



# **CLINUVEL PHARMACEUTICALS** **ANNUAL REPORT 2017**

# CONTENTS

<b>THE PILLARS OF SUCCESS</b>	<b>2</b>
<b>CHAIR'S LETTER</b>	<b>4</b>
<b>MANAGING DIRECTOR'S LETTER</b>	<b>5</b>
<b>DIRECTORS' REPORT</b>	<b>7</b>
<b>REMUNERATION REPORT</b>	<b>12</b>
<b>STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME</b>	<b>22</b>
<b>STATEMENT OF FINANCIAL POSITION</b>	<b>23</b>
<b>STATEMENT OF CASH FLOWS</b>	<b>24</b>
<b>STATEMENT OF CHANGES IN EQUITY</b>	<b>25</b>
<b>NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS</b>	<b>26</b>
<b>DIRECTORS' DECLARATION</b>	<b>47</b>
<b>INDEPENDENT AUDITOR'S REPORT</b>	<b>48</b>
<b>AUDITOR'S INDEPENDENCE DECLARATION</b>	<b>51</b>
<b>SHAREHOLDER INFORMATION</b>	<b>52</b>
<b>MARKET PERFORMANCE</b>	<b>55</b>
<b>GLOSSARY</b>	<b>56</b>

# THE PILLARS OF SUCCESS

## HISTORY

In 2005 the concept of offering systemic photoprotection was born when the CLINUVEL (at the time Epitan Limited) Board of Directors decided to break away from the past and focus on afamelanotide as a medicinal treatment in a rare disease, erythropoietic protoporphyria (EPP). It had taken two decades to arrive at this decision since the discovery of the class of molecules. Scientists and founders had seen in afamelanotide an ideal candidate for lifestyle use, but their endeavours never took off. In 2004 the regulatory hurdles had become too much and the Company found itself on the brink of insolvency without a plan. From then onwards the resurrection of CLINUVEL has been executed to become what we know today.

## STRATEGY

In the midst of the financial market meltdown in 2007, CLINUVEL's management was to seek funding to develop the technology following the newly communicated strategy, and the task to raise sufficient funding at minimal operational costs was enormous. In building new teams in Australia, US, Switzerland, and later Singapore, the strategic outlook was fixed on establishing a company which could survive generations to come. With a focus on specialising in certain domains where competition was absent, the chances for success were deemed fair. In CLINUVEL's case the areas of expertise developed were:

- melanocortins;
- systemic photoprotection;
- optics, physics;
- rare genetic metabolic disorders;
- haematology, porphyria;
- dermatology, skin care;
- controlled-release formulations;
- topical drug delivery;
- financial management;
- operational management;
- drug development, regulatory affairs.

## FOUNDATIONS FOR SUCCESS

A prerequisite for progress and success was the ability to build and grow the talent required to execute. In the corporate setting, CLINUVEL chose for a flat structure, whereby key management was to take on multiple tasks at once, expanding their areas of expertise. Consciously, the Board took the decision to expose staff to a broader professional range and assess their ability to accumulate knowledge and experience.

The Chairman of the Board and the Remuneration Committee have been pursuing a plan to retain key management with a long-term view, while growing the next generation within the Company. Multiple recruits and hires were required to complement the existing talent

and broadening the Company's domains of expertise and capacity to deliver. Simultaneously, the emphasis was to contain costs and aim for financial break-even or cash neutrality to alleviate the Company from equity or debt funding.

## BOARD SUCCESSION

The strategy to ensure continuity was implemented by rotating Board members and assigning them various tasks as time passed. With the rotation and loss of Mr Wayne Millen, Dr Terry Winters, Dr Roger Aston, Dr Hank Agersborg, and Mr Jack Wood, new members were added with Mrs Brenda Shanahan, Mr Elie Ishag, Mr Willem Blijdorp. New Board members will continue to be added while securing retention of knowledge within the Board in transitional stages as new members require time to be introduced to, and become familiar with, the complexity of the CLINUVEL story.

## CLINICAL & REGULATORY DEVELOPMENT

A conscious risk assessment is being made at all stages of the ongoing development of SCENESSE<sup>®</sup>, other melanocortins, and complementary products. Reviews of technology, regulatory environment, and legal framework are continuously being performed to assess the hurdles to overcome when introducing novelty e.g. SCENESSE<sup>®</sup> (afamelanotide 16mg).<sup>1</sup> Here there should be no anxiety to challenge established practices, frameworks, guidelines or legislation in place. Introducing innovation comes with creating a novel environment for the conceptual thinking and technology to be embedded.

SCENESSE<sup>®</sup> has, in some capacity, been subject of reviews and appraisals by more than 14 national competent authorities, more than 35 Ethics Committees, the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) and has been deemed safe and tolerant for human use since CLINUVEL's restart in 2005. The EMA started its formal review in February 2012 and granted marketing authorisation in October 2014, the longest review of a new molecular entity in the Agency's history. The EMA had recognised the complexity of novel technology without contemporary scientific instruments to quantify the veritable disease and treatment impact and its effectiveness: an expected challenge when developing greenfield, novel technology. The EMA initiated the inclusion of expert physicians and patients in its final review process of SCENESSE<sup>®</sup> through an 'Ad-Hoc workshop' and 'plenary CHMP meeting'.

The US FDA has been facing the same appraisal challenges since 2005 but, at various moments, took the decision to invite experts and patient advocacy groups to assess independently of the sponsor, the impact of disease (EPP), severity of symptomatology, best alternative to no treatment, and impact of SCENESSE<sup>®</sup> during the clinical trial program in the US.

SCENESSE<sup>®</sup> was awarded orphan drug designation in 2008, Fast Track Designation in 2016 and is awaiting a decision on Priority Review by the FDA. It is expected at the time of printing, that the formal FDA review of SCENESSE<sup>®</sup> will be completed in the same year.

In completing the European and US regulatory 'cycles,' the Company would have consistently executed its strategy to make SCENESSE<sup>®</sup> available in both continents for adult patients diagnosed with EPP. The missing part is the final development and availability of SCENESSE<sup>®</sup> ENFANCE to juvenile EPP patients. The final clinical development of

a paediatric treatment in EPP hinges on the FDA's review time and approval.

## FINANCIAL MANAGEMENT

The compass was set to execute a program at minimal expenditures and at a magnitude lower than the median number required by peer companies to develop a New Molecular Entity (NME) to commercial stage. CLINUVEL spent A\$170 million in equity funding, in absolute terms a substantial amount, nevertheless a factor four to five less than expended for comparable novel technologies by other pharmaceuticals. At minimal dilutionary cost and carefully timed periodic feedback from the independent auditors, the CFO, financial managers and Board, the Company steered through the Global Financial Crisis and ensured that the Company remained a concern at all times of development. A number of financial metrics remain pivotal to CLINUVEL's progress and success to minimise financial risk.

## INVESTOR POOL

The management of CLINUVEL sought shareholder stability since the meltdown and sell-off by one of the hedge funds on its register in 2007. Having learned from the experience, CLINUVEL's management selectively approached the specialised sector funds, pension funds, asset managers, family offices, institutions to directly invest in the company pursuing a mid-term and long-term strategy. Since 2007 stability in CLINUVEL's share register on the ASX, XETRA-DAX, and US OTC markets has been established. By carefully engaging with, and selecting, the desired investors, the value of CLINUVEL would be protected from unforeseen movements in the register.

In 2016, CLINUVEL became one of the few companies to be selected by NASDAQ in its *International Designation* program to increase international exposure. The US shareholder base has since then increased.

## COMMERCIAL PHASE

In consciously selecting the expert physicians in porphyria in Australia, Latin America, Europe and the US, CLINUVEL established a long-term view and invaluable knowledge on the commercial distribution of SCENESSE®. Treatment capacity, availability of medical staff, ability to provide multidisciplinary care, motivation, knowledge, regulatory and legal compliance are all factors which CLINUVEL's teams are required to assess and monitor to ensure smooth distribution of SCENESSE® in Europe. A similar approach is essential in the future in the US.

Intrinsic knowhow resides with the Company's managers and staff on use of the drug, effectiveness of melanocortins, pharmacology, genetics, biological response, impact of disease, and characterisation of symptomatology. Starting from the premise that this knowledge would be impossible to replicate by third parties, CLINUVEL and its consultants started interacting in 2014 with national advisors, politicians responsible for healthcare, government agencies, insurance groups, individual insurers, and ministries of healthcare to prepare the introduction of a novel technology in each European country, Switzerland and the US. Access to the drug for patients in need in

other countries, such as Australia, will follow. In 2015 the first European countries made SCENESSE® available. A number of countries followed in 2016 and 2017. It is expected that further European countries will complete the assessment of SCENESSE® in 2018. In summary, novel technology competes within the budgetary restraints of each country for a place on the list of national healthcare provisions. This includes SCENESSE® and SCENESSE® will need to go through each individual country's appraisal before access can be provided.

Unique to CLINUVEL's approach is the one of uniform pricing structure applicable to SCENESSE® as a standard of care in EPP worldwide.

## COMMUNICATION & MEDIA

A careful balance is being sought between informing the markets and keeping all interested parties at bay when communicating the internal progress of CLINUVEL. The interest in the Company has grown exponentially over the years, not in the least place due to the progress the Company has made on all fronts. CLINUVEL serves as a fertile ground for many stakeholders to learn and replicate the strategy. In view of the long-term goals CLINUVEL is held to minimise the leakage of knowledge, one of its main assets.

CLINUVEL launched one of the first pharmaceutical social media pages in the history of orphan drugs in 2008 and monitors the growth of social media without moderating or actively providing its content.

Following the expansion thrift of the group, CLINUVEL will be increasing the visibility of the group of companies and products significantly.

## THOUGHT LEADERSHIP IN ORPHAN DRUG DEVELOPMENT

The industry press and, gradually, the mainstream press in Europe are analysing the CLINUVEL story as one which is rewriting the principles of drug development. In an environment where drug companies are asked to revise their business models, CLINUVEL is described as one which has proven to be successful without requiring the traditional levels of funding or building of large teams, and one where longevity has paid off. CLINUVEL's teams operate in all modesty towards their next professional goals while sticking to their business parameters and principles.

## FURTHER DEVELOPMENT CLINUVEL

During the 2017 Annual General Meeting<sup>2</sup>, CLINUVEL will unveil the next steps, including its plans to expand the Group and its rationale. The ultimate aim is to develop SCENESSE® ENFANCE for a paediatric population, grow its product offerings and integrate further functions within the company. For this the retention and growth of talent is the one pillar enabling the aspirations of the CLINUVEL Board.

<sup>1</sup> SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on CLINUVEL's website at [www.clinuvel.com](http://www.clinuvel.com).

<sup>2</sup> CLINUVEL's 2017 Annual General Meeting will be held at 10am on Tuesday 28 November at Arnold Bloch Liebler, 21/333 Collins St, Melbourne.

# CHAIR'S LETTER



Dear friends, shareholders,

I am looking back at a successful and eventful year whereby CLINUVEL continued its distribution in Europe and posted a maiden profit. I am particularly pleased for those investors who have supported the Company since 2005. The past twelve months captured the first four seasons where our teams distributed SCENESSE® (afamelanotide 16mg) to European porphyria patients who

desperately need treatment.

As Chairman I take great pride in having seen the metronomic performance of a management team who have fought to introduce a novel scientific concept of systemic photoprotection, guided regulatory approvals and, most recently, who have combatted European payors resisting the introduction of SCENESSE® for our patients. Despite our successes I am fully aware that global press is calling for greater scrutiny of pharmaceutical companies supplying their products to the greater benefit of healthcare. In my view CLINUVEL stands out from the pack and will strengthen its position as time goes by.

Nevertheless, CLINUVEL's case is truly unique and the lead drug SCENESSE® cannot be compared to any other pharmaceutical product. In more than one way, our Board took a different view from that usually found in our industry in setting corporate motives, funding objectives and targets for achieving success. We aimed to serve and make a difference to patient populations with no viable therapy, in our case erythropoietic protoporphyria (EPP). We calculated the risk of such a decision and focussed the entire Company on this mission (as the late Jack Wood had publicly stood for). Equally, we empowered our management to seek optimal funding solutions at minimum cost and dilution. The reason was to break away from the past and ensure our investors would incur less financial risk while retaining them long term. The funding considerations have been essential in our discussions, since we set out to prove to the industry that one can truly focus a team from lab bench to market and outperform our peers in budgeting at modest levels for global drug development. The argument of bringing down the median amount of dollars for total pharmaceutical development is a prominent theme in the ongoing discussions with insurers.

The decision to develop a program in melanocortins has always been full of unknown outcomes, however the stepwise approach and detailed analyses of options reduce the risks taken by our management team. As we progress, knowledge on the use of melanocortins is increasing on a daily basis, as real-life experiences from physicians and patients come in from Europe. Here we are walking novel paths, since no other Company, thus far, is targeting systemic photoprotection as a pharmaceutical therapy. Knowledge on receptor status, molecular mechanisms, human response and long-term use all assist us further for the development of other melanocortins in the family.

This Board sets the Company's objectives, but here we rely heavily on the vision, execution and persistence of our management. We remained flexible in the approach to reach our targets, not always as one would map out due to further regulatory demands. However, as time passes I witness how our teams are leaving the obstacles behind

them. I believe we cannot ask for more from this team, they are fully committed to taking SCENESSE® to European, US and Australian EPP patients and will not stop before the job is done. Our targets to expand the drug in vitiligo are very much alive, but we decided to focus first on obtaining a US license to distribute the drug to specialised EPP hospitals.

As we enter a new financial year the goal is to expand the CLINUVEL Group in its products and services, and to ensure the Company uses all its knowledge, and existing and newly recruited talent in more than one business domain. Our overall targets were set years ago, but the actual implementation relied heavily on the success of getting SCENESSE® to our European patients. Now that the roll out is under way, management is slowly expanding its skills and will be entering new commercial areas for which we will start our publications in due course.

