

# CLINUVEL PHARMACEUTICALS LTD

A.B.N. 88 089 644 119

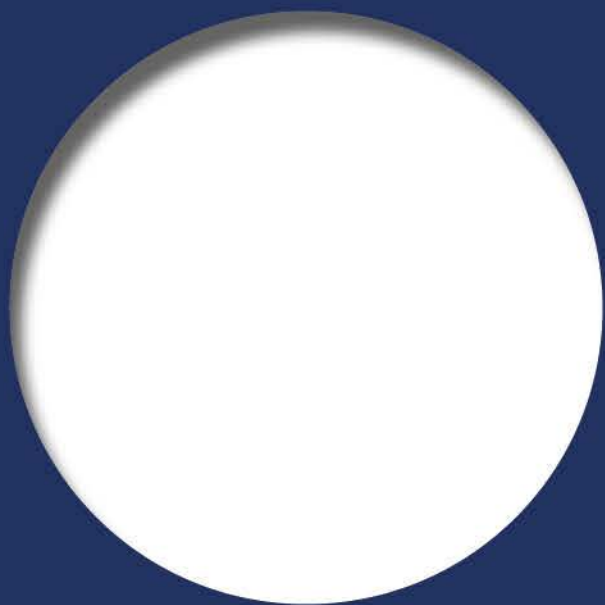
<b>1. Reporting period:</b>		<b>1 July 2024 to 30 June 2025.</b>	
Previous corresponding period:		1 July 2023 to 30 June 2024.	
<b>2. Results for announcement to the market.</b>		<b>Percentage change to 2024</b>	<b>Amount (A\$)</b>
2.1 Revenues from ordinary activities.		<b>Increased 8%</b>	<b>To 95,017,570</b>
2.2 Profit from ordinary activities before tax attributable to members.		<b>Profit has increased 2%</b>	<b>To 51,552,800</b>
2.3 Net profit for the period attributable to members.		<b>Profit has increased 2%</b>	<b>To 36,172,518</b>
2.4 A fully franked final dividend of \$0.05 per ordinary share has been declared.			
2.5 Record date for determining entitlements for the final dividend: 05 September 2025.			
2.6 The CLINUVEL PHARMACEUTICALS LTD audited Annual Report for the year ended 30 June 2025 accompanies this announcement.			
Additional Appendix 4E disclosure requirements, including the Operating and Financial Review for an explanation of the figures reported above, are in the Directors' Report of the attached Annual Report. Where applicable, the Annual Report includes information per items 3 to 14 below:			
<b>3. Refer to the Attachment to Appendix 4E for the Statement of Profit or Loss and Other Comprehensive Income together with notes to the statement.</b>			
<b>4. Refer to the Attachment to Appendix 4E for the Statement of Financial Position together with notes to the statement.</b>			
<b>5. Refer to the Attachment to Appendix 4E for the Statement of Cash Flows together with notes to the statement.</b>			
<b>6. Refer to the Attachment to Appendix 4E for the Statement of Changes in Equity together with notes to the statement.</b>			
<b>7. The Directors have declared a fully franked final dividend of \$0.05 per ordinary share to be paid on 19 September 2025.</b>			
<b>8. No dividend reinvestment plan.</b>			
<b>9. Net Tangible Assets per Security for Year Ended</b>		<b>Net Tangible Assets per Security for Year Ended</b>	
<b>30 June 2025:</b> \$4.77		<b>30 June 2024:</b> \$4.02	
<b>10. The control of entities which had control gained or lost:</b> N/A			
<b>11.</b> N/A			
<b>12. No other significant information.</b>			
<b>13. Foreign entities:</b> Australian Accounting Standards used.			
CLINUVEL, INC. (USA), CLINUVEL (UK) LTD (UK), CLINUVEL AG (Switzerland), CLINUVEL SINGAPORE PTE LTD (Singapore), VALLAURIX PTE LTD (Singapore), CLINUVEL EUROPE LIMITED (Ireland), VALLAURIX MC SARL (Monaco)			
<b>14. COMMENTARY OF RESULTS:</b>			
Commentary in respect of the financial results is provided in the Operating Review and Financial Review of the attached Annual Report.			

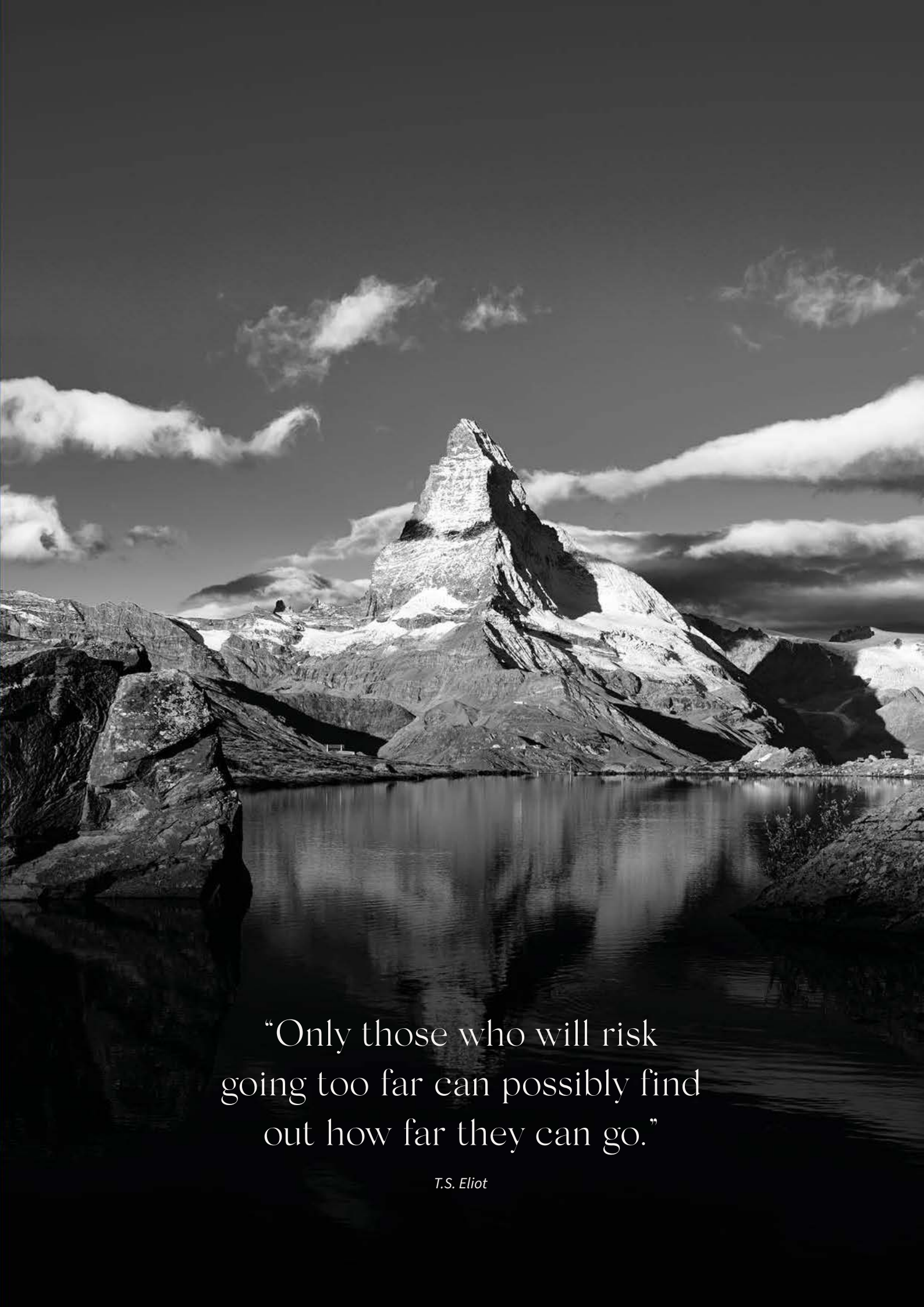
# ANNUAL REPORT 2025



# CLINUVEL

PHARMACEUTICALS LTD





“Only those who will risk  
going too far can possibly find  
out how far they can go.”

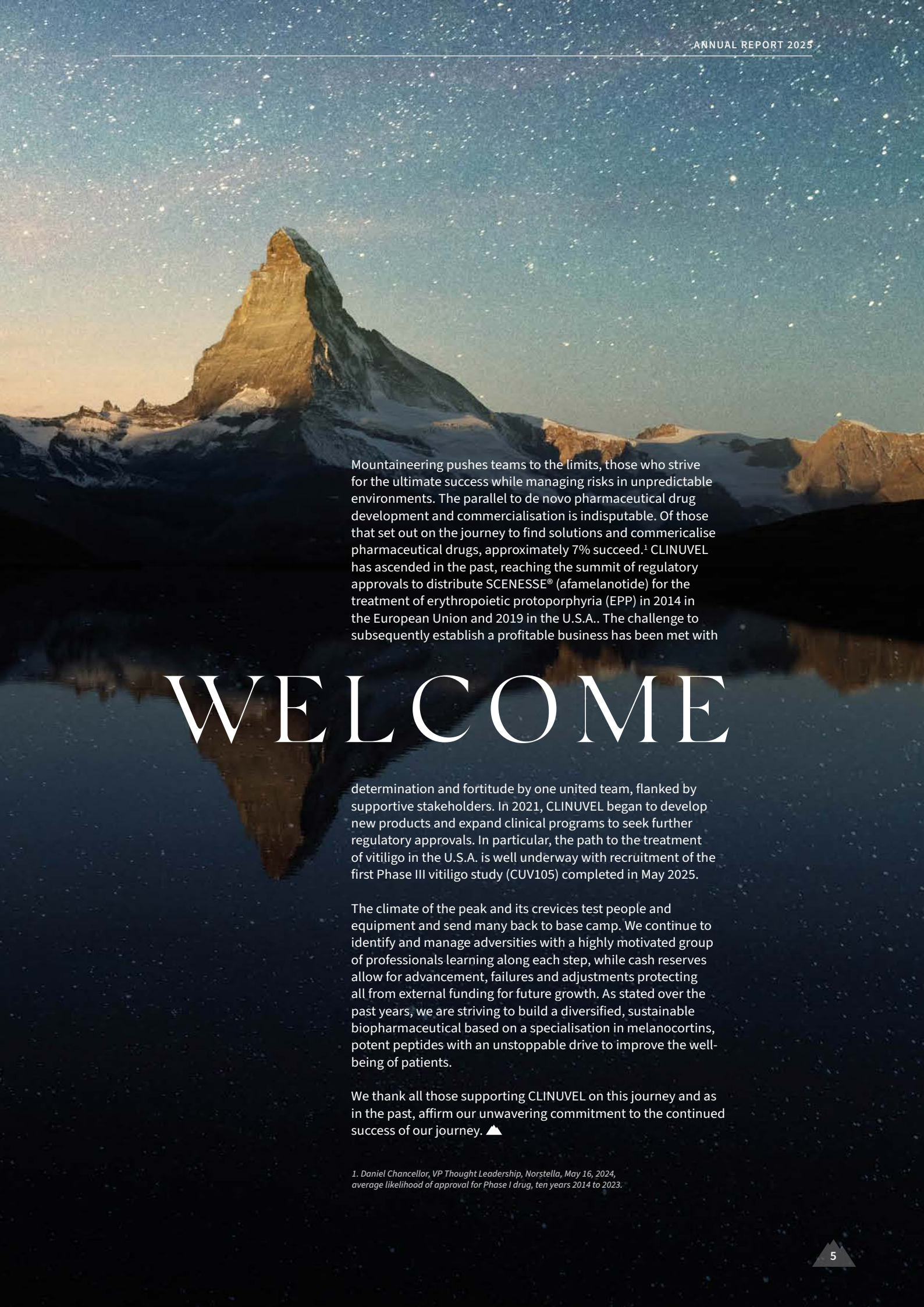
*T.S. Eliot*



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Mountaineering pushes teams to the limits, those who strive for the ultimate success while managing risks in unpredictable environments. The parallel to de novo pharmaceutical drug development and commercialisation is indisputable. Of those that set out on the journey to find solutions and commercialise pharmaceutical drugs, approximately 7% succeed.<sup>1</sup> CLINUVEL has ascended in the past, reaching the summit of regulatory approvals to distribute SCENESSE® (afamelanotide) for the treatment of erythropoietic protoporphyria (EPP) in 2014 in the European Union and 2019 in the U.S.A.. The challenge to subsequently establish a profitable business has been met with

# WELCOME

determination and fortitude by one united team, flanked by supportive stakeholders. In 2021, CLINUVEL began to develop new products and expand clinical programs to seek further regulatory approvals. In particular, the path to the treatment of vitiligo in the U.S.A. is well underway with recruitment of the first Phase III vitiligo study (CUV105) completed in May 2025.

The climate of the peak and its crevices test people and equipment and send many back to base camp. We continue to identify and manage adversities with a highly motivated group of professionals learning along each step, while cash reserves allow for advancement, failures and adjustments protecting all from external funding for future growth. As stated over the past years, we are striving to build a diversified, sustainable biopharmaceutical based on a specialisation in melanocortins, potent peptides with an unstoppable drive to improve the well-being of patients.

We thank all those supporting CLINUVEL on this journey and as in the past, affirm our unwavering commitment to the continued success of our journey. ▲

1. Daniel Chancellor, VP Thought Leadership, Norstella, May 16, 2024, average likelihood of approval for Phase I drug, ten years 2014 to 2023.



Delivering innovative solutions for  
unmet patient and healthcare needs

MISS

# SION







# ION

The CLINUVEL Group works to translate scientific concepts and breakthroughs into commercial products to prevent or treat acute and chronic medical conditions where no alternatives exist.

We are determined in our desire to excel in scientific research and development, building on our global expertise to deliver longitudinal care and novel products for patients and consumers.

The CLINUVEL Group puts its People and Environment as central to the Group's working practice. CLINUVEL focuses its research and development on healthcare problems not yet addressed, aiming to deliver innovative medical and healthcare solutions.



# VALUES

The CLINUVEL Group pledges to adhere to a principal set of values which reflect how we operate and interact with each other while expanding our business.

## **People & Environment**

We work for those who have no alternatives: patients, physicians, and individuals at-risk. We are selective with whom we work, and invest time in the talent we employ. We aspire to create an environment where professionals are able to develop and grow. We aim to present skilled talent with early opportunities, responsibilities, and accountability as part of training the next generation. We strive to build international teams and operate on the basis of gender and ethnic equality. We wish to set an example of excellence in our industry.

## **Approach**

We aim to be innovative in our approach and find solutions for unique, complex and previously neglected healthcare problems. We are determined to remain leaders in our fields of expertise and be creative and diligent in our endeavours. We admit errors, recognise our shortfalls, evaluate, analyse and learn to implement new findings. In improving ourselves we strive to enhance the lives and quality of life of those we serve. We aim not to become complacent and recognise that success can only come from the identification and mastering of obstacles. Our staff embrace optimism and retain focus.

**Technology**

We create, develop, advance, and offer pharmaceutical and healthcare products which are driven by medical need, consumer demand, and a lack of available solutions. Our technologies aim to add value beyond existing offerings. We acknowledge that new technologies require regulatory environments to be primed and markets to be prepared for achieving widespread acceptance and adoption.

**Knowledge Building & Sharing**

Our expertise spans the fields of optical physics, the interaction of light and human biology, and the potential of melanocortin drugs in acute care and life-threatening conditions. We specialise in skin and brain disorders. We are proficient in our understanding of acute, rare, and complex disorders. We advance our ideas and concepts and translate them into effective and practical solutions. We aim to grow our know-how continuously and establish a learned community. Collaboratively we seek to excel in a multifaceted field to arrive at scientific breakthroughs.

**Respect & Appreciation**

We are conscious of the privilege to be productive during our professional lives. We appreciate the significance of being able to function in good health and we value this gift every day. We aim to be sincere in our approach and represent data and facts. We act respectfully and do not harm others. We value our colleagues and co-workers and cherish diversity, equality, respect and harmony. We are passionate towards our objectives and share empathy and compassion for all those we work to serve. ▲



# AMER OPPOR

## SCALING OPERATIONS IN NORTH AMERICA

### **Strategic Context**

CLINUVEL is committed to the development of innovative melanocortin-based products to treat patients with unmet medical needs. Central to our business is an engagement with patient populations within the United States of America who may benefit from our technologies, both directly and through

healthcare professionals. Since the launch of SCENESSE® (afamelanotide), the Company has taken considerable steps to build a commercial footprint to meet the needs of erythropoietic protoporphyria (EPP) patients. We are steadfast to replicate this approach to vitiligo patients in the near-term.



# IC AN TUNITY

## Treatment of EPP

Prior to April 2020, there was no approved treatment for American patients with the acute light-affected disorder, EPP. CLINUVEL developed SCENESSE® as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with EPP, with the U.S. Food and Drug Administration (FDA) approving the drug in October 2019. CLINUVEL promptly commenced commercial distribution in April 2020 to satisfy this unmet need and has successfully built a network of Specialty Centers across the U.S. to treat EPP patients. The ascent to this summit required many years of extensive research and building trust from patients and families, patient associations, physicians, regulators and insurers (both private and government), and broader healthcare networks within the U.S.A. who facilitate patient treatment.

CLINUVEL's early plans were to distribute SCENESSE® through 30 trained and accredited Specialty

Centers, strategically located to enable reasonable patient access to treatment. When this milestone was achieved ahead of schedule, the Company kept adding Specialty Centers to the network. As of 30 June 2025, there are 104 centres across North America and we are targeting to reach 120 by the end of 2025. This network provides convenient patient access to SCENESSE® and provides a ready-made network for the treatment of patients with vitiligo. CLINUVEL intends to continue building and strengthening its Specialty Center network to better meet patients' long-term needs.

Other initiatives in the U.S. have been to establish:

- patient treatment database compliant with the Health Portability and Accountability Act (HIPAA) to ease insurance processes and ensure regularity of treatment;
- unique codes for the drug (J-code) and treatment (CPT

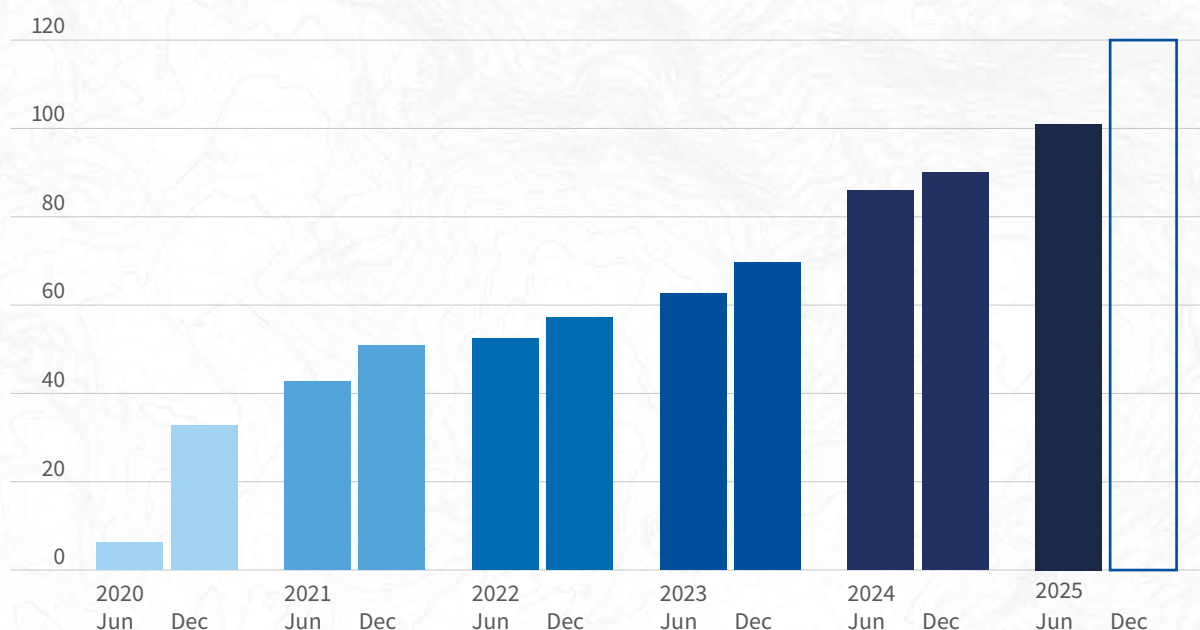
Code®) which serve to streamline reimbursement by insurers – these codes can also be used for additional indications;

- a savings program to assist privately-insured patients with the 'out-of-pocket' costs of treatment; and
- a central distribution facility from which SCENESSE® is delivered as ordered by Specialty Centers.

The impact of U.S. operations on CLINUVEL's financial performance has been positive with a rising trend in revenues evident since the 2021 financial year – refer to the Financial Review on pages 54–63 of this report.

The U.S. team, reporting into the Palo Alto, California office, has increased under the leadership of Dr Linda Teng, Director of North American Operations. The team consists of clinical specialists and patient relations personnel, plus financial services, legal, and investor relations professionals.

**Growth of Specialty Centers in North America**





# **U.S. OPERATIONS**

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**100 SPECIALTY CENTERS**

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**PATIENT REGISTRY**

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**INSURANCE CODES**

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**100 INSURERS**

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**U.S. DISTRIBUTION FACILITY**

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**SAVINGS PROGRAM**

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## Unmet need in vitiligo

Vitiligo is an auto-immune condition which affects around 1% of the world's population, causing visible loss of pigment in the skin. The impact of vitiligo is most severe in patients with darker skin complexions, specifically those with Fitzpatrick skin types IV, V and VI. SCENESSE® – with adjunct narrowband ultraviolet-B (NB-UVB) phototherapy – is currently being evaluated in a Phase III clinical program as a systemic therapy for skin repigmentation. There is currently no systemic treatment available to repigment the skin and no approved therapy for patients with extensive pigment loss (affecting  $\geq 10\%$  of body surface area).

### Raising awareness

In October 2023, the first Phase III study (CUV105) commenced recruitment. Initial case reports of patients treated have demonstrated

considerable repigmentation and that the drug is well tolerated by individual patients. The first case report was released in March 2024 at the American Academy of Dermatology (AAD) Meeting in San Diego.

The AAD Meeting in Orlando, Florida, in March 2025 was the start and one of many important milestones for the Group's U.S. expansion plans. CLINUVEL introduced its pioneering research and future ambitions to 20,000 physicians, clinicians, academics and industry representatives. Visitors to CLINUVEL's Pavilion of Photomedicine learned first-hand about the Company and its expertise in photomedicine. They also heard from people living with vitiligo about the impact of the disease and the potential of a systemic repigmentation therapy. An important outcome was an increased awareness of CLINUVEL's ambitions to prepare a

vitiligo franchise in the U.S.. Attendees understood well the potential of afamelanotide to systemically repigment the skin.

### Clinical developments

CLINUVEL is advancing its clinical program with the first Phase III clinical study (CUV105) completing recruitment in May 2025. Work towards the final design of CUV107 is in progress. Two studies totaling over 400 patients are considered necessary to provide a compelling dossier to the FDA for consideration of an extension to the approved label of SCENESSE® to treat vitiligo.

The Company has released five case reports from CUV105 patients who have received the afamelanotide (with adjunct NB-UVB) therapy. The visual results are compelling, and the feedback from patients and physicians is positive.



## CUV105 CASE REPORTS

### CASE STUDY 1

#### Participant A

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 was seen after Day 140 but near total repigmentation was achieved after continued NB-UVB monotherapy.

Day 0

Baseline



Day 134

7 afamelanotide implants  
39 NB-UVB treatments



Day 222\*

7 afamelanotide implants  
53 NB-UVB treatments



\*82 days after completing study

### CASE STUDY 2

#### Participant B

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\*

No further therapy



\*30 days after completing study



## CUV105 CASE REPORTS

### CASE STUDY 3

#### Participant C

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.

#### Day 0

Baseline



#### Day 134

7 afamelanotide implants  
40 NB-UVB treatments



#### Day 308\*

No further therapy



\*168 days after completing study

### CASE STUDY 4

#### Participant D

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).

#### Day 0

Baseline



#### Day 140

7 afamelanotide implants  
40 NB-UVB treatments



### CASE STUDY 5

#### Participant E

Male, 46 years old, Skin Type V

Diagnosed with vitiligo in 2004.

**PHYSICIAN'S REPORT:** Images demonstrate repigmentation of vitiliginous lesions on right forearm. The red outlines demonstrate the extent of the initially affected skin.

#### Day 0

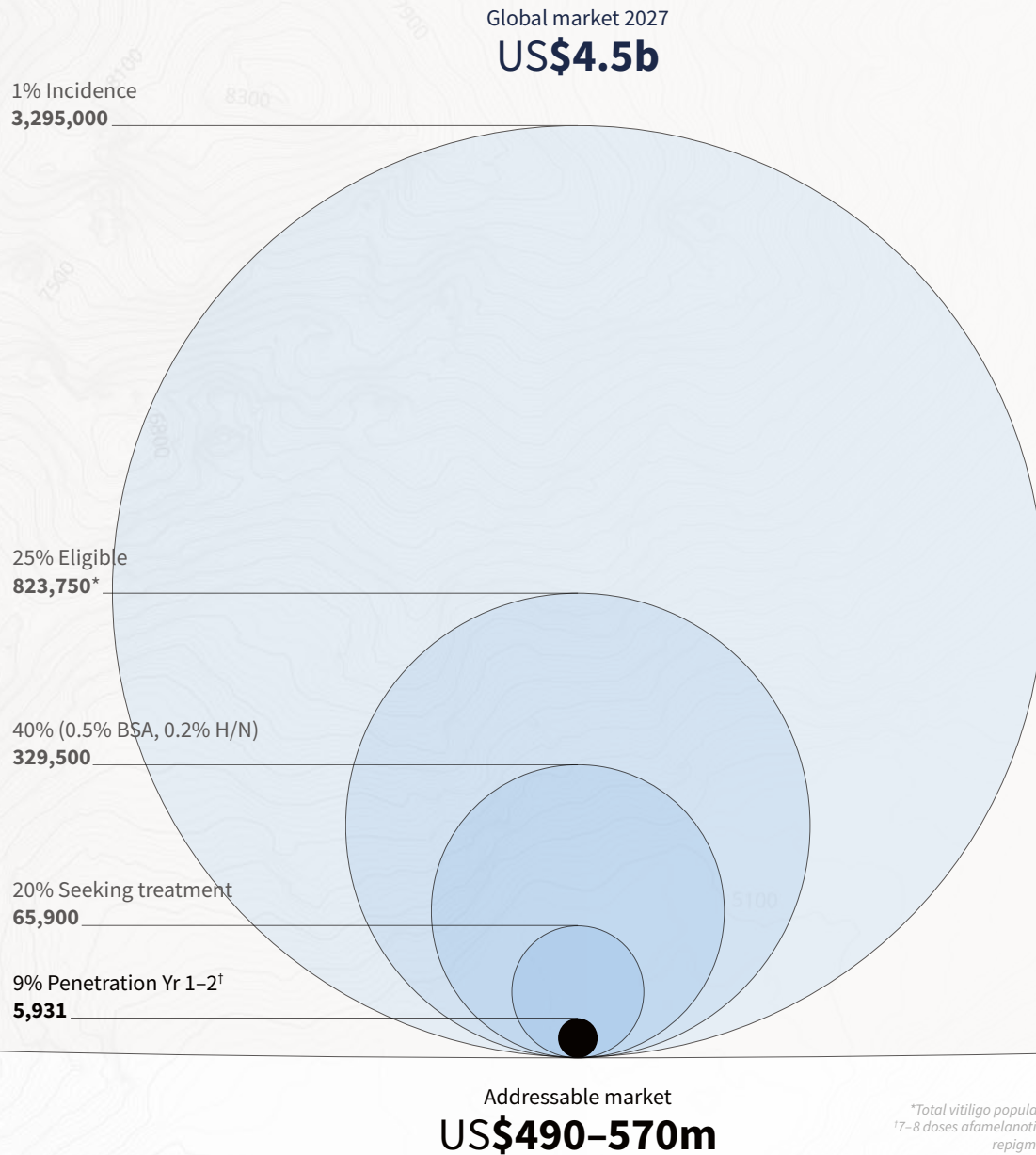
Baseline



#### Day 140

7 afamelanotide implants  
40 NB-UVB treatments



**Market potential**

The expanding network of Specialty Centers across the U.S. and Canada is treating more EPP patients, while being established with the future treatment of vitiligo patients in mind. This network is scalable at low cost. CLINUVEL's presence at the AAD Meeting in Orlando in March 2025 generated a pipeline of over 100

new dermatologists interested in joining this network to treat patients. CLINUVEL aims to expand this network to 120 centres by 1 January 2026, sufficient to support initial commercial plans in vitiligo.

Based on data sources and a range of assumptions, CLINUVEL has provided an indicative model of the

commercial roll out for vitiligo in the U.S.A., with expected revenues of US\$490-570 million in the first two years of distribution.

This would transform the financial profile of the Company.



## Initiatives to add scale

The development of the ACTH formulation NEURACTHEL® continues as a key priority with an objective to obtain regulatory approval to distribute it as a branded generic drug in the first instance.

The distribution of PhotoCosmetic products will also add to the scale of CLINUVEL's business in the U.S..

The U.S. exemplifies the melanocortin house being built by CLINUVEL:

# MELANOCORTIN HOUSE

A pharmaceutical group, diversified and integrated to sustain long-term performance

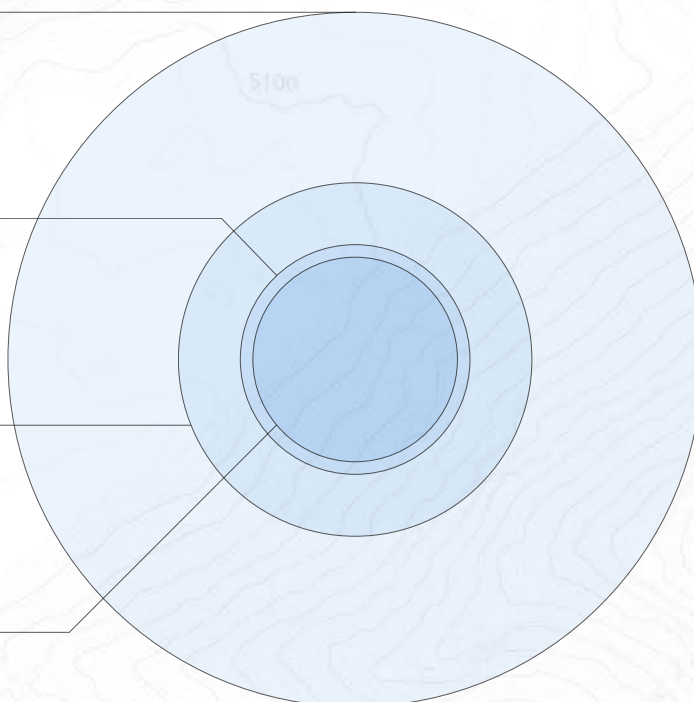
**3** PHARMACEUTICAL PRODUCTS      **5** CONDITIONS TREATED      **3** PHOTOCOSMETIC PRODUCT LINES

**VITILIGO**  
**\$750–870m** TAM \$6.9b

**PORPHYRIA**  
**\$105m** TAM >\$460m

**ACTH**  
**\$230m** TAM \$2b

**PHOTOCOSMETICS**  
**\$77m** TAM \$9.5b



*TAM and penetration figures are in Australian dollars*



## SUMMARY

CLINUVEL has invested incrementally in scaling-up its U.S. commercial operations to meet the needs of larger patient populations. Access to a safe and effective repigmentation therapy would be transformative for many vitiligo patients with darker skin complexions (skin types III–VI). The clinical program continues, while the network of Specialty Centers is being built, the unique codes are ready to be used, the case reports to date are promising, and we are working with determination and focus to the day when systemic repigmentation becomes a reality for vitiligo patients. ▲



# KEY ACHIEVEMENTS

CLINUVEL's achievements in the financial year ending 30 June 2025 spanned key areas of the business:

## **TOWARDS LONG-TERM VALUE**

- Growth in revenues
- Controlled expenses to support expansion
- Ninth consecutive annual profit
- Eighth consecutive dividend
- Further increase in cash reserves
- Board renewal and expansion with three new Non-Executive Directors appointed
- Strategic programs prioritised
- Clinical team restructured to deliver on larger, more complex global programs

## **GROWING DISTRIBUTION OF SCENESSE®**

- Global growth in EPP patients, treatment centres and frequency of dosage
- North American Specialty Centers increased to 104
- Adolescent study CUV052 completed to support SCENESSE® label extension filing
- Submission to European Medicines Agency (EMA) to align the label of SCENESSE® with the U.S.A.
- Filing and validation of New Drug Submission to Health Canada
- Distribution agreement in Argentina with Diligens Salud SA
- SCENESSE® successfully administered to nine-year-old paediatric EPP patient

## DEVELOPING MELANOCORTINS

- Completed recruitment Phase III vitiligo study, CUV105
- Results in Phase II pilot monotherapy vitiligo study, CUV104
- Results in Phase II stroke study, CUV803
- Ongoing formulation and manufacturing development work on the PhotoCosmetic M-lines, “Preserve” and “Bronze”

## ENGAGING RELEVANT GLOBAL COMMUNITIES

- Prominent presence at American Academy of Dermatology Meeting, Orlando, Florida
- Sponsored International Congress of Porphyrrias & Porphyrins (ICPP), results presented for Phase II variegate porphyria study, CUV040
- Long-term safety, effectiveness data on SCENESSE® in EPP presented to European Academy of Dermatology and Venereology Spring Symposium
- Data from German cohort of EPP patients treated with SCENESSE® in European post-authorisation safety study published in Photodermatology, Photoimmunology and Photomedicine journal
- Results of study CUV151 presented at British Association of Dermatologists 104<sup>th</sup> Annual Meeting
- Heightened social media activity
- High profile media engagements – Financial Times, Vogue, Wired
- Active Investor Relations – regular roadshows, briefings, and conference presentations ▲



# FINANCIAL HIGHLIGHTS

CLINUVEL Group has achieved nine years of consecutive revenues growth and profitability with a further increase in cash reserves

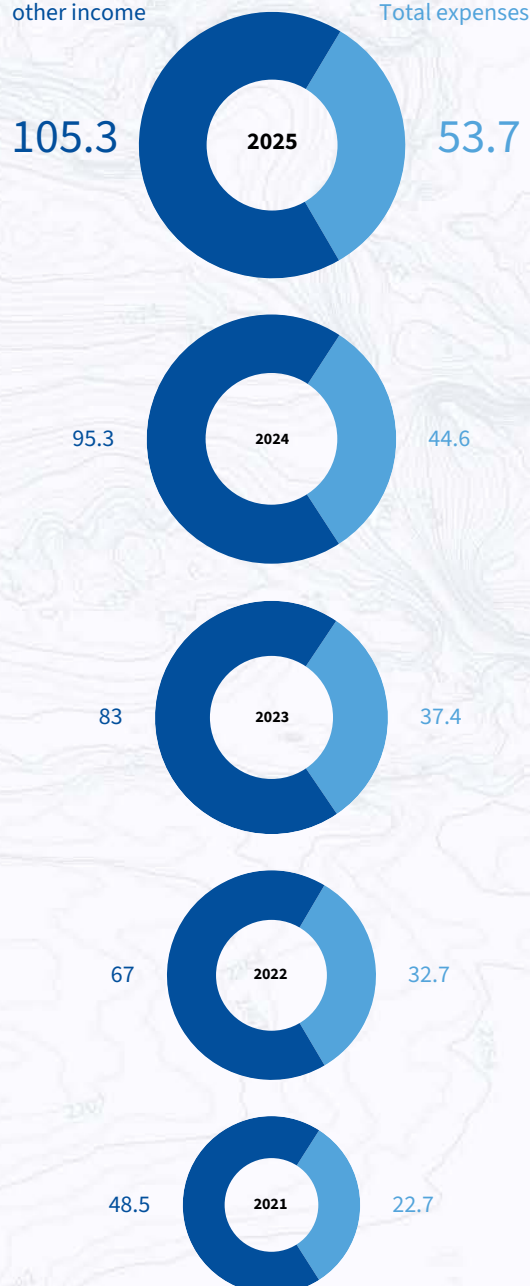


## REVENUES & EXPENSES (A\$m)

- Growth of revenues and expenses were 10% and 20%, respectively, in FY2025
- Over the nine years since commencement of commercial operations, the compound annual growth rate for revenues is 35% compared to 20% for expenses.

Total revenues,  
interest and  
other income

Total expenses

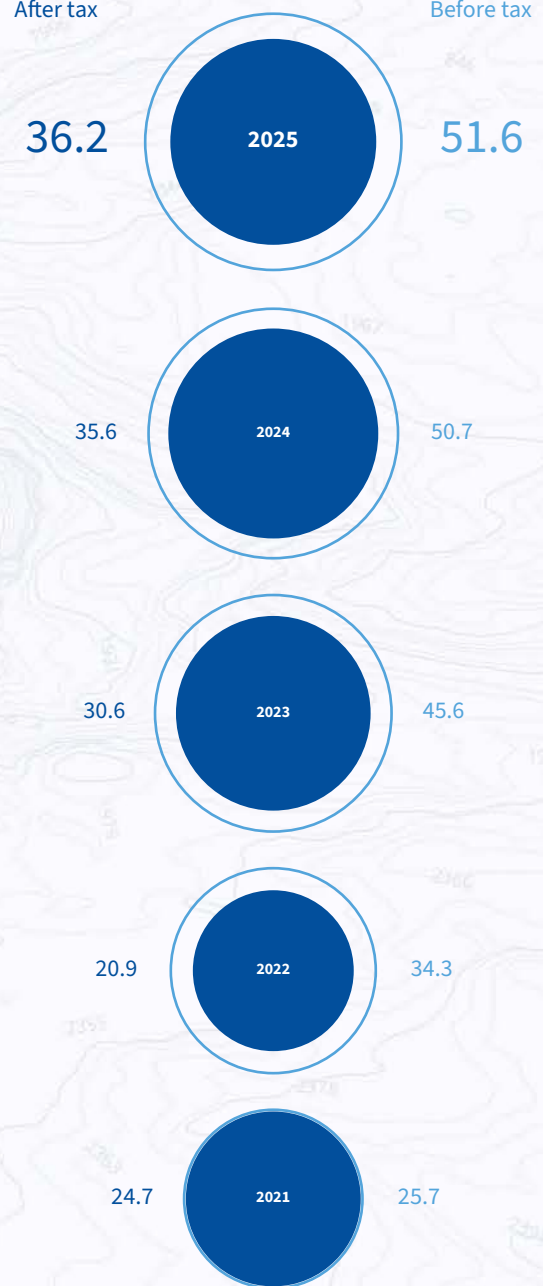


## PROFIT (A\$m)

- Net profit before tax increased by 2% to A\$51.6 million and after tax increased by 2% to A\$36.2 million.
- FY2025 marks the ninth consecutive year of profit.

