed during the year because a vesting condition was not satisfied. The value is determined at the time of lapsing but assuming the condition was satisfied.							

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

Performance Rights were priced using either a binomial or trinomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the pricing model is assumed to be the yield on either 1 year, 2 year, 3 year or 4 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

# ADDITIONAL INFORMATION ON OPTIONS AND RIGHTS ISSUED TO DIRECTORS AND KEY MANAGEMENT PERSONNEL

\* For Retention in the Scheme Trust - Transfer Restrictions Apply

#### REMUNERATION OPTION HOLDINGS OF KEY MANAGEMENT PERSONNEL - 2014

	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED		BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
DIRECTOR							
L.J. Wood	35,000	-	-	35,000	-	-	-

#### REMUNERATION CONDITIONAL PERFORMANCE RIGHTS HOLDINGS OF KEY MANAGEMENT PERSONNEL - 2014

	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	LAPSED AND EXPIRED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
DIRECTOR							
E. Ishag	50,000		-	-	50,000	-	50,000
S.R. McLiesh	80,000		-	-	80,000	-	80,000
B.M. Shanahan	50,000		-	-	50,000	-	50,000
P.J. Wolgen	391,666		-	-	391,666	-	391,666
L.J. Wood	50,000		-	-	50,000	-	50,000
EXECUTIVES							
D.J. Wright	181,875		-	-	181,875	-	181,875
D.M. Keamy	194,940	-	-	-	194,940	-	194,940

#### **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	S OF CASH B	ONUSES AN	ID OPTIO	NS/RIGH1	rs			
		BONUS						OPTIONS /	AND RIGHTS
	PAID	FORFEITED	YEAR GRANTED	TYPE	VESTED	FORFEITED	YEAR OF VESTING	MINIMUM GRANT VALUE YET TO VEST (\$)	MAXIMUM GRANT VALUE YET TO VEST (\$)
Dr. P.J. Wolgen	50%	50%						-	-
Mr. S.R. McLiesh	0%	0%	2010/11	Rights	0%	0%	No limitation	<u>-</u> -	407,336
Will Cit i Wolfeon		0.00	0011/10	D: 11	004	004	No		F0.001
Mr. L.J. Wood	0%	0%	2011/12 2008/09	Rights Options	0%	0%	limitation 2010/11	-	53,381
			2011/12	Rights	0%	0%	No limitation	-	33,363
Mrs. B.M. Shanahan	0%	0%						-	<u>-</u>
			2011/12	Rights	0%	0%	No limitation	-	33,363
Mr. E. Ishag	0%	0%						-	
			2011/12	Rights	0%	0%	No limitation	-	33,363
Dr. D.J. Wright	0%	0%						-	-
			2009/10	Rights	0%	0%		-	87,500
			2011/12	Rights	0%	0%	No limitation	-	42,819
_			2012/13	Rights	0%	0%	No limitation	-	89,100
Mr. D.M. Keamy	0%	0%						-	
_			2009/10	Rights	0%	0%	No limitation	-	40,000
			2011/12	Rights	0%	0%	No limitation	-	69,923
			2012/13	Rights	0%	0%	No limitation	-	89,100

The exercise price for those options granted to Mr. Wood in 2008/09 is \$2.75. The exercise price for those rights granted between 2009/10 and 2013/14 was \$Nil. Excluding the CEO Short Term Incentive, cash bonuses paid to Executives were discretionary.

**SHARES HELD BY KEY MANAGEMENT PERSONNEL**The number of ordinary shares in the Company during the 2014 reporting period held by each of the Group's Key Management Personnel, including their related parties, is set out below:

YEAR ENDED 30 JUNE 2014							
PERSONNEL	BALANCE AT START OF YEAR	GRANTED AS REMUNERATION	RECEIVED ON EXERCISE	OTHER CHANGES	HELD AT THE END OF REPORTING PERIOD		
E. Ishag	72,733	-	-	-	72,733		
S.R. McLiesh	76,000	-	-	-	76,000		
B.M. Shanahan	42,007	-	-	-	42,007		
P.J. Wolgen	577,334	-	-	-	577,334		
L.J. Wood	100,000	-	-	-	100,000		
D.J. Wright	143,124	-	-	-	143,124		
D.M. Keamy	80,220	-	-	-	80,220		

#### **SHARES UNDER OPTION**

DETAIL C OF UNICOUED OLIADES OF INTERESTS UNDER OPTIONS OF DIGUITS							
DETAILS OF UNISSUED SHARES OR INTERESTS UNDER OPTIONS OR RIGHTS							
ENTITY	NUMBER OF SHARES UNDER OPTIONS	NUMBER OF SHARES UNDER RIGHTS	EXERCISE PRICE	CLASS	EXPIRY DATE		
LIVIIII	ONDER OF HORS	ONDERTHORITO	THICL	ULAGO	EXI IIII DAIL		
Clinuvel Pharmaceuticals	-	1,466,482	\$Nil	Ordinary	Upon achievement of specific performance and time-based milestones		

# PERFORMANCE OF CLINUVEL PHARMACEUTICALS LTD AND CONTROLLED ENTITIES

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

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

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

YEAR ENDING JUNE 30										
REGULATORY/ CLINICAL MILESTONE	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Phase II Photoprotective Study										
Phase II PLE Study – Europe/Australia										
Phase II AK Study – Europe/Australia										
Ph II/III EPP Study – Europe/Australia – Trial 1										
Phase III PLE Study – Europe/Australia										
Phase II Solar Urticaria Study – Europe										
Phase II PDT Study – Europe										
Orphan Drug Designation EPP – Europe				•						
Orphan Drug Designation EPP – USA					•					
Orphan Drug Designation SU – Europe										
Investigational New Drug Status - USA										
Phase II EPP Study – USA										
Ph III EPP Study – Europe Trial 2										
Ph III PLE Study – Europe Trial 2										
Ph III EPP Study – USA										
Ph II Vitiligo Studies – Europe/USA										
Ph II Vitiligo Study - Singapore				_						
Orphan Drug Designation EPP – Australia				_			•			
Ph II HHD Study – Italy										
Orphan Drug Designation HHD – Europe										
Orphan Drug Designation HHD – USA										•
Application for marketing authorisation submitted with EMA										

#### LOANS TO DIRECTORS AND EXECUTIVES

No loans were granted to Directors or Executives for the years ending 30 June 2014 and 30 June 2013.

#### **NON-AUDIT SERVICES**

For the year ended 30 June 2014, Grant Thornton Australia provided audit services to the Company. Grant Thornton Australia also provided non-audit services, specifically a fraud gap assessment to identify additional policies and procedures are required, if any, in order to strengthen and maintain its Fraud Control Framework. Details of amounts paid or payable to the auditor for non-audit services provided during the year by the auditor are outlined in Note 18 to the financial statements.

The Directors are satisfied that the provision of non-audit services, during the year, by the auditor is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001. The Directors are of the opinion that the services as disclosed in note 18 to the financial statements do not compromise the external auditor's independence, based on advice received from the Audit Committee, for the following reasons:

- · all non-audit services have been reviewed and approved to ensure that they do not impact the integrity and objectivity of the auditor; and
- none of the services undermine the general principles relating to auditor independence as set out in APES 110 'Code of Ethics for Professional Accountants' issued by the Accounting Professional & Ethical Standards Board, including reviewing or auditing the auditor's own work, acting in a management or decision-making capacity for the Company, acting as advocate for the Company or jointly sharing economic risks and rewards.

For the year ending 30 June 2013 Grant Thornton Australia 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 Director's Report.

#### PROCEEDINGS ON BEHALF OF THE COMPANY

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

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

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

Dr. Philippe Wolgen, MBA MD

Director

Dated this 22nd day of August, 2014

# CORPORATE GOVERNANCE STATEMENT

#### **OVERVIEW**

Corporate governance is the system by which Clinuvel Pharmaceuticals Ltd (or the "Company") is directed and managed. It is the framework within which:

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

This statement outlines the main corporate governance principles and practices of Clinuvel Pharmaceuticals Ltd and is organised under headings based on the Australian Stock Exchange Corporate Governance Council's (ASXCGC) Corporate Governance Principles and Recommendations with 2010 Amendments, 2nd Edition. The Company's Corporate Governance Protocol and Board Charter was most recently comprehensively reviewed and updated in November 2013.

