CLINUVEL

Appendix 4D

ASX Listing Rule 4.2A.3 Half yearly report

Half year ended 31 December 2021

CLINUVEL Pharmaceuticals Limited

ABN 88 089 644 119

Previous corresponding period: Half year ended 31 December 2020

Results for announcement to the market

				($A'000)
Revenues from ordinary activities	Increased	56%	to	24,631
Profit from operating activities before tax attributable to members	Increased	50%	to	8,726
Profit from ordinary activities after tax attributable to members	decreased	10%	to	5,870
Net Profit for the period attributable to members	decreased	10%	to	5,870

Dividends (distribution)

	Amount per security	Franked amount per security
Final dividend (prior year) *	2.5 ¢	Unfranked
Interim dividend	*Nil ¢	*Nil ¢
*CLINUVEL PHARMACEUTICALS LIMITED paid the dividend on 17 September 2021		
Previous corresponding period (31 December 2020)	2.5 ¢	Unfranked
Record date for determining entitlements to the dividend	N/A	N/A

Brief explanation of any of the figures reported above and short details of any bonus or cash issue or other item(s) of importance not previously released to the market:
* Not applicable

Commentary on results

For commentary on the results of CLINUVEL PHARMACEUTICALS LIMITED please refer to the Executive Summary & Key Highlights and the Review of Operations in the attached Directors' Report. The information in the Half Year Report should be read in conjunction with the details and explanations provided herewith, along with the most recent Annual Report. All figures are reported in Australian dollars ($A).

NTA BACKING

	Current period	Previous corresponding period
Net tangible asset backing per ordinary security	$2.14	$1.48

Control gained or lost over entities having material effect

Name of entity (or group of entities)	**N/A**
Consolidated profit (loss) from continuing items after tax of the controlled entity (or groups of entities) since the date in the current period on which control was acquired or lost	N/A
Date from which such profit has been calculated	**N/A**
Profit (loss) from continuing items after tax of the controlled entity or group of entities) while controlled the whole of the previous corresponding period	N/A

Dividends (in the case of a trust, distributions)

Date the dividend (distribution) is payable	N/A
Record date determine entitlements to the dividend (distribution) (i.e. on the basis of proper instruments of transfer received by 5.00pm if securities are not CHESS approved, or security holding balances established by 5.00pm or such later time permitted by SCH business Rules if securities are CHESS approved)	N/A
If it is a final dividend, has it been declared or proposed?	N/A

Details of Aggregate Share of Profits (losses) of Associates and Joint Venture Entities

Group's share of associates' and joint ventures entities:	Current period - $A'000	Previous corresponding period - $A'000
Profit (loss) from continuing activities before tax	N/A	N/A
Income tax on continuing activities	N/A	N/A
Profit (loss) from continuing activities after tax	N/A	N/A
Extraordinary items net of tax	N/A	N/A
Net profit (loss)	N/A	N/A
Adjustments	N/A	N/A
Share of net profit (loss) of associates and joint venture entities	N/A	N/A

CLINUVEL Pharmaceuticals Limited ABN 88 089 644 119 and Controlled Entities Half Year Financial Report Ended 31 December 2021

Directors' report

Your Directors present their report on the Company and its controlled entities for the half year ended 31 December 2021.

Directors

The names of Directors in office at any time during or since the end of the half year are:

- Dr. K. E. Agersborg;
- Mr. W. Blijdorp;
- Prof. J. V. Rosenfeld;
- Mrs. B. M. Shanahan;
- Mrs. S. E. Smith;
- Dr. P. J. Wolgen.

