

# CLINUVEL PHARMACEUTICALS

## ANNUAL REPORT 2016



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# CHAIR'S LETTER



Dear Shareholders,

## **SCENESSE® (AFAMELANOTIDE 16MG) – EUROPEAN ROLL OUT**

Following the approval of SCENESSE® in Europe the Group has adapted and grown its team to facilitate distribution across Europe. New skill sets have been added during this period, with a focus on pharmacovigilance, quality assurance, compliance, and analytical sciences. The evolving team responds to the needs of the business as CLINUVEL expands the availability of SCENESSE® to serve patients diagnosed with erythropoietic protoporphyria (EPP).

Being a new molecular entity and the first to ever address the unmet need in the rare disease EPP, the regulatory authorities expect CLINUVEL to closely manage the product's life cycle. The European approval was accompanied by a comprehensive Risk Management Plan, strict parameters by which CLINUVEL should make the drug available. The Company's focus is on monitoring the ongoing safety of the product (pharmacovigilance), as well as on collecting additional data on the product under conditions of use. We have restricted the product's availability only to those expert centres who have worked with EPP patients and are prepared to undergo the training and accreditation necessary to comply with the demands of the national and European authorities. Two non-interventional post-authorisation studies have been initiated, one of which incorporates the first ever international EPP patient registry, a long-term project designed with experts in the field. While these measures place a burden on physicians and patients to access treatment as well as on CLINUVEL, we are all expected to add significantly to the overall understanding of EPP and patient care in the future.

The first patients were treated under this programme in June 2016, and the team has since received positive feedback from the clinics regarding the impact of treatment and the ongoing need for access to therapy. A larger product roll out is planned for 2017 as we work towards making SCENESSE® available to all known EPP populations in Europe.

## **US REGULATORY PATHWAY**

The clinical demand for SCENESSE® in the US has remained strong since the conclusion of our trial program in 2013. In parallel to the launch of the product in Europe, discussions have continued with the Food and Drug Administration (FDA) to determine the pathway forward for SCENESSE® in the US. Early into the new financial year we saw positive developments for the US EPP program, with recognition from the FDA in the form of Fast Track designation, a regulatory mechanism to expedite the product's regulatory review. Subsequently

the FDA accepted the existing clinical package for SCENESSE® as sufficient for filing a New Drug Application (NDA) for EPP.

Discussions are ongoing with the agency as to the timing of a NDA filing, however we realistically expect the first submissions to be made in the 2016/17 financial year.

## **EXPANDING THE CLINUVEL GROUP**

CLINUVEL holds a unique position in the pharmaceutical space. Few companies succeed in developing a novel drug, even fewer when the target indication has never before been addressed by medicine. Having succeeded along this journey thus far, the Group must now look to capitalise on its position as a leader in the field of melanocortins, and our expertise in the interaction of light and skin.

For some time now, both the Board and the management team have held ambitions to grow CLINUVEL beyond a single product in a single disorder, drawing on our team's experience in R&D, regulatory affairs and commercialisation. The first steps have already been taken, with the development of SCENESSE® in the pigmentary disorder vitiligo and the establishment of our Singaporean joint venture VALLAURIX PTE LTD. At logical points our investors will be kept up to date of progress, keeping in mind our need to protect our first-mover advantage.

The year has been demanding of our teams, and yet they continue to perform within a complex global environment. I thank them for their diligence and continued commitment to the patients we aim to help. I also extend the Board's gratitude and appreciation to all who have made the year a success – investors, shareholders, physicians, and patients.

A handwritten signature in black ink, appearing to read 'Stan McLiesh'. The signature is fluid and cursive, written over a white background.

Stan McLiesh

Chairman

# MANAGING DIRECTOR'S LETTER



Dear Shareholders,

## ANNUAL REVIEW AND VISION

It is with tribute to our patients, the medical communities who are involved with CLINUVEL, and to our teams that I write to you at a time when CLINUVEL is in a position to contemplate further expansion of its operations. Establishing the first steps in European distribution of SCENESSE® (afamelanotide 16mg) is an achievement of which we are proud. In this review, and for those who recently became familiar with the CLINUVEL story, I provide some historical context for the future outlook of the CLINUVEL Group.

## REGULATORY AGENCIES AND PHARMACOVIGILANCE

For more than a decade CLINUVEL has executed a comprehensive program which – from the outset – appeared complex due to a myriad of unique issues. Owing to the novelty of the drug, its pharmacology, mode of action, targeted rare disease and lack of available scientific instruments to measure the impact of the disease on patients' lives, and overall therapy, our teams have faced numerous challenges throughout the journey.

While drawing minimal attention we have worked for 12 years towards obtaining European and US approval for the first melanocortin. Our teams strive for achievement and setting realistic expectations as they have shown long term commitment to the Company. As a first-in-class drug for a rare disease which is not well defined by the medical literature, we could not draw upon analogies within our industry. At the very least, CLINUVEL's numerous antecedents had shown us how not to develop SCENESSE® and the plan was executed accordingly.

In a changing environment of increasing regulatory scrutiny within the post-authorisation phase, our teams are required to constantly adapt and change course. New guidelines, changing personnel, differing views, and governmental pressures are just a few of the factors that urge us to remain flexible.

I see contemporary drug development as a rigorous exercise to demonstrate ongoing safety of a product not only during the testing phase but also throughout compassionate use programs, special access schemes, and after marketing authorisation. The burden of instituting a pharmacovigilance system in each European country, establishing the European EPP Disease Registry, committing to monitor each EPP expert centre, and ensuring the proper management of the drug's distribution are just some of the many measures required, and they come at a substantial financial cost. The societal cost of pharmacovigilance is enormous and collectively, the Company, expert centres, patients, and health care systems and

insurers are all in a conundrum and left with no choice but to share the burden. Yet despite the load a benefit to the Company has arisen: pharmacovigilance measures provide a competitive advantage over any other company wishing to emulate our programs.

## INNOVATION

In discussions with investors and the general public we often encounter a misunderstanding of what constitutes pharmaceutical innovation. Innovation should not be seen to be limited to the product and its pharmacological activity in humans. Behind a novel product which had not previously been developed – such as SCENESSE® – is a new way of writing a dossier, new nomenclature, novel coding, new scientific tools, presenting previously unknown instruments and methodology, novel assays to measure and validation tools, a new pool of expert physicians, and new treatment protocols where no other templates can be used.

Put differently, introducing the concept of protecting light intolerant and chronically ill patients with a pharmaceutically innovative therapy had never been executed before. We needed to introduce this concept to the medical community and convince it of its validity. Often it was the medical community who convinced us how effective the treatment actually was for their stigmatised patients. In vitiligo we will face similar tasks of introducing the concept of repigmenting patients, demonstrating the impact of vitiligo on one's self-esteem and sense of identity, and demonstrating the impact of regaining one's colour. Measuring pigmentation and repigmentation is relatively novel in the field of drug development. We are determined to be the first company to address vitiligo systemically with a pandermal therapy.

## MARKET ACCESS AND PRICING

We have now received the first orders from the Netherlands, Austria, and Italy. The novel therapy introduced a new set of challenges for national insurers. Along the same vein, insurers needed to be made aware of the new therapy, anticipating that each insurer would resist the pricing of the proposed treatment. One could deliberate on health economic arguments and the value of providing treatment to EPP patients who have lived a life deprived of light, sun and outdoor existence. However, the conclusion most insurers and advisory bodies will arrive at is that EPP is not well characterised and understood by most clinical experts, and that the lack of available alternative therapy has made patients desperate for an effective treatment. CLINUVEL is required to inform these payors in a relatively short time for them to develop a deep level of understanding on the chronic disorder EPP.

We are cognisant of having a head start on insurers and advisory bodies. Most importantly, for a long time we have understood that SCENESSE® provides patients with the clinical freedom to lead a life they never could conceive or would have experienced. EPP patients are deprived and starved of light and live in a world of anxiety, not taken seriously by their surroundings.

It was telling that in many ways the experience of patients no longer using SCENESSE® after clinical trials were completed was worse than not knowing that an effective treatment had existed. The abrupt withdrawal of SCENESSE® becomes a concern at the time of writing, since an increasing number of patients refuse to return to their handicapped lives. Our teams have carefully listened to the endless patients' petitions and continued the development and distribution of the drug.

We will use the same approach in our further developments over the next few years for other products and for SCENESSE® in vitiligo. The patients' voice is paramount in CLINUVEL's decision making process. At the end of the day it is patients and expert physicians who hold the fate of a drug in their hands, certainly in orphan diseases.

## EXPANSION

An economist from my Columbia business school days focused his life on deciphering value investment on global exchanges. He passed on to me the memorable lesson of selecting business domains: "successful businesses are always sober in their presentation and from the outside boring, invest in the boring". Although it is counterintuitive to deliberately pursue a boring business, the message sticks along the thoughts of Graham-Dodd's approach.

I tend to agree that sustainable success hinges on execution, flexibility and persistence. Although these attributes are generally less attended to in conventional business literature it goes a long way to explain the delivery of corporate milestones by CLINUVEL's teams. Our financial team led by our CFO Darren Keamy and overseen by the Audit & Risk Committee is focused on keeping an eye for detailed management of expenditures and on realistic forecasting. They execute without frills.

With the current foundation, one can expect that CLINUVEL will seek to expand through organic growth and the identification of new opportunities to allow the entire development program of SCENESSE® and its paediatric version to come to fruition. Our VALLAURIX PTE LTD laboratory team is growing in both number and quality and is working towards the development of complementary products.

I see risks in pharmaceutical development as disproportionate to the ultimate reward of launching a novel product to patients. However, market analyses illustrate that market authorisation of a pharmaceutical in itself creates value due to the relative lack of new products. Here the risk over the product cycle is asymmetrically distributed. By managing these risks over the years we have tailored our attention and resources towards a simpler business model.

Whilst we are all proud of our recent successes, we are in no way complacent about the next sets of challenges of continued European reimbursement, entry in the US, and expanding the Company.

I thank you for your ongoing support and look forward to sharing CLINUVEL's success with you.



Philippe Wolgen

Managing Director, CLINUVEL Group

## CORPORATE GOVERNANCE

CLINUVEL PHARMACEUTICALS LTD and its Board are committed to establishing and achieving the highest standards of corporate governance. The Company's Corporate Governance statement for the year ending 30 June 2016, based on the Australian Securities Exchange Corporate Governance Council's (ASXCGC) Corporate Governance Principles and Recommendations, 3rd Edition, can be found on our website at <http://www.clinuvel.com/en/investors/corporate-governance>

# DIRECTORS' REPORT

The Directors of the Board present their report on the Company and its controlled entities for the financial year ended 30 June 2016 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 E. Ishag (Non-Executive)
- Mr. W. A. Blijdorp (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 Committee (Chair since 28 July 2014), Member of the Audit and Risk Committee

Qualifications: BEd

Shares in CLINUVEL: 191,000

Conditional Performance Rights over shares in CLINUVEL: 85,000

Mr McLiesh has an extensive background in the commercialisation of pharmaceutical products. He was closely involved in the transition of CSL Limited (ASX: CSL) from government ownership through corporatisation to a highly successful listed company as General Manager. During this time he helped CSL expand its international reach, brokering numerous in-licensing agreements, M&A transactions and partnerships with multinational firms.

Mr McLiesh is Vice President of the Board of Ivanhoe Girls Grammar School in Melbourne and was previously a Non-Executive Director of Unilife Medical Solutions Ltd (formerly ASX: UNS). The Chair of CLINUVEL since 2008, Mr McLiesh has been involved in formulating the successful European commercial strategy for SCENESSE® (afamelanotide 16mg).

### DR. PHILIPPE J. WOLGEN (JOINED BOARD 2005)

#### Chief Executive Officer, Managing Director

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

Qualifications: MBA, MD

Shares in CLINUVEL: 2,079,832

Conditional Performance Rights over shares in CLINUVEL: 1,424,864

Dr Wolgen was appointed as Managing Director of CLINUVEL in November 2005 to lead the corporate turnaround of the company.

Under his leadership CLINUVEL reformulated the lead product SCENESSE® (afamelanotide 16mg), identified its medical application and ultimately obtained European marketing authorisation.

SCENESSE® is the first melanocortin drug to have completed a clinical trial program and obtain marketing authorisation in a major market.

Dr Wolgen has been instrumental in rebuilding a share register of long term sophisticated and institutional investors. His international contacts and network contribute to the support CLINUVEL enjoys globally.

He helped CLINUVEL attract approximately AUD100 million in direct funding to develop and launch SCENESSE®. Dr Wolgen is now leading the CLINUVEL Group's expansion, with an immediate focus on the US and the further development of the company's product pipeline. His focus has been to establish a professional management team to persist in the corporate objectives set.

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: 133,969

Conditional Performance Rights over shares in CLINUVEL: 70,000

Mrs Shanahan is an established member of the Australian finance community who has also spent more than two decades working and investing in medical R&D and commercialisation. She is currently a non-executive director of DMP Asset Management, Challenger Limited (ASX: CGF, since 2011) and Bell Financial Group (ASX: BFG, since 2012), a director of the Kimberly Foundation of Australia Ltd, and Chair of both the St Vincent's Medical Research Institute and the Aikenhead Centre for Medical Discovery in Melbourne.

