

CLINUVEL

APPENDIX 4D

ASX Listing Rule 4.2A.3 Half yearly report. Half year ended 31 December 2024

CLINUVEL PHARMACEUTICALS LIMITED

ABN 88 089 644 119

Previous corresponding period: Half year ended 31 December 2023

Results for announcement to the market

					(\$'000)
Revenues from ordinary activities	Increased	10.5%	to		35,646
Profit from operating activities before tax attributable to members	Increased	48.1%	to		21,932
Profit from ordinary activities after tax attributable to members	Increased	28.7%	to		14,075
Net Profit for the period attributable to members	Increased	28.7%	to		14,075

Dividends (distribution)

	Amount per security	Franked amount per security
Final dividend (full the year ended 30 June 2024) *	5.0 ¢	Fully franked
Interim dividend	*Nil ¢	*Nil ¢
<small>*CLINUVEL PHARMACEUTICALS LIMITED paid the dividend on 20 September 2024</small>		
Previous corresponding period (31 December 2023)	5.0 ¢	Fully franked
Record date for determining entitlements to the dividend	N/A	N/A
<small>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</small>		

Net tangible asset backing

	Current period	Previous corresponding period
Net tangible asset backing per ordinary security	\$4.35	\$3.54

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 (\$).

CLINUVEL PHARMACEUTICALS LIMITED

ABN 88 089 644 119 and Controlled Entities Half Year Financial Report Ended 31 December 2024

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 31 December 2024, 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:

Prof. J. V. Rosenfeld	Dr. P. J. Wolgen	Dr. K. E. Agersborg	Mrs. S. E. Smith
Dr P. E. Grimes (appointed 6 Sept 2024)	Mr M. Pringle (appointed 6 Sept 2024)	Mr G. van Dievoet (appointed 6 Sept 2024)	Mrs B. Shanahan (resigned 16 Oct 2024)

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 pleased to provide commentary on the headline results for the CLINUVEL Group for the half year to 31 December 2024.

HEADLINE RESULTS

Comparisons are made to the six months ended 31 December 2023, being the prior corresponding period (pcp):

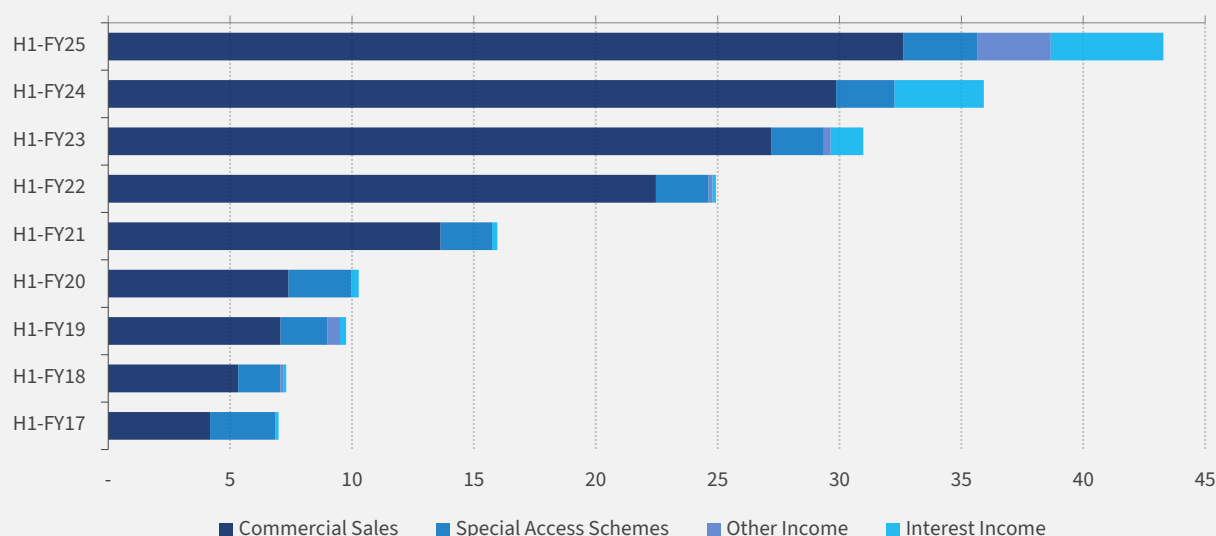
- Consistent double-digit growth in total revenues: 10.5%, and interest income: 26.1%;
- Expansion of clinical and non-clinical development activities: 277.4% increase, total expenses up: 2%;
- Profit before tax result of \$21.93 million: 48.1% increase;
- Profit after tax result of \$14.08 million: 28.7% increase;
- Cash and cash equivalents and Cash held in term deposits continued to increase: up 7.8% to \$198.2 million;
- Earnings per share: 27.1% increase.