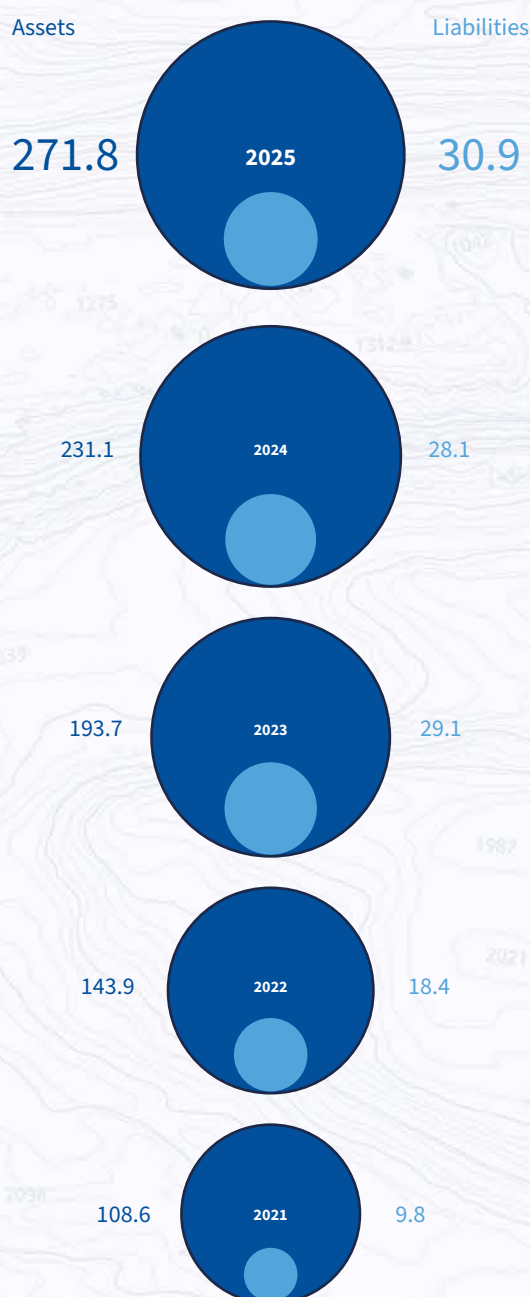
After tax

Before tax



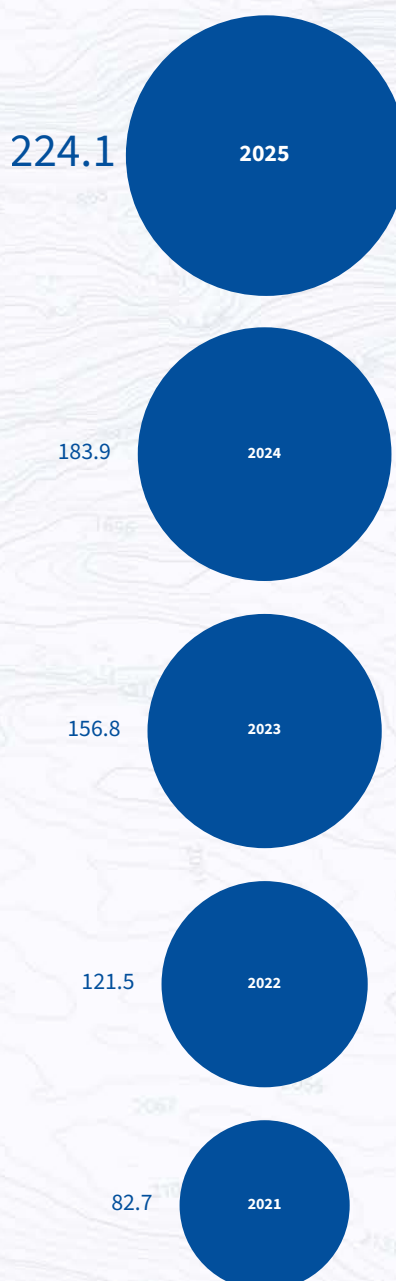
## ASSETS & LIABILITIES (A\$m)

The balance sheet strengthened again in FY2025, with an increase of 19% in net assets to A\$240.8 million.




## CASH RESERVES\* (A\$m)

Cash reserves increased by 22% to A\$224.1 million, enabling the Group to self-finance its expansion initiatives and absorb adverse fluctuations in the operating environment, without resorting to dilutive capital raisings. ▲



\*Cash Reserves equals Cash and Cash Equivalents plus Cash held in term deposits





CLINUVEL continued to maintain positive performance across a range of key indicators in FY2025

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**A\$0.72**  
**EARNINGS PER SHARE**

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**16.3%**  
**RETURN ON EQUITY**

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**A\$0.05**  
**DIVIDEND PER SHARE**

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**NIL**  
**DEBT**

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# CHAIR'S LETTER

A\$105.3m  
**REVENUES & INCOME**

A\$51.6m  
**NET PROFIT BEFORE TAX**

A\$224.1m  
**CASH RESERVES**

16.3%  
**ROE**

A\$0.72  
**EPS**

\*Cash Reserves equals Cash and cash equivalents plus Cash held in term deposits



Dear Shareholders

### **Strong Performance and Progress Towards Key Objectives**

New pharmaceutical development takes considerable time, and commercial success is far from guaranteed as many show us. Despite these challenges, CLINUVEL has proven to be a resilient company with no ongoing debts and the flexibility to strategically use its cash at a time of our choosing. CLINUVEL has continued its advance towards long-term sustainability during FY2025. This is the ninth consecutive year of revenue growth, profit, and net cash inflow – a distinction not mirrored in many biopharmaceutical companies, not in Australia or U.S.. CLINUVEL was recently recognised on Forbes Asia's (August 2025) list of the best 200 publicly listed companies under a billion dollars revenue in the Asia-Pacific region. Notably, fifteen were Australian and only eight pharma companies made the list.

CLINUVEL has a unique business model among pharmaceutical companies, centered on direct physician engagement. CLINUVEL now works with over 120 medical centres in the U.S.A. in which physicians prescribe SCENESSE® for EPP and conduct our vitiligo trials. We are expanding the distribution of SCENESSE® for erythropoietic protoporphyria (EPP), particularly in Europe, seeking approval for the treatment of adolescents, and to harmonise the frequency of treatment with the approved label in the U.S.A.. We continue to seek new markets on a global scale. CLINUVEL has also supplied SCENESSE® on compassionate grounds. As highlighted in the key achievements of the year on pages 22–23, SCENESSE® was – for the first time in history – successfully administered to a nine-year-old paediatric EPP patient.

There were several key highlights of the financial year. The outstanding presentation of CLINUVEL to attendees at the American Academy of Dermatology (AAD) Meeting in Orlando in March 2025 increased our physician base and is expected to be reflected in patient numbers, new participants in our clinical trials, and sales of SCENESSE®, in time. We intend to repeat this display at the AAD meeting in Denver. in March 2026. Secondly, in May 2025 we reported the completion of recruitment of the first Phase III vitiligo study, CUV105. In parallel, progress has also been made on the development of our PhotoCosmetic products and NEURACTHEL®, an ACTH formulation.

### **Board Renewal and Expansion Resulting in Heightened Collaboration**

The Board renewed and expanded during the past year. Mrs Brenda Shanahan retired at the Annual General Meeting in October 2024, concluding her distinguished service to CLINUVEL spanning 17 years, including periods as Chair of the Board and Chair of the Audit & Risk Committee. On behalf of the Board, and on a personal level, I thank Mrs Shanahan for her commitment and dedication to CLINUVEL's journey.



Our three new Non-Executive Directors bring welcome skills to the Board. Mr Matthew Pringle has extensive experience in corporate finance, assurance, governance and strategy and has duly become Chair of the Audit & Risk Committee; Mr Guy van Dievoet has significant experience in international investment banking, specialising in M&A; and Dr Pearl Grimes is a globally recognised dermatologist and leading international authority on vitiligo. Already, the contribution of the new Directors is evident, and the Board has a singular focus to drive growth and achieve further success. The Board is grateful for the support we receive from our Company Secretary, Ms Claire Newstead-Sinclair.

#### **Pleasing Depth of the Executive Team and CEO Succession**

I am continually impressed with the professionalism and commitment of the executive management team and indeed, the commitment of all staff to ensure the pace of activity. The progress of key initiatives continued whilst Dr Wolgen took leave during the year to attend to his health. I specifically thank and congratulate Mr Lachlan Hay for stepping-up to the Acting CEO role to steer the business since March 2025. Dr Wolgen returned to the business full-time in June 2025 to focus on several key initiatives tasked to him by the Board and will return to the CEO role in September 2025. His expertise and experience are highly valued by the Board. As mentioned by Dr Wolgen in his letter in this Annual Report, we also consolidated and enhanced the executive team during the year. Dr Wolgen's employment agreement runs to 30 June 2026. The Board has commenced the process of CEO succession.

#### **Analyst Coverage and Ownership of CLINUVEL**

Late in the 2025 financial year, a new Australian analyst commenced coverage of CLINUVEL. Barrenjoey, a well-regarded financial institution with a strategic partnership with Barclays, became the eighth Australian analyst of CLINUVEL. In addition, two German analysts – Parmantier & Cie and Dr Kalliwoda Research – commenced research coverage over the past year, thus extending our reach to existing and new investors in Europe. Ten analysts now cover CLINUVEL. This provides far greater market reach compared to a starting point of one analyst at the beginning of 2019.

All the analysts covering CLINUVEL have issued target prices above our current share price, so they see the opportunities ahead for the Company. Our Investor Relations team continues to work to expand analyst coverage, as a key channel for our compelling investment proposition to reach new investors.

We welcomed new institutional investors during the year. Institutions hold 34% of the issued shares of CLINUVEL compared to less than 20% at the beginning of 2019. Of this, just over half are Australian based and the rest are roughly split between Europe and the U.S.A.. The diversity of geographical ownership has been well maintained. Europe is the largest region of shareholder concentration, followed by Australia and the U.S.A.. Analysts and qualified institutions have noticed the diversity and foreign ownership on CLINUVEL's register.

The American opportunity (refer pages 12–21) is significant for CLINUVEL. Approximately 28% of our issued capital is held by U.S. based investors and interest has been increasing from North American investors who recognise CLINUVEL's profile as one of the few profitable biopharmaceutical companies. To support this interest and enhance market access to CLINUVEL, the Company announced on 22 August 2025, its intention to upgrade its American Depositary Receipt program from Level I to Level II, listed on Nasdaq, expected to be completed by the end of 2025.

**Acknowledgement of Support of Shareholders**

The Board is acutely aware of the decline in the share price over the course of FY2025 and takes the opportunity to express its appreciation of the ongoing support of long-term investors and new investors who believe in the path of the Company and the incremental value being built for the future. The stability this provides the Company to focus on its expansion initiatives is crucial.

The disconnect between CLINUVEL's share price and its financial and operational performance was addressed by Dr Wolgen at last year's Annual General Meeting. Over the longer-term, however, the progress we make with our strategic objectives – expansion of our markets, acquisition, new product release, completion of clinical trials and their results, and achieving approvals from pharmaceutical regulators – should be reflected in positive movements in the share price. All in all, I have much confidence in our direction and believe we are far better positioned than when the Company saw a significant spike of its share price on two occasions in the past.

The Board is pleased to have declared an eighth consecutive dividend in respect of FY2025 earnings, unchanged at A\$0.05, fully franked for the fourth year, to be paid in September 2025.

**The Journey Ahead Will Add Incremental Long-Term Sustainable Value**

The execution of the strategy of the Company has focused during the year on ongoing distribution of SCENESSE® for EPP, product development, and clinical programs. This should return more immediate results to stakeholders. Vitiligo is critical to the Company's long-term outlook, and in this regard, the five case reports of patients already treated provide insight into the safety and efficacy of SCENESSE® as a systemic repigmentation agent – (see pages 16–18).

The outlook is exciting with commencement of the second vitiligo study, CUV107, planned by the end of Q4 2025 / Q1 2026. Results from the first vitiligo study, CUV105, are expected in the second half of 2026. Launch of melanocortin-based PhotoCosmetic products and the completion of development and regulatory approval of NEURACTHEL® is expected in 2026. Achievement of these milestones will stimulate further market support for CLINUVEL.

I wish all shareholders good health and prosperity for the year ahead.



Professor Jeffrey Rosenfeld  
Chair  
CLINUVEL Group ▲



# MANAGEMENT

Dr Wolgen leads the executive management team who in turn direct their respective teams in the conduct of the business of Group. The executives meet regularly and collaborate on key initiatives to ensure progress is made to achieve annual and longer-term objectives.





#### **Malcolm Bull**

Head of Australian Operations and Investor Relations, Joined 2019  
BEc (Hons, University of Adelaide)  
MEc (Monash University)

Mr Malcolm Bull joined CLINUVEL in January 2019 and initially built out the Company's investor relations program with a focus on analyst and Australian institutional engagement. Recognising the need for greater operational support in Australia amidst the COVID-19 pandemic, Mr Bull's role with CLINUVEL evolved in 2021 to the remit of Head of Australian Operations and Investor Relations. Previously an economist within the Australian Federal Government and private sector, Mr Bull then spent more than two decades in banking across credit, business development and strategy, working with Commonwealth Bank of Australia, Bank of Western Australia, National Australia Bank, and ANZ. This included time in general management for ANZ in the Philippines and as part of the Victorian state management team for CBA Corporate. Mr Bull has managed to attract seven sell-side analysts since his arrival and increased institutional ownership of CLINUVEL from 25% to 34% of issued capital.



#### **Antonella Colucci**

VP, Commercial Affairs, Joined 2011  
MA (European Studies and Global Affairs, Catholic University of the Sacred Heart)  
MA (Modern Languages, IULM Milan)

Mrs Antonella Colucci is responsible for commercial matters ex-North America while working closely with the U.S. team to ensure continuity of business. Having spent many years working within the medical industry in Italy, Mrs Colucci was instrumental in the expansion of CLINUVEL's Italian 648/96 program and subsequent Swiss special access scheme. These two programs – which facilitated subsidised reimbursement of the drug prior to its marketing authorisation – provided CLINUVEL with commercial proof-of-concept for SCENESSE® and laid the foundations for Mrs Colucci to lead the Company's successful commercial activities since 2016. With responsibilities across pricing, compliance, and distribution, Mrs Colucci is currently focused on expanding the Company's commercial reach in both new and existing regions.



#### **Dr Azza Hamila**

Head of Quality Assurance and Drug Safety, Joined 2015  
BPharm (University Claude Bernard)  
MPharm (University Paris Descartes)

Dr Azza Hamila has played a central role in CLINUVEL's commercial scale-up, establishing new internal standards in GxP, with a focus on manufacturing, distribution, and pharmacovigilance. Her work has enabled the Company to achieve long-standing compliance, giving authorities comfort that CLINUVEL conforms to strict international regulations and can maintain the licences necessary to perform critical manufacturing and distribution functions in-house. Dr Hamila's position encompasses both Responsible Person and Qualified Person roles in various jurisdictions within the quality management system, as well as being responsible for supplier management and patient safety. She has previously held quality assurance roles with Orphan Europe (Recordati), Sanofi Aventis, and Roche before joining CLINUVEL in 2015.




**Lachlan Hay**

Chief Operations Officer, Joined 2007  
BA (Media Comms, University of Melbourne)  
MA (International Relations, Freie Universität Berlin)

Mr Lachlan Hay supports the executive and senior management teams as well as maintains responsibility for the delivery of key business objectives. Having joined the business in a corporate communications role in Australia, Mr Hay then assumed roles in Europe and Asia. He was the first General Manager of the UK business, overseeing the introduction of SCENESSE® into European markets since 2016, and assumed a broader operational position in 2021 in response to the needs of the business. On 1 July 2024, Mr Hay assumed the position of Chief Operations Officer, providing him more responsibilities. He is also completing his law degree (LLM).


**Dr Emilie Rodenburger**

Director, Global Clinical Affairs, Joined April 2024  
PharmD (Paris Descartes University, France)  
MSc (Paris-Sud University, France)

Dr Emilie Rodenburger rejoined CLINUVEL in April 2024 as Director Global Clinical Affairs. Returning to CLINUVEL after four years with Roche in senior clinical roles, Dr Rodenburger oversees CLINUVEL's global clinical program, evaluating melanocortin based drugs for a range of disorders of the skin and brain. Her immediate focus will be to ensure full enrolment and analyses of the CUV105 study of SCENESSE® in vitiligo (loss of pigmentation). A pharmacist (PharmD) with a master's degree in cancer biology, Dr Rodenburger previously worked with the CLINUVEL Group for over a decade in clinical development roles in Australia, the U.S.A. and Europe. During this time, she led the Company's first vitiligo trials as well as being one of two clinical managers completing the EPP program resulting in the successful approval and commercialisation of SCENESSE® as the first systemic photoprotective therapy.


**Dr David Soloman**

Head of Regulatory Affairs, Joined April 2025  
BPharm Hons MRPharmS (King's College London, University of London)  
Diploma in Clinical Science (Dip Clin Sci, University of Wales)

Dr Solomon joined CLINUVEL with over 35 years of experience in the pharmaceutical industry. As a pharmacist, he has worked across medical affairs, pharmacovigilance, clinical research and regulatory affairs. Prior to joining CLINUVEL, he worked in both large companies, such as GSK, Roche, Eisai, and UCB, and small biotech start-ups such as GW Pharmaceuticals, EUSA Pharma, and Zogenix. Dr Solomon has led Global Regulatory Affairs Departments, building teams of regulatory professionals in the EU, UK, and U.S.A.. He has experience in orphan disease areas, developing a wide variety of regulatory strategies, across all stages of drug development. Dr Solomon has successfully led teams in the submission and approval of many regulatory filings, including Marketing Authorisation Applications, New Drug Applications, paediatric investigational drugs, fast track applications, and numerous Clinical Trial/Investigational New Drug applications.





#### **Dr Linda Teng**

Director of North American Operations,  
Joined 2007  
BPharm (National Taiwan University)  
Doctor of Health Administration  
(Medical University of South Carolina)

As Director of North American Operations, Dr Linda Teng has established the Company's commercial presence, building a network of Specialty Centers and commercial programs enabling EPP patients to receive treatment in both the U.S.A. and Canada. With a background in clinical pharmacy and clinical pharmaceutical development – at BioMarin and for more than 16 years at CLINUVEL – Dr Teng also heads the vitiligo program in North America. The U.S. team has grown quickly over the past 18 months to incorporate new functions, including patient support and in-house counsel, adding complexity but greater bandwidth to the operations under Dr Teng's purview.



#### **Peter Vaughan**

Chief Financial Officer, Joined 2024  
BBus (Acc) (Swinburne University)  
Snr. Exec. MBA (Melbourne University)  
Member, Institute of Chartered Accountants ANZ  
GAICD, AGIA  
Cert. Climate Change: Financial Risks and Opportunities (Imperial College, London)

Mr Peter Vaughan joined CLINUVEL in April 2024 and assumed the Chief Financial Officer role on 1 July 2024. Mr Vaughan has over 20 years of experience in listed and unlisted companies in Australia, the U.S.A., Europe, and Asia. Most recently with Toys "R" Us ANZ Limited as a strategic financial advisor, he has previously held CFO and Company Secretary roles at Titomic (ASX:TTT), Immuron (ASX:IMC, NASDAQ:IMRN), Amaero (ASX:A3D) and Respiro (ASX:RSH), among others. He has led capital raisings, M&A and licensing deals within life science companies, as well as the dual listing of two Australian companies on the Nasdaq (Immunon Limited and Prima Biomed Limited (now Immutept)). Mr Vaughan is a Chartered Accountant, with a BBus (Accounting) from the Swinburne University of Technology and a Senior Executive MBA from Melbourne Business School. He is also a member of Australian Institute of Company Directors and Governance Institute of Australia.



#### **Dr Dennis Wright**

Chief Scientific Officer, Joined 2005  
BPharm (University of Sydney)  
MSc (University of Sydney)  
PhD (University of Sydney)  
GradCert Health Economics (Monash University)

Dr Dennis Wright has been at the core of the Company's clinical program and regulatory affairs for nearly two decades in the role of Chief Scientific Officer. A pharmacist with a PhD in xenobiotic metabolism, Dr Wright has a pharmaceutical career spanning more than 40 years with Nicholas Kiwi, Faulding/Mayne, CSL and CLINUVEL. During this time, he worked across basic and clinical research, regulatory affairs, pharmacovigilance, business development, in-licensing, and marketing. It is from this diverse background that he has led CLINUVEL's late-stage clinical development program for EPP as well as steering successful regulatory filings for SCENESSE® in Europe, the U.S.A., Australia, and Israel. His role has extended in recent years to facilitate new clinical programs for afamelanotide as well as overseeing new product development and scientific affairs. ▲



# MEMBERS OF THE BOARD

The Board was renewed and extended during FY2025 with the retirement of Mrs Brenda Shanahan and the appointment of three new Non-Executive Directors. The summaries of their skills and experience highlight the diversity and depth of CLINUVEL's Board.



## JEFFREY ROSENFELD AC, OBE

**Non-Executive Director,  
AC, OBE, MBBS, MS, MD, FRACS**

**Appointed 26 November 2019,  
Chair since 1 January 2024**

### Relevant Skills

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

### Background

Prof Rosenfeld is an internationally recognised neurosurgeon with extensive experience in senior healthcare and medical research executive roles and a distinguished and decorated career in the Australian Army. He is a retired Major General and a former Surgeon General, Australian Defence Force-Reserves. He has served on eight deployments to Rwanda, Iraq, Solomon Islands, Bougainville and East Timor. He was the Founding Director of Monash University Institute of Medical Engineering (MIME)-Melbourne. He is developing a bionic vision device to restore vision in people without eyesight, and he is also a leader in brain injury research.

Prof Rosenfeld was Director of Neurosurgery at the Alfred Hospital for fifteen years, concurrently holding Professor and Head of the Department of Surgery at Monash University for nine years. Prof Rosenfeld is active in many community organisations and champions various charitable causes. Prof Rosenfeld has been an active volunteer for the Australian-Aid funded Pacific Islands Project which transfers clinical skills and knowledge to healthcare professionals in Papua New Guinea, Fiji and the Solomon Islands.

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





## PHILIPPE WOLGEN

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**Chief Executive Officer,  
MBA, MD**

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

### **Relevant Skills**

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

### **Background**

Under Dr Wolgen's leadership, a long-term strategy for CLINUVEL was devised. The lead product SCENESSE® was reformulated, its medical application identified, European marketing authorisation was obtained in 2014 and systems were established to self-distribute the prescriptive product in the European Economic Area from June 2016. Dr Wolgen oversaw the submission of the scientific dossier to the U.S. Food & Drug Administration (FDA) under a New Drug Application, which was approved in October 2019. First treatment of U.S. patients commenced in April 2020 through a controlled distribution system set up by the Company. SCENESSE® is the world's first systemic photoprotective drug to have completed a clinical trial program and obtain marketing authorisation in two major markets.

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

Under his tenure a business model was adopted to develop and launch SCENESSE®, guiding the Group through a complex pharmaceutical product development program. His overall business execution and exact financial management is viewed as exemplary within the life sciences industry and the funding strategy he led is considered different and unique within the sector. He is currently leading the Group's expansion, based on both organic and inorganic strategies. His focus has been to establish a professional management team executing corporate objectives of establishing a sustainable, and profitable group diversified from its core pharmaceutical base, to cosmetics and other services within an integrated model.

Dr Wolgen's long track record speaks to a strongly focussed, competitive and conscientious professional who is known to persevere in meeting challenging business objectives. He holds an MBA from Columbia University, NY. Trained as a craniofacial surgeon, Dr Wolgen obtained his MD from the University of Utrecht, the Netherlands.



## KAREN AGERSBORG

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**Non-Executive Director,  
MD**

**Appointed 29 January 2018**

**Relevant Skills**

- pharmaceutical research & development, commercialisation
- relevant knowledge on melanocortins, clinical expertise
- commercial knowhow in U.S. pharmaceuticals
- general management
- experience in private company directorships

**Background**

Dr Agersborg is a clinical endocrinologist with diverse and extensive practice experience in Pennsylvania and New Jersey, U.S.A. She is Board Certified in both Internal Medicine and Endocrinology, Diabetes & Metabolism and holds specific expertise on the class of melanocortins.

Her career has included inpatient, outpatient, and hospitalist positions across a number of prominent medical institutions. She is an Associate Professor of Medicine, teaching medical students and residents in endocrinology. Dr Agersborg had an extensive career in managing commercial sales & distribution at Wyeth Pharmaceuticals (formerly Ayerst Laboratories).

Dr Agersborg has played an integral role in setting the CLINUVEL Group's U.S. regulatory and commercial strategy, resulting in the U.S. FDA's approval of SCENESSE® in October 2019 and the subsequent market launch in 2020.





## SUSAN (SUE) SMITH

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**Non-Executive Director,  
Dipl ClinRisk**

**Appointed 23 September 2019**

**Relevant Skills**

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

**Background**

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

Her past experience is now successfully translating into a diverse portfolio with non-executive director appointments. She is currently Board Chair of The Evewell Group Ltd which operates fully integrated medical centres of excellence dedicated to caring for, and protecting, all aspects of fertility and gynaecological health. Mrs Smith is also a Director of HCA Hope Fund UK, a charity providing financial aid and resources to its healthcare worker members to help them start rebuilding after an extended illness, injury, environmental disasters, or other extraordinary situations.

In the face of the ever-changing healthcare market Mrs Smith fosters first class relationships with a wide range of healthcare stakeholders to provide care of excellence to patients.



## MATTHEW PRINGLE

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**Non-Executive Director,  
BCom, FCPA, FCA, FGIA, FCIS, GAICD**

**Appointed 6 September 2024**

**Relevant Skills**

- governance & strategy
- corporate finance
- audit & assurance

**Background**

Mr Pringle brings over three decades of expertise in corporate finance, audit and assurance, governance, and strategic advisory. He served as a Partner at Pitcher Partners for more than 25 years, where he held key leadership roles including Head of the Corporate Finance Practice, Senior Audit Partner, and Lead of the Corporate Governance and Board Advisory Practice. His extensive experience spans advising boards and executive teams across a broad range of industries, with a focus on enhancing financial performance, governance frameworks, and strategic direction.

Mr Pringle currently serves as a non-executive director on a number of unlisted public, private and for purpose Boards, contributing his deep financial and governance acumen to both commercial and community-focused organisations.





## PEARL GRIMES

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**Non-Executive Director,  
MD**

**Appointed 6 September 2024**

**Relevant Skills**

- relevant knowledge on melanocortins
- clinical expertise
- clinical research & development

**Background**

Dr Pearl Grimes is a globally recognised dermatologist and a leading international authority on vitiligo and pigmentation disorders. She is the Founder and Director of the Vitiligo and Pigmentation Institute of Southern California where she treats patients from all over the world.

Dr Grimes is also the director of the Grimes Institute for Medical and Aesthetic Dermatology, where she expertly treats a wide range of dermatologic health and aesthetic concerns in patients of all ethnicities and skin types.

Dr Grimes also serves as a Clinical Professor of Dermatology at the David Geffen School of Medicine at UCLA and Chief Dermatologist for Versicolor Technologies. She has recently served as President of the Global Vitiligo Foundation and has authored over 175 publications.



## GUY VAN DIEVOET

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**Non-Executive Director,  
LLB, EMM, CEFA**

**Appointed 6 September 2024**

**Relevant Skills**

- corporate strategy
- finance & capital markets
- M&A

**Background**

Mr van Dievoet has significant experience in investment banking, specialising in M&A. In this capacity he has worked for leading financial institutions, including the Merchant bank of IndoSuez in Belgium, ABN-AMRO, Bank BNP Group, and as executive-director for MeesPierson. Over the years he has provided strategic support on corporate growth, structuring and buy-build approaches, and assisted companies listing on the Brussels and Amsterdam Stock Exchanges (EuroNext). ▲



# MANAGING DIRECTOR'S LETTER



Dear Shareholders,

As we reflect on our ninth consecutive year of revenues growth – exceeding A\$105 million (up 10% year-on-year) with a 9-year CAGR of 35% – we may pause and cherish the moment for not just the numbers, but the disciplined execution behind these results. With A\$52 million EBIT (54% margin) and A\$36 million NPAT, we’ve demonstrated the power of our integrated, capital-efficient model: expenses grew at a 20% CAGR over this period, allowed by a surge of revenues at 35%.

### The Foundation We’re Building

Unlike traditional pharma companies that outsource critical functions, we’ve made intentional investments to vertically integrate talent and technology. From organic chemists to data engineers, we’ve assembled a team capable of end-to-end drug development – a rare feat in our industry.

This year, we advanced our three-pillar infrastructure:

- Clinical Trial Scalability:** Automated payment systems and risk-based data management to minimise variability.
- Manufacturing Control:** Progressed ACTH (NEURACTHEL®) for underserved neurological disorders (targeting 2026 U.S. filing).
- Formulation Innovation:** Pioneered melanocortin delivery alternatives and small-molecule technologies in our Singapore Research, Development & Innovation Centre.

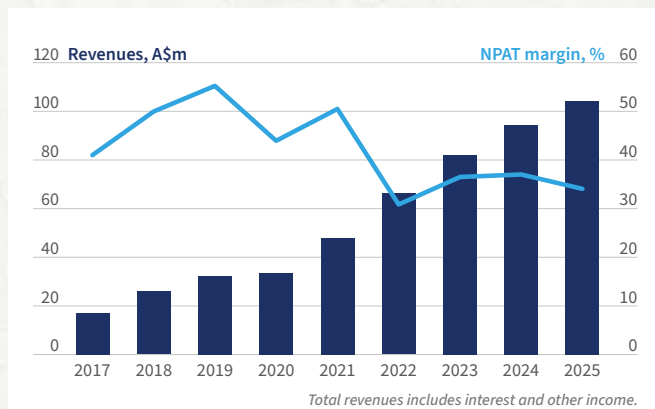
The “CLINUVEL Academy” initiative – sponsoring our staff to executive education, MBAs, law degrees, and specialised training – ensures we cultivate the leadership this unique model requires.

### FY2025 in Review: Strategic Discipline Meets Execution

- From A\$7 million (pre-commercialisation) to A\$105 million in nine years,**
  - a testament to operational leverage and market expansion.
- we have achieved sustainable profitability,**
  - NPAT margin stabilised around a four-year average of 35% despite deliberate R&D ramp-up.
- with zero dilution, zero debt,**
  - cumulative NPAT of A\$202 million, FY2017-2025, entirely self-funded.

The result? EBIT margin in FY2025 remains robust at 54% (57% in FY2024), proving our investments are yielding returns. Early Q1 of FY2026, data shows accelerating demand for SCENESSE®, validating a commercial strategy.

**Total revenues grew 14.6x over 9 years, while maintaining >30% NPAT margins**





### Our Differentiated Approach

While peers chase research growth at any cost, we adhere to risk-adjusted capital allocation:

- halted non-core programs: suspended xeroderma pigmentosum and stroke research to focus on high-probability programs (vitiligo, ACTH).
- countercyclical stewardship: maintained R&D buffers to absorb regulatory turnaround and delays – a rarity in a cash-burning sector.
- concentric expansion: all pipeline candidates (SCENESSE®, PRÉNUMBRA®, NEURACTHEL®, PhotoCosmetics) leverage our core peptide/polymer expertise, de-risking development.

I do not wish our teams to bet on science, rather to build on it. For every undesired outcome in scientific experiments and clinical trials, we find two advanced learnings to be gained. In this manner, we progress to markets which are economically viable and scalable. Quitting is simply not in our vocabulary, and this virtue preserves shareholder value.

### The Road Ahead: Diversification With Discipline

Our Board and management are to be credited for the courage and vision to commit to a pipeline strategy, unconventional yet deliberate:

PRODUCT	MOLECULE	INDICATIONS	MARKET POTENTIAL
SCENESSE®	Afamelanotide	EPP, Vitiligo	US\$790+ million
PRÉNUMBRA®	Afamelanotide	Acute Diseases	TBD
NEURACTHEL®	ACTH	MS, Infantile Spasms	US\$150 million
PhotoCosmetics	Small Melanocortin	Photoprotection	>US\$50 million

### Turning Regulatory Challenges into Therapeutic Breakthroughs

At CLINUVEL, we view each regulatory hurdle not as a barrier, but as a catalyst to innovate – pushing us to develop smarter strategies and uncover new pathways to deliver life-changing therapies. This is not an empty slogan, but actually how we live our professional lives.

### A European Paediatric Journey with SCENESSE®

When the EMA declined to approve SCENESSE® for children in 2025, despite impeccable safety data, our teams refused to accept “no” as the final answer based on data and science. Instead, we:

- pioneered compassionate access programs that have already transformed lives;
- treated our first nine-year-old EPP patient, enabling her to leave her homebound existence and attend school; and
- completed a comprehensive adolescent study (12+ years) with plans to resubmit a revised dossier to the EMA to seek a full approval.

### A Medical Community is Speaking – Loudly

European insurers are already reimbursing SCENESSE® for paediatric EPP cases *based on physician demand* – a powerful endorsement of both medical necessity and our persistent advocacy.

Our team embodies what it takes to succeed in this complex landscape, based on relentless execution, and the difference we have made:

- disproportionate persistence – we outlast the challenges;
- strategic creativity – we find alternative pathways when doors close; and
- resource commitment – we fund multiple approaches simultaneously.

Where others see dead ends, we find detours that ultimately become alleys to approval.

### **Vitiligo Program: Clinical Momentum Translates to Commercial Opportunity**

The past year marked a pivotal inflection point for our vitiligo program, as we successfully completed enrolment of 210 patients in the CUV105 Phase III trial – a milestone that validates both our clinical execution capabilities and the growing recognition of SCENESSE® among global dermatologists.

### **Why This Matters: Beyond the Trial Data**

#### **1. Operational Excellence**

- Drs Teng and Rodenburger demonstrated world-class trial management, coordinating multi-centre studies across three continents with precision. There are rich learnings from the CUV105 clinical study and its recruitment strategy, which will bear fruit for years to come.
- this infrastructure now serves as the foundation for our pivotal CUV107 study – accelerating timelines and reducing costs.

#### **2. Pre-Commercial Success**

- 104 centres have been trained and accredited in North America, targeting 120 by the end of 2025, creating a ready prescriber network for future launches.
- our presence at the American Academy of Dermatology Meeting (in Orlando) drew unprecedented engagement, with a disruptive exhibit strategy that will be replicated in Denver in 2026.

#### **3. Brand Building with Targeted Precision**

- started the runway to “household brand” status in photomedicine among key opinion leaders, despite a lean sub-10% marketing budget.
- converted clinical credibility into real-world demand through:
  - peer-to-peer physician education;
  - digital engagement amplifying trial results; and
  - strategic presence at tier-1 dermatology forums.

### **Why Investors Should Be Energised**

1. multiple shots on goal – our multi-pronged approach de-risks the regulatory process.
2. market demand outpacing approvals – insurers are voting with their feet.
3. proven ability to navigate complexity – each challenge makes our teams smarter.
4. ability to finance research, development & innovation.
5. reserves to absorb and face unexpected set-backs.

The coming year will see us take our hard-won paediatric data back to regulators – armed with even more evidence, even more compelling physicians’ experiences, and even greater determination to make SCENESSE® available to every EPP patient and parent who demands it.

### **A Letter to Shareholders: Strength Through Unity**

As we close this chapter and look to the horizon, I am filled with profound conviction – not just in our strategy, but in the coherent and driven team executing it.

The newly formed Board stands united in a vital truth: strategic vision and shareholder returns are partners, not opponents. While all biotechs are seeking to climb to their respective mountain summits, our debt-free resilience, consistent profitability, and vertically integrated model have positioned us not merely to endure – but to acquire, innovate, and lead the ascendance where others withdraw.



### Leadership Forged in Opportunity

This year marked an important evolution in our corporate stewardship:

- Mr Lachlan Hay has embraced his role with strategic clarity – and as he completes his legal studies in FY2027, we gain yet another lens through which to sharpen our governance.
- CFO, Mr Peter Vaughan mastered his first full year guiding our financial helm, ensuring growth and discipline remained inseparable.
- Dr Dennis Wright led the advancements in research & development in melanocortins and formulations.
- Dr Linda Teng led us to a new chapter of seeding a North American market in vitiligo, overseeing training & accreditation of 104 centres.
- Dr Emile Rodenburger reinstated herself as clinical executive putting all wheels in motion to deliver a first advanced study in vitiligo.
- Mr Malcolm Bull, Head of IR, expanded our sell-side coverage to 10 analysts, bridging the gap between our results and market recognition.
- Dr Azza Hamila led global inspections and audits, and managed manufacturing and regulatory queries.
- Dr David Solomon joined as head of regulatory affairs, building on the expertise of Dr Rose Quadbeck-Diel.
- Mrs Antonella Colucci continued to lead the expansion of SCENESSE® in Europe and Latin America.
- Our Board, enriched by three new voices, has turned rigorous debate into wiser decisions – proving that diversity of thought fortifies, not fractures, progress.
- Mr Lilian Bougy stepped in seamlessly to become European General Manager.
- The mix of new and incumbent managers and staff worked tirelessly to achieve current results.

### To You, Our Shareholders

Most of you are not passive investors – you are owners of an enterprise built to last. My gratitude runs deep, as does my alignment: like you, I am a major shareholder, with personal capital tethered to our long-term success.

The years ahead will reward those who combine:

- patience to ignore short-term noise;
- precision in allocating every dollar; and the
- courage to scale the mountain peaks ahead for the benefit of patients and stakeholders, alike.

We have chosen the harder path – a meaningful one. And together, we will prove its worth.

With resolve,



Philippe Wolgen  
Managing Director  
CLINUVEL Group ▲







A full-page background image featuring a person rappelling down a large, textured rock face covered in moss. The person is positioned on the right side of the frame, suspended by a rope. The sky is a clear blue with wispy white clouds. Below the rock face, a rocky hillside with green vegetation is visible.

