

# APPENDIX 4E

## PRELIMINARY FINAL REPORT

### CLINUVEL PHARMACEUTICALS LTD

A.B.N 88 089 644 119

1.	Reporting period: 1 July 2017 to 30 June 2018.			
	Previous corresponding period: 1 July 2016 to 30 June 2017.			
2.	<b>Results for announcement to the market.</b>			
			<b>Percentage change to 2017</b>	<b>Amount (AUD)</b>
2.1	Revenues from ordinary activities.	Increased	52%	To 25,750,125
2.2	Profit from ordinary activities after tax attributable to members.	Profit has increased	86%	To 13,224,185
2.3	Net profit for the period attributable to members.	Profit has increased	86%	To 13,224,185
2.4	An unfranked final dividend of \$0.02 per ordinary share has been declared.			
2.5	Record date for determining entitlements for the final dividend: 24 September 2018			
2.6	Please see section 14 for a brief explanation of the figures reported above.			
3.	Refer to the Attachment to Appendix 4E for the Statement of Profit or Loss and Other Comprehensive Income together with notes to the statement.			
4.	Refer to the Attachment to Appendix 4E for the Statement of Financial Position together with notes to the statement.			
5.	Refer to the Attachment to Appendix 4E for the Statement of Cash Flows together with notes to the statement.			
6.	Refer to the Attachment to Appendix 4E for the Statement of Changes in Equity together with notes to the statement.			
7.	The Directors have declared an unfranked final dividend of \$0.02 per ordinary share to be paid on 24 September 2018.			
8.	No dividend reinvestment plan.			
9.	Net Tangible Assets per Security for Year Ended 30 June 2018: \$0.82.		Net Tangible Assets per Security for Year Ended 30 June 2017: \$0.53.	
10.	The control of entities which had control gained or lost: N/A.			
11.	N/A			
12.	No other significant information.			
	Foreign entities:			
	CLINUVEL, INC. (USA)			
	CLINUVEL (UK) LTD (UK)			
	CLINUVEL AG (Switzerland)			
	CLINUVEL SINGAPORE PTE LTD (Singapore)			
	VALLAURIX PTE LTD (Singapore)			
13.		Australian Accounting Standards used		

## 14. COMMENTARY OF RESULTS

### Overview

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 2017/18. These events included:

An announcement to the ASX on 21 December 2017 that the first draft assessment from England's National Institute for Health and Care Excellence (NICE) had been published, with SCENESSE® (afamelanotide 16mg) not recommended for reimbursement for the ultra-orphan disorder erythropoietic protoporphyria (EPP). NICE reviews novel medical technologies and makes recommendations for their use by the English National Health Service (NHS). NICE's review of SCENESSE® is by their Highly Specialised Technology (HST) Committee who provide recommendation on the use of new highly specialised medicines and treatments within the NHS in England. This announcement was subsequently followed up on 23 May 2018, whereby NICE published its draft Final Evaluation Document with the HST Committee maintaining its assessment that SCENESSE® did not meet its health-economic criteria for reimbursement under the English NHS for the treatment of EPP. CLINUVEL is currently appealing the decision taken by NICE.

On 29 January 2018 Dr Karen A Agersborg joined the Board of Directors of CLINUVEL. Dr Agersborg, a Board-Certified Endocrinologist in Pennsylvania, USA, currently serving as Clinical Endocrinologist at Reading Hospital, specialising in Endocrinology, Diabetes & Metabolism, followed the retirement of Mr Elie Ishag at the 2017 Annual General Meeting. Mr Ishag had served on the Board of CLINUVEL since February 2011. Dr Agersborg brings added scientific depth to the Board, complementing the existing skills set of the CLINUVEL Board.

On 16 March 2018 CLINUVEL conducted an expert meeting in Vienna, Austria with delegates from 12 countries and 21 expert centres, discussing the ongoing treatment of adult EPP patients with SCENESSE®. The first data on the ongoing safety and use of SCENESSE® in adult patients participating in the European EPP Disease Registry, conducted as part of the post-authorisation safety study (PASS) agreed by CLINUVEL with the European Medicines Agency (EMA), was presented and discussed. The safety profile of SCENESSE® remained unchanged, supported by data in two annual reports and in the periodic safety update reports submitted to the EMA, 61% of patients receiving SCENESSE® had been treatment naïve prior to participating in the PASS. 16% of patients sought treatment in the autumn and winter months. Overall, the expert treatment centres confirmed the monitoring and analysing of the safety profile of SCENESSE® comes with a high administrative burden.

On 25 June 2018 CLINUVEL announced that it had completed the submission of a New Drug Application (NDA) for

SCENESSE® as the first proposed therapy for patients with EPP in the United States. The submission undergoes a rigorous 60-day validation period before a decision is determined as to whether all aspects of the NDA is covered and the review clock commences. An approved NDA will allow CLINUVEL to make SCENESSE® available to adult EPP patients in the US as a first-line therapy. As part of the final NDA dossier, CLINUVEL submitted data and analyses from five clinical trials in EPP, data from Compassionate Use and Special Access Schemes, and data from the real-world experience of EPP patients receiving treatment in Europe. The data set consisted of nearly 6,700 doses in more than 800 patients. The data on the real-world experience, broadly incorporating the first 13 months from launch date of data provided by CLINUVEL to the EMA in its annual reporting under its marketing authorisation, had shown over 98% of patients on treatment request the drug for a second treatment year.

Further product development has occurred in the Singaporean operations of VALLAURIX PTE LTD. The innovation hub to the consolidated entity and an integral part of the longer-term growth plans of the Group, VALLAURIX has focussed on developing SCENESSE® ENFANCE, a formulation for paediatric EPP patients, along with non-prescriptive and prescriptive topical product lines considered complementary to SCENESSE®. For some of these formulations, final presentations and registrations are currently in process. On 1 May 2018 it was announced that CLINUVEL entered into an agreement to acquire the outstanding shares of VALLAURIX PTE LTD held by the minority shareholder, Biotech Lab Singapore Pte Ltd (BLS), for 33,559 CLINUVEL shares.

With CLINUVEL focussing its research and development on new product lines, on 20 February 2018 it unveiled an updated website and Group Values statement as part of a new corporate positioning.

Steady progress has been made in the vitiligo development program. Statistical analysis of the CUV103 exploratory study in Singapore continues, where 18 patients of four ethnicities suffering from generalised vitiligo were treated. The finalisation of this study will determine the preferred path forward in designing and proceeding with a larger clinical study in North America to treat generalised vitiligo with SCENESSE® as a combination therapy with narrowband ultraviolet B phototherapy. CLINUVEL maintains its existing strategy to move into conducting large scale clinical studies in vitiligo only when the US FDA approves the use of SCENESSE® in EPP.

### FINANCIAL COMMENTARY

#### Result of the Consolidated entity ('Group') and Balance Sheet

The Group result for the year ending 30 June 2018 was \$12.942 million profit before tax, compared to a \$7.114 million profit before tax for the prior financial year, an 82% increase. This is the highest before tax profit result in the Group's history and the first time the Group has achieved consecutive profits. The result reinforces the Group's primary strategic focus during the year to progress the commercial rollout of SCENESSE® in Europe and to charge a uniform price point to facilitate fair and equitable supply. Consistent to 2016/17 which experienced a 326% improvement in before tax profit, the growth in commercial revenues from the roll out of SCENESSE® within Europe was the primary reason for the improvement in profit for the current reporting period.

In striving to increase its net asset position, the balance sheet of the Group strengthened 55% during the reporting period, from \$25.444 million at 1 July 2017 to \$39.416 million at 30 June 2018. Current liabilities increased 10% to \$3.470 million whereas trade and other receivables increased 57% to \$5.090 million. The increase in net assets is largely due to the increase in revenues from commercial sales in Europe which saw the Group start with \$23.752 million in cash and financial assets held, and finish with \$36.198 million at 30 June 2018, a 52% increase. Due to the increase in cash reserves generated from operations, there was no debt or equity capital raised in 2017/18 or in 2016/17.

## Revenues

Commercial sales of SCENESSE® in Europe totalled \$21.359 million for 2017/18, compared to \$11.886 million for 2016/17. Unit sales increased 82% year on year, demonstrating the strong demand for the drug in Europe from the EPP patient population who have no other proven and effective therapy available to them. A significant component of this increase when compared to 2016/17 was the recognition of the first full 12 months of supply of SCENESSE® in Germany. Price remained constant in 2017/18, in line with CLINUVEL's policy to charge a uniform price for SCENESSE® across all European countries, including Switzerland. Whilst the increase in revenues was driven by volume upon a consistent and stable uniform price, almost 10% of the increase related to favourable exchange rate movements as a result of a weaker Australian dollar. However this balanced out 83% of the negative price impact to sales from a reduction to the uniform price of SCENESSE® which occurred late in the prior financial year, consequent to the agreement reached with the German National Association of Statutory Health Funds, announced April 2017.

The distribution of SCENESSE® under the Special Access Scheme continued to provide a preventative treatment for adult EPP patients in Switzerland. These reimbursement revenues decreased 15% to \$4.126 million for the 2017/18 year compared to \$4.834 million for the 2016/17 year. This was considered a good result for the Group, as 2017/18 saw the number of units supplied to Switzerland increase by 29% year-on-year. The decrease in reimbursement revenues when compared to the prior year was largely due to the supply of SCENESSE® to Italy for the first two months of 2016/17, a time of year where there is higher demand for SCENESSE®, recorded as special access supply under the Law 648/96 scheme. Since 31 August 2016 all supply of SCENESSE® to EPP expert centres in Italy is now recorded as commercial sales. SCENESSE® was also supplied in two other countries under special access arrangements whereby CLINUVEL received full cost compensation, linked to the uniform price of SCENESSE® sold in Europe under the marketing authorisation.

Included in revenues from ordinary activities is interest received from funds held in bank accounts and term deposits. For 2017/18, interest received was \$0.264 million, equivalent to 2016/17 (also \$0.264 million). The Group held on average 14% more cash in higher-yielding Australian dollar fixed rate term deposits compared to the prior year, but the average interest rate earned on these funds was on average 35 basis points lower year-on-year, reflecting the impact of Australian government monetary policy on term deposit rates on offer. The Group's policy to maintain lower-yielding foreign currencies to cover working capital requirements is reflected in this result. Funds held in non-Australian dollar currency providing a natural hedge against downward movement on the Australian dollar in 2017/18 was on average 67% higher

than in 2016/17. This contributed to the Group reporting a gain of \$0.424 million from holding non-Australian dollar currencies and in holding trade creditors in non-Australian currencies (a \$0.089 million loss for the same period last year) at 30 June 2018.

There is no Australian government refundable tax incentive for the 2017/18 year (\$0.045 million recorded for 2016/17). The absence of a refundable tax offset to be received reflects the Group's current 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.

## Expenditures

The Group maintained its focus on its expenditure mix as it has done throughout the SCENESSE® development program. Overall, total R&D and commercialisation expenditures accounted for 45% of the Group's total expense result for 2017/18, compared to 40% for the 2016/17 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 \$4.053 million in 2016/17, increasing 48% to \$5.985 million in 2017/18. The increase in these overall expenditures reflects the Group's focus throughout the year to further invest in its commercial rollout to secure revenues and to prepare an NDA regulatory submission that meets the FDA's expectations.

Since the granting of market authorisation by the EMA, the Group has focussed on its commercialisation activities in Europe and in its regulatory activities in the USA ahead of advancing its clinical trial program. In 2017/18 the Group concentrated its clinical study efforts on data management and analysis of the Singaporean Phase II clinical study in 18 vitiligo patients evaluating the use of SCENESSE® in a diverse patient group of differing skin types. This is reflected in the reduction in clinical study expenditures of 59% when compared to the prior year, from \$0.130 million in 2016/17 to \$0.054 million in 2017/18. This expense category also included some product development testing work in its VALLAURIX PTE LTD operations.

As set in the Group's objectives, ongoing investment in R&D continued in 2017/18. Expenses toward the drug formulation R&D, manufacture and distribution program increased by 102%, from \$0.857 million in 2016/17 to \$1.733 million in 2017/18. This increase is resultant of a combination of activities necessary to underpin the growth in sales volumes as part of the commercial rollout in Europe during 2017/18 and into future years, and also to support work to complete modules submitted to the FDA in parts under a rolling review. Major expense items included the expensing of inventoriable costs from increased sales units under the commercial distribution program and costs incurred with CLINUVEL's contract implant manufacturer, Evonik Industries, to maintain and optimise the existing manufacturing processes which included work to prepare and finalise key components for the NDA dossier. The increase in the cost of storing, special handling, packing and freighting SCENESSE® in Europe by contracted parties as a result of the increase in the number of sales units also impacted this result.