1. REVENUES, OTHER INCOME AND INTEREST INCOME: increase of 21.1% (pcp) to \$43.29m

The Group reported another strong result for total revenues in the half year to December 2024, encompassing:

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

REVENUES AND INCOME, DECEMBER HALF YEARS (\$m)



Growth was achieved in all revenue and income categories during the six-month period. We experienced a combined increase in commercial sales and reimbursements from the distribution of SCENESSE® of 10.5% compared to the same period in 2023. This reflects continued demand for treatment from 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 gains from foreign exchange gains boosted other income. As a result, total revenues increased by 21.1% to \$43.29 million in the reporting half year.

Consistent demand for SCENESSE® in Europe and the US

The demand for SCENESSE® continues to grow in Europe and the US. Our dedicated clinical and liaison managers in both jurisdictions work concertedly to connect with patients, doctors, and insurers, to ensure patient access and to gain feedback on treatment. In addition, the trend of average usage per patient is positive. Increasing treatment access is particularly important in the US, where growth is being facilitated through a network of Specialty Centres across the country. The number of trained and accredited centres in the North America reached 93 at the end of December 2024 as we aim to reach our announced target of 120 centres by the end of 2025.

We also saw growth in the treatment of patients under Special Access Schemes in Switzerland where treatment has been provided since 2012, and Canada, where the Company now has four treatment centres.

Higher interest rates boost interest income

Using various term deposits, positive net cash flows have increased in recent years. During the reporting period we earned interest income of \$4.62 million (pcp: \$3.66 million) following a deliberate effort to take advantage of a higher interest rate environment. The overall maturity term of the portfolio has been stretched and currently has a weighted average rate above 5% on terms up to 300 days.

Increased other income

The increase in other income during the reporting period was driven by unrealised gains on the restatement of foreign currency account balances pushing other income up to \$3.02 million (pcp: \$0.19 million).

2. EXPENSES: increase by 2% (pcp) to \$21.35m

Total expenses rose 2% compared to the prior six months to 31 December 2023. The marginal overall increase was a result in a shifting of expenditure in some of the main expenditure categories compared to the pcp.

We have outlined previously that personnel, both in number and skill, are a critical element to advance our objectives as we seek to further our programs for future revenue. Our staffing head count increased by 11.5% year on year.

Operational costs have increased to service the activities associated with direct commercial distribution of SCENESSE® and to expand clinical and non-clinical programs, as we had previously foreshadowed.

The increases we experienced were offset by reductions in other expense categories, including materials and related expenses, and non-cash expenses such as share based payments.

In 2021, the Group advised that it was projecting an overall expenditure level – exclusive of investments of a capital nature and communications, branding and marketing expenses – of \$175 million for the five financial years ending June 2025. As at 31 December 2024, with six months remaining on this projection, we have expended \$146 million of the total projected. We are on track to achieve the projection, having completed 90% of the timeline and 83% of the expenditure target.

Personnel-related expenses

↑34%

\$10,781 *	JULY-DEC 2024
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\$ 8,046 *	JULY-DEC 2023
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*\$ amount in thousands.

As a growing R&D company, it is important to continue to maintain a highly experienced workforce to competently manage both the activities for today and the programs that are building future revenues. Without a focused, well-resourced, and suitability qualified workforce collectively striving for the same key organisational goals, the Group would be putting outcomes at risk.

The main focus of our recruitment efforts continues to add to our clinical, regulatory, medical affairs, as well as communications, branding and marketing personnel. As a majority of our workforce are located in international regions, the recent weakening of the Australian dollar would generally push our personnel expenses higher. Fortunately, our revenues are generated outside of Australia, and we maintain a natural hedge against foreign currency expenditures.

Share-based payments

↓82.1%

\$1,009	JULY-DEC 2024
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\$5,643	JULY-DEC 2023
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The non-cash accounting expense for share-based payments expense decreased by 82.1% in the six-month period to 31 December 2024 in comparison to the pcp. The main reason for the reduction is found in the expiration of the Group's main Performance Rights plan in November 2023 and the non-cash accounting expenditures associated with these Performance Rights also ceased to be expended.