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

Executive Summary & Key Highlights Half Year Ending 31 December 2021

Strategy Enables Record Operating Results

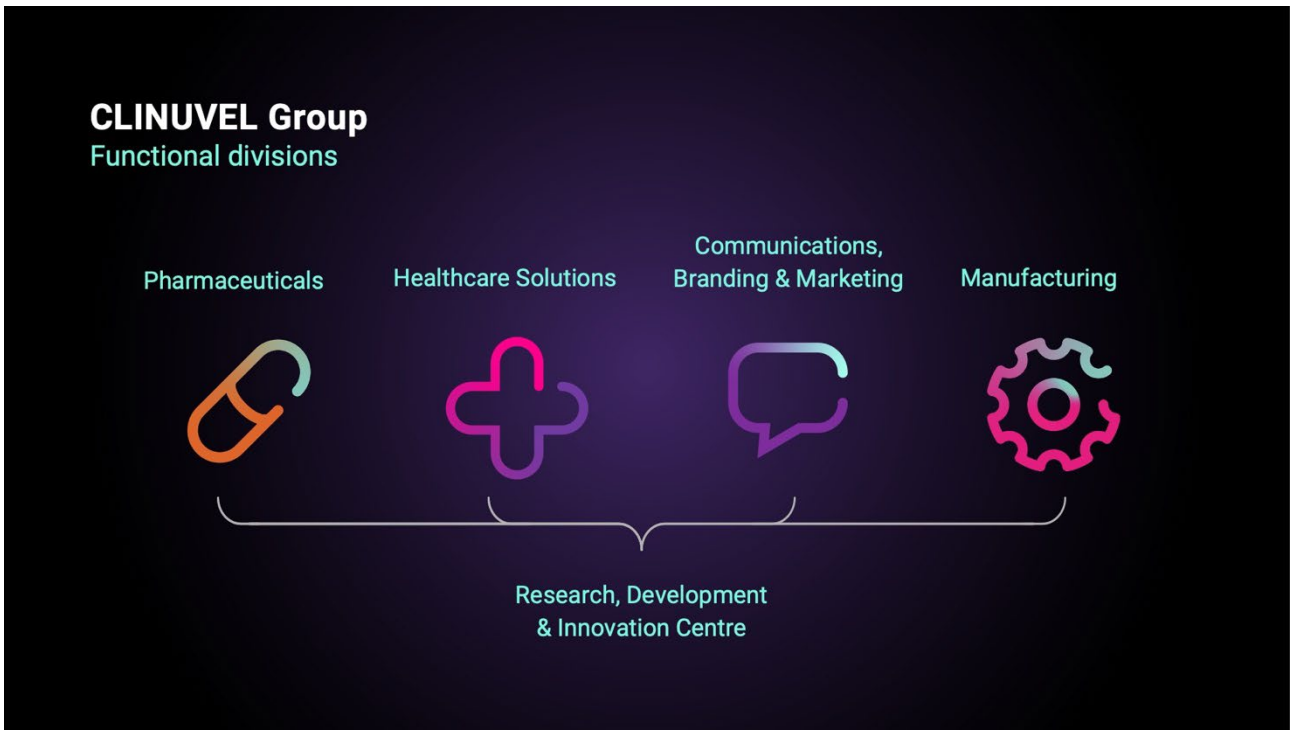
After the COVID-19 induced contraction of the world economy of 3.5% in 2020, the International Monetary Fund (IMF) has reported world economic growth (as measured by the change in real gross domestic product) recovered in 2021. A relatively brisker second half drove economic growth of 5.9% for the year. However, the world economy continues to grapple with the impact of the COVID-19 pandemic, particularly new variants, restrictions on mobility, and vaccinating people. Lower economic growth of 4.4% is expected by the IMF in 2022, as higher energy prices and supply disruptions fuel inflation and uncertainty. This indicates a disrupted recovery and a prolongation of challenging economic conditions.

CLINUVEL saw ongoing and increased demand for SCENESSE® (afamelanotide 16mg) treatment in Europe, Israel and the USA throughout the half year to December 2021. Conscious of rising inflation, CLINUVEL's longstanding, prudent approach to the management of expenses continued, whilst supporting the Company's growth and expansion strategy.

The Group's longstanding strategy from 2005 to the end of the 2020 financial year was to develop and commercialise the lead therapy, SCENESSE® to treat the rare metabolic disorder erythropoietic protoporphyria (EPP). This has resulted in a viable profit-making, dividend paying enterprise which has delivered significant returns to long-term shareholders. Concurrent with the commencement of the 2021 financial year, CLINUVEL outlined the development of a new **multi-pronged growth and expansion strategy**, based on leveraging its know-how and expertise in photomedicine and the family of melanocortin peptides in the function of key organs of the body, **to become an integrated specialty pharmaceutical company, with a sustainable long-term future.**

CLINUVEL has been focussed on generating cash flows from its commercial operations to accumulate sufficient cash reserves to self-finance its expansion strategy and at the same time to create a financial buffer to manage adverse economic conditions. These cash reserves are needed to implement the strategy and execute upon the following objectives:

- Grow commercial operations based on the pharmaceutical drug SCENESSE® for EPP patients;
- Develop innovative melanocortin products to treat a range of indications with an unmet medical need;
- Commercialise non-prescription healthcare solutions (dermatocosmetic products) to a wider population at highest risk of skin cancers due to the long term exposure to ultra-violet (UV) and high energy visible light; and
- Increasingly integrate critical parts of the value chain 'in-house'.



These objectives are supported by the new divisional structure, organised across a core Pharmaceuticals Division, Healthcare Solutions Division, Communications, Branding & Marketing Division, and Manufacturing Division, all underpinned by the Group's Research, Development & Innovation Centre, based in Singapore.

With guidance from the Board of CLINUVEL, the Group's strategy continues to be implemented with stable and effective leadership. The benefit of CLINUVEL's strategy formulation and execution is evident in its independence at a time when many companies have been required to raise debt or equity capital to finance their operations. The high commitment and discipline of the Group underpinned the **record before-tax company result achieved in the financial year ending 30 June 2021** and **this performance trend has continued with a record company before-tax result for the half year ending 31 December 2021**.