Previously Mrs Shanahan was a member of the Australian Stock Exchange and an executive director of a stockbroking firm, a fund management company and an actuarial company. She was also Chair of Challenger Listed Investments Ltd, the reporting entity for four ASX listed firms (CKT, CIF, CDI and CWT).

Mrs Shanahan joined CLINUVEL in 2007, and was Non-Executive Chair of the Board from late 2007 until July 2010. Her depth of experience across global markets and medical research provides significant value to the current Board and Company.

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

#### Non-Executive Director

Member of the Remuneration Committee

Shares in CLINUVEL: 148,195

Conditional Performance Rights over shares in CLINUVEL: 56,500

Mr Ishag is a London based entrepreneur with 50 years of commercial experience, active in European asset management, real estate development and IT. He is an Honorary Life Fellow of the UK Institute of Directors (FIoD). With a background in pharmaceutical chemistry, Mr Ishag is currently the Chairman of European Investments & Developments Ltd, a privately held company with an investment mandate in defined asset classes, property development and cross-

border commercial real estate. Mr Ishag has been extensively involved in the commercial evolution and backing of various successful ventures including IT company Espotting Media.

### MR. WILLEM A. BLIJDDORP (JOINED BOARD 2015)

#### Non-Executive Director

Shares in CLINUVEL: 383,145

Conditional Performance Rights over shares in CLINUVEL: 0

Mr Blijddorp is an international entrepreneur who has helped build privately owned B&S International NV, one of the largest global trading houses, over the past three decades. Mr Blijddorp has led B&S's growth, with the Dutch group – focused on the wholesale and international trading of luxury and fast moving consumer goods and pharmaceutical products – achieving a compounded annual growth rate of 10% for the last decade. Formerly B&S's CEO, Mr Blijddorp now focuses on the company's development and expansion strategy as majority shareholder and supervisory director. In 2014 he was recognised for his expertise in merger and acquisitions and leadership as the Ernst & Young Entrepreneur of the Year in the Netherlands.

Since joining CLINUVEL in 2014, Mr Blijddorp has been actively involved in the Company's long-term strategy for product commercialisation, growth, and development.

### INFORMATION ON COMPANY SECRETARY

#### MR. DARREN M. KEAMY

Company Secretary, Chief Financial Officer

Qualifications: BComm, CPA

Mr Keamy, a Certified Practising Accountant, joined CLINUVEL PHARMACEUTICALS LTD in November 2005 and became Chief Financial Officer of the Company in 2006. He has previously worked in key management accounting and commercial roles in Amcor Limited over a period of nine years and has experience working in Europe in financial regulation and control within the banking and retail pharmaceutical industries.

## MEETING OF DIRECTORS

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

DIRECTOR	BOARD		AUDIT & RISK COMMITTEE		REMUNERATION & NOMINATION COMMITTEE	
	A	B	A	B	A	B
Mrs. B.M. Shanahan	6	6	3	3	-	-
Mr. S.R. McLiesh	6	6	3	3	2	2
Dr. P.J. Wolgen	6	6	3	1	2	2
Mr. E. Ishag	6	5	-	-	2	2
Mr. W. Blijddorp	6	6	-	-	-	-

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

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

## PRINCIPAL ACTIVITIES

The principal activities of the consolidated entity during the financial year were to develop its leading drug candidate 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 and at repigmentation of the skin due to a number of depigmentation disorders. There was no significant change in the nature of activities during the financial year.

## DIVIDENDS PAID OR RECOMMENDED

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

## REVIEW OF OPERATIONS

The consolidated entity's main strategic focus throughout the year, consequent to the European Medicine Agency's (EMA's) granting of marketing authorisation for SCENESSE® (afamelanotide 16mg) in erythropoietic protoporphyria (EPP), was continuing to establish a post-authorisation program to monitor ongoing patient safety and effectiveness. A post authorisation safety study (PASS) was established along with a disease registry, hospital sites were trained and accredited in the collection of data and use of SCENESSE® and a strict pharmacovigilance system to monitor long term patients' safety during the commercial phase of the product was implemented. A final reimbursement pricing structure is being established in key European countries and submissions made to various payors in select European regions for agreement, culminating in the first European commercial launch of SCENESSE® in the 2016 northern hemisphere summer. The R&D program in vitiligo and further melanocortin development has continued throughout the year.

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

CONSOLIDATED ENTITY	2016	2015	CHANGE
	\$	\$	%
Revenues	6,419,707	3,259,962	97%
Net Loss before income tax expense	(3,153,718)	(10,414,376)	70%
Loss after income tax expense	(3,153,718)	(10,414,376)	70%
Basic earnings per share - cents per share	(7.0)	(24.0)	71%
Net tangible assets backing per ordinary share	\$0.38	\$0.25	(52%)
Dividends	Nil	Nil	Nil %

Note: CLINUVEL does not operate individual segments.

Monthly operating average cash spend was 17% greater than the previous year, being \$0.782 million for 2015/16 compared to \$0.667 million for the 2014/15 year. The increase in average monthly spend is primarily due to a year-on-year increase in head count combined with an increase in manufacturing-related expenditures from producing implants available for supply. The group's balance sheet has \$17.835 million in net assets at 30 June 2016 compared to \$11.205 million at 30 June 2015. Current liabilities decreased 6% to \$2.288 million. The

group result for the year ending 30 June 2016 was a \$3.154 million loss, compared to a \$10.414 million loss for the prior financial year, a decrease in the loss of 70%. Non-cash items within the general operations result along with first-time commercial revenues (see following) were the key drivers for the difference.

The current year was the first full year of expenditures incurred by VALLAURIX PTE LTD that is consolidated in the group result. Staffing, non-clinical development work, travel and patent costs totalling \$180,655 were the key expenditure items affecting the group result for 2015/16 (2014/15: \$90,797).

The distribution of SCENESSE® continued in Italy and Switzerland with the ongoing subsidised supply of the drug to provide a preventative treatment for adult erythropoietic protoporphyria (EPP) patients under full-cost compensation Special Access Schemes. These revenues increased 24% to \$3.614 million for the 2015/16 year compared to \$2.912 million for the 2014/15 year. The increase in the compensation price for the subsidised supply under these schemes to maintain uniformity of the price of SCENESSE® sold in Europe under the marketing authorisation more than offset the reduction in the number of implants supplied into Italy and Switzerland as a result of either delaying placing orders through the price negotiation phase or from payors not willing to accept the revised price. The first commercial sales of SCENESSE® occurred in 2015/16 which resulted in \$2.598 million in sales revenues (2014/15: \$ Nil).

Revenues from ordinary activities include interest received from surplus funds held in bank accounts and term deposits, moving from \$0.348 million to \$0.208 million, a 40% decrease. The decrease reflects a combination of lower average cash balances held year-on-year in interest-bearing deposits, higher cash balances held in non-Australian currencies which return negligible interest and lower average interest rate yields on funds held year-on-year due to government monetary policy lowering interest rates on deposits held.

Excluding the Australian government research and development (R&D) refundable tax incentives, R&D and commercialisation expenditures accounted for 37% of the group's total expense result for 2015/16, compared to 18% for the 2014/15 year. R&D and commercialisation costs, comprising clinical study costs, drug delivery research manufacture and distribution, toxicity studies, regulatory fees and research, development and commercialisation-specific overheads such as personnel, were \$3.735 million in 2016 compared to \$2.603 million in 2015.

The Australian government refundable tax incentive of \$0.609 million is a 50% increase to the refundable tax incentive recorded for the 2014/15 year. The increase reflects the expected increase in qualifying expenditures from local activities in connection to the pre-clinical model demonstrating the safety of SCENESSE® in combination with narrowband ultraviolet light therapy. This activity is a regulatory requirement to support the introduction of new combination therapies as the standard of care.

Clinical study costs decreased 42% from \$0.232 million in 2015 to \$0.133 million in 2016. The continuing reduction in expenditures on clinical development costs reflects the Company's focus during 2015/16 on limiting its clinical efforts to completing the Singaporean Phase II clinical study in vitiligo whilst it concentrated its resources on the commercialisation activities in Europe and its regulatory activities in the US.

Expenses toward the drug delivery manufacturing and distribution program increased by 127%, from \$0.450 million in 2014/15 to \$1.022 million in 2015/16. An increase in implant production costs to meet clinical, commercial and special access scheme requirements, along with distribution set up costs to facilitate implant release within the European Union were the primary reasons for the increase.

The average head count in 2015/16 of Research, Development & Commercial personnel employed to oversee and monitor the clinical, regulatory, manufacturing programs and post-marketing programs was more than the head count over the course of 2014/15, resulting in a 28% increase in Research, Development & Commercial overhead costs (from \$1.259 million in 2014/15 to \$1.606 million in 2015/16).

Regulatory affairs related fees for both pre- and post-marketing activities along with non-clinical development costs increased 47%, from \$0.662 million in 2014/15 to \$0.973 million in 2015/16. The increase was largely due to the completion of the pre-clinical chronic toxicology study which commenced in the latter part of the previous financial year as part of its USA vitiligo development program. Establishing the regulatory infrastructure to support the market access of SCENESSE® into Europe and meet its post-authorisation commitments with the EMA, particularly the pharmacovigilance and safety reporting systems, were also a key driver to the 47% increase.

Marketing expenditures in the Company decreased marginally by 3% to \$0.778 million in 2015/16 from \$0.802 million in 2014/15. Savings from reduced conference and meeting sponsorships and share listing costs were offset by increased marketing staff costs.

Patent fees increased 15%, from \$0.232 million in 2014/15 to \$0.266 million in 2015/16. The increase was related to further payments to validate the European EPP patents after the marketing authorisation was obtained, translating the patents to local language and increasing renewal fees resulting from aging patents.

The result from general operations was \$5.591 million in 2015/16 compared to \$10.508 million in 2014/15, a 47% improvement. The major contributor to the decrease in general operations was the expensing of the accounting valuation of share-based payments (Performance Rights) of \$5.676 million in 2014/15 to \$1.670 million in 2015/16. Performance Rights are valued at grant date and expensed over their expected life, whether or not a benefit is received from these amounts, either in the current or future reporting periods. Two of the four performance conditions attached to the 2,789,810 Performance Rights to Directors as approved by shareholders at the November 2014 Annual General Meeting were achieved and subsequently fully expensed in the 2014/15 year.

General operations comprised 55% of the group's total expense result for 2015/16 compared to 75% in 2014/15. Other factors contributing to the 47% decrease in general operations year-on-year are the reduction in legal and corporate advisory fees incurred by the Company in the previous financial year mostly in the Company responding to the unsolicited bid proposal received from Retrophin Inc to acquire all the issued ordinary shares in the Company, reduced travel costs and realised gains from exchange rate movements in transactions conducted in non-Australian currencies.

For the 2015/16 year the group started with \$10.572 million in cash and financial assets and finished with \$13.845 million. In March 2016 the group raised \$8.335 million additional capital. For the reporting date of 30 June 2016, due to movements in the Australian dollar compared to other currencies used to meet working capital requirements, the consolidated entity reported a gain of \$0.187 million from holding foreign currencies and in holding trade creditors in non-Australian currencies (a \$0.064 million gain for the same period last year).

At 30 June 2016 basic earnings per share were -\$0.07 on 47,080,637 issued ordinary shares. This is compared to basic earnings per share of -\$0.24 as at 30 June 2015 on 44,554,787 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 population with a need for repigmentation. These various patient groups range from 5,000 to 45 million. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL PHARMACEUTICALS LTD has operations in Europe, the US and Singapore.

There were a number of significant events in 2015/16. These events include:

a) On 2 July 2015, the Company announced that results from



its pivotal Phase III studies of SCENESSE® in the orphan genetic disorder erythropoietic protoporphyria (EPP) had been published in the New England Journal of Medicine, one of the world's most prestigious medical periodicals.

