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CLINUVEL

APPENDIX 4D

ASX Listing Rule 4.2A.3 Half yearly report. Half year ended 31 December 2023

CLINUVEL Pharmaceuticals Limited

ABN 88 089 644 119
Previous corresponding period: Half year ended 31 December 2022

Results for announcement to the market

				($A'000)
Revenues from ordinary activities	Increased	10%	to	32,257
Profit from operating activities before tax attributable to members	Increased	1%	to	14,806
Profit from ordinary activities after tax attributable to members	Decreased	4%	to	10,936
Net Profit for the period attributable to members	Decreased	4%	to	10,936

Dividends (distribution)

	Amount per security	Franked amount per security
Final dividend (full the year ended 30 June 2023) *	5.0 ¢	Fully franked
Interim dividend	*Nil ¢	*Nil ¢
*CLINUVEL PHARMACEUTICALS LIMITED paid the dividend on 20 September 2023		
Previous corresponding period (31 December 2022)	4.0 ¢	Fully franked
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

Net tangible asset backing

	Current period	Previous corresponding period
Net tangible asset backing per ordinary security	$3.54	$2.78

Control gained or lost over entities having material effect – N/A

Details of aggregate share of profits (losses) of associates and joint venture entities – N/A

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).

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CLINUVEL PHARMACEUTICALS LIMITED ABN 88 089 644 119
and Controlled Entities Half Year Financial Report
Ended 31 December 2023

Directors' Report

Your Directors present today in compliance with the Corporations Act 2001, and Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001, CLINUVEL PHARMACEUTICALS LTD and its Controlled Entities' (the 'Company', or 'Group') report for the half year ended 31st December 2023, the financial results reflecting the financial evolution and growth of the Company.

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 (resigned 21 February 2024	Sir. J. A. Likierman (resigned 20 November 2023)	
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

Message from the Chief Financial Officer

I am very pleased to have the opportunity to provide commentary on the headline results for the CLINUVEL Group for the half year to 31 December 2023.

HEADLINE RESULTS

Comparisons are made to the six months ended 31 December 2022
being the prior corresponding period, or 'pcp':

- Consistent upward growth in revenues, other income, and interest income: 15% increase.
- Expansion of activities across all business segments: 28% increase to total expenses to $20.92 million.
- Profit after tax result of $10.94 million: 4% decrease.
- Profit before tax result of $14.81 million: 1% increase.
- Cash, cash equivalents and cash in term deposits continue to increase: Up 11% to $174.45 million.
- Earnings per share: 4% decrease.

In the 8th consecutive year of profitability, growth was achieved in all revenue and income categories in the reporting period. The combined measure of commercial sales and reimbursements from the distribution of SCENESSE® (afamelanotide 16mg) rose by 10% compared to the same period of 2022. On a constant currency basis, the percentage increase exceeded 4%. This reflects continued demand for treatment by erythropoietic protoporphyria (EPP) patients across all areas of distribution. Higher interest income was earned on cash reserves held at financial institutions in the higher rate environment and this boosted total revenues. As a result, total revenues increased by 15% to $35.73 million in the reporting half year, and net profits of $10.94 million.

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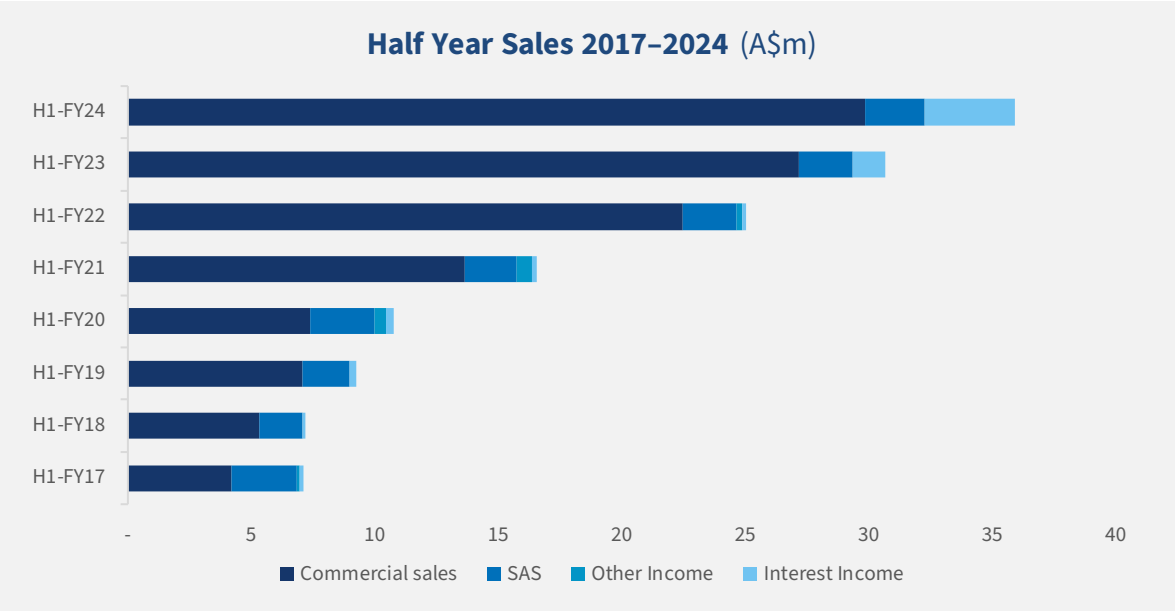
In 2021, we projected overall expenditures, excluding investments of a capital nature and marketing expenses of the PhotoCosmetic product range, to reach $175 million for the five financial years ending June 2025. We are comfortably on track to achieve this projection, having completed 70% of the timeline and 65% ($113.75 million) of the expenditure target. Despite the projected growth in expenditures to reach $175 million over 5 years , the Company has still managed to grow its cash reserves to $174.5 million, exceeding expectations.



