



ANNUAL RESULTS

Financial Year Ending 30 June 2021

CLINUVEL PHARMACEUTICALS LTD

A.B.N. 88 089 644 119

1.	Reporting period:	1 July 2020 to 30 June 2021.		
	Previous corresponding period:	1 July 2019 to 30 June 2020.		
2.	Results for announcement to the market.	Percentage change to 2020		Amount (AUD)
	2.1 Revenues from ordinary activities.	Increased 47%	To	47,975,583
	2.2 Profit from ordinary activities after tax attributable to members.	Profit has increased 64%	To	24,728,247
	2.3 Net profit for the period attributable to members.	Profit has increased 64%	To	24,728,247
	2.4 An unfranked final dividend of \$0.025 per ordinary share has been declared.			
	2.5 Record date for determining entitlements for the final dividend: 03 September 2021.			
	2.6 Refer to the Review of Operations and Financial Condition in the Directors Report to the Attachment to Appendix 4E 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 \$0.025 per ordinary share to be paid on 17 September 2021.			
8.	No dividend reinvestment plan.			
9.	Net Tangible Assets per Security for Year Ended 30 June 2021: \$1.911.	Net Tangible Assets per Security for Year Ended 30 June 2020: \$1.351 (restated)		
10.	The control of entities which had control gained or lost: N/A			
11.	N/A			
12.	No other significant information.			
13.	Foreign entities:	Australian Accounting Standards used		
		CLINUVEL, INC. (USA)		
		CLINUVEL (UK) LTD (UK)		
		CLINUVEL AG (Switzerland)		
		CLINUVEL SINGAPORE PTE LTD (Singapore)		
		VALLAURIX PTE LTD (Singapore)		
		CLINUVEL EUROPE LIMITED (Ireland)		
		VALLAURIX MC SARL (Monaco)		
14.	COMMENTARY OF RESULTS: Commentary in respect of the financial results is provided in the Review of Operations and Financial Condition to the attached Directors' Report.			

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CLINUVEL PHARMACEUTICALS LTD is the parent company of the CLINUVEL group of companies. In this report, unless otherwise stated, references to "CLINUVEL", "the Group", "the Company", "we", "our" and "us" refer to CLINUVEL PHARMACEUTICALS LTD and its controlled entities. In this report, references to the financial year refer to the period 1 July to 30 June unless otherwise stated, references to FY2021 refer to the period 1 July to 30 June 2021, references to FY2020 refer to the period 1 July to 30 June 2020.

All dollar figures are expressed in Australian dollars, unless otherwise stated.

Directors' Report

The Directors of the Board present their report on the Company for the financial year ended 30 June 2021 and the Auditor's Independence Declaration thereon.



WILLEM BLIJDORP

Non-Executive Director, Chair since 30 November 2019, Funda

Appointed 21 January 2015

Committee Membership

Chair of the Remuneration Committee

Chair of the Nomination Committee

Member of the Audit and Risk Committee

Current Directorships and Other Interests

Director of the Supervisory Board of the B&S Group (The Netherlands)

Other Listed Company Directorships (last 3 years)

None

Relevant Interest in Shares and Performance Rights

Shares 1,743,118 Performance Rights -

Relevant Skills

- entrepreneurship, commercial prowess
- general management
- financial management
- experienced in listed company Directorships

Background

Mr Blijdorp is an internationally recognised entrepreneur who has helped build the B&S Group, one of the largest global trading houses, in a period spanning three decades. Mr Blijdorp has led B&S's growth, with the Dutch group focused on specialty distribution services to difficult to serve markets. The B&S Group has global reach and is a leader in its market sector.

Formerly B&S Group's CEO, Mr Blijdorp now serves on its Supervisory Board and is a majority shareholder, focussing on the Group's development and expansion strategy. He led and oversaw the Group's initial public offering on Euronext Amsterdam in March 2018.

In 2014 Mr Blijdorp was recognised for his expertise in mergers and acquisitions and commercial leadership as the Ernst & Young Entrepreneur of the Year in the Netherlands, and runner-up in its European Union awards.

Since becoming a director of CLINUVEL in 2015, Mr Blijdorp has provided a valuable contribution to setting the Group's long-term strategy for product commercialisation, growth, and plans to further diversify CLINUVEL.



PHILIPPE WOLGEN

Chief Executive Officer, MBA, MD

Appointed to Board 1 October 2005, appointed Chief Executive Officer 28 November 2005

Committee Membership

None

Current Directorships and Other Interests

None

Other Listed Company Directorships (last 3 years)

None

Relevant Interest in Shares and Performance Rights

Shares 3,175,321 Performance Rights 1,513,750

Relevant Skills

- pharmaceutical R&D, commercialisation
- clinical expertise
- commercial & entrepreneurial outlook
- executive management, corporate turnarounds
- finance and capital markets
- experienced in listed company Directorships

Background

Under Dr Wolgen's leadership since late 2005, a long-term strategy for CLINUVEL was devised. The lead product SCENESSE® (afamelanotide 16mg) was reformulated, its medical application identified, European marketing authorisation was obtained in 2014 and distributed in the European Economic Area from June 2016. Dr Wolgen oversaw the submission of the scientific dossier to the US Food & Drug Administration (FDA) under a New Drug Application, which was approved in October 2019. First treatment of US patients commenced in April 2020. SCENESSE® is the first melanocortin drug to have completed a clinical trial program and obtain marketing authorisation in two major markets.

Dr Wolgen has been instrumental in the Company's corporate turnaround, rebuilding a share register of long-term professional and institutional investors. He led CLINUVEL to attract more than AU\$110 million in investments, and his international contacts and network contribute to the strategic support CLINUVEL enjoys globally.

Under his tenure a business model was adopted to develop and launch SCENESSE®, guiding the Group through a complex pharmaceutical product development program. His overall business execution and exact financial management is viewed as exemplary within the life sciences industry and the funding strategy he led is considered unique within the sector.

Dr Wolgen is currently leading the Group's expansion, with an immediate focus on the US and the further development of the product pipeline for various market segments. His focus has been to establish a professional management team to execute the corporate objectives set and prepare next generation of managers. Dr Wolgen's long track record speaks to a strongly focussed, competitive and conscientious professional who is known to persevere in meeting challenging business objectives. He holds an MBA from Columbia University, NY. Trained as a craniofacial surgeon, Dr Wolgen obtained his MD from the University of Utrecht, the Netherlands.



BRENDA SHANAHAN

Non-Executive Director, AO, BComm, FAICD, ASIA
Appointed 6 February 2007

Committee Membership

Chair of the Audit and Risk Committee
Member of the Nomination Committee

Current Directorships and Other Interests

Chair of the Aikenhead Centre for Medical Discovery,
Melbourne
Director of SG Hiscock Ltd
Chair, SG Hiscock Medtech Advisory Board
Director of DMP Asset Management Ltd
Director of Rock Art Australia

Other Listed Company Directorships (last 3 years)

Phoslock Water Solutions Ltd (ASX: PHK, since 2017)
Bell Financial Group (ASX: BFG, from 2012 to 2018)

Relevant Interest in Shares and Performance Rights

Shares 233,969 Performance Rights 25,000

Relevant Skills

- research & development in life sciences
- capital market understanding
- executive management
- experienced in listed company Directorships

Background

Mrs Shanahan is a pioneer in the Australian finance community. The first female stockbroker, Mrs Shanahan has also spent more than two decades working and investing in medical R&D and commercialisation. She is currently a non-executive director of Phoslock Water Solutions Ltd. Mrs Shanahan is also a non-executive director of DMP Asset Management Ltd and SG Hiscock Ltd, a director of the Kimberly Foundation of Australia Ltd, and Chair of the Aikenhead Centre for Medical Discovery in Melbourne. In 2021, Mrs Shanahan was recognised as an Officer in the General Division of the Order of Australia.

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 formerly Chair of Challenger Listed Investments Ltd, the reporting entity for four ASX listed firms and formerly a non-executive director of Bell Financial Group (ASX: BFG). Mrs Shanahan has also served and Chaired various Audit and Risk Committees throughout her career, including Challenger Financial Services Group Ltd, Bell Financial Group, Victoria University, JM Financial Group Ltd, SA Water, AWB International Ltd, BT Financial Group and V/Line Passenger.

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.



KAREN AGERSBORG

Non-Executive Director, MD
Appointed 29 January 2018

Committee Membership

Member of the Remuneration Committee
Member of the Nomination Committee

Current Directorships and Other Interests

Fellow of the American Association of Clinical Endocrinologists
Fellow of the American College of Osteopathic Internists.
Doctorate of Osteopathic Medicine

Other Listed Company Directorships (last 3 years)

None

Relevant Interest in Shares and Performance Rights

Shares 5,500 Performance Rights -

Relevant Skills

- pharmaceutical research & development, commercialisation
- relevant knowledge on melanocortins, clinical expertise
- commercial knowhow in US pharmaceuticals
- general management
- experience in private company Directorships

Background

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

Dr Agersborg had an extensive career in managing commercial sales & distribution at Wyeth Pharmaceuticals (formerly Ayerst Laboratories). Dr Agersborg has played an integral role in setting the CLINUVEL Group's US commercial strategy, resulting in the US FDA's approval of SCENESSE® in October 2019.



SUSAN (SUE) SMITH

Non-Executive Director, Dipl ClinRisk
Appointed 23 September 2019

Committee Membership

Member of the Remuneration Committee
Member of the Nomination Committee

Current Directorships and Other Interests

Non-Executive Board Chair of Women's Health (London West One) Ltd
Non-Executive Director of Elite Medicine Ltd
Trustee of the HCA International Foundation

Other Listed Company Directorships (last 3 years)

None

Relevant Interest in Shares and Performance Rights

Shares 420 Performance Rights -

Relevant Skills

- executive healthcare management
- leadership and strategy setting in complex environments
- risk management and governance
- customer relations

Background

Mrs Smith manages an established consultancy business, providing advisory services to a range of healthcare organisations, investors and boards of directors and in 2021 formed SSJ Partnership Ltd, a consultancy specialising in providing regulatory governance support in the healthcare sector. Mrs Smith has led a distinguished career, serving for 14 years as Chief Executive Officer of The Princess Grace Hospital, London, and 11 years as the Chief Executive Officer of The Portland Hospital for Women and Children, London. Mrs Smith's specific expertise is in the implementation of operational strategies within complex and acute care environments, and in the interaction with healthcare authorities and UK regulators. Her most recent role was as the Chief Executive Officer of the Independent Doctors Federation, a membership organisation representing practicing physicians within the UK independent healthcare sector.

Her past experience is now successfully translating into a diverse portfolio with non-executive director appointments, having been successful in completing the *Financial Times* Non-Executive Director Advanced Professional Diploma. She is Board Chair of the Ewell (Harley St) Ltd, a fully integrated centre of medical excellence dedicated to caring for, and protecting, all aspects of fertility and gynaecological health. She also sits on the Advisory Board for SweetTree Home Care Services, providing the bridge between hospital and community care. In the face of the ever-changing healthcare market Mrs Smith fosters first class relationships with a wide range of healthcare stakeholders to build first class services for patients.



JEFFREY ROSENFELD

Non-Executive Director, AC, OBE
Appointed 26 November 2019

Committee Membership

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

Current Directorships and Other Interests

Director of Vision for TBI Ltd
Former Major General, Australian Defence Force (Army Reserve)

Other Listed Company Directorships (last 3 years)

None

Relevant Interest in Shares and Performance Rights

Shares 2,363 Performance Rights -

Relevant Skills

- lifetime experience in providing healthcare
- clinical research and development
- board and committee oversight and governance
- leadership and management

Background

Prof Rosenfeld is an internationally recognised neurosurgeon with extensive experience in senior healthcare and medical research executive roles and a distinguished and decorated career in the Australian Army. He is a retired Major General and a former Surgeon General, Australian Defence Force-Reserves. He has served on eight deployments to Rwanda, Iraq, Solomon Islands, Bougainville and East Timor. He was the Founding Director of Monash University Institute of Medical Engineering (MIME)-Melbourne. He is developing a bionic vision device to restore vision in blind people, and he is also a leader in brain injury research. Prof Rosenfeld was Director of Neurosurgery at the Alfred Hospital for fifteen years, concurrently holding Professor and Head of the Department of Surgery at Monash University for nine years. Prof Rosenfeld is active in many community organisations and champions various charitable causes. Prof Rosenfeld has been an active volunteer for the Australian-Aid funded Pacific Islands Project which transfers clinical skills and knowledge to healthcare professionals in Papua New Guinea, Fiji and the Solomon Islands.

In 2018, Prof Rosenfeld was awarded the Companion of the Order of Australia, which is Australia's highest civilian honour, the Meritorious Service Medal of the United States of America in 2017 and Officer in the Order of the British Empire in 2013. Prof Rosenfeld also became an Emeritus Professor at Monash University in January 2021.

Information on Company Secretary

DARREN KEAMY

Company Secretary, Chief Financial Officer

Qualifications: BComm, CPA, GradDip ACG

Mr Keamy, a Certified Practising Accountant and Company Secretary, 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 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 A\$95 million in capital, and assisted the steering of the Group from a loss-making, pre-revenue position to a commercially focussed profitable enterprise.

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	9	9	3	3			1	1
Dr. P.J. Wolgen	9	9						
Mr. W. Blijdorp	9	9	3	3	5	5	1	1
Dr. K. A. Agersborg	9	8			5	5	1	1
Mrs. S. E. Smith	9	9			5	5	1	1
Prof J. V. Rosenfeld	9	9	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.

The Nomination Committee intends to meet twice a year. The second meeting for the financial year was held 16 July, with at least 2 more meetings to be held in FY2022.

Principle Objectives and Activities

Objectives

CLINUVEL PHARMACEUTICALS LTD (CLINUVEL) is a global biopharmaceutical company focussed on developing and delivering treatments for patients with genetic, metabolic, and life-threatening disorders, as well as healthcare solutions for the general population. CLINUVEL's pioneering work in melanocortins aims to translate scientific breakthroughs to innovative medical solutions for complex problems and thus deliver lifelong care and novel products to patient groups and individuals at high risk of exposure to light.

CLINUVEL's expertise in understanding the interaction of melanocortins and human biology is focussed on developing treatments for patients with genetic and acute diseases who lack therapy. Research into afamelanotide focuses on the use of the hormone in severe light related disorders and depigmentation, and has recently expanded into diseases of the Central Nervous System and various other organs. The patient populations in these diseases range in size from 5,000 to 45 million worldwide.

CLINUVEL has developed and launched the world's first systemic photoprotective drug, SCENESSE® (afamelanotide 16mg), in Europe and the USA. During the year, the scope of CLINUVEL's research and development program was extended to the application of melanocortins to treat acute disorders and vascular anomalies.

The long-term financial objective of the Group is to maximise company value through the distribution of treatments to patients and special populations in need. The key to long-term sustainable performance is to continue targeted research and development of a portfolio of assets centred around its key drug candidate SCENESSE® and its melanocortin derivatives; their successful commercialisation, manufacture, and distribution; and maintaining financial discipline and stability.

Performance Indicators

Management and the Board monitor the overall performance of the Group in the achievement of its

objectives in relation to a defined strategic plan and annual operating and financial budgets.

The Board, with management, have identified a range of key performance indicators (KPIs) that are used annually to monitor performance. Key managers monitor performance against these KPIs and provide regular reports to the Board for review, feedback, and guidance, as necessary. This enables the Board to actively monitor and guide the Group's performance.

Activities

The principal activities of the Group during the financial year were to:

- manage and expand the commercial distribution in Europe and the USA of its leading drug candidate SCENESSE® for the treatment of a rare, genetic metabolic disorder, erythropoietic protoporphyria (EPP);
- progress the ongoing research and development of the Pharmaceutical Division's product pipeline for a range of severe disorders, including:
 - SCENESSE® in combination with narrowband ultraviolet B (NB-UVB) phototherapy and topical pharmaceutical formulations of melanocortin analogues for the treatment of the skin depigmentation disorder, vitiligo;
 - topical based pharmaceutical formulations for photoprotection of the skin;
 - medicinal photoprotection through DNA repair of the skin and initiating first studies in the genetic disorder, xeroderma pigmentosum (XP);
 - commencing first pilot studies to investigate the use of SCENESSE® as a medicinal therapy for acute arterial ischaemic stroke (AIS); and
 - the ongoing development of PRÉNUMBRA®, a new liquid formulation of afamelanotide for the treatment of acute disorders and vascular anomalies.
- through the Healthcare Solutions Division, progress the development of a range of non-prescription, dermatocosmetic products for individuals at high risk of exposure to ultraviolet (UV) and High Energy Visible (HEV) light.

Review of Operations and Financial Condition

There was no significant change in the nature of the Group's activities during the financial year.

Key Features of Business Operations

There are several key features of CLINUVEL's business operations:

- The commercial operations of the Group are undertaken in Europe and the USA.
 - Since June 2016 CLINUVEL has distributed SCENESSE® to EPP patients through accredited EPP Expert Centres, working within the commitments agreed with the European Medicines Agency (EMA) as a condition for continuous marketing authorisation.
 - Since April 2020, CLINUVEL has been distributing treatment for patients with EPP through accredited Specialty Centers in the US, in accordance with the approval of the FDA, granted in October 2019.
- The net price per unit of SCENESSE® is uniform across the jurisdictions in which it operates.
 - Manufacturing and distribution costs specific to each jurisdiction determines the gross price of SCENESSE®.
 - This approach reflects the Group's values of fairness and equitable access to treatment by all patients.
- SCENESSE® is manufactured in the USA by a sole contract manufacturer and is distributed by the Group directly to accredited EPP Expert Centres in Europe and Specialty Centers in the USA.
- CLINUVEL's cash receipts are markedly higher in the northern hemisphere from spring to autumn when ambient light is more intense and demand for treatment from EPP patients is higher.
- The Group has an ongoing clinical interest to further develop SCENESSE® and its derivatives with a focus on vitiligo, a skin depigmentation disorder; and DNA repair of the skin with initial clinical studies to commence in xeroderma pigmentosum (XP); in acute arterial ischaemic stroke (AIS); and in an undisclosed further indication.
- The research and development program has been extended through the development of a second

formulation of afamelanotide, PRÉNUMBRA®, with a focus on its application in acute disorders and vascular anomalies.

- The Group's product development program is conducted through its fully owned Singaporean subsidiary, VALLAURIX PTE LTD (VALLAURIX) with a focus on developing pharmaceutical topical products and other formulations and an over-the-counter, dermatocosmetic product range.
- The Melbourne headquarters of the Group covers the key regulatory affairs, scientific programme, finance, and investor relations functions, whilst the United Kingdom office co-ordinates global operations, communications, and marketing.

Review of Operations

The review of operations for the year ended 30 June 2021 (FY2021) focuses on:

- the distribution of SCENESSE® in Europe and the USA;
- ongoing work to obtain regulatory approval of SCENESSE® in new jurisdictions;
- the expansion of the Group's research and development program to develop SCENESSE® and its analogues for the treatment of patients with a range of severe skin and vascular disorders; and
- the development of non-prescription, dermatocosmetic products.

Distribution of SCENESSE® in Europe

The supply of SCENESSE® to EPP Expert Centres across key European countries, including under a special access scheme to Switzerland, continued in FY2021. During the COVID-19 pandemic, the majority of EPP Expert Centres have continued to prescribe SCENESSE® due to strong patient demand. A small number of Centres either deferred orders or reduced order sizes in the initial months of the COVID-19 infections in the second half of FY2020. These few Centres were not able to provide treatment access to patients, or patients were unable to travel to Centres. Despite the uncertainty surrounding the pandemic, patient demand for SCENESSE® remained high during FY2021, with

existing patients continuing to seek treatment and new patients receiving treatment for the first time.

We continue to progress reimbursement of the cost of treatment with authorities in several European countries.

Distribution of SCENESSE® in the USA

On 8 October 2019, the US FDA approved SCENESSE® to increase pain free light exposure in adult patients with a history of phototoxic reactions from EPP. This was a milestone approval for the Group after 15 years of research and development of SCENESSE® for EPP. Following the FDA's approval, the Group activated its implementation plan for US operations and, within six months of approval, completed the key pre-distribution logistics to commence treatment. These logistics included establishing the business infrastructure, securing correct codes for treatment to ensure seamless operations and reimbursement, initial insurer discussions and agreement to obtain reimbursement for the cost of treatment, and identification of the initial Specialty Centers to be accredited and trained by CLINUVEL.

In April 2021, CLINUVEL recorded its first anniversary of distributing SCENESSE® for adult EPP patients in the USA. Over 60 insurance companies are actively involved in the reimbursement of the cost of treatment, mainly under Prior Authorization (PA). CLINUVEL continues to operate a Savings Program to assist with the out-of-pocket expenses of patients and provides a dedicated patient and healthcare professional website to facilitate patient access to treatment. CLINUVEL actively supports patients and Specialty Centers to liaise with insurance companies to obtain approvals to reimburse the cost of treatment under PA.

The initial target was to accredit up to 30 Specialty Centers across the USA over a phased period by the end of calendar year 2021. CLINUVEL has currently trained and accredited over 40 Specialty Centers which is well ahead of planning. Cash receipts for FY2021 included the first receipts from the supply of SCENESSE® in the US market. The Company's experience is that payment terms are longer in duration in the US than the 30 to 60 days average length of payment term in Europe. After initial revenues were recorded from first-adopter orders prior to 30 June 2020, revenues rose throughout FY2021, underpinned by the progress achieved in the number of Specialty Centers accredited and the approvals under PA with

insurers to reimburse the cost of treatment. These activities were one factor driving the Company's record revenues and profit in FY2021.