As part of CLINUVEL's longer term objectives, increasing the Research, Development & Commercial ('R,D&C') personnel headcount is considered an essential investment to drive the

new product development program in the fully owned subsidiary VALLAURIX PTE LTD and to support the growth in the commercial distribution program in Europe during 2017/18. An increased headcount in the Melbourne, UK and VALLAURIX offices of R,D&C personnel responsible for oversight and monitoring of various clinical, regulatory, manufacturing and post-marketing programs was a key driver behind the 25% increase in R,D&C overheads (from \$2.061 million in 2016/17 to \$2.576 million in 2017/18). Also in this expense group was an 81% year-on-year increase in royalty expenses paid to the implant contract manufacturer. Royalty fees are a function of sales volume and correlate to the movement in commercial sales.

Fees related to regulatory affairs for both pre- and post-marketing activities are directly related to the Group's strategic focus in the current year which is to meet its ongoing pharmacovigilance and risk minimisation commitments with the EMA and to finalise all modules forming the NDA submission in the US. These costs increased 61%, from \$1.005 million in 2016/17 to \$1.623 million in 2017/18. There were continuing costs attached to establishing and building on the regulatory infrastructure to support EPP patient access to SCENESSE® in Europe, in particular the use of third party experts to conduct detailed statistical analysis of the post-authorisation safety study (PASS) as part of CLINUVEL's regular reporting requirements to the EMA and the increased costs related to the PASS commitments. Additionally, when compared to 2016/17 there was a significant increase in costs associated with expert engagement for the Group to finalise its NDA submission, notably in the completion of datasets covering the real-world experience included in the final clinical module of the NDA.

Increases in a range of digital, online marketing and re-branding initiatives during 2017/18, along with an increase in expert meeting and conference sponsorships were the key reasons for the 30% increase in marketing and listing expenditures in the Group, from \$0.811 million in 2016/17 to \$1.051 million in 2017/18. The Group unveiled a new re-brand and identity to reflect both the Group's values and evolution as its focus on research and development pivots towards complementary product lines that will deliver innovative pharmaceutical solutions for complex problems.

The product development of the complementary and follow-on products within the VALLAURIX business required a significant increase to the Group fortifying its intellectual property position in relation to these advancements. This was a major reason for an increase to patent fees from \$0.220 million in 2016/17 to \$0.522 million in 2017/18, a 138% increase. Also contributing to this result were a number of established patents progressing through their relevant validation and their renewal phases, incurring higher national phase fees year-on-year. The Group considers the increase in patent fees to be an essential element to the business to build and to fortify its intellectual property position, supporting its ability to protect future potential revenue streams.

The result from general operations was \$5.735 million in 2017/18 compared to \$4.882 million in 2016/17, a 17% increase. General operations comprised 43% of the Group's total expense result for 2017/18 compared to 49% in 2016/17. Legal fees in connection to matters related to the marketing authorisation and in responding to negotiations with various payors in Europe contributed to the 18% increase in general operations year-on-year. The legal fees directly relate to the maintaining of an established reference price for SCENESSE® as part of its uniform pricing strategy. Included in this expense result was a one-off achievement of a €500,000 long term business generation cash incentive as part of the Managing Director's employment agreement and paid out during 2017/18. The business generation incentive has been a long-standing incentive within the Managing Director's employment agreement, aiming to reward the Managing Director for achieving exceptional business outcomes that contribute to creating corporate value and to motivate retention. The expensing of the accounting valuation of share-based payments (performance rights) was \$0.428 million in 2017/18, marginally higher than the 2016/17 result of \$0.395 million.

Consequent to the purchase by CLINUVEL of the shares held by the non-controlling interest in the VALLAURIX entity, the profit result for VALLAURIX is included in its entirety in the financial result of the Group. (2016/17: \$0.370 million loss whereby the non-controlling interest had a \$0.067 million share of the loss).

The Group has brought to account a deferred tax asset ("DTA") relating to previously unrecognised prior period tax losses, resulting in a credit to income tax expense of \$0.282 million.

### **Cash Flow**

Cash inflows in 2017/18 increased 52% compared to the first full year of commercial sales in 2016/17.

From a cash flow perspective, cash inflows from sales, reimbursements and interest received significantly outweighed the 40% increase in monthly operating average cash spend year-on-year, from \$0.736 million for 2016/17 to \$1.030 million for 2017/18. The increase in average monthly spend is due to a number of factors but primarily through an increase in product manufacturing process optimisation, the recruitment of additional personnel and specialist third-party costs associated with the preparation, finalisation of the NDA submission to the US FDA and remuneration-related expenditures.

### **Earnings per Share**

Growth in earnings per share is a goal of the Group and was achieved in 2017/18. At 30 June 2018 basic earnings per share were \$0.277 on 47,824,427 issued ordinary shares. This is compared to basic earnings per share of \$0.149 as at 30 June 2017 on 47,735,227 issued ordinary shares.

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## DIRECTORS' REPORT

The Directors of the Board present their report on the Company and its controlled entities ('Group') for the financial year ended 30 June 2018 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 – ceased Directorship 28 November 2017)
- Mr. W. A. Blijdorp (Non-Executive)
- Dr K. E. Agersborg (Non-Executive – joined 29 January 2018)

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 the Remuneration Committee (Chair until 28 November 2017)

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, becoming the most successful Australian life-sciences company.

Mr McLiesh has served in public roles and is currently 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) and overseeing the continuity and stability of the CLINUVEL Group.

#### 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 Group.

Under his leadership a long-term strategy for CLINUVEL was devised and the lead product SCENESSE® (afamelanotide 16mg) reformulated, its medical application identified, and European marketing authorisation ultimately obtained. 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 strategic support CLINUVEL enjoys globally.

He led CLINUVEL to attract more than AUD\$95 million in direct funding to develop and launch SCENESSE® and succeeded in guiding the Group 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 Group's product pipeline in various market segments. His focus has been to establish a professional management team to execute the corporate objectives set and to prepare the next generation of managers.

Dr Wolgen's long track record shows a strongly focussed, competitive and ethical professional who perseveres in meeting business objectives. He holds an MBA from Columbia University NY and the London Business School. Trained as a craniofacial surgeon, Dr Wolgen obtained his 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 listed companies Phoslock Water Solutions Ltd (ASX: PHK, since 2017) and Bell Financial Group (ASX: BFG, since 2012), Mrs Shanahan is also a non-executive director of DMP Asset Management, a director of the Kimberly Foundation of Australia Ltd, and Chair of 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. Until 2017, she was Chair of St Vincent's Medical Research Institute and also a non-executive director of Challenger Limited (ASX: CGF). Mrs Shanahan was also formerly 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 Group.

#### Mr. Elie Ishag (joined Board 2011 – ceased directorship 28 November 2017)

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 (FIoD) and has been a member of the IoD since 1964.

**Mr. Willem A. Blijdorp (joined Board 2015)**

Non-Executive Director

Member and Chair of the Remuneration Committee (Chair since 28 November 2017)

Member and Chair of the Nomination Committee (since 27 November 2016)

Shares in CLINUVEL: 1,743,118

Conditional Performance Rights over shares in CLINUVEL: 0

Mr Blijdorp 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 Blijdorp 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 Blijdorp now focuses on the Group’s development and expansion strategy as majority shareholder and supervisory director, overseeing the Group’s initial public offering on Euronext Amsterdam in March 2018.

In 2014 he was recognised for his expertise in merger and acquisitions and leadership as the Ernst & Young Entrepreneur of the Year in the Netherlands.

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

**Dr. Karen A. Agersborg (joined Board 2018)**

Non-Executive Director

**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	8	8	3	3	-	-	2	2
Mr. S.R. McLiesh	8	8	3	3	2	2	2	2
Dr. P.J. Wolgen	8	8	3	2	2	2	-	-
Mr. E. Ishag	4	3	-	-	-	-	-	-
Mr. W. Blijdorp	8	7	-	-	2	2	2	2
Dr. K. A. Agersborg	3	3	-	-	-	-	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.

Shares in CLINUVEL: 2,900

Conditional Performance Rights over shares in CLINUVEL: 0

Dr Agersborg is a Board-Certified Endocrinologist in Pennsylvania, USA, currently serving as Clinical Endocrinologist at Reading Hospital, specialising in Endocrinology, Diabetes & Metabolism. Dr Agersborg had previously worked at Suburban Hospital, Norristown and served as Chief, Endocrinology, Diabetes, Metabolism at Chestnut Hill Hospital.

Prior to obtaining a Doctorate of Osteopathic Medicine at the Philadelphia College of Osteopathic Medicine where she volunteers as Clinical Instructor and prior to completing her Fellowship at Temple University Hospital, Dr Agersborg had an extensive career in managing commercial sales & distribution at Wyeth Pharmaceuticals (formerly Ayerst Laboratories).

Dr Agersborg is a member of the American Osteopathic Association, Fellow of the American Association of Clinical Endocrinologists, and Fellow of the American College of Osteopathic Internists.

**INFORMATION ON COMPANY SECRETARY**

**Mr. Darren M. Keamy**

Company Secretary, Chief Financial Officer

Qualifications: BComm, CPA

Mr Keamy, a Certified Practicing Accountant, joined CLINUVEL in November 2005 and became Chief Financial Officer of the Group 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. He has overseen the financial management of the Group since 2005, played a role in raising AUD\$95 million in capital, and steered the Group throughout the Global Financial Crisis. The Group’s first profitability was achieved under his tenure.

Mr Keamy is currently completing a Graduate Diploma in Applied Corporate Governance with the Governance Institute of Australia.

## PRINCIPAL ACTIVITIES

The principal activities of the Group 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 light and 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. On 29 August 2018, the Board of Directors declared an unfranked dividend of \$0.02 per ordinary share in relation to the full year ended 30 June 2018.

## 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 uniform reimbursement structure for SCENESSE® in key European countries to facilitate post-authorisation supply. Pricing dossiers have been prepared at the country level for assessment and negotiations have been instituted with European payors and further progress to the commercial rollout of SCENESSE® in Europe has occurred. The Group has set its own objectives to surveil the safety aspect of

SCENESSE® as a first-in-class therapy, congruent to the objective of fulfilling the ongoing pharmacovigilance and risk minimisation measures that were agreed with the EMA upon authorisation and which deserved much attention during the year. Periodic safety update reports were submitted to the EMA, demonstrating no changes to the benefit-risk profile of the product and strong ongoing compliance to the risk minimisation measures.

A significant long-term objective of the Group was to arrive at a point where the scientific dossier could be filed with the US FDA given the lack of success by previous management. The Group therefore focussed on preparing a New Drug Application (NDA) submission under a rolling review basis as part of the US regulatory pathway for SCENESSE®. The rolling review enabled the Group to make its NDA submission in parts. The final module submitted in June 2018 included data and analyses from five clinical trials in EPP, data from Compassionate Use and Special Access Scheme, and data from the real-world experience of EPP patients receiving treatment in Europe. The R&D program in vitiligo remained on hold until the FDA would be able to review the scientific dossier of SCENESSE® in EPP.

The scientific focus of its Singaporean operations continued to be the development of complementary non-prescriptive products as well as follow-on prescriptive products, including a product for paediatric EPP patients, to address unmet medical needs in severe and genetic disorders. With an aim to simplify the business structure of the VALLAURIX PTE LTD joint venture and to have full operational control over the Group’s global activities, during the year the Group purchased the shares held by the minority-owned joint venture partner, Biotech Labs Singapore Pte Ltd.

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

Consolidated Entity	2018	2017	Change
	\$	\$	%
Revenues	25,750,125	16,984,536	52%
Net Profit/(Loss) before income tax expense	12,942,406	7,114,286	82%
Profit/(Loss) after income tax expense	13,224,185	7,114,286	86%
Basic earnings per share - cents per share	27.7	14.9	86%
Net tangible assets backing per ordinary share	\$0.820	\$0.533	54%
Dividends	Nil	Nil	Nil

Note: CLINUVEL does not operate individual segments.