1. REVENUES, INTEREST AND OTHER INCOME: increase of 15% (pcp)[1] to $35.73m

The Group reported another strong result for total revenues in the half year to December 2023, encompassing:

- commercial sales,
- reimbursements under special access schemes (SAS),
- other income, and
- interest income.

Consistent demand for SCENESSE® in Europe and the US

Patient demand remains consistently strong in Europe where patients have had access to the drug since June 2016. Calendar year 2023 saw single digit percentage increases in product sales in Europe. The timing of sales orders from larger treatment centres in Europe resulted in sales being recognised earlier in the 2023 calendar year than in 2022, thus impacting the H1FY2024 sales result when compared to H1FY2023.

US revenues have risen in the reporting half year from greater patient outreach facilitated by more Specialty Centers able to administer SCENESSE®, with more than 70 now active. An improvement in the geographic dispersion of centres across the US is enabling higher sales orders and improved patient access. Various initiatives to distribute SCENESSE® to new patients also facilitated higher sales volumes.

Reimbursement under Special Access Schemes in Switzerland remained constant. Treatment access in Switzerland has enabled EPP patients to assume a normal symptom-free life for over 10 years.

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A$ million	Commercial Sales	SAS Reimbursements – Switzerland, Other	Total
HY2024 Reported	29.86	2.40	32.26
HY2024 Constant*	28.40	2.16	30.56
HY2023 Reported	27.19	2.16	29.35
% change (Constant)	4.5%	0%	4.1%
% change (Reported)	9.8%	11.1%	9.9%

* HY2024 revenues converted to A$ monthly at the average conversion rate of the same month used for HY2023

Higher interest rates boost interest income

Positive net cash flows in recent years have allowed the Group to place accumulated cash reserves in term deposits held at banks. This continued in the reporting half year and in the higher interest rate environment, we achieved an interest income result of $3.66 million (H1FY2023: $1.34 million).

2. EXPENSES: increase by 28% (pcp) to $20.92m

Total expenses grew 28% compared to the six months to 31 December 2022. This is a direct reflection of the expanded activities across the business. Our head count continues to rise, our inventories continue to grow to meet future commercial and clinical demand and overall operational costs have increased to service the expansion of our development, commercial and promotional programs.

We had previously projected overall expenditures, excluding investments of a capital nature and marketing expenses of the PhotoCosmetic product range, to reach $175 million for the five financial years ending June 2025. We are comfortably on track to achieve this projection, having completed 70% of the timeline and 65% of the expenditure target.

All numbers to the nearest thousand ($AUD)

Personnel-related expenses

↑32%

$8,046	**JULY–DEC 2023**
$6,097	JULY–DEC 2022

We are a growth Company with a focus on developing our workforce to competently manage as many of its business activities in-house. Without a motivated, dedicated and well qualified workforce collaborating to achieve collective goals, the Group will not be able to meet its objectives.

Average headcount increased 10% when compared to the prior period. The largest staffing increases were in the US and across Europe, with new positions filled to service roles targeting commercial distribution, legal, clinical, regulatory, and medical affairs, as well as new business development. To remain a competitive employer with a highly skilled and incentivised workforce, cost increases to base salary levels were implemented in the reporting period. Nearly 10% of the increase period-on-period related to changes in talent acquisition fees. Finally, with the majority of CLINUVEL's personnel employed outside Australia, approximately a quarter of the increase in personnel-related expenses was impacted by a weaker Australian dollar compared to the pcp.

People and Environment are one of the Group's five principal values, which are central to all the Group's working practices. The Group aspires to create an environment, where our people can develop, excel in their careers, and become the next generation of industry-leading managers.