- b) An announcement on 27 August 2015 confirmed the Company would meet with the US Food and Drug Administration (FDA) to discuss the overall development of SCENESSE® and the filing requirements for a New Drug Application (NDA) for the treatment of EPP (Type C meeting). A follow-on announcement was made on 5 October 2015 confirming the Type C meeting had been held whereby regulatory pathways were discussed and the FDA requested to review photoprovocation and quality of life data.
- c) The Company reached agreement with the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee (PRAC) treatment protocol as part of the agreed risk management plan. This agreement allowed SCENESSE® to be released for commercial supply and made available to patients once pricing reimbursement structures were reviewed and agreed with insurers and competent authorities. This announcement occurred 21 September 2015. On 15 March 2016, further to the agreed risk management plan with the EMA, it was announced the first of the European expert porphyria centres to treat EPP patients with SCENESSE® had undertaken site training and accreditation to ensure compliance with the treatment protocol as part of the PASS. On 22 June 2016 the Company announced the first commercial sale of SCENESSE® in Europe under European marketing authorisation. Patients with EPP in the Netherlands commenced treatment following this delivery.
- d) The announcement on 3 December 2015 of positive preliminary results from the Company's Singaporean Phase II trial (CUV103), evaluating SCENESSE® as a repigmentation therapy in patients with vitiligo. The results were consistent with earlier findings from the US Phase II trial (CUV102). In both studies SCENESSE® was well tolerated and increased repigmentation in patients with darker skin complexions, for whom vitiligo has an intense psychological and significant social impact.
- e) On 12 February 2016 the Company announced that SCENESSE® received an additional orphan drug designation (ODD) from the US FDA for the treatment of cutaneous variants of porphyria. The ODD recognises the potential of SCENESSE® to treat or prevent symptoms in rare forms of porphyria and offers incentives to CLINUVEL to develop the drug for these patients.
- f) A capital raise of A\$8.3million via a private placement to existing and new institutional and professional investors, announced on 15 March 2016. The Company stated that the funds were earmarked to pursue the European commercialisation program for SCENESSE® for patients with EPP. The private placement was made at a price of A\$3.30 per share, representing an issue price equal to the closing price on 10 March 2016 (the date which the trading in Company's shares were placed into a trading halt) and a 2.9% discount to the 10 March 2016 10-day volume weighted average price.
- g) On 24 March 2016 it was announced that the UK National Institute for Health and Care Excellence (NICE) had held a public workshop to scope the benefits and costs of SCENESSE® in the treatment of adult patients with EPP. The workshop is one of the last steps prior to national commissioning of the treatment by the National Health Service (NHS) of England. The workshop included a review of the specific burden of EPP on patients' lives, the number of treatment centres in the UK, on patients eligible for treatment and the lack of a standard of care. Company representatives attended the workshop along with representatives of the EPP patient community, clinical experts and scientists.
- h) The Company joined Nasdaq's International Designation, a new visibility offering by Nasdaq for non-US companies with

established Sponsored Level 1 American Depository Receipt (ADR) programs, on 2 June 2016.

## 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 REPORTING DATE

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

## LIKELY DEVELOPMENTS AND EXPECTED RESULTS

The consolidated entity's strategy is to focus on developing and commercialising SCENESSE® as a medicinal photoprotective solution for patients with EPP and who are most severely affected by exposure to ambient and UV light. Further, the consolidated entity's strategy is to develop and commercialise SCENESSE® as a combination therapy with narrowband ultraviolet B phototherapy for patients with vitiligo in order to promote repigmentation of areas of the skin affected by vitiligo.

In the previous year, the consolidated entity was successful in gaining European regulatory approval for SCENESSE® in EPP in the form of a historical first marketing authorisation. Consequent to the granting of marketing authorisation, the consolidated entity has committed itself to establishing a number of significant post-authorisation commitments which have been agreed with the EMA under a long-term risk management plan for SCENESSE®. The consolidated entity will continue to work with a number of commissioned third parties to support a European EPP Disease Registry to monitor long-term safety and it will continue to invest in existing and new personnel with the necessary skills and expertise to maintain the ongoing requirements of the post-authorisation program in Europe. The consolidated entity intends to increase its sales-focused workforce in Europe to promote initial revenues once pricing agreements per country are established with payors.

Underpinned by the regulatory approval in Europe, along with the information generated from its post-marketing commitments in Europe, the consolidated entity is working towards gaining regulatory approval for SCENESSE® in EPP in other important markets where EPP is prevalent, including North America, in order to increase its ability to commercialise SCENESSE®.

The consolidated entity continues to conduct clinical studies to evaluate the ability of SCENESSE® to activate melanocytes within vitiliginous lesions and achieve repigmentation in combination with NB-UVB in patients with vitiligo. Data from the soon-to-be-completed Phase II study and the pre-clinical model demonstrating the safety of SCENESSE® in combination with narrowband light therapy should result in the consolidated entity moving towards later stage clinical trials.

The consolidated entity has also focused on its manufacturing requirements by working with its contract manufacturer to meet clinical and commercial product supply in line with its timing expectations. The consolidated entity, through its recently established VALLAURIX PTE LTD entity, will also expand its research and development programs into its follow-on portfolio technologies to SCENESSE®, CUV9900 and VLRX001. These melanocortin analogues will be evaluated as an adjuvant maintenance therapy in vitiligo, with the intention of developing both medicinal and non-prescriptive formulations to be administered topically.

The consolidated entity is currently a loss-making enterprise which has only recently reached the commercialisation phase of drug development, 11 years since the start of its program. The long-term financial success of the consolidated entity will be ultimately measured on the basis of achieving a sustainable profit. Key to becoming profitable is not only the successful research and development of its portfolio of assets but also their successful

commercialisation, manufacturing and distribution, and the ability to attract funding to support these activities should the need arise. The following specific risks are reviewed continually by the Board and management as they have the potential to affect the consolidated entity's achievement of the business goals detailed above. This list is not exhaustive.

- Technology – there is a risk that despite obtaining marketing approvals, those products may ultimately prove not to be safe and/or of clinical benefit.
- Supply – there is a risk that the manufacturing process may not result in product batches meeting minimum specification levels, that raw material components could not be sourced to specification, and of non-controllable disruptions to the products' contract manufacturers.
- Clinical & Regulatory – there is a risk that clinical trials will not yield the expected and desired results for the investigational medicinal product(s) to obtain further regulatory approvals.
- Intellectual Property (IP) and market entry– future sales could be impacted to the extent that there is not sufficiently robust patent protection across the consolidated entity's product portfolio that will prevent competitors from entering the marketplace to compete with the consolidated entity's approved products. Also, competitors infringing the consolidated entity's IP rights may adversely impact the consolidated entity's ability to maximise the value to be made from product commercialisation.
- Funding – cash outflows from its operations may be higher than cash inflows. Therefore the ability of the consolidated entity to successfully bring its products to market and achieve a state of positive cash flow is dependent on its ability to access sources of funding while containing its expenditures.
- Management – the consolidated entity's corporate strategy could be impacted adversely if the consolidated entity was not able to retain its key management, members of staff and Board.

## ROUNDING OF AMOUNTS

The Company is a type of Company referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191* and therefore the amounts contained in this report and in the financial report have been rounded to the nearest \$1,000, or in certain cases, to the nearest dollar.

## 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 \$24,700 (2015: \$29,763).

## 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

## PRINCIPAL OBJECTIVE

The Board's strategic objective that underpins its remuneration policy is to retain the Company's unique industry knowledge in relation to the development of SCENESSE® at a critical stage of the Company's evolution. The Board is aware that any disruption to the professional talent input would have a detrimental effect to the Company's ability to progress from an entirely research and development-focused organisation to a commercial revenue-generating enterprise. The Board has strived to secure staff and management of the only pharmaceutical company active in photoprotection and repigmentation and who are critical to the development and commercialisation of an approved, first-in-class 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 with 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 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 captures 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:

- The Managing Director and other executive Directors (if any);
- Non-Executive Directors, including the Company Chair; and
- 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 short and 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 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 both short-term and long-term:

- Short-term (generally cash payment in the form of performance-based incentives at a fixed amount or as a percentage of base salary).
- Long-term (generally based upon the issue of Performance Rights to acquire shares in the Company, along with other fixed amount cash incentives). Prior to the 2015/16 year, Performance Rights were issued under the Company's Conditional Rights Plan, most recently approved by shareholders 12 November 2013 and also the more recent Company's Performance Rights Plan, approved by shareholders at the 2014 Annual General Meeting (AGM). The vesting conditions can be either time and/or performance milestone-based.

## REMUNERATION COMMITTEE

The Board has provided a mandate to the Remuneration 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 Committee obtains independent data to assess the appropriateness of remuneration packages, given trends in comparative companies, industry or related field of expertise. The Remuneration 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 2016, no remuneration recommendations were received from specialist remuneration consultants.

The Corporate Governance Statement provides further information on the role of the Remuneration 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. At the 2015 Annual General Meeting, shareholders approved an increase to the maximum aggregate remuneration payable from \$400,000 to \$550,000. This amount (or some part of it) is to be divided among the Non-Executive Directors as determined by the Board.

As from 1 September 2014, Non-Executive Directors' base fees are presently \$65,000 per annum inclusive of superannuation (previously \$50,000 per annum). The Chair receives \$110,000 per annum inclusive of superannuation (previously \$90,000 per annum) when in a Non-Executive capacity. The Chair's role is for a 12 month term, whereby the Company reserves the right to extend the term for another 12 month period. The Heads of the Audit and Risk and the Remuneration Committees receive an additional \$15,000 per annum inclusive of superannuation when in a Non-Executive capacity, and members of the Audit and Risk and the Remuneration Committees who are not the Committee Chair receive an additional \$5,000 inclusive of superannuation. Directors' fees were increased in the previous financial year to a level considered appropriate given their skills, qualifications and experience comparative to the external market. It was the first increase to Non-Executive Director fees since 2001.

Subject to shareholder approval, Non-Executive Directors can be issued Performance Rights under the Company's Performance Rights Plan. Non-Executive Directors can be issued Performance Rights to align their interests with those 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.

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 pre-specified performance-based targets;
- Discretionary payments for exceptional performance, innovation and/or expansion; and
- Long-term equity participation in the Company's Performance Rights Plans.

Base pay, including superannuation, is reviewed annually by the Remuneration 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 short-term and longer-term incentive components to his Executive remuneration. Longer-term

incentive components include business generation incentives, discretionary payments and equity participation through the Company's Performance Rights Plan. Appropriate targets are set by the Remuneration 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 2015/16 financial year the Remuneration Committee evaluated the performance of the Managing Director and awarded a short-term incentive of 50% to base salary, compared to a short-term incentive of 65% to base salary in the preceding year. However, for 2015/16 the Managing Director received 16.24% less in base salary and short-term employment benefits in comparison to the 2014/15 financial year.

In the 2014/15 year, the Managing Director elected to have paid out 50 days unused and accrued annual leave in lieu of taking such leave in the current and previous years, as permitted by law, totalling \$146,801.

In the most recent Annual General Meeting (AGM), the Company obtained 84.4% of the proxy votes (including votes at the Board's discretion) in favour of adopting the 2014/15 remuneration report, and this resolution was passed by poll. The Company did not receive any further feedback at the AGM on its remuneration practices.

The methods used by the Remuneration Committee to assess Board performance 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 Company's Performance 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 the global corporate strategy and has global responsibility for the safety aspects of the drug and pharmacovigilance. The Acting Chief Scientific Officer is responsible for pre-clinical programs and toxicology, the manufacturing of the drug delivery program, clinical program and setting the regulatory strategies in close coordination with the 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 from its current stage of development, taking into account the risk and 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 Committee. The agreement provides for base salary, short and long-term incentives, other benefits and participation, when eligible, in the Company's Performance Rights Plan. The Managing Director, in consultation with the Remuneration Committee, oversees the service agreements entered into with Company Executives, providing for base salary, incentives, other benefits and participation, when eligible, in the Company's Performance 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 2016, his base salary inclusive of retirement benefits for the year to 30 June 2016 is \$807,109 and his service agreement is with the wholly-owned Singaporean subsidiary entity. Termination payment is set at 12 months of base salary provided the termination is not for a material breach of the agreement. The base salary is CPI indexed. Dr Wolgen is required to provide 12 month's notice.
- Dr Wright's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2016 is \$252,012. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Dr Wright is required to provide 3 month's notice.
- Mr Keamy's term of employment is on-going and his base salary inclusive of superannuation for the year to 30 June 2016 is \$237,458. Termination payments are set at 3 months of base salary provided the termination is not for a material breach of the agreement. Mr Keamy is required to provide 3 month's 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.

### PERFORMANCE RIGHTS:

All Performance Rights issued fall under two Performance Rights Plans:

- a) the Company's Conditional Performance Rights Plan (2009); and
- b) the Company's Performance Rights Plan (2014).

#### a) Conditional Performance Rights Plan (2009)

The Conditional Performance Rights Plan (2009) is available to eligible employees of the Company. Any issue of Rights to Executive Directors requires shareholder approval in accordance with ASX Listing Rules. All Rights convert to one ordinary share of the consolidated entity and 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.

Since the Conditional Performance Rights Plan (2009) was implemented, 872,985 (or 25.1%) of the Performance Rights issued under this Plan have lapsed or have been forfeited.

The Company does not intend to make future issues of Performance Rights under this 2009 Plan.

#### b) Performance Rights Plan (2014)

The Performance Rights Plan (2014) is available to eligible persons of the Company. Any issue of Rights to Executive Directors requires shareholder approval in accordance with ASX Listing Rules. All Rights convert to one ordinary share of the consolidated entity and are issued for nil consideration, have no voting rights, are not listed on the ASX and are non-tradeable (other than with prior written Board consent). They can be converted to ordinary shares at any time once the vesting conditions attached to the Rights have been achieved, whereby, at the discretion of the Board, they will be held by a Scheme Trustee on behalf of the eligible person.

The eligible person cannot trade the shares held by the Scheme Trust without prior written Board consent until the earlier of 7 years from grant date of Performance Rights, when the eligible person ceases employment or when all transfer restrictions are satisfied or waived by the Board in its discretion. Performance Rights under this Plan lapse after 7 years from grant date.

Performance Rights are valued for financial reporting purposes using a binomial valuation model and are represented as accounting values only in the financial statements. Holders of Performance Rights may or may not receive a benefit from these amounts, either in the current or future reporting periods. The value of all Performance Rights granted, exercised and lapsed during the financial year is detailed in the tables within the Remuneration Report.

