

# CLINUVEL PHARMACEUTICALS LTD

A.B.N. 88 089 644 119

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<b>1. Reporting period:</b>	<b>1 July 2023 to 30 June 2024.</b>
Previous corresponding period:	1 July 2022 to 30 June 2023.

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<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 13%</b>	<b>To 88,178,308</b>
2.2 Profit from ordinary activities before tax attributable to members.	<b>Profit has increased 11%</b>	<b>To 50,678,978</b>
2.3 Net profit for the period attributable to members.	<b>Profit has increased 16%</b>	<b>To 35,636,359</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: 6 September 2024.		
2.6 The CLINUVEL PHARMACEUTICALS LTD audited Annual Report for the year ended 30 June 2024 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:		

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<b>3. Refer to the Attachment to Appendix 4E for the Statement of Profit and Other Comprehensive Income together with notes to the statement.</b>
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<b>4. Refer to the Attachment to Appendix 4E for the Statement of Financial Position together with notes to the statement.</b>
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<b>5. Refer to the Attachment to Appendix 4E for the Statement of Cash Flows together with notes to the statement.</b>
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<b>6. Refer to the Attachment to Appendix 4E for the Statement of Changes in Equity together with notes to the statement.</b>
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<b>7. The Directors have declared a fully franked final dividend of \$0.05 per ordinary share to be paid on 20 September 2024.</b>
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<b>8. No dividend reinvestment plan.</b>
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<b>9. Net Tangible Assets per Security for Year Ended</b>	<b>Net Tangible Assets per Security for Year Ended</b>
<b>30 June 2024: \$4.015</b>	<b>30 June 2023: \$3.290</b>

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<b>10. The control of entities which had control gained or lost: N/A</b>
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<b>11. Associates and joint venture entities: N/A</b>
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<b>12. No other significant information.</b>
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<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).
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<b>14. COMMENTARY OF RESULTS:</b> Commentary in respect of the financial results is provided in the Operating and Financial Review of the attached Annual Report.
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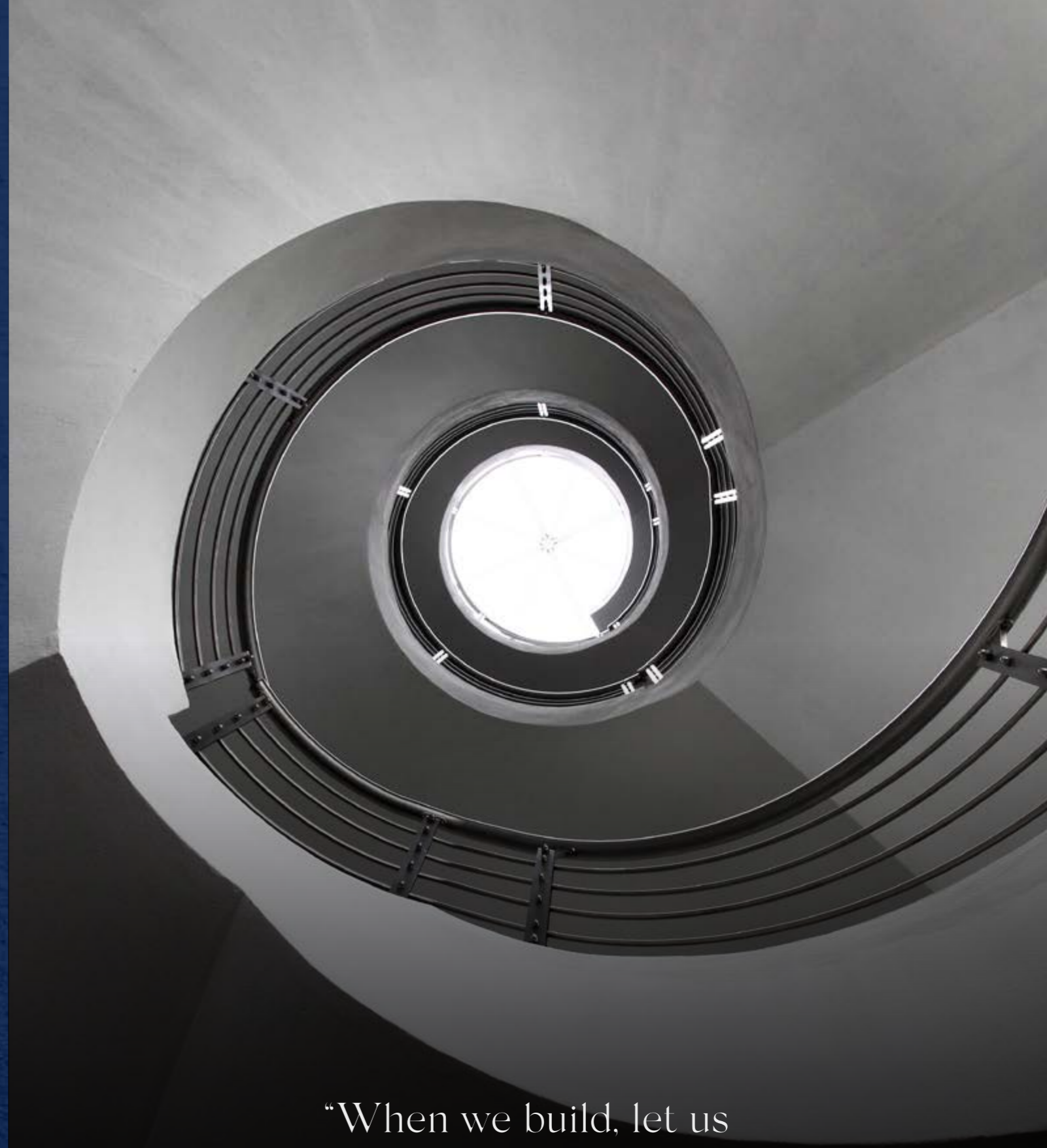
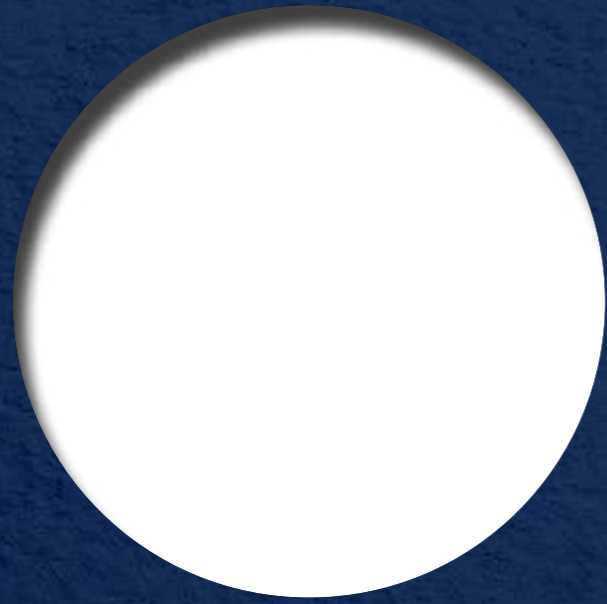
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# ANNUAL REPORT 2024



# CLINUVEL

PHARMACEUTICALS LTD



“When we build, let us  
think that we build forever.”

*John Ruskin*

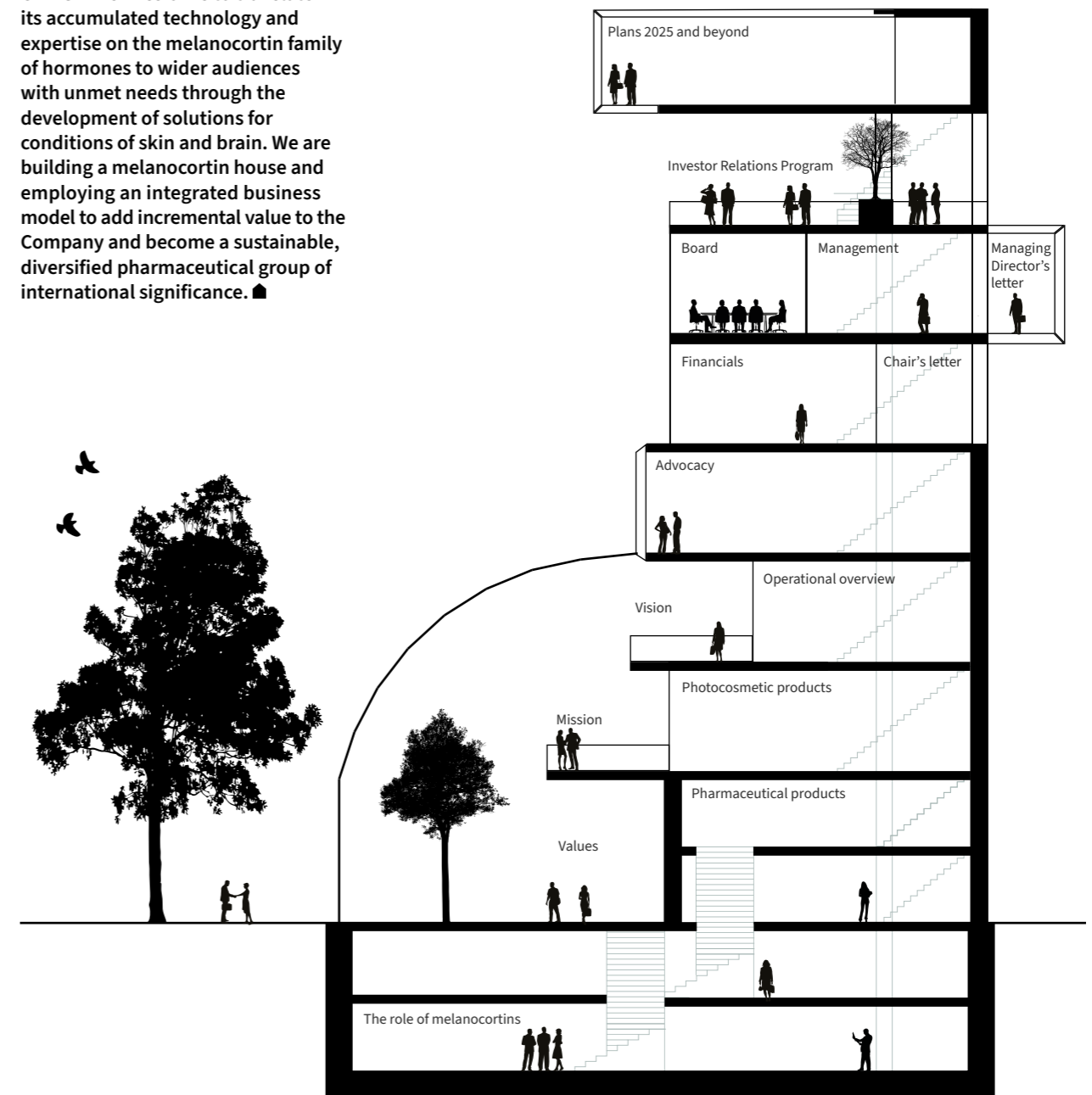
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# BUILDING A MELANOCORTIN HOUSE

CLINUVEL's mission is to translate its accumulated technology and expertise on the melanocortin family of hormones to wider audiences with unmet needs through the development of solutions for conditions of skin and brain. We are building a melanocortin house and employing an integrated business model to add incremental value to the Company and become a sustainable, diversified pharmaceutical group of international significance. 🏡



# MISSION

DELIVERING INNOVATIVE SOLUTIONS  
FOR UNMET PATIENT AND  
HEALTHCARE NEEDS.



# VISION

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. 🏡

# THE ROLE OF MELANOCORTINS IN HUMAN BIOLOGY

## What are melanocortins?

Melanocortins are a group of small protein hormones derived from proopiomelanocortin (POMC). These hormones modulate physiological activity in the body by binding with specific melanocortin receptors (MCRs) on cells across the body. Five MCRs have been identified: MC1R—MC5R.