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Share-based payments

↑47%

$5,643	**JULY–DEC 2023**
$3,827	JULY–DEC 2022

The non-cash accounting charge for share-based payments expense increased 47%. At the start of the financial year, the Group issued 255,750 performance rights, with over 40% of the workforce receiving equity. This is considered an effective long-term incentive tool to promote employee retention and encourage participants to align their interests with fellow owners of the Group. The valuation of these performance rights at the start of the financial year was absent in the prior period. This result was also influenced by the vesting of 716,932 performance rights on 20 November 2023, representing 44% of the total performance rights with a 20 November 2023 vesting date. At the reporting date, the Managing Director no longer holds any long-term equity-based incentives. The total number of performance rights on issue is only 0.57% of issued ordinary shares and held across 32 participants.

Materials and related expenses

↓10%

$4,112	**JULY–DEC 2023**
$4,588	JULY–DEC 2022

Materials and related expenses primarily reflect purchases to support the acquisition and movement of materials used in the production of finished product as well as the purchase and conversion of materials within our development programs. The 10% decline to the prior comparative period reflects an overall improved efficiency within the materials purchased and consumed to manufacture our commercial products, partially offset by increases to materials used in formulation development including the ACTH drug substance materials developed, manufactured and purchased for the NEURACTHEL® Instant release formulation, which is in development.

Finance, corporate and general

↑59%

$2,020	**JULY–DEC 2023**
$1,268	JULY–DEC 2022

The Group's financial and corporate expense result rose 59%, heavily influenced by greater staff movement from international travel throughout the 2023 calendar year. We were very active in connecting our workforce face-to-face, not only with each other, but also with various stakeholders including investors, industry suppliers and potential medical centres who wish to be involved in our various clinical programs. Leveraging the expertise of professional service firms to support the Group to operate efficiently across multiple continents increased, and both IT and facilities fees increased to provide a robust and more enduring infrastructure to an expanding workforce.

Commercial distribution

↑5%

$1,371	**JULY–DEC 2023**
$1,307	JULY–DEC 2022

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One of the Company's essential and most important activities is to ensure our commercial product is provided under Good Distribution Practice and we satisfy all compliance and risk management commitments with the regulatory agencies. The expenditures associated with these activities increased 5% compared to the comparative period. The six months saw fewer regulatory inspection activities and submissions to var regulatory dossiers. However this reduction was offset by the increased costs associated with ensuring readiness to new product serialization guidelines in the USA and providing support for interactions with regulatory authorities.

Legal, insurances and IP

↑44%

$783	**JULY–DEC 2023**
$543	JULY–DEC 2022

The current period saw a focus on asset protection, compliance and risk management, reflected in the 44% increase in expenditures towards legal support IP maintenance and various insurances. This focus on legal assistance and risk protection is also embedded within the personnel expense result with the first-time appointment of an in-house legal counsel in August 2023.

Fees for third party legal assistance was received for a range of business matters in the ordinary course of business, such as debt recovery, with the cost of legal assistance to support the Group in its tireless efforts to enter new markets where reimbursors are unwilling to accept the value of our drug to EPP patients and/or have failed to follow legal requirements in their processes.

Clinical and non-clinical development

↑27%

$752	**JULY–DEC 2023**
$590	JULY–DEC 2022

The Group has embarked on a comprehensive clinical program evaluating the safety and efficacy of melanocortins as therapies for patients with unmet medical needs. Our clinical studies are at various stages of progress. We saw advances in the prior period towards a non-clinical study and multiple clinical studies evaluating the use of afamelanotide in a control group of healthy volunteers with skin prone to DNA photodamage, as well as in patients with xeroderma pigmentosum. These expenses were complemented in the current period by the start-up of the clinical studies announced in 2023 to (a) evaluate afamelanotide to repigment skin affected by vitiligo in a combination therapy with narrowband ultraviolet B (NB-UVB) phototherapy, (b) provide photoprotection for patients with variegate porphyria, and (c) collect data on the use of afamelanotide in adolescent patients with EPP. The growth in these programs saw a 27% increase to the prior period. The expense result for this cost category is anticipated to increase in the near term as patient recruitment progresses in the larger CUV105 vitiligo study and setup progresses for the subsequent CUV107 vitiligo study.

Communication, branding and marketing

↑61%

$661	**JULY–DEC 2023**
$410	JULY–DEC 2022

The activities of the Communication, Branding and Marketing division, established in 2021 to engage in initiatives to promote the CLINUVEL brand and to elevate the exposure of the PhotoCosmetic product range

with the intention to cultivate a global brand, continues to progress. This is reflected in a 61% period-on-period increase, driven by an increase in sponsored events targeting select investor audiences and visual content creation to drive image and brand promotion across social media platforms.