SCENESSE® for EPP in New Jurisdictions

The Group continues to work towards gaining regulatory approval for SCENESSE® for EPP patients in other important markets. This reflects our commitment to provide EPP patients worldwide with access to SCENESSE®.

In October 2020, the Australian Therapeutic Goods Administration (TGA) approved the registration of SCENESSE® for the prevention of phototoxicity in adult patients with EPP, after a nine-month review of the SCENESSE® scientific dossier. This is the first treatment approved for EPP in Australia. Following the TGA approval, SCENESSE® has been registered on the Australian Register of Therapeutic Goods (ARTG) and subject to the agreement of the Pharmaceutical Benefits Advisory Committee, will be made available on the Pharmaceutical Benefit Scheme (PBS) in Australia. It is expected that the drug will be administered by specialists in an outpatient setting through speciality centres.

In February 2021, the Israeli Ministry of Health approved SCENESSE® as a first-line treatment for the prevention of phototoxicity to all adult patients diagnosed with EPP. It is anticipated this first approval of national reimbursement in the Middle East opens the pathway to other countries in the region.

The Collaboration Agreement to treat EPP patients with SCENESSE® under a Named Patient Program (NPP) in the People's Republic of China continues. The collaboration with the local distribution partner focuses on facilitating early access for Chinese EPP patients while collecting data to file for a new drug application (NDA) to the Chinese National Medical Products Administration (NMPA). CLINUVEL and its distribution partner is working with prominent hospitals in China to facilitate EPP patient treatment. It is planned that the NPP will include up to 10 Chinese EPP patients – treated according to US and EU protocols – who will be evaluated during a defined period. Local subsidies are available to enable eligible EPP patients to receive treatment. Following treatment with SCENESSE® under the NPP, CLINUVEL and its partner will evaluate the drug's safety and effectiveness in Chinese EPP patients. The collaboration will also focus on subsequent registration of SCENESSE® on the National

Drug Reimbursement List. On a prevalence basis, an estimated 5,000 Chinese residents suffer from EPP, for which there is no approved therapy in China.

CLINUVEL plans to seek regulatory approval to distribute SCENESSE® in other countries, including European countries not in the EU, the Middle East, Japan and Latin America.

Expansion Singapore Laboratory

New state of the art and expanded laboratories in Singapore were commissioned in August 2020 to further progress R&D on novel melanocortins, and prescription and over-the-counter products. After minor delays due to the COVID-19 pandemic in opening the expanded Company’s Research, Development & Innovation (RDI) Centre, the facility commenced operations with an expanded and skilled team and fitted with specialised technical laboratory equipment to further enhance the progress of its product pipeline and underly a new divisional structure.

The RDI Centre is operated by the Group’s wholly owned subsidiary, VALLAURIX Pte Ltd. The Singapore Economic Development Board (EDB) is supporting this expansion with an award under their Research Incentive Scheme for Companies (RISC). This is part of the Government of Singapore’s incentives to assist Singaporean businesses to develop their research capacity to advance high valued technologies. The EDB award is up to S\$500,000 (A\$547,000) over three years, subject to ongoing conditions being met.

New Organisational Structure

To support the strategic objectives and initiatives of the Group, a new organisational structure of four divisions was implemented during FY2021:



- the Pharmaceuticals Division, CLINUVEL’s core business focussed on developing and delivering products for patients with unmet medical need;
- the Healthcare Solutions Division, concentrated on non-prescription products derived from the know-how and active ingredients used in the Pharmaceuticals Division;
- the Communications, Branding and Marketing Division which prepares communications to wider differentiated audiences, positioning the Group for broader engagement; and the
- Manufacturing Division, focussed on novel formulations and products for CLINUVEL and research, development and production for other companies and research groups in the biopharmaceutical sector.

Pharmaceuticals

Healthcare Solutions

Communications, Branding & Marketing

Manufacturing



Research, Development & Innovation Centre

Underlying the divisional structure is the RDI Centre in Singapore, researching molecular science, biology, and follow-on formulations.

Product Pipeline

The Group has an extensive product development pipeline that encompasses the application of SCENESSE® and other novel treatments for patients with severe genetic, skin, and vascular disorders which lack therapeutic alternatives.

The pipeline includes research and development into:

- a paediatric formulation of SCENESSE® for EPP;
- SCENESSE® for adult vitiligo patients;
- next generation products based on melanocortin analogues CUV9900 and VLRX001, currently being evaluated as an adjuvant maintenance therapy in vitiligo, with the intention of developing these analogues for medicinal purposes to be administered topically;
- a range of over-the-counter products for general photoprotective application;
- the use of melanocortins in DNA repair of the skin;
- the role of afamelanotide in treatment of acute stroke (AIS); and
- the application of a newly developed second formulation of afamelanotide, PRÉNUMBRA®, a non-solid controlled-release formulation, to be evaluated in clinical trials for acute disorders and vascular anomalies.

Vitiligo Program

The Group continues to pursue a clinical program to evaluate the effectiveness of SCENESSE® to activate and repopulate melanocytes within vitiliginous lesions (depigmented skin areas) and achieve repigmentation in combination with NB-UVB phototherapy in patients with vitiligo.

In FY2020 a Type C Guidance Meeting was held with the FDA, the purpose of which was to seek agreement on the design of a multicentre Phase IIb vitiligo clinical study (CUV104) and the data package necessary to support a supplemental New Drug Application (sNDA) filing for SCENESSE® in vitiligo. Following the meeting, CLINUVEL has been liaising with the FDA and clinical experts to finalise the documentation and clinical trial protocol (CUV104) to advance SCENESSE® as the first systemic repigmentation agent in North America.

In March 2021, the FDA held a virtual public meeting on patient-focussed drug development for vitiligo which attracted 1,155 participants. The recognition of vitiligo as a disease needing treatment was encouraging, as was the majority of patients who advised in the meeting that they may or would use a topical treatment if it provided up to 50% repigmentation with modest side-effects.

Subject to agreement of the clinical protocol by the FDA and pending acceptable results on the ongoing safety and efficacy in its vitiligo program, CLINUVEL would seek to file a sNDA for SCENESSE®. A sNDA, referred to as an “efficacy supplement”, is required to add a new indication to the labelling of an approved drug in the USA, with the submission consisting of clinical data supporting the new indication and any additional studies which may be required to support the efficacy and safety in the new indication.

DNA Repair Program

Scientific advancements on melanocortins and CLINUVEL’s programs have shown that afamelanotide can assist in the repair of cellular DNA damage caused by exposure to ultraviolet radiation. In September 2020, CLINUVEL announced the commencement of work to evaluate this effect in humans, with an initial focus on xeroderma pigmentosum (XP), acknowledging a broader application of up to 2 billion people worldwide with a deficiency in their natural DNA repair processes.

The first patient with the XP-C variant dosed with SCENESSE® tolerated the treatment well and work proceeded to the design and approvals necessary to commence formal trials. In November 2020, a trial in healthy patients was approved and, in March 2021, the program was extended to patients with the XP-V variant.

There has been understandable caution by authorities and decision makers about the impact of conducting clinical trials on XP patients during the COVID-19 pandemic. In June 2021, CLINUVEL reached agreement with clinical and academic experts to proceed with clinical studies focusing on patients with the XP-C and XP-V variants. Three trials (CUV150, CUV152 and CUV153) have been designed to assess ultraviolet (UV) induced DNA damage and oxidative stress in XP patients. Dosing of the drug will occur at variable intervals for a maximum of four months. A fourth trial, CUV151, is designed to assess DNA repair in healthy

volunteers. COVID-19 has caused some delay in allowing XP patients to attend the clinics.

Acute Stroke Program

CLINUVEL announced its research program into the role of afamelanotide in the treatment of acute arterial ischaemic stroke (AIS) in October 2020. Stroke is the second most common cause of death and a leading cause of disability worldwide. Of 15 million strokes worldwide, 85% are AIS cases. Existing therapies can treat around 15% to 20% of these cases due to the accessible location of the clot in the M1 (or first branch) region of the main cerebral artery. In the bulk of cases, the clot is in the smaller arteries in the upper regions of the brain and, therefore not eligible for existing clot removing and clot dissolving treatments. Hence, CLINUVEL is seeking to develop a treatment for a significant unmet medical need.

Due to the COVID-19 pandemic, the start of the clinical trial in stroke patients (study CUV801) incurred a delay, but the first AIS patient was treated with afamelanotide in June 2021. In August 2021 an update was provided on the treatment of the first three AIS patients, with treatment well tolerated. Two patients showed improvement in neurological deficit while one patient showed no improvement. The CUV801 study is ongoing.

PRÉNUMBRA®

At the start of FY2021, the Group announced the development of a second formulation of afamelanotide, PRÉNUMBRA®. This non-solid controlled-release formulation provides dosing flexibility as part of the active life-cycle management of afamelanotide to address clinical needs in acute disorders and vascular anomalies. The Group has secured the intellectual property rights for the dosage form in identified indications, as well as the international trademarks for PRÉNUMBRA®. Development of this formulation is progressing and is managed through our RDI centre in Singapore.

Financial Review

The financial year ended 30 June 2021 marks the completion of the Group's fifth consecutive year of achieving a net profit, a positive cash flow result and increased revenue growth.

The result for the Group for FY2021 was a \$25.713 million profit before tax, compared to \$11.541 million for FY2020 (restated from \$13.136 million), a 123%

increase. The result reinforces the Group's success in pursuing a strategy to maintain and grow its commercial operations of SCENESSE® in the EU and the US whilst expanding its existing activities to support product development to prepare for future business growth. Total expenses increased by 2% year-on-year, compared to a 43% increase in Total Revenues and Other Income.

Net Cash provided by Operating Activities was a positive \$19.262 million for FY2021, up from a \$14.188 million positive result for FY2020. After the deployment of cash in investing and financing activities, net cash added \$15.944 million to cash and cash equivalents on the balance sheet after accounting for exchange rate adjustments on foreign currencies held. Cash reserves have increased steadily since 2016 without reliance on debt or equity funding, from \$13.845 million at 30 June 2016 to the 30 June 2021 level of \$82.691 million.

Summary Financials FY2021

Consolidated Entity	FY2021	FY2020 restated
	\$	\$
Revenues and Other Income	48,450,599 +43%	33,909,670 +4%
Net Profit before income tax	25,712,644 +123%	11,540,811 -36.3%
Profit after income tax expense	24,728,247 +64%	15,051,199 -17%
Basic earnings per share	0.500 +64%	0.306 -18.6%
Net tangible assets backing per share	1.911 +41%	1.351 +17%
Dividends	2.5 cents	2.5 cents

Note: CLINUVEL has one operating segment for reporting purposes.

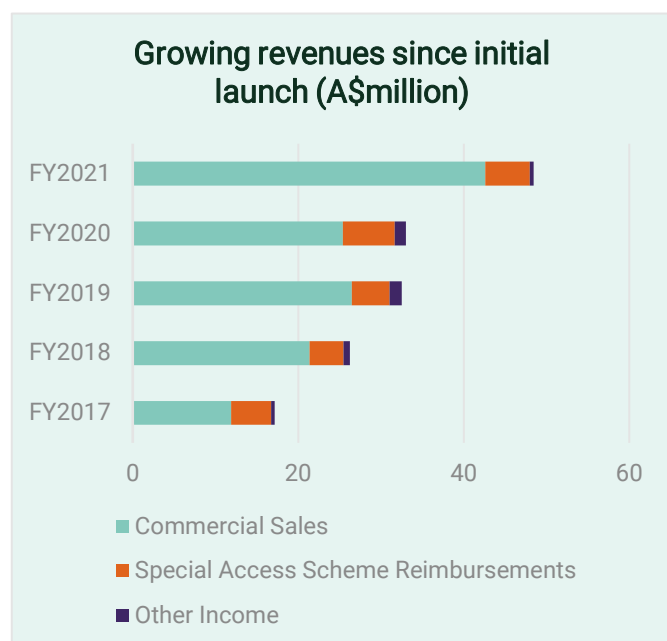
There is an increase in expenses and a corresponding decrease in Net Profit before tax of \$1.596 million for FY2020. Further details are provided in Note 1 to the Financial Statements.

Revenues

The Group achieved a Total Revenue result of \$47.976 million for FY2021. This strong top line result is a 47.3% increase on the prior year of \$32.565 million.

Total revenues have continued to grow year on year since initial launch of SCENESSE® in FY2016, reflecting

the progress made from achieving marketing authorisation in two major markets and the subsequent agreements to establish a price for the medicinal product. The graph below depicts the growth in Total Revenues year on year since FY2017.



A comparison of the FY2021 reported and constant currency results against the FY2020 reported results for Commercial Sales and Special Access Scheme Reimbursements is shown in the table below.

Throughout FY2021, the Australian dollar currency was stronger relative to most other currencies the Group had an exposure to when compared to FY2020. As a result, movements in foreign exchange rates against the Australian dollar presentation currency resulted in a \$3.888 million adverse impact to the reported Total Revenue result for the year.

	Commercial Sales	SAS Reimbursements – Switzerland, Other	Total
AU \$ million			
FY2021 Reported	42.603	5.373	47.976
FY2021 Constant*	46.236	5.627	51.864
FY2020 Reported	26.306	6.259	32.565
% change (Constant)	75.8%	-10.1%	65.7%
% change (Reported)	62.0%	-14.2%	47.8%

* FY2021 revenues converted to A\$ monthly at the average conversion rate of the same month of FY2020

Commercial Sales

Commercial sales for FY2021 were \$42.603 million, a 62% increase to the commercial sales result for FY2020 (\$26.306 million). On a constant currency basis, commercial sales revenues of SCENESSE® increased 75.8% for the year. The Group views its commercial sales as a single operating segment for reporting purposes but provide insights into the trends in key markets below

The increase in commercial sales was also driven by the impact of recognising commercial sales in the USA across a full financial year for the first time. At the end of FY2020, more than forty insurance companies had agreed to reimburse SCENESSE® either via Prior Authorization (PA) or through acceptance of the drug on individual formularies. This number had increased to over 60 by the end of FY2021. The number of Specialty Centers participating in the distribution program who are trained and accredited has now grown to over 40.

Unit sales by month in the US was relatively consistent from the start of the financial year through the winter months in the northern hemisphere, progressively increasing in the latter months of the year, reflecting higher patient enrolment in the time of year where the level of ambient light emission intensifies for EPP patients. This indicates a level of year-round demand for SCENESSE® in the US.

Commercial sales in Europe improved in FY2021 after some disruption was experienced by select EPP Expert Centres in the latter half of FY2020 in responding to the COVID-19 pandemic. There were some competing trends in patient demand and the experience of EPP Expert Centres during the year:

- Patients unwilling or unable to travel to seek treatment during FY2020 returned to seek and receive treatment in FY2021;
- Some EPP Expert Centres treated new patients for the first time, increasing the number of patients they were able to treat;
- A few Centres treating smaller patient numbers reduced orders of SCENESSE®; and
- Other EPP Expert Centres who have been participating under the post-authorisation safety setting for multiple years are gradually reaching a critical mass and experienced relatively steady patient numbers.

A stronger Australian dollar in FY2021 affected the year-on-year increase in commercial sales recorded in

original Euro currency, however the Group still recorded a 4% increase upon converting Euro sales into the Australian reporting currency.

Reimbursements – Special Access Schemes

The distribution of SCENESSE® under Special Access Schemes continued to provide a preventative treatment for adult EPP patients, primarily to Switzerland. SCENESSE® was also supplied outside Switzerland to select countries under a special access arrangement whereby CLINUVEL received full cost compensation, linked to the uniform price of SCENESSE® sold in the European Economic Area under the marketing authorisation.

On a constant currency basis, sales reimbursements from special access schemes decreased 10.0% for the year. The result was driven by a decline in the number of patients seeking treatment in Switzerland, either due to the COVID-19 pandemic, or who are now understood to be receiving treatment in other countries.

Other Income

Interest Revenue and Other Income

Interest received from funds held in bank accounts and term deposits for FY2021 was \$0.342 million compared to \$0.563 million for FY2020.

The positive financial performance of the Group saw an increase over the 12 months to 30 June 2021 of \$15.944 million to its cash reserves. Over the course of FY2021 the Group continued the trend in prior years to transfer more funds into higher-yielding Australian dollar fixed-rate term deposits. The average amount of cash held in term deposits was 27.6% higher than for FY2020. However, the higher cash balances were offset by a lower interest rate yield earned on holding interest-bearing term deposits, averaging 96 basis points less year-on-year. The decrease in interest rate yield reflected the impact of Australian government monetary policy on term deposit rates on offer throughout the year. 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. The average amount of funds held in non-Australian dollar currency in FY 2021 has remained stable, decreasing 3% on average when compared to FY2020. The average amount of Australian currency held year-on-year increased 44%.

The Group recorded other income of \$0.130 million in government grants received in Australia and Singapore to assist companies respond to the economic impact of the COVID-19 pandemic.

Expenditures

Total Expenses for the Group for FY2021 were \$22.738 million, up 2% from FY2020 (\$22.369 million). Expenses were well contained in a period where the Group was focussed to re-invest in the business to expand its activities across the four recently announced divisions: (a) Pharmaceutical, (b) Healthcare Solutions, (c) Communications, Branding & Marketing, and (d) Manufacturing, supported by the RDI Centre. This result occurred in a challenging environment of escalating cost of goods and services across all key inputs to the business.

New expense groupings are reported for FY2021 and FY2020, to reflect the expansion and diversification of activities of the Group.

Clinical & non-Clinical Development

Clinical & non-clinical development expenses reflect the direct investment of the Group in its clinical trial programs targeting the expanded use of SCENESSE® beyond the field of EPP, along with the product development initiatives and paediatric and alternative formulations, including PRÉNUMBRA®. This category includes analytical testing, pre-clinical and non-clinical activities.

Clinical and non-clinical development fees increased 82% from \$0.341 million in FY2020 to \$0.548 million in FY2021. The increase reflects the Group's strategy to advance its research and development initiatives, led by the VALLAURIX operations, after a sustained period of focus on the commercialisation activities following European and US regulatory approval in 2014 and 2019, respectively.

This expense result for FY2021 was driven by:

- Growth in product development and testing services in the VALLAURIX laboratories;
- Completion of pre-clinical studies to support the Group's strategic focus to develop solutions for population groups most at risk of skin damage and cancers; and
- Trial fees toward the stroke study CUV801.

Commercial Distribution

Commercial distribution expenditures ensure our product is provided to end users under Good Distribution Practice and to satisfy our risk management commitments with regulatory agencies. These activities include pharmacovigilance, quality systems, safety reporting, PASS Registry data capture and dossier updates.

During the year new distribution centres with contracted parties and third-party service providers were established in the US to support supply to EPP Specialty Centers. Permits and licenses across participating US states were established. Regulatory dossier changes were submitted and approved. Assistance on market access initiatives in new countries and further pricing negotiation continued throughout the year.

These expenditures in FY2021 were a 1% improvement to FY2020, from \$2.443 million to \$2.421 million, noting:

- Increased freight, product handling, distribution and manufacturing royalty expenses from higher transportation volumes, largely offset by:
- Reduced costs in responding to regulatory audits relating to the manufacturing and quality systems

Materials Expense

Materials and related expenses primarily reflect some of the acquisition purchases to support the production of finished product by the Group's contract manufacturer, along with other materials purchases. The Group continues to prepare for future sales growth and to meet short-term and long-term inventory requirements. The Group concluded a manufacturing campaign to secure raw material peptide via a critical process change to support future scale-up. This is in final stages of validation. Multiple batch manufacturing campaigns were conducted throughout FY2021 and continue into FY2022.

Expenditures on essential materials increased 34%, from \$2.350 million in FY2020 to \$3.650 million in FY2021. The increase reflects both an increase in both the volume and cost of materials required to support manufacture to meet product requirements.

Communication, Branding and Marketing

Communication, Branding and Marketing fees decreased 47%, from \$0.589 million in FY2020 to \$0.314 million in FY2021.

The Group has invested in resources to expand its visibility and to engage with new audiences. It is building a team of professionals experienced in, and capable of, expanding the Company's reach using various media tools and channels to prepare for new product launches whilst communicating the CLINUVEL brand.

The decrease in this expense result is due to:

- Services previously conducted by external parties have being brought in-house;
- Conference attendance and presentation costs in FY2020 not being repeated in FY2021 due to the COVID-19 pandemic

Legal, Insurance and IP

Legal, insurance and IP-related fees decreased 5% from \$1.148 million in FY2020 to \$1.095 million in FY2021.

Incurring expenditures in external legal support, in patent & trademark expenses and various insurances provides the Group with vital property protection and a competitive advantage over others. It also plays an important part in the Group's risk management plans

This expense result was driven by a tapering in overall IP fees partly offset by increases in annual insurances reflecting the growth in scale of the business amid a general softening of the global insurance market.

Personnel

People are integral to the Group's success and are the key driver for executing the Company strategy. The Group increased its workforce in the current year, with an emphasis on distribution, clinical and non-clinical development roles, primarily to drive business growth.

The personnel expense result for FY2021 was \$10.158 million, a 3% reduction from FY2020 of \$10.490 million. FY2020 was restated and included first-time recognition of long-term employee retention benefits of \$1.596 million (FY2021: \$0.118 million).