The Group still has a Performance Rights plan in place, but it only covers a small portion of the current workforce. The Group is working to implement a new, outcome targeted, Performance Rights plan for all staff, excluding the CEO and Board, in 2025 which will be designed to attract, retain and reward employees for the achievement of organisational and department strategic goals set by the organisation. Such a structured Performance Rights plan will seek to align the interests of the employees with the interests of shareholders.

As at 31 December 2024, the Group has 242,225 performance rights on issue held by 28 employees which only represents 0.48% of the current total issued share capital.

Materials and related expenses

↓96.8%

\$130	JULY-DEC 2024
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\$4,112	JULY-DEC 2023
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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 clinical and non-clinical development programs. The 96.8% decline to the pcp reflects an overall improved efficiency within the materials consumed to manufacture our commercial products together with the purchase of materials for use in the formulations of drug substances for programs such as NEURACTHEL® (ACTH) which are still under development.

Commercial distribution

↑24.7%

\$1,710	JULY-DEC 2024
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\$1,371	JULY-DEC 2023
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Ensuring the ongoing registration, safety and compliance of our commercial product with industry regulatory agencies and compliance with Good Distribution Practices, is of the upmost importance to the Group. This is not only to ensure ongoing revenues for the Group, but also to provide trust and confidence in our product for patients and treating physicians.

We experienced a 24.7% increase in commercial distribution costs this period compared to the pcp. Distribution costs rose in direct proportion to the increase in sales volumes and were also impacted by a significant increase in the annual regulatory fees we pay to the European Medicines Agency and US Food and Drug Administration.

Legal, insurance and IP

↓37.9%

\$486	JULY-DEC 2024
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\$783	JULY-DEC 2023
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The 37.9% reduction of expenditures in the legal, insurance and IP category is primarily a reflection of the higher than average expenditures the Group experienced during the prior corresponding six-month period as the Group actioned a program to protect its assets through IP maintenance, insurance and market penetration initiatives. The completion of those activities led to the reduction of expenses in this category.

Clinical and non-clinical development

↑277.4%

\$2,840	JULY-DEC 2024
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\$752	JULY-DEC 2023
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Clinical and non-clinical development expenses, as expected, have increased in the past six-month period in comparison to the pcp, as our clinical programs aiming to establish future revenue streams ramp up. The majority of the increase in expenditures pertains to the patient recruitment progressing in our CUV105 vitiligo study.

Concurrently, our preclinical and formulation work with PRÉNUMBRA® and NEURACTHEL® is advancing to bring multiple revenue opportunities to the Group.

Communications, branding and marketing

↓10.1%

\$594	JULY–DEC 2024
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\$661	JULY–DEC 2023
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There was a minor reduction in the communications, marketing and branding expenditures during the past six-months in comparison to the pcp. The Communications, Branding & Marketing division was 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.

Many of the expenditure activities and programs for this category will be commencing or taking place in the second half of the 2025 financial year.

The largest and most notable activity the organisational will undertake in the near-term period will be a major presence at the 2025 American Academy of Dermatology Annual Meeting to be held 7-11 March in Orlando, Florida (USA).

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

↑140.1%

\$1,219	JULY–DEC 2024
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(\$3,040)	JULY–DEC 2023
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The increased cost in this area directly reflects our change in inventory levels of raw materials, work in progress and finished goods expended during the period to support either commercial, clinical or non-clinical programs compared to the pcp.

Whilst the stocks of our inventories reduced by \$1.2 million during the period, we continue to maintain sufficient inventories to ensure we meet future demands for our commercial and development products.

3. NET PROFITS BEFORE TAX up 48.1%, AFTER TAX up 28.7% (pcp)

The Group once again returned a strong profitability performance with a 48.1% increase in net profits before tax resulting in a 50.7% return on revenue. Net profit after tax (NPAT) increased by 28.7% for the six-month period compared to the pcp, representing a 32.5% return on revenue.

4. EPS: up 27.4% (pcp)

With a 28.7% increase in NPAT, earnings per share measure similarly trended upward, moving from 22.1 cents per share to 28.1 cents per share. The weighted average number of issued ordinary shares increased from 49,546,711 shares in the pcp to 50,067,595 shares in the current period.

5. NET ASSETS: an increase of 7% (from 30 June 2024)

The financial balance sheet strength of the Group continues to grow as reflected in the 7% increase to net assets over the six months, from \$203.0 million to \$217.3 million. We are now into our 20th consecutive year where the Group has remained debt-free.