# OPERATING REVIEW



## Distribution of SCENESSE®

The key activities for FY2025, initiatives and plans in the distribution of SCENESSE® for EPP are detailed below:

ACTIVITY	REVIEW OF FY2025	PLANS – FY2026 AND BEYOND
<b>Existing Regions of Distribution:</b> <ul style="list-style-type: none"> <li>European Union</li> <li>U.S.A.</li> <li>Switzerland</li> <li>Canada</li> <li>Israel</li> </ul>	<ul style="list-style-type: none"> <li>Global growth in patient numbers and doses of SCENESSE® administered, now &gt;18,500 implants in EPP.</li> <li>North American Specialty Centers increased to 104 – 100 in the U.S.A. and 4 in Canada – as of 30 June 2025.</li> <li>Over 100 U.S. insurers maintained.</li> <li>Continued to treat patients in Canada under a special access scheme.</li> <li>Submission to Health Canada for marketing authorisation, filed October 2024 and validated December 2024.</li> </ul>	<ul style="list-style-type: none"> <li>Until new indications are approved, the distribution of SCENESSE® for EPP is the driver of the revenues and cashflows of the business.</li> <li>The focus is to maintain growth across patients, doses and treatment centres, whilst maintaining relationships with physicians and insurers.</li> <li>Targeting 120 Speciality Centers in North America by the end of 2025.</li> <li>Health Canada decision expected Q4 2025.</li> </ul>
<b>Access to New Jurisdictions</b>	<ul style="list-style-type: none"> <li>Colombia – efforts to identify EPP patients for treatment proceeded with partner, Valentech.</li> <li>Argentina – a distribution agreement was signed in January 2025 with Diligens Salud SA.</li> </ul>	<ul style="list-style-type: none"> <li>Treatment of first patients in Colombia and Argentina is expected in 2026.</li> <li>Access is planned to other jurisdictions.</li> </ul>
<b>Increased Dosage Frequency EU</b>	<ul style="list-style-type: none"> <li>Dosage – discussions progressed with the EMA to increase the recommended maximum number of doses of SCENESSE® per year in the EU. The drug's European label currently includes a "recommended maximum" of four implants per annum compared to the FDA's approval to allow treatment every two months, which translates to year-round photoprotection from six doses per annum. Approval of the EMA would harmonise the approved label of SCENESSE® across these jurisdictions.</li> </ul>	<ul style="list-style-type: none"> <li>The EMA's decision on dosage frequency is expected in 2025.</li> </ul>
<b>Treatment of Adolescents</b>	<ul style="list-style-type: none"> <li>This initiative was advanced by the completion of study CUV052 which showed adolescents aged 12 to 17 years experienced similar safety and controlled-release profiles as adult EPP patients.</li> </ul>	<ul style="list-style-type: none"> <li>The results of CUV052 will be submitted to the EMA for consideration of the treatment of adolescent EPP patients in the first half of FY2026 – a cohort of adolescent and paediatric patients continues to receive treatment, fully reimbursed by health insurers, under the care of expert physicians in Europe.</li> </ul>
<b>Publications</b>	<ul style="list-style-type: none"> <li>Data on the experience of EPP patients was published during the past year:               <ul style="list-style-type: none"> <li>Long-term safety and effectiveness data from the use SCENESSE® in EPP was presented to the European Academy of Dermatology and Venereology Spring Symposium in Prague, Czech Republic, in May 2025. Based on EPP patients treated in Italy since 2008, SCENESSE® treatment has resulted in positive clinical benefits, alleviating phototoxic symptoms.</li> <li>The positive experience of a German cohort of EPP patients treated with SCENESSE® in the European post-authorisation safety study was published in March 2025 in the Photodermatology, Photoimmunology and Photomedicine journal.</li> </ul> </li> </ul>	



# Pharmaceutical Product Development & Clinical Programs

## Clinical team restructured and clinical programs prioritised

In a welcome return to the Group, Dr Emilie Rodenburger was appointed Director, Global Clinical Affairs in April 2024. By August, she had redesigned the clinical affairs team, integrating clinical operations, medical monitoring, and data sciences into a streamlined structure capable of delivering on larger, more complex global programs. Dr Rodenburger's journey – from building a foundation and honing her skills with peers to

returning in a leadership capacity – perfectly embodies CLINUVEL's values of growth and investment in talent.

The clinical program, spanning multiple conditions of the skin and brain, was prioritised in November 2024 to focus on programs which offered the highest probability of clinical and commercial success in more the immediate and largest addressable markets with the highest need. The Company is now focused on afamelanotide for porphyrias

(EPP and VP) and vitiligo, and ACTH for a range of indications. The programs in DNA Repair (xeroderma pigmentosum), stroke, and Parkinson's disease were suspended, with a commitment to finish the studies already commenced and to report on their results.

## Key activities

The key activities for the year and plans for FY2026 and beyond are detailed below:

ACTIVITY	REVIEW OF FY2025	PLANS – FY2026 AND BEYOND
NEURACTHEL®	<ul style="list-style-type: none"> <li>The development of instant and modified release formulations and work on manufacturing validation continued in FY2025.</li> </ul>	<ul style="list-style-type: none"> <li>An update on the status of NEURACTHEL® is planned by the end of 2025.</li> <li>Targeting 2026 U.S. filing</li> </ul>
Variegate porphyria (VP)	<ul style="list-style-type: none"> <li>The results of the Phase II VP study, CUV040, were presented to the International Congress of Porphyrins and Porphyrias in Pamplona, Spain in September 2024. SCENESSE® was shown to reduce clinical symptoms and improve patients' quality of life.</li> </ul>	<ul style="list-style-type: none"> <li>CUV053, a pivotal study on SCENESSE® for VP is planned to commence in 2026.</li> </ul>
Vitiligo	<ul style="list-style-type: none"> <li>Recruitment of patients for the Phase III study, CUV105 commenced October 2023 and completed May 2025, ahead of extended June 2025 completion date.</li> <li>The study was fully recruited across 37 clinical sites spanning the U.S., Europe, and Africa.</li> <li>The results of the Phase II pilot monotherapy study, CUV104, were announced in June. The study was conducted at the suggestion of regulatory authorities to assess the safety and efficacy of afamelanotide as a monotherapy in patients with darker skin types (Fitzpatrick IV–VI). The study results confirmed adjunct NB-UVB phototherapy is needed with SCENESSE® to activate repigmentation in vitiligo. Given this, no further studies are planned in afamelanotide as a monotherapy for vitiligo patients.</li> </ul>	<ul style="list-style-type: none"> <li>The last patient recruited to CUV105 will complete treatment in Q4 2025. After the follow-up period, data analysis and cleansing, results of the study will be available in the second half of 2026.</li> <li>In the second half of 2025, CLINUVEL will liaise with regulators and seek their feedback on the progress of the study to date and subsequently finalise the design of the next Phase III study, CUV107.</li> <li>The design and commencement of recruitment of CUV107 is planned by the end of 2025 / early 2026. There will be a one-year recruitment period, six-month treatment and follow-up periods. After data analysis and cleansing, results will be available.</li> <li>Submission of the dossier to the FDA is expected to occur following completion of the clinical program.</li> </ul>
Stroke	<ul style="list-style-type: none"> <li>Results in the Phase II stroke study, CUV803 were announced in March 2025. Nine patients treated with PRÉNUMBRA® Instant tolerated the drug well and 8 out of 9 demonstrated functional improvement (at day 42), whilst 6 out of 9 showed radiological improvement or stability. These results are consistent with the previous CUV801 study and provide a solid basis for resuming the arterial ischaemic stroke program in the future.</li> </ul>	<ul style="list-style-type: none"> <li>The stroke and DNA repair programs were suspended in November 2024 to focus on EPP initiatives, the VP and vitiligo clinical programs, and the PhotoCosmetic product range.</li> </ul>
DNA Repair	<ul style="list-style-type: none"> <li>Study CUV151, evaluating the DNA-repair capacity of afamelanotide on the skin of healthy volunteers exposed to ultraviolet radiation, was presented at the British Association of Dermatologists 104th Annual Meeting, held in Manchester in July 2024. The RNA sequencing results indicate that critical genes expressed after UV-damage can be positively affected with afamelanotide treatment. For the general population, and particularly those with fair skin susceptible to sunburn, the results indicate that afamelanotide can reduce oxidative damage and inflammatory reactions after sun exposure and skin damage.</li> </ul>	





## PhotoCosmetic Products

ACTIVITY	REVIEW OF FY2025	PLANS – FY2026 AND BEYOND
<b>Protect</b>	Work on the PhotoCosmetic product range continued in FY2025: <ul style="list-style-type: none"> <li>• Preparations have been made for the launch of the next generation “Protect” polychromatic product, CYACÉLLE Radiant.</li> </ul>	<ul style="list-style-type: none"> <li>• Media outreach for launch of CYACÉLLE Radiant is planned for the second half 2025.</li> </ul>
<b>Preserve and Bronze</b>	<ul style="list-style-type: none"> <li>• Formulation and manufacturing development work on M-lines, “Preserve” and “Bronze” continued.</li> </ul>	<ul style="list-style-type: none"> <li>• Launch of the M-lines, “Preserve” and “Bronze” is planned for 2026. ▲</li> </ul>



# FINANCIAL REVIEW





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## Financial Review

CLINUVEL has delivered another exceptional year of performance, achieving record revenues, the ninth consecutive year of profitability, and a \$38 million increase in net assets.

Our consistent financial growth reflects the Company's disciplined strategy towards year-on-year improvement, supported by the continued advancement of our clinical pipeline, providing a strong financial foundation to sustain, build and expand future revenue streams.

The SCENESSE® program continues to scale, reaching more patients globally through an increased number of qualified and trained treatment centres supported by increased outreach and marketing initiatives to amplify our patient support, market presence and sales. This broader visibility not only supports product uptake but also enhances clinical trial recruitment, particularly for our vitiligo study, paves the way for the upcoming

launch of our PhotoCosmetics range, and increased company visibility to investors globally.

CLINUVEL's industry presence has been highlighted by our collaboration with global patient and professional foundations supporting communities in vitiligo, porphyria, and rare disorders, which culminated with our major investment in our custom-built Pavilion of Photomedicine at the American Academy of Dermatology Annual Meeting held in Florida in March 2025.

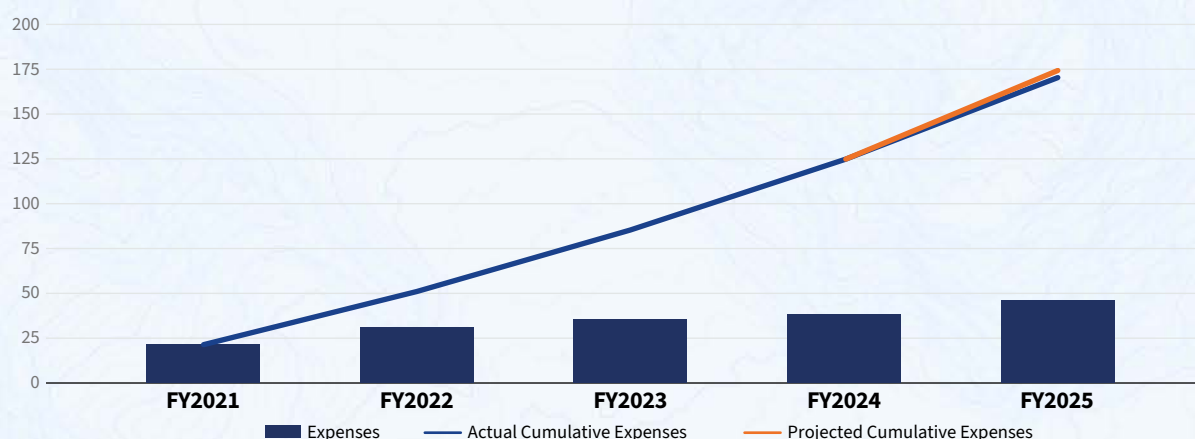
We continue to reinvest in our key strategic assets, namely our people, clinical programs, and infrastructure to build a diversified and sustainable business. In the context of ongoing geopolitical uncertainty, we remain prudent in the deployment of our capital to protect shareholder value while ensuring sufficient resources are delivering projects without reliance on external capital or dilutionary events.

In 2021, our release of our five-year \$175 million strategic expenditure plan (excluding CBM costs) was met with skepticism, particularly within the biotechnology sector where long-term predictability is uncommon. However, CLINUVEL has exceeded expectations by delivering its plan with a total spend of \$171.2 million, \$3.8 million under budget, while consistently delivering year-on-year growth in revenue, profit, and assets.

This achievement reflects a clear strategic vision and high performance of our team, whose ongoing development and success are integral to our culture. At CLINUVEL, our people are our most valuable asset and we're committed to incentivising, retaining, and nurturing identified talent.

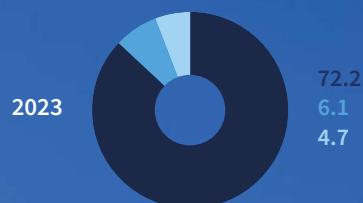
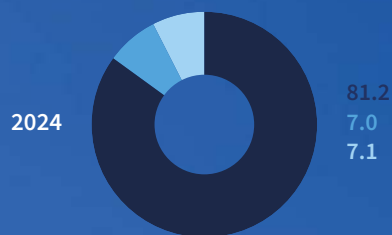
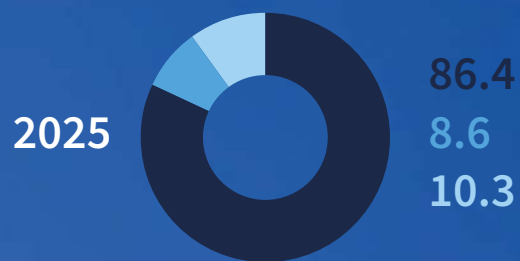
During FY2025, we expanded our teams across operations, clinical development, and communications, branding, and marketing (CBM), ensuring continued alignment and delivery of our growth objectives.

## FIVE-YEAR EXPENSES TO 30 JUNE 2025 (A\$m)



*Actual and projected expenses exclude Communications, Branding & Marketing (CBM) expenses.*

## GROWING REVENUES (A\$m)



Commercial Sales  
 Special Access Scheme Reimbursements  
 Other Income

## Revenue Performance

CLINUVEL reported a 10% increase in total revenue (including interest and other income) for FY2025 for our ninth consecutive year of revenue growth.

Since launching SCENESSE® in 2016, the program has achieved a compound annual growth rate (CAGR) of 35%. Over 18,500 SCENESSE® implants administered to EPP patients globally, demonstrating the sustained success and safety of the program.

Commercial sales, including Special Access Scheme reimbursement revenues, increased by 8% to \$95 million, contributing to total FY2025 revenue of \$105.3 million, up \$10 million from FY2024.



## CLINUVEL'S PERFORMANCE WAS STRONG ACROSS A RANGE OF KEY METRICS

9<sup>th</sup>

**CONSECUTIVE YEAR  
OF REVENUE GROWTH,**  
with a Compound Annual Growth  
Rate (CAGR) of 35%

9<sup>th</sup>

**CONSECUTIVE YEAR  
OF NET PROFIT**

8<sup>th</sup>

**CONSECUTIVE  
ANNUAL DIVIDEND**  
fully franked

10%

**INCREASE IN TOTAL  
REVENUES AND INCOME**  
to \$105.3m

18%

**INCREASE IN  
TOTAL ASSETS**  
to \$271.8m

19%

**INCREASE IN NET ASSETS**  
to \$240.8m

1%

**INCREASE IN BASIC  
EARNINGS PER SHARE**  
to \$0.72 per share

19%

**INCREASE IN NET  
TANGIBLE ASSETS**  
backing per share to \$4.77 per share

## SCENESSE® Market Expansion

The global growth of SCENESSE® sales was driven by increased patient numbers, more frequent dosing, and the expansion of trained and accredited centres. We are well into the second phase of expanding the number of trained and accredited centres across North America which currently

represents 104 centres, supported by over 100 insurers. We remain on track to reach 120 centres by the end of December 2025. Our patient liaison teams continue to play a crucial role in supporting healthcare professionals and patients with treatment access, compliance, distribution logistics, and

navigating insurance governmental and private insurer frameworks.

We were also pleased to execute a distribution agreement in January 2025 with Diligens Salud SA, part of the Scienza Group, for SCENESSE® in another new region, Argentina.

## Other Income

CLINUVEL strengthened its cash reserves with a \$40.2 million increase (22%) in FY2025 reaching a combined \$224.1 million in cash and term deposits. Strong yields from its A\$ and US\$ term deposits generated \$9.4 million in interest income, up 29% from the prior year.

In anticipation of the potential decline in interest rate yields, we elected to extend the average maturity length of our term deposits which now have an average of 309 days with a weighted average yield of 4.70%.

## Expense Management

In line with our expectations, total expenses for FY2025 increased by \$9.1 million (20%) to \$53.7 million reflecting the planned investments we outlined that we'd be making across key areas to support strategic expansion. This expansionary expenditure continues to be closely monitored to ensure it has strategic alignment to value creation and shareholder returns.

### Personnel Expenses

Increased by \$5.9 million (31%) due to headcount growth, particularly across clinical, regulatory, and communications. During the financial year we also bolstered the Board when we welcomed three new Directors each with their own deep intrinsic knowledge and skill in their respective disciplines.

Our employee attract, retain, and reward strategy includes developing an individualised career, performance bonus, and equity-based incentive plan tied to strategic operational targets that align employee goals with that of the organisation to drive company-wide success.

### Materials and Related Expenses

Inclusive of changes in inventories, this item increased by 9% to \$4.5 million during FY2025 as our team, primarily at our Singapore RD&I Centre, continue their investigative development works surrounding new formulations and delivery innovations for NEURACTHEL<sup>®</sup> ACTH, PRÉNUMBRA<sup>®</sup>, and our PhotoCosmetics range.

### Distribution Expenses

Increased by 10% to \$4 million primarily being a direct result of our higher SCENESSE<sup>®</sup> sales volumes

throughout our distribution chain. Throughout the year we investigated and implemented operational efficiencies across our global supply and distribution chains, particularly in light of ever-changing geopolitical conditions and lighted our distribution footprint in both Europe and the U.S..

### Corporate, Finance & General Expenses

These costs remained tightly controlled with only a marginal increase despite growing business activity. This control is the result of a series of operational, administrative and financial process cost reviews as well as system optimisation and advancements.

### Legal, Insurance & IP

Decreased 42% to \$1 million resulting from a reduced level of legal activity during the year and a thorough review of our insurance programs leading to optimised insurance solutions.

### Communications, Branding & Marketing (CBM)

CBM expenditure doubled to \$4.4 million as expected, as we invested in global brand visibility to attract a wider audience. Shareholders and investors have no doubt witnessed CLINUVEL's increased presence across numerous platforms including online and print media, complemented by our physical presence at key industry events over the past 12 months. We have also sponsored and supported numerous key industry and global community events hosted by vitiligo, porphyria and other rare disease foundations, as well as supported organisations who perform research in these areas to support those affected by rare disorders.

Our key investment in this area was in March this year with our custom-built 4,800 sq ft Pavilion of Photomedicine at the prestigious American Academy of Dermatology Annual Meeting in Florida, U.S.A.. This five-day event was attended by more than 20,000 physicians, clinicians, academics and industry representatives who were all captivated and enthralled by CLINUVEL's presence and impact at the event.

As foreshadowed at the end of the last financial year, CLINUVEL has extended its branding presence to distinguish itself from a traditional pharmaceutical company in translating its core pharmaceuticals technology in melanocortins to PhotoCosmetics, creating synergistic revenue opportunities. Our P-Line PhotoCosmetics range will soon commence a pre-marketing launch phase ahead of a full commercial launch in 2026.

### Clinical and Non-Clinical Development

In line with our anticipations, our Clinical and non-clinical development expenses increased by \$5 million to \$7.4 million, representing a 215% increase from FY2024. This is intrinsically linked to the advancement of our core programs, most notably our Phase III CUV105 study for treatment of vitiligo which was fully recruited in May 2025. Our increased expenditure also reflects our efforts in other clinical study programs, including the CUV104 Phase II pilot monotherapy study and the CUV803 Phase II stroke study.

Formulation and manufacturing development work also continued across our PhotoCosmetics M-lines, "Preserve" and "Bronze" product ranges.



## Profit Outcomes

For the fiscal year, the Company reported a Net Profit Before Tax of \$51.6 million, an increase of \$0.87 million (2%), on the prior year. This growth highlights our effective financial stewardship and success in achieving strategic growth objectives whilst maintaining stringent expenditure control.

The Net Profit After Tax of \$36.2 million reflects a 2% increase (\$0.54 million) on the prior year. The significant fall in the Australian dollar during the year gave rise to a larger deferred income tax position from unrealised gains made on international foreign currencies when translating them back into

Australian dollars for IFRS accounting treatment purposes. Whilst this additional deferred tax resulted in a \$1.47 million increase from prior year, there was no change to the overall organisational tax rate. The Company did, however, achieve a \$1.13 million (7%) drop in current tax payable from 31% to 28% as a direct result of tax optimisation strategies implemented.

The potential income tax improvement was somewhat offset by the organisation achieving a combined group revenue of greater than \$100 million this financial year whereby, under Australian Taxation Law, the Company is required to

now pay tax on its accrued unearned revenues on an accrual basis from term deposits held, instead of on a receipts basis when the interest earned from the term deposit is paid. The change in treatment effectively brings forward the cash tax outflow to this year, instead of next year as was previously the case.

Throughout the year, the Company has taken advantage of its scaled workforce, infrastructure, and capacity to drive the significant growth of revenues, assets and clinical programs. With the exception of a couple of areas within the business, scale has now reached its optimal level to support our current programs.

## Balance Sheet Strength

### Cash Reserves and Liquidity Position

During the financial year, our balance of cash reserves, comprising cash and cash equivalents and cash held in term deposits, increased by \$40.2 million (22%) to \$224.1 million compared to FY2024. This growth stemmed from both operational activity net inflows and the strategic decision to increase the average length of the Company's term deposits to a weighted average return of 4.70% over an average term of 309 days. There were no cash inflows from debt or equity financing and for the 20th consecutive year that the Company has remained debt-free.

The returns from prudent liquidity management directly support operational expenditures as well as the extensive commercial, clinical,

and pharmaceutical programs into new revenue streams.

### Balance Sheet and Financial Strength

Maintaining a financially sound Balance Sheet remains of strategic importance to CLINUVEL. This is evidenced by a \$40.6 million increase in total assets and just a \$2.8 million increase in total liabilities, being trade and other payables, reflective of the significant increase in operational activities. CLINUVEL experienced a \$37.8 million (19%) improved net asset position to \$240.8 million and an improved debt-to-equity ratio from 14% in FY2024 down to 13% in FY2025 with no external sources of debt funding.

CLINUVEL's Balance Sheet will not only permit the Company to continue exploring strategic M&A opportunities but also ensures the organisation

can deliver on its strategic product development and clinical programs without being at the mercy of the markets as so many other biotechnology companies have been, particularly in the current times of geopolitical uncertainty.

This non-reliance on external funding to support operations protects, preserves long-term shareholder value avoiding the need for dilution at considerable discounts as is the familiar model of traditional biotechnology companies.

We are actively pursuing several strategic acquisitions and investments that align with growth and diversification objectives, and we anticipate being able to make some positive announcements about these developments in the coming period.

## Operating Cash Flows

Operating cash inflows were primarily driven by global receipts from SCENESSE® distribution, totaled \$93.8 million, up 12% from FY2024, and cash inflows from interest income

earned on term deposits remained steady at \$7.5 million.

Operating cash outflows rose to \$44.4 million largely due to

increased personnel and supplier payments whilst income taxes paid of \$15.7 million was in line with the prior year.

## BALANCE SHEET METRICS

TRADE RECEIVABLES  $\uparrow 5\%$

INVENTORIES  $\downarrow 17\%$

CASH RESERVES  $\uparrow 22\%$

TRADE PAYABLES  $\uparrow 40\%$

INCOME TAX PAYABLES  $\downarrow 8\%$

NO DEBT FINANCING

NO EQUITY RAISED SINCE 2016



## Returning Value To Shareholders

In FY2025, we distributed another \$2.5 million in dividends to shareholders adding to the \$0.252 million paid during the year to buy back shares, resulting in the repurchase of 17,100 shares to enhance shareholder value by reducing dilution.

Underscoring CLINUVEL's commitment to delivering sustainable longer-term returns for shareholders, the Board has declared an eighth consecutive annual dividend, unchanged at \$0.05 per share, fully franked.

## SUMMARY

CLINUVEL continues to strengthen its branding footprint to reach more people across the globe whether they be potential patients, physicians, customers or investors, all whilst delivering on its strategic investments and providing its shareholders with strong returns.

The CLINUVEL team is proud of the positive impact our work is having on patients' lives as we redefine the biotech narrative by balancing innovation with fiscal discipline in the pursuit of creating long-term value for all stakeholders. ▲







# PLANS 2026 AND BEYOND

## OBJECTIVE

Drawing on expertise in the melanocortin family of peptides and photomedicine, diversify towards a sustainable biopharmaceutical group with multiple products treating multiple indications

## FOCUS

As announced in November 2024, the priority is on:  
*Afamelanotide for porphyrias (EPP and VP) and vitiligo*  
*ACTH for a range of indications*  
*PhotoCosmetic products*

Plans in each of these areas are outlined in the Operating Review.

The strategy is being executed using an integrated business model with many of the key functions of a biopharmaceutical undertaken in-house.

### **Engaging Relevant Global Communities**

Investor Relations will continue to communicate CLINUVEL's compelling investment proposition through a range of channels, including conference presentations, investor briefings, group and one-on-one meetings, social media, webinars and podcasts.

Activities to advance the recognition of CLINUVEL's story, brand and innovation, particularly to health-conscious households, will continue. CLINUVEL will present to numerous investor conferences and has already commenced planning its participation in the AAD Meeting to be held in

Denver, Colorado, in March 2026. These activities will be complemented by digital campaigns by CLINUVEL Ambassadors, social media targeted advertisements, and articles in tier one media outlets.

### **Manufacturing**

CLINUVEL is committed to better integrating its supply chain. The Company has communicated this capability could be built in-house or progressed through strategic acquisitions.

### **Growth Through Acquisition**

Over the course of the 2020s to date, CLINUVEL has communicated its intention to grow inorganically through acquisition, conditional on an appropriate target being identified and satisfactory due diligence completed.

### **Upgrade of American Depositary Receipts, Level I to Level II & Nasdaq Listing**

On 22 August 2025, the Company announced its intention to upgrade its American Depositary Receipt program in the U.S.A from Level I to Level II, listed on Nasdaq. This is expected to occur by the end of 2025, subject to successful completion of review by the Securities Exchange Commission and satisfaction of further listing requirements. The initiative reflects the significance of CLINUVEL's American shareholder base at 28% of issued capital and increasing interest of potential U.S. institutional investors as CLINUVEL's profile rises from its activities in EPP and vitiligo, and the relationship building efforts of Investor Relations. The Company is 65% owned by foreign entities versus 35% Australian. CLINUVEL's visibility in the U.S., trading access and investor engagement will be enhanced. No capital raising is proposed and CLINUVEL's primary ASX listing will remain unchanged. ▲



# SUSTAIN

CLINUVEL acknowledges the importance of an integrated and consistent approach to the management of Environmental, Social and Governance (ESG) risks and strives to improve all aspects of responsibility for positive outcomes, year on year.



# ABILITY

## CLINUVEL ESG FRAMEWORK

### CLINUVEL VALUES

#### SOCIAL

##### FAIRNESS AND EQUITY

- Human rights
- Freedom of association
- Equal opportunity
- Value diversity
- Work-life balance
- Training and education
- Supplier standards

#### ENVIRONMENTAL

##### CONSCIOUS OF OUR WORLD

- Recognise climate change
- Energy management
- Safe and responsible materials handling
- No adverse impact on global objectives
- Supplier standards

#### GOVERNANCE

##### RESPONSIBILITY AND COMPLIANCE

- Honesty and integrity
- Corporate governance
- Compliance
- Ethics
- Supplier standards



## CLINUVEL ESG framework and governing principles

The Company's values (outlined on pages 10–11) underpin the practices of the Company and its employees and align to key ESG tenets.

CLINUVEL adheres to the United Nations (UN) Global Compact ten principles of sustainability which cover human rights, labour standards, the environment, and anti-corruption.

## UN GLOBAL COMPACT TEN PRINCIPLES OF SUSTAINABILITY

### HUMAN RIGHTS

- 
- 1** Businesses should support and respect the protection of internationally proclaimed human rights
  - 2** Make sure that they are not complicit in human rights abuses

### LABOUR STANDARDS

- 3** Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining
- 4** The elimination of all forms of forced and compulsory labour

## ANTI-CORRUPTION

**10** Businesses should work against corruption in all its forms, including extortion and bribery

**9** Encourage the development and diffusion of environmentally friendly technologies

**8** Undertake initiatives to promote greater environmental responsibility

## ENVIRONMENT

**7** Businesses should support a precautionary approach to environmental change

**5** The effective abolition of child labour

**6** The elimination of discrimination in respect of employment and occupation

The Ten Principles of the UN Global Compact are derived from the Universal Declaration of Human Rights, the International Labour Organization's Declaration on Fundamental Principles and Rights at Work, the Rio Declaration on Environment and Development, and the United Nations Convention Against Corruption.



## Environmental

CLINUVEL is conscious of the impact of the activities of humanity on the environment and takes a responsible approach to managing its impact on the environment.

CLINUVEL embraces the UN definition of sustainability to meet the needs of the present without compromising the ability of future generations to meet their own needs. Currently, CLINUVEL's activities are conducted by a workforce of about 100 and the Company does not manufacture its products. The direct impact of CLINUVEL's activities on the environment is therefore assessed as low. Reflecting this, CLINUVEL's current focus is on qualitative initiatives to manage its impact on the environment.

Management is accountable to ensure environmental responsibility across all activities and specifically:

- handling and storage of materials and products;
- sourcing of key inputs and products from contract manufacturers who adhere to World Health Organization (WHO) Good Laboratory Practice (GLP) and the principles of current Good

Manufacturing Practice (cGMP), and responsible ESG practices in general;

- conservation of resource and energy use in each of our offices;
- minimisation and management of waste, particularly in our Singapore based Research, Development & Innovation Centre; and
- responsible product packaging.

We are committed to reducing our operational waste and our recycling program is being enhanced by moving towards paperless processes in our operational functions.

With regard to product packaging, CLINUVEL adheres to the environmental standards expected of cosmetic products in the European countries of distribution of CYACÉLLE. In France, for example, CLINUVEL is a member of CITEO which adheres to the principle of Extended Producer Responsibility for household paper and packaging to minimise the waste products produce. A positive start has been made as the primary and secondary product packaging of CYACÉLLE is glass and carton, respectively, and only the cap is made of plastic.

In addition to these initiatives, a split home / office working week in most locations serves to minimise the carbon footprint of employees. Furthermore, employees do not travel frequently to see stakeholders in person and responsibility is vested in senior management to review and approve travel within countries of operation and internationally, to ensure sufficient tangible benefits are realised.

Quantitative measures or metricated targets are not set at this time but will be assessed and introduced as the scale and size of the business increases in the future. Given its low environmental impact, CLINUVEL has received support for this approach from a range of investors, including those institutions with an ESG focus.

Currently, CLINUVEL will be required to prepare a Sustainability Report in accordance with AASB 2 Climate-Related Disclosures from 1 July 2027. CLINUVEL is working towards implementing appropriate processes and internal controls over sustainability information by this date.

## Social

CLINUVEL's key social contribution is the development and distribution of products for unmet patient and healthcare needs.

The paramount focus of CLINUVEL in terms of social responsibility is on the safety of its products and the wellbeing of patients and personnel.

We ensure our products are safe for human use through thorough research and the minimum non-clinical and clinical studies necessary to ensure safety of our products and obtain regulatory approvals of pharmaceutical products in respective jurisdictions. CLINUVEL is committed to the OECD Replacement Reduction and Refinement Principles for non-human studies and ensures all studies undertaken are responsibly designed and conducted by laboratories certified by internationally recognised and respected bodies.

We use ethics committees for study approval, adhere to OECD Testing Guidelines and the principles of GLP.

We ensure the manufacture of goods and distribution of materials and products are undertaken responsibly and ethically. CLINUVEL works with key suppliers that adhere to global regulatory standards (including GLP and GMP) to ensure the quality of its products.

Afamelanotide, the active pharmaceutical ingredient in SCENESSE® and other products, has a positive safety record from over 20,500 administrations for commercial, clinical, and compassionate uses over more than one and a half decades. A rigorous pharmacovigilance program is also maintained and reported to global regulatory authorities to confirm the real-world experience treating adult erythropoietic protoporphyria (EPP) patients with SCENESSE® (afamelanotide).

### Our People

CLINUVEL respects the human rights of employees and freedom of association and exceeds the minimum labour standards expected of an

employer. The Company's focus is to provide employees with 1) a safe, positive, and flexible working environment to support wellbeing, active interaction and productivity, and 2) competitive performance-based remuneration and employment benefits that enable financial independence and acceptable living standards.

In addition, CLINUVEL recognises the importance of and provides the opportunity for positive career development, ensuring succession planning rewards performance and endeavour. This is achieved through Individual Development Plans for all employees and advanced development through the CLINUVEL Academy.

Reflecting the safe working environment provided, there were no injuries or time lost from workplace accidents in FY2025 (Nil in FY2024).

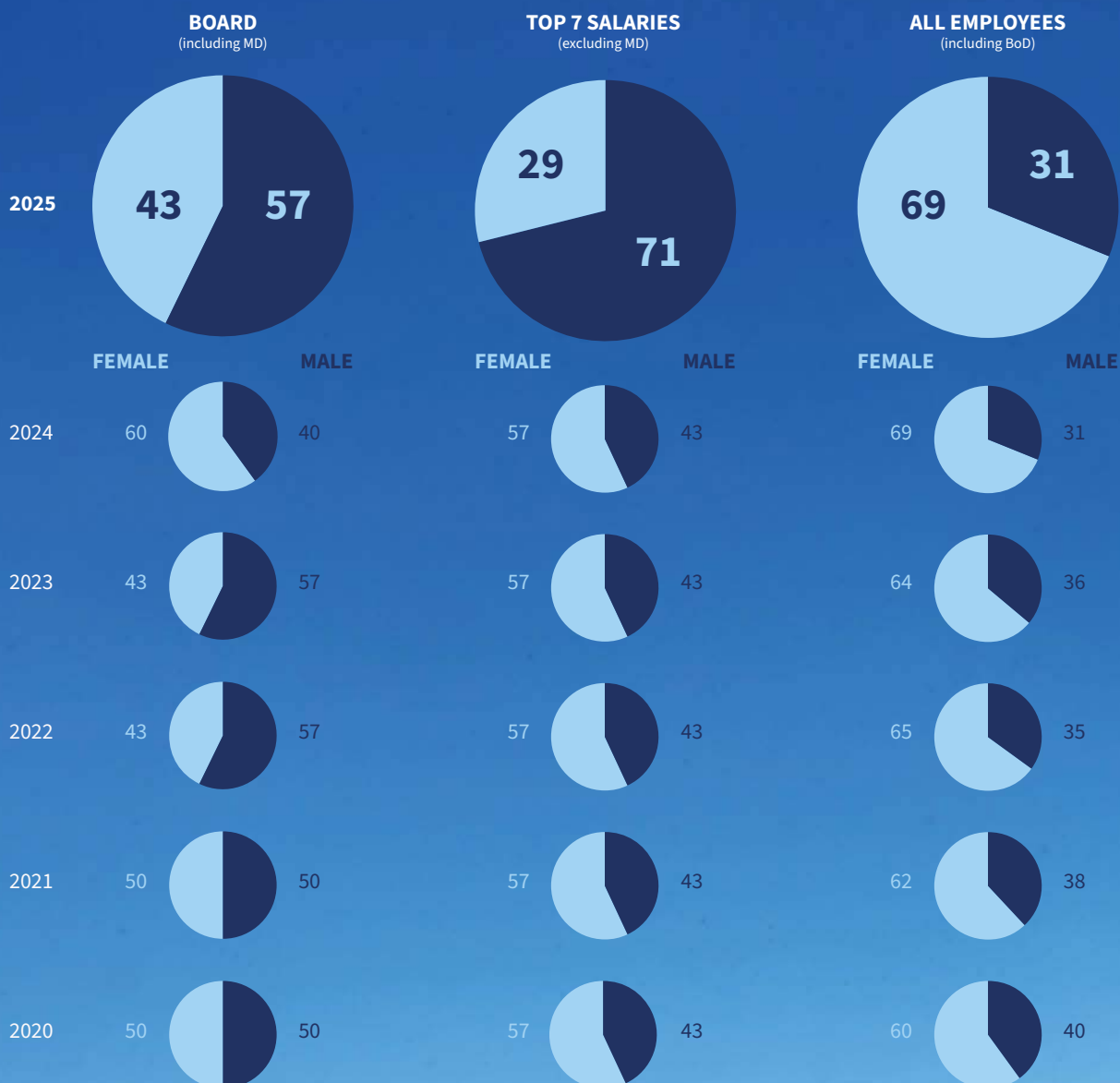
**Reflecting CLINUVEL's social commitment,** SCENESSE® (afamelanotide) was successfully administered during FY2025 to a nine-year-old girl living with severe symptoms of erythropoietic protoporphyria (EPP). The child was suffering from severe phototoxicity and was going through an ordeal preventing her from participating in daily activities. She was living indoors and could not tolerate any form of light. Following treatment, she is now leading a more normal life, including returning to school.

SCENESSE® is approved for the prevention of phototoxicity in adult EPP patients. Since 2021, adolescent EPP patients have received treatment in European EPP Expert Centres, with the treatment reimbursed by insurance companies. Several adolescent patients remain on treatment today.





## DIVERSITY (% female/male)



### Our Diversity Profile

CLINUVEL respects and promotes diversity across our entire workforce and recognises that a diverse workforce contributes to innovation, change and the long-term growth of our business.

CLINUVEL is committed to equality of opportunity which applies to all human beings regardless of gender and gender identification, sexual orientation, race and ethnicity, religion and beliefs, disability, age, and socio-economic status and background. CLINUVEL's commitment to, and track

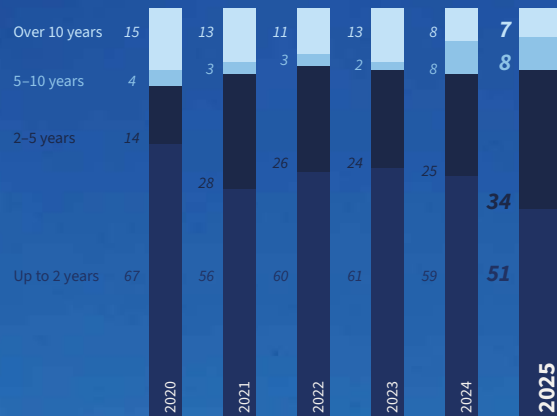
record in, treating all employees with equality extends to its interactions with external stakeholders. Diversity in the workforce is a key indicator of an equitable and fair approach to employees. Diversity is continually monitored by the Board.

CLINUVEL takes pride in its leadership on diversity which is represented in gender, age, nationality and use of languages as illustrated overleaf.