Share Based Payment

The share-based payment charge increased 57% from \$1.659 million in FY2020 to \$2.602 million. This is a non-cash accounting charge for share-based payments

provided to the Managing Director and other staff. The prior year's non-cash charge was less than 12 months charge as the majority of the share-based payments were granted part way through FY2020.

Finance, Corporate and General

Expenditures from finance, corporate and general activities decreased 21% from \$2.054 million in FY2020 to \$1.618 million in FY2021.

Finance, corporate and general costs are reflective of the support function necessary to ensure the execution of the Company's demanding near-term and long-term expansion strategy. The Group operates in seven different locations, with a workforce across four different continents who require the infrastructure and support to execute their important functions. Examples of expenditures include IT, corporate support, listing and registry fees, travel and short-term rents.

The improvement in this expense result year on year was due to a near absence of local and international staff travel, brought on by restrictions in movement by countries dealing with the COVID-19 pandemic.

Depreciation and Amortisation

Depreciation and amortisation increased by \$0.415 million, from \$0.446 million to \$0.861 million. The increase is attributable to 12 months depreciation of the expanded RDI Centre in Singapore.

Changes in inventories of raw materials, work in progress and finished goods

Changes in inventories of raw materials, work in progress and finished goods represents the adjustment to inventory acquisition expenditures in excess of commercial sales. For FY2021, an adjustment was recorded increasing inventory levels by \$1.899 million, demonstrating the Group's strategy to prepare for future near-term sales demand. For FY2020, the result was a \$0.848 million charge to the expense result, reflecting reduction in inventory levels.

Unrealised loss on restating foreign currency balances and currencies held

The presentation currency of the Group is Australian dollars. The Group invoices its commercial sales and special access reimbursement invoices in non-Australian dollar currency. Trade debtors are

recognised in non-Australian currency and cash receipts are received in non-Australian dollar currency.

Unrealised adjustments are brought to account to restate trade debtors and creditors and foreign currencies held to Australian dollar currency as at 30 June.

As a result of the movement in the Australian dollar during FY2021, the Group recorded a \$1.368 million loss as at 30 June 2021 (30 June 2020: \$0.537 million gain).

Deferred Tax Asset

In FY2020, the Group brought to account a deferred tax asset (DTA) relating to previously unrecognised prior period tax losses, resulting in a credit to income tax benefit of \$3.510 million.

In FY2021, the Group utilised carry forward tax losses in the DTA, resulting in a debit to income tax expense of \$0.984 million.

The amount of the DTA account reflects:

- the benefit to be received from utilising unused tax losses against the temporary differences that result in a deferred tax liability for the business; and
- the expected utilisation of unused tax losses against probable near term taxable profits

Balance Sheet

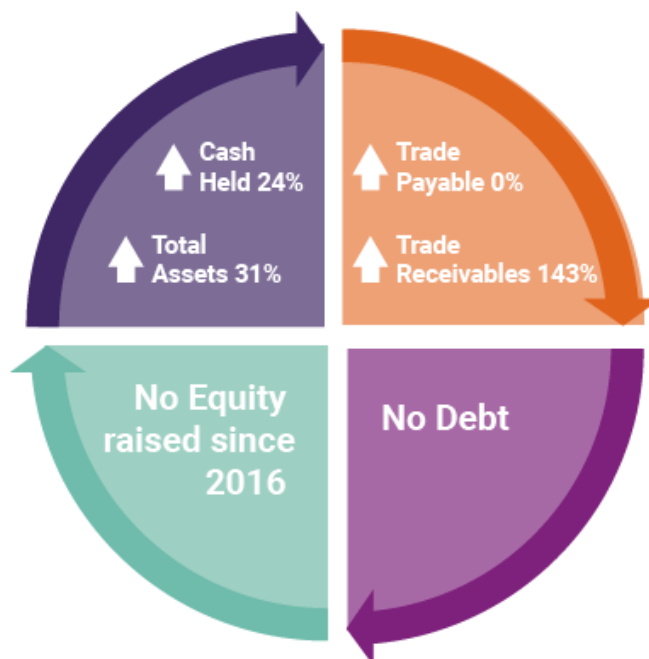
One of the key objectives of the Company is to ensure its Balance Sheet is sufficiently positioned and robust to allow investment in future performance with a financial buffer to respond to unexpected adverse events. The Company has continued to preserve cash and cash equivalents held without need to raise capital and diluting shareholder returns, nor has it raised debt capital and increasing the debt leverage of the Group. The cash position has enabled the Group to withstand anticipated increases to short term liabilities to support the growth of the business and to sudden adverse economic conditions following unexpected events such as the coronavirus pandemic. This remains a deliberate and planned strategy, reflecting CLINUVEL's prudent approach to risk management.

Key Balance Sheet highlights of the year:

The positive cash flows generated by the Company's commercial distribution programs drove the key changes to the balance sheet, increasing cash reserves by 24% from \$66.747 million in FY2020 to \$82.691 million in FY2021.

The increase in US sales combined with longer cash receipt cycle on sales of SCENESSE® in the US when compared to Europe was the main reason for the increase of 143% in trade receivables on the balance sheet in FY2021.

Total liabilities increased 4%, from \$9.475 million to \$9.830 million, with no long-term debt. The ratio of the Company's overall debt to equity is 10%.



Returns on Equity

Returns for FY2021 remain strong and are summarised by:

	FY2021	FY2020 Restated	FY2019	FY2018	FY2017	FY2016
AU \$ million						
Profit attributable to owners of parent	\$24.728	\$15.051*	\$18.134	\$13.224	\$7.180	(\$3.121)
Basic EPS	50.0 cents	30.6 cents*	37.6 cents	27.7 cents	14.9 cents	(7.0) cents
Dividends Paid in Year	\$1.235	\$1.224	\$0.957	-	-	-
Dividends per Share Declared	2.5 cents	2.5 cents	2.5 cents	2.0 cents	-	-
Change in Share Price YoY	20%	(24%)	206%	58%	62%	52%
Return on Equity	25%	21%*	32%	34%	28%	(18%)

Shareholder returns have been generated in both the short-term and the longer-term through: capital appreciation (through Total Shareholder Return exceeding the Nasdaq Biotech Index and ASX200 Healthcare Index since first product launch, and dividend distribution in the past 3 financial years.

* Restated

Investments for Future Performance

The Group's key objectives are to progress CLINUVEL as a world leader in medicinal photoprotection and repigmentation and to support the expansion into other, similar genetic and skin-related disorders, as well as acute disorders and vascular anomalies. In addition to the ongoing development of its active and expanded product pipeline, the Group is actively considering the integration of new functions and capabilities through one or more selective acquisitions.

The Group has deployed working capital throughout the year to prepare for future performance across the following areas:

People	<ul style="list-style-type: none"> Created new roles across all business functions Created new roles across all business functions
Research & Development	<ul style="list-style-type: none"> Commenced operation of larger laboratory with expanded analytical capabilities & fixed asset purchases non-solid dosage formulation development non-clinical development
Clinical	<p>Activities in progress to obtain approvals to move into next phase clinical studies to pursue potential new markets for SCENESSE® in:</p> <ul style="list-style-type: none"> Vitiligo DNA Repair, focussed on XP Acute Stroke (AIS) Undisclosed indication
Manufacturing	<ul style="list-style-type: none"> Program to manufacture raw material peptide via a process change to support future scale-up. Increase product inventories to meet expected commercial and clinical demand
IP	<ul style="list-style-type: none"> Continued to renew and maintain new and existing patents to strengthen its intellectual property position

Capital Structure

The Group is debt free and has a consistent capital structure of ordinary shares on issue plus unlisted securities in the form of conditional performance rights, which will vest on the Group meeting certain performance conditions.

CLINUVEL's outstanding shares on issue remained at 49,410,338 shares to 30 June 2021. There was no issue of new shares through the exercise of performance rights under the Group's performance rights plans or from capital raising.

Dividends Paid or Recommended

Declared & paid in 2020/21	Cents per Share	Amount	Date of Payment
Final	2.50	\$1,235,266	18 September 2020

On 25 August 2021, the Board of Directors declared an unfranked dividend of \$0.025 per ordinary share in relation to the full year ended 30 June 2021.

Cash from Operations and Other Sources of Cash

Overall, the Company generated cash from its operating activities by \$19.262 million in FY2021 (FY2020: \$14.188 million)

Cash inflows from customer receipts increased 32% to \$38.724 million in FY2021, compared to \$29.288 million for FY2020.

Cash outflows for payments to suppliers and employees increased by 23%, from \$16.281 million to \$20.032 million.

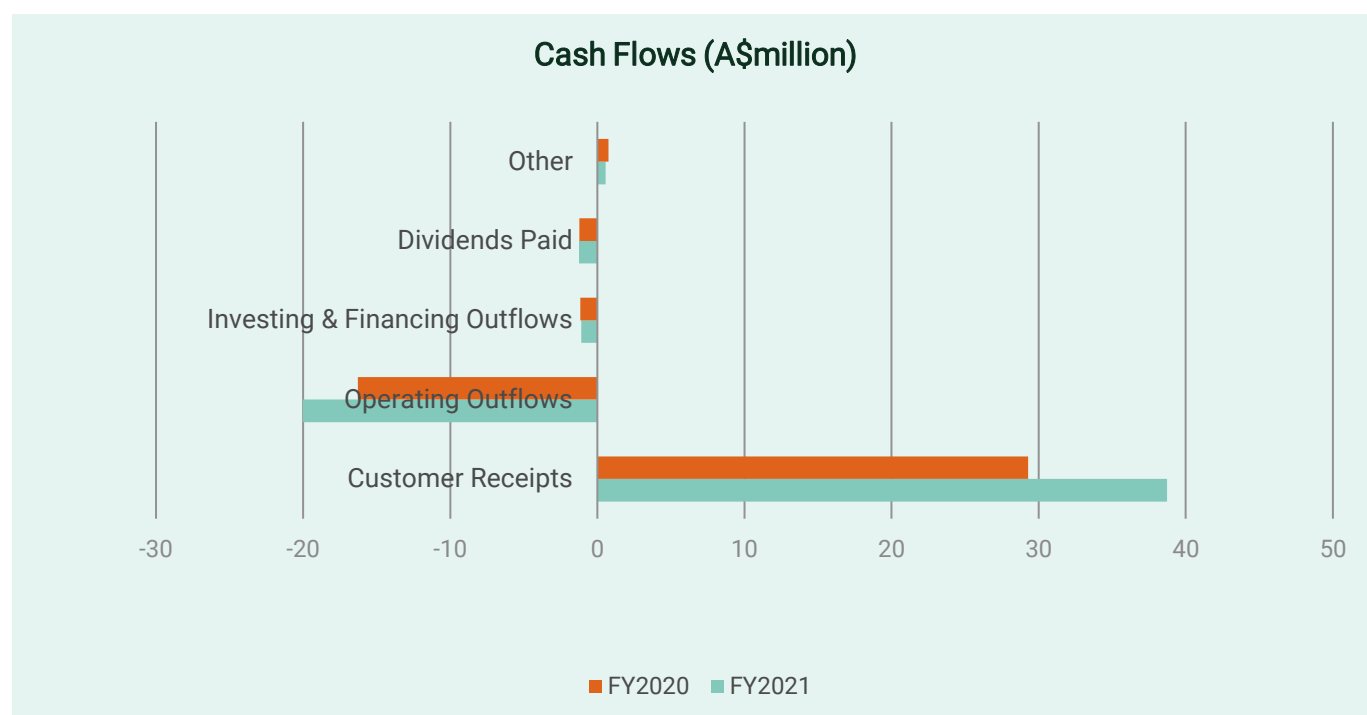
There were also cash outflows of \$0.854 million for the acquisition of property, plant and equipment, \$0.245 million of repayment of borrowing and leasing liabilities, and \$1.235 million for the payment of an unfranked dividend to shareholders in relation to FY2020.

The Groups' policy towards cash management is to:

- Hold cash in at-call bank accounts and place additional cash in short-term term deposits providing favourable rates of interest; and
- Actively manage foreign currency exposure, taking account of recent and expected currency trends, holding foreign currencies as a natural hedge, using market orders, foreign exchange forward contracts and other foreign exchange risk management products, as considered appropriate.

The Group's financial liquidity as at 30 June 2021 is reflected in:

- A quick ratio of 11.3:1 (30 June 2020 8.9:1); and
- Cash and cash equivalents of \$82.691 million, accounting for 80.4% of total current assets (FY2020: \$66.747 million, 88.8% of total current assets).



Material Business Risks

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	<ul style="list-style-type: none"> • Despite obtaining marketing authorisations, those products may ultimately prove not to be safe and/or of clinical or other benefit.
Supply	<ul style="list-style-type: none"> • Manufacturing processes 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. These factors may lead to non-supply of product and/or adverse regulatory outcomes.
Clinical & Regulatory	<ul style="list-style-type: none"> • Clinical trials may not yield the expected and desired results for the investigational medicinal product(s) to obtain further regulatory approvals.
Drug Pricing	<ul style="list-style-type: none"> • Third-party payors may 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Cash outflows from its operations over the long-term 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.
Market Competitor	<ul style="list-style-type: none"> • New entrants could enter the same market to directly compete against CLINUVEL's products with new products proven to be safer, more effective and priced lower than CLINUVEL's.
Management	<ul style="list-style-type: none"> • The Group's corporate strategy could be impacted adversely if the Group was not able to retain its specialised knowledge and areas of expertise, key management, members of staff and/or Board.

Impact of the Coronavirus Pandemic on CLINUVEL's Business

The coronavirus pandemic continues to adversely impact both people's health and global economic activity. Many countries are focussed on vaccinating their populations to provide ongoing protection from the variants of the virus. However, the impact and consequences on how we live, work, and interact will be felt for years.

CLINUVEL is no exception to being impacted by the coronavirus pandemic. However, CLINUVEL's business has proven resilient and is relatively well positioned to manage the difficult operating environment and progress its strategic initiatives.

Demand for SCENESSE®

Access for patients seeking treatment in hospitals was affected during the initial months when population lockdowns across Europe were first instituted in the latter months of FY2020. EPP Expert Centres either deferred orders or reduced order sizes in the initial months of the COVID-19 infections because they were unable to provide treatment access to patients, or patients were unable to travel to them. Notwithstanding the uncertainty surrounding the pandemic, patient demand for SCENESSE® in Europe remained strong, with existing patients continuing to demand treatment and new patients receiving treatment for the first time. CLINUVEL is conscious of the patients it serves and the anxiety and uncertainty they face during the coronavirus-pandemic and it has worked to continue to meet their demand for SCENESSE®.

Research and Development

CLINUVEL's research and development program continued to progress in FY2021. The operations of the laboratory facilities in Singapore were restricted during the circuit-breaker period which overlapped FY2020 to FY2021, with some remote working required. The circuit-breaker also resulted in minor delays to the laboratory expansion project, which was completed in 2020.

Supply of SCENESSE®

The sourcing, manufacturing and controlled distribution of SCENESSE® continued without material disruption or delay from the coronavirus pandemic. Raw material sourcing, manufacturing activities and movement of goods were able to be conducted without materially adversely impacting timeframes. CLINUVEL continuously reviews its operations to assess ongoing supply of SCENESSE® which may be impacted by the coronavirus pandemic.

CLINUVEL's People

CLINUVEL has played a responsible role to assist the global effort to manage the spread of COVID-19. CLINUVEL personnel have adapted to work remotely, attending the office only as necessary and when permitted under government regulations. Video-based communications technology has been maximised whilst local and international travel has been minimised, and in most cases, ceased. Diligence and adaptation under a difficult operating environment by the entire CLINUVEL team has seen productivity and focus remain largely unaffected.

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 25 August 2021, the Board of Directors declared an unfranked dividend of \$0.025 per ordinary share.

Likely Developments and Expected Results

The Group launched SCENESSE® in Europe in June 2016. As part of the conditions attached to the European marketing authorisation, the Group operates an agreed long-term risk management plan under the supervision of the EMA. The Group has been assisted by 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 ongoing requirements will remain in place until such time the EMA decides these are no longer necessary.

The Group has established a reference price for SCENESSE® as part of its uniform pricing strategy in Europe and has entered into pricing agreements with several European countries, and state and private insurance groups. The Group has established a distribution-focused workforce in Europe to support the increase in product volumes and will continue to increase staff numbers as additional pricing agreements per country are established with payors, and as the required pharmacovigilance activities continue to expand.

The Group has focused on its manufacturing requirements by working with its contract manufacturer and raw material supplier to meet commercial product supply in line with its timing

expectations and to pursue ongoing process improvement initiatives to support future increases in supply. These initiatives are part of continuous improvement and will form part of the Group's expenditure base moving forward. The contract manufacturer bear responsibility for the manufacturing standards of the commercial drug product. The Group announced in March 2021 it will establish a Manufacturing Division where it will manufacture own products and will be eventually set up as a contract manufacturer for other pharmaceutical companies and research groups.

SCENESSE® was launched in the US in April 2020. The Group is focussed on securing agreement on reimbursement of SCENESSE® with insurers to make SCENESSE® available to all US patients receptive to the treatment. The Group will continue to expand its resources and activities to support US market entry which includes operating a risk management plan similar to what has been instituted in Europe.

The Group will continue its North American clinical program to evaluate the effectiveness of its lead product to repigment vitiliginous lesions (depigmented skin areas) in combination with NB-UVB light therapy in patients with vitiligo and also as a standalone therapy. This program would include advancing into the next phases of clinical studies to demonstrate the efficacy and long-term safety of SCENESSE® in combination with NB-UVB in the treatment of vitiligo.

The Group also intends to further progress its clinical program with SCENESSE® in other indications, including VP, in DNA Repair with a focus on treating patients with XP, in AIS and in another yet to be disclosed acute indication. To support this likely development, CLINUVEL is advancing PRÉNUMBRA®, a non-solid dosage form of afamelanotide as a potent haemodynamic, vasoactive and anti-oncotic therapeutic agent, initially in adult patients.

The Group expects to advance its product pipeline, progressing the development of the molecules CUV9900 and VLRX001 through the various development phases which may include formulation development, non-clinical and human testing. In

addition, complementary OTC products are being developed and manufactured for clinical use. The Group has increased its resources and expanded its capabilities to progress these projects underway at VALLAURIX.

Ultimately, the long-term financial objective of the Group is to establish a sustainable commercial enterprise serving the needs of unattended populations. 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 additional funding to support these activities should the need arise.

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 2016/91 and therefore the amounts contained in this report and in the financial report may have been rounded to the nearest \$1,000,000 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.

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 2021.

Key Management Personnel ('KMP') has the meaning given in the Australian Corporations Act and who together have the authority and responsibility for planning, directing and controlling the activities of the Group, being:

Name	Position	Term as KMP
Non-Executive Directors		
Mrs. B.M. Shanahan	Non-Executive Director	Full Year
Mr. W.A. Blijdorp	Non-Executive Director	Full Year
Dr. K.A. Agersborg	Non-Executive Director	Full Year
Mrs. S. E. Smith	Non-Executive Director	Full Year
Prof. J. V. Rosenfeld	Non-Executive Director	Full Year
Executive KMP		
Dr. P.J. Wolgen	Managing Director and Chief Executive Officer	Full Year
Dr. D.J. Wright	Chief Scientific Officer	Full Year
Mr. D.M. Keamy	Chief Financial Officer and Company Secretary	Full Year

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

- A. Introduction by the Chair of the Remuneration Committee
- B. Response To Shareholder Feedback and the first strike in FY2020
- C. Remuneration Governance
- D. Executive Remuneration
- E. Non-Executive Remuneration
- F. Service Agreements FY2021
- G. Share Based Remuneration
- H. Details of Remuneration

A INTRODUCTION BY THE CHAIR OF THE REMUNERATION COMMITTEE



Chairman of the Remuneration Committee: Mr Willem Blijdorp

Dear Shareholder,

On behalf of the Remuneration Committee (Committee), I am pleased to present to you our Remuneration Report for the year ended 30 June 2021. Our FY2021 Remuneration Report details our remuneration policy for our Executive KMP and Directors and explains how FY2021 remuneration outcomes for Executive KMP align with CLINUVEL's performance, long-term objectives, and shareholder outcomes.

Our year

FY2021 was another challenging year due to the ongoing COVID-19 pandemic adversely affecting our people and the broader community, as well as impacting CLINUVEL's commercial operations, product supply, productivity, and clinical program. While CLINUVEL's business performance should be assessed in the context of this difficult operating environment, our Board is extremely proud of how our executives, the RDI Centre, finance, clinical, regulatory and the overall team have responded to these challenges and continued to execute our strategy, while ensuring the well-being of our employees and customers.

Despite these impacts, CLINUVEL delivered another year of positive financial performance. FY2021 marked our fifth consecutive year of annual profit (FY2021: PBIT of A\$25.7m) and positive cashflow, which has provided shareholders with a positive return on equity (FY2021: 25%) and earnings per share (FY2021: A\$0.500 cents) over this period. Shareholders have been rewarded with consistent annual dividends over the last three years, and substantial Total Shareholder Return (TSR) growth over the last 15 years as of 30 June 2021 (28% over 1 year, 147% over 3 years, 591% over 5 years, 692% over 15 years).

FY2021 has seen significant expansion in CLINUVEL's research and development (R&D) program, as part of the overall strategy to translate CLINUVEL's proven technology and expertise to a range of pharmaceutical and non-prescription products for unmet patient and consumer needs. Due to the cash reserves accumulated over the last five years, CLINUVEL is in a strong position to fund this expansion.