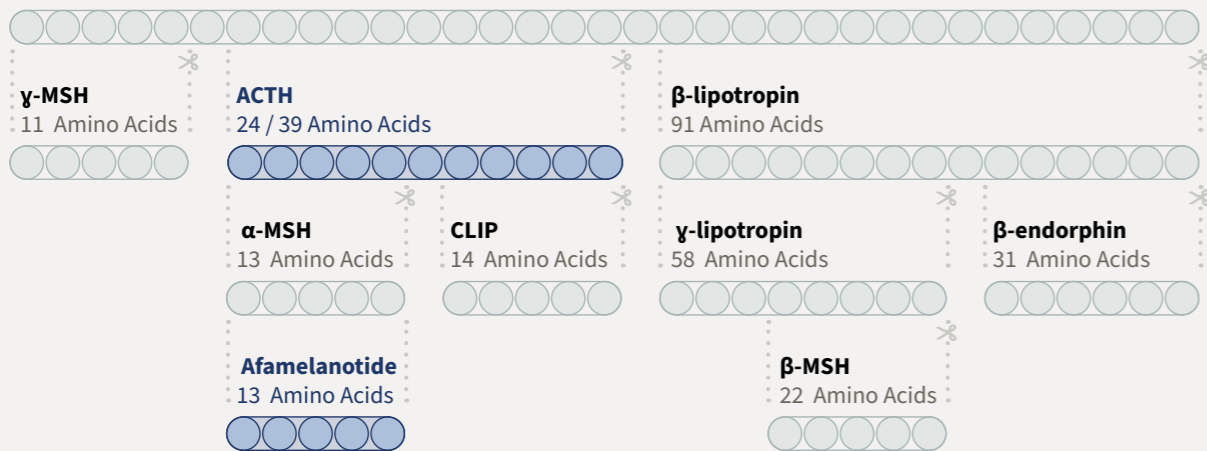
POMC, the precursor molecule to all naturally occurring melanocortins, is widely expressed throughout the human body, although has very little biological

activity. Cleaving POMC into smaller peptides produces melanocortins which are able to bind to receptors on cells and exert their effects. Since these peptides are tissue specific, the body can control the release of specific melanocortins from specific tissues to generate a biologically relevant effect.

The key POMC-derived peptides are  $\alpha$ -MSH, beta-MSH, gamma-MSH and ACTH. All share a key sequence of four amino acids (-HFRW-) which allow them to bind to the various melanocortin

receptors.  $\alpha$ -MSH – the natural hormone of which afamelanotide is an analogue – is formed from the cleaving of ACTH and known to play a role in cells across the human body. Perhaps best known in humans is the role of  $\alpha$ -MSH in dermal pigmentation: epidermal keratinocytes produce and release  $\alpha$ -MSH in response to UV radiation exposure, with  $\alpha$ -MSH then binding to MC1R on melanocytes to activate the synthesis of melanin. This process is known as melanogenesis.  $\alpha$ -MSH is involved in a wide range of other functions in the body, including

### Proopiomelanocortin (POMC) 241 Amino Acids



Melanocortin peptides, ACTH and  $\alpha$ - $\beta$ - $\gamma$ -MSH derive from post-translational processing of POMC, which is also the precursor for opioid peptides and CLIP (corticotropin-like intermediate lobe peptide)

## MELANOCORTIN FAMILY

### MC1R

**TISSUE EXPRESSION**  
ANTI-INFLAMMATORY CELLS  
HAIR FOLLICLE  
MELANOMA CELLS  
MELANOCYTES  
PERIAQUEDUCTAL GREY  
PITUITARY  
SKIN GLANDS  
TESTES

**FUNCTION**  
INFLAMMATION  
PIGMENTATION

**AGONIST**  
 $\alpha$ -MSH

### MC2R

**TISSUE EXPRESSION**  
ADIPOCYTES  
ADRENAL CORTEX  
SKIN

**FUNCTION**  
STEROIDOGENESIS

**AGONIST**  
ACTH

### MC3R

**TISSUE EXPRESSION**  
BRAIN  
GUT  
HEART  
PLACENTA  
TESTES

**FUNCTION**  
ENERGY HOMEOSTASIS  
SEXUAL BEHAVIOUR

**AGONIST**  
 $\alpha$ - $\beta$ - AND  $\gamma$ -MSH

### MC4R

**TISSUE EXPRESSION**  
ADIPOCYTES  
BRAIN

**FUNCTION**  
APPETITE REGULATION

**AGONIST**  
 $\alpha$ - AND  $\beta$ -MSH, ACTH

### MC5R

**TISSUE EXPRESSION**  
ADIPOSE TISSUE  
ADRENAL GLANDS  
BRAIN  
EXOCRINE TISSUES  
KIDNEYS  
LEUCOCYTES  
LUNG  
LYMPH NODES  
MAMMARY GLANDS  
MUSCLES  
OVARIES  
SKELETAL  
TESTES  
UTERUS

**FUNCTION**  
EXOCRINE FUNCTION

**AGONIST**  
 $\alpha$ -MSH, ACTH



DNA repair, immunomodulation, anti-inflammation, energy homeostasis, reproductive system functions, and exocrine gland secretion.

ACTH is the primary effector hormone mediating the HPA (hypothalamo-pituitary-adreno) axis, which regulates a wide range of biological systems to meet day-to-day metabolic needs of the body. Released from the anterior pituitary gland, ACTH binds to MC2R on the adrenal glands, leading to release of the glucocorticoid cortisol. ACTH also binds to, and activates, all five known human melanocortin receptors, regulating immunomodulatory and neuroprotective activity.

β-MSH and γ-MSH are cleaved from the C-terminal and N-terminal ends of POMC, respectively. In humans β-MSH is thought to play a critical role in the regulation of body weight in humans via

its effect on the hypothalamus, while γ-MSH is thought to regulate sodium balance and blood pressure through action on MC3R in the brain and kidneys.

**Melanocortin Receptors**

MCRs are found on cells across the body. Their known distribution and functions are illustrated on page 11.

**MC1R**

MC1R is well-known for mediating adaptive tanning in human skin, although its activation also leads to regulation of a range of other effects, including anti-inflammation, DNA repair and immunomodulation. In addition to melanocytes and keratinocytes in the skin, MC1R is present on cells across wide range of tissues including the liver, brain and adrenal gland.

**MC2R**

MC2R, uniquely for the MCR group, can be bound to and activated only by

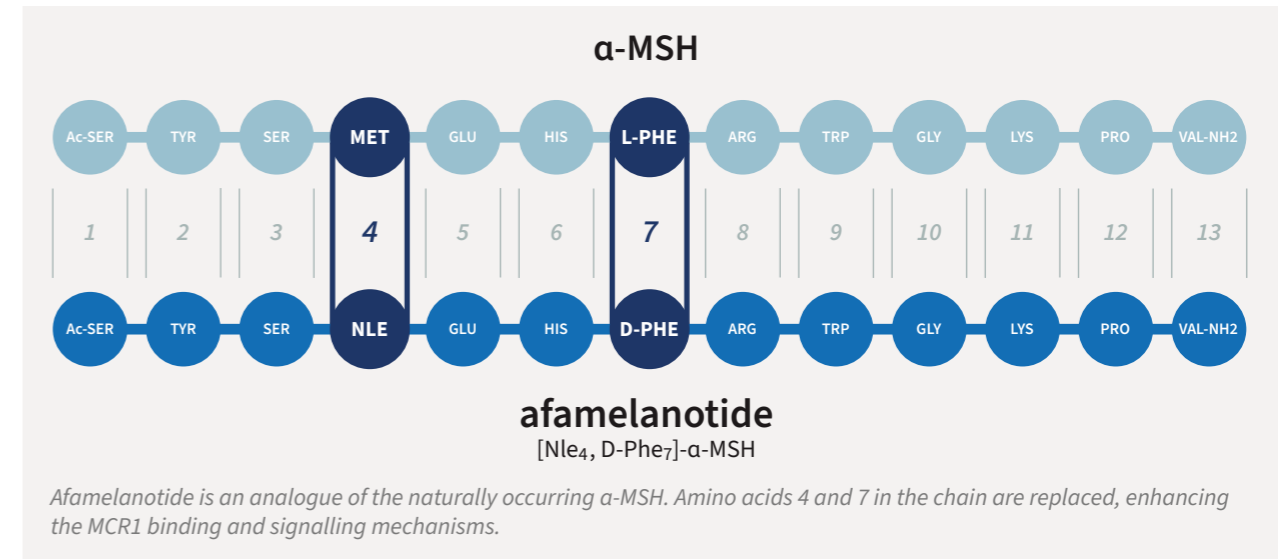
ACTH. MC2R is predominantly found in the adrenal glands where its action leads to cortisol release as part of the HPA axis, although like MC1R it is also present in a wide range of tissues, including skin, adipocytes, and bone.

**MC3R**

MC3R functions include regulation of energy homeostasis, autonomic functions, feeding behaviours, and anti-inflammation. MC3R is normally expressed in the brain, immune cells, placenta, heart, thymus, gut and the eye.

**MC4R**

MC4R has a broad range of functions that include energy homeostasis, feeding behaviour, thermogenesis, sexual function, cardiovascular function, anti-inflammatory, neuroprotection and pigmentation. MC4R is normally expressed in the brain, autonomic nervous system, spinal cord, immune cells, and the eye.



**MC5R**

MC5R functions are still being researched, although evidence suggests that MC5R plays a key role in governing immune reaction and

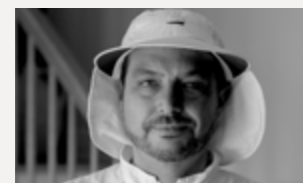
inflammatory response, regulation of sexual behaviour, thermoregulation, and exocrine secretion. MC5R is expressed ubiquitously in peripheral tissues including adrenal glands, liver,

kidney, lung, lymph nodes, thymus, spleen, mammary glands, testis, ovary, uterus, skin, and exocrine glands. ▲

The peer review articles relevant to this feature are listed at <https://www.clinuvel.com/refs-melano-ar24/>

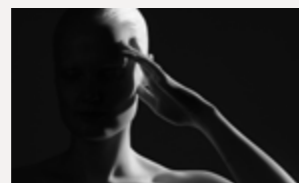
**CLINUVEL'S FOCUS ON CONDITIONS OF SKIN AND BRAIN**

CLINUVEL's areas of interest are summarised below, highlighting the melanocortin technology applied for each condition, the target MCR, and the mode of action that provides the therapeutic treatment of the condition.



**ERYTHROPOIETIC PROTOPORPHYRIA (EPP)**  
A rare metabolic disorder of the haem biosynthesis pathway that causes severe, phototoxic reactions to visible and UV light.

**SCENESSE®, afamelanotide – MC1R**  
Stimulates the production of eumelanin to provide systemic photoprotection from exposure to light and resulting protoporphyrin IX (PPIX) photoexcitation. This prevents phototoxicity in EPP, which is a result of a deficiency of the enzyme ferrochelatase (FECH) which causes PPIX accumulation in the body and skin.



**VARIEGATE PORPHYRIA (VP)**  
A rare metabolic disorder of the haem biosynthesis pathway that causes both phototoxicity and acute attacks.

**SCENESSE®, afamelanotide – MC1R**  
Stimulates the production of eumelanin to provide systemic photoprotection from exposure to light and resulting PPIX photoexcitation. This prevents phototoxicity in VP, which is a result of defects in the enzyme protoporphyrinogen oxidase (PPOX), which cause protoporphyrinogen IX accumulation (then oxidised to PPIX) in the body and skin.



**VITILIGO**  
A skin condition (believed to be auto-immune) resulting in a loss of pigment in the skin, causing profound psychological and social impact.

**SCENESSE®, afamelanotide – MC1R**  
Stimulates melanocytes to produce eumelanin, which in conjunction with NB-UVB results in melanocyte stem cell maturation and migration into vitiligo lesions, resulting in lesion repigmentation.



**XERODERMA PIGMENTOSUM (XP)**  
A rare genetic disorder which impairs the body's ability to repair DNA damaged by exposure to light; leads to extreme risk of skin cancer.

**SCENESSE®, afamelanotide – MC1R**  
Protects the skin from UV damage via multiple mechanisms, including the direct effects of increased melanin levels in the skin, antioxidative pathways and enhanced UV radiation repair mechanisms.



**ARTERIAL ISCHAEMIC STROKE (AIS)**  
An acute life-threatening neurological dysfunction following a blockage of arterial blood flow.

**PRÉNUMBRA®, afamelanotide – MC1R, MC3R, MC4R**  
Thought and evaluated on its supportive role in the reperfusion of brain tissue via vasodilatory effects, in addition to exerting anti-inflammatory effects and anti-oxidative effects within tissue affected by the stroke, potentially improving post-stroke recovery.



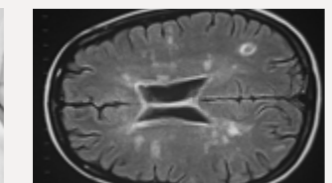
**PARKINSON'S DISEASE (PD)**  
A progressive neurodegenerative condition characterised by the death of dopaminergic neurons in the substantia nigra, accompanied by accumulation of alpha-synuclein (Lewy bodies).

**PRÉNUMBRA®, afamelanotide – MC1R**  
Generates neuroprotective effects via attenuation of α-synuclein-induced dopaminergic neurotoxicity, as well as upregulating anti-inflammatory, anti-oxidative, and DNA repair pathways in a way which could slow disease progression.