In the 28 November 2014 Annual General Meeting, shareholders approved the grant of Performance Rights to Directors under the Performance Rights Plan (2014). Of the proxy votes received, between 87.4% to 89.1% (including votes at the Board's discretion) were in favour of granting Performance Rights to Directors.

## 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 (Managing Director & Chief Executive Officer)
- Mrs. B.M. Shanahan (Non-Executive Director)
- Mr. E. Ishag (Non-Executive Director)
- Mr. W. Blijdorp (Non-Executive Director)
- 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.

**KEY MANAGEMENT PERSONNEL REMUNERATION OF THE COMPANY FOR THE YEARS ENDING 30 JUNE 2016 & 30 JUNE 2015**

	YEAR	SHORT-TERM EMPLOYMENT BENEFITS				LONG-TERM EMPLOYMENT BENEFITS	SHARE-BASED PAYMENTS (ACCOUNTING CHARGE ONLY) <sup>2</sup>	TOTAL
		GROSS SALARY	SHORT TERM INCENTIVE	ANNUAL LEAVE PAID OUT <sup>4</sup>	OTHER <sup>1</sup>	SUPER-ANNUATION / PENSION FUND	PERFORMANCE RIGHTS	
		\$	\$	\$	\$	\$	\$	
<b>DIRECTORS</b>								
Dr. P.J. Wolgen	2016	807,109	373,969	-	20,455	-	1,130,261 <sup>3</sup>	2,331,794
	2015	765,506	462,056	146,801	60,168	2,071	4,862,453 <sup>3</sup>	6,299,055
Mr. S.R. McLiesh	2016	100,457	-	-	-	9,543	44,805	154,805
	2015	95,946	-	-	-	9,115	245,445	350,506
Mrs. B.M. Shanahan	2016	73,059	-	-	-	6,941	44,805	124,805
	2015	70,822	-	-	-	6,728	193,605	271,155
Mr. L.J. Wood	2016	-	-	-	-	-	-	-
	2015	5,417	-	-	-	-	-	5,417
Mr. E. Ishag	2016	70,000	-	-	-	-	31,363	101,363
	2015	66,667	-	-	-	-	135,523	202,190
Mr. W.A. Blijdorp	2016	65,000	-	-	-	-	-	65,000
	2015	29,083	-	-	-	-	-	29,083
<b>OTHER KEY MANAGEMENT PERSONNEL</b>								
Dr. D.J. Wright	2016	232,704	4,000	-	-	19,308	38,575	294,587
	2015	229,265	11,463	-	-	18,783	29,154	288,665
Mr. D.M. Keamy	2016	218,150	11,315	-	-	19,308	120,470	369,243
	2015	200,784	10,500	-	-	18,516	67,778	297,578
<b>TOTAL</b>	2016	<b>1,566,479</b>	<b>389,284</b>	<b>-</b>	<b>20,455</b>	<b>55,100</b>	<b>1,410,279</b>	<b>3,441,597</b>
	2015	<b>1,463,490</b>	<b>484,019</b>	<b>146,801</b>	<b>60,168</b>	<b>55,213</b>	<b>5,533,958</b>	<b>7,743,649</b>

<sup>1</sup> 'Other' includes health insurance, housing, relocation to Singapore and other allowances that may be subject to fringe benefits tax.

<sup>2</sup> As these values are accounting values the key management personnel may or 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. Performance Rights were priced using a binomial pricing model.

<sup>3</sup> \$1,119,935 of the 2016 value (2015: \$4,839,827) relates to the issue of 2,499,810 Performance Rights to Dr. Wolgen which was approved by shareholders of the consolidated entity at the 28 November 2014 Annual General Meeting. Performance Rights are subject to milestones being achieved before they can be exercised.

<sup>4</sup> Unused and accrued annual leave was paid out in lieu of taking such leave during the year, as permitted by law.

**THE RELATIVE PROPORTIONS OF REMUNERATION BETWEEN FIXED AND BASED ON PERFORMANCE FOR THE YEARS ENDING 30 JUNE 2016 AND 30 JUNE 2015**

	2016		2015	
	FIXED REMUNERATION	PERFORMANCE BASED	FIXED REMUNERATION	PERFORMANCE BASED
Dr. P.J. Wolgen	35%	65%	15%	85%
Dr. D.J. Wright	86%	14%	86%	14%
Mr. D.M. Keamy	64%	36%	74%	26%

**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	91,667	\$1.04	Ordinary	25/11/2010	-
CLINUVEL	91,667	\$1.04	Ordinary	25/11/2010	-
CLINUVEL	116,667	\$1.04	Ordinary	25/11/2010	-
CLINUVEL	75,000	\$1.19	Ordinary	14/01/2013	-
CLINUVEL	553,890	\$2.59	Ordinary	28/11/2014	-
CLINUVEL	692,475	\$2.59	Ordinary	28/11/2014	-
CLINUVEL	90,700	\$2.16	Ordinary	17/03/2015	-
CLINUVEL	158,725	\$2.16	Ordinary	17/03/2015	-
CLINUVEL	90,700	\$2.16	Ordinary	17/03/2015	-
CLINUVEL	113,375	\$2.16	Ordinary	17/03/2015	-

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

Nil shares were issued as a result of exercise of options.

**ADDITIONAL INFORMATION ON RIGHTS ISSUED TO KEY MANAGEMENT PERSONNEL**

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

**REMUNERATION CONDITIONAL PERFORMANCE RIGHTS HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2016**

	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	LAPSED AND EXPIRED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
<b>DIRECTORS</b>							
Mr. E. Ishag	56,500	-	-	-	56,500	14,000	42,500
Mr. S.R. McLiesh	85,000	-	-	-	85,000	20,000	65,000
Mrs. B.M. Shanahan	70,000	-	-	-	70,000	20,000	50,000
Dr. P.J. Wolgen	1,424,864	-	-	-	1,424,864	499,890	924,974
Mr. W.A. Blijdorp	-	-	-	-	-	-	-
<b>EXECUTIVES</b>							
Dr. D.J. Wright	128,125	-	-	-	128,125	8,000	120,125
Mr. D.M. Keamy	238,760	-	-	-	238,760	26,000	212,760

**ADDITIONAL INFORMATION - REMUNERATION**

For each cash bonus and right granted, the percentage of the available grant or bonus that was paid or vested in the financial year, and the percentage forfeited due to unmet milestones (including service length), is set out below. Bonuses are paid in the year following the period of performance.

**REMUNERATION DETAILS OF CASH INCENTIVES AND RIGHTS**

	INCENTIVES		PERFORMANCE RIGHTS						
	PAID	FORFEITED	YEAR GRANTED	TYPE	VESTED	FORFEITED	LATEST YEAR FOR VESTING	MINIMUM GRANT VALUE YET TO VEST (\$)	MAXIMUM GRANT VALUE YET TO VEST (\$)
	50%	50%							
Dr. P.J. Wolgen			2010/11	Rights	0%	0%	No limitation	-	300,001
			2014/15	Rights	20%	0%	2021/22	-	1,619,935
	0%	0%							
Mr. S.R. McLiesh			2011/12	Rights	0%	0%	No limitation	-	26,690
			2014/15	Rights	16.7%	0%	2021/22	-	64,800
	0%	0%							
Mrs. B.M. Shanahan			2011/12	Rights	0%	0%	No limitation	-	16,682
			2014/15	Rights	20%	0%	2021/22	-	64,800
	0%	0%							
Mr. E. Ishag			2011/12	Rights	0%	0%	No limitation	-	16,682
			2014/15	Rights	20%	0%	2021/22	-	45,360
	0%	0%							
Mr. W.A. Blijdorp	0%	0%							
	0%	0%							
Dr. D.J. Wright			2011/12	Rights	0%	0%	No limitation	-	42,819
			2012/13	Rights	0%	0%	No limitation	-	29,700
			2014/15	Rights	20%	0%	2021/22	-	69,120
	0%	0%							
Mr. D.M. Keamy			2011/12	Rights	0%	0%	No limitation	-	58,334
			2012/13	Rights	0%	0%	No limitation	-	29,700
			2014/15	Rights	20%	0%	2021/22	-	224,640

The exercise price for those Rights granted between 2009/10 and 2014/15 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 2016 reporting period held by each of the Group's Key Management Personnel, including their related parties, is set out below:

YEAR ENDING 30 JUNE 2016					
PERSONNEL	BALANCE AT START OF YEAR	GRANTED AS REMUNERATION	RECEIVED ON EXERCISE	OTHER CHANGES	HELD AT THE END OF REPORTING PERIOD
Mr. E. Ishag	148,195	-	-	-	148,195
Mr. S.R. McLiesh	191,000	-	-	-	191,000
Mrs. B.M. Shanahan	133,969	-	-	-	133,969
Dr. P.J. Wolgen	2,079,832	-	-	-	2,079,832
Mr. W.A. Blijdorp	383,145	-	-	-	383,145
Dr. D.J. Wright	236,874	-	-	-	236,874
Mr. D.M. Keamy	166,400	-	-	-	166,400

**SHARES UNDER OPTION**

DETAILS OF UNISSUED SHARES OR INTERESTS UNDER OPTIONS OR RIGHTS					
ENTITY	NUMBER OF SHARES UNDER OPTIONS	NUMBER OF SHARES UNDER RIGHTS	EXERCISE PRICE	CLASS	EXPIRY DATE
CLINUVEL PHARMACEUTICALS LTD	-	2,556,250	\$Nil	Ordinary	Upon achievement of specific performance and time-based milestones

**LOANS TO DIRECTORS AND EXECUTIVES**

No loans were granted to Directors or Executives for the years ending 30 June 2016 and 30 June 2015.

## PERFORMANCE OF CLINUVEL PHARMACEUTICALS LTD AND CONTROLLED ENTITIES

The consolidated entity is solely dedicated to the research, development and commercialisation of its unique and medically beneficial technology. It is anticipated the consolidated entity will not derive profit and pay a dividend until commercialisation of the drug under research and development has occurred and sales reach a level which exceeds the cost base of the consolidated entity. With very few peer competitors developing drugs in the field of photoprotection and repigmentation, shareholder interest is promoted through the Company successfully completing clinical trials, achieving regulatory milestones and pursuing potential new and larger markets. The table below shows the progress made in moving through the clinical pathway and into the commercialisation pathway, reflecting the performance of the Executive team, whilst also comparing the progress in moving through these pathways against the movement in the Company's market capitalisation.

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 into the commercialisation phase of its drug which has been subject to sustained research and development.

REGULATORY/CLINICAL MILESTONE	YEAR ENDING 30 JUNE						
	2010	2011	2012	2013	2014	2015	2016
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	■						
Phase II EPP Study – USA	■						
Ph III EPP Study – Europe Trial 2	■						
Ph III PLE Study – Europe	■						
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– EU & USA					●		
Application for marketing authorisation submitted with EMA			■	■	■	■	
VALLAURIX PTE LTD – formulation & melanocortin development							■
Post-marketing authorisation commitments							■
First commercial sales							■
Market capitalisation (A\$ million)	70	50	55	69	72	127	203

**NON-AUDIT SERVICES**

For the year ended 30 June 2016, Grant Thornton Australia provided audit services to the Company. Grant Thornton Australia also provided non-audit services, specifically general tax advice concerning the Australian R&D tax incentive regime. 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.

For the year ending 30 June 2016 Grant Thornton Australia only provided audit services to the Company.

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.

**AUDITOR'S INDEPENDENCE DECLARATION**

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

**PROCEEDINGS ON BEHALF OF THE COMPANY**

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

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

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



Dr. Philippe Wolgen, MBA MD

Director

Dated this 24th day of August, 2016

# STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2016

	NOTE	CONSOLIDATED ENTITY	
		2016	2015
		\$	\$
Total revenues	2	6,419,707	3,259,962
Other income	2	796,531	470,273
Total expenses	2	(10,369,956)	(14,144,611)
Loss before income tax expense		(3,153,718)	(10,414,376)
Income tax expense/(benefit)	3	-	-
Loss after income tax expense		(3,153,718)	(10,414,376)
<b>NET PROFIT/(LOSS) FOR THE YEAR</b>		<b>(3,153,718)</b>	<b>(10,414,376)</b>
<b>OTHER COMPREHENSIVE INCOME</b>			
Items that may be re-classified subsequently to profit or loss			
Exchange differences of foreign exchange translation of foreign operations		273,786	(268,143)
Income tax (expense)/benefit on items of other comprehensive income		-	-
Other comprehensive loss for the period, net of income tax		273,786	(268,143)
<b>TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD</b>		<b>(2,879,932)</b>	<b>(10,682,519)</b>
<b>PROFIT/(LOSS) FOR THE YEAR ATTRIBUTABLE TO:</b>			
Non-controlling interest		(32,518)	(16,343)
Owners of the parent		(3,121,200)	(10,398,033)
		<b>(3,153,718)</b>	<b>(10,414,376)</b>
<b>TOTAL COMPREHENSIVE INCOME/(LOSS) ATTRIBUTABLE TO:</b>			
Non-controlling interest		(32,518)	(16,343)
Owners of the parent		(2,847,414)	(10,666,176)
		<b>(2,879,932)</b>	<b>(10,682,519)</b>
Basic and diluted earnings per share - cents per share	15	(7.0)	(24.0)
The accompanying notes form part of these financial statements.			

# STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2016

	NOTE	CONSOLIDATED ENTITY	
		2016	2015
		\$	\$
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	16(a)	13,844,703	10,572,295
Trade and other receivables	4	4,823,770	1,960,453
Inventory	5	1,082,163	837,135
Other assets	6	222,961	204,623
<b>TOTAL CURRENT ASSETS</b>		<b>19,973,597</b>	<b>13,574,506</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment	7	164,670	69,369
<b>TOTAL NON-CURRENT ASSETS</b>		<b>164,670</b>	<b>69,369</b>
<b>TOTAL ASSETS</b>		<b>20,138,267</b>	<b>13,643,875</b>
<b>CURRENT LIABILITIES</b>			
Trade and other payables	9	1,573,361	1,860,636
Provisions	10	715,017	574,640
<b>TOTAL CURRENT LIABILITIES</b>		<b>2,288,378</b>	<b>2,435,276</b>
<b>NON-CURRENT LIABILITIES</b>			
Provisions	10	15,369	3,308
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>15,369</b>	<b>3,308</b>
<b>TOTAL LIABILITIES</b>		<b>2,303,747</b>	<b>2,438,584</b>
<b>NET ASSETS</b>		<b>17,834,520</b>	<b>11,205,291</b>
<b>EQUITY</b>			
<b>EQUITY ATTRIBUTABLE TO OWNERS OF THE PARENT:</b>			
Contributed equity	11	146,764,500	138,465,335
Reserves	12	4,094,977	2,698,338
Accumulated losses	13	(133,063,239)	(129,942,039)
<b>EQUITY ATTRIBUTABLE TO THE OWNERS OF THE PARENT</b>		<b>17,796,238</b>	<b>11,221,634</b>
<b>EQUITY ATTRIBUTABLE TO NON-CONTROLLING (MINORITY EQUITY) INTEREST</b>		<b>38,282</b>	<b>(16,343)</b>
<b>TOTAL EQUITY</b>		<b>17,834,520</b>	<b>11,205,291</b>

The accompanying notes form part of these financial statements.

# STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2016

	NOTE	CONSOLIDATED ENTITY	
		2016	2015
		\$	\$
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
GST and VAT refunds		534,297	581,114
Receipts from customers		3,648,388	2,545,080
Interest received		167,559	353,960
Payments to suppliers and employees		(9,387,177)	(8,009,966)
<b>NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES</b>	<b>16(B)</b>	<b>(5,036,933)</b>	<b>(4,529,812)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Payments for property, plant and equipment		(98,051)	(12,097)
Proceeds received for property, plant and equipment		-	1,400
<b>NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>		<b>(98,051)</b>	<b>(10,697)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from issue of ordinary shares		8,335,305	250,000
Equity contribution by subsidiary non-controlling interest		89,118	-
Payment of share issue costs		(36,059)	(27,300)
<b>NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES</b>		<b>8,388,364</b>	<b>222,700</b>
<b>NET INCREASE/(DECREASE) IN CASH HELD</b>		<b>3,253,380</b>	<b>(4,317,809)</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR</b>		<b>10,572,295</b>	<b>14,625,583</b>
Effects of exchange rate changes on foreign currency held		19,028	264,521
<b>CASH AND CASH EQUIVALENTS AT END OF THE YEAR</b>	<b>16(A)</b>	<b>13,844,703</b>	<b>10,572,295</b>

The accompanying notes form part of these financial statements.

# STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2016

	SHARE CAPITAL	PERFORMANCE RIGHTS RESERVE	FOREIGN CURRENCY TRANSLATION RESERVE	RETAINED EARNINGS	TOTAL ATTRIBUTABLE TO OWNERS OF PARENT	NON- CONTROLLING INTEREST	TOTAL EQUITY
	\$	\$	\$	\$	\$	\$	\$
<b>BALANCE AT 30 JUNE 2014</b>	133,567,056	1,321,529	116,517	(119,577,370)	15,427,732	-	15,427,732
Issue of Share Capital under private placement	250,000	-	-	-	250,000	-	250,000
Issue of Share Capital under share-based payment	4,650,579	(4,650,579)	-	-	-	-	-
Employee share-based payment options	-	5,642,728	-	33,364	5,676,092	-	5,676,092
Capital raising costs	(2,300)	-	-	-	(2,300)	-	(2,300)
<b>TRANSACTIONS WITH OWNERS</b>	<b>138,465,335</b>	<b>2,313,678</b>	<b>116,517</b>	<b>(119,544,006)</b>	<b>21,351,524</b>	<b>-</b>	<b>21,351,524</b>
<b>LOSS FOR THE YEAR</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(10,398,033)</b>	<b>(10,398,033)</b>	<b>(16,343)</b>	<b>(10,414,376)</b>
<b>OTHER COMPREHENSIVE INCOME:</b>							
Exchange differences of foreign exchange translation of foreign operations	-	-	268,143	-	268,143	-	268,143
<b>BALANCE AT 30 JUNE 2015</b>	<b>138,465,335</b>	<b>2,313,678</b>	<b>384,660</b>	<b>(129,942,039)</b>	<b>11,221,634</b>	<b>(16,343)</b>	<b>11,205,291</b>
Equity contribution by subsidiary non-controlling interest	-	-	-	-	-	87,143	87,143
Issue of Share Capital under private placement	8,335,305	-	-	-	8,335,305	-	8,335,305
Issue of Share Capital under share-based payment	-	-	-	-	-	-	-
Employee share-based payment options	-	1,670,425	-	-	1,670,425	-	1,670,425
Capital raising costs	(36,140)	-	-	-	(36,140)	-	(36,140)
<b>TRANSACTIONS WITH OWNERS</b>	<b>146,764,500</b>	<b>3,984,103</b>	<b>384,660</b>	<b>(129,942,039)</b>	<b>21,191,224</b>	<b>70,800</b>	<b>21,262,024</b>
<b>LOSS FOR THE YEAR</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(3,121,200)</b>	<b>(3,121,200)</b>	<b>(32,518)</b>	<b>(3,153,718)</b>
<b>OTHER COMPREHENSIVE INCOME:</b>							
Exchange differences of foreign exchange translation of foreign operations	-	-	(273,786)	-	(273,786)	-	(273,786)
<b>BALANCE AT 30 JUNE 2016</b>	<b>146,764,500</b>	<b>3,984,103</b>	<b>110,874</b>	<b>(133,063,239)</b>	<b>17,796,238</b>	<b>38,282</b>	<b>17,834,520</b>

# NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2016

## 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's projects. The consolidated entity has successfully raised additional working capital in past years. Should cash flows from its commercialisation activities not provide adequate funding to sustain its research, development and commercialisation projects in the coming financial year, the Directors would consider the need to bring in additional funds from various funding sources.

## 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.

Non-controlling interests, presented as part of equity, represent the portion of a subsidiary's profit or loss and net assets that is not held by the Group. The Group attributes total comprehensive income or loss of subsidiaries between the owners of the parent and the non-controlling interests based on their respective ownership interests.

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 Profit or Loss and Other 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 33.3%

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 Profit or Loss and Other 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) INVENTORY**

Raw, materials, work in progress and finished goods are stated at the lower of cost or net realisable value. Cost comprises, direct material and labour. Costs are assigned to individual items of inventory on the basis of weighted average costs. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

#### **G) RESEARCH AND DEVELOPMENT EXPENDITURE**

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

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

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

Whilst at the end of the financial year the consolidated entity had received European regulatory approval and launched a European product the above criteria have not been fully satisfied to support the recognition and generation of an internally generated intangible asset.

#### **H) INTANGIBLE ASSETS - TRADEMARKS, PATENTS AND SUB-LICENCE**

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

##### **Sub-licence**

The sub-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.

#### **I) PAYABLES**

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

#### **J) EMPLOYEE BENEFITS**

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

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

Provisions made in respect of employee benefits which are not expected to be settled within 12 months are measured as the present value of the estimated future cash outflows to be made by the consolidated entity in respect of services provided by employees up to reporting date. The discount rate used to estimate future cash flows is per the Australian corporate bond rates as commissioned by the Group of 100 and published by Milliman Australia at reporting date.

## **K) DIRECTORS' REMUNERATION – SHARE-BASED PAYMENTS**

Under AASB 2 Share-based Payments, the consolidated entity must determine the fair value of options and Performance Rights issued to employees as remuneration and recognise an expense in the Statement of Profit or Loss and Other Comprehensive Income. This standard is not limited to options and to 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 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 Performance Rights is shown as an expense in profit or loss.

## **L) 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 under Special Access Schemes & Commercial Sales**

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.

## **M) SHARE CAPITAL**

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

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

## **N) EARNINGS PER SHARE**

### **Basic Earnings Per Share**

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

### **Diluted Earnings Per Share**

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

## **O) GOODS AND SERVICES TAX/ VALUE ADDED TAX (GST)**

Revenues, expenses and assets are recognised net of the amount of 'goods and services tax' or 'value 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.

## **P) IMPAIRMENT OF ASSETS**

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

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

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognised in the Statement of Profit or Loss and Other 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 Profit or Loss and Other Comprehensive Income immediately.

## **Q) LEASES**

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

## **R) COMPARATIVES**

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

## **S) PROVISIONS**

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

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

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

## T) FOREIGN CURRENCY TRANSACTIONS AND BALANCES

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

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

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

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

## U) OTHER CURRENT ASSETS

Other current assets comprise prepayments of drug peptide yet to be used in CLINUVEL PHARMACEUTICALS LTD's 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.

## V) 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 binomial 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 LTD ('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.

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.

## W) CRITICAL ACCOUNTING ESTIMATES AND JUDGMENT

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

### Key estimates – share-based payments transactions

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

## X) 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.

## Y) 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 2016 reporting periods, and have not yet been adopted by the Group. The Group's assessment of the impact of these new standards and interpretations is set out below:

### AASB 9 Financial Instruments (December 2014)

AASB 9 introduces new requirements for the classification and measurement of financial assets and liabilities and includes a forward-looking 'expected loss' impairment model and a substantially-changed approach to hedge accounting.

These requirements improve and simplify the approach for classification and measurement of financial assets compared with the requirements of AASB 139. The main changes are:

- Financial assets that are debt instruments will be classified based on: (i) the objective of the entity's business model for managing the financial assets; and (ii) the characteristics of the contractual cash flows.
- Allows an irrevocable election on initial recognition to present gains and losses on investments in equity instruments that are not held for trading in other comprehensive income (instead of in profit or loss). Dividends in respect of these investments that are a return on investment can be recognised in profit or loss and there is no impairment or recycling on disposal of the instrument.
- Introduces a 'fair value through other comprehensive income' measurement category for particular simple debt instruments.
- Financial assets can be designated and measured at fair value through profit or loss at initial recognition if doing so eliminates or significantly reduces a measurement or recognition inconsistency that would arise from measuring assets or liabilities, or recognising the gains and losses on them, on different bases.
- Where the fair value option is used for financial liabilities the change in fair value is to be accounted for as follows:

- the change attributable to changes in credit risk are presented in Other Comprehensive Income ('OCI')
- the remaining change is presented in profit or loss

If this approach creates or enlarges an accounting mismatch in the profit or loss, the effect of the changes in credit risk are also presented in profit or loss. Otherwise, the following requirements have generally been carried forward unchanged from AASB 139 into AASB 9:

- classification and measurement of financial liabilities; and
- derecognition requirements for financial assets and liabilities.

AASB 9 requirements regarding hedge accounting represent a substantial overhaul of hedge accounting that enable entities to better reflect their risk management activities in the financial statements.

Furthermore, AASB 9 introduces a new impairment model based on expected credit losses. This model makes use of more forward-looking information and applies to all financial instruments that are subject to impairment accounting.

The entity is yet to undertake a detailed assessment of the impact of AASB 9. However, based on the entity's preliminary assessment, the Standard is not expected to have a material impact on the transactions and balances recognised in the financial statements when it is first adopted for the year ending 30 June 2019.

#### **AASB 15 Revenue from Contracts with Customers**

AASB 15:

- replaces AASB 15 Revenue and some revenue-related Interpretations:
  - establishes a new control-based revenue recognition model;
  - changes the basis for deciding whether revenue is to be recognised over time or at a point in time;
  - provides new and more detailed guidance on specific topics (e.g., multiple element arrangements, variable pricing, rights of return, warranties and licensing); and
  - expands and improves disclosures about revenue.

The entity is yet to undertake a detailed assessment of the impact of AASB 15. However, based on the entity's preliminary assessment, the Standard is not expected to have a material impact on the transactions and balances recognised in the financial statements when it is first adopted for the year ending 30 June 2019.