Maintaining a strong financial position is a strategic priority for CLINUVEL, enabling us to explore financial opportunities which other peers in the industry simply cannot consider. This strength not only provides CLINUVEL with a level of protection against unforeseen events and economic uncertainty, but also offers the opportunity to pursue, and potentially execute, strategic acquisitions and investments which align with the Group's objectives.

Over the past eight years since the first commercial product launch, the Group has accumulated cash reserves totalling \$198.2 million without reliance on long-term debt or requiring equity funding.

Cash held in term deposits

The Group has taken the opportunity to invest its surplus cash reserves in a series of term deposits which, if needed, can be readily convertible into cash. We strategically chose to take advantage of the favourable term deposit rates through the latter part of 2024 whereby our term deposit portfolio currently yields a weighted average return of 5.04% with an average term around 300 days. In the past six-months our term deposits collectively returned \$4.62 million to support our operational expenditures of our future extensive commercial, clinical, and pharmaceutical programs.

Conclusion

Off the back of a further double-digit growth in revenues during the period, the financial strength of the Group continues to improve to where our current ratio of 18x is the envy of our peers in the life sciences industry and across the securities exchange. Our cash reserves provide the platform for us to expand and expedite our many clinical and preclinical program pathways, not the least of which is bringing our life changing treatment for vitiligo patients to market. All these programs underpin the future foundations of revenue for CLINUVEL as we continue to build our melanocortin house to meet the unmet needs of patients and targeted consumer audiences.

We have the programs, people, and resources to be able to seize the opportunities that lie in front of us.

All of our strategic goals and decisions are made through a clear lens of serving unmet needs whilst ensuring that we are maintaining our sound fiduciary responsibilities maximising shareholder value.

We look forward to delivering a strong full year result for FY2025.



Peter Vaughan
Chief Financial Officer

Review of Operations

Strategy

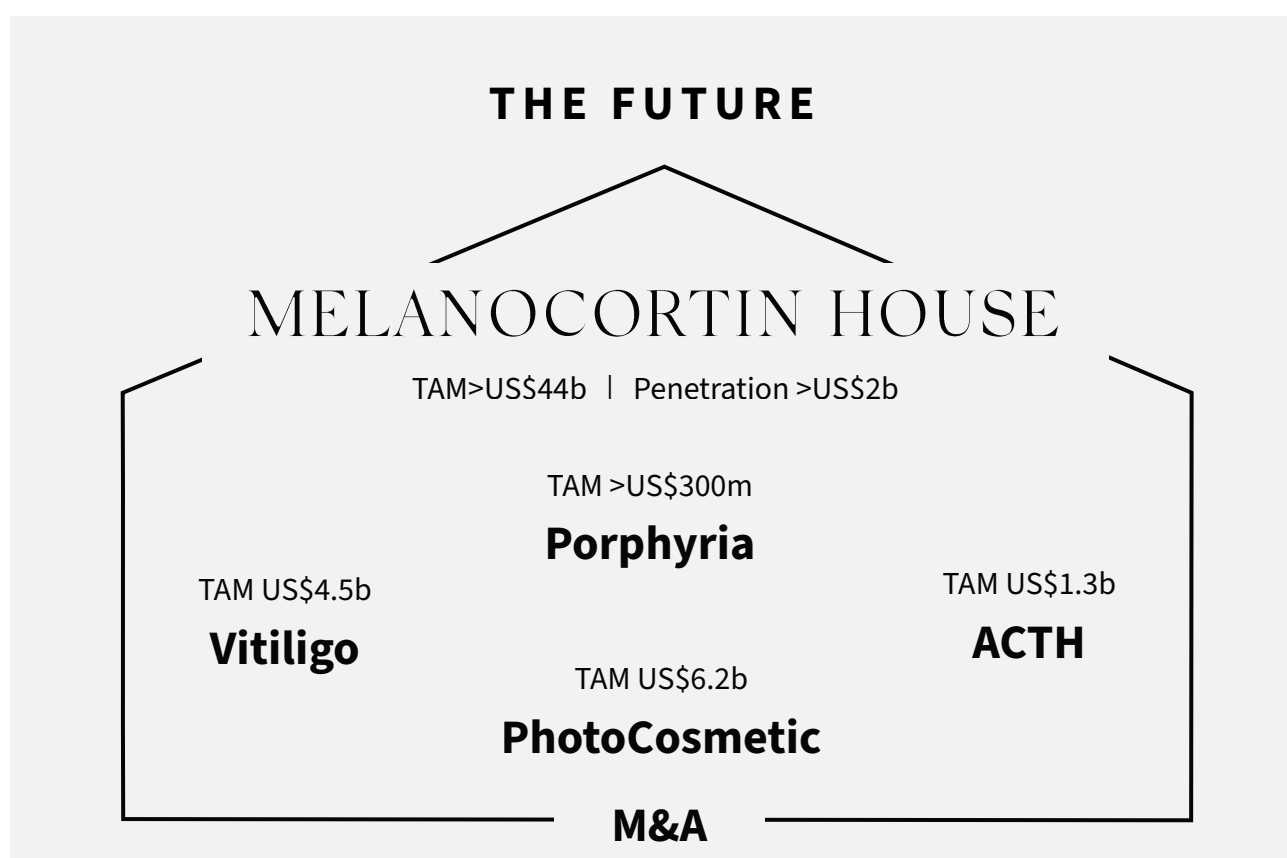
CLINUVEL's strategy from 2006 to 2020 was to develop and commercialise the novel prescription pharmaceutical SCENESSE® for the treatment of patients with the rare metabolic disorder erythropoietic protoporphyria (EPP). The success of this strategy is reflected in successive years of profitability and net cash inflow – now spanning 8 ½ years with this December half year result.