## Result of the Consolidated entity (‘Group’) and Balance Sheet

The Group result for the year ending 30 June 2018 was \$12.942 million profit before tax, compared to a \$7.114 million profit before tax for the prior financial year, an 82% increase. This is the highest before tax profit result in the Group’s history and the first time the Group has achieved consecutive profits. The result reinforces the Group’s primary strategic focus during the year to progress the commercial rollout of SCENESSE® in Europe and to charge a uniform price point to facilitate fair and equitable supply. Consistent to 2016/17 which experienced a 326% improvement in before tax profit, the growth in commercial revenues from the roll out of SCENESSE® within Europe was the primary reason for the improvement in profit for the current reporting period.

In striving to increase its net asset position, the balance sheet of the Group strengthened 55% during the reporting period, from \$25.444 million at 1 July 2017 to \$39.416 million at 30 June 2018. Current

liabilities increased 10% to \$3.470 million whereas trade and other receivables increased 57% to \$5.090 million. The increase in net assets is largely due to the increase in revenues from commercial sales in Europe which saw the Group start with \$23.752 million in cash and financial assets held, and finish with \$36.198 million at 30 June 2018, a 52% increase. Due to the increase in cash reserves generated from operations, there was no debt or equity capital raised in 2017/18 or in 2016/17.

## Revenues

Commercial sales of SCENESSE® in Europe totalled \$21.359 million for 2017/18, compared to \$11.886 million for 2016/17. Unit sales increased 82% year on year, demonstrating the strong demand for the drug in Europe from the EPP patient population who have no other proven and effective therapy available to them. A significant component of this increase when compared to 2016/17 was the recognition of the first full 12 months of supply of SCENESSE® in Germany. Price remained constant in 2017/18, in line with CLINUVEL’s policy to charge a uniform price for SCENESSE® across

all European countries, including Switzerland. Whilst the increase in revenues was driven by volume upon a consistent and stable uniform price, almost 10% of the increase related to favourable exchange rate movements as a result of a weaker Australian dollar. However this balanced out 83% of the negative price impact to sales from a reduction to the uniform price of SCENESSE® which occurred late in the prior financial year, consequent to the agreement reached with the German National Association of Statutory Health Funds, announced April 2017.

The distribution of SCENESSE® under the Special Access Scheme continued to provide a preventative treatment for adult EPP patients in Switzerland. These reimbursement revenues decreased 15% to \$4.126 million for the 2017/18 year compared to \$4.834 million for the 2016/17 year. This was considered a good result for the Group, as 2017/18 saw the number of units supplied to Switzerland increase by 29% year-on-year. The decrease in reimbursement revenues when compared to the prior year was largely due to the supply of SCENESSE® to Italy for the first two months of 2016/17, a time of year where there is higher demand for SCENESSE®, recorded as special access supply under the Law 648/96 scheme. Since 31 August 2016 all supply of SCENESSE® to EPP expert centres in Italy is now recorded as commercial sales. SCENESSE® was also supplied in two other countries under special access arrangements whereby CLINUVEL received full cost compensation, linked to the uniform price of SCENESSE® sold in Europe under the marketing authorisation.

Included in revenues from ordinary activities is interest received from funds held in bank accounts and term deposits. For 2017/18, interest received was \$0.264 million, equivalent to 2016/17 (also \$0.264 million). The Group held on average 14% more cash in higher-yielding Australian dollar fixed rate term deposits compared to the prior year, but the average interest rate earned on these funds was on average 35 basis points lower year-on-year, reflecting the impact of Australian government monetary policy on term deposit rates on offer. The Group's policy to maintain lower-yielding foreign currencies to cover working capital requirements is reflected in this result. Funds held in non-Australian dollar currency providing a natural hedge against downward movement on the Australian dollar in 2017/18 was on average 67% higher than in 2016/17. This contributed to the Group reporting a gain of \$0.424 million from holding non-Australian dollar currencies and in holding trade creditors in non-Australian currencies (a \$0.089 million loss for the same period last year) at 30 June 2018.

There is no Australian government refundable tax incentive for the 2017/18 year (\$0.045 million recorded for 2016/17). The absence of a refundable tax offset to be received reflects the Group's current 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.

## Expenditures

The Group maintained its focus on its expenditure mix as it has done throughout the SCENESSE® development program. Overall, total R&D and commercialisation expenditures accounted for 45% of the Group's total expense result for 2017/18, compared to 40% for the 2016/17 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 \$4.053 million in 2016/17, increasing 48% to \$5.985 million in 2017/18. The increase in these overall expenditures reflects the Group's focus throughout the year to further invest in its commercial rollout to secure revenues and to prepare an NDA regulatory submission that meets the FDA's expectations.

Since the granting of market authorisation by the EMA, the Group has focussed on its commercialisation activities in Europe and in its regulatory activities in the USA ahead of advancing its clinical trial program. In 2017/18 the Group concentrated its clinical study efforts on data management and analysis of the Singaporean Phase II clinical study in 18 vitiligo patients evaluating the use of SCENESSE® in a diverse patient group of differing skin types. This is reflected in the reduction in clinical study expenditures of 59% when compared to the prior year, from \$0.130 million in 2016/17 to \$0.054 million in 2017/18. This expense category also included some product development testing work in its VALLAURIX PTE LTD operations.

As set in the Group's objectives, ongoing investment in R&D continued in 2017/18. Expenses toward the drug formulation R&D, manufacture and distribution program increased by 102%, from \$0.857 million in 2016/17 to \$1.733 million in 2017/18. This increase is resultant of a combination of activities necessary to underpin the growth in sales volumes as part of the commercial rollout in Europe during 2017/18 and into future years, and also to support work to complete modules submitted to the FDA in parts under a rolling review. Major expense items included the expensing of inventoriable costs from increased sales units under the commercial distribution program and costs incurred with CLINUVEL's contract implant manufacturer, Evonik Industries, to maintain and optimise the existing manufacturing processes which included work to prepare and finalise key components for the NDA dossier. The increase in the cost of storing, special handling, packing and freighting SCENESSE® in Europe by contracted parties as a result of the increase in the number of sales units also impacted this result.

As part of CLINUVEL's longer term objectives, increasing the Research, Development & Commercial ('R,D&C') personnel headcount is considered an essential investment to drive the new product development program in the fully owned subsidiary VALLAURIX PTE LTD and to support the growth in the commercial distribution program in Europe during 2017/18. An increased headcount in the Melbourne, UK and VALLAURIX offices of R,D&C personnel responsible for oversight and monitoring of various clinical, regulatory, manufacturing and post-marketing programs was a key driver behind the 25% increase in R,D&C overheads (from \$2.061 million in 2016/17 to \$2.576 million in 2017/18). Also in this expense group was an 81% year-on-year increase in royalty expenses paid to the implant contract manufacturer. Royalty fees are a function of sales volume and correlate to the movement in commercial sales.

Fees related to regulatory affairs for both pre- and post-marketing activities are directly related to the Group's strategic focus in the current year which is to meet its ongoing pharmacovigilance and risk minimisation commitments with the EMA and to finalise all modules forming the NDA submission in the US. These costs increased 61%, from \$1.005 million in 2016/17 to \$1.623 million in 2017/18. There were continuing costs attached to establishing and building on the regulatory infrastructure to support EPP patient access to SCENESSE® in Europe, in particular the use of third party experts to conduct detailed statistical analysis of the post-authorisation safety study (PASS) as part of CLINUVEL's regular reporting requirements to the EMA and the increased costs related to the PASS commitments. Additionally, when compared to 2016/17 there was a significant increase in costs associated with expert engagement for the Group to finalise its NDA submission, notably in the completion of datasets covering the real-world experience included in the final clinical module of the NDA.

Increases in a range of digital, online marketing and re-branding initiatives during 2017/18, along with an increase in expert meeting and conference sponsorships were the key reasons for the 30%

increase in marketing and listing expenditures in the Group, from \$0.811 million in 2016/17 to \$1.051 million in 2017/18. The Group unveiled a new re-brand and identity to reflect both the Group's values and evolution as its focus on research and development pivots towards complementary product lines that will deliver innovative pharmaceutical solutions for complex problems.

The product development of the complementary and follow-on products within the VALLAURIX business required a significant increase to the Group fortifying its intellectual property position in relation to these advancements. This was a major reason for an increase to patent fees from \$0.220 million in 2016/17 to \$0.522 million in 2017/18, a 138% increase. Also contributing to this result were a number of established patents progressing through their relevant validation and their renewal phases, incurring higher national phase fees year-on-year. The Group considers the increase in patent fees to be an essential element to the business to build and to fortify its intellectual property position, supporting its ability to protect future potential revenue streams.

The result from general operations was \$5.735 million in 2017/18 compared to \$4.882 million in 2016/17, a 17% increase. General operations comprised 43% of the Group's total expense result for 2017/18 compared to 49% in 2016/17. Legal fees in connection to matters related to the marketing authorisation and in responding to negotiations with various payors in Europe contributed to the 18% increase in general operations year-on-year. The legal fees directly relate to the maintaining of an established reference price for SCENESSE® as part of its uniform pricing strategy. Included in this expense result was a one-off achievement of a €500,000 long term business generation cash incentive as part of the Managing Director's employment agreement and paid out during 2017/18. The business generation incentive has been a long-standing incentive within the Managing Director's employment agreement, aiming to reward the Managing Director for achieving exceptional business outcomes that contribute to creating corporate value and to motivate retention. The expensing of the accounting valuation of share-based payments (performance rights) was \$0.428 million in 2017/18, marginally higher than the 2016/17 result of \$0.395 million.

Consequent to the purchase by CLINUVEL of the shares held by the non-controlling interest in the VALLAURIX entity, the profit result for VALLAURIX is included in its entirety in the financial result of the Group. (2016/17: \$0.370 million loss whereby the non-controlling interest had a \$0.067 million share of the loss).

The Group has brought to account a deferred tax asset ("DTA") relating to previously unrecognised prior period tax losses, resulting in a credit to income tax expense of \$0.282 million.

## Cash Flow

Cash inflows in 2017/18 increased 52% compared to the first full year of commercial sales in 2016/17.

From a cash flow perspective, cash inflows from sales, reimbursements and interest received significantly outweighed the 40% increase in monthly operating average cash spend year-on-year, from \$0.736 million for 2016/17 to \$1.030 million for 2017/18. The increase in average monthly spend is due to a number of factors but primarily through an increase in product manufacturing process optimisation, the recruitment of additional personnel and specialist third-party costs associated with the preparation, finalisation of the NDA submission to the US FDA and remuneration-related expenditures.

## Earnings per Share

Growth in earnings per share is a goal of the Group and was achieved in 2017/18. At 30 June 2018 basic earnings per share were \$0.277

on 47,824,427 issued ordinary shares. This is compared to basic earnings per share of \$0.149 as at 30 June 2017 on 47,735,227 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 2017/18. These events included:

An announcement to the ASX on 21 December 2017 that the first draft assessment from England's National Institute for Health and Care Excellence (NICE) had been published, with SCENESSE® (afamelanotide 16mg) not recommended for reimbursement for the ultra-orphan disorder erythropoietic protoporphyria (EPP). NICE reviews novel medical technologies and makes recommendations for their use by the English National Health Service (NHS). NICE's review of SCENESSE® is by their Highly Specialised Technology (HST) Committee who provide recommendation on the use of new highly specialised medicines and treatments within the NHS in England. This announcement was subsequently followed up on 23 May 2018, whereby NICE published its draft Final Evaluation Document with the HST Committee maintaining its assessment that SCENESSE® did not meet its health-economic criteria for reimbursement under the English NHS for the treatment of EPP. CLINUVEL is currently appealing the decision taken by NICE.

On 29 January 2018 Dr Karen A Agersborg joined the Board of Directors of CLINUVEL. Dr Agersborg, a Board-Certified Endocrinologist in Pennsylvania, USA, currently serving as Clinical Endocrinologist at Reading Hospital, specialising in Endocrinology, Diabetes & Metabolism, followed the retirement of Mr Elie Ishag at the 2017 Annual General Meeting. Mr Ishag had served on the Board of CLINUVEL since February 2011. Dr Agersborg brings added scientific depth to the Board, complementing the existing skills set of the CLINUVEL Board.