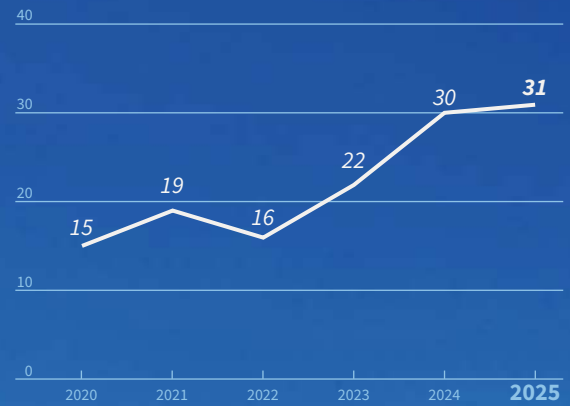
Multiple nationalities and linguistic abilities underly CLINUVEL's diversity beyond gender. The age composition

of employees further highlights the diversity of the CLINUVEL team across seasoned and younger personnel at various stages of their career. All are committed to develop their skills and work together in a highly collaborative way to achieve the objectives of the Company, noting the ongoing stewardship of the Company is provided by Generation X and Baby Boomers and the more experienced of the Millennial generation.

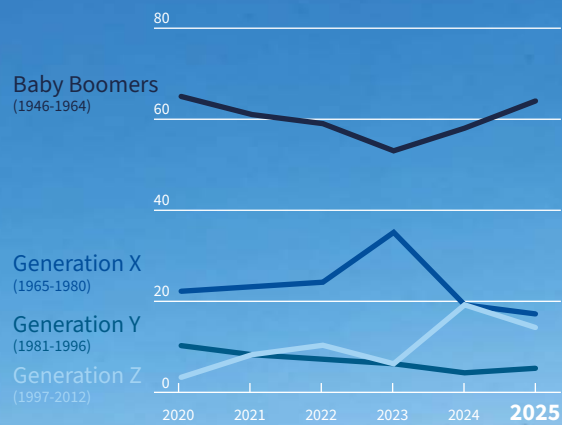
## EMPLOYEE TENURE (% of total employees)



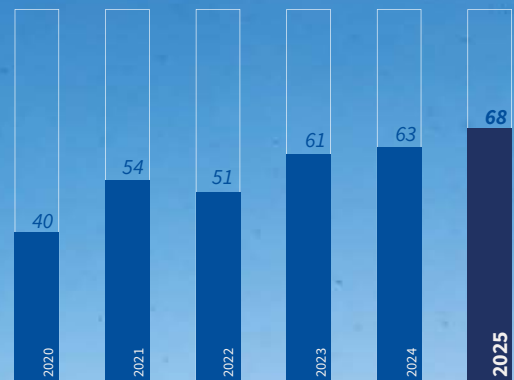
## NATIONALITIES (Number)



## AGE COMPOSITION (%)



## MORE THAN ONE LANGUAGE (%)





PRINCIPLE	CLINUVEL POLICY
<b>1. Lay solid foundations for management and oversight</b>	Board Charter Audit & Risk Committee Charter Remuneration Committee Charter Nomination Committee Charter Commercial Committee Charter Diversity Policy
<b>2. Structure the board to be effective and add value</b>	Board Charter Nomination Committee Charter
<b>3. Instil a culture of acting lawfully, ethically, and responsibly</b>	Code of Conduct and Ethics (found in the Corporate Governance Protocol) Whistleblower Policy Anti-Bribery and Corruption Policy Diversity Policy Share Trading Policy Modern Slavery Statement
<b>4. Safeguard the integrity of corporate reports</b>	Audit and Risk Committee Charter
<b>5. Make timely and balanced disclosure</b>	Continuous Disclosure Policy
<b>6. Respect the rights of security holders</b>	Shareholder Communications Policy (found in the Corporate Governance Protocol)
<b>7. Recognise and manage risk</b>	Audit & Risk Committee Charter Risk Management Policy
<b>8. Remunerate fairly and responsibly</b>	Remuneration Committee Charter Securities Trading Policy

### Governance

CLINUVEL recognises the importance of good corporate governance and the role it plays in ensuring business is conducted honestly, fairly, and legally. CLINUVEL is committed to adopting corporate governance policies to achieve the objectives of acting ethically and responsibly, safeguarding integrity in corporate reporting, making timely and balanced disclosures, as well as recognising and managing risks.

The Board of CLINUVEL reviews its policies and governance practices in reference to the eight Principles of Good Corporate Governance

(Principles) established by the ASX Corporate Governance Council. The policies and governance practices in place are listed under the Principles above.

The Corporate Governance Protocol and the annual Corporate Governance Statement set out the code of conduct and ethics and other policies to ensure conflicts of interest are avoided and a culture of honesty and integrity is maintained which concords with the expectation of responsible management of ESG issues. To extend this point, CLINUVEL adheres to a policy of adequate and correct communication within the

Group, stipulating earnest and direct interaction with its staff and management.

Anti-Bribery and Corruption Policy prohibits illicit behaviour, and a Whistleblower Policy protects employees who (and who are encouraged to) report behaviours not aligned with the high standard of ethics and honesty embodied in CLINUVEL's values and culture.

There were no breaches in the Company's Code of Conduct or Whistleblower reports submitted in FY2025 and up to the date of this Annual Report.



## SUMMARY

The Company's commitment is to continue to evolve and improve ESG practices as an integral part of its focus on continuous improvement and in line with the Company's growth and expansion. ▲

Human Resource policies provide guidance on conflict resolution and communication strategies to be deployed. CLINUVEL adheres to communication guidelines which promote open dialogue with those who seek to interact with CLINUVEL on relevant matters of business, and those who act fairly and openly.

CLINUVEL adheres to Disclosure UK, a searchable database which records annual payments and benefits in kind made by pharmaceutical companies to doctors, nurses, and other health professionals, as part of a Europe-wide initiative to increase transparency in the pharmaceutical-health sector.

Assessment of Key Suppliers Supplier standards have relevance across each ESG area. This is explicit in CLINUVEL's ESG framework. CLINUVEL accepts the responsibility to understand the ESG practices of its suppliers and to use its relationship with them to influence changes to any behaviours and activities considered necessary to avoid underperformance against minimum ESG standards.

CLINUVEL's suppliers are considered responsible and active in their practice of ESG. CLINUVEL's practice has been to assess this on an ongoing basis from regular interactions and reviews of relationships. CLINUVEL

has developed a formal process to assess the adherence of our key suppliers to responsible ESG practices. This is focused on key suppliers based on their ranking in CLINUVEL's annual expenses budget.

CLINUVEL's Corporate Governance Statement and policies can be found on the Company website <https://www.clinuvel.com/about/corporate-governance/>



# ANNUAL

# RESULTS

Financial Year Ending 30 June 2025

*“The CLINUVEL team has delivered what it set out to achieve in FY2025: continued commercial growth while accelerating our Phase III clinical program for vitiligo in a cost-controlled manner. This year’s result sees us deliver a ninth year of profits from the commercial distribution of SCENESSE® for EPP.*

*“All of our key financial metrics – revenues, profit, re-investment in the business and asset growth – continue to increase year-on-year, providing a strong basis for a sustainable bio-pharmaceutical group and enabling us to expedite our objectives for the revenues and growth of tomorrow.”*

Peter Vaughan, Chief Financial Officer





# DIRECTORS' REPORT

The Directors of the Board present their Report on the Company for the financial year ended 30 June 2025 and the Auditor's Independence Declaration thereon.

## Key information on the Directors is summarised below:

### **JEFFREY ROSENFELD**, AC, OBE, MBBS MS MD FRACS

Non-Executive Director

Appointed Non-Executive Director 26 Nov 2019

Appointed Chair of the Board 1 Jan 2024

**Committee Membership:** Member of the Audit and Risk Committee; Member Remuneration Committee; Chair of the Nomination Committee.

**Current Directorships and Other Interests:** Board Member, Connectivity TBI Ltd; Board Chair, New Medical Education Australia Ltd; Representative Honorary Colonel, Royal Australian Army Medical Corps; Emeritus Professor, Monash University; Board Member, Spirit of Australia Foundation.

**Other Listed Company Directorships (last 3 years):** None.

**Relevant Interest in Shares and Performance Rights:** Shares 3,148; Performance Rights – NIL.

### **PHILIPPE WOLGEN**, MBA, MD

Chief Executive Officer

Appointed Director 1 Oct 2005

Appointed Chief Executive Officer 28 Nov 2005

**Committee Membership:** None.

**Current Directorships and Other Interests:** None.

**Other Listed Company Directorships (last 3 years):** None.

**Relevant Interest in Shares and Performance Rights:** Shares 3,425,222; Performance Rights – NIL.

### **KAREN AGERSBORG**, MD

Non-Executive Director

Appointed Non-Executive Director 29 Jan 2018

**Committee Membership:** Member of the Remuneration Committee; Member of the Nomination Committee.

**Current Directorships and Other Interests:** Fellow of the American Association of Clinical Endocrinologist.

**Other Listed Company Directorships (last 3 years):** None.

**Relevant Interest in Shares and Performance Rights:** Shares 13,833; Performance Rights – NIL.

### **SUSAN SMITH**, Dipl ClinRisk

Non-Executive Director

Appointed Non-Executive Director 23 Sep 2019

**Committee Membership:** Chair of the Remuneration Committee; Member of the Nomination Committee, Member of the Commercial Committee.

**Current Directorships and Other Interests:** Director of HCA Hope Fund UK; Board Chair of The Evewell Group Ltd.

**Other Listed Company Directorships (last 3 years):** None.

**Relevant Interest in Shares and Performance Rights:** Shares 420; Performance Rights – NIL.

**MATTHEW PRINGLE**, BCom, FCPA, FCA, FGIA, FCIS, GAICD Non-Executive Director

Appointed Non-Executive Director 6 Sep 2024

**Committee Membership:** Chair of the Audit & Risk Committee; Member of the Commercial Committee.**Current Directorships and Other Interests:** None.**Other Listed Company Directorships (last 3 years):** Director of Navalo Financial Services Group Limited (ASX:PYP), until 30 June 2025.**Relevant Interest in Shares and Performance Rights:** Shares NIL; Performance Rights – NIL.**GUY VAN DIEVOET**, LLB, EMM, CEFA

Non-Executive Director

Appointed Non-Executive Director 6 Sep 2024

**Committee Membership:** Member of the Audit & Risk Committee; Chair of the Commercial Committee.**Current Directorships and Other Interests:** None.**Other Listed Company Directorships (last 3 years):** None.**Relevant Interest in Shares and Performance Rights:** Shares NIL; Performance Rights – NIL.**PEARL GRIMES**, MD

Non-Executive Director

Appointed Non-Executive Director 6 Sep 2024

**Committee Membership:** Member of the Nomination Committee; Member of the Commercial Committee.**Current Directorships and Other Interests:** Director of Vitiligo and Pigmentation Institute of Southern California, Director of Grimes Institute for Medical and Aesthetic Dermatology.**Other Listed Company Directorships (last 3 years):** None.**Relevant Interest in Shares and Performance Rights:** Shares NIL; Performance Rights – NIL.**BRENDA SHANAHAN**, AO, BComm, FAICD, ASIA

Non-Executive Director

Appointed Non-Executive Director 6 Feb 2007

Retired 16 Oct 2024

**Committee Membership:** Chair of the Audit and Risk Committee until 16 October 2024; Member of the Nomination Committee until 16 October 2024.**Current Directorships and Other Interests:** Chair of the Aikenhead Centre for Medical Discovery, Melbourne; Director of SG Hiscock Ltd; Chair, SG Hiscock Medtech; Advisory Board Director of DMP Asset Management Ltd; Director of Rock Art Australia.**Other Listed Company Directorships (last 3 years):** Phoslock Water Solutions Ltd (ASX: PHK, until 18 January 2024).**Relevant Interest in Shares and Performance Rights at Retirement Date:** Shares 196,577; Performance Rights – NIL.

More information on the relevant skills and biography of the current Directors is provided in the feature on pages 36-43 of this Annual Report.

**Information on Company Secretary****Claire Newstead-Sinclair** (BBus (Acc), CA AGIA))

Company Secretary

Appointed: Company Secretary 6 August 2024

**Peter Vaughan** (BBus (Acc), CA, MBA, GAICD, AGIA))

Company Secretary and Chief Financial Officer

Appointed: Company Secretary 28 June 2024 to 6 August 2024

Appointed Chief Financial Officer 1 July 2024



## Meeting of Directors

The following table summarises the number of and attendance at all meetings of Directors during the financial year:

Director	Board		Audit & Risk		Remuneration		Nomination		Commercial	
	A	B	A	B	A	B	A	B	A	B
<b>Mrs B Shanahan</b>	3	3	1	1	0	0	0	0	0	0
<b>Dr P Wolgen</b>	8	8	0	0	0	0	0	0	0	0
<b>Dr K Agersborg</b>	8	8	0	0	12	10	3	3	0	0
<b>Mrs S Smith</b>	8	8	1	1	12	12	3	3	0	0
<b>Prof J Rosenfeld</b>	8	8	3	3	12	12	3	3	0	0
<b>Mr M Pringle</b>	6	6	2	2	0	0	0	0	0	0
<b>Mr G van Dievoet</b>	6	5	2	2	0	0	0	0	0	0
<b>Dr P Grimes</b>	6	6	0	0	0	0	3	3	0	0

Column A indicates the number of meetings held during the period the Director was a member of the Board and/or Board Committee.

Column B indicates the number of meetings attended during the period the Director was a member of the Board and/or Board Committee.

Note: The Managing Director is not a voting member of the Committees and may attend on invitation only.

## Principal Objectives and Activities

CLINUVEL PHARMACEUTICALS LTD (CLINUVEL) is a global specialty biopharmaceutical company focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and the development of melanocortin technology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and CNS conditions which lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the U.S.A., 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).

The principal activities of the Group during the 12 months to 30 June 2025 (FY2025) were to:

- manufacture and commercially distribute its prescription pharmaceutical SCENESSE® in Europe and the U.S.A. for the treatment of the rare, genetic metabolic disorder, EPP;
- research and develop SCENESSE® and the liquid formulation PRÉNUMBRA® (afamelanotide) as medicinal therapies to treat severe disorders, including vitiligo and variegate porphyria;
- develop and manufacture NEURACTHEL® (adrenocorticotrophic hormone; ACTH) in different formulations, to target neurological, endocrinological, and degenerative disorders;
- research, develop, manufacture and pre-launch non-prescription, PhotoCosmetic products for individuals and populations at highest risk of exposure to ultraviolet (UV) and high energy visible (HEV) light, and in need of assistance in DNA repair and melanogenesis of the skin;
- develop and investigate new pharmaceutical formulations melanocortin technology for the treatment of a range of disorders; and
- expand the Group by identifying and attracting new professional talent.

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

The long-term financial objective of the Group is to maximise company value through the development and distribution of treatments to patients and special populations in society, focusing on those who are unattended or unaddressed. The key to long-term sustainable performance is to continue targeted development of a portfolio of assets centred around its innovative pharmaceutical product SCENESSE® and other melanocortin technologies – and their successful commercialisation, manufacture, and distribution – whilst maintaining financial discipline and stability.

## Operating and Financial Review

Highlights of the Company's key activities and operational outcomes are summarised below:

### SCENESSE® - World's First Photoprotective Drug

#### Distribution

- Global growth in patient numbers and doses of SCENESSE® administered in EPP, now >18,500 implants.
- North American Specialty Centers increased to 104 – 100 in the U.S.A. and 4 in Canada – as of 30 June 2025.
- Over 100 U.S. insurers maintained.
- Continued to treat patients in Canada under a special access scheme. Submission to Health Canada for marketing authorisation, filed October 2024 and validated December 2024.

#### New Jurisdictions

- Colombia – efforts to identify EPP patients for treatment proceeded with partner, Valentech.
- Argentina – a distribution agreement was signed in January 2025 with Diligens Salud SA.

#### Dosage Frequency

- Discussions progressed with the EMA to increase the recommended maximum number of doses of SCENESSE® per year in the EU. The drug's European label currently includes a "recommended maximum" of four implants per annum compared to the FDA's approval to allow treatment every two months, which translates to year-round photoprotection from six doses per annum. Approval of the EMA would harmonise the approved label of SCENESSE® across these jurisdictions.

#### Treatment of Adolescents

- This initiative was advanced by the completion of study CUV052 which showed adolescents aged 12 to 17 years experienced similar safety and controlled-release profiles as adult EPP patients.

### Melanocortin – Drug Pipeline

- The development of instant and modified release formulations and work on manufacturing validation continued in FY2025.

### PhotoCosmetic – Products

Work on the PhotoCosmetic product range continued in FY2025:

- Preparations have been made for the launch of the next generation "Protect" polychromatic product, CYACELLE Radiant.
- Formulation and manufacturing development work on M-lines, "Preserve" and "Bronze" continued.

### Clinical Programs – Advanced

#### Variegate porphyria (VP)

- Results of the Phase II VP study, CUV040, were presented to the International Congress of Porphyrins and Porphyrins in Pamplona, Spain in September 2024. SCENESSE® was shown to reduce clinical symptoms and improve patients' quality of life.

#### Vitiligo

- Recruitment of patients for the Phase III study, CUV105 commenced October 2023 and completed May 2025, ahead of the extended June 2025 completion date.
- The study recruited 210 participants across 37 clinical sites spanning the U.S., Europe, and Africa.
- Results of the Phase II pilot monotherapy study, CUV104, were announced in June. The study was conducted at the suggestion of regulatory authorities to assess the safety and efficacy of afamelanotide as a monotherapy in patients with darker skin types (Fitzpatrick IV-VI). The study results confirmed adjunct NB-UVB phototherapy is needed with SCENESSE® to activate repigmentation in vitiligo. Given this, no further studies are planned for afamelanotide as a monotherapy for vitiligo patients.

#### Stroke

- Results in the Phase II stroke study, CUV803, were announced in March 2025. Nine patients treated with PRÉNUMBRA® Instant tolerated the drug well and 8 out of 9 demonstrated functional improvement (at day 42), whilst 6 out of 9 showed radiological improvement or stability. These results are consistent with the previous CUV801 study and provide a solid basis for resuming the arterial ischaemic stroke program in the future.

#### DNA Repair

- Study CUV151, evaluating the DNA-repair capacity of afamelanotide on the skin of healthy volunteers exposed to ultraviolet radiation, was presented at the British Association of Dermatologists 104<sup>th</sup> Annual Meeting, held in Manchester in July 2024. The RNA sequencing results indicate that critical genes expressed after UV-damage can be positively affected with afamelanotide treatment. For the general population, and particularly those with fair skin susceptible to sunburn, the results indicate that afamelanotide can reduce oxidative damage and inflammatory reactions after sun exposure and skin damage.



The financial highlights of the Company for the year ended 30 June 2025 are presented in the following table:

Consolidated Entity	A\$ million	Change
Total Revenues, Interest and Other Income	105.300	Up 10%
Total Expenses	53.747	Up 20%
Net Profit before income tax	51.553	Up 2%
Profit after income tax expense	36.173	Up 2%
Cash and cash equivalents and Cash held in term deposits	224.106	Up 22%
Basic Earnings per Share	\$ 0.72	Up 1%
Net Tangible Assets backing per Share	\$ 4.77	Up 19%
Dividend distribution per Share	\$ 0.05	Stable

A review of the Company's operations and information on the financial results is contained in the features on pages 50-63 of this Annual Report.

## Material Business Risks

The following specific business risks are periodically reviewed by the Board and management, as these have the potential to affect the Group's business strategy, financial position or future performance. It is not possible to identify every risk that could affect the Group's business, and the actions taken to mitigate these risks cannot provide absolute assurance that risks will not materialise. This list is not exhaustive.

Risk	Description	Mitigation Strategies
<b>Technology</b>	Despite obtaining marketing authorisations, the approved products may ultimately prove not to be safe and/or of clinical or other benefit.	The Company has established a comprehensive pharmacovigilance system and conducts intense and continuous safety monitoring, evidenced by the risk management commitments agreed with the European Medicines Agency for the long-term follow-up of patients treated with SCENESSE®. The Group works with key opinion leaders to ensure it responds to any evidence supporting a change to the clinical relevance or change to the safety profile.
<b>Supply</b>	Manufacturing processes may result in product batches not meeting minimum specifications, raw material components not being sourced to specification. The manufacturing process may encounter process issues not previously identified and controlled, and there may be non-controllable disruptions to the operations of the products' contract manufacturers. These factors may lead to delay or non-supply of product and/or adverse regulatory outcomes.	This risk has a high degree of non-controllability, and switching costs would come with potentially long lead times and significant expense. The Company works very closely with its suppliers to ensure scheduling fits forecast requirements and that the manufacturing processes are actively monitored and managed. New suppliers are subject to due diligence processes and key relationships are developed with regulatory agencies to support the Company in the event of supply chain disruption. Insurance protection for stock loss is in place.
<b>Clinical &amp; Regulatory</b>	Clinical trials may not yield the expected and desired results for the investigational medicinal product(s) to obtain further regulatory approvals.	Every clinical trial undergoes a rigorous design process involving third party experts, primary investigators, and the Company's R&D experts, but also on occasions regulatory input, to give each trial the best opportunity to deliver valuable outcomes. A framework is in place to ensure all clinical trials are actively monitored, the sites are adequately trained and supported, patients are recruited and retained, and data is efficiently and accurately analysed. In recent years, there has been less reliance on third-party providers by bringing data analytical functions in-house.
<b>Market Competition</b>	New entrants could enter the same market to directly compete against CLINUVEL's products. CLINUVEL's business could be adversely impacted if new products to the market claim or are proven to be safer and/or more effective and are priced lower than CLINUVEL's products.	The Company is investing in its R&D to investigate and develop new formulations and make improvements to the existing formulation. To de-risk its reliance on one market segment it is investigating afamelanotide and related molecules as a potential therapy in new markets.
<b>Drug Pricing</b>	Third-party payors may not provide insurance coverage or may not be willing to accept the prices agreed with other third-party payors which could adversely affect revenues and profitability. Furthermore, changes in government insurance programs may result in lower prices for our products and could materially adversely affect our ability to operate profitably.	To address this risk, the Company ensures as part of its drug pricing negotiations that it can demonstrate the value of the clinical benefit of the drug and its impact on a patient's quality of life, supported by benchmarking analysis and health economic assessments. External assistance is also used where necessary. This risk could be exacerbated by new market entrants (see above) which would likely see further pressure to lower prices.

<b>Intellectual Property</b>	Future sales could be impacted to the extent there is not sufficiently robust patent protection across the Group's product portfolio to prevent competitors from entering the marketplace with 'generic' versions of the Group's approved products. Competitors infringing the Group's IP rights may adversely impact the Group's ability to maximise the value to be made from product commercialisation.	The Company has created a portfolio of patents and trademarks across various jurisdictions and has utilised regulatory laws enabling market exclusivity that has enabled relatively strong IP protection. It has worked closely with experienced specialists and advisors internationally over many years and it continues to fortify its portfolio by applying for new patents arising from new knowledge gained during its research and development.
<b>Funding</b>	Cash outflows from its operations over the long-term may be higher than cash inflows over the long-term as the Company continues clinical research and furthers product development. The ability for the Group to successfully bring its products to market and achieve consistent positive cash flow is dependent on its ability to maintain revenue streams and to access sources of funding as required while containing its expenditures.	<p>The ability to access additional funding through debt and capital markets, and the competitive terms to obtain the funding, can be dependent on macroeconomic and other factors outside the Company's control, however the Directors are confident that additional funding could be obtained if, and when, necessary. Should additional funding not occur, other measures could be deployed as appropriate, including reducing the scope of business operations. Additional information on the management of its foreign currency and credit risk can be found in Note 20 to the financial statements.</p> <p>Primarily, the Board has instigated a strategy whereby the Company is maintaining a cash level to mitigate longer-term funding risks. A liquidity buffer also ensures the Company is able to retain specialised talent, providing the professionals security and confidence in the Company's financial management.</p>
<b>Management</b>	The corporate strategy could be impacted adversely if the Group was not able to retain its specialised knowledge, skill and areas of expertise from its key members of management, staff and/or Directors.	<p>The Company continually reviews its remuneration, reward, retention options and training to ensure it remains a competitive and attractive employer in a tight labour market. Strategies to promote staff retention include eligibility to participate in Bonus and Equity Plans after an initial period of service has passed, and participation in specialist training and scholarship programs to develop the careers of performing staff. Staff benefits are constantly reviewed to ensure market attractiveness and competitiveness.</p> <p>The Board has instituted a CLINUVEL Academy, providing and sponsoring advanced training and learning opportunities to eligible talent within the Company.</p>
<b>Cyber Security</b>	A breach of the Company's IT systems has the potential to disrupt critical business processes, leading to a loss in privacy, loss in commercially sensitive data and/or reputational damage to the Company.	This risk cannot be comprehensively eliminated however, the Company has in place safeguards to restrict access to the Company's operating systems including multifactor authentication, firewalls, phishing identification software, cloud hosted solutions and regular data back-ups which are regularly maintained and reviewed.

## Dividends Paid or Recommended

Declared & paid in 2023/204	Cents per Share	Amount	Date of Payment
Final	5.00	\$2,503,729	20 September 2024

On 27 August 2025, the Board of Directors declared a fully franked dividend of \$0.05 per ordinary share in relation to the full year ended 30 June 2025.

## Changes in The State of Affairs

The Directors are not aware of any matter or circumstance not otherwise dealt with in this report that has significantly or may significantly affect the operations of the Group.

## Significant Events after the Reporting Date

There has not been any matter, other than reference to the financial statements that has arisen since the end of the financial year that has affected or could significantly affect the operations of the Group, other than:

- On 22 August 2025, the Company announced its intention to upgrade its American Depositary Receipt program from Level I to Level II, listed on Nasdaq, expected to occur by the end of 2025.
- On 27 August 2025, the Board of Directors declared a franked dividend of \$0.05 per ordinary share.

## Likely Developments and Expected Results

The Company is on an expansion path to transform into a highly integrated and diversified biopharmaceutical group. This is expected to result in a company with the ability to sustain greater long-term profitability and performance for the benefit of all stakeholders.



The likely developments to expect on the integration and diversification of the Group are:

#### **Integration**

- Maintenance and development of existing in-house functions
- Continued advance of the activities of the Communications, Branding & Marketing Division
- Assessment of options for self-manufacturing of next generation products, including acquisitions

#### **Diversification**

- Advancement of the product development program
- Continuation of existing clinical programs and release of results
- Announcements of new indications of focus and clinical programs necessary to achieve regulatory approvals

The “Operating Review” and “Financial Review” (on pages 50-63) in this Annual Report details the type of developments and outcomes that occurred in FY2025 as the Company advanced its expansion plans. The feature on “Plans 2026 and Beyond” (on page 65) in this Annual Report sets out likely developments and outcomes expected in FY2026 and beyond as the Company’s expansion continues.

## **Environmental Regulation and Performance**

The Group’s operations are not regulated by any significant environmental regulation under a law of the Commonwealth, or of a State or Territory, or of any other jurisdiction. CLINUVEL is conscious of the impact of mankind on the environment and aims to be a responsible corporate citizen adhering to sound practices on Environmental, Social and Governance (ESG) matters. An update on these practices is provided in the feature on pages 66-75 of the Annual Report.

## **Rounding of Amounts**

The Group is a type of company referred to in ASIC Corporations (Rounding in Financial/Directors’ Reports) Instrument 2016/91 and therefore the amounts contained in this report and in the financial report may have been rounded to the nearest \$1,000,000 or in most other cases, to the nearest dollar.

## **Indemnification of Directors, Officers and Auditors**

During the financial year, the Group paid a premium in respect of a contract insuring the Directors, Company Secretaries and Officers of the Group against a liability incurred as a Director, Company Secretary or Officer to the extent permitted by the Corporations Act 2001. The contract of insurance prohibits disclosure of the nature of the coverage and the amount of the premium.

The Group has not otherwise, during or since the financial year, indemnified or agreed to indemnify a Director, a Company Secretary, an Officer or auditor of the Group or any related body corporate against a liability incurred as such a Director, Company Secretary, Officer or auditor.

## **Directors’ Benefits and Interest in Contracts**

Since the end of the previous financial year no Director has received or become entitled to receive a benefit (other than a benefit included in the total amount of emoluments received or due and receivable by Directors shown in the financial statements and the Remuneration Report), because of a contract that the Director or a firm of which the Director is a member, or an entity in which the Director has a substantial interest has made with a controlled entity.

Further information on these contracts is included in Note 18 to the financial statements.

**Grant Thornton Audit Pty Ltd**

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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 audit of Clinuvel Pharmaceuticals Limited for the year ended 30 June 2025, I declare that, to the best of my knowledge and belief, there have been:

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

A stylized, handwritten signature in grey ink that reads "Grant Thornton".

Grant Thornton Audit Pty Ltd  
Chartered Accountants

A stylized, handwritten signature in grey ink that reads "M A Cunningham".

M A Cunningham  
Partner – Audit & Assurance  
Melbourne, 27 August 2025

[www.grantthornton.com.au](http://www.grantthornton.com.au)  
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# REMUNERATION REPORT

The Remuneration Report forms part of the Directors' Report and provides information about the remuneration practices, policies and outcomes of CLINUVEL PHARMACEUTICALS LTD for its Directors and Other Key Management Personnel for the year ended 30 June 2025.

In accordance with the Corporations Act 2001 (Cth, Corporations Act) for the Company and its controlled entities ("the CLINUVEL Group"), this report has been audited by independent auditor Grant Thornton Audit Pty Ltd.

## **The Remuneration Report is set out under the following main headings:**

- A. Introduction by the Chair of the Remuneration Committee
- B. Non-Executive Directors and Key Management Personnel (KMP)
- C. Remuneration Governance
  - 1) Remuneration Committee
  - 2) Remuneration Recommendations
  - 3) Voting and Feedback from last AGM
- D. Remuneration Approach & Rationale
  - 1) Summary of Remuneration of KMP & MD
  - 2) Remuneration Factors for KMP & MD
    - i) Recruitment, annual retention, social benefits
      - i. Short-term variable & fixed remuneration to KMP, excluding MD
      - ii. Short-term variable & fixed remuneration to MD
    - ii) Long-term benefits
    - iii) Execution & achievement of annual corporate objectives
    - iv) Value generation aligned with shareholders' interests
    - v) Long-term retention
      - i. Long-term incentives (PRs, equity awards) to KMP, excluding MD
      - ii. Long-term incentives (PRs, equity awards) to MD
  - 3) Benefits
  - 4) Claw back provisions
- E. Equity Based Rewards
  - 1) Performance Rights
    - i) Conditional Performance Rights Scheme (2009)
    - ii) Conditional Performance Rights Scheme (2014)
- F. Remuneration Components Benchmarked
- G. Relationship Between Remuneration and Performance
- H. Non-Executive Remuneration
  - 2) Non-Executive Director Fees
  - 3) Non-Executive Director Long-Term Incentives – Equity Compensation
- I. Service Agreements
- J. Details of Remuneration
  - 1) KMP Remuneration – Cash Based Benefits
  - 2) KMP Remuneration - Non-Cash Benefits
  - 3) Remuneration Performance Rights Holdings of KMP - 2025
  - 4) Shares held by KMP
  - 5) Remuneration Details of Equity Incentives (Performance Rights)
  - 6) Remuneration details of Cash Incentives

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

### Chair of the Remuneration Committee

#### Dear Shareholder,

On behalf of the Remuneration Committee (the Committee), I am pleased to present the Remuneration Report for the year ended 30 June 2025. This introduction covers:

- policies and practices of the Committee;
- the Company's approach and framework in relation to the remuneration of Executives and Directors;
- our actions in response to the second strike received against the 2024 Remuneration Report at the 2024 Annual General Meeting (AGM);
- key achievements of the past year and discussion of specific factors determining pay for performance;
- remuneration outcomes for FY2025; and
- executive remuneration for FY2026.



#### Governance policies and practices

The Committee is accountable for the implementation and supervision of CLINUVEL's remuneration policies and practices in relation to the Managing Director (MD), Executive Key Management Personnel (KMP) and Non-Executive Directors (NED). The Committee is tasked to review specific aspects and performance of the key management team annually as outlined in Section C of the Report.

#### Approach to remuneration and remuneration framework

CLINUVEL is a global organisation generating all revenues outside Australia with over 83% of its employees located outside Australia. We recruit and retain talented staff in a highly competitive global market. Our objective is to deliver the most competitive remuneration packages and employment benefits on par with international levels of remuneration that encourage longevity of tenure and attract new managers.

Section D outlines the components of the KMP Executive and MD remuneration frameworks, including fixed based remuneration (FBR), short-term incentives (STI), and long-term incentives (LTI). FBR also includes non-monetary benefits such as health insurance, accommodation, relocation, travel, and statutory benefits. STI is awarded based on achievement of a range of strategic Key Performance Indicators (KPIs). LTI are provided to eligible staff through Conditional Performance Rights (PRs), noting that, since FY2019, PRs have not structured or issued to the MD.

A key part of our approach is to benchmark CLINUVEL's executive remuneration to a comparable group of peers. Comparable means companies of similar complexity and innovative focus, scope and scale, technical and specialised skills, market capitalisation, achievements, and risk profile. Given the extent of CLINUVEL's international operations and the sparsity of comparable companies in Australia, such a peer group cannot be exclusively based on Australian companies. For FY2025, the comparable peer group comprises of 40 companies of which 28 are US listed and 12 are Australian listed. Refer Section F, pages 98-103 for details.

#### Responding to second strike 2024

At the 2024 AGM, the Company's 2024 Remuneration Report received a second strike with 52.1% of the votes cast against the Report – equal to 20.2% of issued capital. This followed the 2023 AGM, where the Company's 2023 Remuneration Report received a first strike with 39.7% of the votes cast against the Report – equal to 16.3% of issued capital.

Our response following each strike has been in consultation with shareholders and advisors to adjust. Based on feedback received, the Company has provided additional detail on its approach to executive remuneration, its practices and remuneration structure, comparison of remuneration to comparable peers, and improved the disclosure of the STI and LTI awarded. In FY2024, the MD's remuneration structure was also simplified with the cessation of all LTIs. Following the expiration of the MD's last LTI in November 2023, the MD is no longer eligible to receive a LTI for the remainder of his Employment Agreement to 30 June 2026.

As required by the Corporations Act, in the event of a second strike (of more than 25% of the issued shares voted) against the Remuneration Report, a spill resolution needs to be put to the Meeting. If more than 50% of votes are cast in favour of a spill resolution, an Extraordinary General Meeting is required to be held to elect a new Board of Directors, excluding the MD. Recognising the disruption and distraction that such a process would cause for this successful and high



performing company, its staff, shareholders and stakeholders and its continuity, shareholders did not vote for a spill at the 2024 AGM. Only 10.2% of votes cast were in favour of a spill, representing 4% of issued capital.

We maintained our communication to stakeholders during the year to explain our approach and practices to executive remuneration and recommend shareholders adopt the 2025 Remuneration Report at the 2025 AGM, without incurring a first strike.

### Key achievements of the past year

Whilst an uncertain global economic environment continued to prevail throughout FY2025, CLINUVEL again achieved an excellent financial and operational outcome. We advanced the expansion of melanocortin products and clinical development for conditions of unmet need and achieved the ninth year of consecutive growth in revenues, profit and net cash inflows.

We continued to expand the CLINUVEL team across a range of professional disciplines to advance our key initiatives. Our ability to attract high calibre candidates to join the team reflects the quality of CLINUVEL's reputation in the labour market and the competitive remuneration and employment benefits offered.

In addition to the expansion of the erythropoietic protoporphyria market, we progressed our product development and clinical programs. Key achievements are on pages 22-23 and pages 24-27 of the Annual Report, but specifically included:

- an increase in awareness of CLINUVEL – its story and expertise – particularly through the AAD Meeting in March 2025 and tier one media articles; and
- the completion of recruitment of the first phase III vitiligo study, CUV105, in May 2025.

Financial achievements for FY2025 are summarised below:

↑10% <b>TOTAL REVENUES</b>	A\$105.3m	↑2% <b>NPBT</b>	A\$51.6m
↑2% <b>NPAT</b>	A\$36.2m	↑18% <b>ASSETS</b>	A\$271.8m
↑22% <b>CASH RESERVES</b>	A\$224.1m	↑1% <b>EPS</b>	A\$0.72
<b>ROE</b>	16.3%	<b>DIVIDEND PER SHARE</b>	A\$0.05

The performance of the Company since the commencement of commercial operations in June 2016 has been excellent with annual revenues growth, rising profitability and cash reserves that underpin our strong balance sheet. Notwithstanding this, the Company's share price has been volatile and contracted in recent years, in direct contrast to the Company's strong ongoing performance. Other life-science companies have also been impacted by negative market sentiment and declines in their share prices. We are confident that CLINUVEL's share price will improve to reflect the long-term value being built across a range of products and clinical programs for conditions of unmet need.

We assess executive remuneration in relation to a range of performance indicators. The share price trend is relevant of course, but this must be balanced with the strong performance of the Company and the achievement of strategic milestones. We are building the business for the future and the maintenance of competitive executive remuneration packages based on the outcome focused performance criteria detailed above ensures the longevity of tenure in our talent and continuity of the business. Downward adjustment of remuneration packages due to a declining trend in the share price which is disconnected from the value being added year on year, will not attract future talent nor retain current professionals. The Company's performance on key measures against peers is covered in Section F.

### Remuneration outcomes FY2025

The tables in Section J of this report set out the remuneration outcomes for the MD, KMP and NED for FY2025.

For FY2025, the MD received:

- Gross FBR of €1,400,504; and a
- STI award of 55% of the maximum opportunity based on the achievement of KPIs outlined in Section D.

It is relevant to note that:

- The MD has not had an active LTI component to his remuneration package since the expiry of the 2019 PRs in November 2023.

- The MD's remuneration package for FY2025 comprised of a FBR, including non-monetary benefits, and an STI component.
- A retention reward, payable in FY2026, was accrued (but not paid) to the amount A\$1.96 million during FY2025.

Whilst the MD's FBR is set higher than the median of the comparable peer group, we consider it to be reflective of his depth of experience, knowledge and performance over many years. However, the MD's total remuneration package is not higher than the median of the comparable peer group.

A total of 30,500 PRs were awarded to KMP during the year, none of which were vested at 30 June 2025.

### Beyond 2025

In June 2024, the Board secured a one-year extension to the MD's 2022 Employment Agreement to 30 June 2026. This outcome means the MD's services were successfully secured for a maximum of two more years to facilitate and complete the Company's strategic transition to a diversified biopharmaceutical. The MD's extended tenure provides continuity of leadership necessary to solidify the executive team and staff to drive towards the objectives outlined in this Annual Report and gives the Board ample time to search for a suitable successor to Dr Wolgen as MD and enable a seamless transition.

The MD's remuneration package for FY2026 is based on his existing FBR and STI remuneration components without any LTI component. The Committee deemed that given the relatively short length remaining of his Employment Agreement to 30 June 2026, it would not have been consistent with market practice to award the MD further equity incentives. Instead, a retention award of up to the equivalent of 200% of FBR, subject to satisfaction of certain conditions, is payable to the MD in FY2026, the final year of his tenure.