In November 2024, the Company announced the prioritisation of three strategic programs to develop melanocortin products, selected based on the highest probability and fastest routes to clinical, regulatory and commercial success:

- **Vitiligo**, evaluating SCENESSE® as a systemic treatment with a late-stage clinical trial program to support a comprehensive submission to regulatory authorities;
- **Adrenocorticotrophic hormone (ACTH)**, though the development of NEURACTHEL® for disorders of the central nervous system; and
- **Porphyrias**, encompassing expansion of treatment of patients with EPP and evaluating SCENESSE® as a treatment for patients with variegate porphyria (VP).

In parallel, CLINUVEL is developing innovative PhotoCosmetic products, preparing launches of three product lines to protect, preserve and bronze the skin.

CLINUVEL is building a house of melanocortins, an integrated and diversified pharmaceutical group delivering long-term performance, addressing unmet patient and skin health needs.



CLINUVEL's strategy also extends to the active assessment of asset acquisitions that enhance the earnings potential and objectives of the Group.

Key Activities

The table below summarises key activities of the Group for the six months to 31 December 2024:

Objective	Progress in six months to 31 December 2024
Building long-term value	<ul style="list-style-type: none"> • Strong financial performance achieved with revenues up 10.5%, expenses up 2% to support the expansion strategy, NPBT up 48.1%, compared to same period 2023, and cash reserves up 7.8% since 30 June 2024 to \$198.2 million • Seventh consecutive dividend declared and paid following FY2024 results • Prioritisation of strategic programs: vitiligo, ACTH & porphyrias • Board renewal: three new Non-Executive Directors appointed • Restructured clinical team
Growing commercial distribution of SCENESSE® for EPP	<ul style="list-style-type: none"> • Treated more patients and distributed more SCENESSE® implants than any 1HFY to date • 93 North American Specialty Centers established (89 USA, 4 Canada) • Filing and validation of New Drug Submission to Health Canada for adult EPP patients, outcome expected in Q4 CY2025. Canadian patients continue to receive treatment under a Special Access Program. • Submitted variation to European label to harmonise with the USA, allowing year-round EPP patient treatment, outcome expected Q1 CY2025
Developing melanocortins	<p>Vitiligo – SCENESSE®</p> <ul style="list-style-type: none"> • CUV105 study inclusion criteria relaxed to encourage recruitment • Extension treatment offered to patients assigned NB-UVB monotherapy • Target recruitment completed by 30 June 2025 <p>Variagate porphyria – SCENESSE®</p> <ul style="list-style-type: none"> • Positive Phase II results in CUV040 <p>DNA repair – SCENESSE®</p> <ul style="list-style-type: none"> • Positive final Phase II results from CUV151 presented to British Association of Dermatologists Meeting in Manchester: afamelanotide shown to assist DNA repair after UV damage (UV-irradiated skin) <p>PhotoCosmetics</p> <ul style="list-style-type: none"> • Advancing three lines of cosmetic products, with first “M line” containing melanocortins due to release in 2026
Increasing visibility	<ul style="list-style-type: none"> • Sponsored 2024 International Congress of Porphyrins & Porphyrins (ICPP) • Presentation of CUV040 results to ICPP • Extensive preparatory work for the upcoming American Academy of Dermatology Annual Meeting in Orlando in March 2025
Global IR engagement	<ul style="list-style-type: none"> • Initiation of research coverage by Dr Kalliwoda Research & Parmantier & Co (nine analysts now cover CLINUVEL) • Conference presentations: Bioshares Biotech conference, Biotech Showcase Melbourne and Bell Potter Healthcare Conference • Non-Deal Roadshows, Melbourne-Sydney and Switzerland-Germany • Increased stakeholder engagement USA • 2024 Annual General Meeting