On 16 March 2018 CLINUVEL conducted an expert meeting in Vienna, Austria with delegates from 12 countries and 21 expert centres, discussing the ongoing treatment of adult EPP patients with SCENESSE®. The first data on the ongoing safety and use of SCENESSE® in adult patients participating in the European EPP Disease Registry, conducted as part of the post-authorisation safety study (PASS) agreed by CLINUVEL with the European Medicines Agency (EMA), was presented and discussed. The safety profile of SCENESSE® remained unchanged, supported by data in two annual reports and in the periodic safety update reports submitted to the EMA, 61% of patients receiving SCENESSE® had been treatment naïve prior to participating in the PASS. 16% of patients sought treatment in the autumn and winter months. Overall, the expert treatment centres confirmed the monitoring and analysing of the safety profile of SCENESSE® comes with a high administrative burden.

On 25 June 2018 CLINUVEL announced that it had completed the submission of a New Drug Application (NDA) for SCENESSE® as the first proposed therapy for patients with EPP in the United States. The submission undergoes a rigorous 60-day validation period before a decision is determined as to whether all aspects of the NDA is covered and the review clock commences. An approved NDA will allow CLINUVEL to make SCENESSE® available to adult EPP

patients in the US as a first-line therapy. As part of the final NDA dossier, CLINUVEL submitted data and analyses from five clinical trials in EPP, data from Compassionate Use and Special Access Schemes, and data from the real-world experience of EPP patients receiving treatment in Europe. The data set consisted of nearly 6,700 doses in more than 800 patients. The data on the real-world experience, broadly incorporating the first 13 months from launch date of data provided by CLINUVEL to the EMA in its annual reporting under its marketing authorisation, had shown over 98% of patients on treatment request the drug for a second treatment year.

Further product development has occurred in the Singaporean operations of VALLAURIX PTE LTD. The innovation hub to the consolidated entity and an integral part of the longer-term growth plans of the Group, VALLAURIX has focussed on developing SCENESSE® ENFANCE, a formulation for paediatric EPP patients, along with non-prescriptive and prescriptive topical product lines considered complementary to SCENESSE®. For some of these formulations, final presentations and registrations are currently in process. On 1 May 2018 it was announced that CLINUVEL entered into an agreement to acquire the outstanding shares of VALLAURIX PTE LTD held by the minority shareholder, Biotech Lab Singapore Pte Ltd (BLS), for 33,559 CLINUVEL shares.

With CLINUVEL focussing its research and development on new product lines, on 20 February 2018 it unveiled an updated website and Group Values statement as part of a new corporate positioning.

Steady progress has been made in the vitiligo development program. Statistical analysis of the CUV103 exploratory study in Singapore continues, where 18 patients of four ethnicities suffering from generalised vitiligo were treated. The finalisation of this study will determine the preferred path forward in designing and proceeding with a larger clinical study in North America to treat generalised vitiligo with SCENESSE® as a combination therapy with narrowband ultraviolet B phototherapy. CLINUVEL maintains its existing strategy to move into conducting large scale clinical studies in vitiligo only when the US FDA approves the use of SCENESSE® in EPP.

## 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 Group.

## 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 Group, other than:

- On 29 August 2018, the Board of Directors declared an unfranked dividend of \$0.02 per ordinary share.

## LIKELY DEVELOPMENTS AND EXPECTED RESULTS

The Group's strategy is to focus on developing and commercialising SCENESSE® as a solution to offer medicinal photoprotection for patients with EPP and who are most severely affected by exposure to ambient and UV light. Further, the Group's strategy is to develop and commercialise SCENESSE® as a combination therapy with narrowband ultraviolet B (NB-UVB) 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 Group's knowledge in photoprotection and repigmentation.

In June 2016 the Group launched SCENESSE® in Europe. As part of the conditions attached to the granting of marketing authorisation,

the Group has been committed to establishing and maintaining a number of significant post-authorisation commitments which have been agreed with and under supervision by the EMA under a long-term risk management plan for SCENESSE®. The Group has been using a number of third parties to support the European EPP Disease Registry to monitor long-term safety and it will continue to invest in existing and new personnel with the appropriate skills and expertise to maintain the ongoing requirements of the post-authorisation program in Europe. The Group has established a reference price for SCENESSE® as part of its uniform pricing strategy and has entered into pricing agreements with several European countries, state and private insurance groups. The Group has increased its distribution-focused workforce in Europe to support the increase in product volumes 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 Group continues to work towards gaining regulatory approval for SCENESSE® for EPP patients in other important markets where EPP is prevalent, including North America, in order to increase its ability to provide EPP patients with access to SCENESSE®.

The Group 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 studies evaluating efficacy and/or safety of SCENESSE® in combination with NB-UVB should result in the Group moving towards later stage clinical trials. The focus on progressing the development of SCENESSE® in vitiligo in the US is dependent upon the US regulator approving the use of SCENESSE® in EPP.

The Group has also focused on its manufacturing requirements by working with its sole 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 for manufacturing the commercial drug product.

The Group, 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 the prior reporting period, the Group 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 objectives of the Group is to achieve and maintain a sustainable profit. Key to longer term 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 Group's achievement of the business goals detailed above. This list is not exhaustive.

- Technology – there is a risk that despite obtaining marketing authorisations, 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, that the manufacturing process may encounter process issues not previously identified and controlled, and of non-controllable disruptions to the operations of 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 Group's product portfolio that will prevent competitors from entering the marketplace to compete with the Group's approved products. Also, competitors infringing the Group's IP rights may adversely impact the Group'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 Group 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 Group's corporate strategy could be impacted adversely if the Group was not able to retain its specialized knowledge and areas of expertise, key management, members of staff and or Board.

## ENVIRONMENTAL REGULATION AND PERFORMANCE

The Group'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 Group 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 Group 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 Group, other than conduct involving wilful breach of duty in relation to the Group. 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 20 to the financial statements.

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## 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 2018.

Key Management Personnel has the meaning given in the Australian Corporations Act and includes all Directors (including Non-Executive) who held their positions throughout the past two financial years and other Key Management Personnel who together have the authority and responsibility for planning, directing and controlling the activities of the Group, being:

- Dr. D.J. Wright (Acting Chief Scientific Officer)
- Mr. D.M. Keamy (Chief Financial Officer and Company Secretary)

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The remuneration report is set out under the following main headings:

- A. Introduction by the Chair of the Remuneration Committee
- B. Principles used to determine the nature and amount of remuneration
- C. Details of remuneration
- D. Service agreements
- E. Share based compensation
- F. Additional information – Remuneration
- G. Additional disclosure – Company Performance

### A. INTRODUCTION BY THE CHAIR OF THE REMUNERATION COMMITTEE

**Chairman of the Remuneration Committee: Mr Willem Blijdorp**

*"I regard my duties as Chairman of the Remuneration Committee as paramount to the wellbeing and longevity of the CLINUVEL group. From the current position of the Company it is imperative for me and my fellow Board members to look ahead and plan for the next few years for the Company to grow and thrive further.*

*In providing the objectives of the Remuneration Committee and its approach to executive remuneration, I briefly share my professional background and outlook which has taken me where I am professionally today.*

*As Chair of the Dutch-publicly listed B&S International, a global leader in trading and logistics, I am used to operating in markets which are often tested by changing legislation, new tariffs and where pressure on pricing is experienced. To navigate these challenges, I have always chosen the most successful leadership teams based on a set of fixed criteria. In my opinion, company executives need to demonstrate strong leadership skills, have an ability to roll up their sleeves, and be able to articulate to the Board of Directors periodically their realistic vision for the company for the years ahead.*

*Above all, I regard the success of a company as a direct reflection of the intelligence, insistence and integrity of the management teams. In this sense, the key management personnel and the company executives can make or break a company, seldom its services or products, and it is the daily quality of the managerial decisions made by the top people at the helm which matter, nothing less in my books.*

*In addition, I want to see in the executive management in all companies with which I involve myself to have a sizable ownership by executive management – in cases up to 20% – to make sure that their objectives are aligned with the 80% owned by other shareholders. This approach has provided me and my shareholders the success I enjoy today, and as Chairman of the Remuneration Committee I am supporting the same criterion when it comes to CLINUVEL's leadership team.*

*In line with the objectives set by CLINUVEL's Board of Directors, the task of the Remuneration Committee, as explained in greater detail in this Remuneration Report is to:*

1. secure the services of excellent management;
2. align the key performance indicators of executive management with those objectives set for the group of companies;
3. evaluate the performance of executive management against
  - a) internal performance criterion;
  - b) international benchmarks in context of this sector;
4. strive for business continuation and sustainability through retention of staff.

*I use this very approach also to assess the attitude and performance of the CLINUVEL key management personnel and its company executives with an eye to grow the Group in the coming period. In July 2018, I invested significant sums of my own capital in CLINUVEL, I have a clear interest to continue the success story of this biotechnology venture.*

*In all the conglomerate of business enterprises I lead, my motto has remained simple: "people work for people", and this holds true for Dr Wolgen and the team around him. In order to succeed in markets where great challenges are expected and met, you need in business execution what I call "eccentric leadership". In Dr Wolgen we have this and it needs to continue for another three years, through to 2021, to meet all CLINUVEL's*



*objectives. While I am certain others could do the job, in my position as Head of the Remuneration Committee, I wish to see continuity for the next term, focus to be sustained, meaning zero distraction from the end game.*

*What is said about the CEO also goes for the steady and reliable financial management by the CFO in overseeing the Group of six companies globally and containing the Company's management of costs. The profitability of CLINUVEL is largely owed to the work of Mr Keamy, hence our strong wish to prolong the CFO-CEO axis.*

*Lastly, we have agreed that the Acting CSO, Dr Wright, will remain as key management personnel while training and providing a basis for succession planning of the next generation of scientific management.*

*Overall, as Chair of the Remuneration Committee I make a periodic assessment of the operations of the Group. In this sense, I do wish to see continuation and no disruption to the CLINUVEL business to maintain enterprise value at a time where the US market beckons, European distribution grows, new products advance, and the growth of managerial talent is taking place under the leadership of the Managing Director.*

*Since initially attending a CLINUVEL shareholder meeting in Melbourne in early 2006 I have witnessed – first from distance, and since 2015 as a Board member – how this Company has plotted and manoeuvred around buoys along its voyage.*

*At multiple cross-roads the Board of Directors has had the choice to intervene or take a more passive attitude towards top management when it came to decisions such as opting to license out the lead technology, sell it off early, or retain it to develop it to today's success. Other key decisions involved, for example, the financial management of the Group, whether to make larger investments in R&D, pursue multiple indications at the same time with one or several technologies, and raise more capital. As a Non-Executive Board member I have an advisory role but am personally more in favour of steadily building the Company and staying in control of our own destiny. While I try to share my strategic vision with current management of CLINUVEL I stay away from imposing too strong views, however I am extremely content with the way we perform.*

*The quality of CLINUVEL's decisions rested on the depth of analyses of the executive management teams giving me and my fellow Board members the confidence that CLINUVEL would navigate and sail around obstacles to make the Company profitable and sustainable. This is the place where we are today.*

*As Chair of the Remuneration Committee I focus on corporate results and the Company's ability to meet the short- and mid-term objectives that are within management's reach.*

*The short-term objectives are found in the key performance indicators (KPIs) set for all personnel, and in more specific terms in those of the other executive Key Management Personnel including the CEO. Several of these KPI's are commercially confidential in nature in an attempt to stay ahead of possible competitors, other indicators are more tailored to general business objectives. The mid-term objectives are directly related to the Group's objectives to achieve profitability and sustainability, and are captured in Business Generation Incentives.*

*In my view, the current successes of CLINUVEL are assigned to the vision, leadership and execution of the current management team headed by our CEO and CFO who are responsible for the financial discipline which has led to today's profitability.*

*The Company's mid-term vision is found back in its "2020 CUV Strategy" explained in the 2017 AGM presentation and it provides this Committee with a framework for the corporate objectives for the foreseeable future. Accordingly, these objectives are reflected in the remuneration packages of the Managing Director, CFO, Acting CSO and in the future of other executive Key Management Personnel to be recruited.*

*In arriving at the executive remuneration packages, we strive to provide overall incentives that secure continuation and no disruption of the business at this critical stage of CLINUVEL. The Committee assesses the criticality of CLINUVEL's business operations based on the following corporate milestones:*

1. *US regulatory clearance for SCENESSE®*
2. *US market entry & distribution of SCENESSE®*
3. *Continuing successful distribution of SCENESSE® throughout the Europe Union*
4. *Establishing a European business unit by March 2019 (post-Brexit)*
5. *New product development of*
  - a) *VLRX001, CUV9900*
  - b) *complementary OTC*
6. *Expansion of the CLINUVEL Group.*

*As the Chair of the Board of Directors Mr McLiesh stated earlier this year in his 'Chair Letter', our immediate task is to finalise a new employment agreement with the Managing Director. I hope to be able to report on these agreements by the end of this calendar year.*

*Herewith, I recommend CLINUVEL's shareholders the remuneration incentives offered to the key management personnel."*

## **B. 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 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 payments in the form of performance-based incentives awarded 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 into account 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 of 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 2018, 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 2017 Annual General Meeting (AGM), the Company obtained 98.44% of the proxy votes (including votes at the Board's discretion) in favour of adopting the 2016/17 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.