**INFANTILE SPASMS (IS)**  
A rare and serious seizure disorder in infants and young children, which can lead to developmental delay and epilepsy in later life.

**NEURACTHEL®, ACTH – MC2R, MC3R, MC4R**  
Exerts antiepileptic properties through a combination of MC2R-activated steroidogenesis and MC3R/MC4R-mediated anti-inflammation in the central nervous system.



**MULTIPLE SCLEROSIS (MS)**  
An auto-immune condition of the central nervous system which leads to impaired neurological function, including motor function.

**NEURACTHEL®, ACTH**  
Exerts immunomodulation by inhibiting the inflammatory effects of immune cells in the central nervous system, and generates an anti-inflammatory effect by reducing production of pro-inflammatory cytokines and inhibiting the activation of nuclear factor (NF)-κB, the master driver of inflammation.



# KEY ACHIEVEMENTS

CLINUVEL CONTINUED ITS ADVANCE TOWARDS  
A DIVERSIFIED BIOPHARMACEUTICAL  
IN THE JUNE 2024 FINANCIAL YEAR

## FINANCIAL PERFORMANCE

- Growth in revenues
- Controlled increase in expenses
- Eighth consecutive annual profit
- Seventh consecutive annual dividend declared
- Continued increase in cash reserves

## STEADY PROGRESS SCENESSE® ACCESS IN EPP

- Increased patients, treatment centres and frequency of dosage
- Partnership commenced with Valentech Pharma in Latin America
- Adolescent study CUV052 expanded and underway

## MELANOCORTIN PRODUCT PORTFOLIO

- PRÉNUMBRA® in use in clinic for stroke patients
- NEURACTHEL® development continued

## AFAMELANOTIDE IN THE CLINIC

- VP – Phase II study CUV040 completed; European Orphan Drug Designation (ODD) granted
- DNA Repair – CUV151 in healthy volunteers completed; CUV152 and CUV156 continue; European ODD granted for XP
- Vitiligo – recruitment Phase III study CUV105 commenced
- AIS – Phase II study CUV803 underway
- Parkinson's – clinical program CUV901 announced

## PHOTOCOSMETICS

- Continued formulation work at the Singapore Research, Development & Innovation Centre
- Increased awareness of audiences of the need for photoprotection
- Prelaunch of CYACËLLE Radiant

## REACHING MORE INVESTORS AND NEW AUDIENCES

- Broadening of communications
- Novel use of social media
- Informative investor briefings
- Increased analyst coverage

# ADVOCACY OF KEY OPINION LEADERS

KEY OPINION LEADERS SPEAK ABOUT THE BENEFITS OF AFAMELANOTIDE



“Afamelanotide has revolutionized my life. With whispers of this treatment in the pipeline for so long, I am delighted that it has been made available in my lifetime.”

**Polańska, A.,** Wegner, J., Nutbohm, P., Staubach, P., Żaba, R., Dańczak-Pazdrowska, A., & Jenerowicz, D. (2024). Afamelanotide in protoporphyria and other skin diseases: A review. *Advances in Dermatology and Allergology*, 41(2), 149–154.

“...afamelanotide was safe, well tolerated and showed possible reduction in infarct core volume in our safety and feasibility study involving small sample of AIS patients. Potent MSH analogues such as afamelanotide have high therapeutic potential in AIS. Further large, randomized studies are required.”

**Stanislaus, V.,** Kam, A., Murphy, L., Wolgen, P., Walker, G., Bilbao, P., & Cloud, G. C. (2023). A feasibility and safety study of afamelanotide in acute stroke patients—An open label, proof of concept, phase IIa clinical trial. *BMC Neurology*, 23(1), 281.

“Afamelanotide is a convincing enriching, sometimes off-label, treatment option that physicians should take advantage of, however in diseases beyond EPP the further studies on a larger group of patients with long-term efficacy evaluation should be considered.”

**O'Reilly, M.,** McGuire, V. A., & Dawe, R. S. (2024). Erythropoietic protoporphyria and afamelanotide: A patient's perspective. *Clinical and Experimental Dermatology*, 49(2), 186–187.

“This study highlights a dramatic clinical benefit of afamelanotide in relation to light tolerance and QoL in protoporphyria”

**Leaf, R. K.** (2024). Afamelanotide for Treatment of the Protoporphyrins: Impact on Quality of Life and Laboratory Parameters in a US Cohort. *Life*, 14(6), 689.



Case study on use of afamelanotide in vitiligo - presented to American Academy of Dermatology, March 2024.

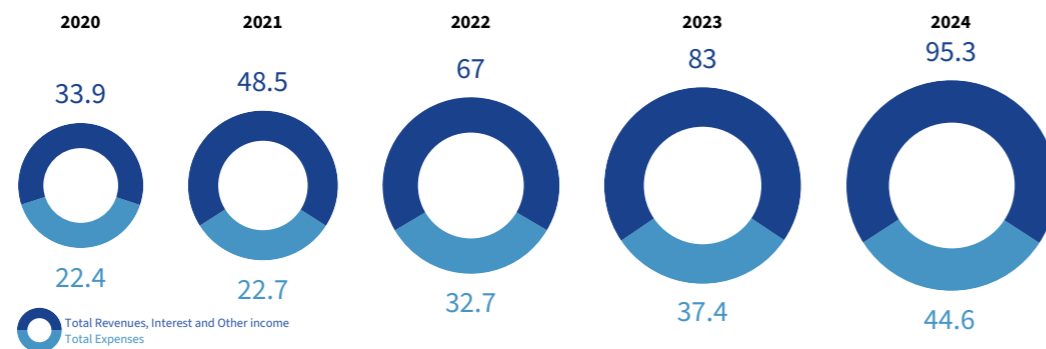
# FINANCIAL HIGHLIGHTS

STRONG PERFORMANCE CONTINUED: EIGHTH CONSECUTIVE ANNUAL PROFIT WITH GROWTH IN REVENUES AND CASH RESERVES

## REVENUES & EXPENSES (A\$m)

Growth of revenues and expenses were 15% and 19%, respectively in FY2024.

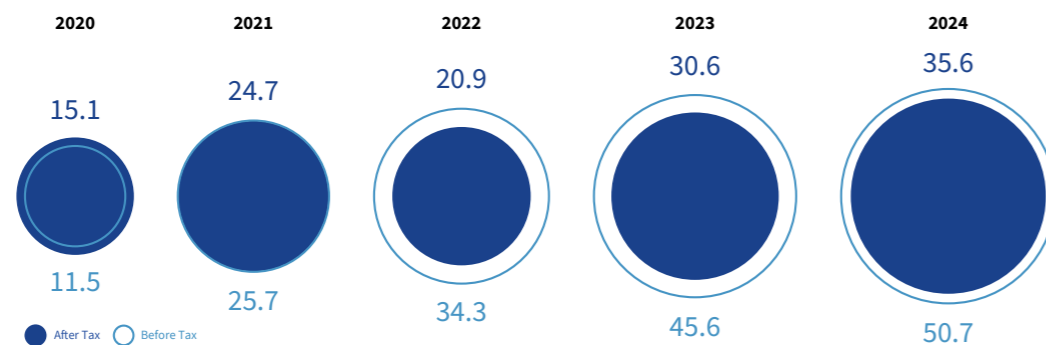
Over the eight years since commencement of commercial operations, the compound annual growth rate for revenues is 38% and 20% for expenses.



## NET PROFIT (A\$m)

Net profit increased before tax and after tax by 11% to A\$50.7 million and 16% to A\$35.6 million, respectively.

FY2024 marks the eighth consecutive year of profit.



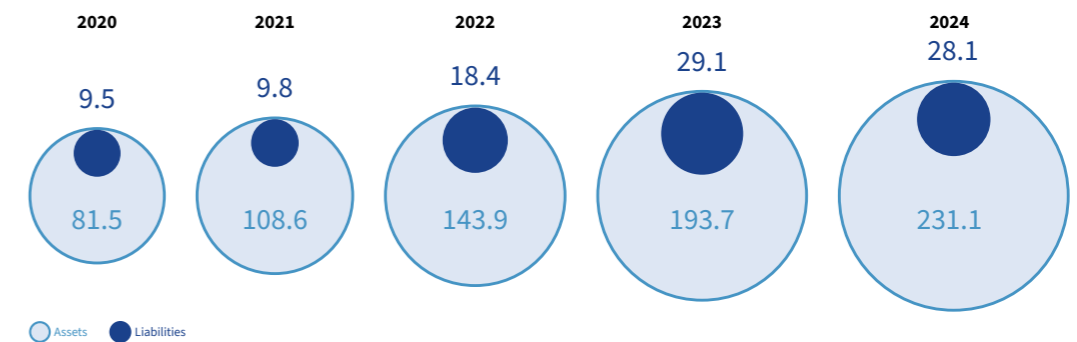
The Company continued to maintain a range of key indicators of high performance in FY2024

**A\$0.72**  
EARNINGS PER SHARE

**18%**  
RETURN ON EQUITY

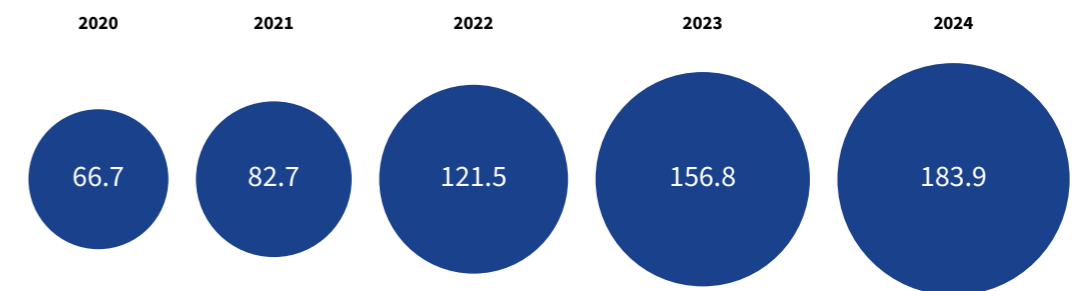
## ASSETS & LIABILITIES (A\$m)

The balance sheet strengthened again in FY2024, with an increase of 23% in net assets.



## CASH RESERVES (A\$m)

Cash reserves increased strongly by 17% to A\$183.9 million which enables the self-financing of the Group's expansion initiatives with a buffer to absorb adverse fluctuations in the operating environment.



**A\$0.05**  
DIVIDEND PER SHARE

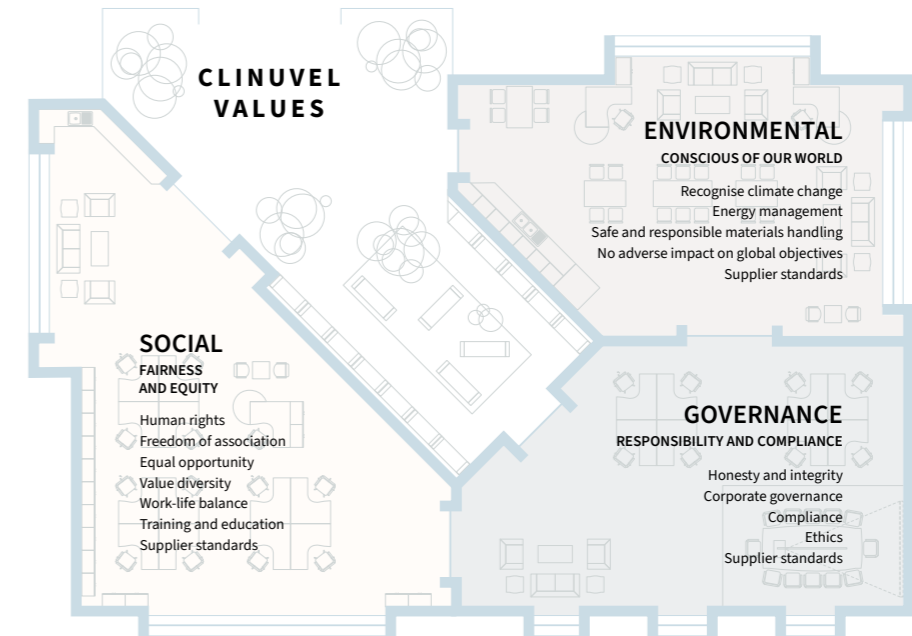
**NIL**  
DEBT

# SUSTAINABILITY

SUSTAINABILITY ENCAPSULATES CLINUVEL'S RESPONSIBLE APPROACH TO THE MANAGEMENT OF ENVIRONMENTAL, SOCIAL AND GOVERNANCE (ESG) RISKS. BUILDING ON THE DETAILED ESG STATEMENT CONTAINED IN THE 2023 ANNUAL REPORT, WE SUMMARISE HERE, CLINUVEL'S APPROACH AND PRACTICES, AND HOW WE MEASURE THE PROGRESS ACHIEVED IN FY2024.