Remuneration Outcomes

CLINUVEL relies on a management team with the right innovative mindset and entrepreneurial spirit to execute our ambitious growth strategy, which will continue to deliver sustainable returns to shareholders. Rewarding and recognising our people fairly is a key priority for the Committee, to ensure we continue to attract, motivate and retain top talent. The Committee believes that the overall remuneration structure appropriately considers short, medium, and long-term strategic priorities across a mix of financial and non-financial measures that contribute to value creation for both the Company and shareholders.

Fixed remuneration increases of 3.5% were applied to the CFO and CSO in FY2021 to improve market positioning, with no fixed pay increases to apply to the CEO for the remainder of his service agreement (other than CPI adjustments).

As outlined above, despite the challenging external environment, several key milestones were achieved in FY2021 across CLINUVEL’s commercial operations, financial performance, R&D program, communications and analyst coverage, and strategy development. Reflecting these achievements, and the effort required to navigate the issues and challenges from the COVID-19 pandemic, the Board determined to award the CEO a FY2021 short-term incentive (STI) award of 70% of maximum opportunity but capped at 53%. The CFO and CSO received STI awards of 82% and 65% of maximum, respectively.

Some of the progress resulted in 6% of the CEO’s FY2020 grant of LTI performance rights to vest up to the end of FY2021 (with a final vesting date of 20 November 2023 for this grant).

Our response to the strike against the FY2020 Remuneration Report

Following the strike against our FY2020 Remuneration Report, the Committee engaged extensively with major shareholders and proxy advisors to understand any concerns with our remuneration framework, and to keep abreast of both Australian and global market practice. In addition, a robust review of CLINUVEL’s remuneration practices and disclosures were completed in FY2021 with support from independent external advisors.

We appreciate and respect all the feedback from our key stakeholders, and we strive to consider a balanced view of all perspectives. However, achieving this balance is no easy feat, given our diverse Australian and international shareholder base. The table in section B details the Committee’s response to the main concerns raised by stakeholders, which include enhanced disclosure and transparency of STI outcomes and how our remuneration approach reflects our significant global presence.

The Committee recognises that improving our remuneration practices will be an iterative process that will consider your ongoing feedback, whilst ensuring we continue to appropriately reward and motivate the best talent for CLINUVEL. The Committee is confident that CLINUVEL’s remuneration framework remains strongly aligned to our vision and strategy, and focuses our executive team on delivering sustainable, long-term value for shareholders.

We thank you all for your thoughtful feedback and look forward to continuing to engage with our stakeholders.

Yours sincerely,

Willem Blijdorp, Chairman of the Remuneration Committee
Amsterdam

B RESPONSE TO SHAREHOLDER FEEDBACK AND THE FIRST STRIKE IN FY2020

In FY2020, the company received a first strike against the Remuneration Report, and has responded to key items of concern that were raised as follows:

Remuneration Component	Issue Raised FY2020	CLINUVEL's Response
Total Fixed Remuneration (TFR)	Significant increase in the CEO's fixed remuneration in FY2020 relative to ASX-listed peers	<p>The Committee acknowledges the feedback received regarding the increase in the CEO's remuneration in FY2020, as part of his new service agreement.</p> <p>In determining the CEO's new remuneration last year, the Board considered that CLINUVEL is a truly global company, with most of its commercial operations and revenues generated in Europe and the US, a RDI Centre located in Singapore, and its CEO based in Europe. As such, CLINUVEL faces the challenge of attracting and retaining high-calibre executives in an increasingly competitive global talent market in the pharmaceutical/biotech industry – particularly given the strong focus on healthcare across the world.</p> <p>The Board is strongly of the view that the CEO's remuneration should reflect this global context, and more importantly, acknowledge Dr Wolgen's proven track record in delivering outstanding business performance and TSR* growth since he became CEO in late 2005 (28% over 1 year, 147% over 3 years, 591% over 5 years, 1,487% over 10 years).*</p> <p>The Board also waited until CLINUVEL's R&D phase was completed and sustained profitability was achieved, before adjusting Dr Wolgen's remuneration in FY2020 to better align with global peers. FY2020 marked the fourth consecutive year of annual profit for the Company (NPAT of A\$15.1 million, EBIT of A\$11.5 million), and the CEO and his team have delivered again in FY2021, with CLINUVEL achieving NPAT of A\$24.7 million and PBIT of A\$25.7 million this year.</p> <p>The CEO will not receive further fixed pay increase for the remainder of his service agreement (other than for CPI adjustments).</p> <p>To provide stakeholders with confidence around how CLINUVEL reviews and sets executive remuneration levels, we have provided enhanced disclosure and transparency in section D. This includes details of benchmarking completed by independent external consultants in March 2021.</p>
STI Plan	Lack of disclosure of STI performance targets.	<p>The Committee continues to consider ways to enhance the levels of disclosure of STI measures and targets, where commercial sensitivity does not prohibit this given the stage of CLINUVEL's development and competitive environment.</p> <p>STI performance measures are carefully selected by the Board, ensuring an appropriate balance between measures that management can influence, and which drive long-term decision making and ultimately shareholder value accretion. A rigorous process is also followed to ensure robust targets are established for all measures to drive high levels of business and individual performance.</p> <p>In FY2021, the Committee has provided greater transparency and granularity to shareholders of STI performance measures and outcomes, without compromising the confidential nature of some of the operational data and information used in compiling these performance measures. Refer to section D for detail.</p>
LTI Plan	Prior LTI grants to the Executive KMP (excluding the CEO) are not linked to profitability or other financial measures.	<p>No LTI performance rights were granted to the other Executive KMP in FY2021, with LTIs last granted in FY2016.</p> <p>LTI performance rights will be granted to the other Executive KMP in FY2022, under a similar structure to the CEO's FY2020 LTI grant to ensure consistency of measures linked to CLINUVEL's long-term strategy.</p> <p>As disclosed on pages 38 to 40 of this report, the CEO's FY2020 LTI grant includes</p>

		<p>several KPIs critical to the commercial growth of CLINUVEL, which are designed around the unique risks and complexities of our business. These KPIs include various financial measures linked to milestones for market capitalisation, cash reserves and sales revenues; all with significantly stretching targets that will likely increase shareholder value, if achieved.</p>
	<p>Significant quantum of LTI granted to the CEO in FY2020, despite a significant number of votes against the allocation at the 2019 AGM (approx. 40%).</p>	<p>The Committee acknowledges that at face value, the LTI grant would attract commentary from stakeholders.</p> <p>However, the CEO's reported LTI quantum of A\$1.65 million for FY2020 (based on a total grant valuation of A\$8.2 million to be realised over the 4-year vesting period) is well below (55%) the median of US-listed peer companies and within range of Australian-listed peers, based on benchmarking completed by an independent external consultant.</p> <p>More importantly, as described above, the Committee is confident that the LTI KPIs represent significantly stretching targets for the CEO, with strong alignment to shareholders returns. As of 30 June 2021, only 6% of the rights have vested, with only 29 months left for Dr Wolgen to achieve vesting of any further awards. If the CEO delivers minimal hurdles over the remainder of the 4-year vesting period, he will earn significantly less given the grant covers a multi-year period.</p>
<p>One-off retention awards</p>	<p>The CEO and CFO are entitled to additional cash-based loyalty/retention awards for each month of service.</p>	<p>The Committee acknowledges that loyalty/retention awards are a variation from Australian market practice. However, as broader economic conditions continue to improve and competition for global talent increases, the Committee believes that attracting, motivating, and retaining high-performing executive KMP is key to maintaining CLINUVEL's outperformance and management stability during this critical stage of our development and commercialisation.</p> <p>The loyalty award is only intended to form part of the remuneration packages of the CEO and CFO for the foreseeable future, with no awards to be granted to any other Executive KMP.</p>

* TSR is calculated using a median share price for the three months to June 30 for each relevant year. Dividends were ignored due to immateriality.

C REMUNERATION GOVERNANCE

(i) Remuneration Committee

The Board has provided a mandate to the Remuneration Committee to assist and advise on determining appropriate remuneration policies for its KMP over time, taking into account 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 non-executive director fees and advice on setting salaries and fees, short- and long-term incentives and employment terms and conditions for its key executives.

The objectives of the Remunerations Committee’s responsibilities are to ensure that:

- a) Remuneration of the Company’s KMP 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 attract, retain and motivate people of high calibre and with unique specialist industry knowledge 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 and provides a clear relationship between performance and remuneration.
- d) The levels and structure of remuneration are benchmarked against relevant international peers and considered against global employment market conditions.
- e) The Company gives due consideration to applicable legal requirements and appropriate standards of governance.

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

(ii) Remuneration Recommendations

Under the provisions of the Committee’s Charter, the Committee may engage the assistance and advice from external remuneration advisors. To ensure that any recommendations made by remuneration consultants are provided without undue influence being exerted by Executives, external remuneration consultants deliver their advice directly to members of the Committee.

In the year ended 30 June 2021, the Remuneration Committee engaged the services of remuneration advisors to provide comparable peer company market data. No remuneration recommendations as defined by the Corporations Act were received from external consultants during the financial year.

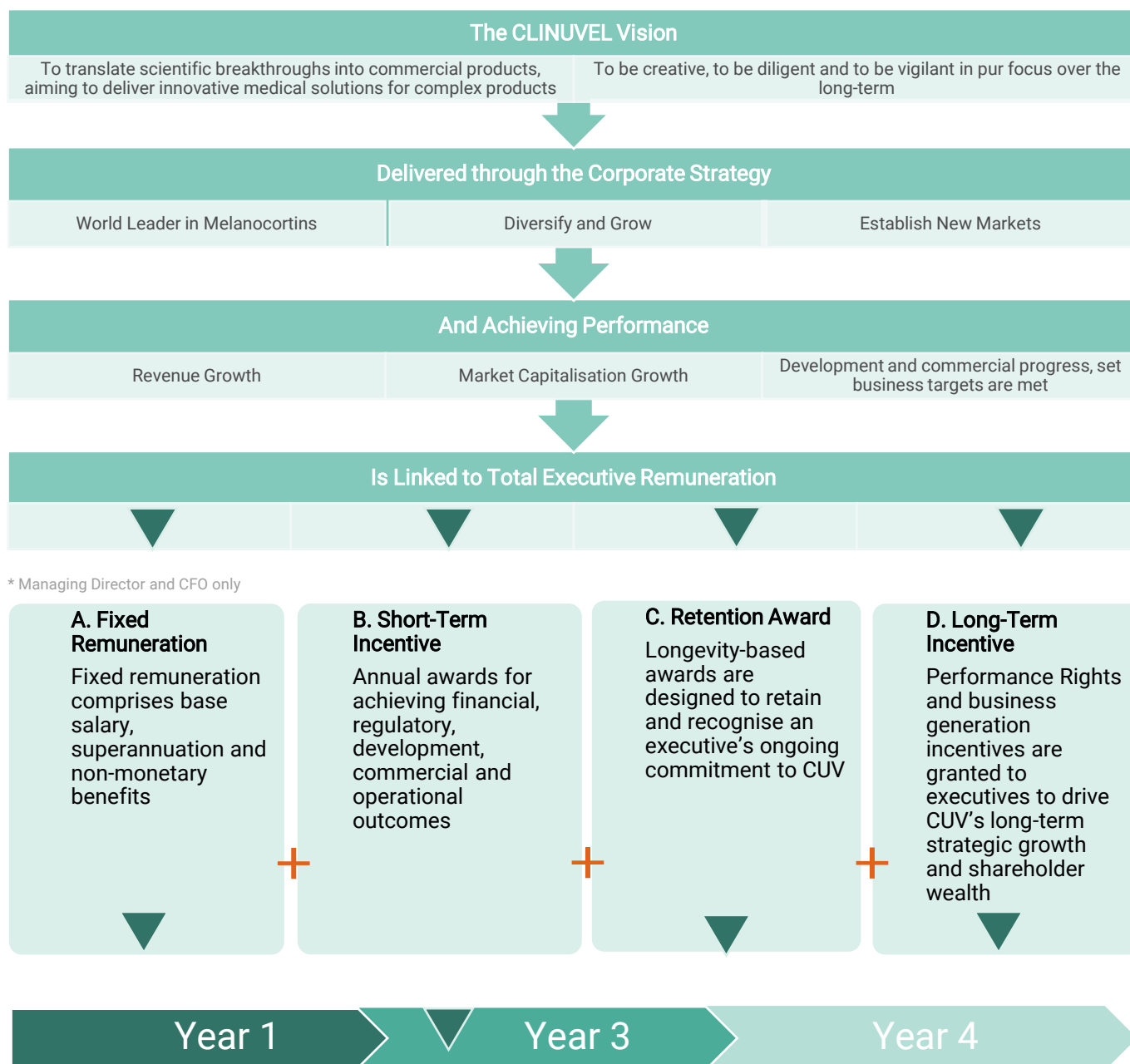
(iii) Voting and feedback at the Company’s last Annual General Meeting

In the 2020 Annual General Meeting (AGM), the Company obtained 67.50% of the proxy votes (including votes at the Board’s discretion) in favour of adopting the 2019/20 remuneration report, and this resolution was carried in favour by poll with 64.65% of votes cast. As more than 25% of the number of votes cast was against this resolution, this constituted a first strike for purposes of the Corporations Act 2001 (Cth). The Company did not receive any further specific feedback at the AGM on its remuneration practices.

D EXECUTIVE REMUNERATION

(i) Executive Remuneration Framework

The following diagram links each of the executive remuneration components to the Company’s mission and strategy.



The Company’s reward framework has historically provided for a mix of fixed pay and variable pay. The variable pay is structured to incentivise:

- 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 and to the Chief Financial Officer, other fixed amount cash incentives, including retention awards to recognise ongoing commitment to the Company).

(ii) Executive Remuneration Structure 2020-21**A. Fixed Remuneration Base Salary and Non-Monetary Benefits**

Fixed remuneration comprises base salary, superannuation and non-monetary benefits including health insurance, accommodation, relocation, travel and statutory benefits

Base salary is set at a level to attract and retain talent with the requisite capabilities to deliver on CLINUVEL's objectives, taking into account seniority, qualifications, skill, experience, length of service, leadership, industry knowledge and level of strategic oversight.

Base salary is regularly tested for market competitiveness by reference to appropriate benchmarks sourced externally and comparing to industry-relevant local and international peer companies.

Base salary may be adjusted each year for changes to CPI. Any adjustments above CPI are in response to individual performance or change in job scope and reviewed and approved by the Remuneration Committee.

B. Short Term Incentive

Short Term Incentives (STIs) are annual payments to reward executives for achieving certain regulatory, development, commercial and operational outcomes which are expected to contribute to increasing shareholder value.

Details of the STI arrangements are as follows:

	Managing Director	Other KMP
Setting and Assessment	Are reset at the start of each financial year by the Remuneration Committee and are assessed at the end of the financial year.	Are reset at the start of each financial year by the Managing Director and are recommended to the Remuneration Committee for their review and approval.
Maximum Opportunity *	100% of Base Salary, payment capped at 465,000 Euros.	Chief Financial Officer: 17% of Base Salary Chief Scientific Officer: 9% of Base Salary
Cessation of employment	STIs will be evaluated for the current performance period on a pro-rata basis.	Must be employed by the Company and not serving a period of notice prior to the end of the relevant financial year. It will not be paid pro-rata should the Other KMP leave employment during the relevant financial year.
Performance hurdles	A mix of financial and non-financial targets. All targets are set having regard to the achievements and performance of the prior year, market conditions and internal forecasts.	A mix of financial and non-financial targets. All targets are set having regard to the achievements and performance of the prior year, market conditions and internal forecasts.
Payment	In the year following the year of achievement.	In the year following the year of achievement.
Disclosure of Performance	The Company's policy is not to disclose commercially sensitive information, consistent with best practice disclosure obligations but will provide information on achieving the performance hurdles to the extent commercially practicable. See the section titled "Relationship between Remuneration and Performance" on pages 43 and 44.	The Company's policy is not to disclose commercially sensitive information, consistent with best practice disclosure obligations but will provide information on achieving the performance hurdles to the extent commercially practicable. See the section titled "Relationship between Remuneration and Performance" on pages 43 & 44.

* For 2021/22 the target opportunity for the Managing Director shall be 100% of Base Salary

*For the year ended 30 June 2021, the Remuneration Committee assessed the **Managing Director's** performance targets which form his Short-Term Incentive and awarded a 70% assessment against the targets.*

For the year ended 30 June 2020, the Managing Director had autonomously chosen to forego the STI awarded for the year and for it to be waived in solidarity with the millions of people who have been impacted and the lives lost

due to the coronavirus pandemic and for the monies to be re-invested in the Company's further research and development

*For the **Other KMP**, For the year ended 30 June 2021 the Managing Director assessed overall performance for the 2020/21 year against the short-term incentives and recommended to the Remuneration Committee and who approved the following assessments against the maximum short-term incentives:*

Chief Scientific Officer: 65%

Chief Financial Officer: 82%

C. Retention Award

Longevity-based awards are remuneration payments to encourage key management retention and to recognise an ongoing commitment to the Company.

In 2019/20 the Managing Director and Chief Financial Officer entered into new service agreements with the Company which included longevity-based award payments as part of overall remuneration. The executives are entitled to receive the following payments for each full month of service to CLINUVEL and its subsidiaries since their original employment start in November 2005.

Managing Director	€5,025
Chief Financial Officer	A\$1,000

The longevity-based awards were at risk of forfeiture for the first 12 months following the 1 July 2019 Effective Date if the executives had provided a notice of termination during this period. The longevity-based award shall be paid to the executives no less than 36 months following the Effective Date of the service agreement unless the service agreement is terminated sooner.

D. Performance Rights

Performance Rights, being an option to acquire ordinary shares of CLINUVEL PHARMACEUTICALS LTD for nil exercise price, are offered to Executive KMP and to staff from time to time to:

- retain and motivate staff and Other Executive KMP to drive the long-term growth and success of the Company;
- to align their interests with increased shareholder wealth over the longer term.

Unlike other equity remuneration plans internationally, performance rights are **not granted to Executives annually**.

Historically, by virtue of the nature of the Company being primarily focussed on business expansion through ongoing research and development, the Performance Conditions attached to Performance Rights have been based on a mix of financial and commercial objectives and non-financial operational targets strongly linked to shareholder value, such as enterprise value and revenue growth.

The Remuneration Committee assesses and recommends to the Board the quantum of Performance Rights amounts based on:

- length of time served prior to issue of performance rights;
- weighted average share price levels at time of issue;
- responsibility levels within the Group;
- current base pay including variable short-term incentive levels;
- industry trends;
- impact on share dilution; and
- nature of vesting (time and/or performance) conditions attached to the issue of Performance Rights.

Performance Rights have vesting periods either up to nearly three years, four years, seven years or undated in duration whereby if the performance conditions are not met by the vesting date, the Performance Rights will lapse. Performance Rights will generally only vest if the Executive remains in employment within the CLINUVEL group of entities at the time of vesting.

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.

Prior to 2020/21, the Performance Rights are exercised into new Shares and are acquired by a Plan Trustee and then, from time to time, transferred to the beneficiary, but generally only when the beneficiary ceases employment (or 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. For

future issues of Performance Rights, it is intended for new Shares to be transferred directly to the participant upon successful achievement of time and performance-based vesting conditions.

For the financial years ended 30 June 2021 and 30 June 2020, no Performance Rights were granted to the **Other Executive KMP**. The Other Executive KMP were last issued performance rights in the 2015/16 financial year.

The Performance Conditions attached to Performance Rights previously issued to Executives (and to non-executive Directors in previous years) issued and unvested at any time during 2020/21 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.

At the 2019 Annual General Meeting, shareholders approved the grant of 1,513,750 Performance Rights to the **Managing Director** and these Performance Rights were offered and issued to the Managing Director, who accepted the offer, on 26 August 2020. Prior to this, the Managing Director was last issued Performance Rights 5 years previous, in the 2014/15 financial year.

By shareholders approving the issue of Performance Rights, the cash-based Business Generation Incentives included in the Managing Director's 2019 service agreement were replaced in its entirety by equity based remuneration to vest upon the Company meeting specific performance conditions.

These Performance Rights have a vesting period of up to four years from date of grant. If the Performance Conditions are not achieved by 20 November 2023, they shall be forfeited and will lapse.

The Board regarded each performance hurdle for the performance conditions at the time of issue to be extremely challenging. This is currently demonstrated in the number of Performance Rights that have vested since date of grant at the 2019 AGM. As at 30 June 2021, of the 1,513,750 granted to the Managing Director at the 2019 AGM, 95,375 performance rights, or 6%, have achieved their vesting conditions.

A summary of the performance conditions granted to the Managing Director in respect of the Performance Rights approved by shareholders at the 2019 AGM are set out in the following pages 38 to 40:

The rationale behind the issue of the performance rights issued to the Managing Director and presented in the "Description of Performance Conditions" are tabled below:

Performance Condition	Rationale
PC1	<ul style="list-style-type: none"> To promote growth in Company value
PC2	<ul style="list-style-type: none"> To diversify the Group whilst maintaining profitability
PC3	<ul style="list-style-type: none"> To ensure conscious and risk-free financial management for further Company growth To provide for financial stability to protect Shareholder value and to act as a counter cyclical buffer during adverse economic conditions
PC4	<ul style="list-style-type: none"> To increase the revenue base
PC5	<ul style="list-style-type: none"> To build further value from internal product development
PC6	<ul style="list-style-type: none"> To expand its existing pharmaceutical product into a new market and increase commercial opportunities
PC7	<ul style="list-style-type: none"> To expand new products in new or existing markets and increase potential revenue base
PC8	<ul style="list-style-type: none"> To incentivise and reward for unanticipated commercial opportunities which are demonstrably value accretive

Business Generation Incentive and Discretionary Payments

Business Generation Incentives (BGIs) are Individual longer-term cash incentive components based on specified performance-based targets which remain for the term of an Executive's service agreement.