#### **AASB 16 Leases**

AASB 16:

- replaces AASB 117 Leases and some lease-related Interpretations
- requires all leases to be accounted for 'on-balance sheet' by lessees, other than short-term and low value asset leases
- provides new guidance on the application of the definition of lease and on sale and lease back accounting
- largely retains the existing lessor accounting requirements in AASB 117
- requires new and different disclosures about leases

The entity is yet to undertake a detailed assessment of the impact of AASB 16. However, based on the entity's preliminary assessment, the Standard is not expected to have a material impact on the transactions and balances recognised in the financial statements when it is first adopted for the year ending 30 June 2020.

## **Z) 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 no operating segments within the definition of AASB 8 Operating Segments.

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% of the revenue from sales reimbursements under special access schemes is generated from seven end users (2015: six end users). 100% of the revenue from commercial sales is from one end user (2015: nil).

## **AA) ROUNDING OF AMOUNTS**

The entity has applied the relief available to it under *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191* and accordingly, amounts in the financial statements and directors' report have been rounded off to the nearest \$1,000, or in certain cases, the nearest dollar.

**2. PROFIT/(LOSS) FROM CONTINUING OPERATIONS**

		CONSOLIDATED ENTITY	
		2016	2015
		\$	\$
<b>(A)</b>	<b>REVENUES</b>		
	Interest revenue – other persons	208,368	348,409
	Sales reimbursements	3,613,764	2,911,553
	Commercial sales	2,597,575	-
	<b>TOTAL REVENUES</b>	<b>6,419,707</b>	<b>3,259,962</b>
<b>(B)</b>	<b>OTHER INCOME</b>		
	Government R&D tax incentive	609,059	406,126
	Gain/(loss) on restating foreign currency creditors and currencies held	187,472	64,147
	<b>TOTAL OTHER INCOME</b>	<b>796,531</b>	<b>470,273</b>
<b>(C)</b>	<b>EXPENSES</b>		
	Clinical development costs	133,461	231,963
	Drug formulation R&D, manufacture & distribution	1,022,082	450,090
	Regulatory (Pre & Post Marketing) & Non-clinical	973,221	662,069
	Clinical, Regulatory & Commercial overheads	1,606,026	1,258,823
	Business marketing & listing	777,725	801,556
	Licenses patents and trademarks	266,072	232,150
	General operations (incl Board)	5,591,369	10,507,960
	<b>TOTAL EXPENSES</b>	<b>10,369,956</b>	<b>14,144,611</b>
<b>(D)</b>	<b>PROFIT/(LOSS) BEFORE INCOME TAX INCLUDES THE FOLLOWING SPECIFIC EXPENSES</b>		
	Employee benefits expense	4,360,203	3,900,848
	Depreciation on property, plant & equipment	25,526	26,539
	Loss on sale of property, plant and equipment	-	29,875
	Share-based payments	1,670,425	5,676,092
	Operating lease expense – minimum lease payments	356,842	339,744

**3. INCOME TAX EXPENSE**

		CONSOLIDATED ENTITY	
		2016	2015
		\$	\$
<b>(A)</b>	<b>THE PRIMA FACIE TAX ON PROFIT (LOSS) IS RECONCILED TO THE INCOME TAX EXPENSE (BENEFIT) AS FOLLOWS:</b>		
	Prima facie tax payable on profit (loss) from ordinary activities before income tax at 30% (2015: 30%):	(946,115)	(3,124,313)
	Add:		
	Tax effect of		
	Non deductible entertainment	939	1,928
	Share-based payments	501,128	1,702,828
	Research and development deduction	396,702	280,087
	(Over)/under provision of income tax in previous years	235,582	(424,901)
	Refundable tax offset	(182,718)	(121,838)
	Other	4,318	23
	Total deferred tax assets not brought to account	9,836	(1,686,186)
<b>(B)</b>	<b>DEFERRED TAX ASSETS ARISING FROM UNCONFIRMED TAX LOSSES AND NET TIMING DIFFERENCES NOT BROUGHT TO ACCOUNT AT REPORTING DATE AS REALISATION OF THE BENEFIT IS NOT REGARDED AS PROBABLE. THE BENEFITS WILL ONLY BE OBTAINED IF THE CONDITIONS SET OUT IN NOTE 1(B) OCCUR:</b>		
	Tax losses	38,852,707	40,540,810
	Net temporary differences	(94,113)	(1,772,380)
	<b>TOTAL</b>	<b>38,758,594</b>	<b>38,768,430</b>

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 ENTITY	
		2016	2015
		\$	\$
<b>CURRENT</b>			
	Trade debtors	2,759,012	1,478,310
	Accrued income	1,320,996	32,731
	Sundry debtors	743,762	449,412
	<b>TOTAL</b>	<b>4,823,770</b>	<b>1,960,453</b>

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.

**AGEING AND IMPAIRMENT LOSSES**

The ageing of the trade receivables for the Group at reporting date was:

	2016			2015		
	AMOUNT IMPAIRED	AMOUNT NOT IMPAIRED	TOTAL	AMOUNT IMPAIRED	AMOUNT NOT IMPAIRED	TOTAL
Not past due	-	2,759,012	2,759,012	-	969,462	969,462
Past due 61-90 days	-	-	-	-	195,711	195,711
Past due >90 days	-	-	-	-	313,137	313,137
<b>TOTAL</b>	<b>-</b>	<b>2,759,012</b>	<b>2,759,012</b>	<b>-</b>	<b>1,478,310</b>	<b>1,478,310</b>

**5. INVENTORY**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
<b>CURRENT INVENTORY</b>		
Raw materials – at cost	364,879	391,156
Finished goods – at cost	717,284	445,979
<b>TOTAL</b>	<b>1,082,163</b>	<b>837,135</b>

**6. OTHER ASSETS**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
<b>CURRENT PREPAYMENTS</b>		
Prepaid peptide	138,080	134,722
Other	84,881	69,901
<b>TOTAL</b>	<b>222,961</b>	<b>204,623</b>

**7. PROPERTY, PLANT AND EQUIPMENT**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
<b>PLANT AND EQUIPMENT</b>		
At cost	405,484	364,171
Less: accumulated depreciation	(319,167)	(299,015)
<b>SUB-TOTAL</b>	<b>86,317</b>	<b>65,156</b>
<b>FURNITURE AND FITTINGS</b>		
At cost	96,044	17,182
Less: accumulated depreciation	(17,691)	(12,969)
<b>SUB-TOTAL</b>	<b>78,353</b>	<b>4,213</b>
<b>TOTAL PROPERTY, PLANT AND EQUIPMENT</b>	<b>164,670</b>	<b>69,369</b>

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

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

	CONSOLIDATED ENTITY		
	PLANT AND EQUIPMENT	FURNITURE AND FITTINGS	TOTAL
	\$	\$	\$
<b>CARRYING AMOUNT AT 30 JUNE 2014</b>	<b>87,614</b>	<b>26,847</b>	<b>114,461</b>
Additions	12,096	-	12,096
Disposals	(105,327)	(62,472)	(167,799)
Depreciation written back on disposal	96,257	43,735	139,992
Depreciations expense	(23,328)	(3,211)	(26,539)
Exchange differences	(2,156)	(686)	(2,842)
<b>CARRYING AMOUNT AT 30 JUNE 2015</b>	<b>65,156</b>	<b>4,213</b>	<b>69,369</b>
Additions	42,496	64,157	106,653
Disposals	(1,184)	-	(1,184)
Depreciation written back on disposal	944	-	944
Depreciations expense	(20,804)	(4,722)	(25,526)
Make-good	-	14,705	14,705
Exchange differences	(291)	-	(291)
<b>CARRYING AMOUNT AT 30 JUNE 2016</b>	<b>86,317</b>	<b>78,353</b>	<b>164,670</b>

**8. INTERESTS IN SUBSIDIARIES**

NAME OF ENTITY	COUNTRY OF INCORPORATION	OWNERSHIP INTEREST	
		2016	2015
<b>PARENT ENTITY</b>			
CLINUVEL PHARMACEUTICALS LTD	Australia	-	-
<b>CONTROLLED ENTITIES</b>			
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%
VALLAURIX PTE LTD	Singapore	82%	82%



**9. TRADE AND OTHER PAYABLES**

		CONSOLIDATED ENTITY	
		2016	2015
		\$	\$
<b>CURRENT</b>			
	Unsecured trade creditors	231,016	260,600
	Sundry creditors and accrued expenses	1,342,345	1,600,036
<b>TOTAL</b>		<b>1,573,361</b>	<b>1,860,636</b>
<b>(A) AGGREGATE AMOUNTS PAYABLE TO:</b>			
	Directors and Director-related entities	373,712	476,516
<b>(B) AUSTRALIAN DOLLAR EQUIVALENTS OF AMOUNTS PAYABLE IN FOREIGN CURRENCIES NOT EFFECTIVELY HEDGED AND INCLUDED IN TRADE AND SUNDRY CREDITORS:</b>			
	US Dollars	-	108,683
	British Pounds	-	204,287
	Swiss Franc	-	-
	Singapore Dollars	201,860	389,607
	Other	164	-
<b>TOTAL</b>		<b>202,024</b>	<b>702,577</b>

For an 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 terms.

**10. PROVISIONS**

		CONSOLIDATED ENTITY	
		2016	2015
		\$	\$
<b>CURRENT</b>			
	Employee benefits	715,017	574,640
<b>TOTAL</b>		<b>715,017</b>	<b>574,640</b>
<b>NON-CURRENT</b>			
	Employee benefits	627	3,308
	Other provisions	14,742	-
<b>TOTAL</b>		<b>15,369</b>	<b>3,308</b>

**MOVEMENTS IN CARRYING AMOUNTS - PROVISIONS**

The carrying amounts and movements in other provisions account are as follows:

	CONSOLIDATED ENTITY	
	MAKE-GOOD	TOTAL
	\$	\$
CARRYING AMOUNT AT 30 JUNE 2015	-	-
Provisions made during the year	14,704	14,704
Unwind of discount	38	38
CARRYING AMOUNT AT 30 JUNE 2016	14,742	14,742

**11. CONTRIBUTED EQUITY****(A) ISSUED AND PAID UP CAPITAL**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
47,080,637 fully paid ordinary shares (2015: 44,554,787)	146,764,500	138,465,335

Ordinary shares have the right to receive dividends as declared and, in the event of winding up the Company, to participate in the proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held. Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company. The Company does not have a limited amount of authorised capital and issued shares do not have a par value.

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

	CONSOLIDATED ENTITY			
	2016		2015	
	NO.	\$	NO.	\$
AT THE BEGINNING OF THE FINANCIAL YEAR	44,554,787	138,465,335	42,391,435	133,567,056
Issued during the year	2,525,850	8,335,305	59,810	250,000
Conditional Rights issued and transferred from Conditional Rights reserve	-	-	2,103,542	4,650,579
Less: transaction costs	-	(36,140)	-	(2,300)
BALANCE AT THE END OF THE FINANCIAL YEAR	47,080,637	146,764,500	44,554,787	138,465,335

**(C) CONDITIONAL PERFORMANCE RIGHTS**

During the year there were no Conditional Performance Rights issued or exercised.

As at 30 June 2016 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\$	2,556,250

**12. RESERVES**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
<b>CONDITIONAL PERFORMANCE RIGHTS RESERVE:</b>		
<b>BALANCE AT THE BEGINNING OF PERIOD</b>	<b>2,313,678</b>	<b>1,321,529</b>
Share-based payment	1,670,425	5,676,092
Transfer to share capital	-	(4,650,579)
Lapsed, forfeited Rights	-	(33,364)
<b>BALANCE AT THE END OF PERIOD</b>	<b>3,984,103</b>	<b>2,313,678</b>
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.		
<b>FOREIGN CURRENCY TRANSLATION RESERVE:</b>		
<b>BALANCE AT THE BEGINNING OF PERIOD</b>	<b>384,660</b>	<b>116,517</b>
Translating foreign subsidiary to current rate at reporting date	(273,786)	268,143
<b>BALANCE AT THE END OF PERIOD</b>	<b>110,874</b>	<b>384,660</b>
<b>TOTAL RESERVES</b>	<b>4,094,977</b>	<b>2,698,338</b>

**13. ACCUMULATED LOSSES**

	CONSOLIDATED ENTITY		NON-CONTROLLING INTEREST	
	2016	2015	2016	2015
	\$	\$	\$	\$
Accumulated losses at the beginning of the year	(129,942,039)	(119,577,370)	(16,343)	-
Transfer from Performance Rights reserve of lapsed & expired Rights	-	33,364	-	-
Net loss attributable to the members of CLINUVEL PHARMACEUTICALS LTD	(3,121,200)	(10,398,033)	(32,518)	(16,343)
<b>ACCUMULATED LOSSES AT THE END OF THE FINANCIAL YEAR</b>	<b>(133,063,239)</b>	<b>(129,942,039)</b>	<b>(48,861)</b>	<b>(16,343)</b>

**14. LEASE COMMITMENTS**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
<b>OPERATING LEASE COMMITMENTS</b>		
Non-cancellable operating leases contracted for but not capitalised in the accounts		
Payable:		
not later than 1 year	155,189	172,795
later than 1 year but not later than 5 years	91,934	33,355
<b>TOTAL</b>	<b>247,123</b>	<b>206,150</b>

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 34 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 ENTITY	
	2016	2015
	\$	\$
(a) Basic earnings per share (cents per share)	(7.0)	(24.0)
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	45,286,317	43,373,683
(c) The numerator used in the calculation of basic earnings per share (\$)	(3,153,718)	(10,414,376)

As at 30 June 2016 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.