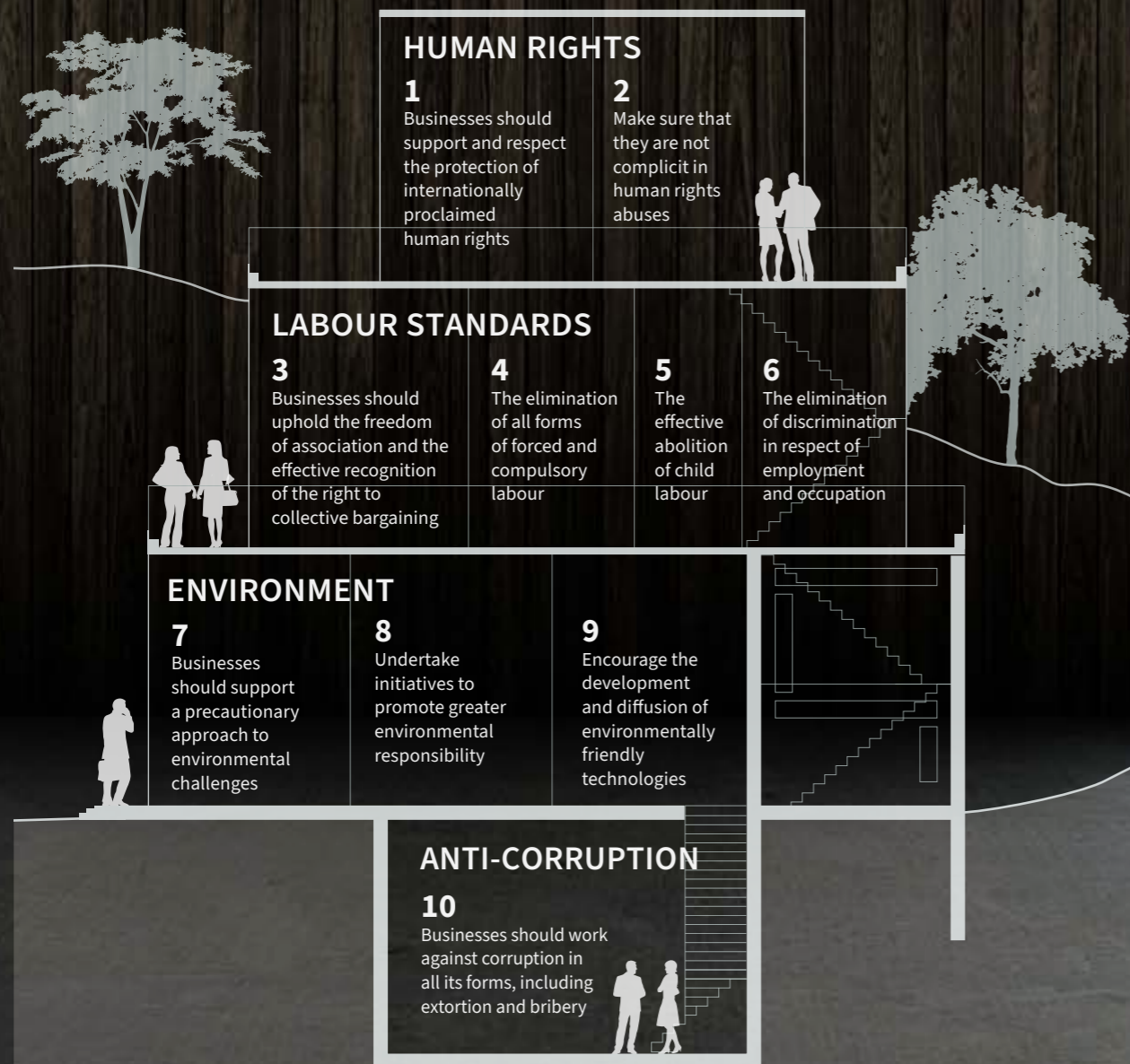
## ESG FRAMEWORK



## CLINUVEL'S ESG APPROACH & PRACTICES

GENERAL	DETAIL
Responsible corporate citizenship	The ESG Framework covers environmental, social and governance practices and policies, underpinned by the Company's values
Adhere to the <a href="#">United Nations (UN) Global Compact</a> ten principles of sustainability	The ten principles cover human rights (2), labour (4), environment (3) and anti-corruption (1) (see diagram and tables on pages 22–25)
We assess our activities have low direct environmental impact	A range of qualitative policies support minimisation of resource use and waste (refer to page 23)
Aligned with UN Sustainable Development Goals	The Company distributes a quality-assured product with a positive safety record assisting the quality of life of patients with no other treatment options
Social practices and policies consistent with the tenets of the UN Global Compact	We champion equal opportunity, diversity, inclusion and people development - refer to social measures on page 24
Active management by Executives and governance by the Board	Executives accountable to report monthly to the Board on ESG issues in their area of responsibility
Reviews of key suppliers undertaken on their ESG practices	Initiated 1 July 2023; reviews completed to date are acceptable to the Company

# UN GLOBAL COMPACT TEN PRINCIPLES OF SUSTAINABILITY



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.



## ENVIRONMENT

KEY AREAS	HOW WE MEASURE PROGRESS
Conscious of the human impact on the environment	Follow UN Global Compact definition of sustainability
We assess the Company's direct environmental impact as low	<ul style="list-style-type: none"> <li>Less than 100 employees as of 30 June 2024</li> <li>Product manufacturing outsourced</li> </ul>
A range of qualitative measures are in place to minimise resource use and waste	<ul style="list-style-type: none"> <li>Responsible product packaging</li> <li>Responsible waste management and materials handling in the laboratory</li> <li>Electronic over paper files – Investor Relations use QR codes for presentations</li> <li>Split home / office working week</li> <li>Executive approval required for travel</li> </ul>
Environmental and climate targets not set	Targets will be appropriate as the scale of activities increase and planned regulatory reporting applies

## SOCIAL

KEY AREAS	HOW WE MEASURE PROGRESS
Responsible corporate citizenship	<ul style="list-style-type: none"> <li>Safety record of SCENESSE® (afamelanotide 16mg) in over 16,000 administrations to EPP patients</li> <li>Regular pharmacovigilance reporting of patient experience to regulators</li> </ul>
Clinical testing involving humans, as required to obtain regulatory approval of pharmaceutical products	<ul style="list-style-type: none"> <li>Adhere to OECD Testing Guidelines and principles of Good Laboratory Practices</li> <li>Privacy of study participants maintained</li> <li>Ethics committees approve studies</li> <li>PhotoCosmetic products tested on humans only</li> </ul>
Clinical testing involving non-humans	<ul style="list-style-type: none"> <li>Adhere to OECD Replacement, Reduction and Refinement Principles</li> <li>Laboratories used meet international standards and certifications</li> </ul>
Facilitate a safe working environment	<ul style="list-style-type: none"> <li>CLINUVEL's premises are high quality and designed to enable active interation and collaboration</li> </ul>
Facilitate a positive working environment	<ul style="list-style-type: none"> <li>Competitive performance-based remuneration and employment benefits</li> <li>HR policies support employee well-being, with leave for illness, including stress and post-menopausal care, maternity, paternity and family care</li> </ul>
Respect human rights	<ul style="list-style-type: none"> <li>Support freedom of association and binary / non-binary designation</li> </ul>
Equal opportunity and people development	<ul style="list-style-type: none"> <li>Policy of no tolerance in relation to discrimination</li> <li>Focus on career development through Individual Development Plans (all employees) and advanced development through the CLINUVEL Academy</li> </ul>
Leader in diversity – refer FY2024 metrics	<ul style="list-style-type: none"> <li><b>Gender: Female / Male quotient (%)</b>: All employees (69/31%); Executives (Top seven excluding MD 57/43%); and Board (including MD 60/40%)</li> <li><b>Nationalities</b>: 30</li> <li><b>Linguistics</b>: 63% of employees speak more than one language</li> <li><b>Age</b>: Generation Z (born 1997-2012) 19%; Generation Y, Millennials (1981-1996) 58%; Generation X (1965-1980) 19%; Baby Boomers (1946-1964) 4%</li> <li><b>Tenure</b>: % of total employees; Up to 2 years 59%; +2 and up to 5 years 25%; +5 and up to 10 years 8%; Over 10 years 8%</li> </ul>



## GOVERNANCE

KEY AREAS	HOW WE MEASURE PROGRESS
General Board oversight	Diligence actively maintained
Monthly reporting to Board	Achieved FY2024
HR Policies	Govern behaviours and have supported positive, productive relationships in FY2024
Code of Conduct and Corporate Values	Emphasise honesty and integrity; Nil breaches reported FY2024
Bribery & Corruption Policy prohibits illicit behaviour	No instances of identified corruption in FY2024
Whistleblower Policy	No reports or need to protect against reprisals in FY2024
Public disclosure of payments to health professionals	Practised in all jurisdictions; signatory of Disclosure UK

# CHAIR'S LETTER



Dear Shareholders

## Focus on the Mission

I was pleased to assume the role of Chair of the CLINUVEL Group mid-way through the 2024 financial year, a year marked by our ongoing focus to advance a range of initiatives to build a house of melanocortin based treatments for long-term sustainability. Our expertise in targeted receptor melanocortins is being applied to conditions of the skin and brain which have unmet medical needs. We are also translating this technology into PhotoCosmetic products for people in the general population to benefit from photoprotection, DNA repair and re-pigmentation (bronzing).

## Achievements FY2024

Let's review the year and the advances made across the range of initiatives:

- The distribution of SCENESSE® for EPP continued to grow in terms of number of patients, prescribing doctors, and centres administering treatment.
- We commenced a partnership with Valentech, enabling important access to treat EPP patients in Latin America, but ceased our partnership in China, until greater certainty over IP protection prevails.
- We expanded the CUV052 study to n=28, covering adolescent and adult patients >50 kg in weight to support the submission for the label expansion of SCENESSE® for adolescent EPP patients.
- In the US, we extended reimbursement of the cost of treatment to US veterans and their families and continued the expansion of Specialty Centers from over 50 to 85, as we head towards 120 centers by the end of 2025. This network is being put in place to treat both EPP and vitiligo patients, ahead of the completion of clinical studies on vitiligo.
- In vitiligo, we formed an expert medical panel, commenced the recruitment of patients for the Phase III study CUV105 in October 2023, and in March 2024 saw positive results experienced by a new patient presented at the American Academy of Dermatology.
- In DNA Repair, we provided readouts for CUV151 showing afamelanotide reduced DNA damage in a healthy population and continued the studies on XP.
- The CUV803 study looking to address arterial ischaemic stroke is also ongoing.
- We announced Parkinson's disease in June as a new indication with a Phase IIa study, CUV901 commencing later this calendar year, involving 6 patients receiving 11 doses of afamelanotide over a study period of 56 days.
- In June we initiated a soft launch of CYACËLLE Radiant, a new polychromatic product providing photoprotection that paves the way for the melanocortin product



Vitiligo case study presented to the American Academy of Dermatology



CYACËLLE Radiant

range under development for the preservation and bronzing of the skin.

Our strong financial performance continued with increased revenues, profit, and net cash inflow achieved for the eighth consecutive financial year. We are pleased with the 15% growth in revenues and ongoing prudent management of expenses achieved in FY2024. Cash reserves\* accumulated further this year from \$156.8 million to \$183.9 million and enable us to finance organic expansion, the share buy-back program, and the flexibility to manage external events and circumstances. The Board was proud to declare a

A\$95.3m  
REVENUES & INCOME

A\$35.6m  
PROFIT

A\$183.9m  
CASH RESERVES\*

18%  
ROE

A\$0.72  
EPS

\*Cash reserves as stated in a non-IFRS measure



seventh consecutive annual dividend to shareholders, which will be paid to shareholders in September.

**People**

We have thoughtfully increased staff numbers in recent years to support the expansion of the Group. We are fortunate to have attracted well-credentialed professionals in a highly competitive international labour market to advance CLINUVEL's objectives over the past years.