BGIs are aimed to:

- reward exceptional business outcomes that contribute to creating significant corporate value without shareholder dilution through equity remuneration; and
- to act as a key retention tool.

The Remuneration Committee reviews BGIs each time there is a renewal to a 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.

Managing Director: Consequent to shareholder approval to grant performance rights to the Managing Director at the 2019 Annual General Meeting, Business Generation Incentives were removed from the Managing Director’s service agreement.

Other Executives: Upon a change to the Chief Financial Officer’s service agreement from 1 July 2019, BGI targets which form part of the overall remuneration package were amended. These longer-term incentives are based on set performance targets which must be achieved before 30 June 2022 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 BGIs for the Chief Financial Officer vary between \$30,000 and \$60,000 per BGI, linked to:

- BGI1: successful regulatory outcome resulting in the first US approval for the use of SCENESSE® (achieved in 2019/20);
- BGI2: expansion of the Company through acquisition and integration of a new entity with demonstrated positive cash flows of the acquired entity for four consecutive quarters post-acquisition; and
- BGI3: participation in an equity or debt funding event if deemed necessary to meet the business needs of the Company

For the 2020/21 financial year, no BGIs were achieved by the Chief Financial Officer.

Managing Director Only: only in the event of exceptional performance, innovation, expansion, acquisitions, manufacturing and business development which do not form part of the STI or not otherwise anticipated at the time of execution of the service agreement.

No discretionary payment was awarded to the Managing Director for the year ended 30 June 2021 or 30 June 2020.

Description of Performance Conditions	Performance Rights granted to Managing Director
<p>PC1 Executive management and staff succeeding in steering the Company to a:</p> <ul style="list-style-type: none"> (i) Market capitalisation of a minimum A\$1,700,000,000 - as measured by a minimum of 15 trading days during the vesting period - 10% of the performance rights under PC1 shall vest, (ii) Market capitalisation of a minimum A\$2,100,000,000 - as measured by a minimum of 15 trading days during the vesting period - 15% of the performance rights under PC1 shall vest, (iii) Market capitalisation of a minimum A\$2,700,000,000 - as measured by a minimum of 15 trading days during the vesting period - 25% of the performance rights under PC1 shall vest, (iv) Market capitalisation of a minimum A\$5,000,000,000 - as measured by a minimum of 15 trading days during the vesting period - 25% of the performance rights under PC1 shall vest, (v) Market capitalisation of a minimum A\$7,500,000,000 - as measured by a minimum of 15 trading days during the vesting period - 25% of the performance rights under PC1 shall vest. <p>To achieve these targets within the vesting period, the Company must generate returns well above the performance of global biotech indices over a similar period, such as the Nasdaq Biotech Index which performed 30.32% over 5 years (ending June 2019) and 5.54% on an annualised basis over the same period.</p> <p>Only in case of a recession in the country of the Company’s primary market exchange (recession defined by a contraction of gross domestic product for 2 consecutive quarters) when the Company’s market capitalisation may be adversely impacted by conditions outside management control, that the market capitalisation targets defined in PC1 (i) to (v) above will be replaced by the following performance targets:</p> <ul style="list-style-type: none"> (i) The Company’s growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 3.0%, 10% of the performance rights under PC1 shall vest, (ii) The Company’s growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 4.0%, 15% of the performance rights under PC1 shall vest, (iii) The Company’s growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 5.0%, 25% of the performance rights under PC1 shall vest, 	<p>450,000</p>

	<p>(iv) The Company's growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 7.0%, 25% of the performance rights under PC1 shall vest,</p> <p>(v) The Company's growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 9.0%, 25% of the performance rights under PC1 shall vest</p>	
PC2	<p>(i) Upon quarterly reporting of A\$60 million in cash and cash equivalents held for 2 consecutive quarters, 15% of PC2 shall vest,</p> <p>(ii) Upon quarterly reporting of A\$70 million in cash and cash equivalents held for 2 consecutive quarters, a further 20% of PC2 shall vest,</p> <p>(iii) Upon quarterly reporting of A\$80 million in cash and cash equivalents held for 2 consecutive quarters, a further 30% of PC2 shall vest,</p> <p>(iv) Upon quarterly reporting of more than A\$150 million in cash and cash equivalents held for 2 consecutive quarters, a further 35% of PC2 will be achieved.</p> <p>Dividends paid out during the vesting period shall be added back to the calculation of the cash reserves. At any time during the vesting period, the ratio between cash and cash equivalents internally generated from the Company's operations and any debt and/or equity financing which increases cash and cash equivalents must be at minimum 2:3 ratio for any of the 5 performance targets under PC2 to be achieved.</p>	105,000
PC3	<p>Successful acquisition of a business entity, defined by:</p> <p>(i) The acquired entity must have generated sales revenue within 6 months of transaction, 50% of PC3 shall vest,</p> <p>(ii) CUV Group becomes or remains profitable within 3 years (plus variability of one year) of transaction as measured by two successive quarters reporting profitability of the two or more combined entities, 50% of PC3 shall vest.</p> <p>For PC3 to be achieved, the acquisition must be considered synergistic to the Company's business operations at the time of acquisition.</p>	105,000
PC4	<p>(i) Upon receipt of first US revenues under the US post-marketing authorization for SCENESSE®, 34% of PC4 shall vest,</p> <p>(ii) US revenues in year 3 to exceed revenues by a minimum of 10% in year 2, a further 33% of PC4 shall vest,</p> <p>(iii) US revenues greater than US\$10,000,000 in a 12-month period leads to vesting of 33% of PC4.</p>	87,500
PC5	<p>(i) Market launch of first non-pharmaceutical ('OTC') product(s) line developed by the VALLAURIX subsidiary entity, 15% of PC5 shall vest,</p> <p>(ii) Total revenues from OTC product lines developed by the VALLAURIX subsidiary entity achieving greater than A\$250,000 in accumulated gross sales, a further 30% of PC5 shall vest</p> <p>(iii) First topical melanogenic formulation to be used either in animal or in human testing, a further 25% of PC5 shall vest,</p> <p>(iv) Upon the completion of the first clinical study of a SCENESSE® paediatric formulation (being the completion of a final clinical study report), a further 30% of PC5 shall vest</p>	175,000
PC6	<p>(i) Upon start (being the closure of recruitment period) of a Phase IIb vitiligo study in North America, 20% of PC6 shall vest,</p> <p>(ii) Upon disclosure to the securities exchange of the results to the Phase IIb vitiligo study in North America, 20% of PC6 shall vest,</p> <p>(iii) After the completion of the Phase IIb vitiligo study in North America and prior to the subsequent Phase IIb/III study, upon holding a Type-C meeting (FDA) and acceptance of study protocol for the Phase IIb/III vitiligo study in North America, a further 20% of PC6 shall vest,</p> <p>(iv) Upon start (being the closure of recruitment period) of the subsequent Phase IIb/III vitiligo study in North America, a further 20% of PC6 shall vest,</p> <p>(v) Upon disclosure to the securities exchange of the results to the subsequent Phase IIb/III vitiligo study in North America, 20% of PC6 shall vest.</p>	262,500
PC7	<p>(i) Upon the regulatory submission to either of EMA, FDA, TGA, PMDA and Swissmedic to approve SCENESSE® or any other molecule or product enhancing the pharmaceutical product line-only offerings of the Company, 25% of PC7 shall vest,</p> <p>(ii) Upon the regulatory approval by either of EMA, FDA, TGA, PMDA and Swissmedic of SCENESSE® or any other molecule constituting a successful evaluation of a scientific dossier, a further 75% of PC7 shall vest.</p>	212,500

PC8	<p>The Board to use its discretion to award performance rights depending on the extraordinary nature of the corporate event(s) achieved and the significant impact on Company's value. It is not certain that these performance rights will be issued during the fixed term of the Conditional Rights Plan, and hence these need to be regarded as a reserve pool enabling the Company to grant in the event of exceptional and unexpected performances which was unanticipated at the time of business planning.</p> <p>These corporate events shall include, but are not limited to, business generation in new markets without the Company engaging in merger and acquisition activity.</p>	116,250
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(iii) Managing Director Remuneration – Further Information

The inherent risk of failure within pharmaceutical development is high and this risk is magnified for the Company due to its specialised and narrow focus on developing and commercialising novel, first-in-class and first-in-line therapies in diseases where there is an unmet clinical need.

The current progress and success of the Company needs to be set against the previous managerial attempts which had posed operational, regulatory and financial challenges. To mitigate the risk and to provide a strong platform to achieve meaningful progress, the Board has followed a business model where most operational skills are retained in-house, where possible, and many management responsibilities are concentrated between the Managing Director (acting in a dual capacity as Chief Executive Officer and Chief Medical Officer) and the 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 quality management) and is responsible for market access. The 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. As the business evolves and progresses through its development path, this centralised management model will continue to evolve, and key management responsibilities will be shared across new and existing senior management throughout the Group.

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

- A maximum level of incentivisation to lead and advance the Company's program from its current stages of development and commercial growth to serve the long-term interest of the Company, taking into account the unique risk and complexity within the business model; and
- It is competitive in international markets, industry and related fields of expertise and providing for specific skillsets.

In the 2019/20 year the Managing Director's service agreement was renewed for a further three years, from 1 July 2019 to 30 June 2022. In determining the level and structure of the remuneration agreed with the Managing Director, the Remuneration Committee considered the following criteria:

- longevity of his 15 years of service as CEO compared against local and international peers;
- track record, integrity and professional qualifications for the position;
- the enterprise value created over the past decade and since first employment;
- the shareholder value created in the past three years leading up to the renewal to the service agreement (from 1 July 2016 to 30 June 2019);
- capability to sustain the Company's focus to maximise profitability following market access; and
- a demonstrated result to attain stability of the business and management team over the long term.

(iv) Executive Remuneration – Peer Benchmarking

One of the objectives of the Remuneration Committee's responsibilities is to ensure that the levels and structure of remuneration are benchmarked against relevant peers and considered against global employment market conditions. CLINUVEL refers to a select group of publicly listed companies on the ASX and, importantly, on international securities exchanges for the purpose of peer group analyses. CLINUVEL is a company operating globally with the bulk of its operations and financial exposure falling outside Australia. Its remuneration structure requires to be competitive to international benchmarks in order to attract and retain existing executive talent at the

highest management levels. The Board firmly contends it cannot limit its benchmarking and consequent setting of the level and structure of its executive remuneration to local Australian companies only.

The selection criteria for these companies are broadly based on comparison of:

- a) businesses of similar complexity and innovative nature;
- b) businesses of similar scope and scale;
- c) sectors requiring highly technical and specialised skills;
- d) businesses of similar value, reflected in market capitalisation;
- e) businesses who have demonstrated similar progress in achieving business outcomes; and
- f) business of similar risk profile.

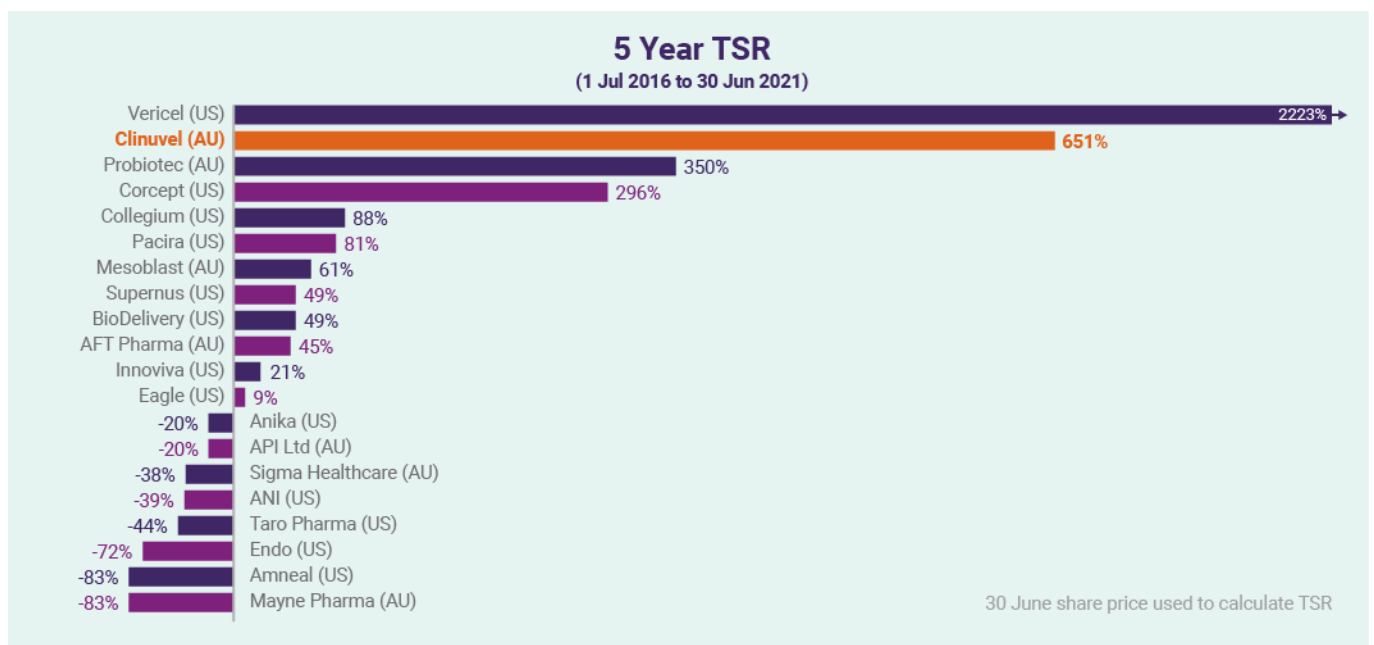
During the year the Managing Director's remuneration was benchmarked against relevant local and international (US) companies using the following quantitative criteria, consistent to the selection criteria listed above:

Benchmarking Criteria	Australian Companies	US Companies
Market Capitalisation:	Between A\$100 million and A\$3 billion	Between US\$500 million and US\$5 billion
Generating Product Revenues:	Yes	Yes
Financial Status:	Positive EBITDA	Positive EBITDA

Six Australian and 13 US life science peer companies (being a mix of medical device, pharmaceutical product and diagnostic focussed companies) were identified. The results of the peer analyses concluded that in the past 5 years, CLINUVEL:

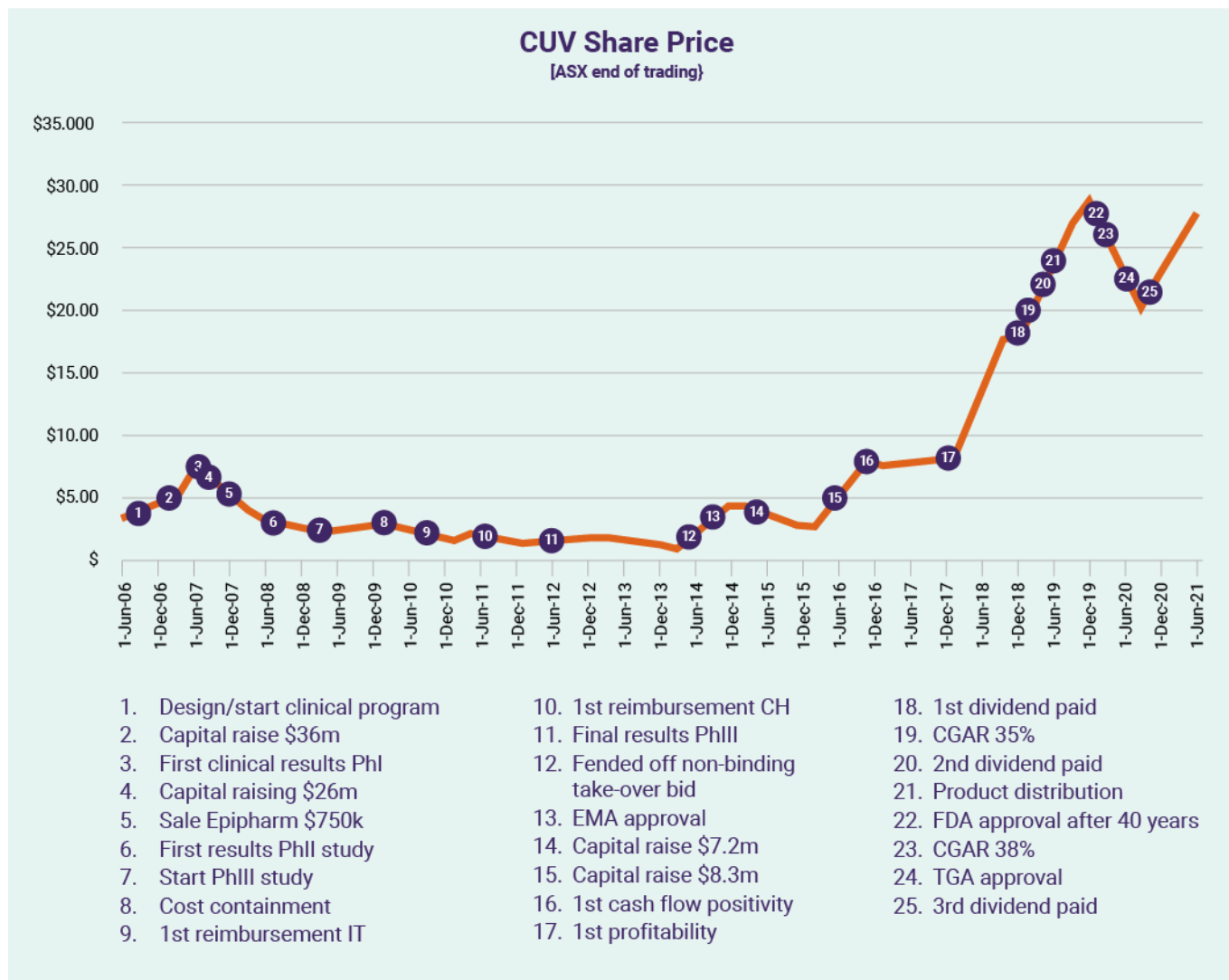
1. had raised far less capital;
2. had incurred significantly less shareholder dilution;
3. had accelerated its revenue growth,
4. had outstripped reported profit and earnings per share, and
5. had delivered a higher total shareholder return than most peers included in the analysis.

The table below compares the Total Shareholder Return between CLINUVEL and the peer companies over the past 5 years:



Throughout FY2021 CLINUVEL was trading at significantly higher P/E multiples than nearly all its Australian and US peers, indicating shareholder expectation that CLINUVEL will deliver superior growth than its peers, a reflection of shareholders' confidence in management executing on the stated strategy.

In comparing Managing Director remuneration to the peer group, the fixed base remuneration was positioned above the median level, whereas the total remuneration level was positioned below the median level. The Board considers the level of fixed base remuneration to be appropriate, considering the long-term outperformance of the Company and the relatively unusual long-term tenure of the Managing Director who has led the Company since 2005, building a profitable and sustainable business whilst delivering higher than normal shareholder return. To further demonstrate this outperformance throughout the Managing Director's tenure, the following graph discloses the relationship between performance and shareholder value since 2005:



(v) Relationship Between Remuneration And Performance

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 both financial and non-financial performance measures have been a key link to driving share price performance and this has been reflected in various performance conditions attached to the long-term equity incentives. The following performance outcomes tabled in the following page, as aligned with the CLINUVEL strategy, were achieved resulting in a performance based STI

incentive rating of 70% of the maximum potential opportunity for the Managing Director. In assessing the KPIs, the Board considered the significant achievements made during the reporting period and the effort required to navigate the issues and challenges facing the company from the COVID-19 pandemic. This included supplying treatment centres across Europe and the United States with uninterrupted supply, working with the centres to access patients and to prepare centres to treat new patients under pending clinical, investigational settings.

Additional objectives were taken into consideration when assessing Other KMP performance by the Board which were considered an essential element of achieving individual performance. However, these are considered commercially sensitive.