### Summary

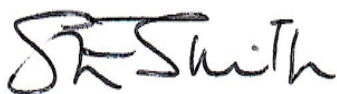
As Chair of the Remuneration Committee, I am pleased to present the Remuneration Report for the financial year ended 30 June 2025 in the pages that follow. The Report will be considered by shareholders at the 2025 AGM, to be held later this year.

Your vote in favour of the Remuneration Report at the 2025 AGM is warranted on four compelling points:

- the Company has continued to perform successfully, achieving excellent operational and financial outcomes, particularly in this, our ninth consecutive year of revenues growth, profit, and net cash inflow;
- the Company belongs to a select group of biopharmaceutical companies globally to remain profitable, building cash reserves while financing its pipeline;
- the MD's remuneration package excludes a LTI component and is well below the median remuneration of the comparable industry peer group; and
- the Company has continued to outperform the mean of its comparable industry peer group in 9-year TSR and Revenues growth and 7-year EPS growth.

The Company has much to achieve in the next 12 months in a challenging operating environment, and your support to adopt the 2025 Remuneration Report will enable us to focus on the achievement of our strategic objectives.

Yours sincerely,



Sue Smith  
Chair of the Remuneration Committee  
CLINUVEL Group



## B. NON-EXECUTIVE DIRECTORS AND KEY MANAGEMENT PERSONNEL (KMP)

KMP has the meaning given in the Accounting Standard AASB 124 and who together have the authority and responsibility for planning, directing and controlling the activities of the Group, being:

Name	Position	Term as KMP
Non-Executive Directors		
<b>Mrs B Shanahan</b>	Non-Executive Director	1 Jul 2024 - 16 Oct 2024
<b>Dr K Agersborg</b>	Non-Executive Director	Full Year
<b>Mrs S Smith</b>	Non-Executive Director	Full Year
<b>Prof J Rosenfeld</b>	Non-Executive Chair	Full Year
<b>Mr M Pringle</b>	Non-Executive Director	6 Sept 2024 onwards
<b>Mr G van Dievoet</b>	Non-Executive Director	6 Sept 2024 onwards
<b>Dr P Grimes</b>	Non-Executive Director	6 Sept 2024 onwards
KMP		
<b>Dr P Wolgen</b>	Managing Director and Chief Executive Officer (CEO)	Full Year
<b>Mr L Hay</b>	Chief Operating Officer (COO)*	Full Year
<b>Dr D Wright</b>	Chief Scientific Officer (CSO)	Full Year
<b>Mr P Vaughan</b>	Chief Financial Officer (CFO)	Full Year
*Acting CEO, from 18 March to present		

## C. REMUNERATION GOVERNANCE

### 1) Remuneration Committee

The Board have mandated the Remuneration Committee to assist and advise on determining an appropriate remuneration framework and policies for its KMP over time, taking into account the relationship between pay and performance, and the results of any evaluations or review processes. The Board has also provided a mandate to the Remuneration Committee to provide advice on setting salaries and fees, short- and long-term incentives and employment terms and conditions for its key executives, and on Non-Executive Director fees.

The Remuneration Committee makes specific remuneration recommendations to the Board on the overall remuneration structure of the Company's KMP ensuring that:

- the remuneration structure of the Company's KMP is aligned with the fiduciary duties of the Board and is in the best interests of Company shareholders and stakeholders taking into account both the Company's strategies and its risks;
- the level and composition of remuneration structure offered is competitively attractive to responsibly attract, retain, and motivate the high calibre professionals uniquely specialised within our industry to achieve the long-term growth and success of the Company;
- an appropriate mixture of total fixed remuneration, and clearly defined at-risk short and long-term incentives, are offered as part of an overall remuneration package to underpin the relationship between remuneration and the Company's strategic performance;
- the levels and structure of remuneration are benchmarked against relevant international peers and considered against global employment market conditions; and
- the Company gives due consideration to applicable legal and governance practice requirements.

Further information regarding the methods used by the Remuneration Committee to assess Board and KMP performance is disclosed in the Corporate Governance Protocol.

## 2) Remuneration Recommendations

Under the provisions of the Committee's Charter, the Committee may engage the assistance and advice from external remuneration firms which could include legal specialists, remuneration advisors and/or proxy advisors. Any recommendations made by remuneration consultants are provided directly to members of the Committee to ensure no undue influence is exerted by any executive.

During the financial year ended 30 June 2025, the Remuneration Committee implemented the recommendations of remuneration advisors on the remuneration of Non-Executive Directors. Under the definition of the Corporations Act, no remuneration recommendations were obtained during the financial year on the remuneration of the MD and KMP.

## 3) Voting and feedback at the Company's last Annual General Meeting

At the 2024 Annual General Meeting (AGM), 52.1% of the votes cast (including votes at the proxy's discretion) voted against the adoption of the 2023/24 Remuneration Report with the other 47.9% voting in favour of its adoption. The resolution was not carried, and as the vote against the Remuneration Report was greater than 25% of the votes cast, this constituted a Second Strike under the Corporations Act, 2001.

As required by the Corporations Act, in the event of a second strike (of more than 25% of the issued shares voted) against the Remuneration Report, a spill resolution needs to be put to the Meeting. If more than 50% of votes are cast in favour of a spill resolution, an Extraordinary General Meeting is required to be held to elect a new Board of Directors, excluding the MD. Recognising the disruption and distraction that such a process would cause for this successful and high performing company, its staff, shareholders and stakeholders and its continuity, shareholders did not vote for a spill at the 2024 AGM. Only 10.2% of votes cast were in favour of a spill and 89.8% against the spill of the Board of Directors.

Following the AGM, the Board consulted with shareholders, proxy advisors and remuneration consultants. Reflecting on the feedback received, the Company has provided additional detail on its approach to executive remuneration, its practices and remuneration structure, comparison of remuneration to comparable peers, and improved the disclosure of the STI and LTI awarded. In FY2024, the MD's remuneration structure was also simplified with the cessation of all LTIs. Following the issuance in 2019 and expiration of the MD's last LTI in November 2023, the MD is no longer eligible to receive a LTI for the remainder of his Employment Agreement to 30 June 2026, which does not accord with market practice.

## D. REMUNERATION APPROACH & RATIONALE

The Remuneration Committee ensures that the Company's remuneration practices align with shareholders' and stakeholder interests, remain transparent, and support the short- and long-term strategic objectives of the Group. Delegated by the Board of Directors, the Remuneration Committee aims to:

- I. attract specific expertise and talent,
- II. retain valuable key management,
- III. train, and invest in the next generation of key managers in critical areas of the business, and
- IV. align the interest of management with those of shareholders.

Given the Company's specific life science technologies and focus, complexities in obtaining a therapeutic outcome and extremely high level of failure-rate in the sector (biopharmaceuticals), the inherent risk within the industry of developing first-in-class drug products, remuneration principles are intentionally focused towards securing the longer-term employment of KMP, staff and Directors within the Group to ensure retention of experienced industry professionals with intrinsic Company knowledge and expertise.

### 1) Summary Remuneration of KMP & MD

The current progress and success of the Company need to be taken in the context of the previously unsuccessful managerial attempts to develop the targeted melanocortin technologies for commercial use. To mitigate the risk and provide a strong platform to achieve meaningful progress, the Board of Directors has overseen a distinct business model to ensure operational skills are retained in-house where possible, and many management responsibilities are concentrated between the MD and the KMP. The MD has the responsibility of guiding and overseeing the execution of the overall corporate strategy, the Group's risk management and has global responsibility for the safety aspects of the lead's drug technology.

The Group's KMP are responsible for critical decision making, executing strategies and thereby generating both short- and long-term accretive value for shareholders. The Remuneration Committee's approach to remuneration for both KMP and the Managing Director aims to reward them for both setting the critical direction to achieve the strategic goals of the



Company as well as executing the plans through the advancement of specific activities and initiatives. Given the benchmarked and significant operational expenditures seen among our peers in our sector, the Committee acknowledges, and values strong and sound financial oversight to contain expenditures in pharmaceutical development to improve long-term performance of the Group.

The Committee recognises the achievement to grow the Company's commercial footprint while improving its financial performance year-on-year. Against the background of the majority of its peers not achieving first-time or continued profitability and or growth, the Committee strives to award its KMP for continuing to build a strong and resilient Balance Sheet. In its considerations, the Committee is reviewing risks and success in biopharmaceutical companies in the U.S. and other markets.

In setting out the strategic objectives for the Company, the Board of Directors aims to provide transparency, clarity and understanding of its rationale to balance short-term variable and fixed remuneration for its KMP with longer-term incentives such as PRs.

In adhering to best practices in executive remuneration internationally and domestically, the Remuneration Committee ensures that interests of KMP are well aligned with those of shareholders.

From time to time, the Remuneration Committee seeks advice from external consultants, external counsel and remuneration specialists to determine the optimum mix of incentives for KMP and the MD relative to the Company's objectives, benchmarks of its peers, and the overall global market talent pool available.

## 2) Remuneration Factors for KMP & MD

Several key factors play a role in the assessment of remuneration for KMP as set by the Remuneration Committee, working in conjunction with remuneration experts and counsel; refer table below.

Remuneration Factors For KMP	Annual Fixed Remuneration	Annual Variable Remuneration	Long-Term Incentives
Function	◊		◊
Critical expertise, background	◊	◊	◊
Seniority, longevity	◊		◊
Key Performance Indicators			
a) Company strategic		◊	
b) Role specific		◊	
Leadership, continued education	◊		
Value added initiatives		◊	◊

When setting fixed and variable remuneration structures for its KMP, executive and senior management, the Remuneration Committee is guided by five key categories. It executes a Company-wide policy to cascade this structure down through the various departments and teams to ensure there is alignment among all staff to strive for a common set of corporate objectives annually.

Categories	Critical components	Considerations	Conditions
<b>i Recruitment, annual retention, social benefits</b>	i) fixed base remuneration at greater than the 75% percentile of the applicable population ii) short-term incentives iii) pension contributions iv) healthcare insurance	cash based	Annual KPIs determine cash-based incentive amounts as a percentage of FBR, conditional on the employee being employed at 30 June each year. FBR is adjusted annually for CPI.
<b>ii Long-term benefits - willingness to undergo advanced training, education to enhance career</b>	i) additional incentives ii) leave days for further studies iii) full or partial sponsorship	cash based	Claw back provision if employee leaves within two years of completion of Company-sponsored education, Masters, PhD or executive course
<b>iii Execute, achievement of annual corporate objectives</b>	i) short-term incentives as percentage of annual FBR	cash based	Total or pro rata award of Key Performance Indicators annually

<b>iv</b>	<b>Value generation aligned with shareholders' interest</b>	i) long-term incentives	non-cash based	Performance Rights awarded and vested annually <sup>1</sup> , conditional upon continuous employment up to vesting date or risk forfeiture
<b>v</b>	<b>Long-term retention</b>	i) retention awards <sup>2</sup> ii) long-term incentives	cash based non-cash based	Exceptional award of cash-based retention awards with a minimum retention term of 24 months, at risk of forfeiture if the executive is no longer employed on the last day of the term. Management and staff are eligible to receive equity awards for long-term service to the Group

<sup>1</sup> Except for the MD, who no longer is eligible to receive PRs (equity)

<sup>2</sup> Was applicable to the former CFO (Mr Darren Keamy) and will be applicable to the MD who will receive a retention award if he remains employed to 30 June 2026.

## i) Recruitment, annual retention, social benefits

The Board strives to award fixed base remuneration to eligible KMP. Paying above market rates for employees aims to attract and retain the top-end professional talent from the pool available to the Group.

In general, STI awards relative to achievement of KPIs are calculated as a percentage of the employee's annual fixed base remuneration. Both FBR and STI are subject to annual adjustments according to consumer price index (CPI) as determined and set by the Remuneration Committee. For the 2025 financial year, CPI increases were implemented to all staff based on the increase in the CPI in their respective regions of employment to ensure CLINUVEL remains competitive in the market to retain employees and support them with their increased cost of living.

Across the Group, pension and superannuation contributions are made individually or through pension schemes depending on the employee's country of residence. The Board strives to comply with all regional and nationwide obligations to contribute to employees' pension schemes, where and when required.

Depending on the region and nation of residence, the Group contributes to healthcare insurance and plans to incentivise employees in accordance to market practices prevailing in life sciences companies.

### Fixed Base Remuneration Salary and Non-Monetary Benefits

FBR comprises base fees, superannuation and may include non-monetary benefits including health insurance, accommodation, relocation, travel and statutory benefits.

FBR is set at a level to attract and retain talent with the requisite capabilities to deliver longer-term strategic outcomes whilst taking into account a range of factors including seniority, qualifications, skill, experience, length of service, leadership, industry knowledge and level of strategic oversight. Explicitly, the Committee takes into account the low success rates among biopharmaceutical peers in establishing profitable ventures, as well as the desire to avoid dilution of shareholders' interests.

FBR is tested annually to ensure market competitiveness through comparison according to appropriate benchmarks recommended and provided by external consultants and in comparison with industry-relevant international and local peer companies.

FBR may be adjusted each year for changes to CPI across different regions individually or as a uniform whole of company change. Any employee FBR adjustments above CPI are in response to individual performance or change in job scope and are overseen by the Remuneration Committee.

### Short-Term Incentives

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

In setting the annual strategic objectives of the Group, the Board of Directors receives recommendations from the Group's KMP and senior managers and reviews this information when setting the annual and longer-term key strategic corporate and organisational objectives to ensure continued and sustained growth.

At the commencement of each financial year, specific KPIs are determined and set for each member of the KMP targeted to their operational role and department, aligned across each of these organisational strategic objectives

The Remuneration Committee sets annual KPIs for all KMP across five key strategic categories. The Remuneration Committee then places a weighting of emphasis across each category relative its overall impact in achieving the Group's strategic objectives, from which Risk Levels are determined based on the difficulty in being able to achieve such an objective to ascertain a likelihood of success.



The table below reflects the annual assessment undertaken by the Remuneration Committee across five categories and aligning KMP to corporate objectives.

Key Performance Indicators comprising the STI* part of annual KMP remuneration		
	Weighting	Risk Level
<b>1. Financial Management</b>		
a) Revenue Growth	20%-30%	High
b) Profit Growth		
c) Organisational Structuring Optimisation		
<b>2. Growth &amp; expansion</b>		
a) Organic growth	15%-25%	High
– R&D output, decision making		
b) Inorganic Growth		
– acquisitions, decision making		
<b>3. Discipline specific, expertise</b>		
Objectives within specific operational discipline	5%-15%	Low
<b>4. R&amp;D pipeline</b>		
a) Preclinical, clinical, regulatory	10%-20%	High
– advancement, read-outs		
– application and formulation enhancements		
– regulatory outcomes, work-arounds		
– Solutions		
<b>5. General Management, Value</b>		
a) People management	1%-10%	Medium
– staff recruitment,		
– staff retention		
– skills mix and diversity composition		
– career advancement		
– Initiatives & activities adding value		

\* STI, awarded annually.

#### i Short-term variable & fixed remuneration to KMP (excluding MD)

To best align KMP with shareholder interests, the Remuneration Committee has set objectives that are:

- a) Corporate strategic; and
- b) Role specific.

The variable, at-risk, objectives are determined annually and consist of two levels of risk:

1. low to medium risk, and
2. high risk.

In line with the Company's agreed strategy to reach and maintain profitability the first variable part of KMP remuneration ("low to medium risk") is dependent on the Group's commercial growth, aligning management's interest with those of the Company's owners. The second variable part ("high risk") is set as harder to achieve stretch targets to reward KMP for gradual increases that underpin true Company value for shareholders.

The fixed portion of the overall remuneration package aims to acknowledge KMP for meeting a number of strategic objectives, activities and value adding initiatives which benefit the Group in the long-term.

The aggregate package of FBR plus a mixture of STIs form the total cash remuneration for KMP, excluding the MD. This remuneration mix is intended to provide market competitive remuneration packages which are offered for similar industry professionals within the European Union, Switzerland, United Kingdom, United States, Asia and Australia.

**KMP**

<b>Setting and Assessment</b>	Are reset at the start of each financial year with the MD making a recommendation to the Remuneration Committee for their review and approval.
<b>Maximum Opportunity</b>	Chief Financial Officer: 10% of Fixed Base Remuneration, assessed annually Chief Operations Officer: 10% of Fixed Base Remuneration, assessed annually Chief Scientific Officer: 5-10% of Fixed Base Remuneration, assessed annually
<b>Continuous Employment</b>	Must be employed by the Company and not serving a period of notice prior to the end of the relevant financial year. STIs will not be paid pro-rata should the KMP cease employment during the relevant financial year.
<b>Performance hurdles</b>	May be a mix of financial and non-financial targets. All targets are set having regard to the achievements and performance of the prior year, market conditions and internal forecasts.
<b>Payment</b>	In the year following the year of achievement.
<b>Disclosure of Performance</b>	The Company's policy is not to disclose commercially sensitive information, consistent with best practice disclosure obligations but will provide information on achieving the performance hurdles to the extent commercially practicable. See the section titled "Relationship between Remuneration and Performance" on pages 104-106.

For the year ended 30 June 2025, the Remuneration Committee assessed overall performance for the 2024/25 year against the STIs, which were recommended by the MD, and approved the following assessments against the maximum STI available to these KMP members:

- Chief Operations Officer – 80%.
- Chief Scientific Officer – 80%.
- Chief Financial Officer – 80%.

Refer table 1, Section J for more detail.

## ii Short-term variable & fixed remuneration to MD

The MD receives fixed and variable remuneration annually, until the end of his Employment Agreement.

In assessing the MD's STI for FY2025, the Remuneration Committee considered a variety of factors that impacted the reporting period, and Dr Wolgen's leadership and judgement to navigate critical issues and challenges facing the Company. The Remuneration Committee considered such factors including ongoing supply constraints and costs, inflationary pressures, the heightened risk placed by markets on life science companies globally, negotiations in key commercial and pricing contracts, decision making and overall management and growth of the Group.

The Committee assessed the treatment of patients across Europe and the United States with uninterrupted supply, working with the centres to increase patient access, the challenges in achieving and maintaining operating margins, and the progress made to expand the existing porphyria markets under pending clinical and investigational settings.

The Committee explicitly assesses the MD's ability to reach and establish a profitable entity in light of the rising costs and dependencies of supply chain.

Historically, the Committee has not awarded 100% towards performance of STIs to the MD (or other KMP), because it sets STIs at maximum stretch.

**Managing Director**

<b>Setting and Assessment</b>	Are reset at the start of each financial year by the Remuneration Committee and are assessed at the end of the financial year.
<b>Maximum Opportunity</b>	100% of Fixed Base Remuneration
<b>Continuous Employment</b>	STIs will be evaluated during any performance period on a pro-rata basis.
<b>Performance Hurdles</b>	May be a mix of financial and non-financial targets. All targets are set having regard to the achievements and performance of the prior year, market conditions and internal forecasts.
<b>Payment</b>	In the year following the year of achievement.
<b>Disclosure of Performance</b>	The Company's policy is not to disclose commercially sensitive information, consistent with best practice disclosure obligations but will provide information on achieving the performance hurdles to the extent commercially practicable.



It reviewed the overall progress of research, clinical programs and regulatory developments, and the progress of the new PhotoCosmetic consumer-oriented business.

CEO Key Performance Indicators	Performance Metric	Weighting	Assessed
Financial year 2025			
<b>Finance Management</b>	Revenue - Consecutive growth		10%
	Profit increase on budget	30%	10%
	Optimise group tax structuring		10%
<b>Growth Expansion</b>	Inorganic Growth – M&A of complementary business or revenue stream		0%
	Organic Growth – further expansion of delivery pipelines	30%	0%
	One new PhotoCosmetics launch		0%
<b>Investor Relations</b>	Attract new institutional investors >2.5%	10%	0%
	Increase independent analyst coverage of CLINUVEL – Europe and USA		0%
<b>R&amp;D Pipeline Development</b>	Vitiligo CUV105 - 100% recruitment		10%
	Vitiligo CUV107 – first patient recruited	25%	0%
	Adolescent EPP – completion of study		5%
	ACTH – manufacture of stable formulation		5%
<b>General Management Initiatives</b>	Recruit key personnel in IT	5%	2.5%
	Review and implement Executive Management team structure		2.5%
<b>TOTAL</b>		<b>100%</b>	<b>55%</b>

In its deliberations, the Committee assessed the MD's ability to solve critical issues, present viable solutions, alternatives and supersede expectations in problem solving. It also assesses annually whether the corporate strategy chosen and implemented results in strong financial outcomes benchmarked against its peers (40: 28 American and 12 Australian companies).

The Remuneration Committee determined that 55% of the maximum potential opportunity for the MD was achieved for FY2025 (FY2024: 60%).

## ii) Long-term benefits

As part of the Board's strategy to retain exceptional talent, professionals with specific expertise and skills are identified and sponsored in part or in full to enter continuous training, accreditation and or post-graduate education. As part of the agreement entered with the individual employee in return for providing part or full sponsorship of an educational program, the employee must serve a minimum continuous employment period of at least two years post completion of the course or training program. Should the employee cease employment with the Group prior to completion of the two year minimum period, a claw back provision recoups the amount of sponsorship paid.

This initiative is part of a wider organisational institutionalised objective to establish a CLINUVEL Academy to encourage eligible staff to develop their long-term ambitions and careers within the Group.

## iii) Execution & achievement of annual corporate objectives

STIs are set for KMP and all staff with the goal of aligning all annual objectives according to function and responsibilities within the Group across all divisions. Annual Key Performance Indicators are set and discussed with KMP and staff as to their weighting, risk, and appropriateness. The Remuneration Committee strives to set KPIs as a stretch target such that the KMP are challenged to meet the corporate objectives and simply not just perform their expected role. KPIs are annually assessed and awarded in full or pro-rata for each member of the KMP as well as for all other employees.

## iv) Value generation aligned with shareholders' interests

Non-cash based LTI, in the form of PRs, are awarded to KMP as part of the 2014 Performance Rights Plan. Under the original 2009 and 2014 Performance Rights Plans, a vesting period of four years was listed to all employees. An amendment was sought to shorten the vesting period to three years from grant date and are awarded upon meeting certain performance conditions. These PRs are awarded conditional to the employee remaining in full or partial employment on the last day of the 36 months vesting period. The MD is not included in these plans and their conditions do not apply, since he is no longer eligible to receive PRs.

## v) Long-term retention

KMP (except the MD) and all other employees are eligible to receive LTI in the form of PRs awarded for long-term service to the Group. The vesting period of the long-term service PRs is up to three years from grant date whereby risk of forfeiture exists until the last day of employment at the vesting date.

### i Long-term Incentives (PRs, equity awards) to KMP (excluding MD)

KMP receive equity annually awards in the form of PRs upon achievement of value-generating performance conditions. The most recent PRs were awarded to KMP in April 2025 and vest or expire in December 2025.

As of 1 January 2024, employees are annually awarded PRs on tenure of service set to secure retention for time served.

For the KMP, the relative percentage of LTIs are highlighted in the table below:

Executive KMP	# Performance Rights on Issue 30 June 2025	# Performance Rights Vested and Exercises	# Performance Rights Lapsed and Expired	Deemed Achieved at Vesting Date
COO	11,600	-	-	0%
CSO	28,125	-	-	0%
CFO	12,500	-	-	0%

During the financial year, 6,250 PRs were exercised and converted to shares. Furthermore, a direct issue of 56,700 shares to KMP and employees occurred in April 2025 as part of a one-off long-term incentive. A separate grant of 290,375 PRs were issued to KMP (excluding the MD) and employees in April 2025.

### ii Long-term incentives (PRs, equity awards) to MD

The employment agreement of the MD was extended by one year to 30 June 2026 (see ASX announcement 28 June 2024). Following advice from external remuneration consultants, proxy advisors, and legal counsel, the Remuneration Committee deemed it appropriate to not award the MD any new PRs or equity incentives beyond the PRs that were issued in 2019 and expired in November 2023. Since then, the MD has had no PRs issued or equity incentives granted and none are outstanding.

To secure the ongoing services of Dr Wolgen as MD for the extension period to 30 June 2026, the Committee implemented a Retention Payment, subject to Dr Wolgen remaining with the business through until 30 June 2026. He is eligible to receive a Retention Payment equivalent to 200% of FBR, subject to the executive satisfying certain conditions. Dr Wolgen will forfeit any entitlement to a Retention Payment where he resigns (for reasons other than fundamental change) or is terminated for cause but will retain the entitlement if his employment is terminated without cause or he resigns for fundamental change.

## 3) Benefits

The Board strives to offer the Group's employees competitive benefits comparable to pay scales within the country and region of residence.

The total incentive package of an employee may include pension contributions, health insurance contributions, healthcare plans or private healthcare insurance, telephone and IT contributions as well as a laptop and professional software licenses, or other such benefits.

Total incentive packages may differ between regions and market conditions at the time of entering an employment agreement.

## 4) Claw back provisions

The Remuneration Committee adheres to a process of retaining the right to claw back and seek recovery of benefits paid to KMP if adverse activities or events have occurred which were detrimental to the Group resulting in financial loss or value. The Remuneration Committee may elect to claw back a previously provided retention award and / or LTI. The Board of Directors, in its discretionary capacity, may elect to reduce, cancel in part or in full, or pursue a claw back process for incentives previously provided to any employee, including any former employees, where misconduct or adverse activities have occurred.

If an employee of the Group has acted dishonestly or failed to act in a way that one would expect according to CLINUVEL's Code of Conduct and corporate governance, the Board may decide to claw back and retrieve part or total of the retention award or equity provisions from the employee.



## E. EQUITY BASED AWARDS

### 1) Performance Rights:

The Group has an ownership-based scheme not only for Directors and other executive KMP but also for employees and select consultants of the Company, which is designed to provide long-term incentives to deliver long-term value.

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

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

#### i) Conditional Performance Rights Scheme (2009)

The Conditional Performance Rights Scheme (2009) has been available to eligible employees of the Company. Any issue of rights to Directors requires shareholder approval in accordance with ASX Listing Rules. All rights are issued for nil consideration, have no voting rights, are not listed on the ASX and are non-tradeable (other than with prior written Board consent). They can be converted to ordinary shares at any time once all vesting conditions attached to the rights have been achieved. The Company may, at the sole discretion of the Board, determine that any shares exercised from vested PRs be acquired by a Plan Trustee and then, from time to time, transferred to participants to the Performance Rights Plan. Unless the PRs are granted with a shorter vesting period, PRs under this plan lapse after seven years from grant date. It is no longer intended to issue PRs under the 2009 Plan.

As at 30 June 2025, 21,725 PRs issued under the 2009 Scheme remain unvested.

#### ii) Performance Rights Plan (2014)

The Performance Rights Plan (2014) is available to eligible persons of the Company. Any issue of rights to Directors requires shareholder approval in accordance with ASX Listing Rules. Any issue of rights to Directors requires shareholder approval in accordance with ASX Listing Rules by since 2020, the Company policy is for Non-Executive Directors to **not** receive PRs or other equity securities in the Company. All rights are issued for nil consideration, have no voting rights, are not listed on the ASX and are non-tradeable (other than with prior written Board consent). They can be converted to ordinary shares at any time once all vesting conditions attached to the rights have been achieved. The Company may, at the sole discretion of the Board, determine that any shares exercised from vested PRs be acquired by a Plan Trustee and then, from time to time, transferred to participants to the Performance Rights Plan. Unless the PRs are granted with a shorter vesting period, PRs under this plan lapse after seven years from grant date.

PRs are valued for financial reporting purposes only, using either a Monte Carlo simulation pricing model or a probability-adjusted binomial valuation pricing model and are represented as accounting values only in the financial statements. Holders of PRs may or may not receive a benefit from these amounts, either in the current or future reporting periods. The value of all PRs granted, exercised, and lapsed during the financial year is detailed in tables within this Remuneration Report.

At the Company's Annual General Meeting held on 31 October 2023, shareholders approved the renewal of the 2014 Performance Rights Plan for a further three years. Under the renewed plan, up to a maximum of 2.25% of the Company's issued share capital may be issued as new PRs, though this maximum number is not intended to be a prediction of the actual number of securities to be issued by the Company under the Plan, as assessed from past conditions met.

As at 30 June 2025, 466,000 PRs issued under the 2014 Performance Right Plan remain outstanding, of which an estimated 385,997 of the PRs (83%) are likely to achieve the underlying performance condition but will not vest until the end of their respective vesting dates if the employee is still employed at that time by the Company.

The underlying conditions for the performance rights issued to Executive KMP during the year are split into three categories which are linked to enhancing corporate value and to promoting longer term retention of skills and knowledge.

Tranche A relates to tenure-based performance conditions, Tranche B relates to organisational based performance conditions and Tranche C relates to departmental based performance conditions. On an overall basis, the likelihood of the criteria being met by Vesting Date is 86%.

## F. REMUNERATION COMPONENTS BENCHMARKED

Benchmarking the remuneration packages of KMP and management occurs annually through the selection of comparable international peer companies according to the selection criteria outlined below. In conjunction with remuneration consultants, external counsel, and taking into account feedback from proxy advisors, the Remuneration Committee arrives at a selection of comparable companies in setting the FBR and total incentive package for KMP, including the MD.eA number of critical components underpin the remuneration practices of the Group whereby the benchmarking of its FBR and STI is compared against the pay scales of peer companies. It is considered critical for the Company's remuneration structure to remain competitive against international benchmarks to attract and retain existing executive talent at the highest managerial calibre. The Board firmly acknowledges that it cannot limit its benchmarking and consequent setting of the level and structure of its executive remuneration against local Australian peer companies only.

International publicly listed companies with the same or similar R&D and commercial risks have been deemed the most appropriate comparable peer group measure given the Group generates all its revenues from Europe, North America and the Middle-East. In addition, over 83% of the total employees of the Group reside and are employed outside Australia. Accordingly, any remuneration benchmarking should also be compared against international pay-scales and practices.

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

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

Selection criteria	Commentary
<b>Biopharmaceuticals</b>	Biopharmaceutical development is regarded as comprising the highest R&D, clinical, regulatory, and commercial risk. Peers are selected internationally on comparable technologies.
<b>Platform technologies</b>	Preference is to select those companies which have translational technology, and or ability to utilise technology in multiple indications, and formulations.
<b>NME/NCE<sup>1</sup></b>	New molecular, chemical entities bear the highest risk due to the novelty and lack of prior art. Peers are identified on the basis of comparable NME/NCE strategies.
<b>Revenue generating</b>	Comparison is drawn with independently operating and mature biopharmaceutical companies, which are debt free and not dependent on equity funding.
<b>Profitable</b>	Selected are the peers which are profitable and demonstrate a CAGR.
<b>Annual Growth</b>	Identified are biopharmaceutical companies which illustrate annual growth in pipeline and activities through self-funding.
<b>Longevity, tenure</b>	Benchmarked against executive management with a minimum tenure of three years, with a proven track record in the industry.
<b>Qualification, background</b>	Selection and benchmarking of management with dual or multiple academic qualifications, with a background in life sciences and proven track of operating in capital markets.
<b>Responsibility, risks</b>	Benchmarked against peer companies, where management bears executive responsibility and proven to manage operational, clinical, regulatory and financial risks longer-term.

<sup>1</sup> New molecular or new chemical entity, indicating complexity and length of R&D

During the year, the MD's remuneration was benchmarked against 12 Australian and 28 U.S. life science peer companies with different profiles, since there are few profitable biotechnology companies globally serving as a benchmark, (except for the mix of medical device, human and animal health prescriptive and over-the-counter pharmaceutical products, healthcare solutions and diagnostic focused companies) using the following criteria:

Benchmarking Criteria	Australian Companies	U.S. Companies
Market Capitalisation:	Between A\$450 million and A\$2.7 billion	Between US\$500 million and US\$1.7 billion
Industry Segment:	Pharmaceutical, Biotech, Medical companies	Biopharma companies



The financial performance of the Company measured against this peer group ranks strongly on TSR, EPS and revenues growth, and ROE criteria. The Company's rankings are shown below:

### PEER GROUP RANKINGS

10<sup>th</sup> / 41

**TSR**

6<sup>th</sup> / 41

**GROWTH IN  
EARNINGS**

4<sup>th</sup> / 41

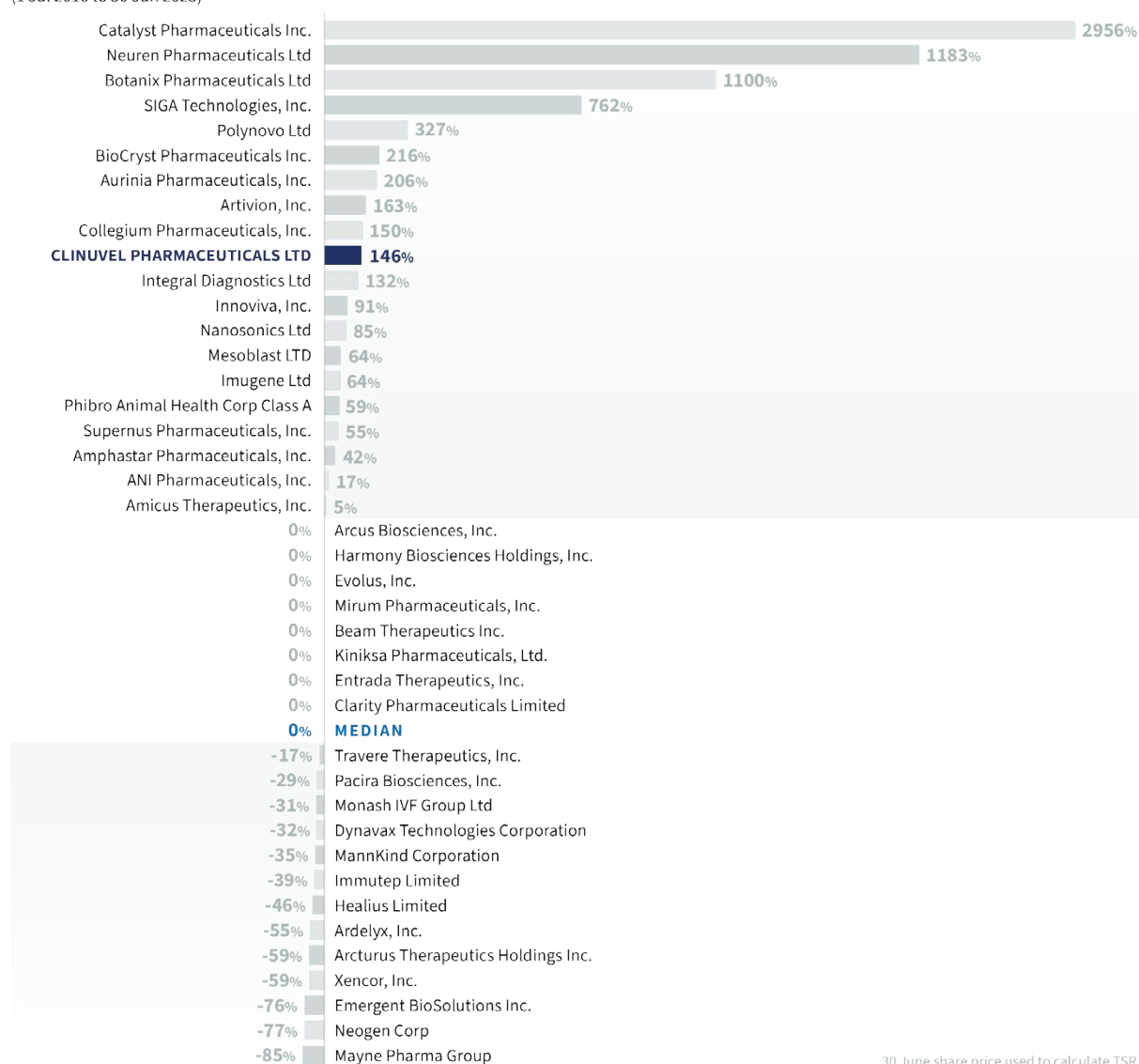
**TOTAL  
REVENUES**

8<sup>th</sup> / 41

**ROE**

#### 9 Year TSR

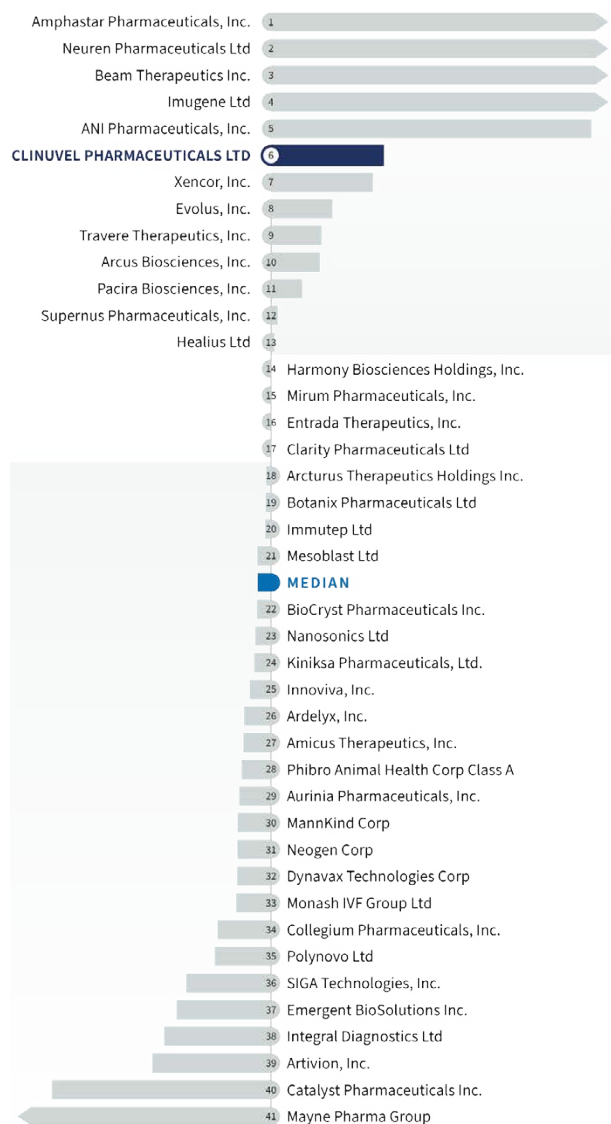
(1 Jul 2016 to 30 Jun 2025)