Capital Management during the Reporting Period

CLINUVEL's performance over the past eight and a half years has driven the accumulation of cash reserves to \$198.2 million as at 31 December 2024. These cash reserves are earmarked for:

- operational expenses;
- product development and clinical programs;
- the acquisition of assets that add to the revenue generating activities of the Group; and
- maintaining a buffer to manage adverse developments and events in the external operating environment.

CLINUVEL's Board and management constantly evaluate the Company's capital management. Where appropriate, measures to redistribute capital to shareholders (including dividends and share buy-backs (SBBs)) are considered. Cash was used in the December half year to finance the business and its expansion, as well as dividends and SBBs.

Post Reporting Date Developments

Key announcements have been made after the 31 December 2024 reporting date.

In January:

- Commencement of a distribution agreement for SCENESSE® for EPP in Argentina.

In February:

- Four case reports from the CUV105 study.
 - Presentation of systemic repigmentation of four patients with Fitzpatrick skin type IV after seven SCENESSE® implants and up to 53 NB-UVB sessions.
 - SCENESSE® well tolerated with positive reports from patients and doctors.
- Preliminary results of CUV052 study in adolescent EPP patients.
 - SCENESSE® was well tolerated by all 28 patients enrolled in the study – 14 adults and 14 adolescents (aged 12 to 17 years).
 - No statistical difference was found between the effect of SCENESSE® on adult and adolescent EPP patients of minimum weight of 50kg.

CUV105 Phase III study – first clinical observations

CASE REPORT 1

- Female, 55 years old, Skin Type IV
- Diagnosed with vitiligo in 2006, slowly progressive disease activity, no previous episodes of repigmentation, and no family history of vitiligo. Unresponsive to previous vitiligo treatments.

Physician's report

80-90% repigmentation seen after Day 140 but near total repigmentation achieved after continued NB-UVB monotherapy.



DAY 0
Baseline



DAY 134
7 afamelanotide implants
39 NB-UVB treatments



DAY 222
82 days after completing study
53 NB-UVB treatments

CASE REPORT 2

- Male, 52 years old, Skin Type IV
- Diagnosed with vitiligo in 2023, progressive disease activity, no previous episodes of repigmentation, and no family history of vitiligo. No history of previous vitiligo treatments.

Physician's report

The patient and our team are pleased with the results. Patient reports greater self esteem post-treatment.



DAY 0
Baseline



DAY 140
7 afamelanotide implants
40 NB-UVB treatments



DAY 170
30 days after
completing study
no further therapy

CUV105 Phase III study – first clinical observations

CASE REPORT 3

- Male, 56 years old, Skin Type IV
- Diagnosed with vitiligo in 1999

Physician's report

First repigmentation seen around day 42, considerable repigmentation seen by day 106. Patient continued to repigment after conclusion of treatment protocol with no further therapy.



CASE REPORT 4

- Male, 56 years old, Skin Type IV
- Diagnosed with vitiligo in 1986

Physician's report

Due to extensive depigmentation, patient is yet to fully repigment. Patient continued to receive NB-UVB treatment following the study and continued to repigment (not shown).



2025 Events

The following key events are expected for the remainder of 2025:

Objective	Event
Growing commercial distribution of SCENESSE® for EPP	<ul style="list-style-type: none"> • Engagement EMA on CUV052 and adolescent EPP patient use of SCENESSE® • EMA decision on SCENESSE® dosage harmonisation for EPP patients • Expand to 120 North American Specialty Centers • Health Canada decision on marketing authorisation, SCENESSE® for EPP
Developing melanocortins	<ul style="list-style-type: none"> • Vitiligo <ul style="list-style-type: none"> – Complete recruitment CUV105 study – Commence study CUV107 • Variegate porphyria <ul style="list-style-type: none"> – Regulatory feedback and commence CUV053 • Stroke <ul style="list-style-type: none"> – CUV803 results • NEURACTHEL® manufacturing update
Increasing visibility	<ul style="list-style-type: none"> • American Academy of Dermatology Annual Meeting • CYACËLLE next generation product launch
Global IR engagement	<ul style="list-style-type: none"> • FY2025 results and non-deal roadshows • Annual General Meeting