In my former executive position at the largest pharmaceutical company in Australia, spanning 28 years, we never had to be concerned about complex communication issues. Blood plasma products attracted a select audience, and we did not need to be concerned too much about competitors and other parties. In 2017 however, CLINUVEL has weathered many more communication challenges. We now know how much interest there is in the innovative ways we develop the Company and products, be it from press, industry, and or other relevant stakeholders. Knowledge is key to remaining competitive in developing novel technologies and business models. Therefore, we will continue to keep a tight lid on our activities to look after our interests.

As to my immediate tasks, I coordinate the activities of the Board of Directors, and need to look after the continuity of the entire team of companies. Most of all this Board is committed to ensure continuity of the management team and staff; here we have an important task ahead. I am very excited about the prospects of the next 12 months, looking towards a wide horizon of opportunities beyond SCENESSE® whereby the Group will obtain prominence beyond our industry.

I remain indebted to our staff, management and Board for the close and harmonious collaboration the past year.

A handwritten signature in black ink, appearing to read 'Stan McLiesh'. The signature is fluid and cursive, with a large initial 'S'.

Stan McLiesh

Chairman

# MANAGING DIRECTOR'S LETTER



Dear shareholders,

The Board of Directors has reviewed the long term strategic options for CLINUVEL (CUV) as the Group has morphed from a development team to a commercial entity. Strategy is a recurring theme of our Board meetings but also part of frequent discussions offline. Although there is much flexibility required in our day to day operations, we have not altered the Company's objectives.

In our thinking it is essential to establish an environment where there is continuous learning, a CLINUVEL Institution of progressive professional advancement where operational managers remain scholars, gaining new skills, analytical techniques, and specific experience. It is commented that at CUV, managers obtain exposure to a multitude of business aspects which they would not obtain in most peer companies. We rotate professionals along our divisions and overseas offices and aim for them to have broader experience than strictly the domain for which they had been hired. I believe talent, both young and more experienced, needs to be exposed to issues which necessitates them to take responsibility. Most of all you must put leaders in a position of assuming accountability. If we want to continue progress, we will need to maintain a culture where errors are accepted and evaluated, and serve for optimising individual and collective growth. Looking back at the past decade, I believe this is a fundamental part of CUV's being.

To further this attitude towards managerial empowerment, in the next 12 months five of our managers are enrolling in bespoke programs to elevate them to the next level of their careers, benefiting the Group as a whole and ultimately our stakeholders. CLINUVEL sponsors these professionals to courses, internal programs and secondment to other companies, service providers and external professionals for them to gain the broadest possible experience. Others are purposely exposed to new areas so to introduce them to broadest fields of pharmaceutical business they usually would not be involved in. It is my conviction the investment in personnel translates significantly into the output of a company midterm, and as a by-product it is satisfying to see professionals actually enjoy coming to work in the morning. The investment in the people around us, in furthering their analytical and reflective minds, is a prerequisite to grow the Company beyond its current offerings and services. A testimony to CUV's environment is that most managers are moving through the professional ranks, and most staff have stayed with the Company for more than seven years.

Another strategic theme is whether, and how much, to expend in our annual R&D budgets. CUV aims to spend 20% to 30% of its budgets on innovation and R&D and this is comparable to mean industry numbers we have previously published. Most successful global companies continue to innovate, as anticipating competitive pressure is mandatory to come out on top in this industry. As published, we laid the foundation in 2014 with the opening of VALLAURIX PTE LTD in Singapore. The aim is to centre all R&D efforts efficiently under one roof, whereby it serves as an experimental and analytical site. The R&D work has gradually progressed for us to eventually launch a suite of novel complementary products as well as furthering the development of a paediatric dosage form. We expect VALLAURIX to

make its first topical product line public in 2018/19, whereby we now await registration of the first products.

There is widespread excitement about the next generation of melanocortins and their applications. As the scientific field evolves and the decision makers in London and Silver Spring gain confidence in the use of melanocortins, a number of indications have presented themselves to offer a meaningful and substantial difference to human lives.

However, in following the CUV mantra of "focus first" we need to concentrate on obtaining US regulatory clearance, a FDA license before the accelerated clinical program in the follow-on molecules will start. I expect that the FDA review of SCENESSE® will be completed in 2018, pending the application for Priority Review. For the Division of Dental and Dermatology Products (DDDP) our dossier is novel requiring much analyses and thinking from the officers, since no other dossier will have been comparable. It is a mammoth effort to change a traditional institution's thinking, given the internal resistance to abandon conventional approaches and patterns which are habitual in regulatory agencies. I am confident, however, that in 2018 SCENESSE® will become the first systemic photoprotective drug in the US, with that event overturning the long history of the drug.

Here SCENESSE® serves as the proof of principle justifying the use of other melanocortins as pharmaceuticals. The European market for SCENESSE® forms just half of our objectives, the US entry has been part of our long desire.

In 2018, we will have new systems to analyse the European erythropoietic protoporphyria (EPP) data more efficiently and swiftly. As is known, SCENESSE® is a "black triangle" pharmaceutical product, subject to ongoing monitoring to ensure no significant safety concerns emerge after and during its use. Although the safety profile of the drug in our hands has been known for more than a decade, we are compelled to follow up with EPP patients for the indefinite future. It goes beyond the realm of this preview to detail the pros and cons of long term pharmacovigilance, but for now we wholly embrace the obligations to do so, since we wish to minimise the 'risk of surprises' for the Company. Clinical data analyses remains one of the core activities for our UK office, and in 2018 we will continue to enhance our pharmacovigilance and distribution team. I look back on our two most recent European Medicines Agency (EMA) inspections and take away that investment in quality management systems, pharmacovigilance systems, the European Disease Registry, and the services provided by pharmacovigilance consultants in various countries has paid off. Our UK team has passed the various tests with fervour and is well equipped to distribute SCENESSE® directly to European expert centres.

Against all these activities, we have arrested our vitiligo program until SCENESSE® obtains US regulatory clearance for EPP. Both economic and regulatory considerations play a role. Given the very same reviewers of afamelanotide 16 mg in a novel indication EPP appraise the drug in vitiligo, it is prudent to gain regulatory certainty first before we start to invest substantial sums in the second indication.

The analyses of the pilot study CUV103 (Singapore) of 18 Asian patients diagnosed with vitiligo slowed down until the FDA dossier has been finalised and the new drug application (NDA) submission is complete. It

has been memorised several times that it would be nothing less than a medical revelation to be able to offer a repigmentation agent to patients of African-American and Hispanic origin, since the progressive disease continues to cause stigmatisation and great suffering in the community. As one often observes among the patient population, losing one's colour has a major impact on both the development of the young and mature patients. My personal wish is very much to see CLINUVEL be the first company in history to introduce a treatment for these patients, this particular social mandate to do something for patients of colour is one we should pursue. Following FDA review of SCENESSE® in EPP, I am confident that in 2018 we can discuss the next Phase IIb or III protocol with the Division of Dental and Dermatology Products to advance the vitiligo program in US patients.

I am often asked what the price of innovation might be for CLINUVEL and whether it is worth it. However, we do not stand alone in leading an effort to introduce novel and complex technology; this phenomenon is seen in utilities, information technology and most recently the automotive industry. I see it as our societal responsibility and moral obligation to provide added economical value and progress our knowledge, this ultimately needs to result in new offerings in medicine. I hear so often from our staff, consultants and physicians that it is a privilege to be part of this innovation journey. It motivates employees and challenges them to solve problems seldom encountered. The enterprise value of CLINUVEL has proven stable the past year, and following the expanding access may well continue to increase.

In terms of finance, we carefully balance the further funding requirements to advance SCENESSE®, the novel melanocortins, and our complementary topical products against the revenues we will likely be able to generate. The same financial metrics as in the past will apply for 2018: cautious budgeting and review of the long-term gains from our investments.

In spite of the resistance received from European insurances, payors and advisory bodies in 2016 and 2017, a number of outcomes resulted in SCENESSE® becoming available for EPP patients in various countries. Pivotal to our success has been to introduce a uniform price across all centres in Europe and Switzerland. This approach of market access to trained and accredited hospitals supplying the treatment on an equitable basis will also apply when we start our foray into the US. In our analyses it was apparent that in a single market and regulated economic zone differential pricing is perhaps something of the past in orphan drugs. Our novel policies are published, well-read and warmly received from industry, however critique has still been received since most pharmaceuticals seek to maximise their profitability by charging various countries different prices for one treatment. I see it only as

reasonable to offer all hospitals the same conditions of supply and similar pricing while the cost of international distribution under cold-transport and currency risk is born by CLINUVEL. It has taken much energy and manpower to break the glass ceiling of insurers, but our teams were never going to rest before we would obtain one outcome based on reason and value to patients.

In EPP the dilemma has always been that one cannot truly quantify the benefit patients receive from SCENESSE®, despite the consistently positive testimonies of hundreds of patients and numerous expert physicians. In innovation, one needs to accept that some phenomenon are not measurable with the limited tools we have. However, the information from clinical practice, statistics and patients' declarations indicate the 'clinical usefulness' of a therapy. These arguments eventually won over the decision makers of national healthcare systems in 2017. In 2018, our teams will continue to make the case for reimbursement of SCENESSE® in a further six European countries where procedures seem protracted and following unnecessary bureaucratic procedures, while stalling and slowing the market access of novel drugs by some countries is clearly a scalable factor for governments and those who have to pay for state funded healthcare.

I conclude by congratulating our long-term investors and staff for having contributed to making SCENESSE® available to EPP patients. As one Italian patient recently explained in front of all Italian expert physicians during a presentation "the drug has not only had dramatic effect for me, but it has impacted my entire family since they now see my real self, freed from all handicaps able to participate in life. I am eternally grateful to the team to have given me a life".

I wish all staff, Board and stakeholders of CLINUVEL a successful and healthy year ahead.



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 2017, 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 2017 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

Member of the Nomination Committee

Qualifications: BEd

Shares in CLINUVEL: 162,774

Conditional Performance Rights over shares in CLINUVEL: 65,000

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 has previously served non-executive roles in the medical device field. The Chair of CLINUVEL since 2010, 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

Non-voting member of the Remuneration Committee

Qualifications: MBA, MD

Shares in CLINUVEL: 2,579,722

Conditional Performance Rights over shares in CLINUVEL: 924,974

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 assisted CLINUVEL attract more than AUD95 million in direct funding to develop and launch SCENESSE® and succeeded in guiding the Company through a complex pharmaceutical development program. Dr Wolgen is now leading the Group's expansion, with an immediate focus on the US and the further development of the Company's product pipeline in various market segments. His focus has been to establish a professional management team to focus on the corporate objectives set and to prepare the next generation of managers.

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)

Member of the Nomination Committee

Qualifications: BComm, FAICD, ASIA

Shares in CLINUVEL: 153,969

Conditional Performance Rights over shares in CLINUVEL: 50,000

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

Member of the Nomination Committee

Shares in CLINUVEL: 162,195

Conditional Performance Rights over shares in CLINUVEL: 42,500

Mr Ishag is a London based entrepreneur with 50 years of commercial experience. With a background in pharmaceutical chemistry, Mr Ishag



is active in European asset management, real estate development and IT. Mr Ishag is currently the Chairman of European Investments & Developments Ltd, a privately held company with an investment mandate in defined asset classes, property development and cross-border commercial real estate. Mr Ishag has been extensively involved in the commercial evolution and backing of various successful ventures. He is an Honorary Life Fellow of the UK Institute of Directors (Hon FIOD) and has been a member of the IoD since 1964.

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

#### Non-Executive Director

Chair of the Nomination Committee (since November 27, 2016)

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. 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 mergers and acquisitions and leadership as the Ernst & Young Entrepreneur of the Year in the Netherlands.

Since joining CLINUVEL in 2015, 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 Keady, 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. Mr Keady is currently completing a Graduate Diploma in Applied Corporate Governance with the Governance Institute of Australia.

## 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 COMMITTEE		NOMINATION COMMITTEE	
	A	B	A	B	A	B	A	B
Mrs. B.M. Shanahan	6	6	2	2	-	-	1	1
Mr. S.R. McLiesh	6	6	2	2	2	2	1	1
Dr. P.J. Wolgen	6	6	2	1	2	1	-	-
Mr. E. Ishag	6	6	-	-	2	2	1	1
Mr. W. Blijddorp	6	6	-	-	-	-	1	1

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 and commercialise 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 Group's main strategic focus throughout the year, consequent to the European Medicine Agency's (EMA's) granting of marketing authorisation for SCENESSE® (afamelanotide 16mg) for the prevention of phototoxicity in adult patients diagnosed with erythropoietic protoporphyria (EPP), was to establish a final, uniform reimbursement structure in key European countries, enter into pricing agreements with European payors and to further progress the commercial rollout of SCENESSE® in Europe. New European EPP expert centres were trained and accredited in the collection of data and use of SCENESSE®, which included participation in the post-authorisation safety study (PASS) as part of the Group's post-authorisation program to monitor ongoing patient safety and effectiveness. Furthermore, the Group focussed on preparing a New Drug Application submission under a rolling review basis as part of the US regulatory pathway for SCENESSE®. The R&D program in vitiligo continued throughout the year. Further melanocortin development, including a product for

paediatric EPP patients and other follow-on product development, continued throughout the year.

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

CONSOLIDATED ENTITY	2017	2016	CHANGE
	\$	\$	%
Revenues	16,984,536	6,419,707	165%
Net Profit/(Loss) before income tax expense	7,114,286	(3,153,718)	326%
Profit/(Loss) after income tax expense	7,114,286	(3,153,718)	326%
Basic earnings per share - cents per share	14.9	(7.0)	314%
Net tangible assets backing per ordinary share	\$0.533	\$0.38	40%
Dividends	Nil	Nil	Nil

Note: CLINUVEL does not operate individual segments.