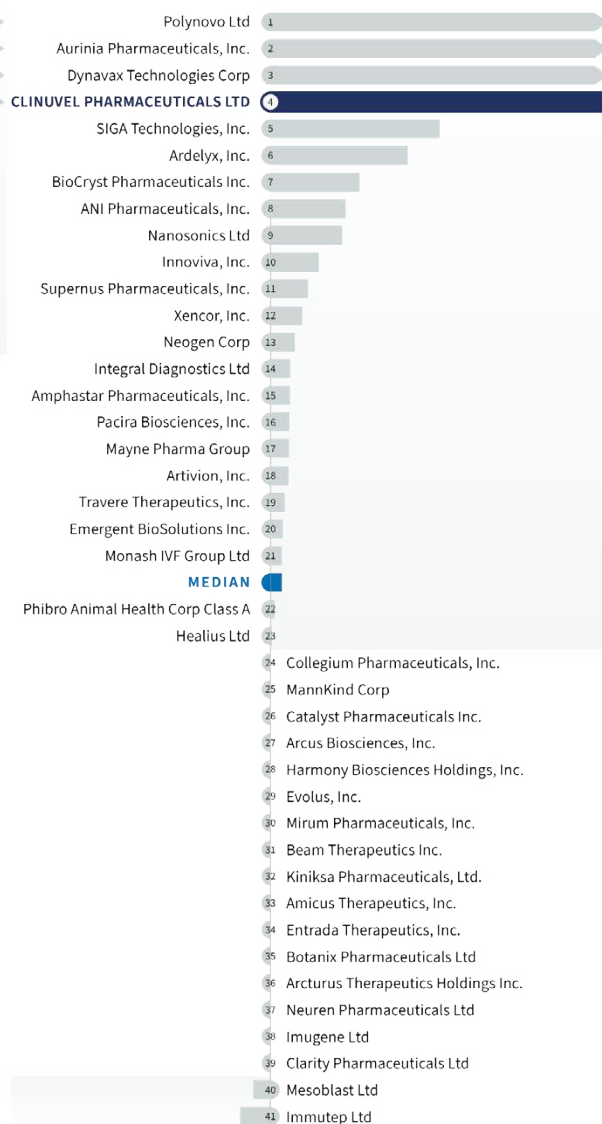
30 June share price used to calculate TSR  
Companies shown as zero have no data for the comparison period

**7 Year EPS Growth Rankings**

(2018 to 2025)

**9 Year Revenues Growth Rankings**

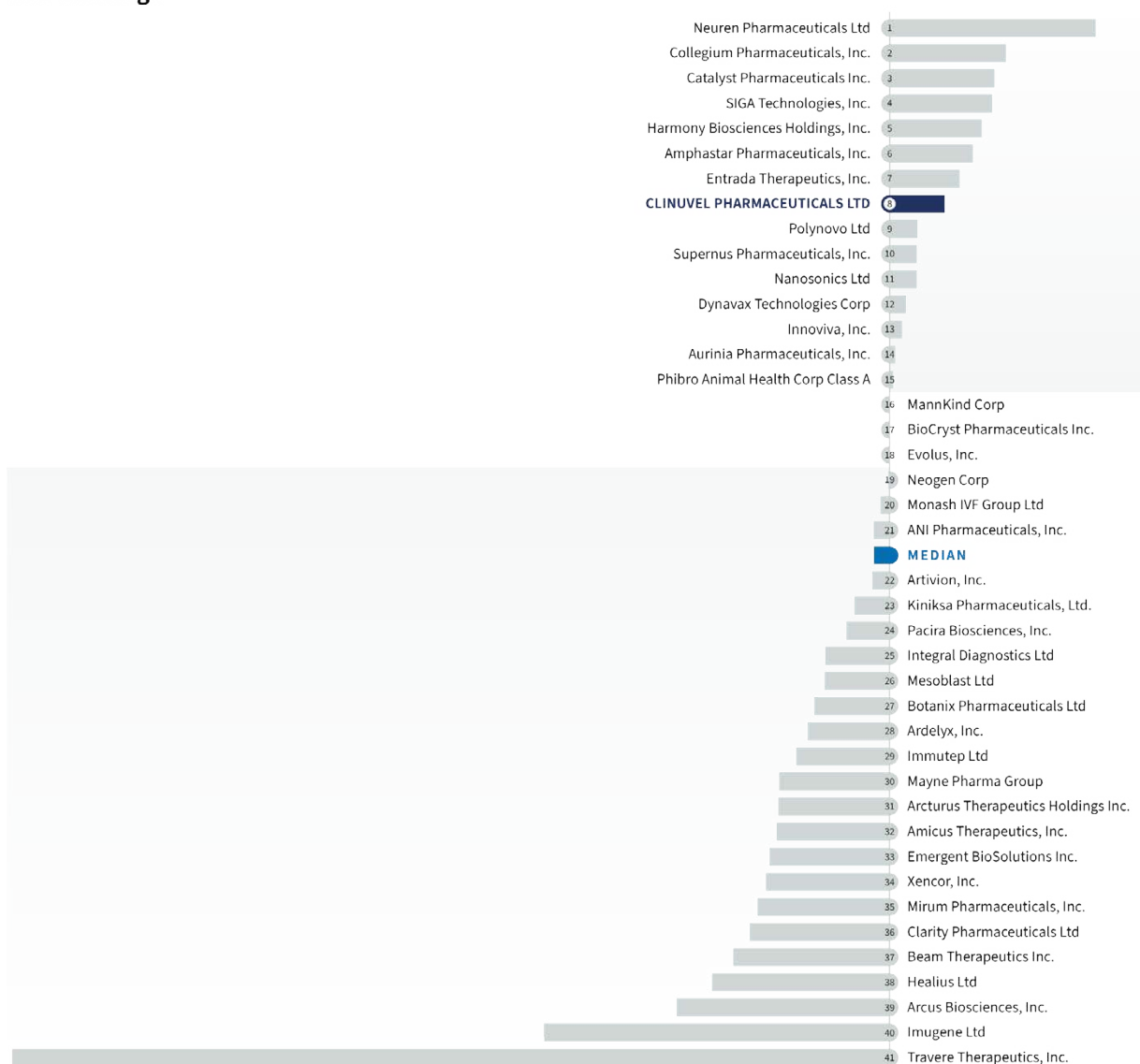
(2016 to 2025)



Companies shown as zero have no data for the comparison period

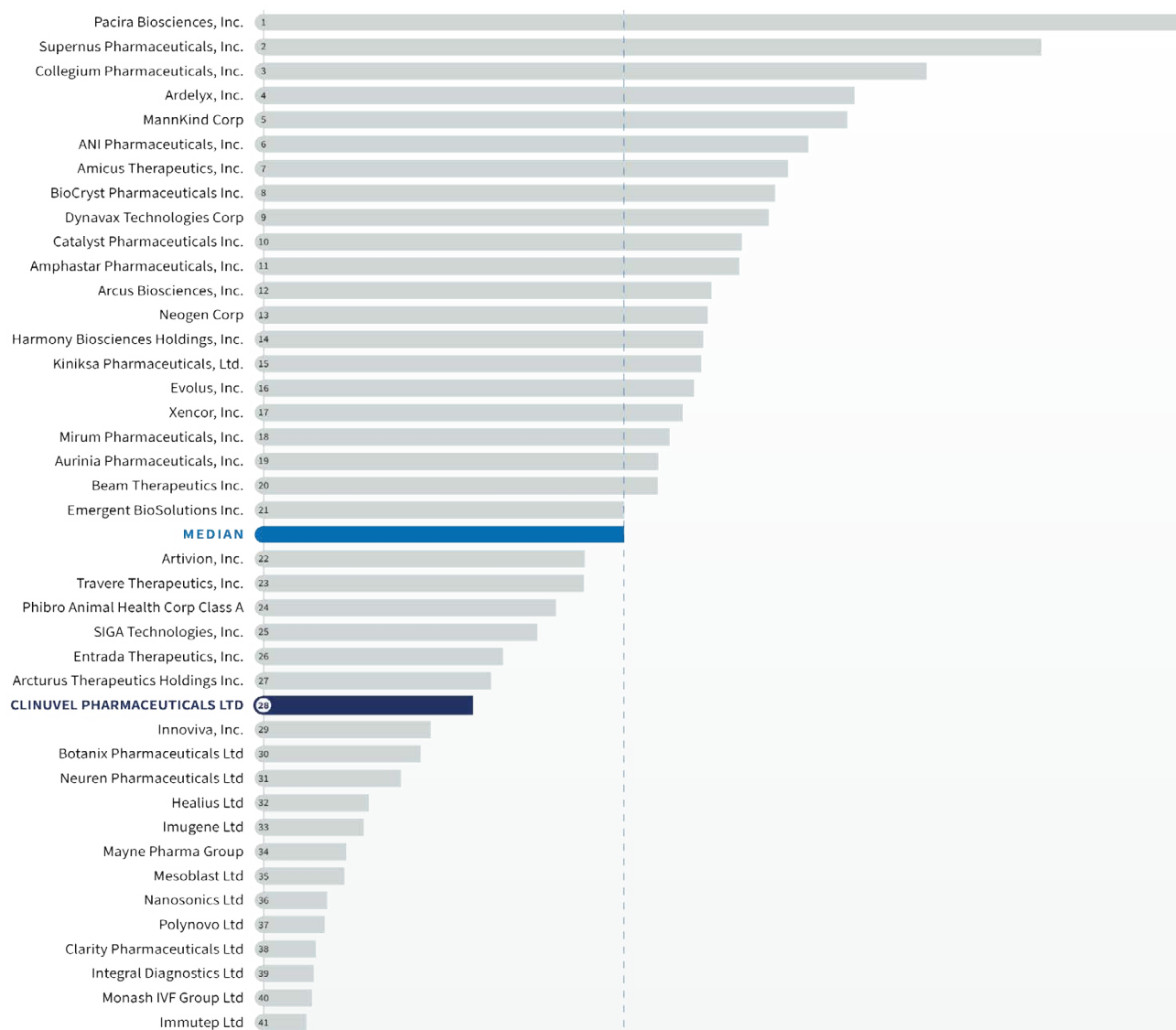


## ROE Rankings



Companies shown as zero have no data for the comparison period

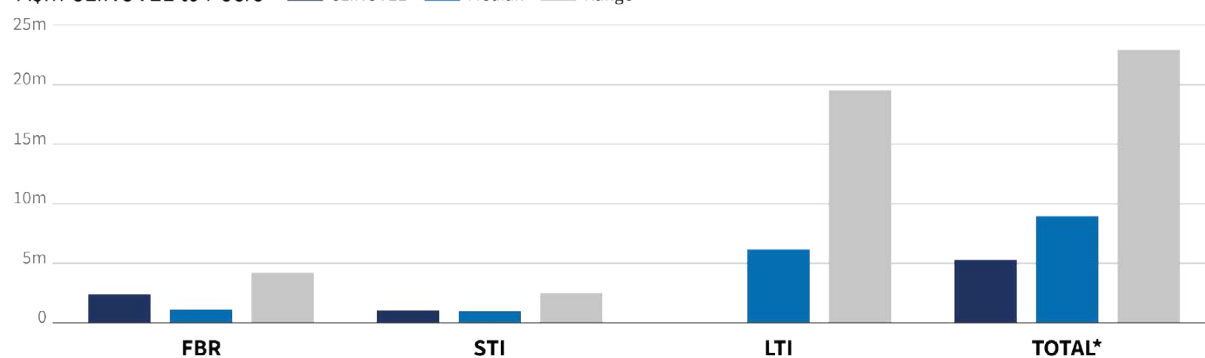
## Total REM comparison (A\$)



For FY2025, the MD's FBR was found to be positioned above the median level of the peer group, whereas the overall remuneration package was *well below* the median level. The Board considers the level of FBR to be appropriate, considering the long-term outperformance of the Company, the relatively unusually long-term tenure of the MD to lead the restructure of the Company since 2005, building a profitable and sustainable business, his deep knowledge of the targeted technologies, whilst delivering shareholder returns.

## FY2025 CEO Remuneration

A\$m CLINUVEL to Peers ■ CLINUVEL ■ Median ■ Range



\*CLINUVEL TOTAL includes A\$1.96m accrued retention award



## G. RELATIONSHIP BETWEEN REMUNERATION AND PERFORMANCE

The Group has dedicated its resources to the ongoing research, development, and commercialisation of its unique and medically beneficial technology. The remuneration and incentive framework, which has been put in place by the Committee, has ensured executive personnel are remunerated to focus on both maximising short-term operating performance and long-term strategic growth leading to shareholder value. A mix of metrics are used to assess achievement of regulatory, development, commercial and operational outcomes; financial metrics in isolation are not necessarily an appropriate measure of executive performance.

Specifically, the Committee looks at relations between overall performance, strategic targets and progress of the Group, and overall shareholder returns.

Milestone	Year Ended 30 June						
	2019	2020	2021	2022	2023	2024	2025
<b>Clinical and R&amp;D</b>							
VALLAURIX PTE LTD – Formulation & melanocortin development							
Adolescent FPP Patient Study SCENESEF®							
Ph II Arterial Ischaemic Stroke Study SCENESE® – Australia							
Ph II DNA Repair Studies – Europe							
Ph II Vitiligo Study – U.S.A.							
Ph III Vitiligo Study – Global							
Ph II Variegate Porphyria Study – EU							
Ph II Arterial Ischaemic Stroke Study PRÉNUMBRA® – Europe							
Commenced development of NEURACTHEL® formulation program							
<b>Regulatory</b>							
Marketing Authorisation – EU EMA (Submission and approval)							
Marketing Authorisation – US FDA (Submission and approval)							
Marketing Authorisation – Australian TGA (Submission and approval)							
Marketing Authorisation - Health Canada (Submission and approval)							
<b>Commercial</b>							
First commercial sales in EU							
First commercial sales in U.S.A.							
Pilot launch, first OTC Product							
<b>Market capitalisation (A\$m)</b>	1,649	1,267	1,517	734	883	770	520
Share Price High (\$)	39.85	45.88	31.23	44.67	28.72	21.45	17.71
Share Price Low (\$)	9.43	12.92	19.53	13.16	15.05	12.96	9.41
Closing Share Price (\$)	33.68	25.65	30.70	14.65	17.88	15.37	10.38
Change in Share Price over 1 Year (%)	206	(24)	20	(52)	20	(14)	(32)
Change in Share Price over 3 Years (%)	680	268	179	(56)	(30)	(50)	(30)
Change in Share Price over 5 Years (%)	1881	803	611	113	62	(54)	(60)
Change in Share Price since 1st Commercial Launch (%)	680	494	611	244	314	256	140
Dividend Paid (cents)	2.0	2.5	2.5	2.5	4.0	5.0	5.0
<b>EBIT (A\$m)</b>	18.115	13.136	25.713	34.321	45.579	50.679	51.553
<b>NPAT (A\$m)</b>	13.224	18.134	16.647	20.878	30.674	35.636	36.172

Analysis of CLINUVEL's share price performance against key life science indices shows a leading and positive outcome over the long-term (the past nine years). However, the Board is cognisant that the relation between the performance of the Company and its volume weighted average share price (VWAP) has not been maintained in recent years. This was the case in FY2025 as CLINUVEL's share price declined by 32.5%, whilst the Company has performed well and grown and there was lesser declines and some recovery evident in key biotech indices.

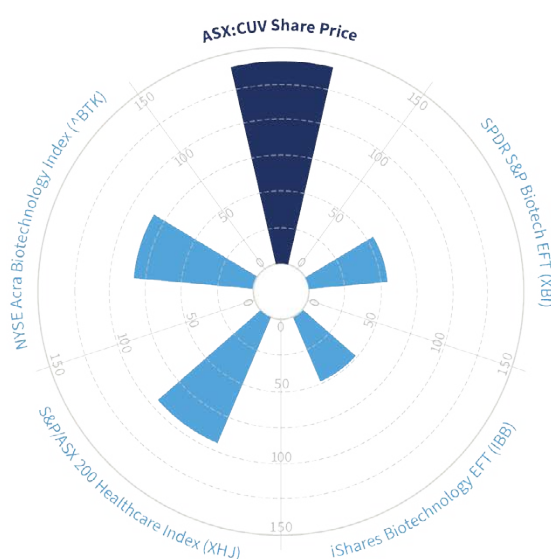
The graphs below show the share price over the past year and nine years compared to key indices and the share price over the longer term showing some of the key milestones that have been achieved.

## ASX:CUV Share Price and Key Indices

(% change, year to June 2025)



(% change, nine years to June 2025)



The Board believes the remuneration mix aligns the other executive KMP and MD to shareholder interest. The remuneration mix for 2024/25 is demonstrated in the table below.

The Board intends to award PR, or LTIs, to KMP (except the MD) in the coming financial year.

## ASX:CUV Share Price (A\$, end of daily trading)



### Milestones

- |                             |                                       |                                 |
|-----------------------------|---------------------------------------|---------------------------------|
| 1 EU distribution SCENESSE* | 9 US Distribution SCENESSE*           | 17 5th dividend paid            |
| 2 1st cash flow positivity  | 10 4th profit                         | 18 7th profit                   |
| 3 1st profit                | 11 3rd dividend paid                  | 19 6th dividend paid            |
| 4 2nd profit                | 12 TGA approval                       | 20 8th profit                   |
| 5 1st dividend paid         | 13 5th profit                         | 21 7th dividend paid            |
| 6 3rd profit                | 14 4th dividend paid                  | 22 CUV105 recruitment completed |
| 7 2nd dividend paid         | 15 Start life-science indices decline |                                 |
| 8 FDA approval              | 16 6th profit                         |                                 |



Position	Fixed Remuneration	STI Cash	LTI Cash	LTI Equity
Managing Director	100%	100% of Base Salary	None	None
<b>Other Executive KMP</b>				
COO	100%	10% of Base Salary	None	None
CSO	100%	9% of Base Salary	None	None
CFO	100%	10% of Base Salary	None	None

## H. NON-EXECUTIVE REMUNERATION

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

### 1) Non-Executive Director Fees

Non-Executive Director fees consist of base fees and committee fees and are inclusive of superannuation and all other contributions.

There are no further retirement benefits. The fees are outlined in the table below:

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

	Board Fees	Audit & Risk Committee	Remuneration Committee	Nomination Committee	Commercial Committee
Board Chair	175,000	-	-	-	-
Non-Executive Director	115,000	-	-	-	-
Committee Chair	-	25,000	25,000	25,000	25,000
Committee Member	-	15,000	15,000	15,000	15,000

\*\* The Managing Director does not receive Board fees for his membership as Director.

Under the Company's Constitution, the maximum aggregate remuneration available for division among the Non-Executive Directors is to be determined by the shareholders in a General Meeting and was set at \$1,200,000 at the 2024 AGM. This amount (or some part of it) is to be allocated to Non-Executive Directors as determined by the Board. The aggregate amount paid to Non-Executive Director for the year ended 30 June 2025 was \$840,814 (2024: \$437,084).

### 2) Non-Executive Director Long-Term Incentive – Equity Compensation

Long-term equity remuneration was formerly provided to Non-Executive Directors via the CLINUVEL Conditional Rights Plan and the Performance Rights Plan. Any issue of PRs to Non-Executive Directors requires shareholder approval. It is not planned for NEDs to participate in long-term equity compensation plans. No Non-Executive Director holds PRs as of 30 June 2025.

## I. SERVICE AGREEMENTS

Remuneration and other terms of employment for the MD and KMP are formalised by a service agreement determined by the Remuneration Committee and accepted by the Board of Directors. The agreement provides for FBR, STI, LTI, other benefits, and participation, when eligible, in the Group's Performance Rights Plan.

The MD makes recommendations to the Remuneration Committee on the service agreements entered into with other KMP, providing for base salary, incentives, other benefits and participation, when eligible, in the Group's Performance Rights Plan.

On appointment to the Board, all NEDs enter into a service agreement with the Company in the form of a letter of appointment which outlines the Board's policies, the Director's responsibilities, and compensation for holding office.

On 28 June 2024, the service agreement for the MD, Dr Wolgen, was extended for one further year to 30 June 2026.

The details of the service agreements to the MD and KMP are:

Name	Dr Philippe Wolgen	Mr Lachlan Hay	Dr Dennis Wright	Mr Peter Vaughan
Duration of contract	24 months (terminating 30 June 2026)	36 months (ending 31 January 2027)	No fixed term	No fixed term
Notice Period (from Company)	12 months	3 months	3 months	2 months
Notice Period (from Managing Director)	12 months	-	-	-
Notice Period (from Executive KMP)	-	3 months	3 months	2 months
Termination Payment without Cause	12 months	3 months	3 months	2 months
Termination Payment with Cause	None	None	None	None
Contract End Date	30 June 2026	31 January 2027	Not applicable	Not applicable



## J. DETAILS OF REMUNERATION

### 1) KMP remuneration of the Company for the years ended 30 June 2025 and 30 June 2024 – Cash Based Benefits

	Year	Gross Salary <sup>4</sup>	Short Term Incentive	Retention Award <sup>1</sup>	Other <sup>2</sup>	Superannuation/ Pension Fund	Total (Excluding Share-Based Payments)
		\$	\$	\$	\$	\$	\$
Dr P Wolgen <sup>3</sup>	2025	1,877,394	926,069	1,964,388	473,898	-	5,241,748
	2024	1,765,068	941,046	-	283,454	-	2,989,568
Mrs B Shanahan	2025	25,411	-	-	-	2,922	28,333
	2024	76,577	-	-	-	8,424	85,001
Dr K Agersborg	2025	124,583	-	-	-	-	124,583
	2024	75,000	-	-	-	-	75,000
Mrs S Smith	2025	146,667	-	-	-	-	146,667
	2024	80,000	-	-	-	-	80,000
Prof J Rosenfeld	2025	176,196	-	-	-	20,263	196,458
	2024	82,583	-	-	-	9,084	91,667
Mr M Pringle	2025	105,188	-	-	-	12,097	117,285
	2023	-	-	-	-	-	-
M G van Dievoet	2025	117,285	-	-	-	-	117,285
	2024	-	-	-	-	-	-
Dr P Grimes	2025	110,202	-	-	-	-	110,202
	2024	-	-	-	-	-	-
Mr W Blijdorp	2025	-	-	-	-	-	-
	2024	82,083	-	-	-	-	82,083
Prof J Likierman	2025	-	-	-	-	-	-
	2024	23,333	-	-	-	-	23,333
Mr L Hay	2025	382,101	30,568	-	107,447	29,932	550,048
	2024	-	-	-	-	-	-
Dr D Wright	2025	315,764	22,049	-	-	29,932	367,745
	2024	305,086	21,966	-	-	27,399	354,451
Mr P Vaughan	2025	285,000	22,800	-	-	29,932	337,732
	2024	-	-	-	-	-	-
Mr D Keamy	2025	180,264	-	-	-	6,529	186,792
	2024	361,594	26,035	30,736	-	27,399	445,763
Total	2025	3,846,055	1,001,486	1,964,388	581,345	131,607	7,524,880
	2024	2,851,324	989,047	30,736	283,454	72,305	4,226,866

<sup>1</sup> The retention reward for Dr Wolgen was accrued (but not paid) to the amount A\$1.96 million during FY2025 and is payable in FY2026.

<sup>2</sup> Other<sup>2</sup> includes health insurance, housing, and other allowances that may be subject to fringe benefits tax.

<sup>3</sup> Dr Wolgen's salary is paid in Euro currency.

<sup>4</sup> Does not include movement in annual leave and long service provisions.

## 2) KMP remuneration of the Company for the years ended 30 June 2025 and 30 June 2024 – Non-Cash Benefits

Share-based payments						
	Year	Total (Excluding Share- Based Payments)	Performance Rights (for accounting purposes only)	Issue of Shares	Total (Including Share- Based Payments)	Performance- based
		\$	\$		\$	%
Dr P Wolgen	2025	5,241,748	-	-	5,241,748	0%
	2024	2,989,568	752,844 <sup>2</sup>	-	3,742,412	20%
Mrs B Shanahan	2025	28,333	-	-	28,333	-
	2024	85,001	-	-	85,001	-
Dr K Agersborg	2025	124,583	-	-	124,583	-
	2024	75,000	-	-	75,000	-
Mrs S Smith	2025	146,667	-	-	146,667	-
	2024	80,000	-	-	80,000	-
Prof J Rosenfeld	2025	196,458	-	-	196,458	-
	2024	91,667	-	-	91,667	-
Mr M Pringle	2025	117,285	-	-	117,285	-
	2024	-	-	-	-	-
Mr G van Dievoet	2025	117,285	-	-	117,285	-
	2024	-	-	-	-	-
Dr P Grimes	2025	110,202	-	-	110,202	-
	2024	-	-	-	-	-
Mr W Blijdorp	2025	-	-	-	-	-
	2024	82,083	-	-	82,083	-
Prof J Likierman	2025	-	-	-	-	-
	2024	23,333	-	-	23,333	-
Mr L Hay	2025	550,048	16,240	38,325	604,613	9%
	2024	-	-	-	-	-
Dr D Wright	2024	367,745	22,843	38,325	428,913	14%
	2024	354,451	428,162	-	782,613	55%
Mr P Vaughan	2025	337,732	31,721	38,325	407,778	17%
	2024	-	-	-	-	-
Mr D Keamy	2025	186,792	-	-	186,792	-
	2024	445,763	2,218,120	-	2,663,883	83%
Total	2025	7,524,880	70,804	114,975	7,710,658	-
	2024	4,226,866	3,399,126	-	7,625,992	-

<sup>1</sup>As these values represent accounting values the KMP may or may not actually receive any benefit from these amounts, either in the current or future reporting periods. Any benefit obtained by the KMP is contingent upon the Company achieving certain performance conditions and the employee remaining in employment to a fixed date. The value of all PRs and share options granted, exercised and lapsed during the financial year is detailed in the following tables within the Remuneration Report. PRs were priced using either the Monte Carlo simulation pricing model or a binomial pricing model. The amount expensed each reporting period includes adjustments to the life-to-date expense of the grants based on the reassessed estimate of achieving non-market performance criteria.

<sup>2</sup> Dr Wolgen is no longer eligible for PR or any form of equity.



### 3) Remuneration Performance Rights holdings of KMP – 2025

	Balance at Start of Year	Issued as Compensation	Exercised*	Lapsed and Expired	Balance at End of Year	Perform Condition met, not exercisable until end Vesting Period*
<b>Directors</b>						
Dr P Wolgen	-	-	-	-	-	-
Mrs B Shanahan	-	-	-	-	-	-
Dr K Agersborg	-	-	-	-	-	-
Mrs S Smith	-	-	-	-	-	-
Prof J Rosenfeld	-	-	-	-	-	-
Mr M Pringle	-	-	-	-	-	-
Mr G van Dievoet	-	-	-	-	-	-
Dr P Grimes	-	-	-	-	-	-
<b>Other KMP</b>						
Mr L Hay	3,600	8,000	-	-	11,600	-
Dr D Wright	18,125	10,000	-	-	28,125	-
Mr P Vaughan	-	12,500	-	-	12,500	-
Mr D Keamy	7,357	-	-	(7,357)	-	-
*Mr D Keamy resigned on 1 July 2024 and therefore is not Key Management Personnel at the end of the reporting period.						

### 4) Shares held by KMP

The number of ordinary shares in the Company during the 2024/25 reporting period held by each of the Group's KMP, including their related parties, is set out below:

Year Ended 30 June 2025					
Personnel	Balance at Start of Year	Granted as Remuneration	Received on Exercise	Other Changes	Held at the End of Reporting Period
Dr P Wolgen	3,425,222	-	-	-	3,425,222
Mrs B Shanahan*	196,577	-	-	(196,577)	-
Dr K Agersborg	5,500	-	-	8,333	13,833
Mrs S Smith	420	-	-	-	420
Prof J Rosenfeld	3,148	-	-	-	3,148
Mr M Pringle	-	-	-	-	-
Mr G van Dievoet	-	-	-	-	-
Dr P Grimes	-	-	-	-	-
Other KMP					
Mr L Hay	139,847	3,500	-	-	143,347
Dr D Wright	188,812	3,500	-	-	192,312
Mr P Vaughan	-	3,500	-	-	3,500
Mr D Keamy**	362,890	-	-	(362,890)	-

\*Ms B Shanahan retired as a Non-Executive Director on 16 October 2024 and therefore is not a Non-Executive Director at the end of the reporting period. The change in holding reflects Mrs B Shanahan's retirement, not a sale of shares.

\*\*Mr D Keamy resigned on 1 July 2024 and therefore is not Key Management Personnel at the end of the reporting period. The change in holding reflects Mr D Keamy's resignation, not a sale of shares.

## 5) Remuneration details of Equity Incentives (Performance Rights)

Equity Incentives (Performance Rights)					
Name	Year Granted	Latest Year of Vesting	Vested in Year	Lapsed & Forfeited in Year	Max Value of Right at Grant Date Yet to Vest
Dr P Wolgen	-	-	-	-	-
Mrs B Shanahan*	-	-	-	-	-
Dr K Agersborg	-	-	-	-	-
Mrs S Smith	-	-	-	-	-
Prof J Rosenfeld	-	-	-	-	-
Mr M Pringle	-	-	-	-	-
Mr G van Dievoet	-	-	-	-	-
Dr P Grimes	-	-	-	-	-
Other KMP					
Mr L Hay	2011/12	no limitation	-	-	\$2,553
Mr L Hay	2024/25	2025/26	-	-	\$69,030
Dr D Wright	2011/12	no limitation	-	-	\$12,853
Dr D Wright	2024/25	2025/26	-	-	\$86,287
Mr P Vaughan	2024/25	2025/26	-	-	\$107,859

On exercise, each PR entitles the KMP to one fully paid ordinary share in the Company. The share price of the Company at the time of exercise is not known. The minimum value of unvested PRs is \$Nil. The exercise price for the PRs granted was \$Nil.

## 6) Remuneration details of cash incentives

Cash Incentives				
Name	Max Potential Opportunity (%)	STI Awarded (%)	STI Forfeited (%)	Total Granted (\$)
Dr P Wolgen	100%	55%	45%	926,0269
Mr L Hay	10%	80%	20%	30,568
Dr D Wright	9%	80%	20%	22,049
Mr P Vaughan	10%	80%	20%	22,800

## Loans to Directors and Executives

No loans were granted to Directors or executives for the years ended 30 June 2025 and 30 June 2024.

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

– END OF AUDITED REMUNERATION REPORT –



## Shares Provided Upon Exercise of Rights

### Details of Shares issued during the financial year as a result of exercise of rights

Entity	Number of shares issued	Issue Price for Shares	Class
CLINUVEL PHARMACEUTICALS LTD	6,250	Nil\$	Ordinary

### Unissued shares under Rights

Entity	Number of Shares under Rights	Exercise Price	Class	Expiry Date
CLINUVEL PHARMACEUTICALS LTD	485,625	Nil\$	Ordinary	Upon achievement of specific performance and time-based milestones or upon cessation of employment
<b>Total as at date of Directors' Report</b>	<b>485,625</b>			

### Auditor's Independence Declaration

The auditor's independence declaration as required by s.307C of the Corporations Act 2001 is included on page 85 of this Annual Report, and forms part of this Directors' Report.

### Proceedings On Behalf Of the Company

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

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



Dr Philippe Wolgen, MBA MD

Managing Director

Dated this 27<sup>th</sup> day of August, 2025

## Statement of Profit and Other Comprehensive Income for the year ended 30 June 2025

	Note	Consolidated Entity	
		2025	2024
		\$	\$
<b>Revenues</b>			
Commercial sales of goods	19	86,384,896	81,218,146
Sales reimbursements	19	8,632,674	6,960,162
<b>Total revenues</b>		<b>95,017,570</b>	<b>88,178,308</b>
Interest income		9,430,521	7,324,871
<b>Total interest income</b>		<b>9,430,521</b>	<b>7,324,871</b>
<b>Other income</b>			
Unrealised gain/(loss) on restating foreign currency balances and currencies held		903,262	(745,764)
Realised foreign currency (loss)/gain on transactions		(75,537)	(14,614)
Government grants and other income		24,183	562,936
<b>Total other income</b>		<b>851,908</b>	<b>(197,442)</b>
<b>Total Revenue, Interest and Other Income</b>		<b>105,299,999</b>	<b>95,305,737</b>
<b>Total expenses</b>			
Personnel-related		24,852,626	18,917,924
Share-based payments		2,001,467	6,107,272
Materials and related expenses		2,674,148	5,201,364
Commercial distribution		3,997,223	3,638,897
Finance, corporate and general		4,462,838	4,454,292
Changes in inventories of raw materials, work in progress and finished goods		1,805,282	(1,107,151)
Clinical and non-clinical development		7,403,595	2,348,296
Legal, insurance and IP		1,007,396	1,743,050
Depreciation and amortisation		1,181,394	1,142,326
Communication, branding and marketing		4,361,230	2,180,489
<b>Total expenses</b>		<b>53,747,199</b>	<b>44,626,759</b>
Profit before income tax		51,552,800	50,678,978
Income tax		-	-
Current	3(a)	14,401,769	15,532,461
Deferred	3(a)	978,513	(489,842)
<b>Income tax expense</b>	<b>3(a)</b>	<b>15,380,282</b>	<b>15,042,619</b>
Operating profit after income tax	15(b)	36,172,518	35,636,359
<b>Net profit for the year</b>		<b>36,172,518</b>	<b>35,636,359</b>
<b>Other comprehensive income</b>			
Items that may be re-classified subsequently to profit or loss			
Exchange differences of foreign exchange translation of foreign operations		(2,379,200)	138,945
<b>Other comprehensive (loss)/income for the period, net of income tax</b>		<b>(2,379,200)</b>	<b>138,945</b>
<b>Total comprehensive income for the period</b>		<b>33,793,318</b>	<b>35,775,304</b>
Basic earnings per share - cents per share	14	72.2	71.5
Diluted earnings per share - cents per share	14	71.8	69.8
The accompanying notes form part of these financial statements.			



## Statement of Financial Position as at 30 June 2025

		Consolidated Entity	
	Note	2025	2024
		\$	\$
<b>Current assets</b>			
Cash and cash equivalents	1(e) ,15(a)	28,020,655	35,200,751
Cash held in term deposits	1(f)	196,085,287	148,667,720
Trade and other receivables	4	27,461,362	26,238,297
Inventories	5	8,821,331	10,626,613
Other current assets		2,580,603	1,330,461
<b>Total current assets</b>		<b>262,969,238</b>	<b>222,063,842</b>
<b>Non-current assets</b>			
Property, plant and equipment	6	6,721,005	6,982,337
Right-Of-Use assets	7	405,951	737,788
Intangible asset		185,030	185,030
Deferred tax assets	3(c)	1,255,448	1,020,344
Lease bonds		213,340	134,208
<b>Total non-current assets</b>		<b>8,780,774</b>	<b>9,059,707</b>
<b>Total assets</b>		<b>271,750,012</b>	<b>231,123,549</b>
<b>Current liabilities</b>			
Trade and other payables	9	9,944,574	7,109,053
Income tax payables		14,547,035	15,851,385
Provisions	10	2,287,949	1,881,898
Lease liabilities	7	431,184	369,861
<b>Total current liabilities</b>		<b>27,210,742</b>	<b>25,212,197</b>
<b>Non-current liabilities</b>			
Deferred tax liabilities	3(d)	3,420,042	2,226,104
Lease liabilities	7	97,344	509,923
Provisions	10	213,258	163,959
<b>Total non-current liabilities</b>		<b>3,730,644</b>	<b>2,899,986</b>
<b>Total liabilities</b>		<b>30,941,386</b>	<b>28,112,183</b>
<b>Net assets</b>		<b>240,808,626</b>	<b>203,011,366</b>
<b>Equity</b>			
Contributed equity	11	169,280,668	168,802,368
Reserves	12	7,895,832	4,245,371
Retained earnings		63,632,126	29,963,627
<b>Total equity</b>		<b>240,808,626</b>	<b>203,011,366</b>
The accompanying notes form part of these financial statements.			

## Statement of Cash Flows for the Year Ended 30 June 2025

	Note	Consolidated Entity	
		2025	2024
		\$	\$
<b><i>Cash flows from operating activities</i></b>			
Receipts from customers		93,794,505	84,020,937
Payments to suppliers and employees		(44,447,740)	(39,504,978)
Income taxes paid		(15,725,799)	(15,648,111)
Interest received		7,450,313	7,633,046
Government grants		24,183	344,394
Proceed from insurance claims		-	208,594
<b>Net cash provided by operating activities</b>	<b>15(b)</b>	<b>41,095,462</b>	<b>37,053,882</b>
<b><i>Cash flows from investing activities</i></b>			
Investment in cash held in term deposits		(47,417,567)	(23,457,711)
Payments for property, plant and equipment		(298,567)	(5,576,215)
<b>Net cash used in investing activities</b>		<b>(47,716,134)</b>	<b>(29,033,926)</b>
<b><i>Cash flows from financing activities</i></b>			
Dividends paid		(2,504,019)	(2,470,227)
Issuance of shares related to employee share schemes		189,000	4,155,010
Payments related to employee share schemes		(189,000)	(4,155,010)
Payment of buy back shares		(251,906)	(754,236)
Payment of lease liabilities		(182,701)	(347,344)
<b>Net cash used in financing activities</b>		<b>(2,938,626)</b>	<b>(3,571,807)</b>
<b>Net (decrease)/increase in cash held</b>		<b>(9,559,296)</b>	<b>4,448,149</b>
<b>Cash and cash equivalents at beginning of the year</b>		<b>35,200,751</b>	<b>31,893,021</b>
Effects of exchange rate changes on foreign currency held		2,379,200	(1,140,419)
<b>Cash and cash equivalents at end of the year</b>	<b>15(a)</b>	<b>28,020,655</b>	<b>35,200,751</b>

The accompanying notes form part of these financial statements.

## Statement of Changes in Equity for the Year Ended 30 June 2025

	Share Capital	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
	\$	\$	\$	\$	\$
<b>Balance at 30 June 2023</b>	<b>151,849,375</b>	<b>19,370,046</b>	<b>3,185,998</b>	<b>(9,774,276)</b>	<b>164,631,143</b>
Exercise of performance rights under share-based payment	17,707,229	(17,707,229)	-	-	-
Lapsed, forfeited rights	-	(6,571,771)	-	6,571,771	-
Employee share-based payment options	-	6,107,272	-	-	<b>6,107,272</b>
Buy back shares	(754,236)	-	-	-	<b>(754,236)</b>
Dividends paid	-	-	-	(2,470,227)	<b>(2,470,227)</b>
<b>Transactions with owners</b>	<b>168,802,368</b>	<b>1,198,318</b>	<b>3,185,998</b>	<b>(5,672,732)</b>	<b>167,513,952</b>
Profit for the year	-	-	-	35,636,359	<b>35,636,359</b>
<b>Other comprehensive income:</b>					
Exchange differences of foreign exchange translation of foreign operations	-	-	(138,945)	-	<b>(138,945)</b>
<b>Total other comprehensive income</b>	<b>-</b>	<b>-</b>	<b>(138,945)</b>	<b>-</b>	<b>(138,945)</b>
<b>Balance at 30 June 2024</b>	<b>168,802,368</b>	<b>1,198,318</b>	<b>3,047,053</b>	<b>29,963,627</b>	<b>203,011,366</b>
Exercise of performance rights under share-based payment	80,424	(80,424)	-	-	-
Issue of shares	649,782	-	-	-	<b>649,782</b>
Employee share-based performance rights	-	1,351,685	-	-	<b>1,351,685</b>
Buy back shares	(251,906)	-	-	-	<b>(251,906)</b>
Dividends paid	-	-	-	(2,504,019)	<b>(2,504,019)</b>
Lapsed, forfeited rights	-	-	-	-	-
<b>Transactions with owners</b>	<b>169,280,668</b>	<b>2,469,579</b>	<b>3,047,053</b>	<b>27,459,608</b>	<b>202,256,908</b>
Profit for the year	-	-	-	36,172,518	<b>36,172,518</b>
<b>Other comprehensive income:</b>					
Exchange differences of foreign exchange translation of foreign operations	-	-	2,379,200	-	<b>2,379,200</b>
<b>Total other comprehensive income</b>	<b>-</b>	<b>-</b>	<b>2,379,200</b>	<b>-</b>	<b>2,379,200</b>
<b>Balance at 30 June 2025</b>	<b>169,280,668</b>	<b>2,469,579</b>	<b>5,426,253</b>	<b>63,632,126</b>	<b>240,808,626</b>



## Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2025

### 1. Summary Of Other Potentially Material Accounting Policies

This note provides a list of other potentially material accounting policies adopted in the preparation of these consolidated financial statements to the extent they have not already been disclosed in the other notes below. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial statements are for the group consisting of CLINUVEL PHARMACEUTICALS LTD and its subsidiaries.