Key Highlights

Reflecting the Group's strategy, positive results were achieved in the half year to 31 December 2021:

- Revenues improved 56% to $24.631 million, compared to the half year to 31 December 2020, the prior corresponding period (previous calendar period, or 'pcp');
- An expense result of $16.203 million, up 67% on the pcp, reflecting the Group's expected and increased investment in the expansion of its R&D and commercial activities to meet its strategic objectives;
- A net profit before tax of $8.726 million, up 50% on the pcp, the twelfth consecutive half year profit result and a Group record for a July to December half year;
- A net profit after tax of $5.870 million, down 10% on the pcp. The after-tax result was influenced by an income tax benefit in the pcp from bringing to account unused tax losses and which are now being utilised in the current period;
- A 20% increase in cash held to $98.992 million, providing a solid foundation to finance further growth and expansion;
- A balance sheet comprising no debt and net equity of $107.291 million; and
- Positive earnings per share of $0.119, a decrease of 11% on the pcp.

Consolidated Entity (for the 6 months ending)	31 Dec 2021	31 Dec 2020	Change
	$	$	%
Revenues	24,631,266	15,743,215	56%
Net Profit before income tax	8,725,828	5,810,821	50%
Profit after income tax expense	5,870,380	6,487,320	-10%
Basic earnings per share	11.9 cents	13.3 cents	-11%
Net tangible assets backing per share	2.144	1.481	45%

Details of the Financial Results

Balance Sheet

One of the key objectives of the Company is to ensure its Balance Sheet is sufficiently robust to allow investment in its pipeline products with a financial buffer to respond to unexpected systemic adverse economic events. The Group has continued to manage cash and cash equivalents and, in doing so, is able to withstand anticipated increases in short-term liabilities to support the business expansion.

A strong balance sheet was maintained, with net assets increasing by 9% during the reporting period. Cash, trade debtors and trade creditors all trended positively. Cash and cash equivalents grew 20% over the six months to 31 December 2021, from $82.69 million to $98.99 million, driven by the positive cash flows generated from the Group's commercial distribution programs in Europe, Israel, and the USA.

The seasonally-driven tapering of orders placed by European EPP Expert Centres in the weeks leading to the 31 December reporting date contributed towards a 37% reduction in Trade and Other Receivables when compared to 30 June 2021. The lower Trade Receivables balance in December also reflects the seasonal impact of lower orders in Europe in months when the risk of exposure to light sources declines. Trade and other payables were successfully reduced by 21% in the same time period.

There was no debt or equity capital raised in the current or previous reporting period. Net tangible assets increased to $2.148 per share. The current ratio as at 31 December 2021 strengthened to 15.3:1 (30 June 2021: 11.8:1) and the ratio of equity to assets is 92.9% (30 June 2021: 90.9%).

In August 2021, the Board of Directors declared an unfranked dividend of $0.025 per share, resulting in a net distribution in September 2021 to shareholders and a reduction in the Group's cash and cash equivalents of $1.235 million (September 2020: $1.235 million).

Revenues

The Group achieved Total Revenues of $24.631 million for H1-FY2022, a 56% increase on the result to the pcp of $15.743 million.

A comparison of the first half results for the 2022 and 2021 financial years on a 'reported' and 'constant currency' basis is provided below in the Commercial Sales and Special Access Scheme Reimbursements categories:

$A million	Commercial Sales	SAS Reimbursements – Switzerland, Other	Total
H1-FY2022 Reported	22.467	2.164	24.631
H1-FY2022 Constant*	22.798	2.305	25.103
H1-FY2021 Reported	13.633	2.110	15.743
% change (Constant)	67.2%	9.2%	59.5%
% change (Reported)	64.8%	2.6%	56.5%

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

On a constant currency basis, revenue from distribution of SCENESSE® increased nearly 60% in the six months to 31 December 2021 compared to the pcp. This result was driven by a combination of:

- Strong growth in the US commercial distribution program. The number of patients who have received the drug has grown with the increase in Specialty Centers who are trained and accredited to administer SCENESSE®. The number of accredited centers has risen from over 30 as at December 2020 to over 40 at December 2021. In addition, the number of national and local private insurers have grown to over 100. On average, each Specialty Center is treating more patients and the number and frequency of orders per site has increased period-on-period. With the drug product code established in early 2021, Prior Authorization approvals have been processed on a more timely basis, thus facilitating swifter access for new patients. After the first full calendar year of commercial sales in the US, we can now evaluate the year-round demand for SCENESSE®. The timing of orders received from Specialty centers suggests US patients are demanding treatment in the cooler months when exposure to light sources generally decreases.

- Consistent patient demand from European EPP Expert Centres. Those EPP Expert Centres who withdrew from treating patients in 2020 to respond to the COVID-19 pandemic have since returned to treat their EPP patient base. Net patient numbers continue to grow in Europe, with many of the existing EPP Expert Centres expanding their capacities to treat new patients under the post-authorisation safety study. Importantly, during H1-FY2022, the Group reached a final, negotiated agreement (the second agreement since 2017) with the German National Association of Statutory Health Insurance Funds (GKV-SV) for the ongoing treatment and reimbursement of SCENESSE® in adult EPP patients. The agreement supports CLINUVEL's policy to charge a uniform net price for SCENESSE® across all European countries.

Reimbursements – Special Access Schemes

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

On a constant currency basis, reimbursements from special access schemes increased 9% in the six months to 31 December 2021 compared to the pcp.