Between the reporting date and the date of the completion of this financial report, 644,590 unlisted Performance Rights became exercisable and were issued into ordinary shares. Otherwise 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 1,911,660 (2015: 2,556,250).

**16. CASH FLOW INFORMATION**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$

**(A) RECONCILIATION OF CASH**

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

Cash at bank	3,936,720	2,840,536
Cash on hand	555	618
Deposits on call	79,147	344,469
Term deposits	9,750,000	7,300,000
Security bonds	78,281	86,672
<b>TOTAL CASH</b>	<b>13,844,703</b>	<b>10,572,295</b>

**(B) RECONCILIATION OF CASH FLOWS FROM OPERATING ACTIVITIES WITH OPERATING PROFIT (LOSS)**

<b>OPERATING PROFIT (LOSS) AFTER INCOME TAX</b>	<b>(3,153,718)</b>	<b>(10,414,376)</b>
Non cash flows in operating (loss):		
Depreciation expense on property, plant & equipment	25,526	26,539
Exchange rate effect on foreign currencies held	(19,028)	(264,521)
Executive share option expense	1,670,425	5,676,092
Loss on sale of non-current assets	-	29,251
Unrealised loss on foreign exchange translation	(273,786)	268,143
Changes in assets and liabilities:		
(Increase)/decrease in receivables	(2,863,317)	(356,822)
(Increase)/decrease in inventories	(245,028)	(837,135)
(Increase)/decrease in prepayments	(18,338)	623,446
Increase/(decrease) in payables	(297,403)	762,304
Increase/(decrease) in provisions	137,734	(42,733)
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(5,036,933)</b>	<b>(4,529,812)</b>

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 3.01% (2015: 3.48%). These deposits have an average maturity date of 165 days (2015: 115 days).

**17. KEY MANAGEMENT PERSONNEL DISCLOSURES****THE DIRECTORS OF CLINUVEL PHARMACEUTICALS LTD 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. E. Ishag (Non-Executive Director)

Mr. W.A. Blijdorp (Non-Executive Director)

**THE OTHER KEY MANAGEMENT PERSONNEL OF CLINUVEL PHARMACEUTICALS LTD 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 ENTITY	
	2016	2015
	\$	\$
<b>SHORT-TERM EMPLOYEE BENEFITS:</b>	1,976,218	2,154,478
Post-employment benefits	55,100	55,213
<b>LONG-TERM BENEFITS:</b>	-	-
Termination benefits	-	-
Share-based payments	1,410,279	5,533,958
<b>TOTAL</b>	<b>3,441,597</b>	<b>7,743,649</b>

No loans or other transactions existed with key management personnel.

**18. AUDITOR'S REMUNERATION**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	67,500	66,500
other services	27,500	-
<b>TOTAL</b>	<b>95,000</b>	<b>66,500</b>

## 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, E. Ishag, W.A. Blijdorp.

### WHOLLY-OWNED GROUP TRANSACTIONS

#### Loans

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 2016 is \$4,370,640 (2015: \$4,370,640).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL, INC. is non-interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD to the extent that a deficiency in net assets exists in CLINUVEL, INC. The loan to CLINUVEL, INC. as at 30 June 2016 is \$10,640,482 (2015: \$10,338,331).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL AG is non-interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD to the extent that a deficiency in net assets exists in CLINUVEL AG. The loan to CLINUVEL AG as at 30 June 2016 is \$18,293,460 (2015: \$19,042,355).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL SINGAPORE PTE LTD is non-interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD to the extent that a deficiency in net assets exists in CLINUVEL SINGAPORE PTE LTD. The loan to CLINUVEL SINGAPORE PTE LTD as at 30 June 2016 is \$215,774 (2015: \$63,026).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL (UK) LTD is non-interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD to the extent that a deficiency in net assets exists in CLINUVEL (UK) LTD. The loan to CLINUVEL (UK) LTD as at 30 June 2016 is \$3,248,740 (2015: \$198,933).

#### Director related and key management personnel transactions and entities

There are no transactions and relationships in existence as at 30 June 2016 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 no operating segments within the definition of AASB 8 Operating Segments.

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% of the revenue from sales reimbursements under special access schemes is generated from seven end users (2015: six end users). 100% of the revenue from commercial sales is from one end user (2015: nil).

## 21. FINANCIAL INSTRUMENTS

CLINUVEL PHARMACEUTICALS LTD and consolidated entities have exposure to the following risks from its use in financial instruments:

- a) Market Risk
- b) Credit Risk
- c) 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.

### A) 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), Singapore dollars (SGD) and Great British pounds (GBP). The parent entity is exposed to the risk of its cash flows being adversely affected by movements in exchange rates that will increase the Australian dollar value of foreign currency payables.

The consolidated entity's policy of managing foreign currency risk is to purchase foreign currencies equivalent to the cash outflow projected over minimum 30 days by the placement of market orders or forward exchange contracts to achieve a target rate of exchange, with protection floors in the event of a depreciating Australian dollar exchange rate, to run for the time between recognising the exposure and the time of payment. In the event of an appreciating Australian dollar, the amount of foreign currency held is minimised at a level to only meet short term obligations in order to maximise gains in an appreciating Australian currency. CLINUVEL does not engage in speculative transactions in its management of foreign currency risk. No forward exchange contracts had been entered into as at 30 June 2016 and as at 30 June 2015.

**THE CONSOLIDATED ENTITY'S EXPOSURE TO FOREIGN CURRENCY RISK AT 30 JUNE 2016**

CONSOLIDATED ENTITY								
2016					2015			
	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	897,509	1,915	(467,104)	432,320	451,661	-	(535,129)	(83,468)
EUR	717,433	2,433,538	(42,150)	3,108,821	497,192	931,000	(35,108)	1,393,084
CHF	500,344	409,378	(129,709)	780,013	477,211	219,519	(130,332)	566,398
GBP	137,621	51,624	(61,149)	128,096	12,875	3,454	(112,669)	(96,340)
SGD	550,442	5,225	(752,847)	(197,180)	335,961	2,730	(738,815)	(400,124)
Other	-	-	(834)	(834)	-	-	-	-

**Sensitivity Analysis of Foreign Currency Risk**

During the financial year the Company had a principal foreign currency transaction risk exposure to the Singapore 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 development program.

For the consolidated entity, a 5% appreciation of the Australian dollar against the Singapore currency would have increased profit and loss and equity by \$81,241 for the year ended 30 June 2016 (2015: \$71,646), on the basis that all other variables remain constant. 5% is considered representative of the market volatility in the Australian/Singapore dollar rate for the period.

For the consolidated entity, a depreciation of the Australian dollar against the Singapore 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 as 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 of Interest Rate Risk**

For the consolidated entity, at 30 June 2016, 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 \$51,523 higher/lower (2015: \$59,612 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. The consolidated entity no longer holds income securities. Neither the consolidated entity nor the parent is exposed to commodity price risk.

**B) 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 eight government funded counterparties across Italian, Swiss and Dutch medical institutions.

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.

**C) LIQUIDITY RISK**

Liquidity risk is the risk the consolidated entity will not be able to meet its financial obligations when they fall due. It is the policy of the consolidated entity to ensure there is sufficient liquidity to meet its liabilities when due without incurring unnecessary loss or damage. The consolidated entity holds cash and 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 whereby revenues will exceed expenditures.

**CONTRACTUAL MATURITIES OF FINANCIAL ASSETS AS AT 30 JUNE 2016**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
<b>CASH AND CASH EQUIVALENTS</b>		
Carrying amount	13,844,703	10,572,295
6 months or less	13,844,703	10,572,295
Greater than 6 months	-	-
<b>TOTAL</b>	<b>13,844,703</b>	<b>10,572,295</b>
<b>OTHER FINANCIAL ASSETS (INCLUDES TRADE AND OTHER RECEIVABLES)</b>		
Carrying amount	4,823,770	1,960,453
6 months or less	4,823,770	1,803,884
Greater than 6 months	-	156,569
<b>TOTAL</b>	<b>4,823,770</b>	<b>1,960,453</b>

**CONTRACTUAL MATURITIES OF FINANCIAL LIABILITIES AS AT 30 JUNE 2016**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
<b>TRADE AND OTHER PAYABLES</b>		
Carrying amount	1,573,361	1,860,636
6 months or less	1,551,891	1,798,917
Greater than 6 months	21,470	61,719
<b>TOTAL</b>	<b>1,573,361</b>	<b>1,860,636</b>

**22. EMPLOYEE BENEFITS**

	CONSOLIDATED ENTITY	
	2016	2015
	\$	\$
<b>THE AGGREGATE EMPLOYEE BENEFIT LIABILITY IS COMPRISED OF :</b>		
Provision for annual leave	413,281	316,271
Provision for long service leave	302,362	261,676
Accrued FBT, payroll, superannuation, pension funds, employee insurances	500,723	660,624
<b>TOTAL</b>	<b>1,216,366</b>	<b>1,238,571</b>



**SHARE-BASED PAYMENTS**

The consolidated entity has two Conditional Performance Rights schemes which are ownership based for key management personnel and select consultants (including Directors) of the Company.

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

**a) Conditional Performance Rights Plan (2009)**

The Conditional Performance Rights Plan (2009) is available to eligible employees of the Company. Any issue of Performance Rights to executive Directors requires shareholder approval in accordance with ASX Listing Rules. All Performance Rights convert to one ordinary share of the consolidated entity, are issued for nil consideration, have no voting rights, are non-transferable and are not listed on the ASX. They can be converted to ordinary shares at any time once the vesting conditions attached to the Performance 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.

**b) Performance Rights Plan (2014)**

The Performance Rights Plan (2014) is available to eligible persons of the Company. Any issue of Performance Rights to executive Directors requires shareholder approval in accordance with ASX Listing Rules. All Performance Rights convert to one ordinary share of the consolidated entity, are issued for nil consideration, have no voting rights, are not listed on the ASX and are non-tradeable (other than with prior written Board consent). They can be converted to ordinary shares at any time once the vesting conditions attached to the Performance Rights have been achieved, whereby, at the discretion of the Board, they will be held by a Scheme Trustee on behalf of the eligible person. The eligible person cannot trade in the shares held by the Scheme Trust without prior written Board consent until the earlier of 7 years from grant date of Performance Rights, when the eligible person ceases employment or when all transfer restrictions are satisfied or waived by the Board in its discretion. Performance Rights under this Plan lapses after 7 years from grant date.

**THE FOLLOWING SHARE-BASED PAYMENT ARRANGEMENTS WERE IN EXISTENCE AT 30 JUNE 2016**

PERFORMANCE RIGHTS SERIES	NUMBER	GRANT DATE	EXPIRY DATE	EXERCISE PRICE	FAIR VALUE AT GRANT DATE
Issued 07/01/2010	10,000	07/01/2010	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	\$1.70
Issued 25/11/2010	299,999	25/11/2010	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	\$1.04
Issued 16/09/2011	381,386	16/09/2011	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	Between \$0.55 and \$0.72
Issued 16/11/2011	90,000	16/11/2011	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	\$0.67
Issued 14/01/2013	75,000	14/01/2013	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	\$1.19
Issued 04/12/2014	1,246,365	28/11/2014	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	\$2.60
Issued 17/03/2015	453,500	17/03/2015	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	\$2.16

**HOLDINGS OF ALL ISSUED CONDITIONAL PERFORMANCE RIGHTS – 2016**

PERFORMANCE RIGHTS SERIES	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	EXPIRED & LAPSED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
Issued 07/01/2010	10,000	-	-	-	10,000	10,000	-
Issued 25/11/2010	299,999	-	-	-	299,999	-	299,999
Issued 16/09/2011	381,386	-	-	-	381,386	-	381,386
Issued 16/11/2011	90,000	-	-	-	90,000	-	90,000
Issued 14/01/2013	75,000	-	-	-	75,000	-	75,000
Issued 04/12/2014	1,246,365	-	-	-	1,246,365	553,890	692,475
Issued 17/03/2015	453,500	-	-	-	453,500	90,700	362,800
<b>TOTAL</b>	<b>2,556,250</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>2,556,250</b>	<b>654,590</b>	<b>1,901,660</b>
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 ranging from 1 year to 10 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 – 2015**

PERFORMANCE RIGHTS SERIES	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	EXPIRED & LAPSED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
Issued 16/10/2009	104,500	-	(104,500)	-	-	-	-
Issued 07/01/2010	10,000	-	-	-	10,000	10,000	-
Issued 25/11/2010	449,166	-	(149,167)	-	299,999	-	299,999
Issued 16/09/2011	447,816	-	(66,430)	-	381,386	-	381,386
Issued 16/11/2011	230,000	-	(90,000)	(50,000)	90,000	-	90,000
Issued 14/01/2013	225,000	-	(150,000)	-	75,000	-	75,000
Issued 04/12/2014	-	2,789,810	(1,543,445)	-	1,246,365	-	1,246,365
Issued 17/03/2015	-	453,500	-	-	453,500	-	453,500
<b>TOTAL</b>	<b>1,466,482</b>	<b>3,243,310</b>	<b>(2,103,542)</b>	<b>(50,000)</b>	<b>2,556,250</b>	<b>10,000</b>	<b>2,546,250</b>
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 10 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	
		2016	2015
		\$	\$
<b>ASSETS</b>			
Current assets		13,674,405	10,198,964
Non-current assets		6,355,032	3,401,189
<b>TOTAL ASSETS</b>		<b>20,029,437</b>	<b>13,600,153</b>
<b>LIABILITIES</b>			
Current liabilities		1,244,389	1,745,213
Non-current liabilities		627	3,308
<b>TOTAL LIABILITIES</b>		<b>1,245,016</b>	<b>1,748,521</b>
<b>EQUITY</b>			
Issued equity		146,764,500	138,465,335
Share-based payments reserve		3,984,119	2,313,694
Accumulated losses		(131,964,198)	(128,927,397)
<b>TOTAL EQUITY</b>		<b>18,784,421</b>	<b>11,851,632</b>
<b>FINANCIAL PERFORMANCE</b>			
Net profit (loss) for the year		(3,036,801)	(9,552,573)
Other comprehensive income		-	-
<b>TOTAL COMPREHENSIVE INCOME</b>		<b>(3,036,801)</b>	<b>(9,552,573)</b>

**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.

**25. ADDITIONAL COMPANY INFORMATION**

CLINUVEL PHARMACEUTICALS LTD is a listed public company incorporated and operating in Australia.