Depreciation and amortisation

↑53%

$575	JULY–DEC 2023
$376	JULY–DEC 2022

The Group made a strategic fixed-asset investment during the period to purchase an office property located in Egham, UK for £2,500,000, net of fees. As the working environment evolves from the working-from-home phenomena of the COVID-19 pandemic, we aspire to offer a physical location for our European-based workforce that will attract and retain talent and encourage work flexibility, collaboration, and productivity. This investment in a flagship fixed asset was a key contributor to a 53% increase in non-cash depreciation expenses period-on-period. It was also a major contributor to the $5.3 million in payments for fixed assets in the investing activities section to the Cash Flow Statement.

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

↑16%

$3,040	JULY–DEC 2023
$2,631	JULY–DEC 2022

We are focussed on our forward business planning and this is demonstrated by the increased change to our raw material and inventories. Future commercial demand for our implant formulation and the build up of stock levels for the raw materials comprising the final formulation saw a $3.0m adjustment to the expense result.

3. NET PROFITS BEFORE TAX up 1%, AFTER TAX down 4% (pcp)

The company continues to maintain strong profitability with an operating margin of 46%. The income tax expense for the period was 20% higher than the pcp, a result impacted by the prior period benefiting from a favourable movement in temporary differences to our deferred tax position and the extent of this benefit was not replicated in the current period.

4. EPS: down 4% (pcp)

With a 4% decrease in NPAT, the earnings per share measure similarly trended downward, moving from 23.0 cents per share to 22.1 cents per share. The weighted average number of issued ordinary shares increased from 49,410,338 shares in the pcp to 49,546,711 shares in the current period.

5. NET ASSETS: an increase of 8.5% (from 30 June 2023)

The financial strength of the Group continues to grow and this is reflected in the 8.5% increase to net assets over the six months, from $164.6 million to $178.6 million. Ensuring a strong and stable balance with liquid assets is crucial for the Group to acquire assets and/or businesses, both small and large relative to its size, and to commit to programs which may require significant working capital in the short and long term. In the seven years from the time of first commercial product launch, the Group has accumulated a cash and term deposit position totalling $174.45 million without reliance on long-term debt or equity funding arrangements. The ratio of the Groups' overall debt to equity has increased slightly from 18% to 18.5%.

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Cash placed in term deposits

Part of our cash management processes is to place cash in term deposits with differing maturity dates which may extend several months from their start date. This allows the Group to manage its short-term cash commitments and in doing so, ensuring a competitive interest yield is obtained without placing cash in investments such as marketable securities.

The Group has consistently considered its cash held in term deposits to meet the criteria of cash and cash equivalents under Australian Accounting Standards as they can be withdrawn on demand prior to their maturity dates and are subject to an insignificant risk in a change to its value.

Over the past several years the Group has generated positive net cash flows from its operations that has resulted in an enviable cash reserve position of $174.5 million at the reporting date. To present the Group's cash position in a more effective manner to users of this report, the Group has revised its accounting policy for reporting its cash and cash equivalents in relation to term deposits and has decided to separately disclose these term deposit assets in the Statement of Financial Position. This treatment aligns with the trend of disclosing entities separately reporting cash placed in term deposits with maturity dates beyond 90 days from acquisition date from their cash and cash equivalents. As a result in the change of accounting policy, the Group has reclassified its cash and cash equivalent result in the prior period comparatives to the financial statements.

Conclusion

The financial strength of the Group continues to improve, with an enviable current ratio of 6.9x. Our cash reserves provide the platform to support our strategic plans to complete our ambitious commercial, clinical and pharmaceutical programs, and to enter new territories through the rollout of consumer-focused PhotoCosmetic products. Revenues continue to grow, and management maintains constant focus on maximising the bottom line. I wish to repeat what I said in this same report 12 months ago - we are dedicated to serving patients and shareholders and continue to work tirelessly with the aim to deliver strong full year results for FY2024.

Darren Keamy

Chief Financial Officer

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Review of Operations

About CLINUVEL

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 specialised populations. 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, assisted 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 erythropoietic protoporphyria (EPP).

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

Key Activities

CLINUVEL's operations in the half year to 31 December 2023 continued to focus on three key activities:

- the distribution of SCENESSE® to treat patients with EPP;
- advancing clinical research with melanocortins for a range of patients with severe disorders; and
- the development of pharmaceutical and PhotoCosmetic products.

The Group employs an integrated business model to progress these activities. Key functions of the business are undertaken 'in-house' rather than outsourced to third parties. This has proved beneficial for the Group, particularly in commercial distribution, and is being extended to the Communications, branding, and marketing of the Group and plans for product manufacturing.