Other Income

The Group recorded other income of $0.159 million. The Group's Singapore subsidiary received a $0.21 million R&D grant from the Singapore Economic Development Board, awarded under their Research Incentive Scheme for Companies in February 2020 to support the expansion of the Group's Singaporean Research, Development and Innovation Centre capabilities. Adjustments from foreign currency movements impacted the Other Income result.

Interest Income

Interest received from funds held in bank accounts and term deposits for H1-FY2022 generated $0.139 million in interest income compared to $0.217 million for H1-FY2021, a 36% decrease.

The Group continued to sustain positive cash flows throughout the reporting period, resulting in an 29% increase to its average cash and cash equivalents balances held when compared to the pcp. The increase to average cash balances earning a fixed rate of interest was offset by a decline in the average interest rate of 52 basis points when compared to the rate earned on funds held in interest bearing accounts across the prior period. The decline in average term deposit rates reflects the impact of Australian government monetary policy on term deposit rates from the two rate cuts to the cash rate in the pcp.

Expenditures

The expense result of $16.203 million in the half year ended 31 December 2021 was up 67% on the pcp. The increase is aligned to the Group's growth and expansion strategy outlined in the Executive Summary and Key Highlights section.

Commentary on specific expense categories follows.

Personnel

People and Environment is one of the Group's five principal values which are central to all of the Group's working practices. The Group aspires to create an environment where our people able to develop and excel in their careers and in turn, facilitate the growth and expansion strategy of the business. The personnel expense result for H1-FY2022 was $5.105 million, a 15% increase from H1-FY2021 of $4.448 million. In H1-FY2022 we expanded the size of our international teams amid an increasingly competitive global employment market, with an emphasis on growing personnel resources within the Communications, Branding and Marketing Division. Increased costs to source new hires also contributed to the Personnel expense result which saw a total average headcount increase between the two reporting periods of nearly 15%.

Materials and Related Expenses

Materials and related expenses primarily reflect purchases to support the acquisition of materials used in the production of finished product by the Group's contract manufacturers and other materials purchases related to the development programs. Expenditures on essential materials and related expenses increased 426%, from $0.767 million in H1-FY2021 to $4.037 million in H1-FY2022.

The Group engaged its contract manufacturer during the reporting period to undertake a number of batch manufacturing campaigns to meet longer term commercial demand, as well as to meet the forecasted clinical supply needs of the expanded R&D program. The increase in the volume of manufacturing campaigns with lower than anticipated yields contributed to the significant increase in materials and related expenses reported. Further campaigns to manufacture finished product are intended in the remainder of FY2022 and beyond.

Other material and related expenses include purchases of both raw material peptide and excipient material in support of the manufacturing campaigns. Other expenses in H1-FY2022 that were absent in the pcp include materials and related purchases on PRENUMBRA®, the liquid drug delivery formulation of afamelanotide.

Share Based Payment

The non-cash share-based payment charge increased 167% from $1.206 million in H1-FY2021 to $3.223 million in H1-FY2022. This is a non-cash accounting charge for share-based payments provided to the Managing Director and other staff. During H1-FY2022, the Group issued 743,174 unlisted performance rights to staff of the CLINUVEL group of companies and the increase in the accounting charge for share-based payments reflects the recent issue of performance rights. With an expiry date of 20 November 2023, each staff member who has been granted performance rights must be employed by CLINUVEL on the expiry date in order to exercise those performance rights whose underlying performance conditions may have otherwise been met.

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.

For H1-FY2022, Commercial distribution expenditures increased 12% from $1.047 million in the pcp to $1.176 million. The increase was impacted by an increasingly challenging global logistic environment coinciding with growth in our European and US commercial distribution programs. Key factors driving this result include:

- outbound freight and handling, distribution and manufacturing royalty expenses from higher transportation volumes;
- increased expenditures towards data collection, handling and processing of information generated from the post-authorisation safety study in Europe which forms a critical role in the risk management commitments agreed with the European Medicines Agency as part of the European marketing authorisation; and
- costs partly offset by a reduced reliance on third party providers to support pricing, market access and post-marketing regulatory affairs activities.

Finance, Corporate and General

Expenditures from finance, corporate and general activities increased 12% from $0.773 million in H1-FY2021 to $0.868 million in H1-FY2022.

Finance, corporate and general expenses drive the overall internal support functions necessary to ensure the execution of the multi-pronged growth 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, audit and tax, listing and registry fees, travel and short-term rents. For the current reporting period there was an increase in travel and accommodation-related expenditures as personnel were increasingly free to travel, compared to the 2020 period where there was a near-absence of staff and Director travel. Taxation support charges and corporate access services connected to shareholder meetings and other activities were other contributing factors to the increase in this expense result.

Legal, Insurance and IP

Legal, insurance and IP-related fees increased 21% from $0.512 million in H1-FY2021 to $0.619 million in H1-FY2022.

The Group takes out various business-related insurances as part of its overall risk management strategy and throughout the 2021 period there was a hardening in the pricing of insurances across most asset classes which saw increases to policy premiums. IP fees remained broadly in line with the prior period. Third party legal assistance was received on a range of matters including the Group's responses to various pricing negotiations in Europe.