STI Outcomes		Year Ended 30 June 2021	
Managing Director			
STIs summarised into Strategic Grouping	Weighting	Rating	Outcome
Growth and Technology Translation	20%	Partially Met	<ul style="list-style-type: none"> Progress made in the development of the PRÉNUMBRA® second afamelanotide formulation Formulations developed for non-pharmaceutical topicals, preparing for commercial scale manufacture Constructing and opening of new VALLAURIX Research, Development & Innovation (RDI) Centre in Singapore Identifying potential acquisition targets to support inorganic expansion of the Group
Manufacturing	25%	Partially Met	<ul style="list-style-type: none"> Inventory management of SCENESSE® to support future commercial and clinical supply Raw material supply secured Targeted alternative manufacturing solutions to allow eventual vertical integration of supply chain within the Group
Financial	35%	Partially Met	<ul style="list-style-type: none"> Fourth Consecutive Annual Profit Announced, 123% increase in PBIT Increase in Cash Reserves, Receipts and Revenues Third Consecutive Annual Dividend Paid Recognised as one of the Financial Times High-Growth Companies of the Asia-Pacific Region for 2020 Maintained uniform pricing in EU, set US price
People and Culture	10%	Met	<ul style="list-style-type: none"> Communications, Branding & Marketing Division established, new team of staff appointed Increased personnel upon expanded RDI Centre in Singapore Key leadership appointments following internal management re-structure
New Initiatives	10%	Partially Met	<ul style="list-style-type: none"> DNA Repair Program announced in XP Patients: <ul style="list-style-type: none"> Initially XP-C patients, extended to XP-V patients Local approvals granted First patient dosed Positive safety assessment of first patient Supporting non-clinical project for assay development completed Stroke Program Announced, with commencement of Phase II pilot study and first patients recruited and dosed DNA Repair Program Announced for Healthy Volunteers <ul style="list-style-type: none"> Local approvals granted
Total	100%	70%	

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

Regulatory, Clinical & Commercial Milestones	Year Ended 30 June				
	2017	2018	2019	2020	2021
Ph II Vitiligo Study - Singapore					
VALLAURIX PTE LTD – formulation & melanocortin development					
First commercial sales in EU					
Submission and subsequent approval for marketing authorisation by the US FDA					
Submission and subsequent approval for marketing authorisation by the Australian TGA					
First commercial sales in US					
Ph II Arterial Ischaemic Stroke Study - Melbourne					
Market capitalisation (A\$ million)	333	527	1,649	1,267	1,517
Share Price High (\$)	9.19	13.52	39.85	45.88	31.23
Share Price Low (\$)	4.10	5.91	9.43	12.92	19.53
Closing Share Price (\$)	6.98	11.01	33.68	25.65	30.70
Change in Share Price over 1 Year (%)	62	58	206	(24)	20
Change in Share Price over 3 Years (%)	311	288	680	268	179
Change in Share Price over 5 Years (%)	328	508	1881	803	611%
Dividend Paid (cents)	-	-	2.0	2.5	2.5

(vi) Executive Remuneration Pay Mix

The Board believes the remuneration mix aligns the Managing Director and Other Executive KMP to shareholder interest. The remuneration mix for 2020/21 is demonstrated as follows:

Position	Fixed Remuneration	STI Cash	LTI Cash ¹	LTI Equity ²
Managing Director	100%	48% of Base Salary	6.9% of Base Salary	134% of Base Salary
Other Executive KMP	100%	Between 9% and 17% of Base Salary	4.6% of Base Salary	-

1. Retention Award earned during 2020/21. For Other Executive KMP, relates to CFO only

2. Shown as total value of performance rights calculated under AASB2 divided by 4 years being the vesting period of the performance rights granted in the year, and includes accelerated expensing of those performance rights which vest during the year

E NON-EXECUTIVE REMUNERATION

The Board seeks an appropriate mix of skill, diversity, experience and specific expertise to steward the Company's success. The Remuneration Committee recommends to the Board individual Non-Executive Director fee levels to attract and retain those with the aforementioned attributes, having regard to global employment market conditions and consultation with specialist remuneration consultants with experience in the healthcare and biotechnology industries.

Non-Executive Director Fees

Non-Executive Director fees consist of base fees and committee fees and are inclusive of superannuation and all other contributions. There are no further retirement benefits. The fees are outlined in the table below:

Annual Non-Executive Director fees (inclusive of superannuation):

	Board Fees		Audit & Risk Committee	Remuneration Committee	Nomination Committee
	Prior to January 1 2021	After January 1 2021			
Chair	110,000	115,000	-	-	-
Non-Executive Director	65,000	70,000	-	-	-
Committee Chair	-	-	15,000	15,000	-
Committee Member	-	-	5,000	5,000	-

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

From 1 January 2021, the Board agreed to increase the Non-Executive Director fees by \$5,000 per annum. The increase was to ensure the level of Non-Executive Director fees remain competitive to attract and retain high-calibre Directors. It was the first increase to Non-Executive Director fees since 2015/16.

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 and was set at \$700,000 at the 2019 AGM. 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 2021 was \$412,500.

Non-Executive Director Long-Term Incentive – Equity Compensation

The long-term equity remuneration was formerly provided to Non-Executive Directors via the CLINUVEL Conditional Rights Plan and the Performance Rights Plan. Any issue of Performance Rights to Non-Executive Directors requires shareholder approval.

The Board had previously considered the relatively small management team comparative to peer companies when setting Non-Executive Director remuneration policy. The Board considered that from time to time its Non-Executive Directors would 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 ensured the interests of all its KMP, including those in a non-executive capacity, were aligned with the interests of the Company and its shareholders within an appropriate control framework, addressing the preference of some shareholders to see Non-Executive Directors have shareholdings in the Group.

It is no longer planned for Non-Executive Directors to participate in long-term equity compensation plans. Only one current Non-Executive Director in Mrs Shanahan still holds Performance Rights, the last date of issue being November 2014.

F SERVICE AGREEMENTS FY2021

Remuneration and other terms of employment for the Managing Director are 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 KMP, providing for base salary, incentives, other benefits and participation, when eligible, in the CLINUVEL Conditional Rights Plan.

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. The details of the service agreements to the Managing Director and Executive KMP are:

Name	Dr Philippe Wolgen ¹	Dr Dennis Wright	Mr Darren Keamy ²
Duration of contract	3 years	No fixed term	3 years
Notice Period (from Company)	12 months	3 months	12 months
Notice Period (from Managing Director)	12 months	-	-
Notice Period (from Executive KMP)	-	3 months	12 months
Termination Payment without Cause	12 months	3 months	12 months
Termination Payment with Cause	None	None	None

1. Expiry Date 30 June 2022

2. Expiry Date 30 June 2022

G SHARE-BASED REMUNERATION

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

Performance Rights:

All Performance Rights that have been issued fall under two Performance Rights plans:

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

1,513,750 Performance rights were approved by shareholders to grant to the Managing Director at the 2019 AGM.

a. Conditional Performance Rights Scheme (2009)

The Conditional Performance Rights Scheme (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. These can be converted to ordinary shares at any time once the vesting conditions attached

to the rights have been achieved, whereby these will be held in a Scheme Trust 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. It is no longer intended to issue Performance Rights under the 2009 Plan.

138,335 Performance Rights issued under the 2009 Scheme remain unvested as at 30 June 2021

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 in a Plan Trust on behalf of the eligible person.

If shares are held in trust, the eligible person cannot trade the shares held by the Plan Trustee 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. Unless the Performance Rights are granted with a shorter vesting period, Performance Rights under this plan lapses after seven years from grant date.

Performance Rights are valued for financial reporting purposes using either a Monte Carlo simulation pricing model or a probability-adjusted binomial valuation pricing 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.

1,646,250 Performance Rights have been issued and 1,550,875 remain unvested under the 2014 Plan. 95,375 Performance Rights have vested but are not yet exercised.

FY2022 Planned Issue of Performance Rights to Staff

The Performance Rights Plan is an important component of the Company's remuneration reward framework which, amongst other things, strives to retain, motivate and incentivise employees to build company value and to align their interests with those of the shareholders of CLINUVEL. The Board wishes to continue incentivising those employees ('participants') who are considered by the Board to be integral to CLINUVEL achieving its future goals of successfully commercialising the Company and executing the expansion of its various R&D and commercial and programs.

In FY2022 the Board intends to issue Performance Rights to select staff. The conditions attached to these Performance Rights will be consistent to the performance conditions and the timelines to those granted to the Managing Director and approved by shareholders at the 2019 AGM. They will also consist of individual-based performance conditions tailored to each participant designed to add to company value should these conditions be met within the vesting period.

The last time employees of the Company were issued with Performance Rights was FY2015.

H DETAILS OF REMUNERATION

KMP remuneration of the company for the years ended 30 June 2021 and 30 June 2020

– Cash Based Benefits

	Year	Gross Salary ³	Short Term Incentive	Business Generation Incentive	Retention Award	Other ¹	Superannuation/Pension Fund	Total (Excluding Share-Based Payments)
		\$	\$	\$	\$	\$	\$	\$
Dr. P.J. Wolgen ²	2021	1,532,499	732,976	-	105,152	296,911	-	2,667,538
	2020 restated	1,577,235	-	-	1,422,022	152,299	-	3,151,556
Mrs. B.M. Shanahan	2021	75,343	-	-	-	-	7,157	82,500
	2020	73,059	-	-	-	-	6,941	80,000
Mr. W.A. Blijdorp	2021	112,500	-	-	-	-	-	112,500
	2020	99,167	-	-	-	-	-	99,167
Dr. K.A. Agersborg	2021	72,500	-	-	-	-	-	72,500
	2020	67,917	-	-	-	-	-	67,917
Mrs. S. E. Smith	2021	72,500	-	-	-	-	-	72,500
	2020	52,667	-	-	-	-	-	52,667
Prof. J. V. Rosenfeld	2021	66,210	-	-	-	-	6,290	72,500
	2020	38,204	-	-	-	-	3,629	41,833
Mr. S.R. McLiesh Ceased directorship 30 November 2019	2021	-	-	-	-	-	-	-
	2020	41,857	-	-	-	-	3,976	45,833
Dr. D.J. Wright	2021	264,818	15,492	-	-	-	21,694	302,004
	2020	257,105	17,355	-	-	-	21,003	295,463
Mr. D.M. Keamy	2021	288,468	40,385	-	13,331	-	21,694	363,878
	2020 restated	278,713	42,364	30,000	173,636	-	21,003	545,716
Total	2021	2,484,838	788,853	-	118,483	296,911	56,835	3,745,920
	2020 restated	2,485,924	59,719	30,000	1,595,658	152,299	56,552	4,380,152

¹ "Other" includes health insurance, housing and other allowances that may be subject to fringe benefits tax.

³ In 2019/20 Dr Wolgen's salary is paid in Singapore dollars (SGD) and in Euro currency. In 2020/21 the salary was paid in Euro currency

³ Does not include movement in annual leave and long service leave provisions.

The natural accretion to Dr Wolgen's annual leave and long service leave entitlements for 2020/21 was \$231,314 (year ending 30 June 2020: \$172,950). For Mr Keamy and Dr Wright, the accretive movement to their annual leave and long service leave entitlements was \$11,172 and \$20,223 respectively (year ending 30 June 2020: \$24,000 and \$3,277 increase respectively)

In 2019/20, upon the renewal of Dr Wolgen's service agreement and the increase to his base salary, the value of his unused annual leave and long service leave entitlements were reset, resulting in a \$365,923 increase to annual leave and long service leave entitlements available to Dr Wolgen.

⁴ The retention award shall be paid to the executives no less than 1 July 2022 unless their service agreement is terminated sooner. See page 36 for further information.

KMP remuneration of the company for the years ended 30 June 2021 and 30 June 2020

– Non-Cash Benefits

	Year	Share-based payments (accounting charge only) ¹			
		Total (Excluding Share-Based Payments)	Performance Rights	Total (Including Share-Based Payments)	% performance-based
		\$	\$	\$	
Dr. P.J. Wolgen ^a	2021	2,667,538	2,312,308	4,979,846	61%
	2020 restated	3,151,556	1,645,205	4,796,761	34%
Mrs. B.M. Shanahan	2021	82,500	-	82,500	
	2020	80,000	-	80,000	
Mr. W.A. Blijdorp	2021	112,500	-	112,500	
	2020	99,167	-	99,167	
Dr. K.A. Agersborg	2021	72,500	-	72,500	
	2020	67,917	-	67,917	
Mrs. S. E. Smith	2021	72,500	-	72,500	
	2020	52,667	-	52,667	
Prof. J. V. Rosenfeld	2021	72,500	-	72,500	
	2020	41,833	-	41,833	
Mr. S.R. McLiesh Ceased directorship 30 November 2019	2021	-	-	-	
	2020	45,833	-	45,833	
Dr. D.J. Wright	2021	302,004	-	302,004	5%
	2020	295,463	1,284	296,747	6%
Mr. D.M. Keamy	2021	363,878	-	363,878	11%
	2020 restated	545,716	4,174	549,890	14%
Total	2021	3,745,920	2,312,308	6,058,228	
	2020 restated	4,380,152	1,650,663	6,030,815	

¹ As these values represent accounting values the KMP may or may not actually receive any benefit from these amounts, either in the current or future reporting periods. Any benefit obtained by the KMP is contingent upon the Company achieving certain performance conditions. 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 either the Monte Carlo simulation pricing model or a binomial pricing model. The amount expensed each reporting period includes adjustments to the life-to-date expense of the grants based on the reassessed estimate of achieving non-market performance criteria.

Remuneration Performance Rights holdings of KMP – 2021

	Balance at Start of Year	Issued as Compensation*	Exercised	Lapsed and Expired	Balance at End of Year	Vested and Exercisable
Directors						
Mrs. B.M. Shanahan	25,000	-	-	-	25,000	-
Dr. P.J. Wolgen	-	1,513,750	-	-	1,513,750	95,375
Mr. W.A. Blijdorp	-	-	-	-	-	-
Dr. K.A. Agersborg	-	-	-	-	-	-
Mrs. S. E. Smith	-	-	-	-	-	-
Prof. J. V. Rosenfeld	-	-	-	-	-	-
Other KMP						
Dr. D.J. Wright	18,125	-	-	-	18,125	-
Mr. D.M. Keamy	32,360	-	-	-	32,360	-

All Performance Rights held at the end of the year are unvested.

* Relates to the approval by shareholders to grant performance rights to the Managing Director at the 2019 AGM.

Shares held by KMP

The number of ordinary shares in the Company during the 2020/21 reporting period held by each of the Group's KMP, including their related parties, is set out below:

Year Ended 30 June 2021						
Personnel	Balance at Start of Year	Granted as Remuneration	Received on Exercise	Other Changes	Held at the End of Reporting Period	
Mrs. B.M. Shanahan	258,969	-	-	(25,000)	233,969	
Dr. P.J. Wolgen	3,504,696	-	-	(329,375)	3,175,321	
Mr. W.A. Blijdorp	1,743,118	-	-	-	1,743,118	
Dr. K.A. Agersborg	5,500	-	-	-	5,500	
Mrs. S. E. Smith	-	-	-	420	420	
Prof. J. V. Rosenfeld	1,693	-	-	670	2,363	
Other KMP						
Dr. D.J. Wright	301,874	-	-	(45,000)	256,874	
Mr. D.M. Keamy	331,343	-	-	(17,755)	313,588	

Terms and conditions of each grant of rights affecting remuneration in the current or future reporting periods

Entity	Number of Rights Granted	Value per Right on Grant Date	Class	Grant Date	Issue date	Expiry Date	Number of Rights Vested	Exercisable Date
CLINUVEL	450,000	\$10.86	Ordinary	20/11/2019	26/08/2020	20/11/2023	0	-
							45,500	26/08/2020
CLINUVEL	1,063,750	\$26.87	Ordinary	20/11/2019	26/08/2020	20/11/2023	21,000	29/01/2021
							28,875	20/05/2021
CLINUVEL	37,976	\$8.97	Ordinary	24/12/2020	24/12/2020	20/11/2023	0	-
CLINUVEL	94,524	\$20.73	Ordinary	24/12/2020	24/12/2020	20/11/2023	0	-

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

Remuneration details of Equity Incentives (Performance Rights)

Equity Incentives (Performance Rights)						
Name	Year Granted	Latest Year of Vesting	Vested in Year	Forfeited in Year	Max Value of Right at Grant Date Yet to Vest	
Dr. P.J. Wolgen	2019/20 *	2023/24	6%	0%	7,542,604	
Mrs. B.M. Shanahan	2011/12	no limitation	-	-	16,682	
Mr. W.A. Blijdorp	-	-	-	-	-	
Dr. K.A. Agersborg	-	-	-	-	-	
Mrs. S. E. Smith	-	-	-	-	-	
Prof. J. V. Rosenfeld	-	-	-	-	-	
Other KMP						
Dr. D.J. Wright	2011/12	no limitation	-	-	12,853	
Mr. D.M. Keamy	2011/12	no limitation	-	-	23,126	

The maximum value of outstanding Performance Rights is unable to be estimated. On exercise, each Performance Right entitles the KMP to one fully paid ordinary share in the Company. The share price of the Company at the time of exercise is not known. The minimum value of unvested performance rights is nil. The exercise price for those Rights granted between 2010/11 and 2014/15 was \$Nil.

* At the 2019 Annual General Meeting, shareholders approved the grant of 1,513,750 performance rights to the Managing Director and these Performance Rights were issued on 26 August 2020.

Remuneration details of cash incentives

Cash Incentives				
Name	Max Potential Opportunity (%)	STI Awarded (%)	STI Forfeited (%)	Total Granted (\$)
Dr. P.J. Wolgen	53%	70%	30%	732,976
Dr. D.J. Wright	9%	65%	35%	15,492
Mr. D.M. Keamy	17%	82%	18%	40,385

Loans to Directors and Executives

No loans were granted to Directors or executives for the years ended 30 June 2021 and 30 June 2020.

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 ¹	Issue Price for Shares	Class
CLINUVEL PHARMACEUTICALS LTD	Nil	Nil\$	Ordinary

¹These 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 by the Trustee for the 2009 Scheme and the 2014 Plan Trust. Shares issued by the Group to eligible participants were issued directly to the Trustee.

DETAILS OF SHARES TRANSFERRED DURING THE YEAR TO EMPLOYEES FROM THE 2009 SCHEME TRUST AND THE 2014 PLAN TRUST

Entity	Number of shares issued ¹	Issue Price for Shares	Class
CLINUVEL PHARMACEUTICALS LTD	1,750,528	Nil\$	Ordinary

¹These shares were issued by the Trustee to the 2009 Scheme and the 2014 Plan 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	1,784,583	\$Nil	Ordinary	Upon achievement of specific performance and time-based milestones or upon cessation of employment
Total as at 30 June 2021	1,784,583	-	-	-

Non-Audit Services

For the year ended 30 June 2021, Grant Thornton Australia provided audit services to the Company. Grant Thornton Australia also provided non-audit services, specifically tax related services. Details of amounts paid or payable to the auditor for non-audit services provided during the year by the auditor are outlined in Note 19 to the financial statements.

The Directors are satisfied that the provision of non-audit services, during the year, by the auditor is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001. The Directors are of the opinion that the services as disclosed in Note 19 to the financial statements do not compromise the external auditor's independence, based on advice received from the Audit Committee, for the following reasons:

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

Auditor's Independence Declaration

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

Proceedings On Behalf Of the Company

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

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

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



Dr. Philippe Wolgen, MBA MD

Director

Dated this 25th day of August, 2021

Statement of Profit and Other Comprehensive Income for the Year Ended 30 June 2021

		Consolidated Entity	
	Note	2021	2020 Restated
		\$	\$
Total revenues	2(a)	47,975,583	32,565,423
Interest income	2(b)	342,203	562,928
Other income	2(c)	132,813	781,319
Total expenses	2(d)	(22,737,955)	(22,368,859)
Profit before income tax expense (benefit)		25,712,644	11,540,811
Income tax expense (benefit)	3(a)	984,397	(3,510,388)
Profit after income tax expense (benefit)		24,728,247	15,051,199
Net profit for the year		24,728,247	15,051,199

Other comprehensive income

Items that may be re-classified subsequently to profit or loss

Exchange differences of foreign exchange translation of foreign operations		(575,253)	592,857
Other comprehensive income/(loss) for the period, net of income tax		(575,253)	592,857
Total comprehensive income for the period		24,152,994	15,644,056
Basic earnings per share - cents per share	16	50.0	30.6
Diluted earnings per share - cents per share	16	48.4	29.8

The accompanying notes form part of these financial statements.

Statement of Financial Position as at 30 June 2021

		Consolidated Entity	
	Note	2021	2020 Restated
		\$	\$
Current assets			
Cash and cash equivalents	17(a)	82,690,982	66,746,521
Trade and other receivables	4	16,088,527	6,612,684
Inventories	5	3,186,670	1,287,914
Other assets	6	882,034	508,818
Total current assets		102,848,213	75,155,937
Non-current assets			
Property, plant and equipment - net	7	1,384,422	1,075,441
Right-Of-Use assets - net	8	1,218,721	1,313,937
Intangible asset - net	9	185,030	185,030
Deferred tax assets - net	3(c)	2,931,188	3,811,500
Total non-current assets		5,719,361	6,385,908
Total assets		108,567,574	81,541,845
Current liabilities			
Trade and other payables	11	4,751,138	4,771,581
Lease liabilities	8	258,236	212,331
Provisions	12	3,697,579	3,278,175
Total current liabilities		8,706,953	8,262,087
Non-current liabilities			
Lease liabilities	8	1,045,236	1,107,224
Provisions	12	77,951	105,727
Total non-current liabilities		1,123,187	1,212,951
Total liabilities		9,830,140	9,475,038
Net assets		98,737,434	72,066,807
Equity			
Contributed equity	13	151,849,375	151,849,375
Reserves	14	5,017,827	1,850,375
Accumulated losses		(58,129,768)	(81,632,943)
Total equity		98,737,434	72,066,807

The accompanying notes form part of these financial statements.

Statement of Cash Flows for the Year Ended 30 June 2021

	Note	Consolidated Entity	
		2021	2020
		\$	\$
Cash flows from operating activities			
Receipts from customers		38,723,858	29,287,833
Payments to suppliers and employees		(20,031,810)	(16,281,001)
Interest received		390,970	636,631
GST and VAT refunds		79,684	423,370
Government grants		99,359	121,535
Net cash provided by operating activities	17(b)	19,262,061	14,188,368
Cash flows from investing activities			
Payments for property, plant and equipment		(854,325)	(888,826)
Net cash used in investing activities		(854,325)	(888,826)
Cash flows from financing activities			
Dividends paid		(1,235,266)	(1,224,021)
Payment of lease liabilities		(200,280)	(243,341)
Payment of interest		(44,405)	(18,501)
Net cash used in financing activities		(1,479,951)	(1,485,863)
Net increase in cash held		16,927,785	11,813,679
Cash and cash equivalents at beginning of the year		66,746,521	54,268,758
Effects of exchange rate changes on foreign currency held		(983,324)	664,084
Cash and cash equivalents at end of the year	17(a)	82,690,982	66,746,521

The accompanying notes form part of these financial statements.