Each activity is detailed below.

Distribution of SCENESSE® for EPP

CLINUVEL continues to distribute SCENESSE® for EPP in Europe, the USA, Israel, and Canada.

Europe

Patient demand for SCENESSE® treatment continues to grow, with a standard of care established through a network of EPP Expert Centres. Swiss patients have now been treated with SCENESSE® under special access arrangements since 2012 with patient retention over 90%.

In September 2023, the Group announced a clinical study (CUV052) would be undertaken to add data to the existing marketing authorization dossier as part of a regulatory application to include adolescent patients to the approved indication for SCENESSE®.

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USA

CLINUVEL has established a nationwide network of over 70 Specialty Centers to facilitate EPP patient treatment with SCENESSE®. More than 110 private and government insurers reimburse the cost of treatment. The objective is to expand the number of Specialty Centers to 120 within the next two years.

Other jurisdictions

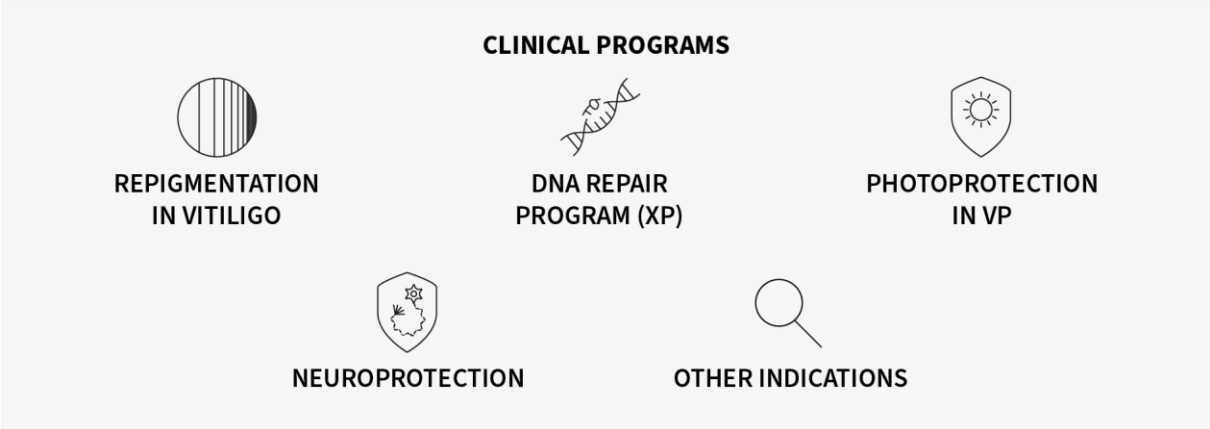
Canadian patients are being treated under a Special Access Program.

The Group continues to work with the Pharmaceutical Benefits Advisory Committee (PBAC) to make the drug available on the Pharmaceutical Benefits Scheme to enable Australian patients to access treatment.

Other jurisdictions are under consideration.

Clinical Programs: therapeutic potential of melanocortins

CLINUVEL's clinical program is focused on evaluating the safety and efficacy of melanocortins as therapies for patients with unmet medical needs.



Repigmentation in vitiligo

Proof of concept studies have shown that afamelanotide can repigment skin in vitiligo as a combination therapy with narrowband ultraviolet B (NB-UVB) phototherapy. A monotherapy Phase II study, CUV104 has been completed, and read-outs are to be announced in 2024. The Phase III CUV105 study, involving up to 200 participants, commenced a 12-month recruitment period in October 2023. The combination study is enrolling darker skinned patients (Fitzpatrick scale IV-VI) on whom the disease can have the greatest impact. A further combination Phase III study, CUV107, is planned to commence during 2024. This is to provide important data in a comprehensive dossier for submission to regulatory authorities.

DNA Repair Program – xeroderma pigmentosum (XP)

Melanocortins, including afamelanotide, have been shown to prevent and repair UV-induced DNA damage. CLINUVEL's DNA Repair program focuses on evaluating the drug in XP patients who have a marked loss of DNA repair function, resulting in an extreme risk of skin cancer. Results of the mechanistic study CUV151, evaluating the DNA repair capacity of afamelanotide on the skin of healthy volunteers exposed to UV radiation were reported in February and August 2023. Damage to the skin – characterised by the UV–erythema dose response – was shown to reduce and melanin density (skin repigmentation) significantly increased. DNA photodamage was also significantly reduced at several points compared to baseline.

Phase II studies in XP patients (CUV152 and CUV156) are ongoing, with further studies to commence in 2024. Promising preliminary results of CUV156 were presented to the 2023 American Academy of Dermatology (AAD) Meeting, and subsequently at the World Congress of Dermatology. Afamelanotide was well tolerated

and key markers of DNA photodamage, including cyclobutene pyrimidine dimers (CPDs), were shown to reduce following treatment.