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 EPP, along with the product development initiatives and paediatric alternative formulations and new products, including PRÉNUMBRA® and NEURACTHEL®. This category includes analytical testing, pre-clinical and non-clinical activities.

Clinical and non-clinical development fees increased 55% from $0.364 million in H1-FY2021 to $0.564 million in H1-FY2022. The increase follows the trend since the Group announced its updated strategy in October 2020 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 approvals.

This expense result for the period was driven by:

- Development costs incurred towards the new dosage forms;
- Further pre-clinical studies to support the Group's strategic focus to develop new and alternative formulations;
- Clinical trial-related fees towards assessing the role of afamelanotide to protect skin and regenerate DNA of the skin damaged from exposure to light;
- New products in development; and
- Regulatory-related fees to prepare dossier applications for review in new jurisdictions.

Depreciation and Amortisation

Depreciation and amortisation decreased 12%, from $0.447 million to $0.393 million. The prior period saw a temporary overlap of amortisation charges for two leaseholds held concurrently as part of the expansion of the Singapore laboratory facilities. In addition, gains were made from re-negotiating the right of use of long-term office space at one of the Group locations.

Communication, Branding and Marketing

Communication, Branding and Marketing fees increased 4%, from $0.173 million in H1-FY2021 to $0.180 million in H1-FY2022.

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. This expense result is highlighted by increased expenditures in visual and other digital marketing initiatives, offset by savings from website builds previously conducted by external parties and now brought in-house.

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 H1-FY2022, an adjustment of $0.040 million was recorded to account for a reduction in the value of inventory held since 30 June 2021, For H1-FY2021, the result was a $0.028 million gain in the expense result, reflecting an increase to the value of inventory held.

Deferred Tax Asset

In H1-FY2021, 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 $0.676 million.

In H1-FY2022, the Group utilised carry forward tax losses in the DTA, resulting in a debit to income tax expense of $2.855 million.

The reduction in the DTA account reflects:

- the benefit received from utilising unused tax losses;
- Increases in temporary differences primarily related to exchange rate movements that result in increases to deferred tax liability for the business; partly offset by
- the expected utilisation of unused tax losses against probable near term taxable profits.

Earnings per Share

The Group earnings per share decreased. Basic earnings per share for the period ended 31 December 2021 was $0.119 on a weighted average number of 49,410,338 issued ordinary shares, compared to the 31 December 2020 result of: $0.133 on 48,639,785 weighted average issued ordinary shares.

Review of Operations

Company Overview

CLINUVEL is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening acute disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel, and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with EPP.

Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA.

Operational Review

Commercial operations in the six months to 31 December 2021 were focused on the distribution of SCENESSE® for EPP patients in Europe, the USA, and Israel. This involved:

- Intensive liaison with porphyria treatment centres and suppliers to ensure continuous supply of the drug to patients;
- Management of the ongoing reimbursement of the cost of treatment; and
- Undertaking the key data collection, compliance, and reporting activities associated with CLINUVEL's obligations under marketing approvals.

European and Swiss Distribution

Demand for treatment continues through Expert Porphyria Centres in the European Union and Switzerland. During the December 2021 half year, the Company was engaged in extensive discussions with the German National Association of Statutory Health Insurance Funds (GKV-SV) to renew the agreement on the reimbursement of the cost of treatment of SCENESSE® for EPP patients in Germany. As announced in January 2022, the negotiations were successfully completed, and a new reimbursement agreement was signed with the GKV-SV. The Agreement reflects trust in CLINUVEL and its transparent and equitable approach to insurers and governments throughout Europe. This is a key milestone agreement for the business as it ensures continuity of treatment to German EPP patients and influences insurers in other countries to continue to reimburse the cost of SCENESSE® treatment.

US Distribution

CLINUVEL has built a distribution network of more than 45 Specialty Centers to provide treatment to EPP patients across the USA. Over 100 national and local insurers are reimbursing the cost of treatment according to individual insurance plans under Prior Authorization arrangements.

Distribution in Other Jurisdictions

Patients in Israel are being treated and we are committed to treat patients in Australia and gain regulatory approvals to distribute SCENESSE® in other jurisdictions.

The Expanded Clinical Program

Having established itself as a world expert in photomedicine and melanocortin drug development, CLINUVEL is conducting clinical trials to evaluate the safety and efficacy of afamelanotide for a range of patients with genetic, metabolic, systemic, and life-threatening, acute disorders. The expanded clinical program progressed during the December 2021 half year with key developments in individual programs reported below.

DNA Repair Program

- The DNA Repair Program aims to assess the ability of afamelanotide to assist the repair of DNA of skin damaged by UV radiation and visible light. This clinical focus is relevant to over two billion people worldwide who have some sort of inefficiency in their natural DNA reparative processes (nucleotide excision repair and basic excision repair).
- The initial focus of the DNA Repair Program is on patients with the rare genetic disorder xeroderma pigmentosum (XP), a life-threatening disorder caused by an inability to repair UV-provoked DNA skin damage.
- Considerable work was undertaken on preparations to commence the first global study in XP. This work culminated in the announcement early in September 2021 that all necessary regulatory and ethics committee approvals to commence a new study had been granted.
- The Company announced in October 2021 that the world first study (CUV156) had commenced with two patients with the XP-C complementation treated, with no adverse reactions reported. As this study progressed, the Company has continued to prepare to commence a new study (CUV151) involving disease-free volunteers of fair complexion as a control group.