Charters and policies referred to are available on the Company's internet site (www.clinuvel.com).

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

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

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

The Board delegates to the Managing Director the authority to manage the Company and its businesses within levels of authority specified by the Board from time to time. The responsibilities and terms of employment, including termination entitlements, for the Managing Director and senior Executives are set out in a formal letter of appointment.

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

The performance of each senior Executive is appraised by the Managing Director annually against agreed targets, set either upon appointment or at the time of prior performance evaluation. Performance targets for senior Executives are reviewed by the Remuneration and Nomination Committee. The Board establishes performance criteria for the Managing Director and the Remuneration and Nomination Committee reviews the performance of the Managing Director against these targets.

For the reporting period, the performances of the Company's senior Executives, including the Managing Director, were evaluated in accordance to the above.

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

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

#### SIZE AND COMPOSITION OF THE BOARD

For the 2013/14 year the Board comprised of four Non-Executive Directors and one Executive Director (the Managing Director). Information about Directors, including their skills, experience, expertise and length of service can be found in pages 8 to 9.

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

The Board's framework for determining Director independence and the Company's materiality thresholds is included in the Board Charter. The Company currently has three Non-Executive Directors considered independent of the Company and its management, having no current or previous business or other relationships that could materially compromise their autonomy as a Director (Mrs. Shanahan, Mr. Ishaq and Mr. McLiesh, who is the Chair. A fourth Director, Mr. Wood, passed away after the year ended 30 June 2014 and a casual vacancy has not yet been filled). The Board has carefully assessed whether the impact of any past or present relationship with the Company, perceived or otherwise, materially interferes their ability to exercise independent judgment. Mr. McLiesh has served on the Board for more than nine years and the Board has determined his length of service does not materially interfere with his ability to act in the best interests of the Company. Thus the Board currently has a majority of independent Non-Executive Directors.

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

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

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

# REMUNERATION AND NOMINATION COMMITTEE - NOMINATION

To increase its effectiveness, the Board has a Remuneration and Nomination Committee. For the 2013/14 year, the Remuneration and Nomination Committee comprised of three Directors (two voting and one non-voting) and was chaired by Mr. Wood. Mr. McLiesh is the other voting member and the committee was comprised of a majority of voting independent Directors. Since July 27th 2014, the Remuneration and Nomination Committee is temporarily comprised of two Directors, one voting and one non-voting. As as a Director is appointed to the Board of Directors a third member of the Committee will be appointed.

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 10. A Committee charter can be found on the Company's internet site.

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

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

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

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

#### THE WORK OF DIRECTORS

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

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

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

#### PERFORMANCE REVIEW

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

A performance review of the Board and committees was made by the Remuneration and Nomination

disclosed in the Committee Charter during the current year.

ACCESS TO INFORMATION

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

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

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

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

#### CODE OF BUSINESS CONDUCT AND ETHICS

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

Committee in accordance with the process to fellow employees, shareholders, customers, suppliers and communities in which we operate.

#### TRADING IN SHARES

Directors' shareholdings at 30 June 2014 are shown on pages 8 to 9 and 25. The Company has a share trading policy in place, details of which are included in the Corporate Governance Protocol available on the Company's internet site. Directors and employees may only buy or sell Clinuvel Pharmaceuticals Ltd shares during specified periods. Also, they are prohibited from buying or selling Clinuvel Pharmaceuticals Ltd shares at any time if they are aware of any price sensitive information that has not been made public. All Clinuvel Pharmaceuticals Ltd share dealings by Directors are promptly notified to the ASX.

#### DIVERSITY POLICY

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

The key elements to the diversity policy are:

- a) To maintain a reasonably balanced gender diversity representation across the entire Company,
- b) For the Remuneration and Nomination Committee to 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 2014 and 30 June 2013 are:

GENDER REPRESENTATION		FEMALE %	MALE %
	30 June 2014	20%	80%
Board	30 June 2013	20%	80%
	30 June 2014	71%	29%
Top 7 salaried employees *	30 June 2013	57%	43%
	30 June 2014	63%	37%
Consolidated entity	30 June 2013	63%	37%

<sup>\*</sup> excludes Executive Director

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

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

#### AUDIT AND RISK COMMITTEE

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 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 10. A Committee charter can be found on the Company's internet site.

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

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

The external audit firm partner in charge of the Clinuvel Pharmaceuticals Ltd financial audit attends committee meetings by invitation. The Committee seeks to ensure the independence of the external auditor. Non-audit services are generally performed by other firms. For the current year, the audit firm's forensic accounting department performed a fraud gap assessment of the Company. The Audit and risk Committee does not consider this service to compromise auditor independence. The Committee's charter requires that individuals playing a significant role in the Clinuvel Pharmaceuticals Ltd audit be rotated every five years. The auditor annually confirms its independence within the meaning of applicable legislation and professional standards.

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

#### CONTINUOUS DISCLOSURE

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

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

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

Clinuvel Pharmaceuticals Ltd strives communicate effectively with shareholders about Company's performance, presenting the Annual Report and other corporate information in clear language, supported where appropriate 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 the ASX, significant briefings, notices of meetings, annual reports and Annual General Meeting presentations 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 the Company's businesses to identify and quantify business risks. Risk management is a key element of the Company's strategic planning, decision making and execution of strategies. The Company's business exposes it to potential risks which are inherent in the R&D, pre-clinical studies, clinical trials, manufacturing, marketing and use of human therapeutic products.

#### B) FINANCIAL RISKS

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.

#### <u>Management</u>

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. The Company'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, which comprised throughout 2013/14 two voting members, being two voting, independent Non-Executive Directors, and was chaired by Mr. Wood. Consequent to the sudden passing of Mr. Wood, the Remuneration and Nomination Committee currently comprises only one voting, independent member which will return to two voting, independent members as soon as a new Board appointment is made.

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 10. 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. In reviewing and making recommendations to the Board, the Committee may take regard to employment market conditions and consult with specialist remuneration consultants with experience in the healthcare and biotechnology industries.

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

Clinuvel Pharmaceuticals Ltd's policy is to reward Executive Directors and senior Executives with a combination of fixed remuneration and short and long- term incentives structured to drive improvements in shareholder value. Employees cannot approve their own remuneration, or that of their direct subordinates.

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

# STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2014

		CO	ONSOLIDATED
	NOTE	2014	2013
		\$	\$
Total revenues	2	2,526,561	1,963,462
Other income	2	463,018	937,026
Total expenses	2	(8,515,468)	(9,703,311)
Loss before income tax expense		(5,525,889)	(6,802,823)
Income tax expense/(benefit)	3	-	
Loss after income tax expense		(5,525,889)	(6,802,823)
NET LOSS FOR THE YEAR		(5,525,889)	(6,802,823)
Other comprehensive income			
Items that will be re-reclassified subsequently to profit or loss			
Exchange differences of foreign exchange translation of foreign operations		(62,916)	(142,665)
Income tax (expense)/benefit on items of other comprehensive income		-	-
Other comprehensive loss for the period, net of income tax		(62,916)	(142,665)
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD		(5,588,805)	(6,945,488)
Basic and diluted earnings per share - cents per share	15	(14.3)	(19.3)
The accompanying notes form part of these financial statements.			

# STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2014

			CONSOLIDATED
	NOTE	2014	2013
		\$	
CURRENT ASSETS			
Cash and cash equivalents	16(a)	14,625,583	12,568,839
Trade and other receivables	4	1,585,377	1,742,870
Other assets	5	828,147	1,356,68
TOTAL CURRENT ASSETS		17,039,107	15,668,394
NON CURRENT ASSETS			
Property, plant and equipment	6	114,461	146,39
TOTAL NON CURRENT ASSETS		114,461	146,397
TOTAL ASSETS		17,153,568	15,814,791
CURRENT LIABILITIES			
Trade and other payables	9	1,105,157	1,452,734
Provisions	10	613,020	493,530
TOTAL CURRENT LIABILITIES		1,718,177	1,946,264
NON CURRENT LIABILITIES			
Provisions	10	7,659	29,23
TOTAL NON CURRENT LIABILITIES		7,659	29,237
TOTAL LIABILITIES		1,725,836	1,975,501
NET ASSETS		15,427,732	13,839,290
EQUITY			
Contributed equity	11	133,567,056	126,710,26
Reserves	12	1,438,046	1,251,22
Accumulated losses	13	(119,577,370)	(114,122,202
TOTAL EQUITY		15,427,732	13,839,290
The accompanying notes form part of these financial sta	tements.		

# STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2014

			CONSOLIDATED
	NOTE	2014	2013
		\$	\$
CASH FLOWS FROM OPERATING ACTIVITIES			
Refund from ATO & for GST and VAT		1,022,947	123,019
Receipts from customers		1,894,734	1,602,434
Interest received		334,308	419,594
Payments to suppliers and employees		(8,060,674)	(9,037,113)
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	16(B)	(4,808,685)	(6,892,066)
CASH FLOWS FROM INVESTING ACTIVITIES			
Payments for property, plant and equipment		(3,436)	(30,849)
Proceeds from investment securities		-	467,458
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES		(3,436)	436,609
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issue of ordinary shares		6,921,098	6,623,259
Payment of share issue costs		(39,308)	(348,413)
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES		6,881,790	6,274,846
NET INCREASE/(DECREASE) IN CASH HELD		2,069,669	(180,611)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR		12,568,839	12,719,025
Effects of exchange rate changes on foreign currency held		(12,925)	30,425
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	16(A)	14,625,583	12,568,839
The accompanying notes form part of these financial statements.			

# STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2014

	SHARE CAPITAL	SHARE OPTION RESERVE	PERFORMANCE RIGHTS RESERVE	FOREIGN CURRENCY TRANSLATION RESERVE	RETAINED EARNINGS	TOTAL EQUITY
BALANCE AT 30 JUNE 2012	119,323,391	12,166	1,898,317	(89,064)	(107,507,474)	13,637,336
Issue of Share Capital under private placement	6,373,245	-	-	-	-	6,373,245
Issue of Share Capital under share-based payment	1,011,391	-	-	-		1,011,391
Employee share-based payment options	-	3,364	(716,223)	-	188,095	(524,764)
Capital raising costs	2,240	-	-	-	-	2,240
TRANSACTIONS WITH OWNERS	126,710,267	15,530	1,182,094	(89,064)	(107,319,379)	20,499,448
Loss for the year					(6,802,823)	(6,802,823)
OTHER COMPREHENSIVE INCOM	E:					
Exchange differences of foreign exchange translation of foreign operations	-	-	-	142,665	-	142,665
BALANCE AT 30 JUNE 2013	126,710,267	15,530	1,182,094	53,601	(114,122,202)	13,839,290
Issue of Share Capital under private placement	6,921,098	-	-	-	-	6,921,098
Issue of Share Capital under share-based payment	-	-	-	-	-	-
Employee share-based payment options	-	(15,530)	139,435	-	70,721	194,626
Capital raising costs	(64,309)		-		-	(64,309)
TRANSACTIONS WITH OWNERS	133,567,056		1,321,529	53,601	(114,051,481)	20,890,785
Loss for the year					(5,525,889)	(5,525,889)
OTHER COMPREHENSIVE INCOM	E:					
Exchange differences of foreign exchange translation of foreign operations	-	-	-	62,916	-	62,916
BALANCE AT 30 JUNE 2014	133,567,056	-	1,321,529	116,517	(119,577,370)	15,427,732

# NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2014

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

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 financial assets. Cost is based on the fair values of the consideration given in exchange for assets. The accounting policies have been consistently applied, unless otherwise stated.

Both the functional and presentation currency of the group and its Australian controlled entities is Australian dollars. The functional currency of certain non Australian controlled entities is not Australian dollars. As a result, the results of these entities are translated to Australian dollars for presentation in the Clinuvel Pharmaceuticals Ltd financial report.

In applying Australian Accounting Standards management must make judgment regarding carrying values of assets and liabilities that are not readily apparent from other sources. Assumptions 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 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.

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 10 Consolidated 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 8 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-derivate financial assets with fixed payments that are not quoted in an active market. They are included in current assets, except those loans and receivables that are due more than 12 months from reporting date.

#### 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 2014 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-licences to develop and commercialise SCENESSE® have expired and the consolidated entity no longer holds the sub-licences. The sub-licences have been fully amortised on a straight line basis over 10 years.

#### 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 binominal options pricing model. The fair value of conditional performance rights is measured by either a binomial or a trinomial model. It is determined at grant date and expensed on a straight- line basis over the vesting period. The fair value of options and conditional performance rights is shown as an expense in profit or loss.

#### K) REVENUE AND OTHER INCOME

#### **Interest**

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

#### Sale Reimbursements

Revenue from reimbursement of implant sales from insurance companies is recognised when the consolidated entity has transferred to the Buyer the significant risks and rewards of ownership of the goods.

#### Government R&D tax incentive

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

#### 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 cashgenerating 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) 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.

#### T) 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.

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

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 reporting 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.

<u>Key estimates – share-based payments transactions</u>

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 either a Black-Scholes, a binomial or a trinomial model, using the assumptions detailed in Note 22.

#### Key judgements – tax losses

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

# W) NEW ACCOUNTING STANDARDS AND INTERPRETATIONS

In the current year, the Group has adopted all of the new and revised Standards and Interpretations issued by the Australian Accounting Standards Board that are relevant to its operations and effective for the current annual reporting period. The adoption of the new and revised standards had minimum or no impact to the Group's financial statements:

- AASB 10 Consolidated Financial Statements.
- AASB 11 *Joint Arrangements* replaces AASB 131 *Interests in Joint Ventures*,
- AASB 12 Disclosure of Interests in Other Entities,
- · AASB 13 Fair Value Measurement, and
- AASB 119 Employee Benefits (2011)

### X) NEW AUSTRALIAN ACCOUNTING STANDARDS ISSUED BUT NOT YET EFFECTIVE

Certain new accounting standards and interpretations have been published that are not mandatory for 30 June 2014 reporting periods, and have not yet been adopted by the Group.

The following new or amendments to existing standards have been published and are mandatory for accounting periods beginning on or after 1 July 2014 or later periods, but have not been adopted. They are expected to result in minimum or no impact to the Group's financial statements.

- AASB 9 Financial Instruments,
- AASB 1031 Materiality (December 2013) and related AASB 2013-9 Amendments to Australian Accounting Standards – Conceptual Framework, Materiality and Financial Instruments,
- AASB 2012-3 Amendments to Australian Accounting Standards – Offsetting Financial Assets and Financial Liabilities.
- AASB 2013-3 *Recoverable Amount Disclosures for Non-Financial Assets*, and
- AASB 2014-1 *Amendments to Australian Accounting Standards.*
- IFRS 15 Revenue from Contracts with Customers

#### Y) SEGMENT REPORTING

A segment is a component of the consolidated entity that earns revenues or incurs expenses whose results are regularly reviewed by the chief operating decision makers and for which discrete financial information is prepared. The consolidated entity has one business segment, being the biopharmaceutical sector, and the majority of its activities is concentrated in researching and developing a sole asset, being its leading drug candidate.

It has established entities in more than one geographical area. Revenues from reimbursement revenue are 100% earned from entities within Europe, which is consistent with the comparative period. The non-current assets that are not held within Australia are immaterial to the group.

100% (2013: 100%) of the revenue from sales reimbursements is generated from three customers.