Monthly operating average cash spend was 5% less than the previous year, being \$0.736 million for 2016/17 compared to \$0.773 million for the 2015/16 year. The slight decrease in average monthly spend is primarily due to a reduction in product manufacturing expenditures

in the 2016/17 year when compared to the 2015/16 year, as a result of the Group preparing implant supply for the commercial rollout of SCENESSE® in Europe. The Group's balance sheet has \$25.444 million in net assets at 30 June 2017 compared to \$17.835 million at 30 June 2016. Current liabilities increased 37.5% to \$3.148 million. The Group result for the year ending 30 June 2017 was a \$7.114 million profit, compared to a \$3.154 million loss for the prior financial year, a significant improvement of 326%. Commercial revenues from the sale of SCENESSE® were the key driver for the improved results.

Commercial sales of SCENESSE® in Europe totalled \$11.886 million for 2016/17, compared to \$2.598 million for 2015/16. The 2016/17 year represented the first full 12 months of sales. Commercial sales in 2015/16 did not commence until product launch in June 2016, with first deliveries to the Netherlands. In 2016/17, a uniform price was set and implemented in the Netherlands along with Italy, Austria and Germany, with first commercial sales commencing in these three countries later in 2016, resulting in a 437% increase in unit sales numbers year-on-year.

The distribution of SCENESSE® continued in Switzerland (ongoing) and Italy (to 31 August 2016) with the ongoing supply of the drug to provide a preventative treatment for adult EPP patients under full-cost compensation Special Access Schemes. These reimbursement revenues increased 34% to \$4.834 million for the 2016/17 year compared to \$3.614 million for the 2015/16 year. The increase occurred despite distribution in Italy under the Law 648/96 scheme ending 31 August 2016, with subsequent orders to Italian customers recorded as commercial sales. As a result, the number of implants ordered under the two full-cost compensation Special Access Schemes decreased 13% in 2016/17 compared to 2015/16. However, 100% of the implants ordered under these schemes in 2016/17 were linked to the commercial sales price of SCENESSE® sold in Europe under the marketing authorisation, compared to only 38% of implants ordered in the 2015/16 year, with the remaining 62% supplied by the Group at the lower subsidised reimbursement price.

Included in revenues from ordinary activities is interest received from surplus funds held in bank accounts and term deposits, increasing 27% year-on-year, from \$0.208 million to \$0.264 million. In 2016/17 there was further downward pressure on average interest rate yields on funds held primarily due to government monetary policy, however the Group held on average 44% more cash in higher-yielding Australian dollar fixed rate term deposits compared to the prior year.

R&D and commercialisation expenditures accounted for 40% of the Group's total expense result for 2016/17, compared to 37% for the 2015/16 year. R&D and commercialisation costs, comprising clinical study costs, drug formulation research, manufacture and distribution, regulatory fees and research, development and commercialisation-specific overheads such as personnel, were \$3.735 million in 2015/16 compared to \$4.053 million in 2016/17.

The Australian government refundable tax incentive of \$0.045 million is a 93% decrease to the refundable tax incentive recorded for the 2015/16 year. The decrease reflects the Group's current strategic focus on its commercialisation activities in Europe and its regulatory activities in the USA which do not permit qualifying expenditures on local or overseas expenditures to be captured under the Australian R&D Tax incentive regime. The 2015/16 year comprised qualifying expenditures from local activities in connection to the pre-clinical model demonstrating safety of SCENESSE® in combination with narrowband ultraviolet light therapy, which completed at the end of 2015/16.

Clinical study costs remained relatively consistent to the prior year, decreasing only 3% from \$0.133 million in 2015/16 to \$0.130 million in 2016/17. Throughout the year the Group has remained focussed on its commercialisation activities in Europe and its regulatory activities in the USA, concentrating its clinical study efforts on the data management and analysis of the Singaporean Phase II clinical study in vitiligo evaluating the use of SCENESSE® in diverse patient groups of various skin complexions.

Expenses toward the drug formulation R&D, manufacture and distribution program decreased 16%, from \$1.022 million in 2015/16 to

\$0.857 million in 2016/17. The prior year included implant production costs in preparation of the commercial launch of SCENESSE® in Europe, to meet Special Access Scheme requirements and future clinical needs, along with one-off distribution set-up costs to facilitate implant release within the European Union. These expenses outweighed the manufacturing costs in 2016/17 which included a provision for raw material obsolescence of \$0.182 million.

Further increases to average head count of Research, Development & Commercial personnel employed to oversee and monitor the clinical, regulatory, manufacturing programs and post-marketing programs in 2016/17 when compared to average head count for the previous year was a key driver behind the 28% increase in Research, Development & Commercial overhead costs (from \$1.606 million in 2015/16 to \$2.061 million in 2016/17). First time royalty expenses paid to the implant contract manufacturer also contributed to the 28% increase year-on-year.

Regulatory affairs related fees for both pre- and post-marketing activities along with non-clinical development costs increased 3%, from \$0.973 million in 2015/16 to \$1.005 million in 2016/17. The absence of expenditures associated with the pre-clinical chronic toxicology study incurred in 2015/16 was offset by costs attached to establishing and building on the regulatory infrastructure to support the market access of SCENESSE® into Europe and to meet its post-authorisation commitments with the EMA. The key drivers to these expenses include pharmacovigilance oversight and safety reporting systems, costs to facilitate post-authorisation safety study participation and regulatory agency fees attached to compliance, audit inspections and dossier maintenance.

Marketing expenditures in the Group increased marginally by 4% to \$0.811 million in 2016/17 from \$0.778 million in 2015/16. Reductions in expenditures on public relation consultants and online marketing was balanced out by marketing design costs within the VALLAURIX PTE LTD joint venture, along with minor increases in marketing staffing costs and conference sponsorships.

Patent fees decreased 17%, from \$0.266 million in 2015/16 to \$0.220 million in 2016/17. The decrease was related to the need for the Group in 2015/16 to validate the European EPP patents after marketing authorisation was obtained, including the need to translate patents to local languages.

The result from general operations was \$4.882 million in 2016/17 compared to \$5.591 million in 2015/16, a 13% improvement. General operations comprised 49% of the Group's total expense result for 2016/17 compared to 54% in 2015/16. Similar to the prior year, the major contributor to the decrease in general operations was the expensing of the accounting valuation of share-based payments (performance rights) of \$0.395 million in 2016/17, compared to \$1.670 million in 2015/16. Fewer performance rights are held in the current period compared to the prior period. Furthermore, 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. Management has assessed the expected life of the unvested performance rights and has determined the expensing of the remaining portion of the value of unvested performance rights not previously expensed should occur in the current and future reporting periods.

Excluding the accounting valuation of performance rights, general operations increased 14% year-on-year. The primary reason for the increase is the expanding activities in (a) Europe to support the commercial rollout of SCENESSE®, and (b) Singapore to support the development programs undertaken by the VALLAURIX PTE LTD joint venture, being staffing costs (including recruitment), travel, and office facilities.

The activities of the VALLAURIX PTE LTD joint venture increased during the year, recording a \$0.370 million loss (2015/16: \$0.181 million) whereby the non-controlling interest has a \$0.067 million share of the loss. An increase in staffing, further non-clinical development work, travel, marketing design and depreciation from equipment purchases were key items affecting the result of the joint venture for 2016/17.

For the 2016/17 year the Group started with \$13.845 million in cash and financial assets and finished with \$23.752 million. There was no capital raised in 2016/17, compared to the 2015/16 year where the Group raised \$8.335 million additional capital. For the reporting date of 30 June 2017, due to movements in the Australian dollar compared to other currencies used to meet working capital requirements, the Group reported a loss of \$0.089 million from holding foreign currencies and in holding trade creditors in non-Australian currencies (a \$0.187 million gain for the same period last year).

At 30 June 2017 basic earnings per share were \$0.149 on 47,735,227 issued ordinary shares. This is compared to basic earnings per share of -\$0.07 as at 30 June 2016 on 47,080,637 issued ordinary shares.

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. Based in Melbourne, Australia, CLINUVEL has operations in Europe, the USA and Singapore, with the UK acting as the EU distribution centre.

There were a number of significant events in 2016/17. These events included:

- a) On 6 July 2016, the Company announced the US Food and Drug Administration (FDA) had granted SCENESSE® a Fast Track designation for the treatment of EPP. The designation recognises the severity and the unmet medical need of the disorder in the USA. The Fast Track designation enables CLINUVEL to file a New Drug Application (NDA) on a rolling basis for US regulatory assessment.
- b) It was announced on 18 July 2016 that the FDA had concluded an initial review of CLINUVEL's clinical data package for its drug SCENESSE® in patients with EPP and deemed CLINUVEL's clinical data package satisfactory for submitting a NDA application. The FDA had requested CLINUVEL submit to them clinical datasets generated from trials of SCENESSE® in EPP conducted over 2006 and 2013. The need to understand the severity of EPP symptoms and clinical effectiveness of SCENESSE® were the basis of the FDA's request.
- c) On 3 August 2016, the Company announced that it has fulfilled the FDA requirement to demonstrate safety in a pre-clinical model prior to progressing further with the clinical development of the combination therapy of its drug SCENESSE® and narrowband UVB (NB-UVB) light in the pigmentation disorder vitiligo. Results of studies to date in vitiligo showed SCENESSE®, in combination with NB-UVB light administered twice or thrice weekly, had a good safety profile and the optimal effectiveness of the combination was identified in patients of darker skin complexion (Fitzpatrick skin types IV, V and VI). Prior to pursuing later stage clinical trials in vitiligo in the USA, the FDA had requested CLINUVEL demonstrate the safety of the drug in combination with NB-UVB light in a pre-clinical model, simulating the proposed human dose regimen. Safety of the combination therapy was confirmed, whereby the No Observed Adverse Effect Level of SCENESSE® was found to be higher than the current clinical dose level of 16mg monthly.
- d) On 9 November 2016, the Company announced it had met with the FDA's Division of Dermatology and Dental Products (DDDP) to discuss the content and format of a NDA submission as part of the US regulatory pathway for SCENESSE®. This meeting, referred to as a pre-NDA meeting, allowed both parties to discuss expectations on timelines and the sequence of submissions of the NDA modules. The Company confirmed the modular dossier on SCENESSE® will be submitted on a rolling basis and after the completion of the submission of the dossier the FDA will observe a validation period of two months. Further confidential

interactions between the DDDP and CLINUVEL will take place as the submission progresses.

- e) An announcement on 18 October 2016 that England's National Institute for Health and Care Excellence (NICE) had made a recommendation to the UK Department of Health for SCENESSE® to be evaluated under the mainstream Single Technology Appraisal (STA) procedure. A further announcement was made on 02 May 2017 whereby NICE had re-evaluated its recommendation to the UK Department of Health to classify SCENESSE® for appraisal under the STA procedure. NICE recommended to the UK Department of Health, who accepted the recommendation, that SCENESSE® be evaluated as a Highly Specialised Technology, which provides a different formal evaluation of the cost-benefit of a proposed therapy to the STA appraisal procedure.
- f) An announcement on 12 April 2017 that the Company had reached agreement with the German National Association of Statutory Health Insurance Funds (GKV-SV) for the treatment of EPP patients with SCENESSE®. The Company had been in mandatory negotiation with GKV-SV regarding the reimbursement price of SCENESSE®. A pricing agreement was reached after the two parties met in arbitration and the outcome was legally binding. The pricing agreement was aligned to the Company's uniform global pricing policy, acknowledging patients are migrating across borders to seek treatment, expert physicians are associated through porphyria networks that transcend borders, and hospitals may seek to collaborate internationally to purchase pharmaceutical products for orphan diseases.

## 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, and to pursue innovation in developing new and follow-on products by leveraging the consolidated entity's knowledge in photoprotection and repigmentation.

At the end of the prior financial year the consolidated entity launched SCENESSE® in Europe. As part of the conditions attached to the granting of marketing authorisation, the consolidated entity has been committed to establishing and maintaining 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 has been using a number of 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 has established a reference price for SCENESSE®, as part of its uniform pricing strategy and has entered into pricing agreements with several European countries. The consolidated entity has increased its sales-focused workforce in Europe to secure initial revenues and will continue to increase staff numbers as more pricing agreements per country are established with payors and as the required pharmacovigilance activities continue to expand.

Underpinned by the regulatory approval in Europe, along with the information generated from its post-marketing commitments in Europe, the consolidated entity continues to work 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 pursue a clinical program to evaluate the ability of SCENESSE® to activate and repopulate melanocytes within vitiliginous lesions and achieve repigmentation in combination with NB-UVB in patients with vitiligo. Data from the clinical and pre-clinical clinical studies evaluating efficacy and/or 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 commercial product supply in line with its timing expectations and to pursue ongoing process improvement initiatives to support future increases in supply. The contract manufacturer bears the responsibility of manufacturing the commercial drug product.

The consolidated entity, through its 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 these analogues along with other technologies for both medicinal and non-prescriptive formulations to be administered topically.

Until this year, the consolidated entity has been a loss-making enterprise dependent on equity funding after only recently reaching the commercialisation phase of drug development, 11 years since the start of its EPP program and 17 years since it joined the ASX. The long-term financial success of the consolidated entity will be ultimately measured on the basis of achieving and maintaining a sustainable profit. Key to maintaining profitability is not only continuing 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 business 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.
- Drug pricing – there is a risk that third party payors will not provide coverage or will not be willing to accept the prices agreed with other third party payors, adversely affecting revenues and profitability. Furthermore, reductions in government insurance programs may result in lower prices for our products and could materially adversely affect our ability to operate profitably.
- 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 over the long term. Therefore the ability of the consolidated entity to successfully bring its products to market and achieve a state of consistent positive cash flow is dependent on its ability to maintain a revenue stream and 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.

## 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.

## 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 may have been rounded to the nearest \$1,000, or in most other cases, to the nearest dollar.

## INDEMNIFICATION AND INSURANCE OF DIRECTORS AND OFFICERS

During or since the end of the financial year the Company has given or agreed to indemnify, or paid or agreed to pay insurance premiums to insure each of the Directors against liabilities for costs and expenses incurred by them in defending any legal proceedings arising from 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. Details of the amount of the premium paid in respect of insurance policies are not disclosed as such disclosure is prohibited under the terms of the contract.