The Executive management team has changed and expanded in FY2024. We were pleased to re-engage Dr Emilie Rodenburger in the position of Director, Global Clinical Affairs in April. As of 1 July 2024, Mr Peter Vaughan took over as Chief Financial Officer (CFO) from Mr Darren Keamy, CLINUVEL's leading finance executive for 19 years. We thank Darren very much for his dedicated service to the Company and wish him well as he takes a well-earned sabbatical. In August 2024, we appointed Ms Claire Newstead-Sinclair as Company Secretary (CS). Previously this role was undertaken by Mr Keamy, but the Board decided that the CFO and CS roles should be separate, particularly as the complexity and

breadth of the business has increased. Reflecting this, the CS role will assume responsibility for the risk management of environmental, social and governance risks as part of the Company's drive to responsible sustainability. We welcome Dr Rodenburger and Mr Vaughan to the Executive management team to help collectively advance our strategic initiatives.

I am also pleased that we secured a one-year extension to the services of Dr Wolgen as Managing Director (MD) and Chief Executive Officer (CEO) to 30 June 2026, providing the assurance of the continuity and advancement of our wide-ranging initiatives under his leadership. This now enables the Board to follow a process of putting longer-term succession in place.

**Board**

We acknowledge the service of Mr Willem Blijdorp, who served just over four years as Chair.

As the new Chair, I instigated a full Governance Review and Board Strategy Review guided by experienced external consultants. These have been completed and have been valuable in the Board's operations.

Since my appointment as Chair on 1 January, I have been actively overseeing the recruitment of new Non-Executive Directors to the Board.

We aim to formalise the recruitment of two to three Non-Executive Directors to the Board in the coming months, following an international search.

There have been no adverse issues from a governance perspective over the past year, further extending CLINUVEL's record of operating at the highest ethical and professional standard. I am sincerely grateful to my fellow Board members for their support and effort over the past year and thank all CLINUVELLIANS for their steadfast focus on the objectives of the Company.

**Shareholders**

We actively engage shareholders on their views of the Company and take them into account in our decisions and communications. Let me provide you a few examples:

- Last October, ex-Chair Willem Blijdorp together with investor relations spoke to shareholders in Australia, New Zealand, Europe and the USA and their feedback is reflected in the extension of

the CEO's contract to June 2026, mentioned above.

- The Capital Markets Briefing in May in Sydney was a good opportunity for me as a newly elected Chair to talk to institutional investors and I was pleased with their understanding of the depth and promise of the pipeline.
- I have also received correspondence from many shareholders and exchanged views on the Company and its progress.

Despite the strong financial performance of the Company, the commercial progress of SCENESSE® and the potential of the pipeline, CLINUVEL's market value was lower in the past year. This is below what we regard as fair value, and given the sufficiency of cash reserves, we implemented a share buy-back program in March to provide some support to the share price. Many shareholders expressed their appreciation of this initiative.

It is important that the Company's course remains steady and focused on our objectives. At this year's Annual General Meeting, I am looking for shareholders to support the uninterrupted direction of the Company to execute our diversification initiatives. The risk of disruption will not be in the interests of shareholders.

**Outlook**

Looking to the future, we are actively executing our vision of a strategic house of melanocortins, maintaining focus on the commercial efforts in EPP, and investing to drive pipeline initiatives. These encompass the drug products, PRÉNUMBRA® and NEURACTHEL®, clinical programs in vitiligo, variegate porphyria, DNA Repair, stroke and Parkinson's, and the development of a range of PhotoCosmetic products.

CLINUVEL is on the path to transform its operating and financial profile through expanded product offerings for

unmet needs. All stakeholders can see the incremental value being built. For example, the first few years of treatment of vitiligo has the potential to generate significant revenues. This is also the case for the distribution of NEURACTHEL® and shareholders have also recognised the potential of our PhotoCosmetic product range. For investors, the rationale for their investment in CLINUVEL is compelling as we strive to advance the strategic priorities to fruition over the coming years.

I wish all stakeholders good health and look forward with you to the advancement of our objectives in the 2025 financial year and beyond. 🍀

Professor Jeffrey Rosenfeld  
Chair  
CLINUVEL Group

**CORPORATE GOVERNANCE**

CLINUVEL PHARMACEUTICALS LTD and its Board are committed to establishing and achieving the highest standards of corporate governance. The Company's Corporate Governance Statement for the year ending 30 June 2024, based on the Australian Securities Exchange Corporate Governance Council's (ASXCGC) Corporate Governance Principles and Recommendations, 4th Edition, can be found on our website at <https://www.clinuvel.com/clinuvel/company-overview/corporate-governance>.



# MANAGEMENT

TEN EXECUTIVES, INCLUDING THE MANAGING DIRECTOR, CONSTITUTE THE EXECUTIVE MANAGEMENT TEAM OF CLINUVEL.

As Managing Director, Dr Wolgen sees his role as the conductor of the orchestra – keeping rhythm and discipline while ensuring the best possible ensemble is in place to do justice to the ‘score’. As the complexity of the business increases, it is imperative to have the right people in place for the multitude of tasks ahead, and the executive team is expected to grow accordingly. The executive team has and will become more visible as they communicate their activities and outcomes to stakeholders.



*“The investor relations team loves telling CLINUVEL’s dynamic story to stakeholders, particularly assisting new shareholders to discover the long-term incremental value being built.”*

## Malcolm Bull

Head of Australian Operations and Investor Relations  
Joined 2019  
BEd (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, and relationship management, 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 six sell-side analysts since his arrival and increased institutional ownership of CLINUVEL from 25% to 35% of issued capital.



*“The positive impact of SCENESSE® on the lives of EPP patients spurs my team every day to work to extend its use to new patients.”*

## 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 US 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.



*"We pride ourselves on vigilance to quality and the standards that are essential to ensure the smooth performance of the business."*

**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.



*"Managing the strategic expansion and daily operations of this international biopharmaceutical group provides our teams an ongoing professional challenge."*

**Lachlan Hay**

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

As Director of Global Operations, Mr Lachlan Hay supports the executive and senior management teams as well as maintaining 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 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).



*"I am proud to have played a leading role as CFO and Company Secretary in CLINUVEL's progression from an R&D based enterprise to a profitable commercial operation, expanding for the future."*

**Darren Keamy**

CFO & Company Secretary  
Joined 2005 – to 1 July 2024  
BComm (Accounting, La Trobe University)  
CPA  
GradDip Applied Corporate Governance  
(Governance Institute of Australia)

Mr Keamy held the dual role of Chief Financial Officer and Company Secretary from 2005 to 1 July 2024. For 19 years, he ensured the Company operated with a high level of financial discipline while maintaining a strong focus on governance and compliance. From early in his time with CLINUVEL, Mr Keamy was responsible for maintaining strict controls to enable the Company to achieve profitability and reinvest in long-term growth. As the business evolved, Mr Keamy oversaw the addition of new entities and structures to both enable commercial sales as well as maintain tax efficiencies. Mr Keamy provided counsel to the Board across his role as well as maintaining corporate governance structures for the Group and leading global compliance. A qualified CPA, Mr Keamy previously held roles with global packaging specialists Amcor in Australia, as well as Salomon Smith Barney (now part of Citigroup) and Superdrug Stores in the UK.

Reflecting the complexities of the business, the Chief Financial Officer and Company Secretary roles have now been separated.



*"It is satisfying to meet the challenge to gain marketing authorisations and subsequently to meet all of the regulatory reporting requirements to maintain them."*

**Dr Rose Quadbeck-Diel**

Snr VP Regulatory Affairs  
Joined 2012  
BSc (Nutrition, Justus Liebig-Universität)  
PhD (Biochemistry, Johann-Wolfgang Goethe-University)

Having spent over 30 years in global regulatory affairs and quality assurance in large and mid-sized pharmaceutical entities in Germany and Switzerland – including Baxter Oncology, Asta Medica, and Mundipharma – Dr Rose Quadbeck-Diel ensures CLINUVEL is compliant with, and able to adapt to, a changing regulatory landscape. In her time with CLINUVEL this has included navigating marketing authorisation filings and compliance, shaping the Company's Brexit response, and implementing new European regulatory initiatives such as the falsified medicines regulations. In recent years Dr Quadbeck-Diel has worked to expand CLINUVEL's regulatory team to prepare long-term regulatory projects and new marketing filings.



*"I am thrilled to re-join CLINUVEL and advance its expanded clinical programs, particularly in vitiligo."*

**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 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 USA 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.



*"Since April 2020, we've built a strong foundation with EPP in the US. Now, we're excited to expand our treatment to vitiligo and other unmet needs."*

**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 USA 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 US 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.



*"I'm excited to join the high performing CLINUVEL team and lead the disciplined financial stewardship as we build the foundations of new revenue streams for future growth."*

**Peter Vaughan**

Chief Financial Officer  
Joined April 2024  
BBus (Acc) (Swinburne University)  
Snr. Exec. MBA (Melbourne University – Business School)  
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 USA, 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 Respiri (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 Immutep)). 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.



*"Applying melanocortin products to treat indications of the skin and brain with unmet needs is exciting. This mission underlies everything we do in the clinical and scientific area of the business."*

**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 USA, 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. 🏠

# BOARD

## SUMMMARIES OF THE SKILLS AND EXPERIENCE OF THE CLINUVEL 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

**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 US Food & Drug Administration (FDA) under a New Drug Application, which was approved in October 2019. First treatment of US patients commenced in April 2020 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 AU\$110 million in investments, and his international contacts and network contribute to the strategic support CLINUVEL enjoys globally.

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



## BRENDA SHANAHAN AO

**Non-Executive Director,  
BComm, FAICD, ASIA**

**Appointed 6 February 2007**

**Relevant Skills**

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

**Background**

Mrs Shanahan is a pioneer in the Australian finance community. The first female stockbroker, Mrs Shanahan has also spent more than two decades working and investing in medical R&D and commercialisation. She is currently a non-executive director of Phoslock Water Solutions Ltd. Mrs Shanahan is also a non-executive director of DMP Asset Management Ltd and SG Hiscock Ltd, a director of the Kimberly Foundation of Australia Ltd, and Chair of the Aikenhead Centre for Medical Discovery in Melbourne. In 2021, Mrs Shanahan was recognised as an Officer in the General Division of the Order of Australia. Previously Mrs Shanahan was a member of the Australian Stock Exchange and an executive director of a stockbroking firm, a fund management company and an actuarial company. Until 2017, she was Chair of St Vincent's Medical Research Institute. Mrs Shanahan was formerly Chair of Challenger Listed Investments Ltd, the reporting entity for four ASX listed firms and formerly a non-executive director of Bell Financial Group (ASX: BFG) and Challenger Limited (ASX: CGF). Mrs Shanahan has also served and Chaired various Audit and Risk Committees throughout her career, including Challenger Financial Services Group Ltd, Bell Financial Group, Victoria University, JM Financial Group Ltd, SA Water, AWB International Ltd, BT Financial Group and V/Line Passenger.

Mrs Shanahan joined CLINUVEL in 2007 and was Non-Executive Chair of the Board from late 2007 until July 2010. Her depth of experience across global markets and medical research provides significant value to the current Board and Group.



## KAREN AGERSBORG

**Non-Executive Director,  
MD**

**Appointed 29 January 2018**

**Relevant Skills**

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

**Background**

Dr Agersborg is a clinical endocrinologist with diverse and extensive practice experience in Pennsylvania and New Jersey, USA. 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 US regulatory and commercial strategy, resulting in the US FDA's approval of SCENESSE® in October 2019 and the subsequent market launch in 2020.



## SUSAN (SUE) SMITH

**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 Ewell 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. 🏠

# MANAGING DIRECTOR'S LETTER



Dear Shareholders,

Success in biopharmaceuticals involves exploring uncharted territories while working out an attitude to risk. It is a balancing act that requires a team with a certain disposition who have a clear philosophy to follow. Our core technology has been fine-tuned over the space of 43 years. To put our industry in context, in that time three companies have abandoned their attempts to clinically develop melanocortin technology.

That is to say, our scientists, physicians and managers have faced daunting challenges in their efforts to turn chemical novelty into economic reality. And yet, they have achieved that goal. Today, CLINUVEL is comprised of a global team that works cohesively across seven locations. These individuals devote their time and energy to build a profitable group that solves healthcare problems, while striving to become a global brand. That is the mission we have set ourselves and which we have an unwavering commitment to fulfil. Now to the future: how and when to propel the Company towards the next phase of growth and valuation?

One of our core beliefs is that many minds working together will solve problems related to melanocortin technologies more quickly. Technology is subordinate to the calibre of staff. My main priority has been to position CLINUVEL among the handful of biopharmaceutical companies that are financially independent. Less than 9% of such firms make money and we are one of them. Unfettered by fundraising constraints, we have

increased the pace of development of treatments for vitiligo, DNA repair, stroke, porphyrias, Parkinson's disease and other healthcare products. We have achieved our primary goal, which was ensuring that both patients and early investors benefit from these actions. Now we find ourselves in the secondary stage of financing this project, as this letter explains. I will share the rationale behind our approach to finance, development and expansion over the last 12 months.