2. PROFIT/(LOSS) FROM CONTINUING OPERATIONS

	tor II/(E000) Friom Continuono di Enamono	CONSOLIDA		
		2014	2013	
		\$	\$	
(A)	REVENUES			
	Interest revenue – other persons	326,469	410,464	
	Sales reimbursements	2,200,092	1,552,998	
TOTA	L REVENUES	2,526,561	1,963,462	
(B)	OTHER INCOME			
	Government R&D tax incentive	463,018	937,026	
TOTA	L OTHER INCOME	463,018	937,026	
(C)	EXPENSES			
	Clinical development costs	708,430	1,414,488	
	Drug delivery research costs	563,307	913,451	
	Regulatory and toxicity studies	313,404	467,936	
	R&D overheads	1,672,698	1,694,413	
	Business marketing & listing	516,139	602,802	
	Licenses patents and trademarks	177,510	166,451	
	General operations (incl Board)	4,541,370	4,516,150	
	Net loss on disposal of financial assets held at fair value through profit and		202,683	
	Net gains on revaluation of financial assets held at fair value through profit		(216,545)	
	Gain on restating foreign currency creditors and currencies held		(58,518)	
	Loss on restating foreign currency creditors and currencies held	22,610	-	
TOTA	L EXPENSES	8,515,468	9,703,311	
(D)	PROFIT/(LOSS) BEFORE INCOME TAX INCLUDES THE FOLLOWING SPECIFIC EXPENSES			
	Employee benefits expense	5,029,112	4,834,921	
	Depreciation	37,471	48,772	
	Amortisation of patents, trademarks & sub-licence	-	9,200	
	Loss on sale of property, plant and equipment	2,851	1,689	
	Share based payments	194,626	486,627	
	Operating lease expense – minimum lease payments	315,216	244,213	

#### 3. INCOME TAX EXPENSE

		CONSOLIDA		
		2014	2013	
		\$	\$	
(A)	THE PRIMA FACIE TAX ON PROFIT (LOSS) IS RECONCILED TO THE INCOME TAX EX	PENSE (BENEFIT)	AS FOLLOWS:	
	Prima facie tax payable on profit (loss) from ordinary activities before income tax at 30% (2013: 30%)	(1, 657,767)	(2,040,847)	
Add:				
Tax e	ffect of			
	non deductible amortisation	683	281	
	non deductible legal fees	-	2,760	
	share based payments	58,388	145,988	
	research and development deduction	309,082	319,988	
	(over)/under provision of income tax in previous years	(192,510)	753,741	
	net (gain) on revaluation of financial assets at fair value through profit and loss	<u>-</u> _	(64,963)	
	annual sub-license fees		4,585	
	net loss on disposal of financial assets	-	60,805	
	Deferred tax assets not brought to account	(1,482,124)	817,662	
(B)	DEFERRED TAX ASSETS ARISING FROM UNCONFIRMED TAX LOSSES AND NET TIN BROUGHT TO ACCOUNT AT BALANCE DATE AS REALISATION OF THE BENEFIT IS N THE BENEFITS WILL ONLY BE OBTAINED IF THE CONDITIONS SET OUT IN NOTE 1(I	IOT REGARDED AS		
Tax lo	sses	37,373,387	35,204,403	
Net te	emporary differences	(291,143)	395,717	
		37,082,244	35,600,120	

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

#### 4. TRADE AND OTHER RECEIVABLES

	CONSOLIDATED		
	2014	2013	
	\$	\$	
CURRENT			
Trade debtors	1,059,223	734,848	
Accrued income	38,281	46,120	
Sundry debtors	487,873	961,902	
TOTAL CURRENT	1,585,377	1,742,870	

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
	2014	2013
	\$	\$
CURRENT PREPAYMENTS		
Peptide	727,145	1,201,458
Other	101,002	155,227
TOTAL	828,147	1,356,685

#### 6. PROPERTY, PLANT AND EQUIPMENT

		CONSOLIDATED
	2014	2013
	\$	\$
PLANT AND EQUIPMENT		
At cost	457,402	474,830
Less: accumulated depreciation	(369,788)	(362,291)
SUB-TOTAL	87,614	112,539
FURNITURE AND FITTINGS		
At cost	79,653	79,653
Less: accumulated depreciation	(52,806)	(45,795)
SUB-TOTAL	26,847	33,858
TOTAL PROPERTY, PLANT AND EQUIPMENT	114,461	146,397

#### MOVEMENTS IN CARRYING AMOUNTS - PROPERTY, PLANT AND EQUIPMENT

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

	PLANT AND EQUIPMENT	FURNITURE AND FITTINGS	TOTAL
	\$	\$	\$
CONSOLIDATED ENTITY			
CARRYING AMOUNT AT 30 JUNE 2012	137,239	41,761	179,000
Additions	19,770	-	19,770
Disposals	(32,779)	-	(32,779)
Depreciation written back on disposal	31,090	-	31,090
Depreciations expense	(40,859)	(7,903)	(48,762)
Exchange differences	(1,922)	-	(1,922)
CARRYING AMOUNT AT 30 JUNE 2013	112,539	33,858	146,397
Additions	3,436	-	3,436
Disposals	(25,448)	-	(25,448)
Depreciation written back on disposal	22,598	-	22,598
Depreciations expense	(30,461)	(7,011)	(37,472)
Exchange differences	4,950	-	4,950
CARRYING AMOUNT AT 30 JUNE 2014	87,614	26,847	114,461

#### 7. INTANGIBLE ASSETS

7. INTANGIBLE ASSETS	0	
		ONSOLIDATED
	2014	2013
	\$	\$
SUB-LICENCE TO DEVELOP AND COMMERCIALISE SCENESSE®*		
At cost		7,472,983
Less: accumulated amortisation	-	(7,472,983)
SUB-TOTAL SUB-TOTAL	-	-
* The sub-license expired during 2013-14.		
TRADEMARKS		
At cost	68,281	68,281
Less: accumulated amortisation of trademarks	(68,281)	(68,281)
SUB-TOTAL SUB-TOTAL	-	-
PATENTS		
At cost	23,718	23,718
Less: accumulated amortisation of patents	(23,718)	(23,718)
SUB-TOTAL SUB-TOTAL	-	-
TOTAL	-	-

#### **MOVEMENTS IN CARRYING AMOUNTS - INTANGIBLE ASSETS**

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

	SUB-LICENCE	TRADEMARKS AND PATENTS	TOTAL
	\$	\$	\$
CARRYING AMOUNT AT 30 JUNE 2012	-	9,200	9,200
Additions	-	-	
Impairment		-	-
Amortisation expense	-	(9,200)	(9,200)
CARRYING AMOUNT AT 30 JUNE 2013		-	-
Additions	-	-	
Impairment	-	-	-
Amortisation expense	-	-	-
CARRYING AMOUNT AT 30 JUNE 2014	-	-	-

Amortisation expense is included in the line item 'Total expenses' in the consolidated statement of comprehensive income.

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

#### **8. INTERESTS IN SUBSIDIARIES**

NAME OF ENTITY	COUNTRY OF INCORPORATION	OWNERSH	IP INTEREST
		2014	2013
Parent entity			
Clinuvel Pharmaceuticals Ltd	Australia		-
Controlled entities			
A.C.N. 089 584 467 Pty Ltd	Australia	0%	100%
A.C.N. 108 768 896 Pty Ltd	Australia	100%	100%
Clinuvel (UK) Ltd	United Kingdom	100%	100%
Clinuvel, Inc	United States	100%	100%
Clinuvel AG	Switzerland	100%	100%
Clinuvel Singapore Pte Ltd	Singapore	100%	100%
A.C.N. 089 584 467 Pty Ltd was de-registered during t	he course of 2013/14.		