## 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

The Remuneration Report, which forms part of the Directors' Report, provides information about the remuneration of the Directors of CLINUVEL PHARMACEUTICALS LTD and other Key Management Personnel for the year ended 30 June 2017.

Key Management Personnel has the meaning given in the Australian Corporations Act and includes 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)

Unless otherwise stated, Key Management Personnel held their positions throughout the past two financial years. Dr Wright and Mr Keamy are considered Other Executive Key Management Personnel.

## PRINCIPLES USED TO DETERMINE THE NATURE AND AMOUNT OF REMUNERATION

The principles and objectives underlying the Board's remuneration policy in relation to its key management personnel are to ensure that:

- a) Remuneration of the Company's key management personnel is aligned with the interests of the Company and its shareholders within an appropriate control framework, taking into account 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 with unique industry knowledge in photoprotection, repigmentation and melanocortins 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 the Company and individual performance and remuneration of key management personnel.
- f) The Company complies with applicable legal requirements and appropriate standards of governance.

The Company's reward framework provides a mix of fixed and variable pay, the 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, and in relation to the Managing Director, other fixed amount cash incentives).

## REMUNERATION COMMITTEE

The Board has provided a mandate to the Remuneration Committee to evaluate its remuneration policies and practices over time, taking account of pay outcomes and the relationship between pay and performance, and the results of any evaluations or review processes. The Board has also 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, key management personnel and Executives.

The Remuneration Committee specifically reviews and makes recommendations to the Board on the total remuneration package for the Managing Director, including short term and long term incentives for the Managing Director. It also reviews and makes recommendations to the Board on the total level of remuneration of Non-Executive Directors and for individual fees for Non-Executive Directors and the Chair, including any additional fees payable for membership of Board committees. The Remuneration Committee also reviews and approves recommendations from the Managing Director on total levels of remuneration for senior executives reporting to the Managing Director, including their participation in short and long term incentive schemes.

The Remuneration Committee takes regard to industry benchmarks, global employment market conditions and the requirements of corporate governance best practice in Australia. It may commission independent research and obtain 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 specific experience in the healthcare industry as part of making and reviewing remuneration recommendations.

The methods used by the Remuneration Committee to assess Board performance is disclosed in the Corporate Governance Protocol.

## REMUNERATION RECOMMENDATIONS

For the year ended 30 June 2017, no remuneration recommendations were received from specialist remuneration consultants for the purpose of section 9B to the Corporations Act 2001.

## VOTING AND FEEDBACK AT THE COMPANY'S LAST ANNUAL GENERAL MEETING

In the 2016 Annual General Meeting (AGM), the Company obtained 97.66% of the proxy votes (including votes at the Board's discretion) in favour of adopting the 2015/16 remuneration report, and this resolution was passed by poll. The Company did not receive any further specific feedback at the AGM on its remuneration practices.

## NON-EXECUTIVE REMUNERATION

The Board seeks an appropriate mix of skill, diversity, experience and expertise and the Remuneration Committee recommends to the Board individual Non-Executive Director fee levels, having regard to global employment market conditions and consultation with specialist remuneration consultants with experience in the healthcare and biotechnology industries.

### DIRECTOR FEES

Under the Company's Constitution, the maximum aggregate remuneration available for division among the Non-Executive Directors is to be determined by the shareholders in a General Meeting. The most recent determination was at the 2015 Annual General Meeting, shareholders approved an aggregate remuneration payable of \$550,000. This amount (or some part of it) is to be divided among the Non-Executive Directors as determined by the Board. The aggregate amount paid to Non-Executive Directors for the year ended 30 June 2017 was \$325,000.

Non-Executive Director fees consist of base fees and committee fees. The fees are outlined in the table below:

ANNUAL NON-EXECUTIVE DIRECTOR FEES (INCLUSIVE OF SUPERANNUATION)		
BOARD FEES		\$
Base – Chair *		110,000
Base – Non-chair		65,000
Committee Fees		
Audit & Risk	Chair	15,000
	Member	5,000 *
Remuneration	Chair	15,000 *
	Member	5,000
Nomination	Chair	-
	Member	-

\* The Chair of the Board is a member of all Committees but does not receive any additional committee fees in addition to his base fee.

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

### LONG TERM INCENTIVE

The long-term equity remuneration is provided to Directors and certain employees via the CLINUVEL Conditional Rights Plan. See section "SHARE-BASED REMUNERATION" in this Remuneration Report for further information.

### EXECUTIVE REMUNERATION MANAGING DIRECTOR

The Managing Director's remuneration structure is reviewed every three years to ensure:

- A maximum level of motivation and incentivisation to lead and advance the Company's program from its current stages of development and commercial growth, taking into account the risk and complexity within this particular business model;
- It is competitive in international markets, industry and related fields of expertise;
- Leadership and operational management is incentivised to serve the long term interests of the Company

It includes:

- Base pay and health insurance, accommodation, relocation, travel and superannuation 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 (are only in the event of exceptional performance, innovation and/or expansion and which do not form part of short term incentives or longer term business generation incentives); and
- Long-term equity participation in CLINUVEL'S Performance Rights Plan.

The inherent risk of failure within pharmaceutical development is high and this risk is magnified for the Company due to its focus on developing and commercialising a novel, first-in-class drug in diseases where there is an unmet clinical need. To mitigate the risk and to provide a strong platform to achieve success, the Board has adopted a business model where most operational tasks are being retained in-house, where possible, and most management responsibilities are 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 overall corporate strategy, has global responsibility for the safety aspects of the drug (including pharmacovigilance) and is responsible for commercial drug pricing and reimbursement negotiations. The Acting Chief Scientific Officer is responsible for pre-clinical programs, 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 internal Commercial Management Committee, set up to oversee the best commercial options for the Company. As the business evolves and progresses through its development path, it is expected that this centralised management model will also evolve and key management responsibilities will be shared across new and existing senior management throughout the consolidated entity.

The current Remuneration structure is designed to maximise the motivation, retention and incentivisation of the Managing Director to lead and advance the Company's program from its current stage of development, to navigate the Company through the early stages of commercial distribution and to establish a Company which develops new products and markets, taking into account the risk and complexity of the current 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.

For the 2016/17 year, the Managing Director's base salary was \$786,717, a reduction of 2.6% to the 2015/16 year (\$807,109).

Base pay is reviewed annually and generally adjusted to consider changes in CPI. Base salary for the Managing Director was adjusted 1.3% on July 1 2016. Due to domicile, the Managing Director's salary is paid in Singapore dollars by the consolidated group's Singapore subsidiary company and is subject to exchange rate movements when reported in Australian dollars.

### SHORT TERM INCENTIVE

The Managing Director has individual short-term incentives which are evaluated over the 2016/17 base salary amount.

Individual and overall corporate performance targets are set at the start of each financial year by the Remuneration Committee. The performance-based targets are typical of a global life sciences company at its stage of development and early commercial product distribution. The focus on growth in corporate value has been centred on achievement of regulatory, development, commercial and operational outcomes, where financial metrics are not necessarily an appropriate measure of executive performance as may be commonly expected in other market segments and industries.

The Board considers specific 2016/17 performance-based targets to be commercially sensitive, therefore specific targets are not disclosed. The targets are centred on:

- Commercial distribution rollout of SCENESSE® in Europe
- Progress in regulatory filings
- Financial management and corporate affairs
- Research & development of follow-on products

Generally, quantifying the 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 2016/17 financial year the Remuneration Committee evaluated the performance of the Managing Director and the Board approved a short-term incentive of 64.5% to base salary. This compares to a short-term incentive of 50% to base salary in the preceding year.

In arriving at this assessment, the Remuneration Committee considered the following links to an increase in corporate value:

- the achievement of a uniform distribution structure for SCENESSE® across key European reference countries at reasonable and satisfactory terms,
- first-time positive 12 month cash flow result for the consolidated entity.

### LONG-TERM INCENTIVE

The Managing Director has individual longer-term cash incentive components, referred to as business generation incentives, to his Executive remuneration, along with equity participation through CLINUVEL's Performance Rights Plan.

The business generation incentives have been aimed to reward the Managing Director for achieving exceptional business outcomes that contribute to creating corporate value and to act as a key retention tool. The business generation incentives comprise of key performance milestones and remain for the duration of the Managing Director's service agreement.

The business generation incentives have formed part of the Managing Director's service agreements since 2010. The current business generation incentives are triggered either upon the Company signing license agreements in key geographical areas or if an accumulated financial benefit in excess of €10,000,000 has been received by the Company if the Company has elected to self-distribute SCENESSE® upon commercialisation. The largest of the business generation incentives that is tied to license agreements or financial benefits from self-distribution is €500,000.

The Board reviews the business generation incentives each time the Company and the Managing Director enters into a new service agreement to ensure these incentives are linked to the Company's longer-term strategies it considers most likely to achieve the best possible outcomes for the Company and its shareholders.

No business generation incentives were achieved during 2016/17.

The Managing Director is provided with long-term equity remuneration via the CLINUVEL Conditional Rights Plan. See section "SHARE-BASED REMUNERATION" in this Remuneration Report for further information.

### OTHER EXECUTIVE KEY MANAGEMENT PERSONNEL

Remuneration packages for Other Executive Key Management Personnel may include:

- Base pay (including statutory benefits);
- Short-term incentive payments that can be awarded through the achievement of pre-specified performance-based and time-based targets; and
- Long-term equity participation in CLINUVEL'S Performance Rights Plan.

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.

Base pay is reviewed annually by the Managing Director who makes recommendations to the Remuneration Committee and who subsequently reviews these recommendations, Base pay is generally adjusted annually to consider changes in CPI and to ensure the Executive's pay is commensurate with the responsibilities and contribution of the Executive. The Other Executive Key Management Personnel all received increases to base salary from 1 July 2016.

### SHORT-TERM INCENTIVE

Short-term incentives are individually set by the Managing Director at the start of each financial year and these incentives are recommended to the Remuneration Committee for their review and approval.

For 2016/17, it was determined the following percentage of base salary as the appropriate quantum for the short-term incentives for each Other Executive Key Management Personnel to be evaluated against:

- Acting Chief Scientific Officer: 5%
- Chief Financial Officer: 12%

The short-term incentives are a blend of individual performance based incentives and can have a component for time served to encourage staff retention. Each performance-based target is based on specific individual responsibilities and objectives typical for these roles in a global life sciences company at its stage of development and early commercial product launch. The performance-based incentives covered revenue generation, regulatory progress, manufacturing, research and development and corporate affairs.

For 2016/17, the Managing Director assessed overall performance against the short term incentives and recommended to the Remuneration Committee and who approved the following assessments against the maximum short term incentives:

- Acting Chief Scientific Officer: 50%
- Chief Financial Officer: 83.3%

### LONG-TERM INCENTIVE

The other Executive Key Management Personnel are provided with long-term equity remuneration via the CLINUVEL Conditional Rights Plan. See section "SHARE-BASED REMUNERATION" in this Remuneration Report for further information.

### 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 CLINUVEL Performance Rights Plan.

The Managing Director, in consultation with the Remuneration Committee, oversees the service agreements entered into with other Executive Key Management Personnel, providing for base salary, incentives, other benefits and participation, when eligible, in the CLINUVEL Performance Rights Plan.

The details of the service agreements to the Managing Director and Executive Key Management Personnel are:

NAME	Dr Philippe Wolgen	Dr Dennis Wright	Mr Darren Keamy
DURATION OF CONTRACT	3 years	No fixed term	No fixed term
NOTICE PERIOD (FROM COMPANY)	12 months	3 months	3 months
NOTICE PERIOD (FROM EXECUTIVE KEY MANAGEMENT PERSONNEL)	12 months	3 months	3 months
TERMINATION PAYMENT WITHOUT CAUSE	12 months	3 months	3 months
TERMINATION PAYMENT WITH CAUSE	None	None	None

### SHARE-BASED REMUNERATION

The consolidated entity has an ownership based scheme for Directors, Other Executive Key Management Personnel, employees and select consultants of the Company and is designed to provide long-term incentives to deliver long-term value.

#### LONG-TERM INCENTIVE – MANAGING DIRECTOR & OTHER EXECUTIVE KEY MANAGEMENT PERSONNEL

The consolidated entity's remuneration strategy for the Managing Director and Other Executive Key Management Personnel is to attract, retain and motivate people of high calibre with unique industry knowledge in photoprotection, repigmentation, melanocortins and diseases of unmet medical need to work towards the long-term growth and success of the Company.

The mix of longer-term incentive remuneration with short-term (12 months or less) remuneration is aimed to encourage retention and to maintain performance over multiple years as appropriate for the Company's lifecycle.

Performance rights are not granted to the Managing Director and Other Executive Key Management Personnel annually. To date, by virtue of the nature of the Company primarily focussed on research and development, the performance conditions have been based on non-financial strategic goals linked to shareholder value which has uncertain, longer-term anticipated milestone dates.

#### LONG-TERM INCENTIVE – NON-EXECUTIVE DIRECTORS

In structuring its Non-Executive Director Remuneration policy, the Board considers the number of employees across the consolidated entity, which averaged less than 25 in total during the course of 2016/17, and the small management team comparative to peer companies, to oversee the Company's initiatives. The Board considers that from time to time its Non-Executive Directors must become involved in steering management and engage in certain operational matters that would not commonly be expected of those in a non-executive capacity. Furthermore, the Company endeavours to ensure the interests of its Key Management Personnel are aligned with the interests of the Company and its shareholders within an appropriate control framework and addressing the preference of some shareholders to see Non-Executive Directors have relatively significant shareholdings in the consolidated entity.

Subject to shareholder approval, and at the discretion of the Board, Non-Executive Directors can be issued performance rights under the Company's Performance Rights Plan (2014), which has replaced the Company's Conditional Performance Rights Plan (2009).

### PERFORMANCE RIGHTS

All performance rights that have been 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)

840,985 performance rights issued under the 2009 Plan remain unvested as at 30 June 2017 and 1,031,272 performance rights issued under the 2014 Plan remain unvested at 30 June 2017.