Arterial Ischaemic Stroke (AIS)

- Globally, at least ten million people per annum suffer an ischaemic stroke and are ineligible for treatment with existing therapies. Afamelanotide is known to offer neuroprotection and act as a potent anti-oxidative hormone. The drug therapy is assessed on its ability to improve blood flow and increase the delivery of oxygen and nutrients to deprived brain tissue in stroke patients.
- In June 2021, afamelanotide was administered to a first patient diagnosed with AIS enrolled in a world first clinical trial (CUV801). In August 2021 we reported that treatment was well tolerated by three

patients who were discharged from critical care after no drug-related adverse effects were experienced. COVID-19 related lockdowns subsequently delayed further progress at the treating hospital in Australia.
- After lockdown restrictions were removed, clinicians proceeded to treat the next three of the planned six patients of the study. The Company announced the completion of enrolment in the CUV801 study in January 2022. Importantly, no drug related adverse reactions were reported in the six patients treated. The study will now be completed and data analysed, with results expected later in the year.

Vitiligo

- Vitiligo affects up to 45 million individuals worldwide, with no current approved therapy. In initial studies, afamelanotide has been shown the ability to repigment vitiliginous lesions as a combination therapy.
- The Company continued to prepare and co-ordinate preparatory work to reach agreement with the US Food and Drug Administration on the design of a new North American vitiligo study and towards the end of the half year, the Company announced an agreement on the design. The focus is on patients of darker skin complexion (Fitzpatrick IV-VI), for whom the need for repigmentation treatment is regarded as the greatest due to visible disease causing a loss of identity. CLINUVEL will now proceed to commence a study (CUV104) to assess the role of afamelanotide as a monotherapy to repigment the skin and improve the quality of life of patients.

Other Programs

A range of other research and development programs are underway and are mentioned below to round-out the expansive pipeline of pharmaceutical products:

- the development of a paediatric formulation of afamelanotide for EPP patients under 18 years of age;
- the variegate porphyria (VP) program, a related indication to EPP, with a clinical study (CUV040) to be progressed when all requisite approvals and clinical support is confirmed;
- work on the requisite ethics committee and regulatory approvals needed to progress a further clinical indication;
- ongoing development of PRÉNUMBRA®, a liquid formulation of afamelanotide for flexible treatment options in a range of indications;
- the development of topical formulations of melanocortins for a range of indications and target users; and
- the development and application of NEURACTHEL®, a novel formulation of the melanocortin adrenocorticotropic hormone (ACTH), for neurological, endocrinological and degenerative disorders, to be announced.

The Healthcare Solutions Division

The Healthcare Solutions Division is working to translate the accumulated technological know-how and expertise in chemistry, dosage forms and melanocortins built over two decades of research and development to the general population in need of protection and regeneration from exposure to UV and high energy visible light. The focus in the half year to December 2021 was to progress the development of the first non-prescription, dermatocosmetic product and the distribution and marketing arrangements to target individuals in need. This work establishes infrastructure to engage relevant audiences and launch the first polychromatic product in 2022.

Other Activities

The Company held the Annual General Meeting of Shareholders in virtual format on 10 November 2021. A record number of shareholders voted on the resolutions of the Meeting which were all voted in accordance with the Directors' recommendations. The Chair and Managing Director presented to the Meeting and the Board of Directors answered shareholder questions.

An Operations Update, two Investor Webinars and a Strategic Update were issued during the six months to 31 December 2021 and CLINUVEL also presented at key conferences, specifically the H. C. Wainwright

Global Investment Conference, the Morgans Value in the Vines Conference and the Jefferies London Healthcare Conference. This trend continued in 2022 with a presentation to the H. C. Wainwright Bioconnect Conference in January.

All the Company's announcements and key media interviews during this period are available on the CLINUVEL website, with other updates available on the CLINUVEL News website.

Included in this document is the Half Year Report Appendix 4D, together with the Financial Report, this Directors' Report and Declaration and Audit Independent Review Report relating to the half year ended 31 December 2021.

This Half Year Report forms part of this announcement to the Australian Securities Exchange Limited and should be read in conjunction with CLINUVEL's Annual Report for the year ended 30 June 2021.

Auditor Independence Declaration

The independence declaration of our auditor as per section 307C of the Corporations Act is attached and forms part of the Directors' Report.

Signed in accordance with a resolution of the Board of Directors made pursuant to section 306(3) of the Corporations Act 2001.