The Registered office is:

Level 5, 160 Queen St  
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 2016 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. Philippe Wolgen, MBA MD

Director

Dated this 28th day of August, 2016



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

### **Report on the financial report**

We have audited the accompanying financial report of Clinuvel Pharmaceuticals Limited (the "Company"), which comprises the consolidated statement of financial position as at 30 June 2016, 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  
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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 2016 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 10 to 17 of the directors' report for the year ended 30 June 2016. 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 2016, complies with section 300A of the Corporations Act 2001.

A handwritten signature in blue ink, appearing to read "Grant Thornton".

GRANT THORNTON AUDIT PTY LTD  
Chartered Accountants

A handwritten signature in blue ink, appearing to read "B.A. Mackenzie".

B.A. Mackenzie  
Partner - Audit & Assurance

Melbourne, 25 August 2016



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

### **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 2016, 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

B. A. Mackenzie  
Partner - Audit & Assurance

Melbourne, 25 August 2016

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# SHAREHOLDER INFORMATION AS AT 30 SEPTEMBER 2016

Additional information as at 30 September 2016 required by the ASX and not shown elsewhere in this report is as follows:

## 1. SHAREHOLDING

### A) DISTRIBUTION OF SHAREHOLDER NUMBERS

CATEGORY (SIZE OF HOLDING)	TOTAL HOLDERS	UNITS	ORDINARY FULLY PAID SHARES
			% OF ISSUED CAPITAL
1-1,000	1,811	698,569	1.46
1,001-5,000	698	1,653,931	3.47
5,001-10,000	137	1,021,479	2.14
10,001-100,000	200	5,339,440	11.19
100,001-999,999,999	27	39,011,808	81.74
<b>TOTAL</b>	<b>2,873</b>	<b>47,725,227</b>	<b>100.00</b>

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

TOTAL	MINIMUM PARCEL SIZE	HOLDERS	UNITS
Minimum \$ 500.00 parcel at \$ 6.06 per unit	83	256	5,755

### C) SUBSTANTIAL SHAREHOLDINGS (ACCORDING TO MOST RECENT SUBSTANTIAL HOLDER DISCLOSURES RECEIVED UP TO 3 OCTOBER 2016)

NAME	NO. ORDINARY SHARES & AMERICAN DEPOSITORY RECEIPTS
Lagoda Investment Management, LLC	4,720,236
FIL Limited	4,531,171
A.C.N. 108 768 896 Pty Ltd*	3,721,898
Ender 1 LLC	2,340,824

\* Inclusive of the relevant interest of shareholder Dr Philippe Jacques Wolgen for 2,474,836 quoted ordinary shares, as disclosed in a further substantial holder disclosure notice dated 10 August 2016.

### 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	9,622,582	20.16
2.	NATIONAL NOMINEES LIMITED	8,091,144	16.95
3.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	6,310,798	13.22
4.	ACN 108 768 896 PTY LTD	3,720,898	7.80
5.	ENDER 1 LLC	2,590,824	5.43
6.	CITICORP NOMINEES PTY LIMITED	1,667,617	3.49
7.	DR MARK EDWIN BADCOCK	842,078	1.76
8.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	784,143	1.64
9.	NATIONAL NOMINEES LIMITED <DB A/C>	695,725	1.46
10.	BIOTECH LAB SINGAPORE PTE LTD	604,598	1.27
11.	M BADCOCK AND P CHU SUPERANNUATION FUND PTY LTD	500,000	1.05
12.	BNP PARIBAS NOMS PTY LTD <DRP>	488,259	1.02
13.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	403,958	0.85
14.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <EUROCLEAR BANK SA NV A/C>	364,471	0.76
15.	HEADSTART GLOBAL HOLDINGS LTD	337,633	0.71
16.	ABN AMRO CLEARING SYDNEY NOMINEES PTY LTD <CUSTODIAN A/C>	274,033	0.57
17.	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	203,959	0.43
18.	MR DAVID JOHN LEWIS	200,000	0.42
19.	MR DAVID WILLIAM TREVORROW	195,122	0.41
20.	DR CORINNE GINIFER	183,849	0.39
<b>TOTALS: TOP 20 HOLDERS OF ORDINARY FULLY PAID SHARES (TOTAL)</b>		<b>38,081,691</b>	<b>79.79</b>
<b>TOTAL REMAINING HOLDERS BALANCE</b>		<b>9,643,536</b>	<b>20.21</b>

**2. COMPANY SECRETARY**

The name of the Company Secretary is:  
Darren Keamy

**3. REGISTERED OFFICE**

The address of the principle registered office in Australia at 30 September 2016 was:

Level 5, 160 Queen St  
Melbourne, VIC 3000  
Telephone: +61 3 9660 4900  
Fax: +61 3 9660 4999  
Email: mail@clinuvel.com  
Website: http://www.clinuvel.com

As of 17 October 2016, the principle registered office in Australia is:

Level 6, 15 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 2016: Nil.

**7. DIRECTORY  
NON-EXECUTIVE CHAIR**

Stan McLiesh

**NON-EXECUTIVE DIRECTORS**

Brenda Shanahan, Elie Ishag, Willem Blijdorp

**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

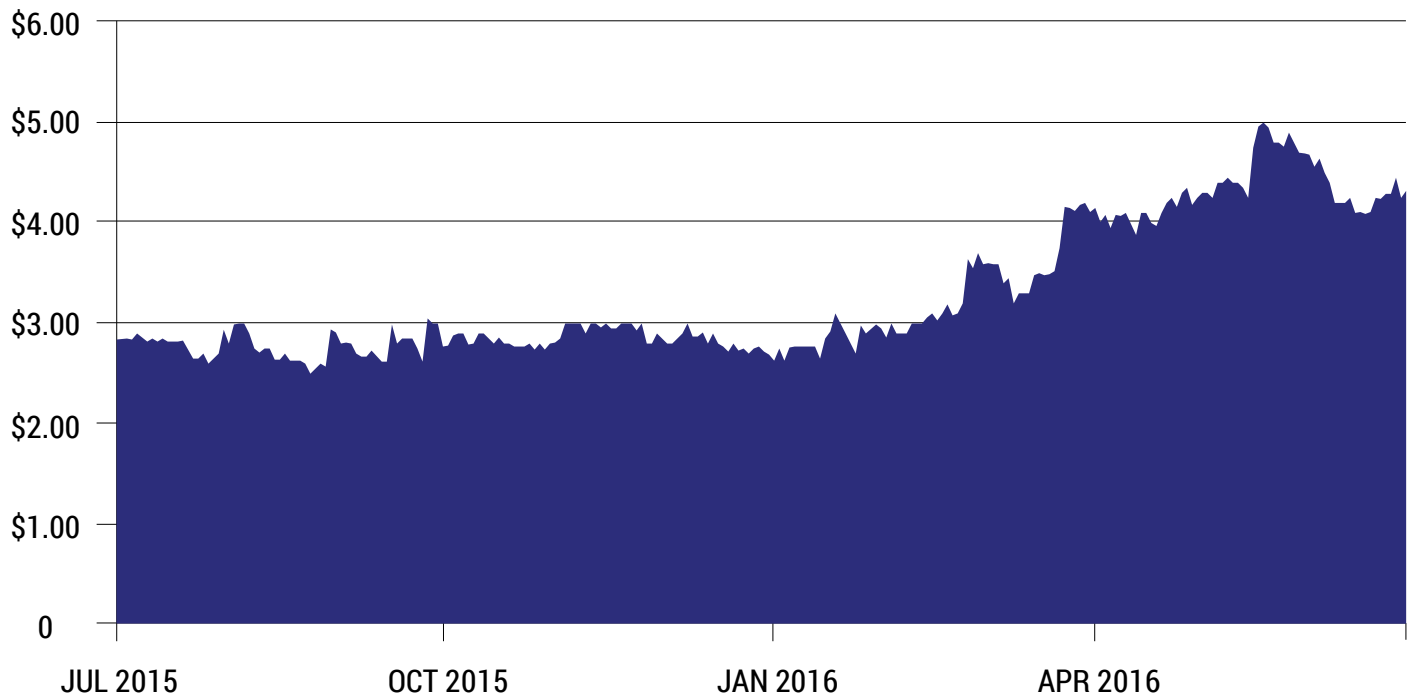
100 Victoria Embankment, London EC4Y 0DH, United Kingdom

**IP LAWYER**

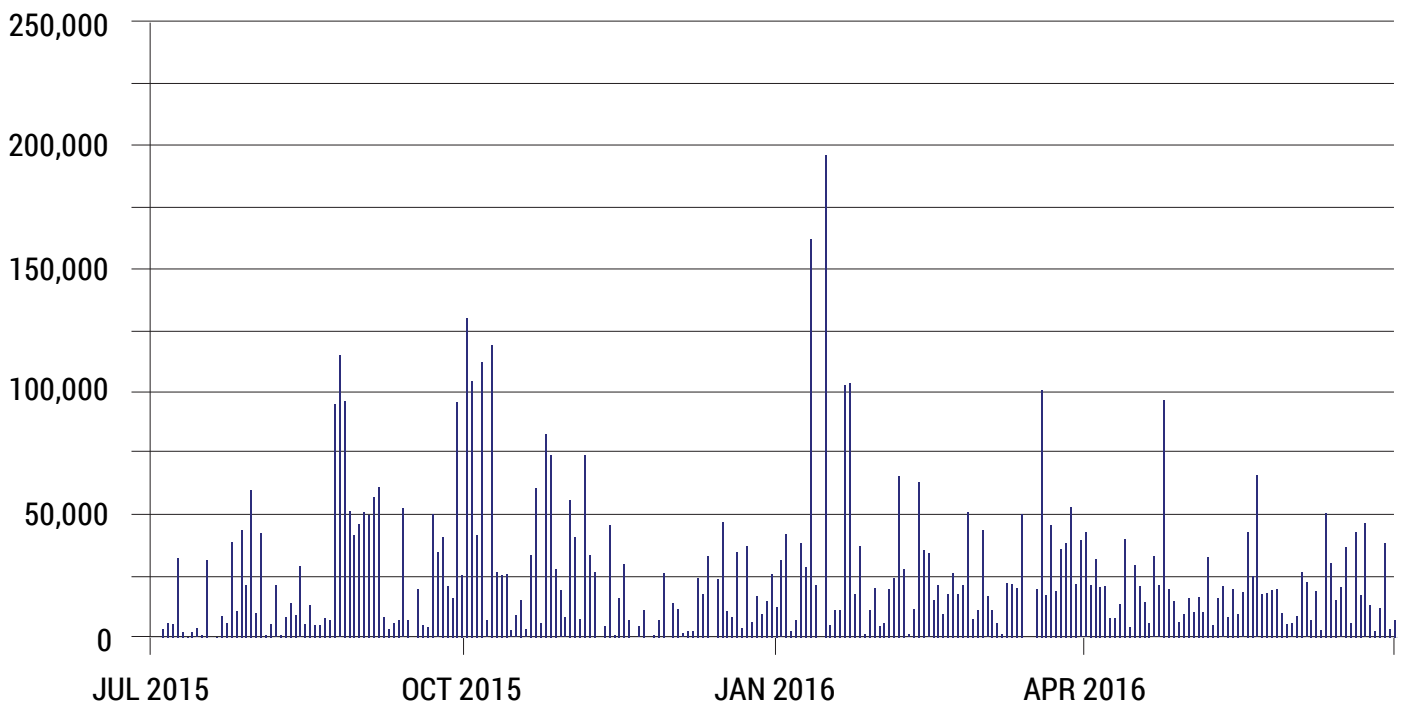
Dipl.-Ing Peter Farago  
Baadestr 3, Munich 80, Germany

# 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/m<sup>2</sup>.

### 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.

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