#### 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 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.

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

The Performance Rights Plan (2014) is available to eligible persons of the Company. Any issue of rights to 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 lapses 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.



Further details of the company's share-based remuneration are tabled below:

<p><b>NUMBER OF PERFORMANCE RIGHTS THAT ARE DETERMINED</b></p>	<p><b><u>EXECUTIVE KEY MANAGEMENT PERSONNEL</u></b></p> <p>The Remuneration Committee assesses and recommends to the Board the quantum of performance rights amounts based on:</p> <ul style="list-style-type: none"> <li>• length of time served prior to issue of performance rights</li> <li>• weighted average share price levels at time of issue</li> <li>• responsibility levels within the consolidated entity</li> <li>• current base pay including variable short term incentive levels</li> <li>• industry trends</li> <li>• impact on share dilution</li> <li>• nature of vesting (performance) conditions attached to the issue of performance rights</li> </ul> <p><b><u>DIRECTORS</u></b></p> <p>The Remuneration Committee assesses and recommends to the Board for shareholders to approve the quantum of performance rights amounts based on:</p> <ul style="list-style-type: none"> <li>• tenure of the Director at time of issue of performance rights</li> <li>• weighted average share price levels at time of issue</li> <li>• Chair and Committee representation</li> <li>• involvement in steering management</li> <li>• industry trends</li> <li>• impact on share dilution</li> <li>• nature of vesting (performance) conditions attached to the issue of performance rights</li> </ul>
<p><b>SELECTION OF PERFORMANCE CONDITIONS AFFECTING UNVESTED PERFORMANCE RIGHTS IN THE CURRENT AND FUTURE REPORTING PERIOD</b></p>	<p>The performance conditions attached to those performance rights issued to Non-executive Directors in 2014 and unvested at any time during 2016/17 relate to long-term (multi year) strategic, non-financial objectives and they were chosen because they are considered to be significant for long-term sustainability of the consolidated entity and longer-term value creating in nature.</p>
<p><b>NATURE OF PERFORMANCE CONDITIONS AFFECTING UNVESTED PERFORMANCE RIGHTS IN THE CURRENT AND FUTURE REPORTING PERIOD</b></p>	<p>A. Upon submission of a dossier to the US FDA applying for market approval of SCENESSE®</p> <p>B. Granting market approval for SCENESSE® by the US FDA (not attached to Non- Executive Directors)</p> <p>C. Securing sufficient funding to secure 5 performance conditions (including the performance condition 'Granting market approval for SCENESSE® by the US FDA') (not attached to Non- Executive Directors)</p> <p>D. Announcement of commercial partnership to distribute SCENESSE® (or derivative of) (not attached to Managing Director)</p> <p>E. The earlier of: (a) second molecule in new formulation, or (b) paediatric formulation for afamelanotide (Other Executive Key Management Personnel and staff only)</p> <p>F. Upon European revenues under the EMA market authorisation achieving €10,000,000 in a 12 month period (Other Executive Key Management Personnel and staff only)</p>
<p><b>ASSESSING PERFORMANCE CONDITIONS</b></p>	<p>The achievement of the performance condition is assessed and approved by the Board when it is considered satisfied or the condition has otherwise been waived by the Board.</p>
<p><b>UPON VESTING OF PERFORMANCE RIGHTS</b></p>	<p>The performance rights are exercised into new Shares and are acquired by a Plan Trustee and then, from time to time, transferred to the Non-Executive Director, but generally only when the non-executive ceases their Directorship. The Company may determine and conclude agreements with the Plan Trustee, and enforce or prosecute any rights and obligations under such agreements, without reference or recourse to a participant under the Plan.</p>

No new performance rights were granted to Non-Executive Directors for the year's ended 30 June 2017 and 30 June 2016.

No new performance rights were granted to Executive Directors or Other Executive Key Management Personnel for the years ended 30 June 2017 and 30 June 2016.

**KEY MANAGEMENT PERSONNEL REMUNERATION OF THE COMPANY FOR THE YEARS ENDING 30 JUNE 2017 & 30 JUNE 2016**

	YEAR	POST-EMPLOYMENT BENEFITS				SHARE-BASED PAYMENTS (ACCOUNTING CHARGE ONLY) <sup>2</sup>	TOTAL
		GROSS SALARY	SHORT-TERM INCENTIVE	OTHER <sup>1</sup>	SUPER-ANNUATION / PENSION FUND	PERFORMANCE RIGHTS	
		\$	\$	\$	\$	\$	\$
<b>DIRECTORS</b>							
Dr. P.J. Wolgen	2017	786,717	508,058	26,205	-	265,103	1,586,083
	2016	807,109	373,969	20,455	-	1,130,261 <sup>3</sup>	2,331,794
Mr. S.R. McLiesh	2017	100,457	-	-	9,543	10,229	120,229
	2016	100,457	-	-	9,543	44,805	154,805
Mrs. B.M. Shanahan	2017	73,059	-	-	6,941	10,229	90,229
	2016	73,059	-	-	6,941	44,805	124,805
Mr. E. Ishag	2017	70,000	-	-	-	7,161	77,161
	2016	70,000	-	-	-	31,363	101,363
Mr. W.A. Blijdorp	2017	65,000	-	-	-	-	65,000
	2016	65,000	-	-	-	-	65,000
<b>OTHER KEY MANAGEMENT PERSONNEL</b>							
Dr. D.J. Wright	2017	238,056	5,952	-	19,616	10,120	273,744
	2016	232,704	4,000	-	19,308	38,575	294,587
Mr. D.M. Keamy	2017	229,694	22,570	-	19,616	30,384	302,264
	2016	218,150	11,315	-	19,308	120,470	369,243
TOTAL	2017	1,562,983	536,580	26,205	55,716	333,226	2,514,710
	2016	1,566,479	389,284	20,455	55,100	1,410,279	3,441,597

<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 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.

**THE RELATIVE PROPORTIONS OF REMUNERATION BETWEEN FIXED AND BASED ON PERFORMANCE FOR THE YEARS ENDING 30 JUNE 2017 AND 30 JUNE 2016**

	2017		2016	
	FIXED REMUNERATION	PERFORMANCE BASED	FIXED REMUNERATION	PERFORMANCE BASED
Dr. P.J. Wolgen	51%	49%	35%	65%
Dr. D.J. Wright	94%	6%	86%	14%
Mr. D.M. Keamy	82%	18%	64%	36%

**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	692,475	\$2.59	Ordinary	28/11/2014	-
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	-

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

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

**REMUNERATION PERFORMANCE RIGHTS HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2017**

	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	-	(14,000)	-	42,500	-	42,500
Mr. S.R. McLiesh	85,000	-	(20,000)	-	65,000	-	65,000
Mrs. B.M. Shanahan	70,000	-	(20,000)	-	50,000	-	50,000
Dr. P.J. Wolgen	1,424,864	-	(499,890)	-	924,974	-	924,974
Mr. W.A. Blijdorp	-	-	-	-	-	-	-
<b>EXECUTIVES</b>							
Dr. D.J. Wright	128,125	-	(8,000)	-	120,125	-	120,125
Mr. D.M. Keamy	238,760	-	(26,000)	-	212,760	-	212,760

**SHARES HELD BY KEY MANAGEMENT PERSONNEL**

The number of ordinary shares in the Company during the 2017 reporting period held by each of the Group's Key Management Personnel, including their related parties, is set out below:

YEAR ENDING 30 JUNE 2017					
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	-	14,000	-	162,195
Mr. S.R. McLiesh	191,000	-	20,000	(48,226)	162,774
Mrs. B.M. Shanahan	133,969	-	20,000	-	153,969
Dr. P.J. Wolgen	2,079,832	-	499,890	-	2,579,722
Mr. W.A. Blijdorp	383,145	-	-	-	383,145
Dr. D.J. Wright	236,874	-	8,000	-	244,874
Mr. D.M. Keamy	166,400	-	26,000	-	192,400

## ADDITIONAL INFORMATION - REMUNERATION

For each cash incentive and right granted, the percentage of the available grant or cash incentive that was paid or vested in the financial year, and the percentage forfeited due to unmet milestones (including service length), is set out below. Cash incentives 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 (\$)
	64.5%	35.5%							
Dr. P.J. Wolgen			2010/11	Rights	0%	0%	No limitation	-	300,001
			2014/15	Rights	0%	0%	2021/22	-	1,619,935
	0%	0%							
Mr. S.R. McLiesh			2011/12	Rights	0%	0%	No limitation	-	26,690
			2014/15	Rights	0%	0%	2021/22	-	64,800
	0%	0%							
Mrs. B.M. Shanahan			2011/12	Rights	0%	0%	No limitation	-	16,682
			2014/15	Rights	0%	0%	2021/22	-	64,800
	0%	0%							
Mr. E. Ishag			2011/12	Rights	0%	0%	No limitation	-	16,682
			2014/15	Rights	0%	0%	2021/22	-	45,360
Mr. W.A. Blijdorp	0%	0%							
	50%	50%							
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	0%	0%	2021/22	-	69,120
	83.3%	16.7%							
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	0%	0%	2021/22	-	224,640

The exercise price for those rights granted between 2009/10 and 2014/15 was \$Nil.

## LOANS TO DIRECTORS AND EXECUTIVES

No loans were granted to Directors or Executives for the years ending 30 June 2017 and 30 June 2016.

## 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 & COMMERCIAL MILESTONES	YEAR ENDING 30 JUNE				
	2013	2014	2015	2016	2017
Ph III EPP Study – USA					
Ph II Vitiligo Studies – EU & USA					
Ph II Vitiligo Study - Singapore					
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)	69	72	127	203	333
Share Price High (\$)	2.73	2.00	5.10	5.00	9.19
Share Price Low (\$)	1.50	0.92	1.30	2.50	4.10
Closing Share Price (\$)	1.81	1.70	2.84	4.32	6.98
Change in Share Price over 1 Year (%)	11	(6)	67	57	62
Change in Share Price over 3 Years (%)	(20)	3	74	139	311

## END OF AUDITED REMUNERATION REPORT

### SHARES PROVIDED UPON EXERCISE OF RIGHTS

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

ENTITY	NUMBER OF SHARES ISSUED <sup>1</sup>	ISSUE PRICE FOR SHARES	CLASS
CLINUVEL	654,590	Nil\$	Ordinary
CLINUVEL	10,000	Nil\$	Ordinary

<sup>1</sup>These shares were issued by the consolidated entity during the year after performance conditions attached to the rights were considered met. Those shares issued by the consolidated entity to Directors and Employees are held for retention in the Scheme Trust. Shares issued by the consolidated entity to eligible participants were issued directly.

#### DETAILS OF SHARES TRANSFERRED DURING THE YEAR TO EMPLOYEES FROM THE SCHEME TRUST

ENTITY	NUMBER OF SHARES ISSUED <sup>1</sup>	ISSUE PRICE FOR SHARES	CLASS
CLINUVEL	45,600	Nil\$	Ordinary

<sup>1</sup>These shares were issued by the Scheme Trustee to departing employees who resigned from the consolidated entity during the year or to existing employees who had their transfer restrictions waived by the Board in their discretion.

**UNISSUED SHARES UNDER OPTION**

ENTITY	NUMBER OF SHARES UNDER RIGHTS	EXERCISE PRICE	CLASS	EXPIRY DATE
CLINUVEL PHARMACEUTICALS LTD	840,985	\$Nil	Ordinary	Upon achievement of specific performance and time-based milestones or upon cessation of employment
CLINUVEL PHARMACEUTICALS LTD	692,475	\$Nil	Ordinary	28 November 2021
CLINUVEL PHARMACEUTICALS LTD	338,800	\$Nil	Ordinary	17 March 2022
	1,872,260	-	-	-

**NON-AUDIT SERVICES**

For the year ended 30 June 2017, Grant Thornton Australia only provided audit services to the Company. During the year ended 30 June 2016, Grant Thornton Australia provided non-audit services, specifically general tax advice concerning the Australian R&D tax incentive regime. No such non-audit services were provided for the year ended 30 June 2017. Details of amounts paid or payable to the auditor for non-audit services provided during the year by the auditor are outlined in Note 18 to the financial statements.

The Directors are satisfied that the provision of non-audit services, during the year ended 30 June 2016, 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 30th day of August, 2017

# STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2017

	NOTE	CONSOLIDATED ENTITY	
		2017	2016
		\$	\$
Total revenues	2	16,984,536	6,419,707
Other income	2	185,168	796,531
Total expenses	2	(10,055,418)	(10,369,956)
Profit/(loss) before income tax expense		7,114,286	(3,153,718)
Income tax expense/(benefit)	3	-	-
Profit/(loss) after income tax expense		7,114,286	(3,153,718)
<b>NET PROFIT/(LOSS) FOR THE YEAR</b>		<b>7,114,286</b>	<b>(3,153,718)</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		(13,854)	273,786
Income tax (expense)/benefit on items of other comprehensive income		-	-
Other comprehensive loss for the period, net of income tax		(13,854)	273,786
<b>TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD</b>		<b>7,100,432</b>	<b>(2,879,932)</b>
<b>PROFIT/(LOSS) FOR THE YEAR ATTRIBUTABLE TO:</b>			
Non-controlling interest		(66,541)	(32,518)
Owners of the parent		7,180,827	(3,121,200)
		<b>7,114,286</b>	<b>(3,153,718)</b>
<b>TOTAL COMPREHENSIVE INCOME/(LOSS) ATTRIBUTABLE TO:</b>			
Non-controlling interest		(66,541)	(32,518)
Owners of the parent		7,166,973	(2,847,414)
		<b>7,100,432</b>	<b>(2,879,932)</b>
Basic earnings per share - cents per share	15	14.9	(7.0)
Diluted earnings per share - cents per share	15	14.3	(7.0)
The accompanying notes form part of these financial statements.			

# STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2017

	NOTE	CONSOLIDATED ENTITY	
		2017	2016
		\$	\$
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	16(a)	23,752,312	13,844,703
Trade and other receivables	4	3,239,127	4,823,770
Inventory	5	1,241,608	1,082,163
Other assets	6	236,576	222,961
<b>TOTAL CURRENT ASSETS</b>		<b>28,469,623</b>	<b>19,973,597</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment	7	137,341	164,670
<b>TOTAL NON-CURRENT ASSETS</b>		<b>137,341</b>	<b>164,670</b>
<b>TOTAL ASSETS</b>		<b>28,606,964</b>	<b>20,138,267</b>
<b>CURRENT LIABILITIES</b>			
Trade and other payables	9	2,294,228	1,573,361
Provisions	10	853,374	715,017
<b>TOTAL CURRENT LIABILITIES</b>		<b>3,147,602</b>	<b>2,288,378</b>
<b>NON-CURRENT LIABILITIES</b>			
Provisions	10	15,337	15,369
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>15,337</b>	<b>15,369</b>
<b>TOTAL LIABILITIES</b>		<b>3,162,939</b>	<b>2,303,747</b>
<b>NET ASSETS</b>		<b>25,444,025</b>	<b>17,834,520</b>
<b>EQUITY</b>			
<b>EQUITY ATTRIBUTABLE TO OWNERS OF THE PARENT:</b>			
Contributed equity	11	148,413,095	146,764,500
Reserves	12	2,820,212	4,094,977
Accumulated losses	13	(125,847,024)	(133,063,239)
<b>EQUITY ATTRIBUTABLE TO THE OWNERS OF THE PARENT</b>		<b>25,386,283</b>	<b>17,796,238</b>
<b>EQUITY ATTRIBUTABLE TO NON-CONTROLLING (MINORITY EQUITY) INTEREST</b>		<b>57,742</b>	<b>38,282</b>
<b>TOTAL EQUITY</b>		<b>25,444,025</b>	<b>17,834,520</b>

The accompanying notes form part of these financial statements.



# STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2017

	NOTE	CONSOLIDATED ENTITY	
		2017	2016
		\$	\$
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
GST and VAT refunds		193,012	114,166
Government R&D Tax Incentive Refund		588,018	420,131
Receipts from Customers		17,924,257	3,648,388
Interest received		233,682	177,149
Payments to suppliers and employees		(9,022,033)	(9,396,767)
<b>NET CASH PROVIDED BY/(USED IN) OPERATING ACTIVITIES</b>	16(B)	<b>9,916,936</b>	<b>(5,036,933)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Payments for property, plant and equipment		(67,479)	(98,051)
<b>NET CASH PROVIDED BY/(USED IN) INVESTING ACTIVITIES</b>		<b>(67,479)</b>	<b>(98,051)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from issue of ordinary shares		-	8,335,305
Equity contribution by subsidiary non-controlling interest		85,082	89,118
Payment of share issue costs		-	(36,059)
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>		<b>85,082</b>	<b>8,388,364</b>
<b>NET INCREASE IN CASH HELD</b>		<b>9,934,539</b>	<b>3,253,380</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR</b>		<b>13,844,703</b>	<b>10,572,295</b>
Effects of exchange rate changes on foreign currency held		(26,930)	19,028
<b>CASH AND CASH EQUIVALENTS AT END OF THE YEAR</b>	16(A)	<b>23,752,312</b>	<b>13,844,703</b>

The accompanying notes form part of these financial statements.

# STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2017

	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 2015</b>	138,465,335	2,313,678	384,660	(129,942,039)	11,221,634	(16,343)	11,205,291
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
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>PROFIT/(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>
Equity contribution by subsidiary non-controlling interest	-	-	-	-	-	86,001	86,001
Issue of Share Capital under share-based payment	1,648,595	(1,648,595)	-	-	-	-	-
Employee share-based payment options	-	359,976	-	35,388	395,364	-	395,364
<b>TRANSACTIONS WITH OWNERS</b>	<b>148,413,095</b>	<b>2,695,484</b>	<b>110,874</b>	<b>(133,027,851)</b>	<b>18,191,602</b>	<b>124,283</b>	<b>18,315,885</b>
<b>PROFIT/(LOSS) FOR THE YEAR</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>7,180,827</b>	<b>7,180,827</b>	<b>(66,541)</b>	<b>7,114,286</b>
<b>OTHER COMPREHENSIVE INCOME:</b>							
Exchange differences of foreign exchange translation of foreign operations	-	-	13,854	-	13,854	-	13,854
<b>BALANCE AT 30 JUNE 2017</b>	<b>148,413,095</b>	<b>2,695,484</b>	<b>124,728</b>	<b>(125,847,024)</b>	<b>25,386,283</b>	<b>57,742</b>	<b>25,444,025</b>

# NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2017

## 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

### 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 Profit or Loss.

### **E) INVESTMENTS AND OTHER FINANCIAL ASSETS**

#### **Financial assets at fair value through profit or loss (FVTPL)**

The consolidated entity does not hold financial assets at fair value through profit and loss (FVTPL) at balance date. FVTPL include financial assets that are either classified as held for trading or that meet certain conditions and are designated at FVTPL upon initial recognition. All derivative financial instruments fall into this category, except for those designated and effective as hedging instruments, for which the hedge accounting requirements apply. Assets in this category are measured at fair value with gains or losses recognised in profit or loss. The fair values of financial assets in this category

are determined by reference to active market transactions or using a valuation technique where no active market exists.

#### **Loans and receivables**

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. After initial recognition, these are measured at amortised cost using the effective interest method, less provision for impairment. Discounting is omitted where the effect of discounting is immaterial. The Group's trade and most other receivables fall into this category of financial instruments. Individually significant receivables are considered for impairment when they are past due or when other objective evidence is received that a specific counterparty will default. Receivables that are not considered to be individually impaired are reviewed for impairment in groups, which are determined by reference to the industry and region of a counterparty and other shared credit risk characteristics. The impairment loss estimate is then based on recent historical counterparty default rates for each identified group.

### **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 high quality 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 conditional 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 conditional performance rights. It also extends to other forms of equity based remuneration. The fair value of options is measured by the use of the binominal options pricing model. The fair value of conditional performance rights is measured by either a binomial or a trinomial model. It is determined at grant date and expensed on a straight-line basis over the vesting period. The fair value of options and conditional performance rights is shown as an expense in profit or loss.

**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. The Group's R&D tax incentive program is currently derived from expenditure only.

**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 'valued added tax' as it is known in certain jurisdictions (GST), except:

- where the amount of GST incurred is not recoverable from the taxation authority, it is recognised as part of the costs of acquisition of an asset or as part of an item of expense; or
- for receivables and payables which are recognised inclusive of GST.

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

**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 Profit or Loss immediately.

Where an impairment loss subsequently reverses, the carrying amount of the asset (cash-generating unit) is increased to the revised estimate of its recoverable amount, but only to the extent that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset (cash-generating unit) in prior years. A reversal of an impairment loss is recognised in the Profit or Loss immediately.

**Q) LEASES**

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

**R) COMPARATIVES**

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

**S) PROVISIONS**

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

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

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

## T) 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 still in development stage and yet to be used in the Group's R&D 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 2017 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; and

- 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.

#### **AASB 2014-10 Amendments to Australian Accounting Standards – Sale or Contribution of Assets between an Investor and its Associate or Joint Venture**

The amendments address a current inconsistency between AASB 10 Consolidated Financial Statements and AASB 128 Investments in Associates and Joint Ventures.

The amendments clarify that, on a sale or contribution of assets to a joint venture or associate or on a loss of control when joint control or significant influence is retained in a transaction involving an associate or a joint venture, any gain or loss recognised will depend on whether the assets or subsidiary constitute a business, as defined in AASB 3 Business Combinations. Full gain or loss is recognised when the assets or subsidiary constitute a business, whereas gain or loss attributable to other investors' interests is recognised when the assets or subsidiary do not constitute a business.

This amendment effectively introduces an exception to the general requirement in AASB 10 to recognise full gain or loss on the loss of control over a subsidiary. The exception only applies to the loss of control over a subsidiary that does not contain a business, if the loss of control is the result of a transaction involving an associate or a joint venture that is accounted for using the equity method.

Corresponding amendments have also been made to AASB 128.

The entity is yet to undertake a detailed assessment of the impact of AASB 2014-10. 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 2016-5 Amendments to Australian Accounting Standards – Classification and Measurement of Sharebased Payment Transactions**

This Standard amends AASB 2 Share-based Payment to address:

- The accounting for the effects of vesting and non-vesting conditions on the measurement of cash-settled share-based payments;
- The classification of share-based payment transactions with a net settlement feature for withholding tax obligations; and
- The accounting for a modification to the terms and conditions of a share-based payment that changes the classification of the transaction from cash-settled to equity-settled.

The entity is yet to undertake a detailed assessment of the impact of AASB 2016-5. 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.

#### **Interpretation 22 Foreign Currency Transactions and Advance Consideration**

Interpretation 22 looks at what exchange rate to use for translation when payments are made or received in advance of the related asset, expense or income.

Although AASB 121 The Effects of Changes in Foreign Exchange Rates sets out requirements about which exchange rate to use when recording a foreign currency transaction on initial recognition in an entity's functional currency, the IFRS Interpretations Committee had observed diversity in practice in circumstances in which an entity recognises a non-monetary liability arising from advance consideration. The diversity resulted from the fact that some entities were recognising revenue using the spot exchange rate at the date of

the receipt of the advance consideration while others were using the spot exchange rate at the date that revenue was recognised.

Interpretation 22 addresses this issue by clarifying that the date of the transaction for the purpose of determining the exchange rate to use on initial recognition of the related asset, expense or income (or part of it) is the date on which an entity initially recognises the non-monetary asset or non-monetary liability arising from the payment or receipt of advance consideration. If there are multiple payments or receipts in advance, the entity shall determine a date of the transaction for each payment or receipt of advance consideration.

The entity is yet to undertake a detailed assessment of the impact of Interpretation 22. However, based on the entity's preliminary assessment, the Interpretation 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.

#### **IFRIC 23 Uncertainty Over Income Tax Treatments**

IFRIC 23 clarifies how the recognition and measurement requirements of IAS 12 Income Taxes are applied where there is uncertainty over income tax treatments.

The entity is yet to undertake a detailed assessment of the impact of IFRIC 23. However, based on the entity's preliminary assessment, the Interpretation 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 eight end users (2016: seven end users). 100% of the revenue from commercial sales is from twelve end users (2016: one end user).

## **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	
	2017	2016
	\$	\$
<b>(A) REVENUES</b>		
Interest revenue – other persons	264,394	208,368
Sales reimbursements	4,833,653	3,613,764
Commercial sales	11,886,489	2,597,575
<b>TOTAL REVENUES</b>	<b>16,984,536</b>	<b>6,419,707</b>
<b>(B) OTHER INCOME</b>		
Government R&D tax incentive	45,314	609,059
Gain/(loss) on restating foreign currency creditors and currencies held	-	187,472
Realised net currency gain on transactions	139,854	-
<b>TOTAL OTHER INCOME</b>	<b>185,168</b>	<b>796,531</b>
<b>(C) EXPENSES</b>		
Clinical development	129,806	133,461
Drug formulation R&D, manufacture & distribution	857,204	1,022,082
Regulatory (Pre & Post Marketing) & Non-clinical	1,005,223	973,221
Clinical, Regulatory & Commercial overheads	2,060,701	1,606,026
Business marketing & listing	811,434	777,725
Licenses patents and trademarks	219,714	266,072
General operations (incl Board)	4,882,282	5,591,369
Foreign currency translation losses	89,054	-
<b>TOTAL EXPENSES</b>	<b>10,055,418</b>	<b>10,369,956</b>
<b>(D) PROFIT/(LOSS) BEFORE INCOME TAX INCLUDES THE FOLLOWING SPECIFIC EXPENSES</b>		
Employee benefits expense	4,817,187	4,360,203
Depreciation on property, plant & equipment	53,138	25,526
Loss on sale of property, plant and equipment	33,740	-
Share-based payments	395,364	1,670,425
Operating lease expense – minimum lease payments	345,482	356,842

**3. INCOME TAX EXPENSE**

CONSOLIDATED ENTITY		
	2017	2016
	\$	\$
<b>NUMERICAL RECONCILIATION OF INCOME TAX BENEFIT AND TAX AT THE STATUTORY RATE</b>		
PROFIT/(LOSS) BEFORE INCOME TAX EXPENSE	7,114,286	(3,153,718)
Tax at the statutory tax rate of 30%	2,134,286	(946,115)
<b>TAX EFFECT AMOUNTS WHICH ARE NOT DEDUCTIBLE/(TAXABLE) IN CALCULATING TAXABLE INCOME:</b>		
Non deductible entertainment	1,275	939
Share-based payments	118,609	501,128
Research and development deduction	36,498	396,702
(Over)/under provision of income tax in previous years	157,146	235,582
Refundable tax offset	(13,594)	(182,718)
Other	-	4,318
	<b>2,434,220</b>	<b>9,836</b>
Current year temporary differences not recognised	375,949	(94,113)
Prior year gains/(losses) now recognised	(2,810,169)	84,277
<b>INCOME TAX EXPENSE/(BENEFIT)</b>	<b>-</b>	<b>-</b>

**TAX LOSSES NOT RECOGNISED**

Unused tax losses for which no deferred tax asset has been recognised	121,081,247	129,195,313
<b>POTENTIAL TAX BENEFIT AT 30%</b>	<b>36,324,374</b>	<b>38,758,594</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		
	2017	2016
	\$	\$
<b>CURRENT</b>		
Trade debtors	2,966,173	2,759,012
Accrued income	94,048	1,320,996
Sundry debtors	178,906	743,762
<b>TOTAL</b>	<b>3,239,127</b>	<b>4,823,770</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:

	2017			2016		
	AMOUNT IMPAIRED	AMOUNT NOT IMPAIRED	TOTAL	AMOUNT IMPAIRED	AMOUNT NOT IMPAIRED	TOTAL
Not past due	-	2,756,649	2,756,649	-	2,759,012	2,759,012
Past due 61-90 days	-	209,524	209,524	-	-	-
Past due >90 days	-	-	-	-	-	-
<b>TOTAL</b>		<b>2,966,173</b>	<b>2,966,173</b>	<b>-</b>	<b>2,759,012</b>	<b>2,759,012</b>