Dr Philippe Wolgen

Managing Director

Dated this 23rd day of February 2022

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Independent Auditor's Review Report

To the Members of Clinuvel Pharmaceuticals Limited

Report on the review of the half-year financial report

Conclusion

We have reviewed the accompanying half-year financial report of Clinuvel Pharmaceuticals Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2021, and 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 half year ended on that date, a description of accounting policies, other selected explanatory notes, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Clinuvel Pharmaceuticals Limited does not comply with the *Corporations Act 2001* including:

(a) giving a true and fair view of the Group's financial position as at 31 December 2021 and of its performance for the half year ended on that date; and

(b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001.*

Basis for Conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the Auditor's Responsibilities for the Review of the Financial Report section of our report. We are independent of the Company 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 annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Directors' responsibility for the half-year financial report

The Directors of the Company are responsible for the preparation of the half-year 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 half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2021 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Grant Thornton Audit Pty Ltd
Chartered Accountants

M A Cunningham
Partner – Audit & Assurance

Melbourne, 23 February 2022

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE HALF YEAR ENDED 31 DECEMBER 2021

	CONSOLIDATED	
	31 December 2021	31 December 2020
	$	$
Revenues		
Commercial sales of goods	22,467,332	13,633,153
Sales reimbursements	2,163,934	2,110,062
Total revenues	**24,631,266**	**15,743,215**
Interest income	139,339	216,707
Total interest income	**139,339**	**216,707**
Other Income (loss)		
Government grants	209,670	83,597
Realised net currency gain (loss) on transactions	(34,982)	26,485
Unrealised loss on restating foreign currency creditors and currencies held	(16,010)	(550,798)
Total other income (loss)	**158,678**	**(440,716)**
Expenses		
Personnel-related	5,104,904	4,448,097
Materials and related expenses	4,036,712	766,979
Share-based payments	3,223,269	1,206,309
Commercial distribution	1,175,653	1,046,647
Finance, corporate and general	868,121	772,726
Legal, insurances and IP	618,574	511,968
Clinical and non-clinical development	563,977	364,281
Depreciation and amortisation	392,695	447,084
Communication, branding and marketing	179,825	172,534
Changes in inventories of raw materials, work in progress and finished goods	39,725	(28,240)
Total expenses	16,203,455	9,708,385
Profit before related income tax expenses	**8,725,828**	**5,810,821**
Income tax expense (benefit)	2,855,448	(676,499)
Net profit for the year	**5,870,380**	**6,487,320**
Other comprehensive income		
Items that may be re-classified subsequently to profit or loss		
Exchange differences of foreign exchange translation of foreign operations	695,518	(440,340)
Other comprehensive income/(loss) for the period, net of income tax	695,518	(440,340)
Total comprehensive income for the period	**6,565,898**	**6,046,980**
Basic earnings per share - cents per share	11.9	13.3
Diluted earnings per share - cents per share	11.4	12.7

This statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes to the financial statements.

STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2021

	CONSOLIDATED	
	31 December 2021	30 June 2021
	$	$
Current assets		
Cash and cash equivalents	98,992,349	82,690,982
Trade and other receivables	10,092,097	16,088,527
Inventories	3,146,944	3,186,670
Other assets	879,155	882,034
Total current assets	**113,110,545**	**102,848,213**
Non-current assets		
Property, plant and equipment - net	1,204,943	1,384,422
Right-Of-Use assets - net	1,076,624	1,218,721
Intangible assets - net	185,030	185,030
Deferred tax assets - net	75,740	2,931,188
Total non-current assets	2,542,337	5,719,361
Total assets	**115,652,882**	**108,567,574**
Current liabilities		
Trade and other payables	3,762,383	4,751,138
Provisions	3,344,819	3,697,579
Lease liabilities	267,060	258,236
Total current liabilities	7,374,262	8,706,953
Non-current liabilities		
Lease liabilities	902,699	1,045,236
Provisions	84,586	77,951
Total non-current liabilities	987,285	1,123,187
Total liabilities	**8,361,547**	**9,830,140**
Net assets	107,291,335	98,737,434
Equity		
Contributed equity	151,849,375	151,849,375
Reserves	8,922,876	5,017,827
Accumulated losses	(53,480,916)	(58,129,768)
Total equity	**107,291,335**	**98,737,434**

This statement of financial position should be read in conjunction with the accompanying notes to the financial statements.

STATEMENT OF CHANGES IN EQUITY
FOR THE HALF YEAR ENDED 31 DECEMBER 2021

	Share Capital	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
	$	$	$	$	$
Balance at 1 July 2020	**151,849,375**	**1,751,223**	**99,152**	**(81,632,944)**	**72,066,806**
Issue of Share Capital under share-based payment	-	-	-	-	**-**
Employee share-based payment options	-	1,196,115	-	10,194	**1,206,309**
Dividends paid	-	-	-	(1,235,266)	**(1,235,266)**
Transactions with owners	151,849,375	2,947,338	**99,152**	(82,858,016)	72,037,849
Profit for the year	-	-	-	6,487,320	**6,487,320**
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	(440,340)	-	**(440,340)**
Total other comprehensive income	-	-	**(440,340)**	-	(440,340)
Balance at 31 December 2020	**151,849,375**	**2,947,338**	**(341,188)**	**(76,370,696)**	**78,084,829**
Balance at 1 July 2021	**151,849,375**	**4,343,422**	**674,405**	**(58,129,768)**	**98,737,434**
Issue of Share Capital under share-based payment	-	-	-	-	**-**
Employee share-based payment options	-	3,209,531	-	13,738	**3,223,269**
Dividends paid	-	-	-	(1,235,266)	**(1,235,266)**
Transactions with owners	151,849,375	7,552,953	**674,405**	(59,351,296)	100,725,437
Profit for the year				5,870,380	5,870,380
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	695,518	-	**695,518**
Total other comprehensive income	-	-	**695,518**	-	695,518
Balance at 31 December 2021	**151,849,375**	**7,552,953**	**1,369,923**	**(53,480,916)**	**107,291,335**