Photoprotection for variegate porphyria (VP) patients

VP patients experience phototoxic reactions and skin fragility following sun exposure. Results from the first study of SCENESSE® in CP (CUV040) are to be announced in the first half of calendar year 2024.

Neuroprotection: treating arterial ischaemic stroke (AIS)

Melanocortins, including afamelanotide are known to offer neuroprotection, providing potent antioxidative effects. Afamelanotide is suggested to increase blood flow and nutrients to the affected areas, as it is active on blood vessels and reduces fluid formation. It thereby protects tissue and restores the blood brain barrier, mechanisms under evaluation in ischaemic stroke patients. The second Phase II study in AIS patients, CUV803 is ongoing with the liquid formulation of afamelanotide, PRÉNUMBRA® Instant being administered to patients with mild to severe strokes.

Other Indications

Following the resolution of intellectual property issues linked to melanocortins during 2023, we plan to announce new indications for clinical studies as part of our mission to translate our expertise into commercial products for the treatment of medical conditions where no alternatives currently exist.

Product Development

Pharmaceuticals

PRÉNUMBRA®

CLINUVEL is developing novel formulations of afamelanotide as PRÉNUMBRA®, reflecting the anticipated need for dosing flexibility in identified patient groups. The first - PRÉNUMBRA® Instant – is under evaluation in stroke, with modified-release formulations in development.

NEURACTHEL®

Development work to manufacture the adrenocorticotropic (ACTH) drug substance and the product, NEURACTHEL® Instant continues with increased scale of batch production.

PhotoCosmetics

CYACÊLLE – Polychromatic Photoprotective Screen

After a pilot launch in March 2023, global launch events are, as previously communicated, planned for 2024.

DNA Repair Assist and Melanogenesis

PhotoCosmetic product lines to assist the repair of photodamaged skin and promote melanogenesis continue to be developed by the Group's Singapore based Research, Development & Innovation Centre.

Integration

After seven and a half years of direct commercial distribution of SCENESSE®, the value of this direct approach by delivering higher margins and profit to the business is proven.

Communications, Branding & Marketing Division

This division is largely in place with a wide range of professionals engaged in key initiatives aiming to make the Company a household name in photoprotection in conjunction with the planned launch of the PhotoCosmetic product ranges.

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Manufacturing Division

The Company is establishing its manufacturing capabilities and continues to execute its strategy to integrate virtual and physical manufacturing operations.

Other Activities

Investor Relations activities in the reporting period included Investor Briefings in Monaco, Melbourne and Sydney, presentations to conferences – the J.P. Morgan Bio Tech Round Table and the Bell Potter Healthcare Conference, and Non-Deal Roadshows in Melbourne, Sydney, Hong Kong, with a focus on institutions.

The Company held the 2023 Annual General Meeting (AGM) of shareholders on 31 October. The in-person AGM was streamed live and featured a panel discussion with CLINUVEL Directors, hosted by independent analysts Dr Melissa Benson and Dr Shane Storey of financial services firm, Wilsons Advisory. The Managing Director's presentation to the AGM also provided Strategic Update VII.

All resolutions of the AGM were passed with the resolution to accept the 2023 Remuneration Report receiving less than 75% in favor.

All the Company's announcements during this period are available on CLINUVEL's website with other updates available on 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 2023.

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 2023.

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 22nd day of February 2024

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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 2023, 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, 22 February 2024

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Statement of Profit or Loss and other comprehensive income for the half year ended 31 December 2023

	CONSOLIDATED	
	31 December 2023	31 December 2022
	$	$
Revenues		
Commercial sales of goods	29,861,453	27,193,717
Sales reimbursements	2,395,432	2,161,325
Total revenues	**32,256,885**	**29,355,042**
Interest income	3,663,718	1,337,297
Total interest income	**3,663,718**	**1,337,297**
Other income (loss)		
Unrealised gain (loss) on restating foreign currency balances and currencies held	(713,946)	195,440
Government grants and other income	544,987	11,367
Realised net currency gain (loss) on transactions	(21,747)	77,032
Total other income (loss)	**(190,706)**	**283,839**
Total revenue, interest and other income	**35,729,897**	**30,976,178**
Expenses		
Personnel-related	8,046,164	6,097,368
Share-based payments	5,643,074	3,827,168
Materials and related expenses	4,111,930	4,587,757
Finance, corporate and general	2,019,906	1,268,072
Commercial distribution	1,371,292	1,307,064
Legal, insurances and IP	783,052	543,014
Clinical and non-clinical development	752,499	590,253
Communication, branding and marketing	660,940	410,119
Depreciation and amortisation	575,430	376,086
Changes in inventories of raw materials, work in progress and finished goods	(3,040,089)	(2,630,674)
Total expenses	**20,924,198**	**16,376,227**
Profit before related income tax expenses	**14,805,699**	**14,599,951**
Income tax expense	3,869,656	3,212,276
Operating profit after income tax	10,936,043	11,387,675
Net profit for the half year	**10,936,043**	**11,387,675**
Other comprehensive income		
Items that may be reclassified subsequently to profit or loss		
Exchange differences of foreign exchange translation of foreign operations	(90,011)	373,640
Other comprehensive income for the period, net of income tax	(90,011)	373,640
Total comprehensive income for the period	**10,846,032**	**11,761,315**
Basic earnings per share - cents per share	22.1	23.0
Diluted earnings per share - cents per share	21.2	22.0