Statement of Changes in Equity for the Year Ended 30 June 2021

	Share Capital	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
	\$	\$	\$	\$	\$
Balance at 30 June 2019	151,314,175	654,324	698,092	(95,486,738)	57,179,853
Exercise of Performance Rights under share-based payment	535,200	(535,200)	-	-	-
Employee share-based payment options	-	1,632,099	-	26,614	1,658,713
Dividends Paid	-	-	-	(1,224,021)	(1,224,021)
Transactions with owners	151,849,375	1,751,223	698,092	(96,684,145)	57,614,545
Profit for the year	-	-	-	16,646,859	16,646,859
Prior Year Restatement (Note 1(y))	-	-	(6,083)	(1,595,657)	(1,601,740)
Profit for the year restated	-	-	(6,083)	15,051,202	15,045,119
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	(592,857)	-	(592,857)
Total other comprehensive income	-	-	(592,857)	-	(592,857)
Balance at 30 June 2020 restated	151,849,375	1,751,223	99,152	(81,632,943)	72,066,807
Exercise of Performance Rights under share-based payment	-	-	-	-	-
Employee share-based payment options	-	2,592,199	-	10,194	2,602,393
Dividends Paid	-	-	-	(1,235,266)	(1,235,266)
Transactions with owners	151,849,375	4,343,422	99,152	(82,858,015)	73,433,934
Profit for the year	-	-	-	24,728,247	24,728,247
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	575,253	-	575,253
Total other comprehensive income	-	-	573,253	-	573,253
Balance at 30 June 2021	151,849,375	4,343,422	674,405	(58,129,768)	98,737,434

Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2021

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.

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.

All the Group's subsidiaries are wholly-owned and there are no longer non-controlling interests with ownership interests in any of the Group's subsidiaries.

b) Going Concern

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 acquire new entities with projects of interest and to undertake the research, development and commercialisation of existing 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 finance potential acquisitions or 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.

In March 2020, the World Health Organisation declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continues to spread worldwide. The spread of COVID-19 has caused significant volatility in Australian and international markets. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the Australian and international economies. The length or severity of this pandemic cannot be reasonably estimated. The Company does not consider the impact of COVID-19 produced a material adverse impact on its consolidated financial position, consolidated results of operations, and consolidated cash flows in the financial year 2021.

The Company has sufficient amounts of cash to be able to continue as a going concern and therefore will be able to realise its assets and extinguish its liabilities in the normal course of business and at the amounts stated in the financial statements.

c) 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 2021 and 30 June 2020 after management judgement was applied to assess whether its unused tax losses and tax offsets could be utilised by future taxable profits. It was determined:

- The consolidated entity has experienced consecutive years of profitability and revenue growth;
- Current pricing agreements with European payors are not expected to change in the next financial year;
- An increase to consolidated entity revenues are expected in the near term from making SCENESSE® available in the USA;
- Whilst internal targets continue to expect ongoing profitability in the near term, there is uncertainty around expected future taxable income in the longer term as part of the business strategy to expand the Company.

d) 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.

e) 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 asset's 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%
- Leasehold improvement: 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.

f) Investments And Other Financial Assets

Recognition and derecognition

Financial assets and financial liabilities are recognised when the Group becomes a party to the contractual provisions of the financial instrument and are measured initially at fair value adjusted by transactions costs, except for those carried at fair value through profit or loss, which are measured initially at fair value. Subsequent measurement of financial assets and financial liabilities are described below.

Financial assets are derecognised when the contractual rights to the cash flows from the financial asset expire, or when the financial asset and substantially all the risks and rewards are transferred. A financial liability is derecognised when it is extinguished, discharged, cancelled or expired.

Classification and initial measurement of financial assets

Except for those trade receivables that do not contain a significant financing component and are measured at the transaction price in accordance with AASB 15, all financial assets are initially measured at fair value adjusted for transaction costs (where applicable).

Subsequent measurement of financial assets

For the purpose of subsequent measurement, financial assets, other than those designated and effective as hedging instruments, are classified into the following categories upon initial recognition:

- financial assets at amortised cost;
- financial assets at fair value through profit or loss (FVPL);
- debt instruments at fair value through other comprehensive income (FVOCI); and
- equity instruments at FVOCI.

Classifications are determined by both:

- the entity's business model for managing the financial assets; and
- the contractual cash flow characteristics of the financial assets.

All income and expenses relating to financial assets that are recognised in profit or loss are presented within finance costs, finance income or other financial items, except for impairment of trade receivables which is presented within other expenses.

Financial assets at amortised cost

Financial assets are measured at amortised cost if the assets meet the following conditions (and are not designated as FVPL):

- they are held within a business model whose objective is to hold the financial assets and collect its contractual cash flows; and
- the contractual terms of the financial assets give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding.

After initial recognition, these are measured at amortised cost using the effective interest method. Discounting is omitted where the effect of discounting is immaterial. The Group's cash and cash equivalents, trade and most other receivables fall into this category of financial instruments

Impairment of financial assets

Trade and other receivables

The Group makes use of a simplified approach in accounting for trade and other receivables and records the loss allowance at the amount equal to the expected lifetime credit losses. In using this practical expedient, the Group uses its historical experience, external indicators and forward-looking information to calculate the expected credit losses using a provision matrix.

The Group assess impairment of trade receivables on a collective basis as they possess credit risk characteristics based on the days past due.

Classification and measurement of financial liabilities

The Group's financial liabilities include trade and other payables.

Financial liabilities are initially measured at fair value, and, where applicable, adjusted for transaction costs unless the Group designated a financial liability at fair value through profit or loss.

Subsequently, financial liabilities are measured at amortised cost using the effective interest method except for derivatives and financial liabilities designated at FVPL, which are carried subsequently at fair value with gains or losses recognised in profit or loss (other than derivative financial instruments that are designated and effective as hedging instruments).

All interest-related charges and, if applicable, changes in an instrument's fair value that are reported in profit or loss are included within finance costs or finance income.

g) Inventories

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.

h) 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 and US regulatory approval and launched a European and US product the above criteria have not been fully satisfied to support the recognition and generation of an internally generated intangible asset.

i) Intangible Assets – Trademarks and Patents

Trademarks and patents 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 trademarks and patents had been fully amortised.

j) 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.

k) Employee Benefits

Provision is made for benefits accruing to employees in respect of wages and salaries, loyalty payment, 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.

l) Revenue And Other Income

Revenue arises from the sale of SCENESSE® implants.

The Group's revenue from contracts with customers arise from the commercial sales of goods and sales reimbursements. Commercial sales of goods are the

commercial sales of SCENESSE® implants in Europe and USA. Sales reimbursements are the distribution of SCENESSE® under special access reimbursement schemes. The special access reimbursement scheme provides for the import and supply of an unapproved therapeutic good to a single patient on a case-by-case basis.

To determine whether to recognise revenue, the Group follows a 5-step process:

- 1) identifying the contract with a customer;
- 2) identifying the performance obligations;
- 3) determining the transaction price;
- 4) allocating the transaction price to the performance obligations; and
- 5) recognising revenue when/as performance obligation(s) are satisfied.

Based on the above revenue recognition process and the nature of all revenue streams from contracts with customers, the Group recognises revenues as earned from commercial sales of goods and sales reimbursements as earned when performance obligations are satisfied at a point in time, which is when control of the product passes to the customer, or generally upon receipt of shipment.

Seasonal nature of revenue from contracts with suppliers

Due to patients seeking treatment in the spring, summer and autumn months, there remains a seasonal demand for SCENESSE®. As such, fluctuations caused by seasonal demand impact the Group's operations.

Note "Revenue" provides additional disclosures disaggregating revenue by geographical market and the timing of revenue recognition.

Interest

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

Government R&D tax incentive

Other income from the Australian 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. There was no other income from the government R&D tax incentive for the year ended 30 June 2021.

Government Grant

Government grants represents the Job Support Scheme, Property Tax Rebate and the Boosting Cash Flow for Employer schemes from Australian and Singaporean governments in response to ongoing novel coronavirus (COVID-19) pandemic. Government grants are recognised in the financial statements at their fair values when there is a reasonable assurance that the Consolidated Entity will comply with the requirements and that the grant will be received.

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 share 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

The Group considers whether a contract is, or contains, a lease. A lease is defined as ‘a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration’. To apply this definition, the Group assesses whether the contract meets three key evaluations which are whether:

- the contract contains an identified asset, which is either explicitly identified in the contract or implicitly specified by being identified at the time the asset is made available to the Group;
- the Group has the right to obtain substantially all of the economic benefits from use of the identified asset throughout the period of use, considering its rights within the defined scope of the contract; or
- the Group has the right to direct the use of the identified asset throughout the period of use. The Group assess whether it has the right to direct ‘how and for what purpose’ the asset is used throughout the period of use.

At lease commencement date, the Group recognises right-of-use assets and lease liabilities on the balance sheet. The right-of-use asset is measured at cost, which is made up of the initial measurement of the lease liability, any initial direct costs incurred by the Group, an estimate of any costs to dismantle and remove the asset at the end of the lease, and any lease payments made in advance of the lease commencement date (net of any incentives received).

The Group depreciates the right-of-use assets on a straight-line basis from the lease commencement date to the earlier of the end of the useful life of the right-of-use assets or the end of the lease term which is currently between 2 – 6 years. Instead of performing an impairment review on the right-of-use assets at the date of initial application, the Group has relied on its historic assessment as to whether leases were onerous immediately before the date of initial application of AASB 16. The Group also assesses the right-of-use assets for impairment when such indicators exist.

Lease payments included in the measurement of the lease liability are made up of fixed payments (including in substance fixed), variable payments based on an index or rate, amounts expected to be payable under a residual value guarantee and payments arising from options reasonably certain to be exercised.

Subsequent to initial measurement, the liability will be reduced for payments made and increased for interest. It is remeasured to reflect any reassessment or modification, or if there are changes in in-substance fixed payments.

The Group has elected to account for short-term leases and leases of low-value assets using the practical expedients. Instead of recognising a right-of-use asset and lease liability, the payments in relation to these are recognised as an expense in profit or loss on a straight-line basis over the lease term.

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 of conditional performance rights is measured by a Monte Carlo simulation pricing model for those performance rights with market capitalisation hurdles and either a binomial or a trinomial model for those performance rights not linked to the price of the shares of CLINUVEL PHARMACEUTICALS LTD ('non-market vesting conditions'). It is determined at grant date and expensed on a straight-line basis over the vesting period. 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 binomial or a trinomial model, using the assumptions detailed in Note 23. The total expense is brought to account over the vesting period which for some instruments requires the group to form judgements associated with the timing and probability of vesting conditions.

Key judgements – tax losses

Given the Company's and each individual entities' history of losses, the Group has recognised a deferred tax asset with regard to unused tax losses and other temporary differences. 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.

Uncertainty Over Income Tax Treatments

The Group has adopted Interpretation 23 from 1 July 2019, based on an assessment of whether it is 'probable' that a taxation authority will accept an uncertain tax treatment. This assessment takes into account that, for certain jurisdictions in which the Group operates, a local tax authority may seek to open a group's books as far back as inception of the group. Where it is probable, the Group has determined tax balances consistently with the tax treatment used or planned to be used in its income tax filings. Where the Group has determined that it is not probable that the taxation authority will accept an uncertain tax treatment, the most likely amount or the expected value has been used in determining taxable balances (depending on which method is expected to better

predict the resolution of the uncertainty). There has been no significant impact from the adoption of Interpretation 23 in this reporting period.

x) 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 Group has identified its operating segments based on the internal reports that are reviewed and used by the Chief Executive Officer (the Chief Operating Decision Maker) in assessing performance and in determining the allocation of resources. The Group operates in a single operating segment, being the biopharmaceutical sector, and the majority of its activities are concentrated on researching, developing and commercialising a sole asset, being its leading drug candidate. Accordingly, the Group's consolidated total assets are the total reportable assets of the operating segment.

The Group has established entities in more than one geographical area. The non-current assets that are not held within Australia are immaterial to the Group. The revenues earned from external customers by geographical location is detailed above. The consolidated entity has one operating segment within the definition of AASB 8 Operating Segments.

y) Restatement of Comparative Amounts

The Group has restated its comparatives for the year ended 30 June 2020 in these consolidated statements after re-assessing the accounting treatment of the Loyalty Payment employee benefits granted to the Managing Director and Chief Financial Officer upon the renewal of their employment contracts, the benefits disclosed in the Remuneration Report to the 2020 Annual Report. The re-assessment of the treatment of the benefits determined the amount to be recognised over its service period commencing at the time of renewal of employment agreement to its vesting date.

The impact of this treatment on the 30 June 2020 profit and loss is an overstatement of profit of \$1.596 million.

There is no impact on the cash flow position of the Group reported as at 1 July 2019 and 30 June 2020 as the adjustment represents a non-cash entry.

The accounting treatment has been corrected by restating each of the affected financial statement line items for the prior period as follows:

Balance Sheet (extract)	30 June 2020	Increase/(Decrease)	30 June 2020 (Restated)
Provisions-current	1,676,435	1,601,740	3,278,175
Liabilities – current	6,660,347	1,601,740	8,262,087
Liabilities - total	7,873,298	1,601,740	9,475,038
Net Assets	73,668,547	(1,601,740)	72,066,807
Reserves	1,856,458	(6,083)	1,850,375
Accumulated losses	(80,037,286)	(1,595,657)	(81,632,943)
Total Equity	73,668,547	(1,601,740)	72,066,807
Statement of profit or loss and other comprehensive income (extract)	30 June 2020	Increase/(Decrease)	30 June 2020 (Restated)
Total expenses	(20,773,199)	(1,595,660)	(22,368,859)
Profit before income tax expense (benefit)	13,136,471	(1,595,660)	11,540,811
Net Profit for the year	16,646,859	(1,595,660)	15,051,199
Other comprehensive income/(loss) for the period, net of income tax	592,857	0	592,857
Total comprehensive income for the period	17,239,716	(1,595,660)	15,644,056
Parent Company Information (extract)	30 June 2020	Increase/(Decrease)	30 June 2020 (Restated)
Liabilities – current	2,460,733	173,636	2,634,369
Liabilities - total	2,466,023	173,636	2,639,659
Accumulated losses	(76,805,002)	(173,636)	(76,978,638)
Total Equity	76,795,596	(173,636)	76,621,960
Net Profit for the year	16,769,727	(173,636))	16,596,091
Total comprehensive income for the period	16,769,727	(173,636)	16,596,091

2. Profit/(Loss) From Continuing Operations

	Consolidated Entity	
	2021	2020 Restated
	\$	\$
(a) Revenues*		
Commercial sales of goods	42,602,594	26,306,148
Sales reimbursements	5,372,989	6,259,275
Total revenues	47,975,583	32,565,423
(b) Interest income		
Interest income	342,203	562,928
Total interest income	342,203	562,928
(c) Other income		
Unrealised gain on restating foreign currency balances and currencies held	-	537,460
Government grants	129,734	126,611
Realised foreign currency gain on transactions	3,079	116,584
Miscellaneous	-	664
Total other income	132,813	781,319
(d) Expenses		
Clinical and non-clinical development	547,553	341,304
Commercial distribution	2,421,204	2,443,435
Changes in inventories of raw materials, work in progress and finished goods	(1,898,756)	848,170
Communication, branding and marketing	313,986	589,458
Depreciation and amortisation	861,432	446,129
Finance, corporate and general	1,618,430	2,053,990
Legal, insurance and IP	1,095,415	1,147,508
Personnel-related	10,157,625	10,489,716
Materials and related expenses	3,650,304	2,350,347
Share-based payments	2,602,393	1,658,802
Unrealised loss on restating foreign currency balances and currencies held	1,368,369	-
Total expenses	22,737,955	22,368,859
(e) Profit/(loss) before income tax includes the following specific expenses		
Employee benefits expense	9,630,783	9,588,568
Share-based payments	2,602,393	1,658,713
Expense relating to short-term leases	241,385	296,481
Depreciation of right-of-use assets	319,962	263,154
Depreciation on property, plant & equipment	499,625	164,474
Loss on sale of property, plant and equipment	90,136	-

*Revenues have been disaggregated by pattern of revenue at a point in time.

3. Income Tax Expense

	Consolidated Entity	
	2021	2020 Restated
	\$	\$
(a) Income tax expense (benefit)		
Current	104,085	-
Deferred	880,312	(3,510,388)
Income tax expense (benefit)	984,397	(3,510,388)
Deferred tax included in income tax expense (benefit) comprises:		
(Increase) decrease in deferred tax assets	1,612,242	(3,751,243)
Increase (decrease) in deferred tax liabilities	(731,930)	240,855
	880,312	(3,510,388)
(b) Numerical reconciliation of income tax expense (benefit) and tax at the statutory rate		
Profit before income tax benefit	25,712,644	11,540,811
Tax at the statutory tax rates of 26.0% in 2021 and 27.5% in 2020	6,685,287	3,173,723
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Permanent differences - Australia	417,537	1,182,470
	7,102,824	4,356,193
Recognition of DTA on additional losses utilised in year	(1,075,497)	(1,389,312)
Recognition of DTA on losses at year end	(5,042,930)	(6,742,994)
Recognition of temporary differences - Australia	-	265,725
Income tax expense (benefit)	984,397	(3,510,388)
Tax losses not recognised		
Unused tax losses for which no deferred tax asset has been recognised	25,737,879	46,780,392
Potential tax benefit at 26.0% in 2021 and 27.5% in 2020	6,691,849	12,864,608
(c) Deferred tax assets		
Deferred tax asset comprises temporary differences attributable to:		
Carry forward tax losses	5,042,930	6,742,993
Intangibles	433,722	449,065
Provisions	210,094	126,932
Accrued Expenses	26,797	39,617

Lease liabilities	48,719	15,897
	5,762,262	7,374,504
Movements		
Opening balance	7,374,504	3,623,260
Carry forward tax losses	6,118,426	8,571,113
Deferred tax assets utilised	(7,818,490)	(4,866,870)
Intangibles	(15,343)	57,803
Lease liabilities	32,823	(35,573)
Accrued Expenses	(12,821)	19,681
Provisions	83,163	5,090
	5,762,262	7,374,504
(c) Deferred tax liabilities		
Deferred tax liability comprises temporary differences attributable to:		
Unrealised gains/loss on loans to subsidiaries	(2,774,312)	(3,525,637)
Accrued income	(16,787)	(32,429)
Right-of-use assets	(49,195)	(15,142)
Intangibles	9,220	10,204
	(2,831,074)	(3,563,004)
Movements		
Opening balance	(3,563,004)	(3,322,148)
Unrealised gains/loss on loans to subsidiaries	751,326	(305,891)
Right-of-use assets	(34,053)	36,983
Accrued income	15,642	20,276
Intangibles	(985)	7,776
	(2,831,074)	(3,563,004)
Total	2,931,188	3,811,500

The tax rates used in this report are the corporate tax rate of 26% in 2021 and 27.5% in 2020.

4. Trade and Other Receivables

	Consolidated Entity	
	2021	2020
	\$	\$
Current		
Trade debtors	15,811,629	6,349,664
Interest receivables	64,565	117,923
Sundry debtors	212,333	145,097
Total	16,088,527	6,612,684

Trade debtors are recognised initially at the amount of consideration that is unconditional, when they are recognised at fair value. They are subsequently measured at amortised cost using the effective interest method and due to their short-term nature, their carrying amount is considered to be the same as their fair value. Trade debtors are generally due for settlement within 30 to 90 days from date of invoice. Collectability is regularly reviewed at an operating unit level. The Group does not have a history of bad debts and the review of trade debtors outside the normal terms indicate full recoverability.

5. Inventories

	Consolidated Entity	
	2021	2020
	\$	\$
Current		
Raw materials – at cost	504,565	255,037
Provision for obsolescence – raw materials	(159,712)	(51,655)
Work in progress – at cost	2,637,386	380,882
Finished goods – at cost	204,431	703,650
Total	3,186,670	1,287,914

6. Other Assets

	Consolidated Entity	
	2021	2020
	\$	\$
Current		
Prepaid peptide	472,184	105,139
Other prepayments	409,850	403,679
Total	882,034	508,818

7. Property, Plant And Equipment

	Consolidated Entity	
	2021	2020
	\$	\$
Plant and equipment		
At cost	775,324	560,483
Less: accumulated depreciation	(292,057)	(216,643)
Sub-total	483,267	343,840
Furniture and fittings		
At cost	40,629	122,555
Less: accumulated depreciation	(18,181)	(82,916)
Sub-total	22,448	39,639
Leasehold improvements		
At cost	1,253,373	758,299
Less: accumulated amortisation	(374,666)	(66,337)
Sub-total	878,707	691,962
Total property, plant and equipment	1,384,422	1,075,441

Movements in Carrying Amounts – Property, Plant and Equipment

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

	Plant and Equipment	Furniture and Fittings	Leasehold Improvements	Total
	\$	\$	\$	\$
Carrying amount at 30 June 2019	179,004	59,703	99,144	337,851
Additions	264,686	7,639	630,017	902,342
Disposals	(1,792)	(16,432)	-	(18,224)
Depreciation written back on disposals	1,513	16,432	-	17,945
Depreciation expense	(99,571)	(27,703)	(37,199)	(164,473)
Carrying amount at 30 June 2020	343,840	39,639	691,962	1,075,441
Additions	260,291	7,944	623,356	891,591
Disposals	(45,450)	(89,871)	(128,282)	(263,603)
Depreciation written back on disposals	37,279	70,680	69,552	177,511
Depreciation expense	(112,693)	(5,944)	(377,881)	(496,518)
Carrying amount at 30 June 2021	483,267	22,448	878,707	1,384,422

8. Right-of-Use Assets and Lease Liabilities

	Consolidated Entity	
	2021	2020
	\$	\$
Right-of-use assets		
At cost	1,538,929	1,693,596
Less: accumulated depreciation	(320,208)	(379,659)
Total right-of-use assets	1,218,721	1,313,937

	Consolidated Entity	
	2021	2020
	\$	\$
Lease liabilities		
Lease liabilities - Current	258,236	212,331
Lease liabilities - Non-current	1,045,236	1,107,224
Total lease liabilities	1,303,472	1,319,555

Lease liability is measured at the present value of the lease payments unpaid at that date, discounted using the interest rate implicit in the lease if that rate is readily available or the Group's incremental borrowing rate of 3.5% in 2021 and 2020.