**5. INVENTORY**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>CURRENT</b>		
Raw materials – at cost	512,651	364,879
Provision for Obsolescence – Raw materials	(181,675)	-
Work in progress – at cost	466,716	-
Finished goods – at cost	443,916	717,284
<b>TOTAL</b>	<b>1,241,608</b>	<b>1,082,163</b>

**6. OTHER ASSETS**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>CURRENT</b>		
Prepaid peptide	137,444	138,080
Other prepayments	99,132	84,881
<b>TOTAL</b>	<b>236,576</b>	<b>222,961</b>

**7. PROPERTY, PLANT AND EQUIPMENT**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>PLANT AND EQUIPMENT</b>		
At cost	113,178	405,484
Less: accumulated depreciation	(56,258)	(319,167)
<b>SUB-TOTAL</b>	<b>56,920</b>	<b>86,317</b>
<b>FURNITURE AND FITTINGS</b>		
At cost	124,123	96,044
Less: accumulated depreciation	(43,702)	(17,691)
<b>SUB-TOTAL</b>	<b>80,421</b>	<b>78,353</b>
<b>TOTAL PROPERTY, PLANT AND EQUIPMENT</b>	<b>137,341</b>	<b>164,670</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 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>
Additions	34,212	28,078	62,290
Disposals	(326,519)	-	(326,519)
Depreciation written back on disposal	290,038	-	290,038
Depreciations expense	(27,128)	(26,010)	(53,138)
Make-good	-	-	-
Exchange differences	-	-	-
<b>CARRYING AMOUNT AT 30 JUNE 2017</b>	<b>56,920</b>	<b>80,421</b>	<b>137,341</b>

**8. INTERESTS IN SUBSIDIARIES**

NAME OF ENTITY	COUNTRY OF INCORPORATION	OWNERSHIP INTEREST	
		2017	2016
<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 of America	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	
		2017	2016
		\$	\$
<b>CURRENT</b>			
	Unsecured trade creditors	579,466	231,016
	Sundry creditors and accrued expenses	1,714,762	1,342,345
<b>TOTAL</b>		<b>2,294,228</b>	<b>1,573,361</b>
<b>(A) AGGREGATE AMOUNTS PAYABLE TO:</b>			
	Directors and Director-related entities	501,443	373,712
<b>(B) AUSTRALIAN DOLLAR EQUIVALENTS OF AMOUNTS PAYABLE IN FOREIGN CURRENCIES NOT EFFECTIVELY HEDGED AND INCLUDED IN TRADE AND SUNDRY CREDITORS:</b>			
	Singapore Dollars	-	201,860
	Other	-	164
<b>TOTAL</b>		<b>-</b>	<b>202,024</b>

For an analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 21.

<b>(C) TERMS AND CONDITIONS:</b>			
Trade and sundry creditors are non-interest bearing and normally settled on 30 day terms.			

**10. PROVISIONS**

		CONSOLIDATED ENTITY	
		2017	2016
		\$	\$
<b>CURRENT</b>			
	Employee benefits	853,374	715,017
<b>TOTAL</b>		<b>853,374</b>	<b>715,017</b>
<b>NON-CURRENT</b>			
	Employee benefits	1,169	627
	Other provisions	14,168	14,742
<b>TOTAL</b>		<b>15,337</b>	<b>15,369</b>

**MOVEMENTS IN CARRYING AMOUNTS - PROVISIONS**

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

		CONSOLIDATED ENTITY	
		MAKE-GOOD	TOTAL
		\$	\$
<b>CARRYING AMOUNT AT 30 JUNE 2016</b>		<b>14,742</b>	<b>14,742</b>
	Provisions made during the year	-	-
	Unwind of discount	(574)	(574)
<b>CARRYING AMOUNT AT 30 JUNE 2017</b>		<b>14,168</b>	<b>14,168</b>

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

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
47,735,227 fully paid ordinary shares (2016: 47,080,637)	148,413,095	146,764,500

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			
	2017		2016	
	NO.	\$	NO.	\$
AT THE BEGINNING OF THE FINANCIAL YEAR	47,080,637	146,764,500	44,554,787	138,465,335
Issued during the year	-	-	2,525,850	8,335,305
Conditional Rights issued and transferred from Conditional Rights reserve	654,590	1,648,595	-	-
Less: transaction costs	-	-	-	(36,140)
<b>BALANCE AT THE END OF THE FINANCIAL YEAR</b>	<b>47,735,227</b>	<b>148,413,095</b>	<b>47,080,637</b>	<b>146,764,500</b>

**(C) CONDITIONAL PERFORMANCE RIGHTS**

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

EXPIRY DATE	EXERCISE PRICE	NUMBER OF SECURITIES
Upon achievement of various performance milestones	Nil\$	654,590

As at 30 June 2017 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 PERFORMANCE RIGHTS
Upon achievement of various performance milestones	Nil\$	1,872,260

**12. RESERVES**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>CONDITIONAL PERFORMANCE RIGHTS RESERVE:</b>		
BALANCE AT THE BEGINNING OF PERIOD	3,984,103	2,313,678
Share-based payment	395,364	1,670,425
Transfer to share capital	(1,648,595)	-
Lapsed, forfeited Rights	(35,388)	-
BALANCE AT THE END OF PERIOD	2,695,484	3,984,103
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>		
BALANCE AT THE BEGINNING OF PERIOD	110,874	384,660
Translating foreign subsidiary to current rate at reporting date	13,854	(273,786)
BALANCE AT THE END OF PERIOD	124,728	110,874
<b>TOTAL RESERVES</b>	<b>2,820,212</b>	<b>4,094,977</b>

**13. ACCUMULATED LOSSES**

	CONSOLIDATED ENTITY		NON-CONTROLLING INTEREST	
	2017	2016	2017	2016
	\$	\$	\$	\$
Accumulated losses at the beginning of the year	(133,063,239)	(129,942,039)	(48,861)	(16,343)
Transfer from Performance Rights reserve of lapsed & expired Rights	35,388	-	-	-
Net profit/(loss) attributable to the members of CLINUVEL PHARMACEUTICALS LTD	7,180,827	(3,121,200)	(66,541)	(32,518)
<b>ACCUMULATED LOSSES AT THE END OF THE FINANCIAL YEAR</b>	<b>(125,847,024)</b>	<b>(133,063,239)</b>	<b>(115,402)</b>	<b>(48,861)</b>

**14. LEASE COMMITMENTS**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>OPERATING LEASE COMMITMENTS</b>		
Non-cancellable operating leases contracted for but not capitalised in the accounts		
Payable:		
not later than 1 year	169,686	155,189
later than 1 year but not later than 5 years	125,375	91,934
<b>TOTAL</b>	<b>295,061</b>	<b>247,123</b>

Operating leases comprises commitments for office premises and miscellaneous equipment.

No contingent rental clauses exist in lease agreements. Lease agreements range from 3 months to 28 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	
	2017	2016
	\$	\$
(a) Basic earnings per share (cents per share)	14.9	(7.0)
(a) Diluted earnings per share (cents per share)	14.3	(7.0)
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	47,670,194	45,286,317
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	49,626,791	47,973,642
(c) The numerator used in the calculation of basic earnings per share (\$)	7,114,286	(3,153,718)

As at 30 June 2017 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.

As at 30 June 2016, the Company was in a net loss position. It also had on issue unlisted performance rights over unissued capital. At this date, these performance rights are considered anti dilutive and were excluded from the calculation of diluted earnings per share. Therefore basic and diluted earnings per share were the same as at 30 June 2016.

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.

**16. CASH FLOW INFORMATION**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$

**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	14,209,196	3,936,720
Cash on hand	1,376	555
Deposits on call	129,048	79,147
Term deposits	9,350,000	9,750,000
Security bonds	62,692	78,281
<b>TOTAL CASH</b>	<b>23,752,312</b>	<b>13,844,703</b>

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

<b>OPERATING PROFIT (LOSS) AFTER INCOME TAX</b>	<b>7,114,286</b>	<b>(3,153,718)</b>
Non cash flows in operating (loss):		
Depreciation expense on property, plant & equipment	53,138	25,526
Exchange rate effect on foreign currencies held	26,930	(19,028)
Executive share option expense	395,364	1,670,425
Loss on sale of non-current assets	33,740	-
Unrealised loss on foreign exchange translation	13,854	(273,786)
Changes in assets and liabilities:		
(Increase)/decrease in receivables	1,584,644	(2,863,317)
(Increase)/decrease in inventories	(159,444)	(245,028)
(Increase)/decrease in prepayments	(13,616)	(18,338)
Increase/(decrease) in payables	729,715	(297,403)
Increase/(decrease) in provisions	138,325	137,734
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>9,916,936</b>	<b>(5,036,933)</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 2.80% (2016: 3.01%). These deposits have an average maturity date of 208 days (2016: 165 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 12 for further information.

## KEY MANAGEMENT PERSONNEL COMPENSATION

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>SHORT-TERM EMPLOYEE BENEFITS:</b>		
Post-employment benefits	2,125,768	1,976,218
	55,716	55,100
<b>LONG-TERM BENEFITS:</b>		
Termination benefits	-	-
Share-based payments	333,226	1,410,279
<b>TOTAL</b>	<b>2,514,710</b>	<b>3,441,597</b>

No loans or other transactions existed with key management personnel.

## 18. AUDITOR'S REMUNERATION

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	92,500	90,000
other services	-	5,000
<b>TOTAL</b>	<b>92,500</b>	<b>95,000</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 where 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 2017 is \$4,370,640 (2016: \$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 where a deficiency in net assets exists in CLINUVEL, INC. The loan to CLINUVEL, INC as at 30 June 2017 is \$10,411,946 (2016: \$10,640,482).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL AG is non-interest bearing. Repayment of the loan will occur throughout commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in CLINUVEL AG. The loan to CLINUVEL AG as at 30 June 2017 is \$12,310,580 (2016: \$18,293,460).

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 where a deficiency in net assets exists in CLINUVEL SINGAPORE PTE LTD. The loan to CLINUVEL SINGAPORE PTE LTD as at 30 June 2017 is \$365,080 (2016: \$215,774).

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 where a deficiency in net assets exists in CLINUVEL (UK) LTD. The loan to CLINUVEL (UK) LTD as at 30 June 2017 is \$5,074,245 (2016: \$3,248,740).

#### 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 eight end users (2016: seven end users). 100% of the revenue from commercial sales is from twelve end users (2016: one end user).

## 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. It is also exposed to the risk of movements in foreign currency exchange rates for those currencies which sales and reimbursement receipts are received.

The consolidated entity's policy of managing foreign currency risk is to hold foreign currencies equivalent to the cash outflow projected over minimum 30 days by the placement of market orders or have in place 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 2017 and as at 30 June 2016.

## THE CONSOLIDATED ENTITY'S EXPOSURE TO FOREIGN CURRENCY RISK AT 30 JUNE 2017

CONSOLIDATED ENTITY								
2017					2016			
	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	1,169,412	-	(517,812)	651,600	897,509	1,915	(467,104)	432,320
EUR	5,561,436	1,743,103	(181,161)	7,123,378	717,433	2,433,538	(42,150)	3,108,821
CHF	1,493,230	399,610	(141,331)	1,751,509	500,344	409,378	(129,709)	780,013
GBP	624,997	42,624	(293,698)	373,923	137,621	51,624	(61,149)	128,096
SGD	1,128,840	12,415	(978,457)	312,798	550,442	5,225	(752,847)	(197,180)
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 Euro. Assuming all other variables remain constant, a depreciation in the Australian dollar is advantageous to the consolidated entity as sales receipts received in Euro foreign currency allows for conversion to a higher amount of Australian dollars.

For the consolidated entity, a 5% appreciation of the Australian dollar against the Singapore currency would have decreased profit and loss and equity by \$293,857 for the year ended 30 June 2017 (2016: \$83,663), on the basis that all other variables remain constant. 5% is considered representative of the market volatility in the Australian dollar/Euro rate for the period.

For the consolidated entity, an appreciation of the Australian dollar against the Euro 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 fixed 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 2017, 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 \$91,831 higher/lower (2016: \$51,523 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 government funded counterparties across Italian, Swiss, German, Austrian 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 2017**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>CASH AND CASH EQUIVALENTS</b>		
Carrying amount	23,752,312	13,844,703
6 months or less	23,752,312	13,844,703
Greater than 6 months	-	-
<b>TOTAL</b>	<b>23,752,312</b>	<b>13,844,703</b>

**OTHER FINANCIAL ASSETS (INCLUDES TRADE AND OTHER RECEIVABLES)**

Carrying amount	3,239,127	4,823,770
6 months or less	3,239,127	4,823,770
Greater than 6 months	-	-
<b>TOTAL</b>	<b>3,239,127</b>	<b>4,823,770</b>

**CONTRACTUAL MATURITIES OF FINANCIAL LIABILITIES AS AT 30 JUNE 2017**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>TRADE AND OTHER PAYABLES</b>		
Carrying amount	2,294,228	1,573,361
6 months or less	2,265,478	1,551,891
Greater than 6 months	28,750	21,470
<b>TOTAL</b>	<b>2,294,228</b>	<b>1,573,361</b>

**22. EMPLOYEE BENEFITS**

	CONSOLIDATED ENTITY	
	2017	2016
	\$	\$
<b>THE AGGREGATE EMPLOYEE BENEFIT LIABILITY IS COMPRISED OF :</b>		
Provision for annual leave	527,970	413,281
Provision for long service leave	326,573	302,362
Accrued FBT, payroll, superannuation, pension funds, employee insurances	715,930	500,723
<b>TOTAL</b>	<b>1,570,473</b>	<b>1,216,366</b>

**SHARE-BASED PAYMENTS**

The consolidated entity has two conditional performance rights scheme which is 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. 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 rights to Executive Directors requires shareholder approval in accordance with ASX Listing Rules. All rights convert to one ordinary share of the consolidated entity are issued for nil consideration, have no voting rights, are non-transferable and are not listed on the ASX. They can be converted to 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.