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## **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 2018 was \$320,750.

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):

<b>BOARD FEES</b>		<b>\$</b>
<b>Base – Chair *</b>		<b>110,000</b>
<b>Base – Non-chair</b>		<b>65,000</b>
<b>COMMITTEE FEES</b>		
<b>Audit &amp; Risk</b>	Chair	15,000
	Member	5,000 *
<b>Remuneration</b>	Chair	15,000 *
	Member	5,000
<b>Nomination</b>	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 “E – Share-Based Remuneration” in this Remuneration Report for further information.

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## 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; and
- 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 (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 it’s specialised and narrow focus on developing and commercialising a novel, first-in-class and first-in-line therapies 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 Group.

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 2017/18 year, the Managing Director's base salary was \$818,348, an increase of 4% to the 2016/17 year (\$786,717). Of the 4% increase, 1.1% is attributable to exchange rate movements.

Base pay is reviewed annually and generally adjusted to consider changes in CPI. Base salary for the Managing Director was adjusted 2.9% on 1 July 2017. 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 2017/18 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 2017/18 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, with an emphasis on the US;
- Financial management and corporate affairs; and
- 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 2017/18 financial year the Remuneration Committee evaluated the performance of the Managing Director and the Board approved a short-term incentive of 56.7% to base salary. This compares to a short-term incentive of 64.5% 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 consolidation of a uniform distribution structure for SCENESSE® across key European reference countries at reasonable and satisfactory terms, maintaining a consistent and uniform pricing policy, underpinning greater access to EPP patients and resulting in a material increase in commercial revenue; and
- the first ever filing of a New Drug Application submission to the US FDA under a rolling review basis as part of the US regulatory pathway for SCENESSE®.

### **Long-Term Incentive – Business Generation 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 at rewarding 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. They remain current within the term of the Managing Director's employment agreement or within six months from cessation or termination.

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.

The Managing Director achieved a business generation incentive in 2017/18. He received €500,000 upon the Company receiving an accumulated financial benefit in excess of €10,000,000 from self-distribution.

### **Long-Term Incentive – Share-Based Remuneration**

The Managing Director is provided with long-term equity remuneration via the CLINUVEL Conditional Rights Plan. See section "E – 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;

- Longer-term business generation incentive payments through the achievement of pre-specified performance-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 2017.

#### **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 2017/18, 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: 9%
- Chief Financial Officer: 14%

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 2017/18, 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: 75%
- Chief Financial Officer: 87%

#### **Long-Term Incentive – Business Generation Incentive**

During 2017/18, business generation incentives were introduced to the remuneration package for the Chief Financial Officer. These longer-term incentives must be achieved before 30 June 2019 and are linked to the Company achieving exceptional business outcomes that contribute to creating corporate value and to act as a key retention tool. The business generation incentives are \$60,000 for each incentive and are linked to successful listing of the Company on an overseas exchange and expansion of the Company through acquisition with demonstrated positive cash flows of the acquired entity post-acquisition.

#### **Long Term Incentive – Share-Based Remuneration**

The Other Executive Key Management Personnel are provided with long-term equity remuneration via the CLINUVEL Conditional Rights Plan. See section "E – Share-Based Remuneration" in this Remuneration Report for further information.

## C. DETAILS OF REMUNERATION

## KEY MANAGEMENT PERSONNEL REMUNERATION OF THE COMPANY FOR THE YEARS ENDING 30 JUNE 2018 &amp; 30 JUNE 2017

	Year	Gross Salary	Short Term Incentive	Business Generation Incentive	Post-employment benefits		Share-based payments (accounting charge only) <sup>2</sup>	Total
					Other <sup>1</sup>	Super-annuation/Pension Fund	Performance Rights	
		\$	\$		\$	\$	\$	\$
Dr. P.J. Wolgen	2018	818,348	464,033	762,394	36,405	-	207,097	2,288,277
	2017	786,717	508,058	-	26,205	-	265,103	1,586,083
Mr. S.R. McLiesh	2018	100,457	-	-	-	9,543	8,041	118,041
	2017	100,457	-	-	-	9,543	10,229	120,229
Mrs. B.M. Shanahan	2018	73,059	-	-	-	6,941	8,041	88,041
	2017	73,059	-	-	-	6,941	10,229	90,229
Mr. E. Ishag	2018	29,166	-	-	-	-	2,816	31,982
	2017	70,000	-	-	-	-	7,161	77,161
Mr. W.A. Blijdorp	2018	73,750	-	-	-	-	-	73,750
	2017	65,000	-	-	-	-	-	65,000
Dr. K.A. Agersborg	2018	27,833	-	-	-	-	-	27,833
	2017	-	-	-	-	-	-	-
<b>Other Key Management Personnel</b>								
Dr. D.J. Wright	2018	244,959	16,535	-	-	20,049	16,664	298,207
	2017	238,056	5,952	-	-	19,616	10,120	273,744
Mr. D.M. Keamy	2018	246,922	30,124	-	-	20,049	53,086	350,181
	2017	229,694	22,570	-	-	19,616	30,384	302,264
<b>Total</b>	2018	<b>1,614,494</b>	<b>510,692</b>	<b>762,394</b>	<b>36,405</b>	<b>56,582</b>	<b>295,745</b>	<b>3,276,312</b>
	2017	<b>1,562,983</b>	<b>536,580</b>	<b>-</b>	<b>26,205</b>	<b>55,716</b>	<b>333,226</b>	<b>2,514,710</b>

<sup>1</sup> 'Other' includes health insurance, housing 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.

## THE RELATIVE PROPORTIONS OF REMUNERATION BETWEEN FIXED AND BASED ON PERFORMANCE FOR THE YEARS ENDING 30 JUNE 2018 AND 30 JUNE 2017

	2018		2017	
	Fixed Remuneration	Performance Based	Fixed Remuneration	Performance Based
Dr. P.J. Wolgen	37%	63%	51%	49%
Dr. D.J. Wright	89%	11%	94%	6%
Mr. D.M. Keamy	76%	24%	82%	18%

#### D. 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 Conditional 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

#### E. SHARE-BASED REMUNERATION

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

##### Long-term Incentive – Managing Director & Other Executive Key Management Personnel

The Group’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 being 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 Group, which averaged less than 25 in total during the course of 2016/17 and 27 for the course of 2017/18, 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 Group.

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). All future issues of performance rights will be made under the 2014 Plan.

##### Performance Rights:

All performance rights that have been issued fall under two performance rights plans:

- a) the CLINUVEL Conditional Performance Rights Plan (2009); and
- b) the CLINUVEL Performance Rights Plan (2014).

815,987 performance rights issued under the 2009 Plan remain unvested as at 30 June 2018 and 934,573 performance rights issued under the 2014 Plan remain unvested at 30 June 2018.

- 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 Group 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 seven years.

The eligible employee can request for shares to be transferred from the Scheme Trust after seven 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 Group 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 seven 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 seven 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>Executive Key Management Personnel</b></p> <ul style="list-style-type: none"> <li>• The Remuneration Committee assesses and recommends to the Board the quantum of performance rights amounts based on:</li> <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 Group</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>Directors</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 2017/18 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 Group 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>	<ul style="list-style-type: none"> <li>A. Upon submission of a dossier to the US FDA applying for market approval of SCENESSE®</li> <li>B. Granting market approval for SCENESSE® by the US FDA (not attached to Non-Executive Directors)</li> <li>C. Securing sufficient funding to secure 5 performance conditions (including the performance sufficient condition ‘Granting market approval for SCENESSE® by the US FDA’) (not attached to Non- Executive Directors)</li> <li>D. Announcement of commercial partnership to distribute SCENESSE® (or derivative of) (not attached to Managing Director)</li> <li>E. The earlier of: (a) second molecule in new formulation, or (b paediatric formulation for afamelanotide (Other Executive Key Management Personnel and staff only)</li> <li>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, this performance condition was achieved in 2017/18)</li> </ul>
<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 years ended 30 June 2018 and 30 June 2017.

No new performance rights were granted to Executive Directors or Other Executive Key Management Personnel for the years ended 30 June 2018 and 30 June 2017.

**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	-
CLINUVEL	4,500	\$4.20	Ordinary	05/09/2017	-
CLINUVEL	5,500	\$4.20	Ordinary	05/09/2017	-

**REMUNERATION PERFORMANCE RIGHTS HOLDINGS OF KEY MANAGEMENT PERSONNEL – 2018**

	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	42,500	-	-	(42,500)	-	-	-
Mr. S.R. McLiesh	65,000	-	-	-	65,000	-	65,000
Mrs. B.M. Shanahan	50,000	-	-	-	50,000	-	50,000
Dr. P.J. Wolgen	924,974	-	-	-	924,974	-	924,974
Mr. W.A. Blijdorp	-	-	-	-	-	-	-
Dr. K.A. Agersborg	-	-	-	-	-	-	-
<b>Executives</b>							
Dr. D.J. Wright	120,125	-	(8,000)	-	112,125	-	112,125
Mr. D.M. Keamy	212,760	-	(26,000)	-	186,760	-	186,760

**SHARES HELD BY KEY MANAGEMENT PERSONNEL**

The number of ordinary shares in the Company during the 2018 reporting period held by each of the Group's Key Management Personnel, including their related parties, is set out below:

<b>Year Ending 30 June 2018</b>					
Personnel	Balance at Start of Year	Granted as Remuneration	Received on Exercise	Other Changes	Held at the End of Reporting Period
Mr. E. Ishag	162,195	-	-	-	162,195
Mr. S.R. McLiesh	162,774	-	-	-	162,774
Mrs. B.M. Shanahan	153,969	-	-	-	153,969
Dr. P.J. Wolgen	2,579,722	-	-	-	2,579,722
Mr. W.A. Blijdorp	383,145	-	-	-	383,145
Dr. K.A. Agersborg	-	-	-	2,900	2,900
Dr. D.J. Wright	244,874	-	8,000	-	252,874
Mr. D.M. Keamy	192,400	-	26,000	-	218,400

**F. 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, excepting the Business Generation Incentive which is paid in the year of achievement.

**REMUNERATION DETAILS OF CASH INCENTIVES AND RIGHTS**

Incentives				Performance Rights						
		Paid	Forfeited	Year Granted	Type	Vested	Forfeited	Latest Year for Vesting	Min Grant Value Yet to Vest (\$)	Max Grant Value Yet to Vest (\$)
Dr. P.J. Wolgen	STI	57%	43%							
	BGI	100%	0%							
				2010/11	Rights	0%	0%	No limitation	-	312,001
				2014/15	Rights	0%	0%	2021/22	-	1,619,935
Mr. S.R. McLiesh		0%	0%							
				2011/12	Rights	0%	0%	No limitation	-	26,690
				2014/15	Rights	0%	0%	2021/22	-	64,800
Mrs. B.M. Shanahan		0%	0%							
				2011/12	Rights	0%	0%	No limitation	-	16,682
				2014/15	Rights	0%	0%	2021/22	-	64,800
Mr. E. Ishag		0%	0%							
				2011/12	Rights	0%	100%	No limitation	-	-
				2014/15	Rights	0%	100%	2021/22	-	-
Mr. W.A. Blijdorp		0%	0%	-	-	-	-	-	-	-
Dr. K.A. Agersborg		0%	0%	-	-	-	-	-	-	-
Dr. D.J. Wright		75%	25%							
				2011/12	Rights	0%	0%	No limitation	-	42,819
				2012/13	Rights	0%	0%	No limitation	-	29,700
				2014/15	Rights	25%	0%	2021/22	-	51,840
Mr. D.M. Keamy		87%	13%							
				2011/12	Rights	0%	0%	No limitation	-	58,334
				2012/13	Rights	0%	0%	No limitation	-	29,700
				2014/15	Rights	25%	0%	2021/22	-	168,480

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 2018 and 30 June 2017.