Unexpectedly, this period has been overshadowed by the tragic loss in August of our esteemed colleague and a dedicated supporter of CLINUVEL, Professor Marcus Maurer, Chair of the Dermatology Department at Berlin's renowned Charité University Hospital. I would like to pay tribute to Marcus, taking the moment to express my longstanding admiration for a person who was larger-than-life, optimistic, light-hearted and always stood above the matter. I only wish I had done this during his lifetime.



In memory of  
**Professor Marcus Maurer**  
*"a revolutionary thinker in dermatology, an inspiration and statue of optimism for all who had met Marcus"*

Marcus was one of the first physicians I contacted back in 2004, as part of lengthy diligence on CLINUVEL (at the time, Epitan). Marcus immediately understood the potential of SCENESSE® in treating EPP and various photodermatoses. He accompanied our managers to Germany's BfArM, the European Medicines Agency, and reimbursement authorities (GBA, GKV), and spoke about afamelanotide at numerous conferences. Not only was Marcus one of the most ethical professionals one could meet, but he also radiated charisma and demonstrated an innate compassion for patients and staff alike. He was, he is, a luminous being.

One very occasionally meets someone who makes an immediate impact, leaves an indelible impression and whose energy makes collaborating joyful and exciting. Marcus was this very person. He leaves behind his partner and three children, and his departure from this world leaves us with an ineffable void. Our clinical research with Charité must continue in his name, that is the way Marcus had wanted it. CLINUVEL's work will stand on his shoulders, a giant in dermatology.

## Risk Management & Efficiencies

The past year reminded us once again of the steep development and financial risks posed by the relatively high number of Complete Response Letters issued by the FDA, as well as the many drugs that leading insurance companies rejected, owing to concerns about new molecular entities (NMEs). It is worth noting that developing and commercialising novel hormones for untreated diseases—as CLINUVEL has chosen to do—is a



much riskier endeavour than it is for biosimilars, radiopharmaceuticals, generics, diagnostics, devices and managed care.

All medical technologies and services developed by listed life-science companies will eventually be collated in a life-science index. On closer inspection however, these distinct businesses are incomparable in such a pared-back format, owing to their differing objectives and risk profiles. Dotmatics, an analysis firm that aggregates biochemical and clinical data, recently revealed that the costs of drug development have surpassed US\$1.5 billion over the last decade. Meanwhile regulatory and commercial success rates remain steady, at less than 10%. Higher spending does not guarantee fixed results.

I felt strongly that CLINUVEL, as a leading specialist in developing NMEs, needed to be insulated from operational and financial risks, particularly given increased volatility in global markets. Managing the Company's development in a conventional manner, with less focus to funding requirements and

by diversifying its pipeline early on, would have left CLINUVEL dependent on equity investors or debt financing. We estimate this would have diluted shareholders' ownership of CLINUVEL by more than 1,600% (assuming we would have secured funding at all).

So, we took a different path. Once management and majority shareholders agreed to aim for economic sovereignty, we focused our resources on limiting drug development and set out to self-distribute our lead product, SCENESSE®. Thanks to this strategy, CLINUVEL's financial metrics have strengthened year-on-year. Our robust balance-sheet has enabled us to seize promising growth opportunities by developing our portfolio of melanocortin technologies and pursuing new ventures which will result in new revenue streams.

In parallel to our attention to risk, we have sought operational efficiencies. We first set annual agendas, aligning all parts of the business and establishing key performance indicators for staff. These included working in cross-functional teams to cross-pollinate expertise; assigning

regional responsibilities; and integrating research & development and innovation output. Over the last year, we rolled out a multi-weighted model to guide clinical and regulatory decision-making. The aim was to provide our managers with a blueprint to secure efficacy and commercial viability of new drug candidates. The model aims to save considerable sums by avoiding costly clinical and regulatory programmes which do not meet the commercial criteria down the line. New systems will be added in 2025 too. ERP<sup>1</sup>, CRM<sup>2</sup> systems, eQMS<sup>3</sup> and intelligence platforms will ensure that data and information are readily available across the Group.

At CLINUVEL, we all understand the need to deliver results and meet deadlines. Those who embrace the Group culture, being enthusiastic and motivated to solve problems, build a meaningful career. At the same time, we are swimming against tides in the post-pandemic labour market. Recruitment agencies such as Randstad report up to a 30% turnover in pharmaceuticals, a number that raises concerns about the retention of key knowledge.

To combat this trend, we are on a perpetual search for the next generation of technical and business talent. The Group continually conducts interviews to identify promising candidates and shape

positions to suit the brightest individuals. To increase retention and incentives for long careers at the Company, we established the CLINUVEL Academy in 2024. The initiative offers eligible managers a structured training program, post-graduate education, and advanced learning opportunities, in return for long-term service.

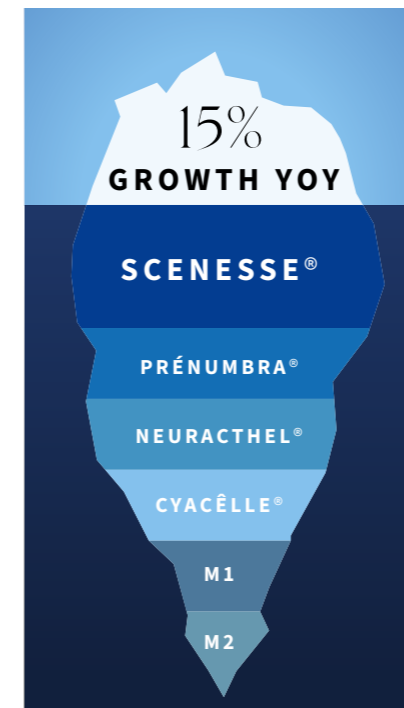
**The Next Phase of Growth: 2024–2026**

For the last decade, our financial planning has been centred around establishing a Group that remains at the vanguard of pharmaceutical development, giving shape to the next set of melanocortin technologies. To make this a reality, we came up with a business model in which longer-term development would be self-financed. Now with our melanocortin portfolio (SCENESSE®, PRÉNUMBRA®, NEURACTHEL®) and the PhotoCosmetics ranges (CYACÉLLE® and CYACÉLLE® RADIANT), we are on the cusp of translating peptide technologies to help a host of rare or untreated diseases; realising a future of new delivery methods; and reformulating our technology to suit consumer healthcare.

We are embracing novel thinking on financial systems, distribution networks, artificial intelligence, branding activities, social media, broader ambassadors' communication and ERP, distribution, and market access. We are preparing the Company to integrate new skills in engineering, bio-analytics, and formulation development, while also diversifying our offering and markets by targeting both pharmaceutical and consumer healthcare.

Over the last year, we have increased the number of trained and accredited North American Specialty Centres from 67 to 87 (with two now active in Canada), in anticipation of entering the North American vitiligo market. We aim to add another 33 such centres by the end of 2025. These centres will prescribe SCENESSE®, according to the conditions of the drug's use for vitiligo patients who have lost pigmentation in their skin, and in many cases, their identity.

Dr Linda Teng has done a remarkable job of converting sceptical physicians in North America into keen followers and long-term prescribers, thanks to years of persistence by her team.







Across the Atlantic, Mrs Antonella Colucci has successfully headed European and Swiss market access, distribution, and logistics. Over 90% of patients continue treatment with SCENESSE® and the therapy is in demand. Patients express high levels of satisfaction and report an improved quality of life, as two new papers illustrate: “Afamelanotide for Treatment of the Protoporphyrrias: Impact on Quality of Life and Laboratory Parameters in a US Cohort” from Massachusetts General Hospital; and “Association of quality of life measures with afamelanotide treatment in patients with erythropoietic protoporphyria and x-linked protoporphyria: A retrospective cohort study”, from Henry Ford Hospital in Detroit.

Our patient registry makes these studies possible. It contains uninterrupted follow-up data on patients worldwide which in turn, fuels the growth in the number of centres, prescribers, patients and treatments administered. This makes more doctors and patients aware of the therapy’s long-term benefits.

Against these achievements, how do we measure the eighth consecutive year of growth in earnings, a continuum carefully planned to facilitate our ambitions? We have built up a hefty vault of cash—currently A\$183.9m in cash reserves, an increase of 17% the past financial year—and an annual compounded growth rate over seven years of 34%. This enables us to more rapidly able to integrate new technologies and companies. We are always on the lookout for acquisition opportunities when the time is right and when we can sufficiently mitigate integration risk. This would continue the Group’s expansion and subsequent growth of the management team.

#### **Investor & Public Relations, Communications**

New Australian institutions have purchased over 3% in aggregate of CLINUVEL’s shares (CUV) over the last 12 months. Existing institutional investors also increased their holdings over the same period, taking institutional ownership of CUV to 35% of issued capital. Retail stakeholders (including high-net-worth individuals and family offices) also expanded their stake, to

40% of issued capital. We are buoyed by our supporters’ optimism. One high-net-worth investor in the United States recently grew their holdings to one million shares, or 2% of issued capital. Given the ebullient interest in North America, we have recruited our first investor relations manager for this market, Mr Myles Clouston, who is an experienced analytics expert in the life sciences sector.

In October 2023 we welcomed Bell Potter, one of Australia’s largest financial advisory firms, commencing research on the Company for their client base which spans individuals, institutions and corporations. This was followed by Morgans Financial and Morningstar initiating coverage a month later. Mr Malcolm Bull, who leads our Investor Relations (IR) efforts, has attracted six sell-side analysts and acts as the point of liaison with our new Australian institutional investors.

Our consumer-facing communications have also progressed in leaps and bounds. This year we made a first low-cost foray into social media, engaging specialised ambassadors with their

own histories of solar damage and skin cancers to raise awareness of the first PhotoCosmetic product CYACÉLLE®. We also recruited our first professional writer, a journalist formerly of The Economist, to create content and opinion pieces for targeted online audiences. A strategic goal remains to deliver articles and engaging, relevant content in digital formats. In the next 24 months, we intend to identify additional influential ambassadors (CUVAs) who can share the CLINUVEL story.

We started the CUVIPs program, engaging intriguing personalities with a public profile and communicating our story with their “followers” in both the virtual and digital worlds. Bringing novel healthcare products to a consumer market requires a long runway. Time and patience are key. Two aims drive our global branding campaign: first, a desire to achieve household name recognition within the next two years. Second, to make CLINUVEL known as a brand synonymous with world-leading innovation in both photomedicine and PhotoCosmetics.

We are focusing on raising brand awareness ahead of the launch of the M1 and M2 lines in 2026, transdermal formulations containing melanocortins. These will be a world first. The Annual Meeting of the American Academy of Dermatology in Orlando next spring presents another opportunity to promote the Company’s industry-defining technologies and bold moves into consumer skincare. We look forward to seeing you there.

One of the year’s digital highlights was the event in February hosted by Ms Stefani Germanotta (whom you may know as Lady Gaga) and Mr Michael Polansky at their home in Los Angeles. At this star-studded, intimate evening we presented CLINUVEL’s pioneering technology and future ambitions to Silicon Valley’s investor community and professionals in the entertainment industry.

The night yielded dazzling results. Content from the evening reached 3.4m people in the days following the event, boosted by Ms Germanotta’s influential profile and mega-influencers

such as Ms Dylan Mulvaney. It was proof that a combination of high-profile events, curated social-media campaigns and broader exposure outside pharmaceutical circles will launch CLINUVEL into new, valuable conversations. From here onwards, it is about repetition of messages and having a presence at key global events.

#### **Collaboration Post-pandemic**

By now, the world has endured seven million deaths from COVID-19 and a total of 776 million confirmed cases (refer [World Health Organisation](#)), with many more undocumented. Among other things, the pandemic created seismic shifts in working habits. By Q1 2023 we were well adapted to a new reality of Zoom calls at kitchen tables. After this new-found freedom, it was clear that we would not revert to the pre-pandemic norm of five days in the office per week. We posed ourselves two questions: how to maintain productivity and where would work suffer without daily interactions? A year on, we have settled into a new rhythm. Teams working in offices tend to come in two or three times a week, in line with the



global average for the post-pandemic workplace. CLINUVEL staff who require a physical laboratory have no option other than to attend full time, however.