#### 9. TRADE AND OTHER PAYABALES

		C	ONSOLIDATED
		2014	2013
		\$	\$
CURR	ENT		
	Unsecured trade creditors	178,450	184,016
	Sundry creditors and accrued expenses	926,707	1,268,718
TOTAL		1,105,157	1,452,734
(A)	AGGREGATE AMOUNTS PAYABLE TO:		
	Directors and Director-related entities	485,851	641,185
(B)	AUSTRALIAN DOLLAR EQUIVALENTS OF AMOUNTS PAYABLE IN FOREIGN CURREN HEDGED AND INCLUDED IN TRADE AND SUNDRY CREDITORS:	CIES NOT EFFECT	IVELY
	British pounds	12,330	9,644
	Swiss Franc	637,069	665,379
	Other	<u>-</u> _	1,080
TOTAL		649,399	676,103
For an a	analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 21.		
(C)	TERMS AND CONDITIONS:		
	Trade and sundry creditors are non-interest bearing and normally settled on 30 day terr	ns.	

#### 10. PROVISIONS

		CONSOLIDATED
	2014	2013
	\$	\$
CURRENT		
Employee benefits	613,020	493,530
NON CURRENT		
Employee benefits	7,659	29,237

#### 11. CONTRIBUTED EQUITY

#### (A) ISSUED AND PAID UP CAPITAL

(1) 100012 11112 11112 01 0111 11112		
		CONSOLIDATED
	2014	2013
	\$	\$
42,391,435 fully paid ordinary shares (2013: 38,217,038)	133,567,056	126,710,267

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.

#### 11. CONTRIBUTED EQUITY (CONTINUED)

#### **B) MOVEMENTS IN ORDINARY SHARE CAPITAL**

			С	ONSOLIDATED
		2014		2013
	NO.	\$	NO.	\$
AT THE BEGINNING OF THE FINANCIAL YEAR	38,217,038	126,710,267	34,651,874	119,323,391
Issued during the year				
Private placement	4,174,397	6,921,098	2,983,726	6,373,245
Conditional rights issued and transferred from conditional rights reserve	-		581,438	1,011,391
Less: transaction costs		(64,309)	-	2,240
BALANCE AT THE END OF THE FINANCIAL YEAR:	42,391,435	133,567,056	38,217,038	126,710,267

#### (C) CONDITIONAL PERFORMANCE RIGHTS

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

EXPIRY DATE	EXERCISE PRICE	NUMBER OF CONDITIONAL RIGHTS
Upon achievement of various performance milestones	Nil\$	Nil
During the year the following conditional performance rights wer	e exercised, resulting in t	he issue of fully paid ordinary shares:

EXPIRY DATE	EXERCISE PRICE	NUMBER OF CONDITIONAL RIGHTS
Upon achievement of various performance milestones	Nil\$	Nil

As at 30 June 2014 the following conditional performance rights existed which if exercised, would result in the issue of fully paid ordinary shares:

EXPIRY DATE	EXERCISE PRICE	NUMBER OF CONDITIONAL RIGHTS
Upon achievement of various performance milestones	Nil\$	1,466,482

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.

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		CONSOLIDATED
	2014	2013
	\$	\$
SHARE OPTION RESERVE		
BALANCE AT THE BEGINNING OF PERIOD	15,530	12,166
Share based payment	1,300	3,364
Lapsed, forfeited Options	(16,830)	-
BALANCE AT THE END OF PERIOD	-	15,530

The Executive share option reserve arises on the grant of share options to Executive and Directors under the Executive share option scheme. Amounts are transferred out of the reserve and into issued capital when the options are exercised and to retained earnings when options lapse.

#### **CONDITIONAL PERFORMANCE RIGHTS RESERVE**

BALANCE AT THE BEGINNING OF PERIOD	1,182,094	1,898,317
Share based payment	193,326	483,263
Transfer to share capital		(1,011,391)
Lapsed, forfeited Rights	(53,891)	(188,095)
BALANCE AT THE END OF PERIOD	1,321,529	1,182,094

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	53,601	(89,064)
Translating foreign subsidiary to current rate at Balance Date	62,916	142,665
BALANCE AT THE END OF PERIOD	116,517	53,601
TOTAL DECEDIFO	1 420 046	1 051 005

#### 13. ACCUMULATED LOSSES

		CONSOLIDATED
	2014	2013
	\$	\$
ACCUMULATED LOSSES AT THE BEGINNING OF THE YEAR	(114,122,202)	(107,507,474)
Transfer from Share Option reserve of lapsed & expired Options	16,830	<u>-</u>
Transfer from Performance Rights reserve of lapsed & expired Rights	53,891	188,095
Net loss attributable to the members of Clinuvel Pharmaceuticals Ltd	(5,525,889)	(6,802,823)
ACCUMULATED LOSSES AT THE END OF THE FINANCIAL YEAR	(119,577,370)	(114,122,202)

#### 14. LEASE COMMITMENTS

		CONSOLIDATED
	2014	2013
	\$	\$
OPERATING LEASE COMMITMENTS		
Non-cancellable operating leases		-
Contracted for but not capitalised in the accounts:		
Payable:		
not later than 1 year	155,090	203,526
later than 1 year but not later than 5 years	-	562
TOTAL	155,090	204,088

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

No contingent rental clauses exist in lease agreements. Lease agreements range from 3 months to 9 months as from the reporting date and contain renewal options. Fixed increases are factored into some of the agreements.

#### 15. EARNINGS PER SHARE (EPS)

		CONSOLIDATED
	2014	2013
	\$	\$
(a) Basic Earnings Per Share (cents per share)	(14.3)	(19.3)
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of Basic Earnings Per Share	38,697,380	35,295,370
(c) The numerator used in the calculation of Basic Earnings Per Share (\$)	(5,525,889)	(6,802,823)

As at 30 June 2014 the Company had on issue unlisted performance rights over unissued capital. These rights are not considered dilutive as they do not increase the net loss per share.

Other than the issue of 75,000 ordinary shares on 7th August 2014 from the exercise of performance rights in relation to an achieved performance milestone, 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 rights are considered anti dilutive and have been excluded from the calculation of diluted earnings per share. Therefore basic and diluted earnings per share are the same. The number of performance rights that could potentially dilute earnings per share in the future, as at the date of this report, is 1,391,482 (2013: 1,563,616).

#### **16. CASH FLOW INFORMATION**

	C	ONSOLIDATED
	2014	2013
	\$	
(A) RECONCILIATION OF CASH		
Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled to sheet as follows	the related items in	the balance
Cash at bank	2,024,641	1,274,559
Cash on hand	978	1,49
Deposits on call	316,842	1,224,026
Term deposits	12,200,000	10,000,000
Security bonds	83,122	68,763
TOTAL CASH	14,625,583	12,568,839
(B) RECONCILIATION OF CASH FLOWS FROM OPERATING ACTIVITIES WITH OPERATING I	PROFIT (LOSS)	
OPERATING PROFIT (LOSS) AFTER INCOME TAX	(5,525,889)	(6,802,823
NON CASH FLOWS IN OPERATING (LOSS):		
Depreciation expense	37,472	48,772
Exchange rate effect on foreign currencies held	12,925	(30,425
Amortisation expense		9,200
Executive share option expense	194,626	486,62
Loss on sale of non-current assets	2,851	1,689
Realised loss on disposal of financial assets at fair value through profit and loss		202,683
Net loss on revaluation of financial assets held at fair value		(216,545
Unrealised loss on foreign exchange translation	57,965	142,686
CHANGES IN ASSETS AND LIABILITIES:		
(Increase)/decrease in receivables	159,024	(985,663
(Increase)/decrease in prepayments	529,023	270,562
Increase/(decrease) in payables	(374,594)	(263,866
Increase/(decrease) in provisions	97,912	245,03
NET CASH USED IN OPERATING ACTIVITIES	(4,808,685)	(6,892,066)

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

The effective interest rate on short-term deposits was 3.83% (2013: 4.43%). These deposits have an average maturity date of 125 days (2013: 102 days).