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

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Statement of Financial Position as at 31 December 2023

	CONSOLIDATED	
	31 December 2023	30 June 2023 Restated
	$	$
Current assets		
Cash and cash equivalents	38,817,216	31,893,021
Cash held in term deposits	135,631,977	124,920,516
Trade and other receivables	13,075,215	22,214,646
Inventories	12,559,551	9,519,462
Prepayments	1,415,194	1,070,153
Total current assets	**201,499,153**	**189,617,798**
Non-current assets		
Property, plant and equipment	6,976,910	2,017,861
Right-of-use assets	911,708	833,326
Intangible assets	185,030	185,030
Deferred tax assets	1,976,278	1,059,541
Other assets	132,267	-
Total non-current assets	**10,182,193**	**4,095,758**
Total assets	**211,681,346**	**193,713,556**
Current liabilities		
Trade and other payables	6,482,107	7,649,572
Income tax payable	20,849,463	16,094,178
Provisions	1,698,928	1,450,120
Lease liabilities	355,808	300,843
Total current liabilities	**29,386,306**	**25,494,713**
Non-current liabilities		
Deferred tax liabilities	2,784,396	2,757,516
Lease liabilities	713,058	699,022
Provisions	147,564	131,162
Total non-current liabilities	**3,645,018**	**3,587,700**
Total liabilities	**33,031,324**	**29,082,413**
Net assets	**178,650,022**	**164,631,143**
Equity		
Contributed equity	169,556,603	151,849,375
Reserves	3,830,109	22,556,044
Accumulated earnings (losses)	5,263,310	(9,774,276)
Total equity	**178,650,022**	**164,631,143**

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

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Statement of Changes in Equity for the half year ended 31 December 2023

	Share Capital $	Performance Rights Reserve $	Foreign Currency Translation Reserve $	Retained Earnings $	Total Equity $
Balance at 1 July 2022	**151,849,375**	**10,380,258**	**1,731,838**	**(38,402,428)**	**125,559,043**
Employee share-based payment options	-	3,827,168	-	-	**3,827,168**
Dividends paid	-	-	-	(1,976,414)	**(1,976,414)**
Transactions with owners	**151,849,375**	**14,207,426**	**1,731,838**	**(40,378,842)**	**127,409,797**
Profit for the year	-	-	-	11,387,675	**11,387,675**
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	373,640	-	**373,640**
Total other comprehensive income	-	-	**373,640**	-	**373,640**
Balance at 31 December 2022	**151,849,375**	**14,207,426**	**2,105,478**	**(28,991,167)**	**139,171,112**
Balance at 1 July 2023	**151,849,375**	**19,370,046**	**3,185,998**	**(9,774,276)**	**164,631,143**
Issue of share capital on exercise of share-based payment	17,707,228	(17,707,228)	-	-	**-**
Employee share-based payment options	-	(928,696)	-	6,571,770	**5,643,074**
Dividends paid	-	-	-	(2,470,227)	**(2,470,227)**
Transactions with owners	**169,556,603**	**734,122**	**3,185,998**	**(5,672,733)**	**167,803,990**
Profit for the year				10,936,043	**10,936,043**
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	(90,011)	-	**(90,011)**
Total other comprehensive income	-	-	**(90,011)**	-	**(90,011)**
Balance at 31 December 2023	**169,556,603**	**734,122**	**3,095,987**	**5,263,310**	**178,650,022**