**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 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 in the shares held by the Scheme Trust without prior written Board consent until the earlier of 7 years from grant date of performance right, 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.

**THE FOLLOWING SHARE-BASED PAYMENT ARRANGEMENTS WERE IN EXISTENCE AT 30 JUNE 2017**

PERFORMANCE RIGHTS SERIES	NUMBER	GRANT DATE	EXPIRY DATE	EXERCISE PRICE	FAIR VALUE AT GRANT DATE
Issued 07/01/2010	-	07/01/2010	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	\$0.50
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	375,986	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	692,475	28/11/2014	7 years from Grant Date	\$ Nil	\$2.59
Issued 17/03/2015	338,800	17/03/2015	7 years from Grant Date	\$ Nil	\$2.16

**HOLDINGS OF ALL ISSUED CONDITIONAL PERFORMANCE RIGHTS – 2017**

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)	-	-	-	-
Issued 25/11/2010	299,999	-	-	-	299,999	-	299,999
Issued 16/09/2011	381,386	-	-	(5,400)	375,986	-	375,986
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	-	(553,890)	-	692,475	-	692,475
Issued 17/03/2015	453,500	-	(90,700)	(24,000)	338,800	-	338,800
<b>TOTAL</b>	<b>2,556,250</b>	<b>-</b>	<b>(654,590)</b>	<b>(29,400)</b>	<b>1,872,260</b>	<b>-</b>	<b>1,872,260</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 – 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.

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

CLINUVEL PHARMACEUTICALS LTD		
	2017	2016
	\$	\$
<b>ASSETS</b>		
Current assets	21,789,154	13,674,405
Non-current assets	6,287,177	6,355,032
<b>TOTAL ASSETS</b>	<b>28,076,331</b>	<b>20,029,437</b>
<b>LIABILITIES</b>		
Current liabilities	1,415,118	1,244,389
Non-current liabilities	1,169	627
<b>TOTAL LIABILITIES</b>	<b>1,416,287</b>	<b>1,245,016</b>
<b>EQUITY</b>		
Issued equity	148,413,095	146,764,500
Share-based payments reserve	2,695,500	3,984,119
Accumulated losses	(124,448,551)	(131,964,198)
<b>TOTAL EQUITY</b>	<b>26,660,044</b>	<b>18,784,421</b>
<b>FINANCIAL PERFORMANCE</b>		
Net profit (loss) for the year	7,551,035	(3,036,801)
Other comprehensive income	-	-
<b>TOTAL COMPREHENSIVE INCOME</b>	<b>7,551,035</b>	<b>(3,036,801)</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 6, 15 Queen Street  
Melbourne VIC 3000  
Ph: (03) 9660 4900

# DIRECTORS' DECLARATION

In the opinion of the Directors:

1. the financial statements and notes of the consolidated entity are in accordance with the Corporations Act 2001, including:
  - a) giving a true and fair view of the consolidated entity's financial position as at 30 June 2017 and of its performance for the year ended on that date; and
  - b) complying with Accounting Standards; and
  - c) complying with International financial Reporting Standards as disclosed in Note 1.
2. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.
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 30th day of August, 2017





The Rialto, Level 30  
525 Collins St  
Melbourne Victoria 3000

Correspondence to:  
GPO Box 4736  
Melbourne Victoria 3001

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

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

### Report on the audit of the financial report

#### Opinion

We have audited the financial report of Clinuvel Pharmaceuticals Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 30 June 2017, 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, and notes to the consolidated financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion, the accompanying financial report of Clinuvel Pharmaceuticals Limited the Group, is in accordance with the *Corporations Act 2001*, including:

- a Giving a true and fair view of the Group's financial position as at 30 June 2017 and of its performance for the year ended on that date; and
- b Complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

#### Basis for Opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Group in accordance with the independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to the Directors of the Company, would be in the same terms if given to the Directors as at the time of this auditor's report.

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

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

'Grant Thornton' refers to the brand under which the Grant Thornton member firms provide assurance, tax and advisory services to their clients and/or refers to one or more member firms, as the context requires. Grant Thornton Australia Ltd is a member firm of Grant Thornton International Ltd (GTIL). GTIL and the member firms are not a worldwide partnership. GTIL and each member firm is a separate legal entity. Services are delivered by the member firms. GTIL does not provide services to clients. GTIL and its member firms are not agents of, and do not obligate one another and are not liable for one another's acts or omissions. In the Australian context only, the use of the term 'Grant Thornton' may refer to Grant Thornton Australia Limited ABN 41 127 556 389 and its Australian subsidiaries and related entities. GTIL is not an Australian related entity to Grant Thornton Australia Limited.

Liability limited by a scheme approved under Professional Standards Legislation.



### Key Audit Matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report of the current period. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Key audit matter	How our audit addressed the key audit matter
<p><b>Performance rights – Note 11</b></p> <p>Clinuvel has unvested performance rights in 2010, 2013, 2014 and 2015 which vest upon achievement of specific non-market performance conditions where the vesting dates are estimated at time of grant of performance rights. Management reassess the performance rights periodically to revise vesting dates for each unvested performance condition based on current information. The majority of remaining unvested performance conditions are tied to submission of a dossier to the US Food and Drug Administration (FDA) applying for market approval of Scenesse (the Company's product). The performance conditions are also subject to market approval by the US FDA and securing sufficient funding necessary to obtain that approval.</p> <p>The assessment of the performance conditions and when they are expected to be met requires a high degree of management judgement. This area is a key audit matter due to the inherent subjectivity involved in the management's judgement relating to the assumptions used to value the rights including estimates of likely vesting dates.</p>	<p>Our procedures included, amongst others:</p> <ul style="list-style-type: none"> <li>• Obtaining management calculations and verifying mathematical accuracy;</li> <li>• Validating completeness of outstanding performance rights by verifying the number of rights issued back to agreements and to ASX announcements;</li> <li>• Enquiring with management to obtain an understanding of vesting date revisions;</li> <li>• Examining underlying documentation supporting vesting date revisions and ensuring consistency with our knowledge of the entity</li> <li>• Ensuring share-based payment expenses were recorded in the correct period in line with vesting conditions; and</li> <li>• Assessing adequacy of the Company's disclosures in respect to share-based payments.</li> </ul>

### Information Other than the Financial Report and Auditor's Report Thereon

The Directors are responsible for the other information. The other information comprises the information included in the Group's annual report for the year ended 30 June 2017, but does not include the financial report and our auditor's report thereon. The annual report is expected to be made available to us after the date of this auditor's report.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

### Responsibilities of the Directors' 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* and for 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.

In preparing the financial report, the Directors are responsible for assessing the Group to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.



### **Auditor's Responsibilities for the Audit of the Financial Report**

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: [http://www.auasb.gov.au/auditors\\_files/ar1.pdf](http://www.auasb.gov.au/auditors_files/ar1.pdf). This description forms part of our auditor's report.

### **Report on the Remuneration Report**

#### **Opinion on the Remuneration Report**

We have audited the Remuneration Report included in pages 11 to 20 of the directors' report for the year ended 30 June 2017.

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Limited, for the year ended 30 June 2017, complies with section 300A of the *Corporations Act 2001*.

#### **Responsibilities**

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.

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

GRANT THORNTON AUDIT PTY LTD  
Chartered Accountants

A handwritten signature in blue ink that reads "B A Mackenzie".

B A Mackenzie  
Partner - Audit & Assurance

Melbourne, 30 August 2017



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 Clinuvell Pharmaceuticals Limited

In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of Clinuvell Pharmaceuticals Limited for the year ended 30 June 2017, I declare that, to the best of my knowledge and belief, there have been:

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

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

GRANT THORNTON AUDIT PTY LTD  
Chartered Accountants

A handwritten signature in blue ink that reads "B A Mackenzie".

B A Mackenzie  
Partner - Audit & Assurance

Melbourne, 30 August 2017

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

'Grant Thornton' refers to the brand under which the Grant Thornton member firms provide assurance, tax and advisory services to their clients and/or refers to one or more member firms, as the context requires. Grant Thornton Australia Ltd is a member firm of Grant Thornton International Ltd (GTIL). GTIL and the member firms are not a worldwide partnership. GTIL and each member firm is a separate legal entity. Services are delivered by the member firms. GTIL does not provide services to clients. GTIL and its member firms are not agents of, and do not obligate one another and are not liable for one another's acts or omissions. In the Australian context only, the use of the term 'Grant Thornton' may refer to Grant Thornton Australia Limited ABN 41 127 556 389 and its Australian subsidiaries and related entities. GTIL is not an Australian related entity to Grant Thornton Australia Limited.

# SHAREHOLDER INFORMATION AS AT 30 SEPTEMBER 2017

Additional information as at 30 September 2017 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	ORDINARY FULLY PAID SHARES	
		UNITS	% OF ISSUED CAPITAL
1-1,000	1,694	639,897	1.34
1,001-5,000	672	1,588,771	3.33
5,001-10,000	127	948,085	1.99
10,001-100,000	193	5,000,664	10.48
100,001-999,999,999	26	39,557,810	82.87
<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 \$ 6.73 per unit	75	256	4,706

### 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	5,255,680
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.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	15,655,597	32.80
2.	J P MORGAN NOMINEES AUSTRALIA LIMITED	9,765,177	20.46
3.	ACN 108 768 896 PTY LTD	3,655,298	7.66
4.	ENDER 1 LLC	2,590,824	5.43
5.	CITICORP NOMINEES PTY LIMITED	1,544,853	3.24
6.	DR MARK EDWIN BADCOCK	706,672	1.48
7.	M BADCOCK AND P CHU SUPERANNUATION FUND PTY LTD	621,302	1.30
8.	NATIONAL NOMINEES LIMITED <DB A/C>	596,911	1.25
9.	BNP PARIBAS NOMS PTY LTD <DRP>	589,429	1.23
10.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	557,128	1.17
11.	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	411,513	0.86
12.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <EUROCLEAR BANK SA NV A/C>	381,851	0.80
13.	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT DRP>	328,063	0.69
14.	HEADSTART GLOBAL HOLDINGS LTD	286,133	0.60
15.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	242,607	0.51
16.	MR DAVID WILLIAM TREVORROW	210,202	0.44
17.	MR DAVID JOHN LEWIS	200,000	0.42
18.	DR MICHAEL JAMES FISH	180,361	0.38
19.	DR CORINNE GINIFER	173,849	0.36
20.	RUSTY HAMMER PTY LTD <ARCHIPELAGO HOLDINGS SF A/C>	153,040	0.32
<b>TOTALS: TOP 20 HOLDERS OF ORDINARY FULLY PAID SHARES (TOTAL)</b>		<b>38,850,810</b>	<b>81.39</b>
<b>TOTAL REMAINING HOLDERS BALANCE</b>		<b>8,884,417</b>	<b>18.61</b>

**2. COMPANY SECRETARY**

The name of the Company Secretary is:  
Darren Keamy

**3. REGISTERED OFFICE**

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 2017: 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**

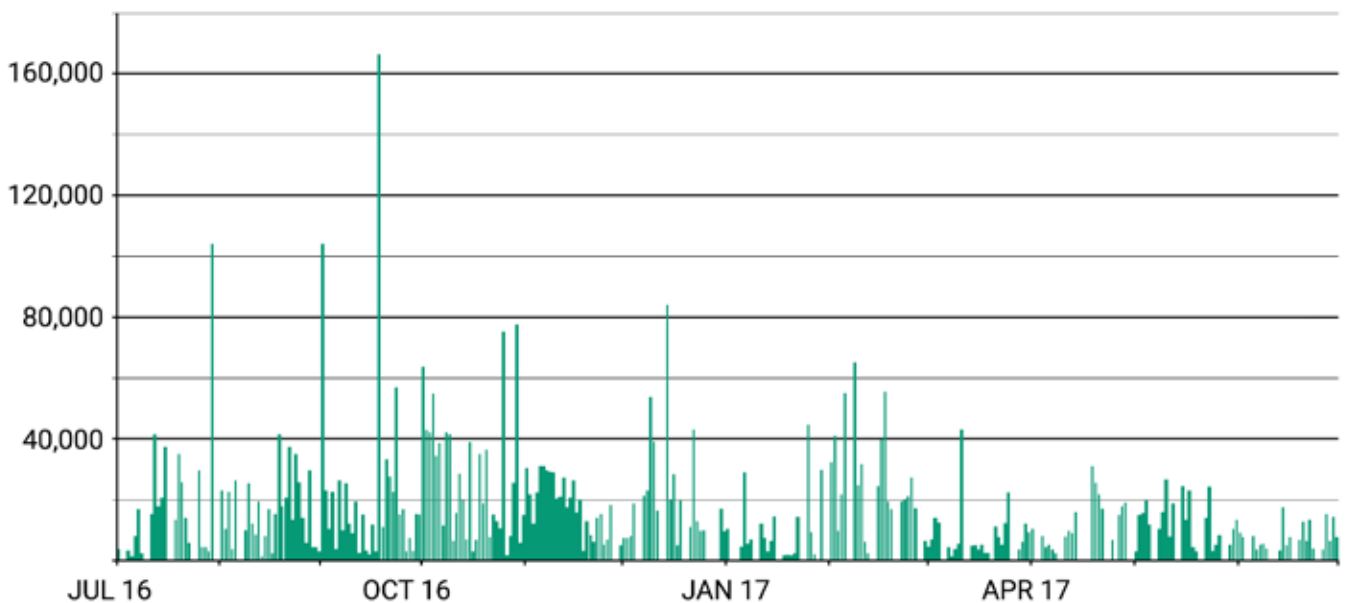
Dipl.-Ing Peter Farago  
Baadestr 3, Munich 80, Germany

# 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.



[www.clinuvel.com](http://www.clinuvel.com)

© CLINUVEL PHARMACEUTICALS LTD 2017