This statement of changes in equity should be read in conjunction with the accompanying notes to the financial statements.

STATEMENT OF CASH FLOWS
FOR THE HALF YEAR ENDED 31 DECEMBER 2021

	CONSOLIDATED	
	31 December 2021	31 December 2020
	$	$
Cash flows from operating activities		
Receipts from customers	30,905,099	17,281,031
GST and VAT refunds	225,689	22,312
Government grants	210,078	80,801
Interest received	113,196	200,711
Payments to suppliers and employees	(14,129,762)	(8,397,033)
Net cash provided by/(used in) operating activities	17,324,300	9,187,822
Cash flows from investing activities		
Payments for property, plant and equipment	(56,444)	(794,870)
Net cash provided by/(used in) investing activities	(56,444)	(794,870)
Cash flows from financing activities		
Repayment of borrowing and leasing liabilities	(130,641)	(132,488)
Repayment of interest	(17,451)	(13,439)
Dividends paid	(1,235,266)	(1,235,266)
Net cash provided by/(used in) financing activities	(1,383,358)	(1,381,193)
Net increase in cash held	**15,884,498**	**7,011,759**
Cash and cash equivalents at beginning of the year	**82,690,982**	**66,746,521**
Effects of exchange rate changes on foreign currency held	416,869	(840,183)
Cash and cash equivalents at end of the year	**98,992,349**	**72,918,097**

This statement of cash flows should be read in conjunction with the accompanying notes to the financial statements.

Notes to the condensed financial statements

For the Half Year Ended 31 December 2021

Statement of Accounting Policies, General Information and Basis of Preparation of The Half Year Financial Report

The half year financial report is a general-purpose financial report prepared in accordance with the Corporations Act 2001 and AASB 134 Interim Financial Reporting. The half year financial report does not include notes of the type normally included in an Annual Report and shall be read in conjunction with the most recent annual financial report. The accounting policies adopted in the preparation of the half year financial report are consistent with those adopted and disclosed in the Group's 2021 annual financial report for the financial year ended 30 June 2021.

Contingent liabilities and assets

There are no known significant contingent liabilities or contingent assets as at the date of this report.

Dividends paid or recommended

A final unfranked dividend for 2021 of 2.5 cents per share was paid on 17 September 2021 and a final unfranked dividend for 2020 of 2.5 cents per share was paid on 18 September 2020.

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.

Basic earnings per share were $0.119 on a weighted average number of 49,410,338 issued ordinary shares. This compares with restated basic earnings per share of $0.133 as at 31 December 2020 on a weighted average number of 48,639,785 issued ordinary shares.

Events subsequent to balance date

There has not been any matter that has affected, or could significantly affect, the operations of the Consolidated Entity subsequent to balance date.

Revenue

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

	Six months to 31 December 2021			Six months to 31 December 2020		
	Commercial sales of goods	Sales reimbursements	Total	Commercial sales of goods	Sales reimbursements	Total
	$'000	$'000	$'000	$'000	$'000	$'000
Europe & USA	22,467	93	22,560	13,633	95	13,728
Switzerland, Others	-	2,071	2,071	-	2,015	2,015
Total	22,467	2,164	24,631	13,633	2,110	15,743

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

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.

Share-Based Payments

During the reporting period, 743,174 performance rights were issued to staff of the CLINUVEL Group of companies. 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. An illiquidity discount was applied to the pricing model. The fair value per right at grant date varies between $18.74 and $26.22.

Directors' Declaration

In the opinion of the Directors:

1. The financial statements and notes, of the company and 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 31 December 2021 and its performance for the half year ended on that date;
   b) with Accounting Standard AASB134 Interim Financial Reporting and the Corporations Regulations 2001; and
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.

This declaration is made in accordance with a resolution of the Board of Directors pursuant to section 303(5) of the Corporations Act 2001.

DR PHILIPPE WOLGEN

Director

Dated this 23rd day of February 2022

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Auditor's Independence Declaration

To the Directors of Clinuvel Pharmaceuticals Limited

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Clinuvel Pharmaceuticals Limited for the half-year ended 31 December 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 review; and

b no contraventions of any applicable code of professional conduct in relation to the review.

Grant Thornton Audit Pty Ltd
Chartered Accountants

M A Cunningham
Partner – Audit & Assurance

Melbourne, 23 February 2022