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 27th day of February 2025



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Auditor's Independence Declaration

To the Directors of Clinovel Pharmaceuticals Limited

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Clinovel Pharmaceuticals Limited for the half-year ended 31 December 2024. 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, 27 February 2025

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Statement of Profit or Loss and other comprehensive income for the half year ended 31 December 2024

	CONSOLIDATED	
	31 December 2024	31 December 2023
	\$	\$
Revenues		
Commercial sales of goods	32,612,568	29,861,453
Sales reimbursements	3,033,315	2,395,432
Total revenues	35,645,883	32,256,885
Interest income	4,618,935	3,663,718
Total interest income	4,618,935	3,663,718
Other income (loss)		
Unrealised gain (loss) on restating foreign currency balances and currencies held	3,026,602	(713,946)
Realised net currency loss on transactions	(8,377)	(21,747)
Government grants and other income	2,282	544,987
Total other income (loss)	3,020,507	(190,706)
Total revenue, interest and other income	43,285,325	35,729,897
Expenses		
Personnel-related	10,780,883	8,046,164
Clinical and non-clinical development	2,839,763	752,499
Finance, corporate and general	1,976,474	2,019,906
Commercial distribution	1,709,626	1,371,292
Changes in inventories of raw materials, work in progress and finished goods	1,219,464	(3,040,089)
Share-based payments	1,008,953	5,643,074
Depreciation and amortisation	607,839	575,430
Communication, branding and marketing	593,912	660,940
Legal, insurances and IP	486,003	783,052
Materials and related expenses	130,094	4,111,930
Total expenses	21,353,011	20,924,198
Profit before income tax	21,932,314	14,805,699
Income tax	7,856,979	3,869,656
Net profit for the year	14,075,335	10,936,043
Other comprehensive income		
Items that may be re-classified subsequently to profit or loss		
Exchange differences of foreign exchange translation of foreign operations	1,961,503	(90,011)
Total comprehensive income for the period	16,036,838	10,846,032
Basic earnings per share - cents per share	28.1	22.1
Diluted earnings per share - cents per share	28.0	21.2

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 2024

	CONSOLIDATED	
	31 December 2024	30 June 2024
	\$	\$
Current assets		
Cash and cash equivalents	16,820,595	35,200,751
Cash held in term deposits	181,400,153	148,667,720
Trade and other receivables	16,285,900	26,238,297
Inventories	9,407,149	10,626,613
Prepayments	3,651,309	1,330,461
Total current assets	227,565,106	222,063,842
Non-current assets		
Property, plant and equipment	6,535,896	6,982,337
Right-Of-Use assets	571,870	737,788
Intangible assets	185,030	185,030
Deferred tax assets	1,211,541	1,020,344
Lease bonds	135,489	134,208
Total non-current assets	8,639,826	9,059,707
Total assets	236,204,932	231,123,549
Current liabilities		
Trade and other payables	5,649,131	7,109,053
Income tax payable	5,141,888	15,851,385
Lease liabilities	388,636	369,861
Provisions	1,924,275	1,881,898
Total current liabilities	13,103,930	25,212,197
Non-current liabilities		
Lease liabilities	326,741	509,923
Provisions	191,775	163,959
Deferred tax liabilities	5,280,675	2,226,104
Total non-current liabilities	5,799,191	2,899,986
Total liabilities	18,903,121	28,112,183
Net assets	217,301,811	203,011,366
Equity		
Contributed equity	168,550,461	168,802,368
Reserves	7,215,827	4,245,371
Retained earnings	41,535,523	29,963,627
Total equity	217,301,811	203,011,366

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 2024

	CONSOLIDATED					Total Equity \$
	Share Capital \$	Performance Rights Reserve \$	Foreign Currency Translation Reserve \$	Retained Earnings \$		
Balance at 1 July 2023	151,849,375	19,370,046	3,185,998	(9,774,276)		164,631,143
Employee share-based payment options	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
Balance at 1 July 2024	168,802,368	1,198,318	3,047,053	29,963,627		203,011,366
Employee share-based payment options	-	1,008,953	-	-		1,008,953
Share buy back	(251,907)	-	-	-		(251,907)
Dividends paid	-	-	-	(2,503,439)		(2,503,439)
Transactions with owners	168,550,461	2,207,271	3,047,053	27,460,188		201,264,973
Profit for the year				14,075,335		14,075,335
Other comprehensive income:						
Exchange differences of foreign exchange translation of foreign operations	-	-	1,961,503	-		1,961,503
Total other comprehensive income	-	-	1,961,503	-		1,961,503
Balance at 31 December 2024	168,550,461	2,207,271	5,008,556	41,535,523		217,301,811