#### a) Basis Of Preparation

The financial report is a general purpose financial report that has been prepared in accordance with Australian Accounting Standards, other authoritative pronouncements of the Australian Accounting Standards Board and the Corporations Act 2001. Compliance with Australian Accounting Standards ensures the consolidated financial statements and notes of the consolidated entity with International Financial Reporting Standards ("IFRS"). CLINUVEL PHARMACEUTICALS LTD is a for-profit entity for the purposes of reporting under Australian Accounting Standards.

The financial report has been prepared on an accruals basis and is based on historical costs and does not take into account changing money values or, except where stated, current valuations of financial assets. Cost is based on the fair values of the consideration given in exchange for assets. The accounting policies have been consistently applied, unless otherwise stated.

Both the functional and presentation currency of the Group and its Australian controlled entities is Australian dollars. The functional currency of certain non-Australian controlled entities is not Australian dollars. As a result, the results of these entities are translated to Australian dollars for presentation in the CLINUVEL PHARMACEUTICALS LTD financial report.

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

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

#### b) Principles Of Consolidation

The consolidated financial statements are prepared by combining the financial statements of all the entities that comprise the consolidated entity, being the Company (the parent entity) and its subsidiaries as defined in Australian Accounting Standard Board (AASB 10). Consistent accounting policies are employed in the preparation and presentation of the consolidated financial statements.

The consolidated financial statements include the information and results of each subsidiary from the date on which the Company obtains control and until such time as the Company ceases to control such entity. In preparing the consolidated financial statements, all intercompany balances and transactions, and unrealised profits arising within the consolidated entity are eliminated in full.

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

#### c) Going Concern

The financial statements of the consolidated entity have been prepared on a going concern basis. The consolidated entity's operations are subject to risk factors that could materially impact the financial performance and position of the consolidated entity.

The going concern basis assumes that, if required, future capital raisings will be available to enable the consolidated entity to acquire new entities with projects of interest and to undertake the research, development and commercialisation of existing projects and that the subsequent commercialisation of products will be successful. The consolidated entity has successfully raised additional working capital in past years. Should cash flows from its commercialisation activities not provide adequate funding to finance potential acquisitions or sustain its research, development and commercialisation projects in the coming financial year, the Directors would consider the need to bring in additional funds from various funding sources. The Company has sufficient amounts of cash to be able to continue as a going concern and therefore will be able to realise its assets and extinguish its liabilities in the normal course of business and at the amounts stated in the financial statements.

## d) Income Tax

### Current Tax

Current tax is calculated by reference to the amount of income tax payable or recoverable in respect of the taxable profit or loss for the period. It is calculated using tax rates and tax laws that have been enacted or substantially enacted by reporting date. Current tax for current and prior periods is recognised as a liability to the extent it is unpaid.

### Deferred Tax

Deferred tax is accounted for using the comprehensive balance sheet liability method in respect of temporary differences arising from differences between the carrying amount of assets and liabilities in the financial statements and corresponding tax base of those items.

In principle, deferred tax liabilities are recognised on all taxable differences. Deferred tax assets are recognised for deductible temporary differences and unused tax losses to the extent that it is probable that sufficient unused tax losses and tax offsets can be utilised by future taxable profits. However, deferred tax assets and liabilities are not recognised if the temporary differences giving rise to them arise from the initial recognition of assets and liabilities (other than as a result of a business combination) which affect neither taxable income nor accounting profit. Furthermore, a deferred tax liability is not recognised in relation to taxable temporary differences arising from goodwill.

Deferred tax liabilities are recognised for taxable temporary differences arising on investments in subsidiaries, except where the consolidated entity is able to control the reversal of the temporary differences and it is probable that the temporary differences will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with these investments and interests are only recognised to the extent that it is probable that there will be sufficient taxable profits against which to utilise the benefits of the temporary differences and they are expected to reverse in the foreseeable future.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period(s) when the asset and liability giving rise to them are realised or settled, based on tax rates (and tax laws) that have been enacted or substantially enacted by reporting date. The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the consolidated entity expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets and liabilities are offset when they relate to income taxes levied by the same taxation authority and the Company/consolidated entity intends to settle its current tax assets and liabilities on a net basis.

### Tax Consolidation

The Company and its wholly-owned Australian entities are part of a tax-consolidation group under Australian taxation law. CLINUVEL PHARMACEUTICALS LTD is the head entity of the tax-consolidation group.

### Current And Deferred Tax For The Period

Current and deferred tax is recognised as an expense or income in the Statement of Profit or Loss and Other Comprehensive Income, except when it relates to items credited or debited directly to equity, in which case the deferred tax is also recognised directly in equity, or where it arises from the initial accounting for a business combination, in which case it is taken into account in the determination of goodwill or discount on acquisition.

A deferred tax asset has been recognised as at 30 June 2025 and 30 June 2024 after management judgement was applied to assess whether its unused tax losses and tax offsets could be utilised by future taxable profits.

It was determined:

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

## e) Cash and Cash Equivalents

Cash and cash equivalents comprise of cash on hand and at call deposits held with banks or financial institutions. The cash at bank amounts earns floating rates based on daily bank account interest rates. The carrying amounts of cash and cash equivalents represent fair value. Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes.

## f) Cash Held in Term Deposits

Cash Held in Term Deposits comprises of term deposits, bank bills and investments in money market instruments held with banks or financial institutions which are easily convertible to a known amount of cash and subject to an insignificant risk of change in value. The carrying amounts of cash held in term deposits equivalents represent fair value. The term deposits are readily convertible to cash within 31 days' notice and after a market-related rate reduction to the interest on the term deposit principal is applied. Part of our cash management processes is to place cash in term deposits with banks and financial institutions with differing maturity dates which may extend several months from their commencement 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.

## g) Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost or net realisable value. Cost comprises, direct material and labour. Costs are assigned to individual items of inventory on the basis of weighted average costs. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

## h) Other Current Assets

Other current assets comprise prepayments of drug peptide still in development stage and yet to be used in the Group's R&D program and prepayments for certain insurances yet to expire, along with other general prepayments. The expenditures represent an unused expense and therefore a decrease in future economic benefit has yet to be incurred.

## i) Property, Plant and Equipment

Plant and equipment are stated at cost less accumulated depreciation and impairment. Cost includes expenditure that is directly attributable to the acquisition of the item. In the event that settlement of all or part of the purchase consideration is deferred, cost is determined by discounting the amounts payable in the future to their present value as at the date of acquisition.

During this financial year, 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.

Depreciation is calculated on a straight-line basis over the estimated useful life of the assets as follows:

- |                          |                         |
|--------------------------|-------------------------|
| • Land                   | Not depreciated         |
| • Building               | Over 50 years           |
| • Plant and equipment    | Between 4 to 10 years   |
| • Furniture and fittings | Between 5 to 10 years   |
| • Leasehold improvements | Over the term of leases |

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each financial year-end. Gains and losses on disposal of assets are determined by comparing proceeds upon disposal with the asset's carrying amount. These are included in the Profit or Loss.

## j) Leases

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

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

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



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

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

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

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

## **k) Investments And Other Financial Assets**

### **Recognition And Derecognition**

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

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

### **Classification And Initial Measurement Of Financial Assets**

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

### **Subsequent Measurement Of Financial Assets**

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

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

Classifications are determined by both:

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

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

### **Financial Assets At Amortised Cost**

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

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

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

### **Impairment Of Financial Assets - Trade And Other Receivables**

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

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

### **Classification And Measurement of Financial Liabilities**

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

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

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

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

## **l) Impairment Of Assets**

At each reporting date, the consolidated entity reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where the asset does not generate cash flows that are independent from other assets, the consolidated entity estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment annually and whenever there is an indication that the asset may be impaired. Recoverable amount is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risk specified to the asset for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognised in the Profit or Loss immediately.

Where an impairment loss subsequently reverses, the carrying amount of the asset (cash-generating unit) is increased to the revised estimate of its recoverable amount, but only to the extent that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset (cash-generating unit) in prior years. A reversal of an impairment loss is recognised in the Profit or Loss immediately.

## **m) Payables**

Trade payables and other accounts payable are recognised when the consolidated entity becomes obliged to make future payments resulting from the purchase of goods and services, incurred prior to the end of the financial year.

## **n) Employee Benefits**

Provision is made for benefits accruing to employees in respect of wages and salaries, loyalty payment, annual leave and long service leave when it is probable that settlement will be required and they are capable of being measured reliably.

Provisions made in respect of employee benefits expected to be settled within 12 months, are measured at their nominal values using the remuneration rate expected to apply at the time of settlement.

Provisions made in respect of employee benefits which are not expected to be settled within 12 months are measured as the present value of the estimated future cash outflows to be made by the consolidated entity in respect of services provided by employees up to reporting date. The discount rate used to estimate future cash flows is per the Australian high quality corporate bond rates.

## **o) Provisions**

Provisions are recognised when a present obligation to the future sacrifice of economic benefits becomes probable, and the amount of the provision can be measured reliably.

The amount recognised as a provision is the best estimate of the consideration required to settle the present obligation at reporting date, taking into account the risks and uncertainties surrounding the obligation. Where a provision is

measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows.

When some or all of the economic benefits required to settle a provision are expected to be recovered from a third party, the receivable is recognised as an asset if it is virtually certain that recovery will be received, and the amount of the receivable can be measured reliably.

## **p) Share Capital**

Ordinary share capital is recognised at the fair value of the consideration received by the Company.

Any transaction costs arising on the issue of ordinary shares are recognised directly in equity as a reduction of the share proceeds received.

## **q) Earnings Per Share**

### **Basic Earnings Per Share**

Basic earnings per share is determined by dividing net profit after income tax attributable to members of the Company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year.

### **Diluted Earnings Per Share**

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares.

## **r) Revenue and Other Income**

### **Revenue Arises From The Sale Of SCENESSE® Implants**

The Group's revenue from contracts with customers arise from the commercial sales of goods and sales reimbursements. Commercial sales of goods are the commercial sales of SCENESSE® implants in Europe and U.S.A. Sales reimbursements are the distribution of SCENESSE® under special access reimbursement schemes. The special access reimbursement scheme provides for the import and supply of an unapproved therapeutic good to patients, often on a case-by-case basis.

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

- a) identifying the contract with a customer;
- b) identifying the performance obligations;
- c) determining the transaction price;
- d) allocating the transaction price to the performance obligations; and
- e) recognising revenue when/as performance obligation(s) are satisfied.

Based on the above revenue recognition process and the nature of all revenue streams from contracts with customers, the Group recognises revenues as earned from commercial sales of goods and sales reimbursements (constrained by variable considerations, which include return and rebates) when performance obligations are satisfied at a point in time, which is when control of the goods passes to the customer or generally upon receipt of shipment, at an amount that reflects the consideration to which the Group expects to be entitled in exchange for the goods.

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

Note 19 provides additional disclosures disaggregating revenue by geographical market.

### **Interest**

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

### **Government Grant**

Government grants represent the Research Incentive Scheme for Companies provided by the Singapore Economic Development Board, along with the Rebate Cash Grant and Progressive Wage Credit Scheme Payout from Singaporean government. Government grants are recognised in the financial statements at their fair values when there is a reasonable assurance that the Consolidated Entity will comply with the requirements and that the grant will be received.



## s) Research And Development Expenditure

Expenditure on research activities is recognised as an expense in the period in which it is incurred. Where no internally generated intangible asset can be recognised, development expenditure is recognised as an expense in the period as incurred. An intangible asset arising from development (or from the development phase of an internal project) is recognised if, and only if, all of the following is demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The consolidated entity uses its critical judgement in continually assessing whether development expenditures meet the recognition criteria of an intangible asset.

Whilst at the end of the financial year the consolidated entity had received European and US regulatory approval and launched a European and U.S. product the above criteria have not been fully satisfied to support the recognition and generation of an internally generated intangible asset.

## t) Goods And Services Tax/Value Added Tax (GST)

Revenues, expenses and assets are recognised net of the amount of 'goods and services tax' or 'valued added tax' as it is known in certain jurisdictions (GST), except:

- where the amount of GST incurred is not recoverable from the taxation authority, it is recognised as part of the costs of acquisition of an asset or as part of an item of expense; or
- for receivables and payables which are recognised inclusive of GST.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables. Cash flows are included in the Statement of Cash Flow on a gross basis. The GST component of cash flows arising from investing and financing activities which is recoverable from, or payable to, the taxation authority is classified as operating cash flows.

## u) Comparatives

Where necessary, comparatives have been reclassified and repositioned for consistency with current year disclosure.

## v) Foreign Currency Transactions and Balances

All foreign currency transactions during the financial year are brought to account using the exchange rate in effect at the date of the transaction. Foreign currency monetary items at reporting date are translated at the exchange rate existing at reporting date. Non-monetary assets and liabilities carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when the fair value was determined. Exchange differences are recognised in profit or loss in the period in which they arise as defined in AASB 121.

Foreign subsidiaries that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- At the spot rate at reporting date for assets and liabilities; and
- At average monthly exchange rates for income and expenses.

Resulting differences are recognised within equity in a foreign currency translation reserve.

## w) Share-Based Payment Transactions

Benefits are provided to employees of the Group in the form of share-based payment transactions, whereby employees render services in exchange for shares or rights over shares ("equity-settled transactions").

The cost of these equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value of conditional performance rights is measured by a Monte Carlo simulation pricing model for those performance rights with market capitalisation hurdles and either a binomial or a trinomial model for those performance rights not linked to the price of the shares of CLINUVEL PHARMACEUTICALS LTD ("non-market vesting conditions"). It is determined at grant date and expensed on a straight-line basis over the vesting period. In valuing equity-settled transactions, no account is taken of any performance conditions, other than conditions linked to the price of the shares of CLINUVEL PHARMACEUTICALS LTD ("market conditions").

The cost of equity-settled transactions is recognised, together with a corresponding increase in equity, over the period in which the performance conditions are fulfilled, ending on the date on which the relevant employees become fully entitled to the award ("vesting date").

The cumulative expense recognised for equity-settled transactions at each reporting date until vesting date reflects (i) the extent to which the vesting period has expired and (ii) the number of awards that, in the opinion of the Directors of the Group, will ultimately vest. This opinion is formed based on the best available information at reporting date. No adjustment is made for the likelihood of market performance conditions being met as the effect of these conditions is included in the determination of fair value at grant date.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified. In addition, an expense is recognised for any increase in the value of the transaction as a result of the modification, as measured at the date of modification. Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately.

However, if a new award is substituted for the cancelled award and designated as a replacement award on the date that it is granted, the cancelled and new award are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of earnings per share.

## **x) Critical Accounting Estimates and Judgement**

The Directors evaluate estimates and judgements incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the Group.

### **Key Estimates – Share-Based Payments Transactions**

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined using either a Monte Carlo simulation pricing model for market conditions, or a Binomial Options Valuation pricing model for non-market conditions, using the assumptions detailed in Note 21. The total expense is brought to account over the vesting period which for some instruments requires the group to form judgements associated with the timing and probability of vesting conditions.

### **Key Judgements – Trade Debtors**

In applying the Group's accounting policy to trade debtors, significant judgement is involved in assessing the expected credit loss of trade debtors amounts. The Group uses ageing of trade debtors and use judgement to assess the expected credit loss of trade debtors taking into account historical loss experience and other forward-looking factors specific to the debtors and the economic environment. The value of trade debtors is included in Note 4.

### **Key Judgements – Tax Losses**

Given the Company's and each individual entities' history of losses, the Group has recognised a deferred tax asset with regard to unused tax losses and other temporary differences. The Directors have determined the Group will generate sufficient taxable income against which the unused tax losses and other temporary differences can be utilised. The value of tax losses both recognised and not recognised is included in Note 3.

### **Uncertainty Over Income Tax Treatments**

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

## **y) Segment Reporting**

A segment is a component of the consolidated entity that earns revenues or incurs expenses whose results are regularly reviewed by the Chief Operating Decision Maker 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 consolidated entity has formed four Divisions – Pharmaceuticals, Healthcare Solutions, Communications Branding & Marketing, and Manufacturing but operates in a single operating segment, being the biopharmaceutical

sector, and the majority of its activities continue to be concentrated on researching, developing and commercialising a sole asset in the biopharmaceutical sector, being its leading drug candidate. Accordingly, the consolidated entity has one operating segment within the definition of AASB 8. 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 in Note 19. The Group has one operating segment within the definition of AASB 8 Operating Segments.

## **z) New Australian Accounting Standards Issued But Not Yet Effective**

The Group has not adopted any new accounting standards or interpretations during the financial year. The Group is yet to undertake a detailed assessment of the impact of any new accounting standards or interpretations that are not effective. However, based on the Group's preliminary assessment, new accounting standards or interpretations are not expected to have a material impact on the transactions and balances recognised in the consolidated financial statements for the year ended 30 June 2025.

## **2. Profit/(Loss) From Continuing Operations**

Profit/(loss) before income tax includes the following specific expenses	Consolidated Entity	
	2025	2024
Employee benefits expense	24,379,103	17,861,812
Depreciation on property, plant & equipment	786,664	753,184
Amortisation of right-of-use assets	359,079	331,932
Operating lease expense – minimum lease payments	182,701	339,011
Bank charges	39,611	41,562
Loss on sale of property, plant and equipment	1,428	-



### 3. Income Tax Expense

	Consolidated Entity	
	2025	2024
	\$	\$
<b>(a) Income tax expense</b>		
Current	14,401,769	15,532,461
Deferred	978,513	(489,842)
<b>Income tax expense</b>	<b>15,380,282</b>	<b>15,042,619</b>
<b>Deferred tax included in income tax benefit comprises:</b>		
Decrease/(increase) in deferred tax assets	(105,286)	(110,542)
Increase/(decrease) in deferred tax liabilities	1,083,799	(379,300)
	<b>978,513</b>	<b>(489,842)</b>
<b>(b) Numerical</b>		
Profit before income tax expense	51,552,800	50,678,978
Tax at the statutory tax rates of 30% in 2025 and 2024	15,465,840	15,203,693
<i>Tax effect amounts which are not deductible/(taxable) in calculating taxable income:</i>		
Other non-deductible (deductible) expenses for tax purposes	(85,558)	(161,074)
<b>Income tax expense</b>	<b>15,380,282</b>	<b>15,042,619</b>
<b>Tax losses not recognised</b>		
Unused tax losses for which no deferred tax asset has been recognised	21,400,277	18,301,957
<b>(c) Deferred tax assets</b>		
Carry forward tax losses	1,128,410	856,768
Intangibles	567,170	572,581
Provisions	227,715	256,668
Accrued expenses	140,922	225,869
Lease liabilities	44,438	71,804
	<b>2,108,655</b>	<b>1,983,690</b>
<b>Reconciliation to the Statement of Financial Position</b>		
Total deferred tax assets	2,108,655	1,983,690
Set-off of deferred tax liabilities that are expected to reverse in the same period	(853,207)	(963,346)
	<b>1,255,448</b>	<b>1,020,344</b>
<b>Movements</b>		
Opening balance	1,983,690	1,870,775
Carry forward tax losses	271,642	(155,103)
Accrued expenses	(84,947)	164,169
Provisions	(28,953)	23,388
Lease liabilities	(27,366)	61,162
Intangibles	(5,411)	19,299
	<b>2,108,655</b>	<b>1,983,690</b>
<b>(c) Deferred tax liabilities</b>		
Unrealised foreign exchange gains	(4,208,154)	(2,744,331)
Right-of-use assets	(69,031)	(124,435)
Intangibles	3,936	18,449
Accrued income	-	(339,133)
	<b>(4,273,249)</b>	<b>(3,189,450)</b>
<b>Reconciliation to the Statement of Financial Position</b>		
Total deferred tax liabilities	(4,273,249)	(3,189,450)
Set-off of deferred tax assets that are expected to reverse in the same period	853,207	963,346
	<b>(3,420,042)</b>	<b>(2,226,104)</b>
<b>Movements</b>		
Opening balance	(3,189,450)	(3,568,750)
Unrealised foreign exchange gains	(1,463,825)	398,113
Accrued income	339,134	81,756
Right-of-use assets	55,405	(114,327)
Intangibles	(14,513)	13,758
	<b>(4,273,249)</b>	<b>(3,189,450)</b>
Deferred tax assets include US deferred tax assets that cannot be offset with Australian deferred tax liabilities. The tax rates used in this report are the Australian corporate tax rate of 30% in 2025 and 2024, income tax rate of 21% for US entity in 2025 and 2024 and income tax rate of 25% for UK entity in 2025 and 2024.		

## 4. Trade and Other Receivables

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Current</b>		
Trade debtors	24,318,824	25,162,556
Interest receivables	3,110,651	1,130,444
Sundry debtors	184,845	94,803
Expected credit losses	(152,958)	(149,506)
<b>Total</b>	<b>27,461,362</b>	<b>26,238,297</b>
<p>Trade debtors are recognised initially at the amount of consideration that is unconditional, when they are recognised at fair value. They are subsequently measured at amortised cost using the effective interest method and due to their short-term nature their carrying amount is considered to be the same as their fair value. A provision for expected credit losses (ECL) is recognised based on the difference between the contractual cashflows due in accordance with the contract and all the cash flows that the Group expects to receive. The Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment. As at 30 June 2025, the Group had a provision for expected credit loss of \$152,958 (2024 \$149,506). No write off of ECL in 2025 and 2024.</p>		

	\$	\$
<b>Expected credit losses</b>		
Opening balance as at 1 July	(149,506)	(166,158)
Reversal of / (provision for) expected credit losses	(3,452)	16,652
<b>Closing balance as at 30 June 2025</b>	<b>(152,958)</b>	<b>(149,506)</b>

## 5. Inventories

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Current</b>		
Raw materials – at cost	683,836	571,169
Work in progress – at cost	5,172,639	7,026,835
Finished goods – at cost	2,964,856	3,028,609
<b>Total</b>	<b>8,821,331</b>	<b>10,626,613</b>
<p>During the financial year there was write-off of inventory totalling \$784,711 (2024: \$0).</p>		

## 6. Property, Plant and Equipment

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Land and building</b>		
At cost	5,015,767	4,967,769
Less: accumulated depreciation	(118,665)	(76,327)
<b>Sub-total</b>	<b>4,897,102</b>	<b>4,891,442</b>
<b>Plant and equipment</b>		
At cost	2,091,995	1,849,823
Less: accumulated depreciation	(1,050,992)	(758,157)
<b>Sub-total</b>	<b>1,041,003</b>	<b>1,091,666</b>
<b>Furniture and fittings</b>		
At cost	95,034	92,293
Less: accumulated depreciation	(48,817)	(35,639)
<b>Sub-total</b>	<b>46,217</b>	<b>56,654</b>
<b>Leasehold improvements</b>		
At cost	1,987,000	1,987,000
Less: accumulated amortisation	(1,250,317)	(1,044,425)
<b>Sub-total</b>	<b>736,683</b>	<b>942,575</b>
<b>Total property, plant and equipment</b>	<b>6,721,005</b>	<b>6,982,337</b>

### Movements in Carrying Amounts –Property, Plant and Equipment

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

	Land & Building	Plant And Equipment	Furniture And Fittings	Leasehold Improvements	Total
		\$	\$	\$	\$
Carrying amount at 1 July 2023	-	997,376	19,216	1,001,269	2,017,861
Additions	4,967,769	379,071	46,690	98,951	5,492,481
Disposals	-	(16,635)	-	-	(16,635)
Depreciation written back on disposals	-	14,133	-	-	14,133
Depreciations expense	(76,327)	(282,279)	(9,252)	(157,645)	(525,503)
<b>Carrying amount at 30 June 2024</b>	<b>4,891,442</b>	<b>1,091,666</b>	<b>56,654</b>	<b>942,575</b>	<b>6,982,337</b>
Additions	47,997	247,829	2,741	-	298,567
Disposals/reallocation	-	(5,656)	-	-	(5,656)
Depreciation written back on disposals	-	-	-	-	-
Depreciations expense	(42,337)	(292,836)	(13,178)	(205,892)	(554,243)
<b>Carrying amount at 30 June 2025</b>	<b>4,897,102</b>	<b>1,041,003</b>	<b>46,217</b>	<b>736,683</b>	<b>6,721,005</b>



## 7. Right-of-Use Assets and Lease Liabilities

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Right-of-use assets</b>		
At cost	1,762,660	1,762,660
Less: accumulated amortisation	(1,356,709)	(1,024,872)
<b>Total right-of-use assets</b>	<b>405,951</b>	<b>737,788</b>

### Movements in Carrying Amounts – Right-Of-Use Assets

Movements in the carrying amounts for right-of-use assets between the beginning and the end of the financial year.

	Consolidated Entity	
	Right-of-use Assets	\$
Carrying amount at 1 July 2023		833,326
Additions		284,945
Disposals		(52,682)
Amortisation		(331,932)
Currency translation differences		4,131
<b>Carrying amount at 30 June 2024</b>		<b>737,788</b>
Additions		-
Disposals		-
Amortisation		(331,837)
Currency translation differences		-
<b>Carrying amount at 30 June 2025</b>		<b>405,951</b>

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Lease liabilities</b>		
Lease liabilities - Current	431,184	369,861
Lease liabilities - Non-current	97,344	509,923
<b>Total lease liabilities</b>	<b>528,528</b>	<b>879,784</b>

Lease liability is measured at the present value of the lease payments unpaid at that date, discounted using the interest rate implicit in the lease if that rate is readily available or the Group's incremental average borrowing rate of 5.12 % in 2025 and 6.26% in 2024

## 8. Interests in Subsidiaries

Name of Entity	Type of Entity	Ownership Interest		Country of Incorporation
		2025	2024	
<b>Parent entity</b>				
CLINUVEL PHARMACEUTICALS LTD	Body Corporate	-	-	Australia
<b>Controlled entities</b>				
A.C.N. 108 768 896 PTY LTD*	Body Corporate	-	100%	Australia
CLINUVEL (UK) LTD	Body Corporate	100%	100%	United Kingdom
CLINUVEL, INC.	Body Corporate	100%	100%	United States of America
CLINUVEL AG	Body Corporate	100%	100%	Switzerland
CLINUVEL SINGAPORE PTE LTD	Body Corporate	100%	100%	Singapore
VALLAURIX PTE LTD	Body Corporate	100%	100%	Singapore
CLINUVEL EUROPE LIMITED	Body Corporate	100%	100%	Ireland
VALLAURIX MC SARL	Body Corporate	100%	100%	Monaco
*Deregistered on the 4th of June 2025				

## 9. Trade and Other Payables

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Current</b>		
Unsecured trade creditors	2,550,597	2,345,436
Sundry creditors and accrued expenses	7,393,977	4,763,617
<b>Total</b>	<b>9,944,574</b>	<b>7,109,053</b>
(a) Aggregate amounts payable to:		
<b>Directors and Director-related entities</b>	<b>3,218,831</b>	<b>952,653</b>
(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade and Sundry creditors:		
Canadian dollars	3,216	3,750
British Pounds	-	85,880
Other	-	603
<b>Total</b>	<b>3,216</b>	<b>90,233</b>
For an analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 20.(c) Terms and conditions: Trade and sundry creditors are non-interest bearing and normally settled on 30 day terms.		

## 10. Provisions

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Current</b>		
Employee benefits	2,287,949	1,881,898
<b>Total</b>	<b>2,287,949</b>	<b>1,881,898</b>
<b>Non-current</b>		
Employee benefits	127,787	84,721
Other provisions	85,471	79,238
<b>Total</b>	<b>213,258</b>	<b>163,959</b>

## 11. Contributed Equity

### (a) Issued And Paid Up Capital

	Consolidated Entity	
	2025	2024
	\$	\$
50,123,630 fully paid ordinary shares (2024: 50,077,780)	169,280,668	168,802,368
<p>Ordinary shares have the right to receive dividends as declared and, in the event of winding up the Company, to participate in the proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held. Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company. The Company does not have a limited amount of authorised capital and issued shares do not have a par value.</p>		

### (b) Movements In Ordinary Share Capital

	Consolidated Entity			
	No.	2025	No.	2024
		\$		\$
<b>At the beginning of the financial year</b>	<b>50,077,780</b>	<b>168,802,368</b>	<b>49,410,338</b>	<b>151,849,375</b>
Issued during the year	56,700	649,782	-	-
Conditional rights issues and transferred from conditional rights reserve	6,250	80,424	716,932	17,707,229
Buy back shares	(17,100)	(251,906)	(49,490)	(754,236)
Less: transaction costs	-	-	-	-
<b>Balance at the end of the financial year</b>	<b>50,123,630</b>	<b>169,280,668</b>	<b>50,077,780</b>	<b>168,802,368</b>

### (c) Conditional Performance Rights

During the year the following conditional performance rights were exercised, resulting in the issue of fully paid ordinary shares:

Expiry date	Exercise Price	Number of Securities
<b>Upon achievement of various performance milestones</b>	<b>\$ Nil</b>	<b>6,250</b>

As at 30 June 2025, the year the following conditional performance rights existed which if exercised, resulting in the issue of fully paid ordinary shares:

Expiry date	Exercise Price	Number of Conditional Rights
<b>Upon achievement of various performance milestones</b>	<b>\$ Nil</b>	<b>499,825</b>



## 12. Reserves

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Conditional performance rights reserve:</b>		
<b>Balance at the beginning of period</b>	<b>1,198,318</b>	<b>19,370,046</b>
Share-based payment expenses	1,351,685	6,107,272
Transfer to share capital	(80,424)	(17,707,229)
Lapsed, forfeited rights	-	(6,571,771)
<b>Balance at the end of period</b>	<b>2,469,579</b>	<b>1,198,318</b>
The conditional performance rights reserve arises on the grant of conditional performance rights to eligible employees under the conditional performance rights plan. Amounts are transferred out of the reserve and into issued capital when the rights are exercised and to retained earnings when rights lapse.		
<b>Foreign currency translation reserve:</b>		
<b>Balance at the beginning of period</b>	<b>3,047,053</b>	<b>3,185,998</b>
Translating foreign subsidiary to current rate at reporting date	2,379,200	(138,945)
<b>Balance at the end of period</b>	<b>5,426,253</b>	<b>3,047,053</b>
<b>Total reserves</b>	<b>7,895,832</b>	<b>4,245,371</b>

## 13. Short-Term Lease Commitments

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Operating lease commitments</b>		
Non-cancellable operating leases contracted for but not capitalised under AASB 16 as they are short-term and are payable as follows:		
not later than 1 year	7,185	66,942
later than 1 year but not later than 5 years	-	-
<b>Total</b>	<b>7,185</b>	<b>66,942</b>
Operating leases comprises commitments for limited license agreement of furnished office accommodation and office equipment The limited license agreement has no contingent rental clauses and contains renewal options.		

## 14. Earnings Per Share (EPS)

	Consolidated Entity	
	2025	2024
	\$	\$
(a) Basic earnings per share (cents per share)	72.2	71.5
(a) Diluted earnings per share (cents per share)	71.8	69.8
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	50,076,045	49,834,035
(b) Weighted average number of performance rights on issue in respect of share based payments during the year	303,971	1,192,679
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	50,380,016	51,026,713
(c) The numerator used in the calculation of basic earnings per share (\$)	36,172,518	35,636,359
There have been no other transactions involving ordinary shares or potential ordinary shares that would significantly change the number of ordinary shares outstanding between the reporting date and the date of the completion of this financial report.		

## 15. Cash Flow Information

	Consolidated Entity	
	2025	2024
	\$	\$
<b>(a) Reconciliation of cash</b>		
<i>Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled to the related items in the balance sheet as follows:</i>		
Cash at bank	26,096,892	18,102,718
Cash on hand	1,479	1,818
Deposits on call	1,707,254	16,874,047
Security bonds	215,030	222,168
<b>Total cash and cash equivalents</b>	<b>28,020,655</b>	<b>35,200,751</b>
<b>(b) Reconciliation of cash flows from operating activities with operating profit (loss)</b>		
<b>Operating profit after income tax</b>	<b>36,172,518</b>	<b>35,636,359</b>
<b>Non cash flows in operating profit after income tax:</b>		
Exchange rate effect on foreign currencies held	(2,801,764)	808,148
Unrealised loss (gain) on foreign exchange translation	2,379,200	(138,945)
Share-based payments	2,001,467	6,107,272
Depreciation expense on property, plant & equipment	786,664	753,184
Amortisation expense on right-of-use assets	359,079	331,932
<b>Changes in assets and liabilities:</b>		
(Increase)/decrease in receivables	(1,223,065)	(4,023,652)
(Increase)/decrease in inventories	1,805,282	(1,107,151)
(Increase)/decrease in other current assets	(1,250,142)	(260,308)
(Increase)/decrease in deferred tax assets	(235,104)	39,197
(Increase)/decrease in lease bonds	(79,132)	(134,208)
Increase/(decrease) in payables	2,835,520	(648,316)
Increase/(decrease) in income tax payables	(1,304,350)	(242,793)
Increase/(decrease) in provisions	455,351	464,574
Increase/(decrease) in deferred tax liabilities	1,193,938	(531,411)
<b>Net cash used in operating activities</b>	<b>41,095,462</b>	<b>37,053,882</b>
Cash at bank earns floating rates based on daily bank deposit rates. The carrying amounts of cash and cash equivalents represent fair value.		

## 16. Key Management Personnel

	Consolidated Entity	
	2025	2024
	\$	\$
Short-term employee benefits	5,428,884	4,123,825
Long-term benefits	1,964,388	30,736
Share-based payments	185,779	3,399,126
Post-employment benefits	131,607	72,306
<b>Total</b>	<b>7,710,658</b>	<b>7,625,993</b>
No loans or other transactions existed with key management personnel.		

## 17. Auditor's Remuneration

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Amounts received or due and receivable by Grant Thornton Audit Pty Ltd for:</b>		
Audit services and review	241,170	249,126
<b>Total</b>	<b>241,170</b>	<b>249,126</b>

## 18. Related Party Disclosures

### Wholly-Owned Group Transactions

	2025	2024
<b>Transactions with other related parties</b>	\$	\$
<i>All figures disclosed are reported in USD.</i>	USD	USD
<b>Sales and purchases of goods and services</b>		
Sale of goods to entities associated with Directors	261,284	-
Purchases of goods and services from entities associated with Directors	303,628	-
<b>Outstanding balances arising from sales/purchases of goods and services</b>		
The following balances are outstanding at the end of the reporting period in relation to transactions with related parties:		
Current receivables	459,314	-
Current payables	74,428	-
<b>Terms and conditions</b>		
All transactions were transacted in USD on normal commercial terms and conditions and at market rates.		
Outstanding balances are unsecured and are repayable in cash.		

### Director Related And Key Management Personnel Transactions And Entities:

There are no loan transactions and relationships in existence as at 30 June 2025 and 2024 between Directors and the Company and its related entities.

## 19. Segment Information

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.



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

	2025			2024		
	Europe & USA (\$'000)	Switzerland, Others (\$'000)	Total (\$'000)	Europe & USA (\$'000)	Switzerland, Others (\$'000)	Total (\$'000)
Commercial sales of goods	86,385	-	86,385	81,218	-	81,218
Sales reimbursements	335	8,298	8,633	265	6,695	6,960
<b>Total revenue</b>	<b>86,720</b>	<b>8,298</b>	<b>95,018</b>	<b>81,483</b>	<b>6,695</b>	<b>88,178</b>
<b>Total expenses</b>			<b>(53,747)</b>			<b>(44,627)</b>
<b>Net profit before tax</b>			<b>51,553</b>			<b>50,679</b>
<b>Income tax</b>			<b>(15,380)</b>			<b>(15,043)</b>
<b>Net profit after tax</b>			<b>36,173</b>			<b>35,636</b>
<b>Property, plant and equipment</b>	<b>5,089</b>	<b>1,632</b>	<b>6,721</b>	<b>5084</b>	<b>1,899</b>	<b>6,982</b>

The Group has a number of customers to which it provides its leading drug candidate, all of which is recognised at a point in time. Three customers comprise 31% of external total revenue (2024: two customers each comprise 12% of external total revenue).

## 20. Financial Instruments

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

- Market Risk
- Credit Risk
- Liquidity Risk

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

### a) Market Risk

Market risk is the risk of changes to market prices of foreign exchange purchases, interest rates and/or equity prices resulting in a change in value of the financial instruments held by the consolidated entity. The objective to manage market risk is to ensure exposures are contained within acceptable parameters, to minimise costs and to stabilise existing assets.

#### Foreign Currency Risk

The consolidated entity is exposed to foreign currency risk on future commercial transactions and recognised assets and liabilities that are denominated in a currency other than the functional currency of each of the Group's entities, primarily US dollars (USD), Euros (EUR), Swiss francs (CHF), Singapore dollars (SGD) and Great British pounds (GBP). The parent entity is exposed to the risk of its cash flows being adversely affected by movements in exchange rates that will increase the Australian dollar value of foreign currency payables. It is also exposed to the risk of movements in foreign currency exchange rates for those currencies which sales and reimbursement receipts are received.

The consolidated entity's policy of managing foreign currency risk is to hold foreign currencies equivalent to the cash outflow projected over minimum 30 days by the placement of market orders or have in place forward exchange contracts to achieve a target rate of exchange, with protection floors in the event of a depreciating Australian dollar exchange rate, to run for the time between recognising the exposure and the time of payment. In the event of an appreciating Australian dollar, the amount of foreign currency held is minimised at a level to only meet short-term obligations in order to maximise gains in an appreciating Australian currency. CLINUVEL does not engage in speculative transactions in its management of foreign currency risk. No forward exchange contracts had been entered into as at 30 June 2025 and as at 30 June 2024.