I believe that tempting professionals back the office will require employers to rethink their offer to workers. This will entail disrupting the former notion of “office” and presenting an entirely novel concept to staff. Flexibility is essential: commuting outside peak traffic; state-of-the-art facilities that include wellness and meditation rooms; a nursery for children; and cooking facilities. In sum, creating an environment of privilege may incentivise valued staff back to the office. In Britain, we took advantage of a depressed commercial real-estate market to purchase a highly-valued office close to London. Once the refit of our premises is complete, we anticipate that the Britain-based team will reevaluate the inconvenience of leaving home, considering the benefits offered at the new facilities.

**Research & Development, Innovation**  
Direct investment in research, development and innovation amounts to more than 40% of our net profits. Our Board and senior personnel are acutely aware of the risks associated with

innovating melanocortins. And yet, we are confident that it is a gamble worth taking. It would pay off handsomely, in the shape of the competitive position that CLINUVEL would attain at the end of successfully developing a drug for untreated diseases. A case-in-point is the market for porphyria, a new venture that has generated returns on equity of more than 24% on average since we started commercialising.

We have invested resources into the VALLAURIX Singapore team this year, adding new skills, new capital expenditures and new analytical methods with an eye to advancing three pharmaceutical products and the three PhotoCosmetic lines. We are continuously evaluating whether these investments in melanocortin-based technologies increase long-term value, or whether the funds would be more usefully spent elsewhere. Time versus output remains a critical metric of how we assess resource allocation. Thus far, we are compelled to develop the next melanocortin products, serving unmet, lucrative markets.

Finally, in February this year we launched the Photomedicine Foundation, an important, worthy

initiative which donates the fruits of R&D to underprivileged communities. African patients with xeroderma pigmentosum will receive treatment and skin-protecting PhotoCosmetics funded by the Foundation. We will focus on patients with darker skin, children and those handicapped by light.

#### **Board and Management Composition**

We acknowledge the contributions of Willem Blijdorp, who served nine years as a Board member and four years as Chairman. He gave commercial input at critical moments in CLINUVEL's history. His business acumen and wider commercial views are missed. I also wish to thank Andrew Likierman for serving during an interim period, and for kindly providing his financial views when they were needed. As this letter goes to print, we are poised to welcome new members who will bring diverse skills to the Board.

Across the Group, our priority is building a team with complementary experience and skills. We are also committed to achieving gender parity and increasing ethnic diversity. Our current ratio of female to male employees is 69:31. We are striving to maintain a minimum of 40% female representation on the

Board (the current make-up is 60:40 female:male). Other measures of diversity are detailed in the feature on Sustainability in this Annual Report. At the same time, we are establishing a skills-based organisation where we employ and develop professionals who can meet both current and future objectives. These range from R&D to clinical, analytics, commercial, consumer health, branding and communications.

In the meantime, succession planning for the executive team is progressing well. In July Mr Peter Vaughan replaced Mr Darren Keamy as Chief Financial Officer after 19 years at the Group; and new executives are being added to the team of ten, with Mr Lachlan Hay stepping up to the role of Chief Operations Officer on 1 July. The aim is to appoint a new Chief Executive Officer prior to my departure in June 2026, giving sufficient time for an orderly handover. The Company will continue its trajectory with new management in place by 2026. That presses us to realise all ambitions in less than 24 months.

#### **Summary**

This past year has been defined by exciting advances, supported by activities to consolidate and realise these strides forwards. CLINUVEL ranks among the few financially independent biopharmaceuticals on a solid growth trajectory. This has attracted numerous new investors to CLINUVEL, drawn by our fundamentals, long-term approach and risk management. To our delight, retail investors in Germany reached more than 1,900 in the past 12 months and their interest in the Company was warmly received during an over-subscribed meeting in Düsseldorf last March. German-speaking countries will receive further investor relations attention in the year ahead.

We are bullish on the outlook for SCENESSE®. The market for the

therapy is expanding year-on-year and insurers have already started to reimburse teenagers aged 15 and older. Eventually, we will add the adolescent population to our total pool of patients—a true milestone. With the new talent and specific skills that have entered the Company, we have also begun gearing up to enter the North American vitiligo market. This will reap significant rewards.

The bold combination of pharmaceuticals and healthcare is already lending the Company global exposure. We have laid the foundations for developing, manufacturing and distributing the first PhotoCosmetic products, while preparing for the flagship M-lines. Of course, we remain aware that two distinct businesses compound risks. Yet we possess the funds to take calculated risks, and we are confident in our ability to succeed.

Our leadership continues to evolve, protecting CLINUVEL's core identity as we innovate. Of the executive team of ten, eight have been with the Company for more than 15 years, and we welcome a new tier of talented senior managers. We have seen the addition of Mr Benson Chao (Legal Counsel), Ms Claire Newstead-Sinclair (Company Secretary), Mr Vaughan (CFO), and the return of Dr Emile Rodenburger (Director, Global Clinical Affairs). We are pleased to have Mr Clouston join us to build an IR program in the US; and Ms Marga Arrom-Bibiloni to lead the branding activities for the consumer healthcare branch of the business.

There are many new prodigies and emerging stars within the Group. Our task is to design programmes for individuals destined to have a long and rewarding career with us, under the umbrella of the CLINUVEL Academy. I am convinced these investments are worthwhile and that they will pay

off in the long-term. I look back at a year where a valuable team carried out quality and pharmacovigilance; regulatory; R&DI; clinical; finance and compliance; investor relations; public relations; a CBM team performed with creative talent; and strong general management.

The avid reader and biopharma investor will also know that CLINUVEL only discloses a fraction of our activities, as it is not in our interest to feed competitors with valuable knowledge. With the bulk of our work below the surface, we look forward to the days when we can reveal our value accretive technologies to enter new markets, protected by intellectual property patents.

The key objective for me now is to fulfil a life's ambition: to leave behind a prosperous biopharmaceutical company, which houses unique individuals, talents and personalities collectively doing good for those who benefit from our medical innovations. The journey to realising this goal has brought with it humility, shared by all who are associated with CLINUVEL from new Board members to our experienced executive team. This is a robust foundation which we can build upon.

That only leaves me to thank the CLINUVEL team for delivering great financials and you, for staying with us.

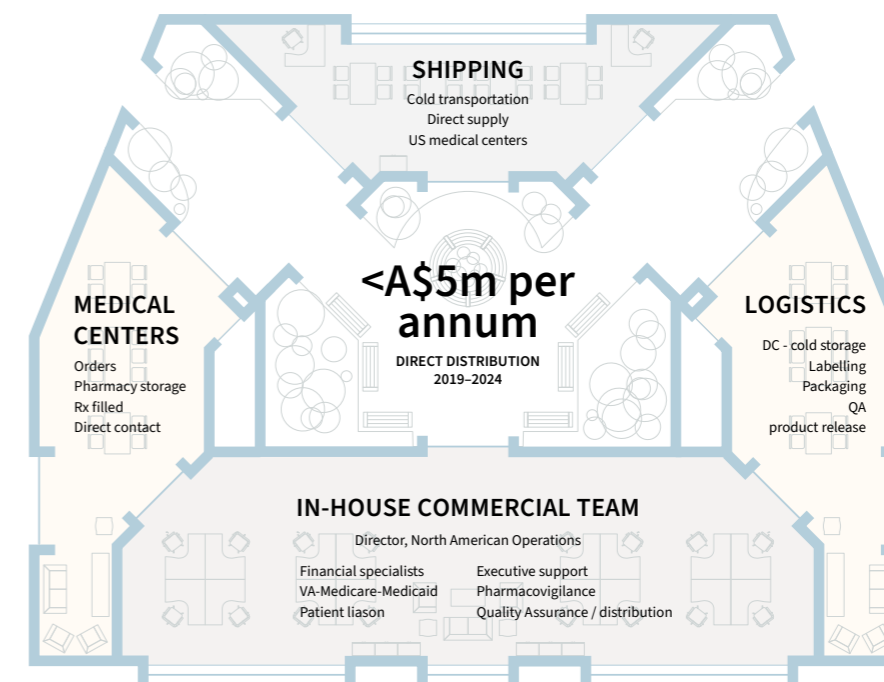


Philippe Wolgen  
Managing Director  
CLINUVEL Group



# OPERATING & FINANCIAL REVIEW

## US COMMERCIAL INFRASTRUCTURE



### 1 - ESTABLISHING AND EXPANDING ACCESS TO SCENESSE®

CLINUVEL has established SCENESSE® as the standard of care for the treatment of adult EPP patients in Europe and North America. Since its commercial launch in Europe in 2016, the Company has worked to facilitate access to SCENESSE® for all eligible EPP patients who demand treatment. More recently, efforts have also focused on addressing clinical requests to treat a wider group of EPP patients, most notably adolescent EPP patients. In FY2024, CLINUVEL enabled treatment access for the largest groups of EPP patients to date, with treatment uptake increasing in both Europe and the USA. The Company expects greater uptake in the coming year as more eligible patients are identified and able to access treatment, and CLINUVEL's team works to expand the regions where SCENESSE® is available for

prescription. As of 30 June 2024, more than 16,000 doses of SCENESSE® have been administered to EPP patients worldwide.

**Expert treatment network**  
EPP patients have traditionally received treatment from a number of different medical specialties, reflecting the complexity of the diagnosis, treatment and care needed over a patient's lifetime. In introducing SCENESSE®, CLINUVEL has sought to encourage multi-disciplinary care and worked with clinical and academic experts to establish a network of trained and accredited centres across Europe and the USA. The Company distributes SCENESSE® directly to centres and ensures appropriate use according to regulatory requirements.

The US Specialty Center network has grown throughout the course of FY2024, with over 85 clinics now trained and accredited to administer SCENESSE®. To better engage with this network and facilitate patient treatment, CLINUVEL has invested in new talent to work directly with prescribing physicians and their administrative teams, liaise with patients, and interact with payors, as well as ensuring compliance through a controlled distribution network. With reference to direct distribution costs, in integrating the distribution and logistics in-house, CLINUVEL is able to scale the system for future distribution of SCENESSE® and other prescription products. We are now working to expand to 120 trained and accredited centres as a foundation for the prescription of SCENESSE® for additional indication, such as vililigo.

		PRECLINICAL	PHASE I	PHASE II	PHASE III	COMMERCIAL
SKIN	<b>SCENESSE®</b> (afamelanotide 16mg) in adult EPP patients (EEA, UK, CH, USA, ISL, CAN, AUS)					
	<b>SCENESSE®</b> (afamelanotide 16mg) in adolescent EPP					
	<b>SCENESSE®</b> (afamelanotide 16mg) in adolescent and adult vitiligo					
	<b>SCENESSE®</b> (afamelanotide 16mg) in adolescent and adult XP					
	<b>SCENESSE®</b> (afamelanotide 16mg) in variegate porphyria					
	<b>CUV9900</b> transdermal					
BRAIN	<b>PRÉNUMBRA®</b> in arterial ischaemic stroke patients					
	<b>PRÉNUMBRA®</b> in Parkinson's disease					
	<b>NEURACTHEL®</b> instant – infantile spasms, multiple sclerosis					
	<b>NEURACTHEL®</b> modified release – CNS					

XP; xeroderma pigmentosum | IS; infantile spasms | MS; multiple sclerosis | CNS; central nervous system.

**Clinical benefit**

A growing body of evidence reflects the clinical demand for the product. Feedback on SCENESSE® use is in near-real time, enabling CLINUVEL's teams to identify and address challenges as they arise, as well as supporting global research efforts. The European EPP Disease Registry – the EEDR, created in 2016 as part of an agreed risk management plan for SCENESSE® and hosted by the Erasmus Medical Center in Rotterdam – captures pseudonymised data from the ongoing use of the treatment and is now the largest EPP registry in the world. Publications from EEDR data have demonstrated the ongoing clinical benefit from SCENESSE® treatment, as well as highlighting the long-term safety profile of the product.

**Broadening access**

After two years of review and interactions with the European Medicines Agency (EMA) to expand the label for SCENESSE® to include use in adolescent patients, CLINUVEL chose to withdraw its application. The variation – originally filed in 2022 – incorporated data and analyses from the use of SCENESSE® since 2006 and

narrowed the adolescent use to focus on patients aged 15-17 years with a minimum bodyweight of 60kg. After continued dialogue between the Company and the Agency, the EMA opined that it would not know whether a benefit-risk profile of SCENESSE® for adolescent EPP patients was established. CLINUVEL withdrew the variation application following an oral hearing of the CHMP, preparing a future submission containing additional data.

The Company has continued to receive clinical requests to facilitate access to SCENESSE® for adolescent patients under conditions of use through full reimbursement as well as compassionate access programs. Seven adolescent EPP patients have received SCENESSE® treatment for up to two years under these conditions of use. None of these programs or patients have been impacted by the withdrawal of the European variation and the Company expects that further adolescent patients will receive treatment. In parallel, clinical support has been received to commence a pharmacokinetic study (CUV052) in adolescent and adult (aged 12-

70) EPP patients. The study design comprises one implant administration to patients of 50kg body weight and above, comparing adolescent and adult patients and evaluating the safety and clinical benefits of SCENESSE®. Data from the CUV052 study will be submitted to global regulators to support further filings.