17. KEY MANAGEMENT PERSONNEL DISCLOSURES					
THE DIRECTORS OF CLINUVEL PHARMACEUTICALS LIMITED DURING THE YEAR WERE:					
Mr. S.R. McLiesh (Non-Executive Chair)					
Mrs. B.M. Shanahan (Non-Executive Director)					
Dr. P.J. Wolgen (Managing Director)					
Mr. L.J. Wood (Non-Executive)					
Mr. E. Ishag (Non-Executive)					
THE OTHER KEY MANAGEMENT PERSONNEL OF CLINUVEL PHARMACEUTICALS LIMITED DURING THE YEAR WERE:					

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

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

Please see the Remuneration Report from page 14 for further information.

#### **KEY MANAGEMENT PERSONNEL COMPENSATION**

		CONSOLIDATED
	2014	2013
	\$	\$
Short-term employee benefits	2,497,924	2,401,140
Post-employment benefits	55,558	51,094
Long-term benefits	-	
Termination benefits	-	
Share-based payments	134,574	312,572
TOTAL	2,688,056	2,764,806

#### 18. AUDITOR'S REMUNERATION

		CONSOLIDATED
	2014	2013
	\$	\$
AMOUNTS RECEIVED OR DUE AND RECEIVABLE BY GRANT THORNTON FOR:		
audit services and review	63,024	63,014
non-audit services	6,000	-
TOTAL	69,024	63,014

#### 19. RELATED PARTY DISCLOSURES

#### DIRECTORS

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

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

#### WHOLLY-OWNED GROUP TRANSACTIONS

#### Loans

The loan receivable by Clinuvel Pharmaceuticals Ltd from A.C.N. 089 584 467 Pty Ltd was intended to be repaid upon commercialisation of the Company's drug candidate. The sub-licenses the subject of the loan receivable have expired. A.C.N. 089 584 467 Pty Ltd was de-registered during the course of the year and the loan receivable was forgiven.

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 2014 is \$4,370,640 (2013: \$4,370,640).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel Inc is interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in Clinuvel, Inc. The loan to Clinuvel, Inc as at 30 June 2014 is \$7,532,904 (2013: \$6,549,360).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel AG is interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in Clinuvel AG. The loan to Clinuvel AG as at 30 June 2014 is \$13,785,105 (2013: \$10,709,418).

The loan receivable by Clinuvel Pharmaceuticals Ltd from Clinuvel Singapore Pte Ltd is interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of Clinuvel Pharmaceuticals Ltd to the extent that a deficiency in net assets exists in Clinuvel Singapore Pte Ltd. The loan to Clinuvel Singapore Pte Ltd as at 30 June 2014 is \$223,722 (2013: \$91,873).

Director related and key management personnel transactions and entities:

There are no transactions and relationships in existence as at 30 June 2014 between Directors and the Company and its related entities.

#### 20. SEGMENT INFORMATION

A segment is a component of the consolidated entity that earns revenues or incurs expenses whose results are regularly reviewed by the chief operating decision makers and for which discrete financial information is prepared. The consolidated entity has one business segment, being the biopharmaceutical sector, and the majority of its activities is concentrated in researching and developing a sole asset, being its leading drug candidate.

It has established entities in more than one geographical area. Revenues from reimbursement revenue are 100% earned from entities within Europe, which is consistent with the comparative period. The non-current assets that are not held within Australia are immaterial to the group.

100 % (2013: 100%) of the revenue from sales reimbursements is generated from three customers.

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

#### FOREIGN CURRENCY RISK

The consolidated entity is exposed to foreign currency risk on future commercial transactions and recognised assets and liabilities that are denominated in a currency other than the functional currency of each of the group's entities, primarily US dollars (USD), Euros (EUR), Swiss francs (CHF) and Singapore dollars (SGD). 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 maximie 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 2014 and as at 30 June 2013.

#### THE CONSOLIDATED ENTITIES EXPOSURE TO FOREIGN CURRENCY RISK AT 30 JUNE 2014

			COV			COV	ISOLIDATED	
				2014				2013
	CASH & CASH EQUIVALENTS	TRADE DEBTORS & OTHER ASSETS	TRADE, OTHER PAYABLES & PROVISIONS	TOTAL	CASH & CASH EQUIVALENTS	TRADE DEBTORS & OTHER ASSETS	TRADE, OTHER PAYABLES & PROVISIONS	TOTAL
USD	624,258	-	(55,802)	568,456	368,227	-	(166,729)	201,498
EUR	492,416	694,500	(86,543)	1,100,373	364,656	613,875	(121,127)	857,404
CHF	250,827	157,440	(785,710)	(377,443)	239,201	-	(821,674)	(582,473)
GBP	<del>-</del>	-	(6,820)	(6,820)	-	-	(5,856)	(5,856)
SEK	-	-	-	-	-	-	(7,418)	(7,418)
SGD	169,306	-	(40,844)	128,462	48,703	-	(5,107)	43,596

#### SENSITIVITY ANALYSIS

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

For the consolidated entity, a 10% appreciation of the Australian dollar against the US currency would have increased profit and loss and equity by \$147,990 for the year ended 30 June 2014 (2013: \$277,962), on the basis that all other variables remain constant. 10% is considered representative of the market volatility in the Australian/US dollar rate for the period.

For the consolidated entity, a 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 2014, 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 \$50,861 higher/lower (2013: \$52,572 higher/lower)

This analysis assumes all other variables are held constant.

#### PRICE RISK

Clinuvel Pharmaceuticals Ltd and its consolidated entities was formerly exposed to price risk in its investments in income securities classified in the Statement of Financial Position as held for trading. All income securities were liquidated during the course of the year and there are no future plans to invest in income securities. Neither the consolidated entity nor the parent is exposed to commodity price risk.

#### **CREDIT RISK**

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. Exposure to credit risk in trade debtors is limited to three counterparties, being two Italian government funded medical institutions and a Swiss government funded medical institution.

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

#### LIQUIDITY RISK

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

#### 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 to service future liquidity needs.

#### CAPITAL RISK MANAGEMENT

The consolidated entity's equity is limited to shareholder contributions, supported by the cash inflows received from the full cost reimbursement programs in Italy and Switzerland for providing SCENESSE® to EPP patients. 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 2014		
		CONSOLIDATED
	2014	2013
	\$	\$
CASH AND CASH EQUIVALENTS		
Carrying amount	14,625,583	12,568,839
6 months or less	14,625,583	12,539,218
Greater than 6 months	-	29,621
TOTAL	14,625,583	12,568,839
OTHER FINANCIAL ASSETS (INCLUDES TRADE AND OTHER RECEIVABLES)		
Carrying amount	1,585,377	1,742,870
6 months or less	1,507,546	1,742,870
Greater than 6 months	77,831	-
TOTAL	1,585,377	1,742,870
	2014	2013
	\$	\$
TRADE AND OTHER PAYABLES	<del>_</del>	<b>_</b>
Carrying amount	1,105,157	1,452,734
6 months or less	1,105,157	1,452,734
Greater than 6 months		-
TOTAL	1,105,157	1,452,734
22. EMPLOYEE BENEFITS		
		CONSOLIDATED
	2014	2013
	\$	\$
THE AGGREGATE EMPLOYEE BENEFIT LIABILITY IS COMPRISED OF:		
Provision for annual leave	383,277	319,364
Provision for long service leave	237,402	203,403
Accrued FBT, payroll, superannuation, pension funds, employee insurances	640,403	810,198
TOTAL	1,261,082	1,332,965

#### A) SHARE BASED PAYMENTS

The consolidated entity formerly had a share option scheme (which will no longer issue further share options under the scheme and all share options which have been issued under the scheme are fully expired) and has a conditional performance rights scheme which is ownership based for key management personnel and select consultants (including Directors) of the Company.