## G. ADDITIONAL DISCLOSURE – COMPANY PERFORMANCE OF CLINUVEL PHARMACEUTICALS LTD AND CONTROLLED ENTITIES

The Group has been solely dedicated to the research, development and commercialisation of its unique and medically beneficial technology. The remuneration and incentive framework, which has been put in place by the Board, has ensured executive personnel are focussed on both maximising short-term operating performance and long-term strategic growth to promote shareholder value. The focus on growth in shareholder 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 and is commonly expected in other market segments. In recent years the Board has recognised that non-financial performance measures have been a key link to driving share price performance and this has been reflected in the performance conditions attached to the long-term equity incentives.

The table below shows the progress made in moving through the clinical pathway and into the commercialisation pathway, reflecting the performance of executive management. The table also links to share price performance.

Regulatory, Clinical & Commercial Milestones	Year Ending 30 June				
	2014	2015	2016	2017	2018
Ph II Vitiligo Study - Singapore					
Orphan Drug Designation HHD- EUR&USA	★				
Application for marketing authorisation submitted with EMA					
VALLAURIX PTE LTD – formulation & melanocortin development					
Post-marketing authorisation commitments					
First commercial sales					
Application for marketing authorisation submitted with FDA					
Market capitalisation (A\$ million)	72	127	203	333	527
Share Price High (\$)	2.00	5.10	5.00	9.19	13.52
Share Price Low (\$)	0.92	1.30	2.50	4.10	5.91
Closing Share Price (\$)	1.70	2.84	4.32	6.98	11.01
Change in Share Price over 1 Year (%)	(6)	67	57	62	58
Change in Share Price over 3 Years (%)	3	74	139	311	288

### 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	89,200	Nil\$	Ordinary

<sup>1</sup>These shares were issued by the Group during the year after performance conditions attached to the rights were considered met. Those shares issued by the Group to Directors and Employees are held for retention in the Scheme Trust. Shares issued by the Group 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	103,500	Nil\$	Ordinary

<sup>1</sup>These shares were issued by the Scheme Trustee to departing employees who resigned from the Group 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	649,975	\$Nil	Ordinary	28 November 2021
CLINUVEL PHARMACEUTICALS LTD	254,100	\$Nil	Ordinary	17 March 2022
CLINUVEL PHARMACEUTICALS LTD	5,500	\$Nil	Ordinary	5 September 2024
	<b>1,750,560</b>	-	-	-

**NON-AUDIT SERVICES**

For the years ended 30 June 2018 and 30 June 2017, Grant Thornton Australia only provided audit services to the Company.

**AUDITOR'S INDEPENDENCE DECLARATION**

The auditor's independence declaration as required by s.307C of the Corporations Act 2001 is included and forms part of this 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 29th day of August, 2018

## STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2018

	Note	Consolidated Entity	
		2018	2017
		\$	\$
Total revenues	2	25,750,125	16,984,536
Other income	2	485,838	185,168
Total expenses	2	(13,293,557)	(10,055,418)
Profit/(loss) before income tax expense		12,942,406	7,114,286
Income tax (expense)/benefit	3(a)	281,779	-
Profit/(loss) after income tax expense		13,224,185	7,114,286
<b>Net profit/(loss) for the year</b>		<b>13,224,185</b>	<b>7,114,286</b>
<b>Other comprehensive income</b>			
<i>Items that may be re-classified subsequently to profit or loss</i>			
Exchange differences of foreign exchange translation of foreign operations		(493,287)	(13,854)
Income tax (expense)/benefit on items of other comprehensive income			
Other comprehensive income/(loss) for the period, net of income tax		(493,287)	(13,854)
<b>Total comprehensive income/(loss) for the period</b>		<b>12,730,898</b>	<b>7,100,432</b>
<b>Profit/(loss) for the year attributable to:</b>			
Non-controlling interest		-	(66,541)
Owners of the parent		13,224,185	7,180,827
		<b>13,224,185</b>	<b>7,114,286</b>
<b>Total comprehensive income/(loss) attributable to:</b>			
Non-controlling interest		-	(66,541)
Owners of the parent		12,730,898	7,166,973
		<b>12,730,898</b>	<b>7,100,432</b>
Basic earnings per share - cents per share	16	27.7	14.9
Diluted earnings per share - cents per share	16	26.7	14.3
The accompanying notes form part of these financial statements.			

**STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2018**

	Note	Consolidated Entity	
		2018	2017
		\$	\$
<b>Current assets</b>			
Cash and cash equivalents	17(a)	36,198,451	23,752,312
Trade and other receivables	4	5,090,271	3,239,127
Inventory	5	641,285	1,241,608
Other assets	6	339,062	236,576
<b>Total current assets</b>		<b>42,269,069</b>	<b>28,469,623</b>
<b>Non-current assets</b>			
Property, plant and equipment	7	168,739	137,341
Intangible assets	8	185,030	-
Deferred tax assets	3(c)	281,779	-
<b>Total non-current assets</b>		<b>635,548</b>	<b>137,341</b>
<b>Total assets</b>		<b>42,904,617</b>	<b>28,606,964</b>
<b>Current liabilities</b>			
Trade and other payables	10	2,499,915	2,294,228
Provisions	11	970,906	853,374
<b>Total current liabilities</b>		<b>3,470,821</b>	<b>3,147,602</b>
<b>Non-current liabilities</b>			
Provisions	11	17,808	15,337
<b>Total non-current liabilities</b>		<b>17,808</b>	<b>15,337</b>
<b>Total liabilities</b>		<b>3,488,629</b>	<b>3,162,939</b>
<b>Net assets</b>		<b>39,415,988</b>	<b>25,444,025</b>
<b>Equity</b>			
<b>Equity attributable to owners of the parent:</b>			
Contributed equity	12	148,614,908	148,413,095
Reserves	13	3,481,916	2,820,212
Accumulated losses	14	(112,680,836)	(125,847,024)
<b>Equity attributable to the owners of the parent</b>		<b>39,415,988</b>	<b>25,386,283</b>
<b>Equity attributable to non-controlling (minority equity) interest</b>		<b>-</b>	<b>57,742</b>
<b>Total equity</b>		<b>39,415,988</b>	<b>25,444,025</b>

The accompanying notes form part of these financial statements.

**STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2018**

	Note	Consolidated Entity	
		2018	2017
		\$	\$
<b>Cash flows from operating activities</b>			
GST and VAT refunds		183,842	193,012
Government R&D tax incentive		53,069	588,018
Receipts from customers		23,705,378	17,924,257
Interest received		290,566	233,682
Payments to suppliers and employees		(12,539,522)	(9,022,033)
<b>Net cash provided by/(used in) operating activities</b>	17(b)	<b>11,693,333</b>	<b>9,916,936</b>
<b>Cash flows from investing activities</b>			
Payments for property, plant and equipment		(75,123)	(67,479)
<b>Net cash provided by/(used in) investing activities</b>		<b>(75,123)</b>	<b>(67,479)</b>
<b>Cash flows from financing activities</b>			
Proceeds from issue of ordinary shares		-	-
Equity contribution by subsidiary non-controlling interest		-	85,082
Payment of share issue costs		-	-
<b>Net cash provided by financing activities</b>		<b>-</b>	<b>85,082</b>
<b>Net increase in cash held</b>		<b>11,618,210</b>	<b>9,934,539</b>
<b>Cash and cash equivalents at beginning of the year</b>		<b>23,752,312</b>	<b>13,844,703</b>
Effects of exchange rate changes on foreign currency held		827,929	(26,930)
<b>Cash and cash equivalents at end of the year</b>	17(a)	<b>36,198,451</b>	<b>23,752,312</b>
The accompanying notes form part of these financial statements.			

## STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2018

	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 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 private placement	-	-	-	-	-	-	-
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
Capital raising costs	-	-	-	-	-	-	-
<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>
Profit/(loss) for the year	-	-	-	7,180,827	7,180,827	(66,541)	7,114,286
<b>Other comprehensive income:</b>							
Exchange differences of foreign exchange translation of foreign operations	-	-	13,854	-	13,854	-	13,854
<b>Total other comprehensive income</b>	<b>-</b>	<b>-</b>	<b>13,854</b>	<b>-</b>	<b>13,854</b>	<b>-</b>	<b>13,854</b>
<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>
Equity contribution by subsidiary non-controlling interest	-	-	-	-	-	-	-
Issue of Share Capital under share-based payment	201,813	(201,813)	-	-	-	-	-
Employee share-based payment options	-	370,230	-	57,405	427,635	-	427,635
Purchase of shares held in subsidiary from non-controlling interest	-	-	-	-	-	(173,144)	(173,144)
Transfer of Accumulated Loss of non-controlling interest to owner upon purchase of minority interest	-	-	-	(115,402)	(115,402)	115,402	-
<b>Transactions with owners</b>	<b>148,614,908</b>	<b>2,863,901</b>	<b>124,728</b>	<b>(125,905,021)</b>	<b>25,698,516</b>	<b>-</b>	<b>25,698,516</b>
Profit/(loss) for the year	-	-	-	13,224,185	13,224,185	-	13,224,185
<b>Other comprehensive income:</b>							
Exchange differences of foreign exchange translation of foreign operations	-	-	493,287	-	493,287	-	493,287
<b>Total other comprehensive income</b>	<b>-</b>	<b>-</b>	<b>493,287</b>	<b>-</b>	<b>493,287</b>	<b>-</b>	<b>493,287</b>
<b>Balance at 30 June 2018</b>	<b>148,614,908</b>	<b>2,863,901</b>	<b>618,015</b>	<b>(112,680,836)</b>	<b>39,415,988</b>	<b>-</b>	<b>39,415,988</b>

# NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2018

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

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

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

The going concern basis assumes that, if required, future capital raisings will be available to enable the consolidated entity to undertake the research, development and commercialisation of its projects and that the subsequent commercialisation of products will be successful. The financial statements take no account of the consequences, if any, of the inability of the consolidated entity to obtain adequate funding or of the effects of unsuccessful research, development and commercialisation of the consolidated entity projects. The consolidated entity has successfully raised additional working capital in past years. 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 9 of the Financial Statements.

### b) Income Tax

#### Current Tax

Current tax is calculated by reference to the amount of income tax payable or recoverable in respect of the taxable profit or loss for the 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.

The deferred tax asset has been recognised as at 30 June 2018 based on the following management judgements:

- The consolidated entity has experienced consecutive years of profitably and revenue growth
- Current pricing agreements with European payors not expected to change in the next financial year
- Internal targets continue to expect ongoing profitability in the near term

#### **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 probable 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 binomial 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 23.

##### Key judgements – tax losses

Given the Company's and each individual entities' history of losses, the Group has not recognised a deferred tax asset with regard to unused tax losses and other temporary differences until this year. For the first time, the Directors have determined the Group will generate sufficient taxable income against which the unused tax losses and other temporary differences can be utilised. The value of tax losses both recognised and 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 2018 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

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'); and
  - 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 118 Revenue, AASB 111 Construction Contracts 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, when this Standard is first adopted for the year ending 30 June 2019, there will be no material impact on the transactions and balances recognised in the financial statements.

### 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.

Based on the entity's assessment, it is expected that the first-time adoption of AASB 16 for the year ending 30 June 2019 will have a material impact on the transactions and balances recognised in the financial statements, in particular:

- lease assets and financial liabilities on the balance sheet will increase by \$282,449 and \$267,744 respectively (based on the facts at the date of the assessment);
- there will be a reduction in the reported equity as the carrying amount of lease assets will reduce more quickly than the carrying amount of lease liabilities; and
- operating cash outflows will be lower and financing cash flows will be higher in the statement of cash flows as principal repayments on all lease liabilities will now be included in financing activities rather than operating activities. Interest can also be included within financing activities.

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.