9. Intangible asset

	Consolidated Entity	
	2020	2019
	\$	\$
Goodwill		
At cost	185,030	185,030
Less: impairment	-	-
Total	185,030	185,030

Goodwill is not amortised but is measured at cost less any accumulated impairment losses. Impairment occurs when a business unit's recoverable amount falls below the carrying value of its net assets. The method used to determine the recoverable amount is price analysis of peer companies. The results of the impairment test show that the business unit's recoverable amount exceeds the carrying value of its net assets, inclusive of goodwill. Consequently, there is no goodwill impairment as at 30 June 2021.

10. Interests in Subsidiaries

Name Of Entity	Country Of Incorporation s	Ownership Interest	
		2021	2020
Parent entity			
CLINUVEL PHARMACEUTICALS LTD	Australia	-	-
Controlled entities			
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%	100%
CLINUVEL EUROPE LIMITED	Ireland	100%	100%
VALLAURIX MC SARL	Monaco	100%	100%

11. Trade and Other Payables

	Consolidated Entity	
	2021	2020
	\$	\$
Current		
Unsecured trade creditors	2,323,560	1,429,855
Sundry creditors and accrued expenses	2,427,578	3,341,726
Total	4,751,138	4,771,581
(a) Aggregate amounts payable to:		
Directors and Director-related entities*	735,701	865,192
(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade and Sundry creditors:		
Danish Krone	271	-
Israeli Shekel	105	10,875
Other	-	-
	376	10,875

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

*Accrued short-term employee benefits

c) Terms and conditions:

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

12. Provisions

	Consolidated Entity	
	2021	2020 Restated
	\$	\$
Current		
Employee benefits	3,697,579	3,278,175
Total	3,697,579	3,278,175
Non-current		
Employee benefits	13,166	5,290
Provision for make good	64,785	100,437
Total	77,951	105,727

13. Contributed Equity

(a) Issued and Paid-Up Capital

	Consolidated Entity	
	2021	2020
	\$	\$
49,410,338 fully paid ordinary shares (2020: 49,410,338)	151,849,375	151,849,375

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			
	2021		2020	
	No.	\$	No.	\$
At the beginning of the financial year	49,410,338	151,849,375	48,960,633	151,314,175
Issued during the year	-	-	-	-
Conditional rights issues and transferred from conditional rights reserve	-	-	449,705	535,200
Less: transaction costs	-	-	-	-
Balance at the end of the financial year	49,410,338	151,849,375	49,410,338	151,849,375

(c) Conditional Performance Rights

During the year to 30 June 2021, no 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\$	0

As at 30 June 2020, the year the following conditional performance rights were exercised, resulting in the issue of fully paid ordinary shares:

Expiry date	Exercise Price	Number of Conditional Rights
Upon achievement of various performance milestones	Nil\$	449,705

14. Reserves

	Consolidated Entity	
	2021 \$	2020 Restated \$
<i>Conditional Performance Rights reserve:</i>		
Balance at the beginning of period	1,751,223	654,324
Share-based payment	2,602,393	1,658,713
Transfer to share capital	-	(535,200)
Lapsed, forfeited rights	(10,194)	(26,614)
Balance at the end of period	4,343,422	1,751,223
<i>Foreign currency translation reserve:</i>		
Balance at the beginning of period	99,152	698,092
Translating foreign subsidiary to current rate at reporting date	575,253	(592,857)
Balance at the end of period	674,405	105,235
Prior Year Restatement	-	(6,083)
Balance at the end of period restated	674,405	99,152
Total reserves	5,017,827	1,850,375

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.

15. Short-Term Lease Commitments

	Consolidated Entity	
	2021	2020
	\$	\$
<i>Short-term lease commitments</i>		
Non-cancellable operating leases contracted for but not capitalised under AASB 16 as they are short-term and are payable as follows:		
not later than 1 year	111,817	104,983
later than 1 year but not later than 5 years	17,177	7,873
Total	128,994	112,856

Short-term leases comprise commitments for limited license agreement of furnished office accommodation. The limited license agreement has no contingent rental clauses and contains renewal options.

16. Earnings Per Share (EPS)

	Consolidated Entity	
	2021	2020 Restated
	\$	\$
(a) Basic earnings per share (cents per share)	50.0	30.6
(a) Diluted earnings per share (cents per share)	48.4	29.8
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	49,410,338	49,260,026
(b) Weighted average number of performance rights on issue in respect of share based payments during the year	1,720,732	1,198,897
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	51,131,070	50,458,922
(c) The numerator used in the calculation of basic earnings per share (\$)	24,728,247	15,051,199

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	
	2021	2020 Restated
	\$	\$
<i>(a) Reconciliation of cash:</i>		
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	34,572,626	23,872,909
Cash on hand	1,317	574
Deposits on call	2,241,903	1,480,550
Term deposits	45,550,000	41,094,576
Security bonds	325,136	297,912
Total cash and cash equivalents	82,690,982	66,746,521
<i>(b) Reconciliation of cash flows from operating activities with operating profit (loss)</i>		
Operating profit after income tax	24,728,247	16,646,859
Prior year restatement	-	(1,595,660)
Operating profit after income tax restated	24,728,247	15,051,199
Non cash flows in operating profit after income tax:		
Depreciation expense on property, plant & equipment	499,625	164,474
Amortisation expense on right-of-use assets	319,962	263,154
Exchange rate effect on foreign currencies held	983,325	(664,084)
Executive share option expense	2,602,393	1,658,713
Unrealised loss (gain) on foreign exchange translation	575,253	(592,857)
Loss on sale of non-current assets	90,136	-
Changes in assets and liabilities:		
(Increase)/decrease in receivables	(9,475,843)	(2,456,468)
(Increase)/decrease in inventories	(1,898,756)	848,170
(Increase)/decrease in other assets	(413,782)	82,698
Increase/(decrease) in payables	(20,443)	2,661,315
(Increase)/decrease in deferred tax assets	880,312	(3,510,388)
Increase/(decrease) in provisions	391,632	682,442
Net cash used in operating activities	19,262,061	14,188,368

Cash at bank earns floating rates based on daily bank deposit rates. The carrying amounts of cash and cash equivalents represent fair value. Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes. The term deposits are readily convertible to cash and subject to an insignificant risk of changes in value. The effective interest rate on short-term deposits was 0.70% (2020: 1.55%). These deposits have an average maturity date of 233 days (2020: 199 days).

18. Key Management Personnel

	Consolidated Entity	
	2021	2020 Restated
	\$	\$
Short-term employee benefits	3,570,602	2,697,942
Post-employment benefits	56,835	56,552
Long-term benefits	118,483	1,625,658
Share-based payments	2,312,308	1,650,663
Total	6,058,228	6,030,815

No loans existed with key management personnel, except accrued short-term employee benefits.

19. Auditors' Remuneration

	Consolidated Entity	
	2021	2020
	\$	\$
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	113,000	97,000
tax and advisory services	10,000	43,000
Total	123,000	140,000

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 2021 is \$4,370,640 (2020: \$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 2021 is \$21,780,429 (2020: \$12,840,377).

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 2021 is \$13,972,152 (2020: \$13,945,079).

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 2021 is \$642,292 (2020: \$604,342).

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 2021 is \$13,900,471 (2020: \$15,661,324).

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 2021 is \$5,752,040 (2020: \$3,615,257).

The loan payable by CLINUVEL PHARMACEUTICALS LTD to VALLAURIX MC SARL 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 VALLAURIX MC SARL. The loan from VALLAURIX MC SARL as at 30 June 2021 is -\$3,973,021 (2020: -\$1,949,434). VALLAURIX MC SARL was incorporated as a wholly- owned entity of the consolidated group during 2019-20.

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL EUROPE LIMITED is non-interest bearing. Repayment of the loan will commence upon commercialisation of CLINUVEL EUROPE LIMITED'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 CLINUVEL EUROPE LIMITED. The loan to CLINUVEL EUROPE LIMITED as at 30 June 2021 is \$5,039,479 (2020: \$0). CLINUVEL EUROPE LIMITED was incorporated as a wholly- owned entity of the consolidated group during 2018-19.

Director related and Key Management Personnel transactions and entities:

There are no loan transactions and relationships in existence as at 30 June 2021 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 Group has identified its operating segments based on the internal reports that are reviewed and used by the Chief Executive Officer (the Chief Operating Decision Maker) in assessing performance and in determining the allocation of resources. The Group operates in a single operating segment, being the biopharmaceutical sector, and the majority of its activities are concentrated on researching, developing and commercialising a sole asset, being its leading drug candidate. Accordingly, the Group's consolidated total assets are the total reportable assets of the operating segment.

The Group has established entities in more than one geographical area. The non-current assets that are not held within Australia are immaterial to the Group. The revenues earned from external customers by geographical location is detailed above. The consolidated entity has one operating segment within the definition of AASB 8 Operating Segments.

The Group's revenue disaggregated by primary geographical markets is as follows:

30 June 2021				30 June 2020			
	Commercial sales of goods	Sales reimbursements	Total		Commercial sales of goods	Sales reimbursements	Total
	\$'000	\$'000	\$'000		\$'000	\$'000	\$'000
European Economic Area & USA	42,603	139	42,742		26,306	137	26,443
Switzerland, Others	-	5,234	5,234		-	6,122	6,122
Total	42,603	5,373	47,976		26,306	6,259	32,565

The Group's revenue disaggregated by pattern of revenue recognition and the Group recognises all revenue based on a point in time.

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 2021 and as at 30 June 2020.

The consolidated entities exposure to foreign currency risk at 30 June 2021

				Consolidated Entity				
				2021				2020
				\$				\$
	Cash and Cash Equivalents	Trade Debtors and Other Assets	Trade, Other Payables and Provision	TOTAL	Cash and Cash Equivalents	Trade Debtors and Other Assets	Trade, Other Payables and Provision	TOTAL
USD	5,089,237	6,829,485	(1,888,178)	10,030,544	2,026,377	1,325	(513,704)	1,513,998
EUR	9,330,841	3,709,227	(2,956,578)	10,083,490	9,405,452	2,472,442	(1,720,287)	10,157,607
CHF	1,623,549	664,643	(137,695)	2,150,497	2,118,158	1,057,956	(322,229)	2,853,885
GBP	420,266	100,453	(205,788)	314,931	456,886	32,982	(336,497)	153,371
SGD	521,309	233,263	(283,017)	471,555	1,559,596	150,072	(171,080)	1,538,588
ILS	-	214,500	(255)	214,245	-	-	(25,771)	(25,771)
DKK	-	-	(1,272)	(1,272)	-	-	--	-

Sensitivity Analysis

During the financial year the Company had a principal foreign currency transaction risk exposure to the US dollar. Assuming all other variables remain constant, 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 10% appreciation of the Australian dollar against the US currency would have decreased profit and loss and equity by \$1,447,684 for the year ended 30 June 2021 (2020: \$50,077 increase), on the basis that all other variables remain constant. 10% is considered representative of the market volatility in the Australian dollar/US dollar rate for the period.

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

The Group's exposure to other foreign currency movements is not considered 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 2021, if interest rates had changed by +/- 15 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 \$106,400 higher/lower (2020: \$89,952 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 nearly thirty counterparties across German, Italian, Swiss, Dutch, US 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.

	Consolidated Entity	
	2021	2020
	\$	\$
Trade and other payables		
Carrying amount	4,751,138	4,771,581
6 months or less	4,737,110	4,659,117
Greater than 6 months	14,028	112,464
Total	4,751,138	4,771,581
Lease liabilities		
Carrying amount	1,303,472	1,319,555
6 months or less	147,447	144,170
Greater than 6 months	1,156,025	1,175,385
Total	1,303,472	1,319,555

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 the European Economic Area, USA 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 expenditure.

Contractual maturities of financial assets as at 30 June 2021

	Consolidated Entity	
	2021	2020
	\$	\$
Cash and cash equivalents		
Carrying amount	82,690,982	66,746,521
6 months or less	69,053,415	52,406,687
Greater than 6 months	13,637,567	14,339,834
Total	82,690,982	66,746,521
Other financial assets (includes trade and other receivables)		
Carrying amount	16,088,527	6,612,684
6 months or less	15,619,400	6,597,634
Greater than 6 months	469,127	15,050
Total	16,088,527	6,612,684

23. 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.

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. It is no longer intended to issue performance rights under the 2009 Plan.

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.

As at 30 June 2021, the Company via its wholly owned subsidiary ACN 108768896 Pty Ltd acting in its capacity as trustee for the 2009 Scheme Trust and the 2014 Plan Trust, holds 2,780,840 shares (2020: 4,530,568 shares).

The following share-based payment arrangements were in existence at 30 June 2021

Performance Rights Series	Number	Grant Date	Expiry Date	Exercise Price	Fair Value at Grant Date
Issued 16/09/2011	113,335	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	25,000	16/11/2011	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	\$0.67
Issued 26/08/2020	1,513,750	20/11/2019	20/11/2023	\$ Nil	between \$10.86 & \$26.87 *
Issued 24/12/2020	132,500	24/12/2020	20/11/2023	\$ Nil	between \$8.98 & \$20.74 *

Holdings of All Issued Conditional Performance Rights – 2021

Performance Rights Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Vested and Exercisable	Unvested
Issued 16/09/2011	127,710	-	-	(14,375)	113,335	-	113,335
Issued 16/11/2011	25,000	-	-	-	25,000	-	25,000
Issued 26/08/2020	-	1,513,750	-	-	1,513,750	95,375	1,418,375
Issued 24/12/2020	-	132,500	-	-	132,500	-	132,500
Total	152,710	1,646,250	-	(14,375)	1,784,585	95,375	1,689,210
Weighted average exercise price	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil

For Performance Rights issued in 2011

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.

For Performance Rights issued in 2020

Performance Rights were priced using either a Monte Carlo simulation pricing model for market conditions, or a Binomial Options Valuation pricing model for non-market conditions, taking into account factors specific to the Performance Rights Plan, such as the vesting period. For non-market conditions, the value of each performance right is multiplied by the number of performance rights expected to vest to arrive at a valuation. The performance rights expire the earlier of 7 years from date of grant of rights or 20 November 2023. 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. The exercise conditions are non-marketable. For the Performance Rights issued 24 December 2020, an illiquidity discount was applied to the pricing model.

Holdings of All Issued Conditional Performance Rights – 2020

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	208,332	-	(208,332)	-	-	-	-
Issued 16/09/2011	263,206	-	(135,496)	-	127,710	-	127,710
Issued 16/11/2011	65,000	-	-	(40,000)	25,000	-	25,000
Issued 17/03/2015	105,875	-	(105,875)	-	-	-	-
Issued 05/09/2017	Market	-	-	-	-	-	-
Total	642,413	-	(449,703)	(40,000)	152,710	-	152,710
Weighted average exercise price	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil

Performance Rights were priced using either a binomial or trinomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk-free rate used in the pricing model is assumed to be the yield on ranging from 1 year to 10 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

On 26 August 2020 1,513,750 conditional performance rights were issued to the Managing Director, consequent to shareholder approval at the 2019 Annual General Meeting. These performance rights were priced using Monte Carlo simulation pricing model for those performance rights with market capitalisation hurdles and a binomial model for those performance rights linked to non-market vesting conditions. The vesting period is up to 4 years from date of shareholder approval. 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.

24. CLINUVEL PHARMACEUTICALS LTD Parent Company Information

	CLINUVEL PHARMACEUTICALS LTD	
	2021	2020 Restated
	\$	\$
Assets		
Current assets	73,061,479	58,556,682
Non-current assets	34,530,668	20,704,937
Total assets	107,592,147	79,261,619
Liabilities		
Current liabilities	3,284,678	2,634,369
Non-current liabilities	126,355	5,290
Total liabilities	3,411,033	2,639,659
Equity		
Issued equity	151,849,375	151,849,375
Share-based payments reserve	4,343,422	1,751,223
Accumulated losses	(52,011,683)	(76,978,638)
Total equity	104,181,114	76,621,960
Financial performance		
Net profit for the year	23,741,882	16,596,091
Total comprehensive income	23,741,882	16,596,091

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 25th August 2021, the Board of Directors declared an unfranked dividend of \$0.025 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 11, 535 Bourke 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 2021 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 28 to 53 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 25th day of August, 2021

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 2021, 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 2021 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 (including Independence Standards)* (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.

Deferred tax asset – Note 3

The Group has recognised deferred tax assets of \$2.93m (2020: \$3.81m) in accordance with AASB 112 *Income Taxes*. These are primarily attributable to historic losses generated by the income tax consolidated group.

There are also \$25.74m (2020: \$46.78m) of unused carry-forward tax losses from its foreign subsidiaries not currently sitting on the balance sheet.

An assessment is required as to whether sufficient future taxable profits are likely to be generated to enable the assets to be realised.

This is a key audit area due to the following:

- The degree of judgement required in assessing management's estimates of future taxable profits to enable the asset to be realised;
- The Group undertaking transactions in a number of tax jurisdictions which require the Group to make significant judgements about the interpretation of tax legislation and the application of accounting standard; and
- The nature of cross-border tax arrangements and our need to involve taxation specialists with cross border transactions experience and expertise in transfer pricing in key jurisdictions.

Our procedures included, amongst others:

- Holding discussions with management to obtain an understanding of the policy applied for the recognition of deferred tax and assessment of profitability of the group in the near future;
- 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;
- Utilising our internal taxation specialists to assess that carry-forward losses are available for use;
- Assessing the competence and objectivity of management's tax expert used, to assist in the preparation of the valuation of the deferred tax asset;
- Checking the accuracy of input data and evaluating formulas and assumptions applied in the computation of the deferred tax asset;
- Utilising our transfer pricing specialists to assist in our assessment of the cross-border transactions made between Group entities in different tax jurisdictions;
- Utilising our internal taxation specialists to assist in the assessment of the determination of the tax bases; and
- Assessing the adequacy of the group's disclosure in relation to the carrying value of deferred tax assets.

Share based payments – Note 23

In December 2020, the Group issued 132,500 rights to the Group's Director of International Operations. The performance rights issued were allocated in two tranches:

1. Tranche A is conditional on market capitalisation over a three-year period from the Grant date.
2. Tranche B is conditional on achieving non-market based performance conditions over a three year period from the Grant date.

Performance rights were valued at \$1.1m for accounting and reporting purposes using the Monte Carlo simulation and Binomial Options Valuation method. The value will be expensed over the vesting period (up to 3 years).

The share-based payments expense for FY21 is \$2.60m (2020: \$1.66m), which is inclusive of the 1,513,750 performance rights issued to the Group's CEO in December 2019. Under AASB 2 *Share-Based Payments*, management are required to value the performance rights and assess the expected vesting date for achievements of the milestones.

This area is a key audit matter due to the degree of judgement required in valuing the performance rights as well as determining estimates of the vesting dates.

Our procedures included, amongst others:

- Reviewing the relevant agreements to obtain an understanding of the contractual nature of the share-based payment arrangements;
- Obtaining management's option valuations and associated share-based payment support;
- Utilising our internal valuation specialist to review the valuation performed by management's expert;
- Holding discussions with management to understand the share-based payment arrangements in place and, where applicable, evaluating management's assessment of the likelihood of meeting the performance conditions attached to the share-based payments;
- Reviewing management's determination of fair value of the share-based payments issued, considering the appropriateness of the valuation model used and assessing the valuation inputs;
- Assessing the allocation of the share-based payment expense over the relevant vesting period (assessing appropriateness of the vesting period);
- Evaluating management's forecasts to validate consistency of vesting dates for performance milestones; and
- Assessing the adequacy of the disclosures in the financial report.

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 2021, 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: https://www.auasb.gov.au/auditors_responsibilities/ar1_2020.pdf. This description forms part of our auditor's report.

Report on the remuneration report

Opinion on the remuneration report

We have audited the Remuneration Report included in pages 28 to 53 of the Directors' report for the year ended 30 June 2021.

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Limited, for the year ended 30 June 2021 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



M A Cunningham
Partner – Audit & Assurance

Melbourne, 25 August 2021

Auditor's Independence Declaration

To the Directors of Clinuvel Pharmaceuticals Limited

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the audit of Clinuvel Pharmaceuticals Limited for the year ended 30 June 2021, 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



M A Cunningham
Partner – Audit & Assurance

Melbourne, 25 August 2021