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 2024

	CONSOLIDATED	
	31 December 2024	31 December 2023
	\$	\$
Cash flows from operating activities		
Receipts from customers	49,785,752	43,579,579
Payments to suppliers and employees	(23,362,750)	(20,128,194)
Income taxes paid	(15,612,487)	(24,295)
Interest received	2,153,617	2,317,570
GST and VAT refunds	185,950	93,406
Government grants and other income	2,262	541,777
Net cash provided by operating activities	13,152,344	26,379,843
Cash flows from investing activities		
Investments in cash held in term deposits	(29,943,048)	(10,711,461)
Payments for property, plant and equipment	(57,861)	(5,301,549)
Net cash used in investing activities	(30,000,909)	(16,013,010)
Cash flows from financing activities		
Dividends paid	(2,503,439)	(2,470,227)
Payments for share buy back	(251,907)	-
Payments of lease liabilities	(186,905)	(164,263)
Net cash used in financing activities	(2,942,251)	(2,634,490)
Net (decrease) / increase in cash held	(19,790,816)	7,732,343
Cash and cash equivalents at beginning of the year	35,200,751	31,893,021
Effects of exchange rate changes on foreign currency held	1,410,660	(808,148)
Cash and cash equivalents at end of the year	16,820,595	38,817,216

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 2024

Statement of material accounting policy information, 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.

During the half year ended 31 December 2024, the Group changed its method of accounting for depreciation from diminishing value method to straight-line method for all classes of property, plant, and equipment. This change is effective as of 1 July 2024. The Group believes that the straight-line method provides a more accurate reflection of the consumption of economic benefits over their useful lives and enhances the comparability of its financial statements. The change in accounting method did not have a material effect on the Group's financial statements. The change resulted in a minor adjustment to depreciation expense for the half year ended 31 December 2024, which is not expected to significantly impact the overall financial results. Other than the change in accounting method of depreciation, the accounting policies adopted in the preparation of the half year financial report are consistent with those adopted and disclosed in the Group's 2024 annual financial report for the financial year ended 30 June 2024.

Related party transactions

As disclosed to the Australian Securities Exchange on 6th September 2024, Dr Pearl Grimes has become a Non-Executive Director of CLINUVEL. Dr Grimes is also a director of the Vitiligo and Pigmentation Institute of Southern California which maintains an arms-length relationship with CLINUVEL as an administration site for SCENESSE® based on normal commercial terms and conditions.

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 2024 of 5.0 cents per share was paid on 20 September 2024 and a final fully franked dividend for 2023 of 5.0 cents per share was paid on 20 September 2023.

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.

Basic earnings per share were \$0.281 on a weighted average number of 50,067,595 issued ordinary shares as at 31 December 2024. This compares with restated basic earnings per share of \$0.221 as at 31 December 2023 on a weighted average number of 49,546,711 issued ordinary shares.

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.

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 the balance date.

Revenue

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

	Six Months to 31 December 2024			Six Months to 31 December 2023		
	Commercial Sales of Goods	Sales Reimbursements	Total	Commercial Sales of Goods	Sales Reimbursements	Total
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
Europe & USA	32,613	-	32,613	29,862	-	29,862
Switzerland, Others	-	3,033	3,033	-	2,395	2,395
Total	32,613	3,033	35,646	29,862	2,395	32,257

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.

Depreciation Method

At the commencement of this financial year the Group elected to change its historical depreciation methodology from the diminishing value methodology to a straight-line depreciation methodology. The total variance resulting from the change in the depreciation calculation methodologies was immaterial during the six-months to 31 December 2024.

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 2024 and of its performance for the half year ended on that date;
 - b) complying 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 27th day of February 2025



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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 statement of financial position as at 31 December 2024 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, including material accounting policy information, 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 financial position as at 31 December 2024 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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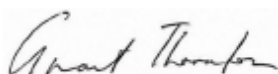
Directors' responsibility for the half-year financial report

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 for the review of the financial report

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 2024 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, 27 February 2025