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 2023

	CONSOLIDATED	
	31 December 2023	31 December 2022 Restated
	$	$
Cash flows from operating activities		
Receipts from customers	43,579,579	36,134,507
Payments to suppliers and employees	(20,128,194)	(15,462,848)
Interest received	2,317,570	340,110
Government grants and other income received	541,777	-
GST and VAT refunds	93,406	11,279
Income tax paid	(24,295)	-
Net cash provided by operating activities	**26,379,843**	**21,023,048**
Cash flows from investing activities		
Payments for property, plant and equipment	(5,301,549)	(395,085)
Investments in cash held in term deposits	(10,711,461)	(21,889,016)
Net cash used in investing activities	**(16,013,010)**	**(22,284,101)**
Cash flows from financing activities		
Dividends paid	(2,470,227)	(1,976,414)
Repayment of lease liabilities	(164,263)	(169,657)
Net cash used in financing activities	**(2,634,490)**	**(2,146,071)**
Net increase (decrease) in cash held	**7,732,343**	**(3,407,124)**
Cash and cash equivalents at beginning of the year	**31,893,021**	**27,409,282**
Effects of exchange rate changes on foreign currency held	(808,148)	712,202
Cash and cash equivalents at end of the half year	**38,817,216**	**24,714,360**

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

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Notes to the condensed financial statements

For the half year ended 31 December 2023

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 2023 annual financial report for the financial year ended 30 June 2023 excepting the policy regarding the classification of cash held in term deposits with maturity dates beyond 90 days from their acquisition date, as outlined below.

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 fully franked dividend for 2023 of 5.0 cents per share was paid on 20 September 2023 and a final fully unfranked dividend for 2022 of 4.0 cents per share was paid on 21 September 2022.

Reclassification of comparative amounts

The Group has restated its consolidated Statement of Financial Position for the year ended 30 June 2023 to reclassify cash term deposits with maturity dates beyond 90 days from their acquisition date, from cash and cash equivalents to cash held in term deposits. This is after a review of its accounting policy and how it is applied to term deposits considered readily convertible to a known amount of cash and subject to an insignificant risk of changes in value.

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

Statement of Financial Position (extract)	30 June 2023	Increase/(Decrease)	30 June 2023 (Restated)
Cash and cash equivalents	156,813,537	(124,920,516)	**31,893,021**
Cash held in term deposits	**-**	124,920,516	**124,920,516**
Total Assets	**193,713,556**	**-**	**193,713,556**

The comparative amount for the consolidated Statement of Cash Flows for the half year ended 31 December 2022 has been restated to present the movement of cash into cash in term deposits as a net cash flow from investing activity. The treatment has been changed by reclassifying each of the affected financial statement line items for the prior period as follows:

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Statement of Cash Flows (extract)	31 December 2022	Increase/(Decrease)	31 December 2022 (Restated)
Investments in cash held in term deposits	**-**	(21,889,016)	(21,889,016)
Net cash used in investing activities	(395,085)	(21,889,016)	**(22,284,101)**
Net increase (decrease) in cash held	18,481,892	(21,889,016)	**(3,407,124)**
Cash and cash equivalents at beginning of the year	121,509,282	(94,100,000)	**27,409,282**
Effects of exchange rate changes on foreign currency held	712,202	-	**712,202**
Cash and cash equivalents at end of the year	**140,703,376**	**(115,989,016)**	**24,714,360**

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 Group, 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 $0.221 on a weighted average number of 49,546,711 issued ordinary shares as at 31 December 2023. This compares with restated basic earnings per share of $0.230 as at 31 December 2022 on a weighted average number of 49,410,338 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 Group subsequent to balance date.

Revenue

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

	Six months to 31 December 2023			Six months to 31 December 2022		
	Commercial Sales of Goods	Sales Reimbursements	Total	Commercial Sales of Goods	Sales Reimbursements	Total
	$'000	$'000	$'000	$'000	$'000	$'000
Europe & USA	29,862	-	29,862	27,194	-	27,194
Switzerland, Others	-	2,395	2,395	-	2,161	2,161
Total	29,862	2,395	32,257	27,194	2,161	29,355

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 Group 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 Group has one operating segment within the definition of AASB 8 Operating Segments.

Share-based payments

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 total valuation. For those performance rights issued under the current Performance Rights Plan, the performance rights expire the earlier of seven years from date of grant of rights or at a pre-defined date. 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 those performance rights issued on or after 24 December 2020 and whose valuations affected the reporting period, an illiquidity discount was applied to the pricing model. The fair value per right at grant date varies between $8.97 and $26.22 for those performance rights affecting the reporting period.

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Directors' Declaration

In the opinion of the Directors:

1. The financial statements and notes, of the company and of the Group, 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 2023 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 22nd day of February 2024

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Independent Auditor's Review Report

To the Members of Clinuvel Pharmaceuticals Limited

Report on 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 condensed statement of financial position as at 31 December 2023, and the consolidated condensed statement of profit or loss and other comprehensive income, consolidated condensed statement of changes in equity and consolidated condensed 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's does not comply with the *Corporations Act 2001* including:

a giving a true and fair view of the Clinuvel Pharmaceuticals Limited's financial position as at 31 December 2023 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.

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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 2023 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, 22 February 2024