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 2014:

PERFORMANCE RIGHTS SERIES		NUMBER	GRANT DATE	EXPIRY DATE	EXERCISE PRICE	FAIR VALUE AT GRANT DATE
Issued	16/10/2009	104,500	16/10/2009	Upon achievement of specific performance milestones	\$ Nil	\$2.00
Issued	07/01/2010	10,000	07/01/2010	Upon achievement of specific performance milestones	\$ Nil	\$1.70
Issued	25/11/2010	449,166	25/11/2010	Upon achievement of specific performance milestones	\$ Nil	\$1.04
Issued	16/09/2011	447,816	16/09/2011	Upon achievement of specific performance milestones	\$ Nil	Between \$0.55 and \$0.72
Issued	16/11/2011	230,000	16/11/2011	Upon achievement of specific performance milestones	\$ Nil	\$0.67
Issued	14/01/2013	225,000	14/01/2013	Upon achievement of specific performance milestones	\$ Nil	\$1.19

#### **OPTION HOLDINGS OF ALL ISSUED OPTIONS - 2014**

OPTIONS SERIES	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	EXPIRED AND LAPSED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
Issued 18/11/2008	35,000	-	-	35,000	-	-	-
TOTAL	35,000	-	-	35,000	-	-	-
Weighted average exercise price	\$2.75	-	-	\$2.75	-	-	-

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 - 2014

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	114,500	-	-	(10,000)	104,500	-	104,500
Issued 07/01/2010	10,000	-	-	-	10,000	10,000	
Issued 25/11/2010	449,166	-	-	-	449,166	-	449,166
Issued 16/09/2011	499,950	-	-	(52,134)	437,816	-	437,816
Issued 16/11/2011	230,000	-	-	-	230,000	-	230,000
Issued 14/01/2013	225,000	-	-	-	225,000	-	225,000
TOTAL	1,528,616	-	-	(62,134)	1,466,482	10,000	1,456,482
Weighted average exercise price	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil

Performance Rights were priced using either a binomial or trinomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the pricing model is assumed to be the yield on either the 1 year, 2 year, 3 year or 4 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

#### HOLDINGS OF ALL ISSUED CONDITIONAL PERFORMANCE RIGHTS - 2013

PERFORMANCE RIGHTS SERIES	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	EXPIRED AND LAPSED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
Issued 16/10/2009	150,500	-	(36,000)	-	114,500	-	114,500
Issued 07/01/2010	17,500	-	(3,750)	(3,750)	10,000	10,000	
Issued 25/11/2010	900,000	-	(265,834)	(185,000)	449,166	-	449,166
Issued 16/09/2011	863,779	-	(275,854)	(87,975)	499,950	-	499,950
Issued 16/11/2011	230,000	-	-	-	230,000	-	230,000
Issued 14/01/2013	-	225,000	-	-	225,000	-	225,000
TOTAL	2,161,779	225,000	(581,438)	(276,725)	1,528,616	10,000	1,518,616
Weighted average exercise price	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil

Performance Rights were priced using either a binomial or trinomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the pricing model is assumed to be the yield on either the 1 year, 2 year, 3 year or 4 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

#### 23. CLINUVEL PHARMACEUTICALS LTD PARENT COMPANY INFORMATION

	CLINUVEL PHARMACEUTICALS LTD		
	2014	2013	
	\$	\$	
ASSETS			
Current assets	14,606,906	13,670,505	
Non-current assets	1,591,697	1,038,350	
TOTAL ASSETS	16,198,603	14,708,855	
LIABILITIES	<u> </u>		
Current liabilities	643,805	725,809	
Non-current liabilities	7,659	29,237	
TOTAL LIABILITIES	651,464	755,046	
EQUITY			
Issued equity	133,567,056	126,710,253	
Share-based payments reserve	1,321,544	1,197,639	
Accumulated losses	(119,341,461)	(113,954,083)	
TOTAL EQUITY	15,547,139	13,953,809	
FINANCIAL PERFORMANCE			
Net profit (loss) for the year	(5,316,657)	(5,894,843)	
Other comprehensive income	-	-	
TOTAL COMPREHENSIVE INCOME	(5,316,657)	(5,894,843)	

#### 24. 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, other than the following events:

- a) On July 28th July, the consolidated entity announced it had received an unsolicited conditional proposal from Retrophin, Inc. (NASDAQ: RTRX) on 17th July to acquire all of the ordinary shares in Clinuvel via scheme of arrangement.
- b) On August 8th 2014, the consolidated entity announced its Board, in conjunction with its advisers, had evaluated the unsolicited proposal received from Retrophin, Inc., the subject of the July 28th announcement. The Board believed the proposal materially undervalued the consolidated entity and therefore declined the proposal.

#### 25. ADDITIONAL COMPANY INFORMATION

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

The Registered office is:

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

# **DIRECTORS' DECLARATION**

In the opinion of the Directors:

- 1. the financial statements and notes of the consolidated entity are in accordance with the Corporations Act 2001, including:
- a) giving a true and fair view of the consolidated entity's financial position as at 30 June 2014 and of their performance for the year ended on that date; and
- b) complying with Accounting Standards; and
- c) complying with International financial Reporting Standards as disclosed in Note 1
- 2. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.
- 3. the remuneration disclosures set out in the Annual Report comply with Australian Accounting Standards 124 Related Party Disclosures and the Corporations Regulations 2001.

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

DR P.J. WOLGEN

DIRECTOR

Dated this 22nd day of August, 2014



The Rialto, Level 30 525 Collins St Melbourne Victoria 3000

Correspondence to: GPO Box 4736 Melbourne Victoria 3001

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

# Independent Auditor's Report To the Members of Clinuvel Pharmaceuticals 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 2014, the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information and the directors' declaration of the consolidated entity comprising the Company and the entities 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 in accordance with Australian Accounting Standards and the Corporations Act 2001. The Directors' responsibility also includes such internal control as the Directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error. The Directors also state, in the notes to the financial report, in accordance with Accounting Standard AASB 101 Presentation of Financial Statements, the financial statements comply with International Financial Reporting Standards.

#### **Auditor's responsibility**

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

Grant Thornton Audit Pty Ltd ACN 130 913 594 a subsidiary or related entity of Grant Thornton Australia Ltd ABN 41 127 556 389

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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 of the financial report that gives a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Directors, as well as evaluating the overall presentation of the financial report.

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

#### Independence

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

#### **Auditor's opinion**

In our opinion:

- a the financial report of Clinuvel Pharmaceuticals 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 2014 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 11 to 22 of the directors' report for the year ended 30 June 2014. 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 2014, complies with section 300A of the Corporations Act 2001.

GRANT THORNTON AUDIT PTY LTD

Chartered Accountants

M.A. Cunningham

Partner - Audit & Assurance

Melbourne, 22 August 2014



The Rialto, Level 30 525 Collins St Melbourne Victoria 3000

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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 2014, I declare that, to the best of my knowledge and belief, there have been:

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

GRANT THORNTON AUDIT PTY LTD

Chartered Accountants

Michael Cunningham

Partner - Audit & Assurance

Melbourne, 22 August 2014

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# SHAREHOLDER INFORMATION AS AT 30 SEPTEMBER 2014

Additional information, as at 30 September 2014 required by the ASX and not shown elsewhere in this report is as follows:

#### 1. SHAREHOLDING

#### A) DISTRIBUTION OF SHAREHOLDER NUMBERS

	QUOTED ORDINARY SHARES		UNQUOTED P	ERFORMANCE RIGHTS
CATEGORY (SIZE OF HOLDING)	TOTAL HOLDERS	UNITS	TOTAL HOLDERS	UNITS
1-1,000	1,878	751,534	-	
1,001-5,000	829	2,012,254	1	3,500
5,001-10,000	173	1,305,116	1	10,000
10,001-100,000	204	5,197,921	9	331,876
100,001-999,999,999	28	33,199,610	5	996,106
TOTAL	3,112	42,466,435	16	1,341,482

#### B) SHAREHOLDINGS HELD IN LESS THAN MARKETABLE PARCELS

TOTAL	526	39,340

#### C) SUBSTANTIAL SHAREHOLDINGS (ACCORDING TO LATEST SUBSTANTIAL HOLDER DISCLOSURES)

NAME	NO. ORDINARY SHARES & AMERICAN DEPOSITORY RECEIPTS	
Retrophin, Inc	3,311,906	7.80%
FIL Limited	2,788,449	6.57%
Ender 1, LLC	2,340,824	5.51%

#### **D) VOTING RIGHTS**

The voting rights attaching to each class of equity securities are set out below:

#### (I) ORDINARY SHARES

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

#### (II) PERFORMANCE RIGHTS

Performance Rights have no voting rights.