AASB Interpretation 23 Uncertainty Over Income Tax Treatments

AASB Interpretation 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 AASB Interpretation 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 and commercial sales are 100% earned from entities within Europe and Switzerland, 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 three end users (2017: eight end users). 100% of the revenue from commercial sales is from nineteen end users (2017: twelve end users).

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	
	2018	2017
	\$	\$
<b>(a) Revenues</b>		
Interest revenue – other persons	264,452	264,394
Sales reimbursements	4,126,413	4,833,653
Commercial sales of goods	21,359,260	11,886,489
<b>Total revenues</b>	<b>25,750,125</b>	<b>16,984,536</b>
<b>(b) Other income</b>		
Government R&D tax incentive	147	45,314
Gain/(loss) on restating foreign currency creditors and currencies held	423,562	
Realised net currency gain on transactions	62,129	139,854
<b>Total other income</b>	<b>485,838</b>	<b>185,168</b>
<b>(c) Expenses</b>		
Clinical development	53,642	129,806
Drug formulation R&D, manufacture & distribution	1,733,082	857,204
Regulatory (Pre & Post Marketing) & Non-clinical	1,622,829	1,005,223
Clinical, Regulatory & Commercial overheads	2,575,752	2,060,701
Business marketing & listing	1,051,125	811,434
Licenses, patents and trademarks	522,135	219,714
General operations (incl Board)	5,734,992	4,882,282
Foreign currency translation losses	-	89,054
<b>Total expenses</b>	<b>13,293,557</b>	<b>10,055,418</b>
<b>(d) Profit/(loss) before income tax includes the following specific expenses</b>		
Employee benefits expense	5,947,097	4,817,187
Depreciation on property, plant & equipment	43,898	53,138
Depreciation - make-good	645	-
Loss on sale of property, plant and equipment	-	33,740
Share-based payments	427,635	395,364
Operating lease expense – minimum lease payments	310,667	345,482

## 3. INCOME TAX EXPENSE

	Consolidated Entity	
	2018	2017
	\$	\$
<b>(a) Income tax expense/benefit</b>		
Recognition of opening deferred tax assets	-	-
Recognition of opening deferred tax liabilities	-	-
Deferred tax expense/(benefit)	(281,779)	-
<b>Income tax expense/(benefit)</b>	<b>(281,779)</b>	<b>-</b>
<b>Deferred tax included in income tax expense/(benefit) comprises:</b>		
(Increase)/decrease in deferred tax assets	(3,124,408)	-
Increase/(decrease) in deferred tax liabilities	2,842,629	-
	<u>(281,779)</u>	<u>-</u>
<b>(b) Numerical reconciliation of income tax benefit and tax at the statutory rate</b>		
Profit/(loss) before income tax expense	12,942,406	7,114,286
Tax at the statutory tax rate of 30%	3,882,722	2,134,286
<i>Tax effect amounts which are not deductible/(taxable) in calculating taxable income:</i>		
Non deductible entertainment	774	1,275
Share-based payments	128,291	118,609
Research and development deduction	-	36,498
Fines and Penalties	96	-
(Over)/under provision of income tax in previous years	228,836	157,146
Refundable tax offset	(44)	(13,594)
Other	-	-
	<u>4,240,675</u>	<u>2,434,220</u>
Recognition of temporary differences	1,747,139	-
Current year temporary differences not recognised	-	375,949
Previously unrecognised tax losses now recognised	(6,728,893)	(2,810,169)
Adjustment for overseas subsidiary losses not brought into account	459,300	-
<b>Income tax expense/(benefit)</b>	<b>(281,779)</b>	<b>-</b>
<b>Tax losses not recognised</b>		
Unused tax losses for which no deferred tax asset has been recognised	106,945,662	121,081,247
Potential tax benefit at 30%	32,083,699	36,324,374

<b>(c) Deferred tax assets</b>		
Deferred tax asset comprises temporary differences attributable to:		
Intangibles	441,212	-
Accrued Expenses	3,116	-
Provisions	152,491	-
Carry forward tax losses	2,572,499	-
Other	(44,910)	-
	<b>3,124,408</b>	<b>-</b>

Movements		
Opening balance	-	-
Recognition of opening deferred tax assets	4,788,520	-
Intangibles	81,476	-
Accrued Expenses	96	-
Provisions	(116,880)	-
Carry forward tax losses	2,572,500	-
Other	(44,910)	-
Deferred tax assets utilised	(4,156,394)	-
	<b>3,124,408</b>	<b>-</b>

<b>(c) Deferred tax liabilities</b>		
Deferred tax liability comprises temporary differences attributable to:		
Intangibles	32,412	-
Accrued income	(20,375)	-
Unrealised gains/loss on loans to subsidiaries	(2,854,666)	-
	<b>(2,842,629)</b>	<b>-</b>

Movements		
Opening balance	-	-
Recognition of opening deferred tax liability	(2,379,265)	-
Intangibles	(33,642)	-
Accrued income	7,839	-
Unrealised gains/loss on loans to subsidiaries	(437,561)	-
	<b>(2,842,629)</b>	<b>-</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	
	2018	2017
	\$	\$
<b>Current</b>		
Trade debtors	4,937,083	2,966,173
Accrued income	67,916	94,048
Sundry debtors	85,272	178,906
<b>Total</b>	<b>5,090,271</b>	<b>3,239,127</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:

	2018			2017		
	Total	Amount impaired	Amount not impaired	Total	Amount impaired	Amount not impaired
Not past due	4,667,587	-	4,667,587	2,756,649	-	2,756,649
Past due 61-90 days	219,634	-	219,634	209,524	-	209,524
Past due >90 days	49,862	-	49,862	-	-	-
<b>TOTAL</b>	<b>4,937,083</b>	<b>-</b>	<b>4,937,083</b>	<b>2,966,173</b>	<b>-</b>	<b>2,966,173</b>

**5. INVENTORY**

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Current</b>		
Raw materials – at cost	454,257	512,651
Provision for obsolescence – raw materials	(147,888)	(181,675)
Work in progress – at cost	-	466,716
Finished goods – at cost	334,916	443,916
<b>Total</b>	<b>641,285</b>	<b>1,241,608</b>

**6. OTHER ASSETS**

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Current</b>		
Prepaid peptide	145,190	137,444
Other prepayments	193,872	99,132
<b>Total</b>	<b>339,062</b>	<b>236,576</b>

**7. PROPERTY, PLANT AND EQUIPMENT**

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Plant and equipment</b>		
At cost	187,032	113,178
Less: accumulated depreciation	(81,323)	(56,258)
<b>Sub-total</b>	<b>105,709</b>	<b>56,920</b>
<b>Furniture and fittings</b>		
At cost	125,189	124,123
Less: accumulated depreciation	(62,159)	(43,702)
<b>Sub-total</b>	<b>63,030</b>	<b>80,421</b>
<b>Total property, plant and equipment</b>	<b>168,739</b>	<b>137,341</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 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>
Additions	76,606	1,066	77,672
Disposals	(2,750)	-	(2,750)
Depreciation written back on disposal	626	-	626
Depreciations expense	(25,693)	(18,457)	(44,150)
Make-good	-	-	-
Exchange differences	-	-	-
<b>Carrying amount at 30 June 2018</b>	<b>105,709</b>	<b>63,030</b>	<b>168,739</b>

**8. GOODWILL**

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Goodwill</b>		
At cost	185,030	-
Less: impairment	-	-
<b>Sub-total</b>	<b>185,030</b>	<b>-</b>

## 9. INTERESTS IN SUBSIDIARIES

Name Of Entity	Country Of Incorporation	Ownership Interest	
		2018	2017
<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	100%	82%

## 10. TRADE AND OTHER PAYABLES

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Current</b>		
Unsecured trade creditors	428,562	579,466
Sundry creditors and accrued expenses	2,071,353	1,714,762
<b>Total</b>	<b>2,499,915</b>	<b>2,294,228</b>
(a) Aggregate amounts payable to:		
Directors and Director-related entities	464,770	501,443
(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade and Sundry creditors:		
Singapore dollars	490,277	-
<b>Total</b>	<b>490,277</b>	<b>-</b>

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

(c) Terms and conditions:

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

**11. PROVISIONS**

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Current</b>		
Employee benefits	970,906	853,374
<b>Total</b>	<b>970,906</b>	<b>853,374</b>
<b>Non-current</b>		
Employee benefits	3,197	1,169
Other provision	14,611	14,168
<b>Total</b>	<b>17,808</b>	<b>15,337</b>

**Movements in Carrying Amounts - Provisions**

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

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Carrying amount at 30 June</b>	<b>14,168</b>	<b>14,742</b>
Provisions made during the year	-	-
Unwind of discount	443	(574)
<b>Carrying amount at 30 June</b>	<b>14,611</b>	<b>14,168</b>

**12. CONTRIBUTED EQUITY****(a) Issued and Paid Up Capital**

	Consolidated Entity	
	2018	2017
	\$	\$
47,824,427 fully paid ordinary shares (2017: 47,735,227)	148,614,908	148,413,095

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			
	2018		2017	
	No.	\$	No.	\$
<b>At the beginning 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>
Issued during the year	-	-	-	-
Conditional rights issues and transferred from conditional rights reserve	89,200	201,813	654,590	1,648,595
Less: transaction costs	-	-	-	-
<b>Balance at the end of the financial year</b>	<b>47,824,427</b>	<b>148,614,908</b>	<b>47,735,227</b>	<b>148,413,095</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\$	89,200

As at 30 June 2018 the following conditional performance rights existed which if exercised, would result in the issue of fully paid ordinary shares:

Expiry date	Exercise Price	Number of Conditional Rights
Upon achievement of various performance milestones	Nil\$	1,750,560

**13. RESERVES**

	Consolidated Entity	
	2018	2017
	\$	\$
<i>Conditional Performance Rights reserve:</i>		
<b>Balance at the beginning of period</b>	<b>2,695,484</b>	<b>3,984,103</b>
Share-based payment	427,635	395,364
Transfer to share capital	(201,813)	(1,648,595)
Lapsed, forfeited rights	(57,405)	(35,388)
<b>Balance at the end of period</b>	<b>2,863,901</b>	<b>2,695,484</b>
The Conditional Performance Rights reserve arises on the grant of conditional performance rights to eligible employees under the Conditional Performance Rights Plan. Amounts are transferred out of the reserve and into issued capital when the rights are exercised and to retained earnings when rights lapse.		
<i>Foreign currency translation reserve:</i>		
<b>Balance at the beginning of period</b>	<b>124,728</b>	<b>110,874</b>
Translating foreign subsidiary to current rate at reporting date	493,287	13,854
<b>Balance at the end of period</b>	<b>618,015</b>	<b>124,728</b>
<b>Total reserves</b>	<b>3,481,916</b>	<b>2,820,212</b>

**14. ACCUMULATED LOSSES**

	Consolidated	Non-controlling interest	Consolidated	Non-controlling interest
	2018	2018	2017	2017
	\$	\$	\$	\$
Accumulated losses at the beginning of the year	(125,847,024)	(115,402)	(133,063,239)	(48,861)
Transfer from performance rights reserve of lapsed & expired rights	57,405		35,388	-
Transfer from purchase of non-controlling interest	(115,402)	115,402	-	-
Net profit/(loss) attributable to the members of CLINUVEL PHARMACEUTICALS LTD	13,224,185	-	7,180,827	(66,541)
<b>Accumulated losses at the end of the financial year</b>	<b>(112,680,836)</b>	<b>-</b>	<b>(125,847,024)</b>	<b>(115,402)</b>

**15. LEASE COMMITMENTS**

	Consolidated Entity	
	2018	2017
	\$	\$
<i>Operating lease commitments</i>		
Non-cancellable operating leases contracted for but not capitalised in the accounts		
Payable:		
not later than 1 year	315,095	169,686
later than 1 year but not later than 5 years	211,095	125,375
<b>Total</b>	<b>526,190</b>	<b>295,061</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 34 months as from the reporting date and contain renewal options. Fixed increases are factored into some of the agreements.

**16. EARNINGS PER SHARE (EPS)**

	Consolidated Entity	
	2018	2017
	\$	\$
(a) Basic earnings per share (cents per share)	27.7	14.9
(a) Diluted earnings per share (cents per share)	26.7	14.3
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	47,742,803	47,670,194
(b) Weighted average number of performance rights on issue in respect of share based payments during the year	1,847,841	1,956,597
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	49,590,644	49,626,791
(c) The numerator used in the calculation of basic earnings per share (\$)	13,224,185	7,114,286

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.