**The Consolidated Entities Exposure To Foreign Currency Risk At 30 June 2025**

	2025					2024				
	Cash and Cash Equivalents	Cash Held In Term Deposits	Trade Debtors and Other Assets	Trade, Other Payables and Provisions	TOTAL	Cash and Cash Equivalents	Cash Held In Term Deposits	Trade Debtors and Other Assets	Trade, Other Payables and Provisions	TOTAL
USD	11,751,172	30,000,000	9,166,832	(1,317,094)	<b>49,600,910</b>	1,600,443	20,000,000	9,213,442	(1,588,919)	<b>29,224,966</b>
EUR	2,285,792	1,750,000	4,814,066	(3,469,789)	<b>5,380,069</b>	4,907,251	-	6,755,698	(2,458,873)	<b>9,204,076</b>
SEK	-	-	1,314,856	-	<b>1,314,856</b>	-	-	971,172	-	<b>971,172</b>
CHF	328,626	-	576,339	(111,575)	<b>793,390</b>	1,016,656	-	28,451	(122,923)	<b>922,184</b>
SGD	701,083	-	188,906	(342,604)	<b>547,385</b>	527,674	-	155,324	(272,159)	<b>410,839</b>
GBP	511,333	-	284,032	(779,661)	<b>15,704</b>	376,258	-	211,781	(574,237)	<b>13,802</b>
CAD	-	-	90,019	(2,884)	<b>87,135</b>	-	-	-	(3,433)	<b>(3,433)</b>
BRL	-	-	-	-	<b>-</b>	-	-	-	(2,114)	<b>(2,114)</b>
ILS	-	-	-	-	<b>-</b>	-	-	-	(89)	<b>(89)</b>

**Sensitivity Analysis**

During the financial year the Company had a principal foreign currency transaction risk exposure to the Euro currency. Assuming all other variables remain constant, a depreciation in the Australian dollar is advantageous to the consolidated entity as sales receipts received in Euro foreign currency allows for conversion to a higher amount of Australian dollars.

For the consolidated entity, an 7.1% appreciation of the Australian dollar against the Euro currency would have decreased profit and loss and equity by \$2,054,230 for the year ended 30 June 2025 (2024: \$622,563 decrease), on the basis that all other variables remain constant. 7.1% is considered representative of the market volatility in the Australian dollar/Euro rate for the period.

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

The Group's exposure to other foreign currency movements is not considered as material.

**Interest Rate Risk**

The consolidated entity holds fixed interest-bearing assets therefore exposure to interest rate risk exists. It does not hold interest bearing liabilities.

The consolidated entity currently finances its operations through reserves of cash and liquid resources and does not have a borrowing requirement. In order to be protected from, and to take advantage of, interest rate movements it is the consolidated entity's policy to place cash into term deposits and other financial assets at both fixed and variable (floating) rates. The Board monitors the movements in interest rates in combination with current cash requirements to ensure the mix and level of fixed and floating returns is in the best interests of the consolidated entity.

**Sensitivity Analysis**

For the consolidated entity, at 30 June 2025, if interest rates had changed by +/- 50 basis points from the year-end rates (a movement considered reflective of the level of interest rate movements throughout the course of the financial year), with effect from the beginning of the year, profit and equity would be \$1,027,290 higher/lower (2024: 5,234,216 higher/lower). This analysis assumes all other variables are held constant.

**Price Risk**

CLINUVEL PHARMACEUTICALS LTD and its consolidated entities was formerly exposed to price risk in its investments in income securities classified in the Statement of Financial Position as held for trading. Neither the consolidated entity nor the parent is exposed to commodity price risk.

**b) Credit Risk**

Credit risk arises from the potential failure of counterparties to meet their contractual obligations, resulting in a loss to the consolidated entity.

Credit risk in relation to the consolidated entity is the cash and cash equivalents deposited with banks, trade and other receivables. Exposure to credit risk in trade debtors is limited to over forty counterparties across German, Italian, Swiss, Dutch, U.S. and other medical institutions who are reimbursed by government or private insurance payors.

The maximum credit exposure is the carrying value of the cash and cash equivalents deposited with banks, trade and other debtors and foreign, wholly-owned subsidiaries.

### c) Liquidity Risk

Liquidity risk is the risk the consolidated entity will not be able to meet its financial obligations when they fall due. It is the policy of the consolidated entity to ensure there is sufficient liquidity to meet its liabilities when due without incurring unnecessary loss or damage. The consolidated entity holds cash and cash equivalents in liquid markets. It does not hold financing facilities, overdrafts or borrowings.

#### Fair Value Estimation

The fair value of financial assets and financial liabilities must be estimated for recognition and measurement for disclosure purposes.

The fair value of financial instruments traded in active markets is based on quoted market prices at reporting date. The quoted market price for the consolidated entity is the bid price. For longer-term debt instruments held by the consolidated entity, dealer quotes are used to determine fair value. The consolidated entity formerly held investments in income securities classified in the Statement of Financial Position as held for trading. These financial instruments were traded in active markets and based on quoted market prices.

The carrying value of trade payables is assumed to approximate their fair values due to their short-term nature.

The consolidated entity manages its liquidity needs by carefully identifying expected operational expenses by month and ensuring sufficient cash is on hand, across appropriate currencies, in the day-to-day bank accounts for a minimum 30 day period. When further liquidity is required, the consolidated entity draws down on its cash under management to service future liquidity needs.

#### Contractual Maturities Of Financial Liabilities As At 30 June 2025

	Consolidated Entity	
	2025	2024
	\$	\$
<b>Trade and other payables</b>		
Carrying amount	9,944,574	7,109,053
6 months or less	9,771,737	7,082,494
Greater than 6 months	172,837	26,559
<b>Total</b>	<b>9,944,574</b>	<b>7,109,053</b>
<b>Lease liabilities</b>		
Carrying amount	528,528	879,784
6 months or less	231,863	178,694
Greater than 6 months	296,665	701,090
<b>Total</b>	<b>528,528</b>	<b>879,784</b>

#### Capital Risk Management

The consolidated entity's equity is limited to shareholder contributions, supported by the cash inflows received from providing SCENESSE® to EPP patients under both the full cost special access reimbursement programs such as in Switzerland and from commercial sales currently in the European Economic Area and U.S.A. Its capital management objectives are limited to ensuring the equity available to the Company will allow it to continue as a going concern and to realise adequate shareholder return by progressing in its developmental research of SCENESSE®, to file for successful marketing authorisation in new jurisdictions and achieving a status whereby revenues will consistently exceed expenditure.



## Contractual Maturities Of Financial Assets As At 30 June 2025

	Consolidated Entity	
	2025	2024
	\$	\$
<b><i>Cash and cash equivalents</i></b>		
Carrying amount	28,020,655	35,200,751
6 months or less	28,020,655	35,200,751
<b>Total</b>	<b>28,020,655</b>	<b>35,200,751</b>
<b><i>Cash held in term deposits</i></b>		
Carrying amount	196,085,287	148,667,720
6 months or less	100,082,133	65,125,316
Greater than 6 months	96,003,154	83,542,404
<b>Total</b>	<b>196,085,287</b>	<b>148,667,720</b>
<b><i>Other financial assets (includes trade and other receivables)</i></b>		
Carrying amount	27,461,362	26,238,297
6 months or less	26,624,065	25,799,352
Greater than 6 months	837,297	438,945
<b>Total</b>	<b>27,461,362</b>	<b>26,238,297</b>

Cash at bank earns floating rates based on daily bank deposit rates. The carrying amounts of cash and cash equivalents represent fair value. Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes. The term deposits are readily convertible to cash within 31 days' notice and after a market-related rate reduction to the interest on the term deposit principal is applied. Term deposits are subject to an insignificant risk of changes in value.

## 21. Share-Based Payments

The consolidated entity has two conditional performance rights schemes which are ownership based for key management personnel and select consultants (including Directors) of the Company. The number of rights granted is subject to approval by the Remuneration Committee. Rights currently have specific terms and conditions, being the achievement of performance and time-based milestones set by the Directors of the consolidated entity.

### Conditional Performance Rights Plan (2009)

The Conditional Performance Rights Plan (2009) was available to eligible employees of the Company. Any issue of rights to executive Directors requires shareholder approval in accordance with ASX Listing Rules. All rights convert to one ordinary share of the consolidated entity are issued for nil consideration, have no voting rights, are non-transferable and are not listed on the ASX. They can be converted to ordinary shares at any time once the vesting conditions attached to the rights have been achieved, whereby they will be held by a Scheme Trustee on behalf of the eligible employee for up to seven years. The eligible employee can request for shares to be transferred from the Scheme Trust after seven years or at an earlier date if the eligible employee is no longer employed by the Company or all transfer restrictions are satisfied or waived by the Board in its discretion.

The Company does not intend to issue further performance rights under the 2009 Plan.

### Performance Rights Plan (2014)

The Performance Rights Plan (2014) is available to eligible persons of the Company. Any issue of rights to Executive Directors requires shareholder approval in accordance with ASX Listing Rules. All rights convert to one ordinary share of the consolidated entity are issued for nil consideration, have no voting rights, are not listed on the ASX and are non-tradeable (other than with prior written Board consent). They can be converted to ordinary shares at any time once the vesting conditions attached to the rights have been achieved, whereby, only at the discretion of the Board, they may be held by a Scheme Trustee on behalf of the eligible person. The eligible person cannot trade in the shares held by the Scheme Trust without prior written Board consent until the earlier of seven years from grant date of performance right, when the eligible person ceases employment or when all transfer restrictions are satisfied or waived by the Board in its discretion. Performance rights under this plan lapse after seven years from grant date.

### The Following Share-Based Payment Arrangements Were In Existence At 30 June 2025

	Performance Rights Series	Number	Grant date	Expiry Date	Exercise Price	Fair Value at Grant Date
Issued	16/09/2011	21,725	16/09/2011	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	Between \$0.55 and \$0.72
Issued	29/06/2023	80,750	29/06/2023	30/06/2025	\$ Nil	between \$9.16 & \$14.26 *
Issued	29/06/2023	114,500	29/06/2023	30/06/2026	\$ Nil	between \$9.16 & \$14.26 *
Issued	15/04/2025	282,850	15/04/2025	31/12/2025	\$ Nil	\$8.63
* these performance rights are a mixture of market and non-market conditions, the fair values applied to those performance rights expected to vest from the time of grant						

### Holdings Of All Issued Conditional Performance Rights – 2025

Performance Rights Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Performance Condition Met, not exercisable until end Vest Period	Performance Condition Not Met, not exercisable until end Vest Period
Issued 16/09/2011	29,082	-	-	(7,357)	21,725	-	21,725
Issued 05/05/2022	7,500	-	(6,250)	(1,250)	-	-	-
Issued 29/06/2023	229,750	-	-	(34,500)	195,250	58,627	136,623
Issued 15/04/2025	-	290,375	-	(7,525)	282,850	-	282,850
<b>Total</b>	<b>266,332</b>	<b>290,375</b>	<b>(6,250)</b>	<b>(50,632)</b>	<b>499,825</b>	<b>58,627</b>	<b>158,348</b>
Weighted average exercise price	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil

**For Performance Rights issued in 2011** Performance Rights were priced using either a binomial or trinomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the instrument, and the risk free rate used in the pricing model is assumed to be the yield on ranging from 1 year to 10 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

**For Performance Rights Issued in 2020 to 2025** Performance Rights were priced using either a Monte Carlo simulation pricing model for market conditions, or a Binomial Valuation pricing model for non-market conditions, taking into account factors specific to the Performance Rights Plan, such as the vesting period. For non-market conditions, the value of each performance right is multiplied by the number of performance rights expected to vest to arrive at a valuation. The performance rights expire the earlier of 7 years from date of grant of rights or 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 the Performance Rights issued on and after 24 December 2020, an illiquidity discount was applied to the pricing model.

## Holdings Of All Issued Conditional Performance Rights – 2024

Performance Rights Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Performance Condition Met, not exercisable until end Vest Period	Performance Condition Not Met, not exercisable until end Vest Period
Issued 16/09/2011	38,333	-	-	(9,251)	29,082	-	29,082
Issued 26/08/2020	1,513,750	-	(301,125)	(1,212,625)	-	-	-
Issued 24/12/2020	132,500	-	(61,146)	(71,354)	-	-	-
Issued 26/08/2021	682,360	-	(354,661)	(327,699)	-	-	-
Issued 05/06/2022	7,500	-	-	-	7,500	1,250	6,250
Issued 29/06/2023	255,750	-	-	(26,000)	229,750	184,271	45,479
<b>Total</b>	<b>2,630,193</b>	<b>-</b>	<b>(716,932)</b>	<b>(1,646,929)</b>	<b>266,332</b>	<b>185,521</b>	<b>80,811</b>
Weighted average exercise price	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil

### For Performance Rights issued in 2011

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

### For Performance Rights Issued in 2022 to 2025

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

## 22. CLINUVEL PHARMACEUTICALS LTD

### Parent Company Information

	CLINUVEL PHARMACEUTICALS LTD	
	2025	2024
	\$	\$
<b>Assets</b>		
Current assets	224,707,806	184,283,878
Non-current assets	52,200,423	55,207,108
<b>Total assets</b>	<b>276,908,229</b>	<b>239,490,986</b>
<b>Liabilities</b>		
Current liabilities	16,361,656	18,960,091
Non-current liabilities	3,527,803	2,420,996
<b>Total liabilities</b>	<b>19,889,459</b>	<b>21,381,087</b>
<b>Equity</b>		
Issued equity	169,280,679	168,802,380
Share-based payments reserve	2,469,890	1,198,628
Accumulated losses	85,268,201	48,108,891
<b>Total equity</b>	<b>257,018,770</b>	<b>218,109,899</b>
<b>Financial performance</b>		
Net profit for the year	34,655,290	39,507,563
<b>Total comprehensive income</b>	<b>34,655,290</b>	<b>39,507,563</b>



**a) Guarantees Entered Into By The Parent Entity**

The parent entity provides certain financial guarantees to its subsidiaries. No liability is recognised in relation to this guarantee as the fair value of the guarantee is considered immaterial. These guarantees are related to the subsidiaries' abilities to meet their obligations to their employees.

The parent entity provides financial commitments for certain subsidiaries for the amount necessary to enable those entities to meet their obligations as and when they fall due.

**b) Contingent Liability**

The parent entity did not have any material contingent liabilities as at 30 June 2025 and 2024.

**c) Contractual Commitments for the Acquisition of Property, Plant and Equipment**

The parent entity did not have any material contractual commitments for the acquisition of property, plant and equipment as at 30 June 2025 and 2024.

**23. Subsequent Events**

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

- On 22 August 2025, the Company announced its intention to upgrade its American Depositary Receipt program from Level I to Level II, listed on Nasdaq, expected to occur by the end of 2025.
- On 27 August 2025, the Board of Directors declared an unfranked dividend of \$0.05 per ordinary share.

**24. Additional Company Information**

CLINUVEL PHARMACEUTICALS LTD is a listed public company incorporated and operating in Australia.

**The Registered office is:**

Level 22, 535 Bourke Street  
Melbourne VIC 3000  
Ph: (03) 9660 4900

## Consolidated Entity Disclosure Statement as at 30 June 2025

The Australian Government passed a Treasury Laws Amendment (Making Multinationals Pay Their Fair Share – Integrity and Transparency) Act 2024 such that the Corporations Act now requires Australian public companies to disclose the following information regarding each of its subsidiary entities in the annual financial reports for financial years commencing on or after 1 July 2024:

Name of Entity	Type of Entity	Trustee Partner or Participant in JV	% of Share Capital	Place of business/ Country of incorporation	Australian resident or foreign resident	Foreign jurisdiction(s) of foreign residents
<b>Parent entity</b>						
CLINUVEL PHARMACEUTICALS LTD	Body Corporate	-	100%	Australia	Australia	Australia
<b>Controlled entities</b>						
A.C.N. 108 768 896 PTY LTD*	Body Corporate	-	-	Australia	Australia	Australia
CLINUVEL (UK) LTD	Body Corporate	-	100%	United Kingdom	Foreign	United Kingdom
CLINUVEL, INC.	Body Corporate	-	100%	United States of America	Foreign	United States of America
CLINUVEL AG	Body Corporate	-	100%	Switzerland	Foreign	Switzerland
CLINUVEL SINGAPORE PTE LTD	Body Corporate	-	100%	Singapore	Foreign	Singapore
VALLAURIX PTE LTD	Body Corporate	-	100%	Singapore	Foreign	Singapore
CLINUVEL EUROPE LIMITED	Body Corporate	-	100%	Ireland	Foreign	Ireland
VALLAURIX MC SARL	Body Corporate	-	100%	Monaco	Foreign	Monaco

\*Deregistered on the 4th of June 2025

### Consolidated Entity Disclosure Statement – Basis of Preparation

#### Basis of Preparation

This Consolidated Entity Disclosure Statement (CEDS) has been prepared in accordance with the Corporations Act 2001 and includes required information for each entity that was part of the consolidated entity as at the end of the financial year.

#### Consolidated entity

This CEDS includes only those entities consolidated as at the end of the financial year in accordance with AASB 10 Consolidated Financial Statements (AASB 10).

#### Determination of Tax Residency

Section 295 (3A) of the Corporations Act 2001 defines tax residency as having the meaning in the Income Tax Assessment Act 1997. The determination of tax residency involves judgment as there are currently several different interpretations that could be adopted, and which could give rise to a different conclusion on residency.

In determining tax residency, the consolidated entity has applied the following interpretations:

- Australian tax residency  
The consolidated entity has applied current legislation and judicial precedent, including having regard to the Tax Commissioner's public guidance.
- Foreign tax residency  
Where necessary, the consolidated entity has used independent tax advisers in foreign jurisdictions to assist in its determination of tax residency to ensure applicable foreign tax legislation has been complied with.

# DIRECTORS' DECLARATION

In the opinion of the Directors:

- 1) the financial statements and notes of the consolidated entity are in accordance with the Corporations Act 2001, including:
  - a) giving a true and fair view of the consolidated entity's financial position as at 30 June 2025 and of its performance for the year ended on that date;
  - b) complying with Accounting Standards; and
  - c) complying with International Financial Reporting Standards as disclosed in Note 1.
- 2) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable; and
- 3) the audited remuneration disclosures set out in pages 86 to 111 of the Directors' Report comply with Section 300A of the Corporations Act 2001.
- 4) this declaration is made in accordance with a resolution of the Board of Directors. The Directors have been given the declarations by the Chief Executive Officer and Chief Financial Officer required by Section 295A of the Corporations Act 2021.
- 5) The consolidated entity disclosure statement on page 142 is true and correct.

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



Dr Philippe Wolgen, MBA, MD  
Director

Dated this 27<sup>th</sup> day of August, 2025



**Grant Thornton Audit Pty Ltd**

Level 22 Tower 5  
Collins Square  
727 Collins Street  
Melbourne VIC 3008  
GPO Box 4736  
Melbourne VIC 3001  
T +61 3 8320 2222

## Independent Auditor's Report

### To the Members of Clinuvel Pharmaceuticals Limited

#### Report on the audit of the financial report

##### Opinion

We have audited the financial report of Clinuvel Pharmaceuticals Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 30 June 2025, the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including material accounting policy information, the consolidated entity disclosure statement and the directors' declaration.

In our opinion, the accompanying financial report of the Group is in accordance with the *Corporations Act 2001*, including:

- a giving a true and fair view of the Group's financial position as at 30 June 2025 and of its performance for the year ended on that date; and
- b complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

##### Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

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

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### Key audit matters

We have determined that there are no key audit matters to communicate in our report.

### Information other than the financial report and auditor's report thereon

The Directors are responsible for the other information. The other information comprises the information included in the Group's annual report for the year ended 30 June 2025 but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

### Responsibilities of the Directors for the financial report

The Directors of the Company are responsible for the preparation of:

- a the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* (other than the consolidated entity disclosure statement); and
- b the consolidated entity disclosure statement that is true and correct in accordance with the *Corporations Act 2001*, and

for such internal control as the Directors determine is necessary to enable the preparation of:

- i. the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error; and
- ii. the consolidated entity disclosure statement that is true and correct and is free of misstatement, whether due to fraud or error.

In preparing the financial report, the Directors are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

### Auditor's responsibilities for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: [https://www.auasb.gov.au/media/bwvicgre/ar1\\_2024.pdf](https://www.auasb.gov.au/media/bwvicgre/ar1_2024.pdf). This description forms part of our auditor's report.

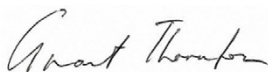
**Report on the remuneration report****Opinion on the remuneration report**

We have audited the Remuneration Report included in pages 86 to 111 of the Directors' report for the year ended 30 June 2025.

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Limited, for the year ended 30 June 2025 complies with section 300A of the *Corporations Act 2001*.

**Responsibilities**

The Directors of the Company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.



Grant Thornton Audit Pty Ltd  
Chartered Accountants



M A Cunningham  
Partner – Audit & Assurance  
Melbourne, 27 August 2025

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Grant Thornton Audit Pty Ltd





# SHAREHOLDER INFORMATION

As at 12 August 2025



Additional information as at 12 August 2025 required by the Australian Securities Exchange not shown elsewhere in this report is as follows:

## 1 – SHAREHOLDING

### A. DISTRIBUTION OF SHAREHOLDER NUMBERS

Ordinary fully paid shares			
Category (size of holding)	Total holders	Units	% Of issued capital
1-1,000	4,620	1,398,933	2.79
1,001-5,000	1,135	2,658,716	5.30
5,001-10,000	188	1,422,294	2.84
10,001-100,000	187	4,819,835	9.62
100,001 & Over	25	39,823,852	79.45
Total	6,155	50,123,630	100.00

### B. SHAREHOLDINGS HELD IN LESS THAN MARKETABLE PARCELS

Total	Minimum parcel size	Holders	Units
Minimum \$500.00 parcel at \$12.09 per unit	42	673	13,620

### C. SUBSTANTIAL SHAREHOLDINGS

Name	No. Ordinary shares & American Depositary Receipts
The Bank of New York Mellon Corporation <sup>1</sup>	3,854,043
Dr Philippe Wolgen <sup>2</sup>	3,425,222
Ender 1 LLC <sup>3</sup>	2,340,824

1. As disclosed in substantial holder notice dated 30 January 2024.

2. As disclosed in director's interest notice dated 27 November 2023. Actual shareholding on 12 August 2025 is 3,425,222.

3. As disclosed in substantial holder notice dated 16 September 2013. Actual shareholding on 12 August 2025 is 2,590,824.



**D. VOTING RIGHTS**

**The voting rights attaching to each class of equity securities are set out below:**

**Ordinary shares:** Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company.

**Performance Rights:** Performance Rights have no voting rights.

**E. LARGEST SHAREHOLDERS**

Position	Name	Number of ordinary fully paid shares held	% held of issued ordinary capital
1.	HSBC Custody Nominees (Australia) Limited	9,683,928	19.32
2.	BNP Paribas Nominees Pty Ltd (Clearstream)	5,807,164	11.59
3.	Citicorp Nominees Pty Limited	4,324,933	8.63
4.	BNP Paribas Nominees Pty Ltd	3,642,332	7.27
5.	Dr Philippe Jacques Wolgen	3,425,222	6.83
6.	J P Morgan Nominees Australia Pty Limited	3,231,434	6.45
7.	Ender 1 LLC	2,590,824	5.17
8.	BNP Paribas Nominees Pty Ltd (IB AU Noms Retail Client)	2,389,515	4.77
9.	HSBC Custody Nominees (Australia) Limited - A/C 2	1,179,682	2.35
10.	Emilino Group Pty Ltd (Emilino Super Fund A/C)	600,000	1.20
11.	National Nominees Limited	459,695	0.92
12.	BNP Paribas Nominees Pty Ltd (Agency Lending A/C)	308,064	0.61
13.	Dr Mark Edwin Badcock	270,255	0.54
14.	Mr Darren Michael Keamy	242,890	0.48
15.	Mr David William Trevorrow	229,600	0.46
16.	Dr Dennis Wright	192,312	0.38
17.	Mr David John Lewis	185,000	0.37
18.	Mr Trent Sheldon Redding	174,800	0.35
19.	Mr Simon John Bown	146,000	0.29
20.	Rusty Hammer Pty Ltd (Archipelago Holdings Super Fund A/C)	144,175	0.29
<b>Totals: Top 20 holders of ordinary fully paid shares (total)</b>		<b>39,227,825</b>	<b>78.26</b>
<b>Total remaining holders balance</b>		<b>10,895,805</b>	<b>21.74</b>

## 2 – COMPANY SECRETARY

### The name of the Company Secretary is:

Claire Newstead-Sinclair

## 3 – REGISTERED OFFICE

### The principle registered office in Australia is:

Level 22, 535 Bourke Street  
Melbourne, VIC 3000, Australia  
Telephone: +61 3 9660 4900

**Fax:** +61 3 9660 4999

**Email:** mail@clinuvel.com

**Website:** <https://www.clinuvel.com>

## 4 – REGISTER OF SECURITIES

Computershare Investor Services Pty Ltd  
Yarra Falls, 453 Johnston St, Abbotsford,  
VIC 3067, Australia  
Telephone: +61 3 9415 4000

## 5 – AUSTRALIAN SECURITIES EXCHANGE LIMITED

**Quotation has been granted for all the ordinary  
shares on all Member Exchanges of the  
Australian Securities Exchange Limited (ASX):**

- ASX: CUV

### The Company's shares are also traded on:

- Börse Frankfurt, Germany, under the code UR9;  
and
- Over-the-Counter Market, USA, as a Level 1,  
American Depositary Receipt (ADR), under  
the code CLVLY. Each ADR of the Company  
is equivalent to one ordinary share of the  
Company, as traded on the ASX. The Bank of  
New York Mellon is the depositary bank.

## 6 – RESTRICTED SECURITIES

### Restricted securities on issue at 30 June, 2025:

Nil.

## 7 – DIRECTORY

### Non-Executive Chair

Prof Jeffrey Rosenfeld

### Non-Executive Directors

Dr Karen Agersborg  
Susan Smith  
Matthew Pringle  
Dr Pearl Grimes  
Guy van Dievoet

### Managing Director and Chief Executive Officer

Dr Philippe Wolgen

### Chief Operating Officer

Lachlan Hay

### Chief Scientific Officer

Dr Dennis Wright

### Chief Financial Officer

Peter Vaughan

### Auditor

Grant Thornton Audit Pty Ltd  
Collins Square, Tower 5, Level 22,  
727 Collins Street, Melbourne,  
VIC 3008, Australia

### Bankers

National Australia Bank (NAB)  
Western Branch, 460 Collins St,  
Melbourne, VIC 3000, Australia

J. P. Morgan Chase & Co. (JPM)  
85 Castlereagh Street, Sydney,  
NSW 2000, Australia

### Legal Counsel

Arnold Bloch Leibler  
Level 21, 333 Collins St, Melbourne,  
VIC 3000, Australia

### Sidley Austin LLP

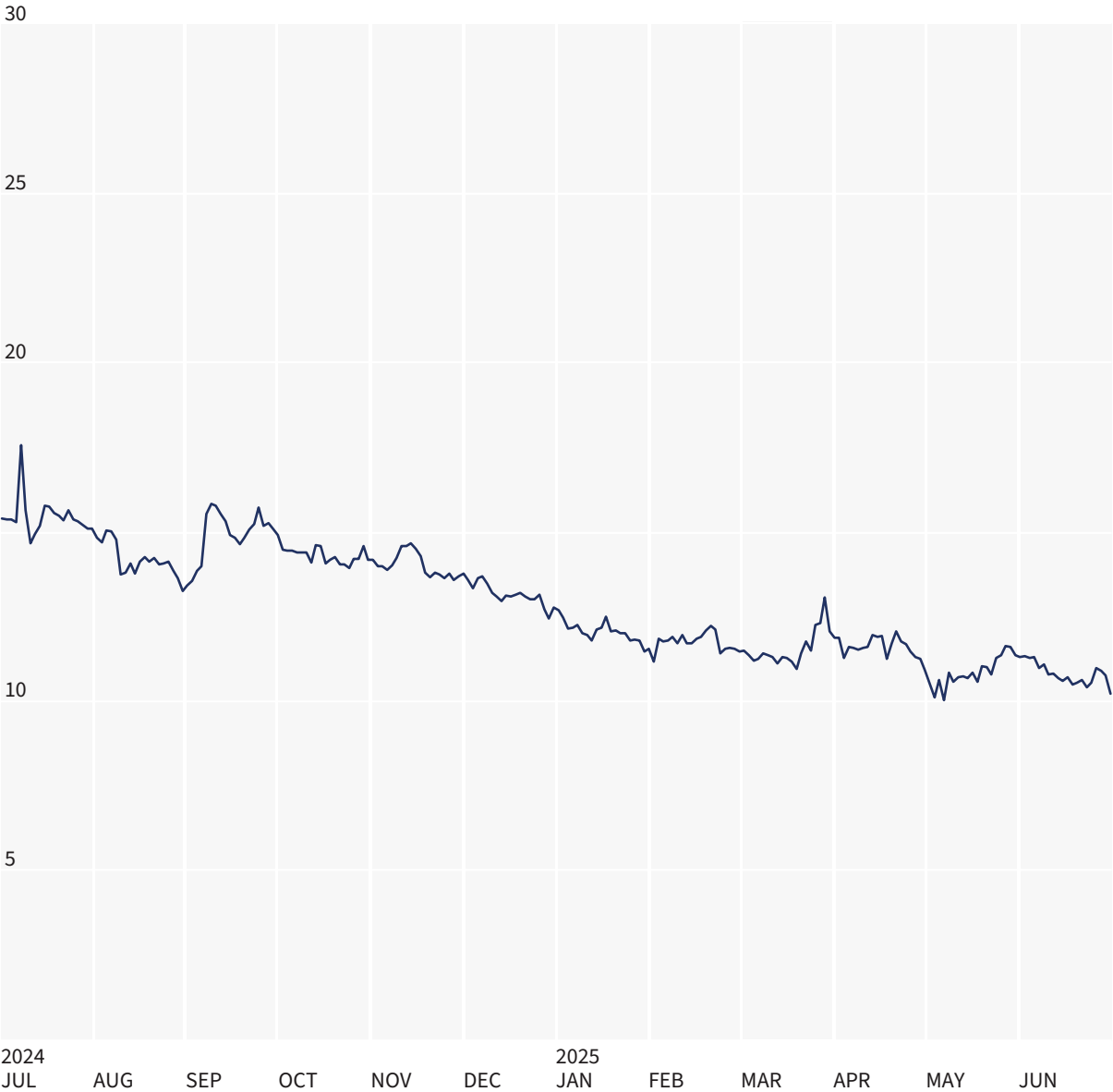
Woolgate Exchange, 25 Basinghall Street,  
London, EC2V 5HA, United Kingdom

### IP Lawyer

Dipl.-Ing Peter Farago  
Baadestr 3, Munich 80, Germany

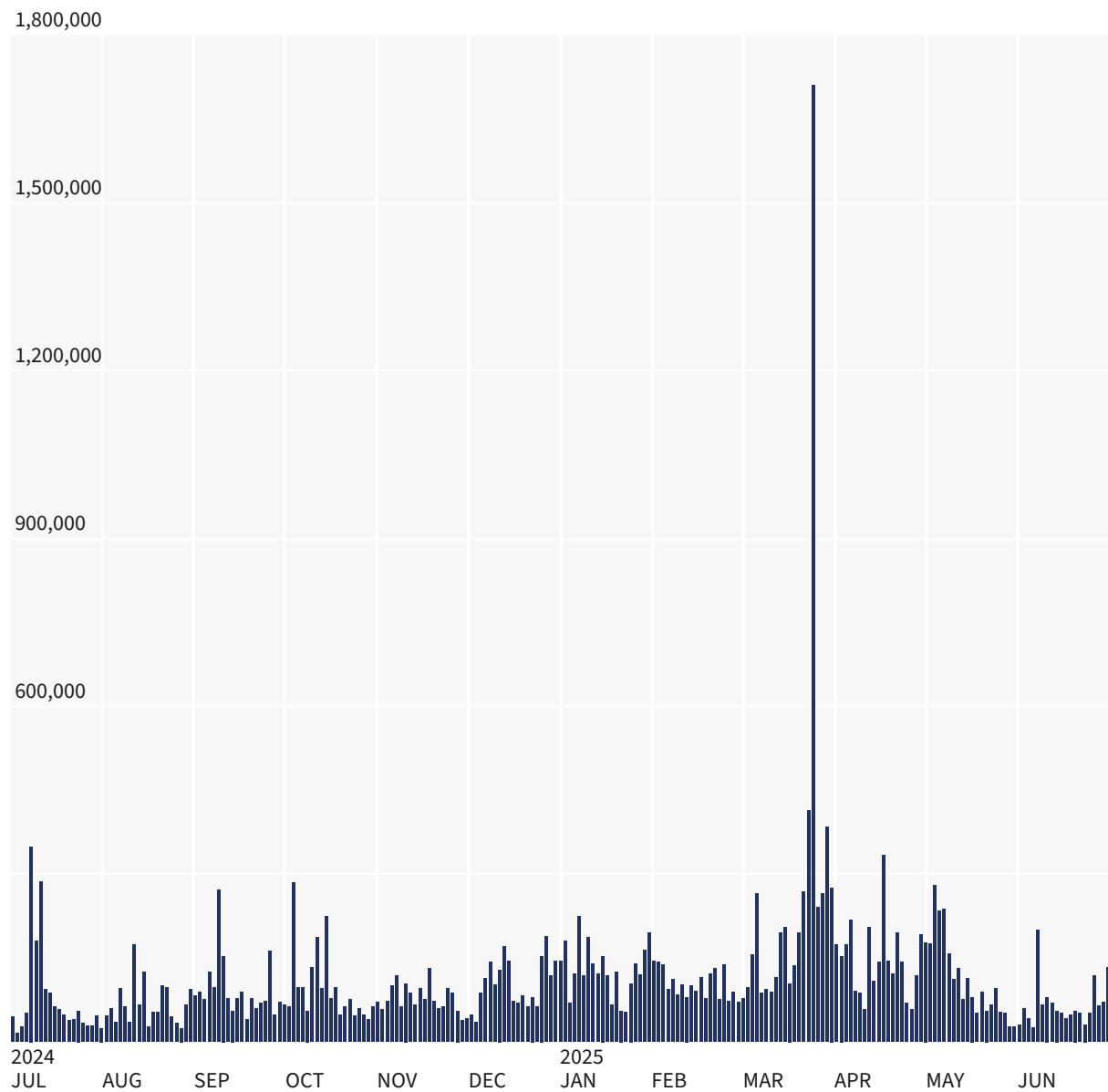
# MARKET PERFORMANCE

## ASX:CUV – Share Price (A\$)





## ASX:CUV – Daily Trading Volume (No.)



# GLOSSARY

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## **Alpha-melanocyte stimulating hormone ( $\alpha$ -MSH)**

A peptide hormone which activates and stimulates the production and release of (eu)melanin in the skin (melanogenesis), with strong anti-oxidative properties.

## **Dermatocosmetics (PhotoCosmetics)**

Specially formulated products designed to assist skin health with a focus on anti-ageing, and repair and regeneration of the skin. PhotoCosmetics combine a dermatological action to treat the skin and a cosmetic action to cleanse, moisturise, and alter the appearance of an individual's skin.

## **European Medicines Agency (EMA)**

The decentralised body of the European Union regulating medical drugs and devices.

## **Eumelanin**

A black or brown pigment mainly concerned with the protection of the skin by absorbing incoming UV radiation. This protective ability warrants melanin to be termed a photoprotectant (a substance capable of providing protection against radiation from the sun).  $\alpha$ -msh acts specifically to stimulate (eu)melanin synthesis.

## **Food and Drug Administration (FDA)**

The U.S.A.'s regulatory agency for food, tobacco, medicines, and medical devices.

## **High Energy Visible (HEV) light**

A particularly high-frequency, high-energy light in the blue/violet band, ranging from 400 nm to 480 nm in the visible light spectrum. HEV generates oxidative stress, accelerates skin ageing and increases hyperpigmentation.

## **Melanin**

The dark pigment synthesised by melanocytes; responsible for skin pigmentation.

## **Melanocortins**

Melanocortins are a group of peptide hormones, consisting of adrenocorticotropin hormone (ACTH),  $\alpha$ -melanocyte stimulating hormone ( $\alpha$ -MSH), beta-melanocyte-stimulating hormone ( $\beta$ -MSH), and gamma-melanocyte-stimulating hormone ( $\gamma$ -MSH) which are derived from proopiomelanocortin (POMC) in the pituitary gland.

## **Melanocortin receptors**

Melanocortins exert their effects by binding to and activating melanocortin receptors, a family

of five (MC1R to MC5R) seven-transmembrane g-protein coupled receptors (GPCRs) that affect different body functions. The receptors are widespread throughout the body, exhibiting myriad ligand affinities, tissue and cell distribution, and downstream effects.

## **Melanogenesis**

The process whereby melanin is produced in the body.

## **Narrowband Ultraviolet B (NB-UVB) phototherapy**

Therapy which utilises an ultraviolet B light source to activate melanin in vitiliginous lesions of the skin.

## **Phase I**

The first trials of a new drug candidate in humans, phase I trials are designed to evaluate how a new drug candidate should be administered, to identify the highest tolerable dose and to evaluate the way the body absorbs, metabolises and eliminates the drug.

## **Phase II**

A phase II trial is designed to continue to test the safety of the drug candidate, and begins to evaluate whether, and how well, the new drug candidate works (efficacy). Phase II trials often involve larger numbers of patients.

**Phase IIb/Phase III**

Advanced-stage clinical trials that should conclusively demonstrate how well a therapy based on a drug candidate works. Phase III trials can be longer and typically much larger than phase II trials, and frequently involve multiple test sites. The goal is statistically determining whether a therapy clinically improves the health and well-being of patients undergoing treatment while remaining safe and well-tolerated.

**Pharmacodynamics**

The study of the time course of a drug's actions in the body.

**Pharmacokinetics**

The part of pharmacology that studies the release and availability of a molecule and drug in the human body.

**PhotoCosmetics**

CLINUVEL's product range of dermatocosmetics.

**Photodermatoses**

Photodermatoses are a variety of skin conditions that develop as a result of exposure to ultraviolet radiation or visible light.

**Photoprotection**

Protection from light and ultraviolet

radiation. Melanin provides natural photoprotection to skin, whilst sunscreens provide artificial photoprotection.

**Subcutaneous**

Underneath the skin.

**Sustained release/controlled-release**

Process whereby a drug is released from a formulation over a period of time.

**Therapeutic Goods Administration (TGA)**

Australia's regulatory agency for medicinal products and devices.

**Ultraviolet (UV) radiation**

Part of the electromagnetic spectrum at wavelengths below 400 nanometers, also called the invisible portion of light. There are three sub-types of UV: UVC <280 nm; UVB 280–320 nm; UVA 320–400 nm.







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