#### E) LARGEST SHAREHOLDERS

POSITION	NAME	NUMBER OF ORDINARY FULLY PAID SHARES HELD	% HELD OF ISSUED ORDINARY CAPITAL
1.	J P MORGAN NOMINEES AUSTRALIA LIMITED	9,119,091	21.47
2.	CITICORP NOMINEES PTY LIMITED	4,581,453	10.79
3.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	4,567,800	10.76
4.	NATIONAL NOMINEES LIMITED	4,443,245	10.46
5.	ENDER 1, LLC	2,340,824	5.51
6.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	1,742,122	4.10
7.	ACN 108 768 896 PTY LTD	1,106,266	2.61
8.	DR MARK EDWIN BADCOCK	570,200	1.34
9.	NATIONAL NOMINEES LIMITED <db a="" c=""></db>	539,142	1.27
10.	M BADCOCK AND P CHU SUPERANNUATION FUND PTY LTD	500,000	1.18
11.	HEADSTART GLOBAL AGGRESSIVE HOLDINGS LTD	379,515	0.89
12.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <euroclear a="" bank="" c="" nv="" sa=""></euroclear>	365,436	0.86
13.	ABN AMRO CLEARING SYDNEY NOMINEES PTY LTD <custodian a="" c=""></custodian>	354,732	0.84
14.	MR MARK WILLIAM ILIFF + MRS PATRICIA MARIE ANDREWS <mwi a="" c="" fund="" super=""></mwi>	351,074	0.83
15.	HEADSTART GLOBAL HOLDINGS LTD	337,633	0.80
16.	BIOTECH LAB SINGAPORE PTE LTD	301,568	0.71
17.	DR MICHAEL JAMES FISH	180,361	0.42
18.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	180,227	0.42
19.	DR CORINNE GINIFER	173,849	0.41
20.	MR DAVID JOHN LEWIS	142,294	0.34
TOTALS: TOP 20 HOLDERS OF ORDINARY FULLY PAID SHARES (TOTAL)		32,276,832	76.01
TOTAL REMAINING HOLDERS BALANCE		10,189,603	23.99

#### 2. COMPANY SECRETARY

The name of the Company Secretary is:

Darren Keamy

#### 3. REGISTERED OFFICE

The address of the principle registered office in Australia is:

Level 14/190 Queen St Melbourne, Vic 3000 Telephone: +61 3 9660 4900 Fax: +61 3 9660 4999 Email: mail@clinuvel.com Website: http://www.clinuvel.com

#### 4. REGISTER OF SECURITIES

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

Tel: +61 3 9415 4000

# 5. AUSTRALIAN SECURITIES EXCHANGE LIMITED

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

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

- Germany: Frankfurt and XETRA: UR9
- USA: Level 1 American Depositary Receipt (ADR) code: CLVLY (ADR Custodian: Bank of New York Mellon)

#### 6. RESTRICTED SECURITIES

Restricted securities on issue at June 30 2014: Nil.

#### 7. DIRECTORY

NON-EXECUTIVE CHAIR Stan McLiesh

NON-EXECUTIVE DIRECTORS Brenda Shanahan, Elie Ishaq

MANAGING DIRECTOR AND CHIEF EXECUTIVE OFFICER Dr Philippe Wolgen

ACTING CHIEF SCIENTIFIC OFFICER
Dr Dennis Wright

CHIEF FINANCIAL OFFICER AND COMPANY SECRETARY Darren Keamy

#### AUDITOR

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

#### BANKER

National Australia Bank (NAB) Western Branch, 460 Collins St, Melbourne, VIC 3000, Australia

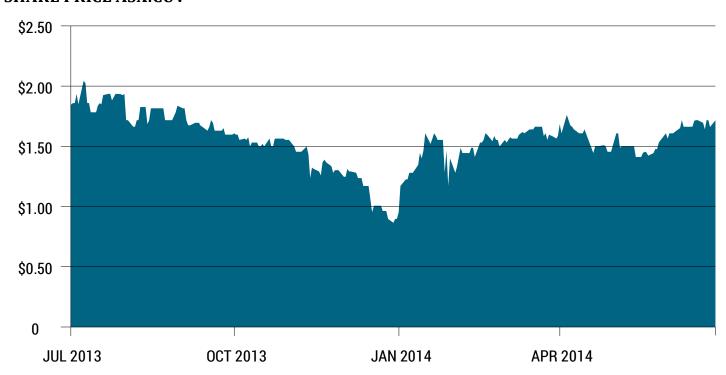
LEGAL COUNSEL Arnold Bloch Leibler Level 21, 333 Collins St, Melbourne, VIC 3000, Australia

Bristows LLP 100 Victoria Embankment, London EC4Y 0DH, United Kingdom

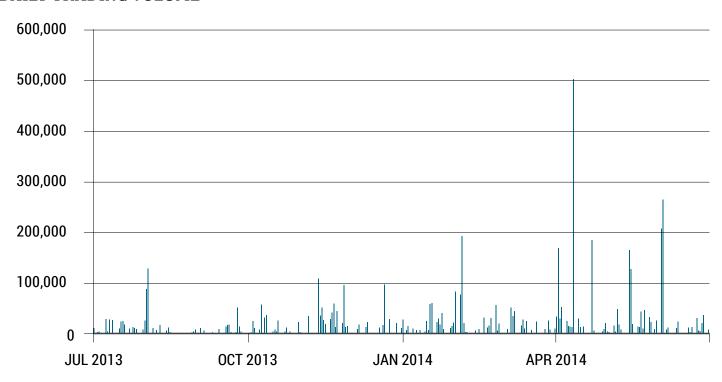
# IP LAWYER Dipl.-Ing Peter Farago Baadestr 3, Munich 80, Germany

# **MARKET PERFORMANCE**

#### **SHARE PRICE ASX:CUV**



#### **DAILY TRADING VOLUME**



# **GLOSSARY**

# ALPHA-MELANOCYTE STIMULATING HORMONE (A-MSH)

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.

#### **EUROPEAN MEDICINES AGENCY (EMA)**

The decentralised body of the European Union regulating medical drugs and devices.

#### **ERYTHEMA (ACTINIC-SOLAR)**

Reddening of the dermis (the top layer of skin), with or without 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).  $\alpha$ -MSH acts specifically to stimulate (eu) melanin synthesis.

#### FOOD AND DRUG ADMINISTRATION (FDA)

The USA's regulatory agency for food, tobacco, medicines 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.

#### MARKETING AUTHORISATION APPLICATION (MAA)

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

#### **MELANIN**

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

#### **MELANOCYTES**

The cells in the skin that produce melanin.

#### **MELANOGENESIS**

The process whereby melanin is produced in the body.

#### MINIMUM ERYTHEMA DOSE (MED)

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

## NARROWBAND ULTRAVIOLET B (NB-UVB) PHOTOTHERAPY

Therapy which utilises an ultraviolet B light source to activate melanin in vitiliginous lesions of the skin.

#### **NEW DRUG APPLICATION (NDA)**

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

#### 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 IIB/PHASE III

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

#### PHARMACODYNAMICS

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

#### **PHARMACOKINETICS**

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

#### **PHOTODERMATOSES**

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

#### **PHOTOPROTECTION**

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

#### **SUBCUTANEOUS**

Underneath the skin.

#### SUSTAINED RELEASE/CONTROLLED-RELEASE

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

#### **THYMINE DIMERS**

DNA changes which are characteristic of UV damage.

#### THERAPEUTIC GOODS ADMINISTRATION (TGA)

Australia's regulatory agency for medicinal products and devices.

#### **ULTRAVIOLET (UV) RADIATION**

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