**17. CASH FLOW INFORMATION**

	Consolidated Entity	
	2018	2017
	\$	\$
(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	16,628,038	14,209,196
Cash on hand	1,411	1,376
Deposits on call	5,511,118	129,048
Term deposits	13,975,000	9,350,000
Security bonds	82,884	62,692
<b>Total cash</b>	<b>36,198,451</b>	<b>23,752,312</b>
(b) Reconciliation of cash flows from operating activities with operating profit (loss)		
<b>Operating profit (loss) after income tax</b>	<b>13,224,185</b>	<b>7,114,286</b>
Non cash flows in operating (loss):		
Depreciation expense on property, plant & equipment	44,542	53,138
Exchange rate effect on foreign currencies held	(827,929)	26,930
Executive share option expense	427,635	395,364
Loss on sale of non-current assets	-	33,740
Unrealised loss on foreign exchange translation	493,287	13,854
Changes in assets and liabilities:		
(Increase)/decrease in receivables	(1,851,144)	1,584,644
(Increase)/decrease in inventories	600,323	(159,444)
(Increase)/decrease in prepayments	(102,486)	(13,616)
Increase/(decrease) in payables	205,687	729,715
- fixed asset purchases in payables	(358,991)	-
(Increase)/decrease in deferred tax assets	(281,779)	-
Increase/(decrease) in provisions	120,003	138,325
<b>Net cash used in operating activities</b>	<b>11,693,333</b>	<b>9,916,936</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 2.45% (2017: 2.80%). These deposits have an average maturity date of 216 days (2017: 208 days).

**18. KEY MANAGEMENT PERSONNEL**

	Consolidated Entity	
	2018	2017
	\$	\$
Short-term employee benefits	2,923,985	2,125,768
Post-employment benefits	56,582	55,716
Long-term benefits		
Termination benefits		
Share-based payments	295,745	333,226
<b>Total</b>	<b>3,276,312</b>	<b>2,514,710</b>

No loans or other transactions existed with key management personnel.

## 19. AUDITORS' REMUNERATION

	Consolidated Entity	
	2018	2017
	\$	\$
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	94,500	92,500
other services	-	-
<b>Total</b>	<b>94,500</b>	<b>92,500</b>

## 20. RELATED PARTY DISCLOSURES

### 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 2018 is \$4,370,640 (2017: \$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 2018 is \$10,885,890 (2017: \$10,411,946).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL AG is non-interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in CLINUVEL AG. The loan to CLINUVEL AG as at 30 June 2018 is \$12,543,948 (2017: \$12,310,580).

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 2018 is \$183,473 (2017: \$365,080).

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 2018 is \$10,036,005 (2017: \$5,074,245).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from VALLAURIX PTE LTD is non-interest bearing. Repayment of the loan will commence upon commercialisation of VALLAURIX PTE LTD's product(s). A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in VALLAURIX PTE LTD. The loan to VALLAURIX PTE LTD as at 30 June 2018 is \$194,110 (2017: \$0).

Director related and Key Management Personnel transactions and entities:

There are no transactions and relationships in existence as at 30 June 2018 between Directors and the Company and its related entities.

## 21. 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 and commercial sales are 100% earned from entities within Europe, and Switzerland 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 three end users (2017: eight end users). 100% of the revenue from commercial sales is from nineteen end users (2017: twelve end users).

## 22. FINANCIAL INSTRUMENTS

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

- Market Risk
- Credit Risk
- Liquidity Risk

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

### 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 2018 and as at 30 June 2017.

**The consolidated entities exposure to foreign currency risk at 30 June 2018**

	Consolidated Entity							
	2018				2017			
	Cash and Equivalents	Trade Debtors Other Assets	Trade, Other Payables and Provisions	TOTAL	Cash and Equivalents	Trade Debtors Other Assets	Trade, Other Payables and Provisions	TOTAL
USD	1,338,322	128	(284,361)	<b>1,054,089</b>	1,169,412-		(517,812)	<b>651,600</b>
EUR	6,187,830	2,567,725	(338,398)	<b>8,417,157</b>	5,561,436	1,743,103	(181,161)	<b>7,123,378</b>
CHF	2,001,399	418,766	(98,142)	<b>2,322,023</b>	1,493,230	399,610	(141,331)	<b>1,751,509</b>
GBP	778,795	31,119	(227,841)	<b>582,073</b>	624,997	42,624	(293,698)	<b>373,923</b>
SGD	883,859	12,048	(1,323,892)	<b>(427,985)</b>	1,128,840	12,415	(978,457)	<b>162,798</b>

**THE CONSOLIDATED ENTITIES EXPOSURE TO FOREIGN CURRENCY RISK AT 30 JUNE 2018**

**Sensitivity Analysis**

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 Euro currency would have decreased profit and loss and equity by \$983,765 for the year ended 30 June 2018 (2017: \$293,857), 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**

For the consolidated entity, at 30 June 2018, if interest rates had changed by +/- 25 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 \$65,123 higher/lower (2017: \$45,916 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 approximately twenty-two counterparties across German, Italian, Swiss, Dutch and other medical institutions who are reimbursed by government or private insurance payors.

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 providing SCENESSE® to EPP patients under both the full cost special access reimbursement programs and from commercial sales

currently in Europe and Switzerland. Its capital management objectives are 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®, to file for successful marketing authorisation in new jurisdictions and achieving a status whereby revenues will consistently exceed expenditures.

#### Contractual maturities of financial assets as at 30 June 2018

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Cash and cash equivalents</b>		
Carrying amount	36,198,451	23,752,312
6 months or less	29,748,451	23,752,312
Greater than 6 months	6,450,000	-
<b>Total</b>	<b>36,198,451</b>	<b>23,752,312</b>
<b>Other financial assets (includes trade and other receivables)</b>		
Carrying amount	5,090,271	3,239,127
6 months or less	5,040,409	3,239,127
Greater than 6 months	49,862	-
<b>Total</b>	<b>5,090,271</b>	<b>3,239,127</b>

#### Contractual maturities of financial liabilities as at 30 June 2018

	Consolidated Entity	
	2018	2017
	\$	\$
<b>Trade and other payables</b>		
Carrying amount	2,499,941	2,294,186
6 months or less	2,479,749	2,265,478
Greater than 6 months	20,192	28,750
<b>Total</b>	<b>2,499,941</b>	<b>2,294,228</b>

#### 23. EMPLOYEE BENEFITS

	Consolidated Entity	
	2018	2017
	\$	\$
<b>The aggregate employee benefit liability is comprised of:</b>		
Provision for annual leave	591,833	527,970
Provision for long service leave	382,270	326,573
Accrued FBT, payroll, superannuation, pension funds, employee insurances	686,256	715,930
<b>Total</b>	<b>1,660,359</b>	<b>1,570,473</b>

**SHARE-BASED PAYMENTS**

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

The number of rights granted is subject to approval by the Remuneration Committee. 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 seven years. The eligible employee can request for shares to be transferred from the Scheme Trust after seven 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 seven 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 seven years from grant date.

**The following share-based payment arrangements were in existence at 30 June 2018**

Performance Rights Series	Number	Grant date	Expiry Date		Exercise Price	Fair Value at Grant Date
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	65,000	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	4/12/2014	674,975	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
Issued	5/09/2017	5,500	5/09/2017	7 years from Grant Date	\$ Nil	\$4.20

**Holdings of All Issued Conditional Performance Rights – 2018**

Performance Rights Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Vested and Exercisable	Unvested
Issued 25/11/2010	299,999	-	-	-	299,999	-	299,999
Issued 16/09/2011	375,986	-	-	-	375,986	-	375,986
Issued 16/11/2011	90,000	-	-	(25,000)	65,000	-	65,000
Issued 14/01/2013	75,000	-	-	-	75,000	-	75,000
Issued 04/12/2014	692,475	-	-	(17,500)	674,975	-	674,975
Issued 17/03/2015	338,800	-	(84,700)	-	254,100	-	254,100
Issued 05/09/2017	-	10,000	(4,500)	-	5,500	-	5,500
<b>Total</b>	<b>1,872,260</b>	<b>10,000</b>	<b>(89,200)</b>	<b>(42,500)</b>	<b>1,750,560</b>	<b>-</b>	<b>1,750,560</b>

Weighted average exercise price	\$Nil						
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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 – 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						
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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.

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

	CLINUVEL PHARMACEUTICALS LTD	
	2018	2017
	\$	\$
<b>Assets</b>		
Current assets	31,460,940	21,789,154
Non-current assets	11,152,447	6,287,177
<b>Total assets</b>	<b>42,613,387</b>	<b>28,076,331</b>
<b>Liabilities</b>		
Current liabilities	1,664,993	1,415,118
Non-current liabilities	3,197	1,169
<b>Total liabilities</b>	<b>1,668,190</b>	<b>1,416,287</b>
<b>Equity</b>		
Issued equity	148,614,908	148,413,095
Share-based payments reserve	2,863,901	2,695,500
Accumulated losses	(110,533,612)	(124,448,551)
<b>Total equity</b>	<b>40,945,197</b>	<b>26,660,044</b>
<b>Financial performance</b>		
Net profit (loss) for the year	13,972,344	7,551,035
Other comprehensive income	-	-
<b>Total comprehensive income</b>	<b>13,972,344</b>	<b>7,551,035</b>

**25. SUBSEQUENT EVENTS**

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

- On 29 August 2018, the Board of Directors declared an unfranked dividend of \$0.02 per ordinary share

**26. 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 2018 and of its performance for the year ended on that date; and
  - b) complying with Accounting Standards; and
  - c) complying with International Financial Reporting Standards as disclosed in Note 1
2. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable; and
3. the audited remuneration disclosures set out in pages 13 to 25 of the Directors Report comply with Section 300A of the Corporations Act 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 29th day of August, 2018

# 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 2018, 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 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 2018 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 auditor 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 believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

## 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>Deferred tax asset – Note 3</b></p> <p>Clinuvel has recognised deferred tax assets of \$281,779 (2017: nil) in accordance with AASB 112 “Income Taxes”. These are primarily attributable to historic losses generated by the income tax consolidated group. An assessment is required as to whether sufficient future taxable profits are likely to be generated to enable the assets to be realised.</p> <p>We focused on this area because as deferred tax is recognised for the first time, there is an increased risk that the asset may not meet the recognition criteria of the Australian Accounting Standards.</p> <p>This area is a key audit matter due to the degree of judgement required in assessing management’s estimates of future taxable profits to enable the assets to be realised.</p>	<p>Our audit procedures included, amongst others:</p> <ul style="list-style-type: none"> <li>• Holding discussions with management to obtain an understanding of the policy applied for the recognition of deferred tax and assessment of profitability of the company in the near future;</li> <li>• Evaluating management’s forecast of future taxable income by assessing the key underlying assumptions such as future taxable income against historic performance and market trends;</li> <li>• Assessing the competence and independence of managements tax expert used, to assist in the preparation of the valuation of the deferred tax asset;</li> <li>• Checking the accuracy of input data and evaluating formulas and assumption used for the computation of the deferred tax asset;</li> <li>• Utilising our internal taxation specialists to assist in this assessment of the determination of the tax bases; and</li> <li>• Assessing the adequacy of the group’s disclosure in relation to the carrying value of deferred tax assets.</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 2018, but does not include the financial report and our auditor’s report thereon.

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's ability 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\\_responsibilities/ar1.pdf](http://www.auasb.gov.au/auditors_responsibilities/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 the Directors' report for the year ended 30 June 2018.

In our opinion, the Remuneration Report of Clinuvell Pharmaceuticals Limited, for the year ended 30 June 2018 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.



Grant Thornton Audit Pty Ltd  
Chartered Accountants



B A Mackenzie  
Partner – Audit & Assurance

Melbourne, 29 August 2018

## Auditor's Independence Declaration

### To the Directors of Clinuvel Pharmaceuticals Limited

I In accordance with the requirements of section 307C of the Corporations Act 2001, as lead auditor for the audit of Clinuvel Pharmaceuticals Limited for the year ended 30 June 2018, I declare that, to the best of my knowledge and belief, there have been:

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



Grant Thornton Audit Pty Ltd  
Chartered Accountants



B A Mackenzie  
Partner - Audit & Assurance

Melbourne, 29 August 2018