In May 2024, CLINUVEL announced the signing of a strategic partnership with rare disease specialists Valentech Pharma to introduce SCENESSE® as a treatment for erythropoietic protoporphyria (EPP) patients in Latin America. The two companies are now working to enable patient access through both special access programs and regulatory pathways. Recently enacted legislation in a range of Latin American countries has supported the introduction and use of drugs for patients with severe and rare conditions, reflecting similar statutes in Europe and North America. An estimated 1 in 200,000 individuals in Latin America are burdened by EPP.

CLINUVEL continues to evaluate new opportunities to expand patient access to SCENESSE®.

## 2 – PHARMACEUTICAL PRODUCT DEVELOPMENT & CLINICAL PROGRAMS

CLINUVEL is a global leader in the development and commercialisation of melanocortins. Having established SCENESSE® as the standard of care for EPP, the Company is now working to address unmet patient need in a range of severe and life-threatening disorders of skin and brain with melanocortin-based products.

CLINUVEL's clinical development program follows a decision model whereby the introduction of melanocortins to address disorders must have a high level of clinical and academic support, where there is a strong rationale for the introduction of technology and the ability to conduct a clinical program, and where the program is likely to result in a product which is commercially viable. This relies heavily on the team's existing knowledge of the potential of melanocortins, while working closely with global experts in a range of relevant fields.

Afamelanotide, the active ingredient in the SCENESSE® controlled-release

injectable implant and the instant-release PRÉNUMBRA® injectable formulation, binds to melanocortin receptors on cells across the body and is recognised as playing a role in photoprotection, DNA repair, melanogenesis, and as an anti-oxidative and anti-oncotic. Throughout FY2024 CLINUVEL has pursued clinical programs with afamelanotide for a range of disorders of the skin and brain. Highlights for the year include:

- Commencement of the first Phase III study of SCENESSE® for vitiligo patients. The CUV105 study seeks to confirm earlier clinical results that showed SCENESSE® – in combination with narrowband ultraviolet B (NB-UVB) phototherapy – resulted in faster, deeper repigmentation in vitiligo patients than NB-UVB monotherapy. Up to 200 patients will be enrolled in the study across sites worldwide. In August, the Company announced a change to the inclusion criterion of the study, retaining all patients in the study, extending its recruitment to

- June 2025.
- A new case study on the clinical efficacy of SCENESSE® in vitiligo was presented to the American Academy of Dermatology (AAD) meeting in San Diego in March 2024. The patient presenting with a Fitzpatrick Skin Type IV was diagnosed with vitiligo and had historically been unresponsive to other treatments. The patient had received seven SCENESSE® implants and 39 NB-UVB treatments over 134 days. Significant repigmentation of vitiliginous lesions on the face, neck, torso, and back was observed. The patient was reported to be thrilled with the repigmentation and to have regained her identity.
- Positive results from the DNA Repair Program. Biopsy analyses from the CUV151 study, evaluating the DNA repair capacity of afamelanotide on skin of healthy volunteers exposed to UV radiation, showed that DNA photodamage was significantly reduced following afamelanotide treatment. Further analyses from

## CLINICAL PROGRAM SUMMARY

INDICATION	PRODUCT	TRIALS / PROGRAM STATUS
Adolescent EPP	SCENESSE®	CUV052 ongoing, n=28, Pharmacokinetic study in adolescent and adult EPP patients
Vitiligo, adolescents and adults	SCENESSE®	CUV104 ongoing, Phase II n=6  CUV105 ongoing, Phase III n=200, Combination afamelanotide + NB-UVB vs NB-UVB monotherapy  CUV107 in setup, Phase III n=200
Variegate porphyria	SCENESSE®	CUV040 complete, further studies in development
DNA repair, xeroderma pigmentosum, adolescents and adults	SCENESSE®	CUV156 ongoing, Phase II n=6, XPC patients  CUV151, healthy volunteer study complete  CUV152 ongoing, Phase II n=6, XPC and XPV patients  CUV154 in setup, Phase II n=26, XPA, XPC, XPE and XPV patients  CUV158 in setup, healthy volunteer study n=10
Arterial Ischaemic Stroke	PRÉNUMBRA® instant	CUV803 ongoing, Phase II n=12, evaluating safety, changes in neurological and cognitive functions
Parkinson's Disease	PRÉNUMBRA® instant	CUV901 in setup, Phase IIa n=6, evaluating safety, impact on α-synuclein in blood
Infantile spasms, multiple sclerosis	NEURACTHEL® instant	Program in setup
Undisclosed CNS disorders	NEURACTHEL® modified release	Program in setup

CUV151 – released on 5 July 2024 – use RNA sequencing to show that afamelanotide significantly reduced the number of differentially expressed genes (DEGs) following UV irradiation. The genes evaluated are found as being central in the regulation of DNA repair and inflammatory reactions following solar and UV exposure.

- Positive results from the first study of SCENESSE® as a treatment for variegate porphyria patients. The six-month CUV040 study evaluated whether the drug could offer systemic

photoprotection to VP patients and reduce the impact of dermatological symptoms. All six patients experienced a positive change – improvement of symptoms and ability to expose to light up to three times baseline scores using the validated Clinical Global Impression of Change tool – in disease severity after treatment. Two physician assessment tools determined the degree of skin dysfunction and disease at a given timepoint, with a median decline in disease severity compared to baseline. Counts of new skin lesions

(wounds, blisters and/or ulcers) on light-exposed skin revealed a decrease over time with the median lesion count decreased from 10.5 to 3 across the treatment period. All patients also experienced decreased fragility of sun exposed skin following treatment.

- European orphan drug designations (ODDs) were granted for afamelanotide for both xeroderma pigmentosum and variegate porphyria, recognising the drug's potential to treat these patients. CLINUVEL submitted clinical

from both programs to support the ODD applications, the first time a global regulator has reviewed data on the use of afamelanotide in either XP or VP. The ODDs entitle CLINUVEL to receive incentives throughout the development programs and, importantly, post-authorisation. This includes reduced fees for regulatory activities and ten years of market exclusivity post-approval. As SCENESSE® is already an approved medication, marketing authorisation for XP or VP would be added as a

label extension (type II variation) for the drug, rather than through a completely new authorisation application process.

- The commencement of the CUV052 study to generate pharmacokinetic data on the use of SCENESSE® in adolescent and adult EPP patients. CLINUVEL aims to enrol 28 EPP patients (aged 12-70) in the study across three European EPP Expert Centres. The study design comprises one implant administration to patients of

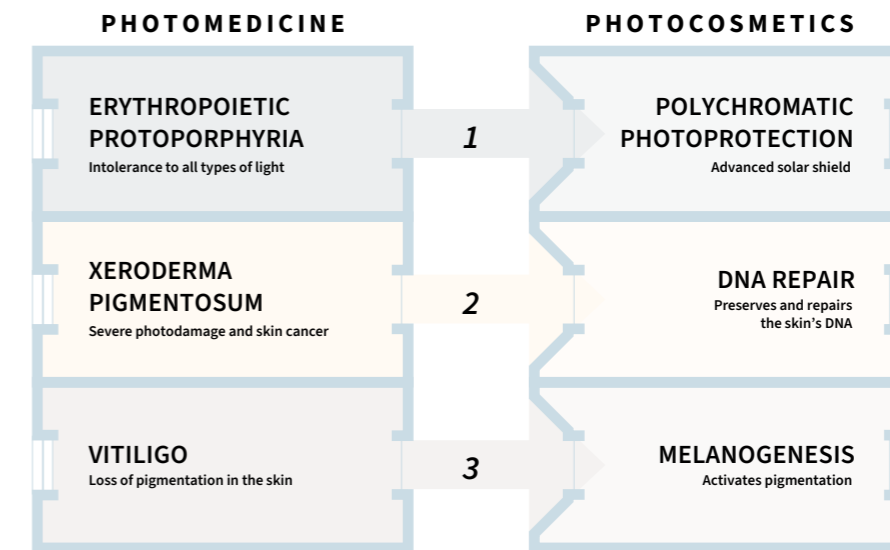
50kg body weight and above, thereby comparing adolescent and adult patients and evaluating the safety and clinical benefits of SCENESSE®. Data from CUV052 will be submitted to global regulatory agencies to support an extension of the SCENESSE® label to treat adolescent patients. Prior to the commencement of CUV052, seven adolescent EPP patients had received fully reimbursed SCENESSE® treatment for up to two years under conditions of use.

“Afamelanotide is massive for me, I feel extremely fortunate that this drug has been made available in Scotland and my wish is that everyone living with EPP gets access to this life-changing treatment.”

*O'Reilly, M., McGuire, V. A., & Dawe, R. S. (2024). Erythropoietic protoporphyria and afamelanotide: A patient's perspective. Clinical and Experimental Dermatology, 49(2), 186–187.*



## TARGETED TECHNOLOGY TRANSLATION



### 3 - PHOTOCOSMETIC PRODUCTS

**Translating technology from unmet medical needs to the demands of many**

CLINUVEL is a leader in photomedicine by developing novel products to provide photoprotection, DNA repair and repigmentation of the skin to people in need of treatment:

- First evaluated in clinical trials in 2006, CLINUVEL's pharmaceutical drug, SCENESE® has been providing photoprotection to EPP patients since 2010 in Italy and 2012 in Switzerland under special access schemes. Following regulatory approvals, EPP patients have been treated in the EU since 2016 and the USA since 2020.

- The results to date of the DNA Repair Program have generated clinical evidence to support the use of melanocortins to prevent and repair photodamage.
- CLINUVEL's work in the pigment loss disorder vitiligo promises to break new ground in the understanding of the health and function of melanocytes, the cells that produce pigmentation in skin.

We are evolving our proposition from biopharmaceutical products that address the unmet needs of patient groups, to the provision of solutions to meet the contemporary global desires of the wider

population. Mirroring our expertise in photomedicine, our focus is on three PhotoCosmetic product lines that:

- PROTECT the skin from the life-threatening risks of sun exposure.
- PRESERVE the skin, preventing premature ageing through photodamage and increasing longevity to the body's biggest organ; and
- BRONZE the skin for overall health and well-being, not only without solar risk, but also as a means of protection.

The PROTECT line offers polychromatic screens, CYACËLLE and CYACËLLE



Discussions on the Company hosted by Lady Gaga and Mr Sean Parker

Radiant, and the PRESERVE and BRONZE product lines, the “M-lines”, will contain melanocortins.

**Progress in the past year**

The focus of the year has been on:

- Promotion of CLINUVEL as an emerging brand in

- PhotoCosmetics; and
- Ongoing formulation work in the Singapore RD&I Centre which resulted in the launch of two new polychromatic products.

During the year we rebranded the business through a new website and

corporate campaigns that have raised the visibility of the organisation. We continue to grow our audience to create a base of support and drive our mission forward.

The highest profile event of the year was held in February at the Malibu home of home of Ms Stefani Germanotta (Lady Gaga) and her partner, Mr Michael Polansky. CLINUVEL's pioneering technology and the PhotoMedicine Foundation (refer page 76) was introduced to the most prolific investors and philanthropists in Silicon Valley, and key influencers and advocates in health and beauty. We thank Ms Stefani Germanotta, who is vested in health and well-being as an owner of a beauty business, and many long-term stateside supporters of CLINUVEL who came to the fore to support the event. The event was a success achieving 3.4 million Instagram views and:

- Highlighted the support of CLINUVEL by long-term investors, Mr Sean Parker and Mr Michael Polansky, who are industry-leading entrepreneurs renowned for spotting companies on an explosive upward trajectory;
- Raised awareness of CLINUVEL to



- new influential circles in beauty, business and global entertainment, and probably most importantly;
- Gained a strategic foothold into the beauty industry thanks to a feature in the *Business Of Fashion*, an established luxury publication part-owned by the *Financial Times*, and the main reference for the fashion and beauty industry today.

May 2024 signalled a new chapter for CLINUVEL's PhotoCosmetics with the launch of two new products in the PROTECT line, CYACELLE Radiant in gold and bronze tints. These pioneering tinted mineral solar shields repel UVB,

UVA and blue light, and high energy wavelengths that penetrate the skin's deepest layers. This triple protection is designed to optimise the skin's longevity, while a skin smoothing tint acts as foundation and enhances your natural radiance. This launch is a prelude to our M-line range, PRESERVE, which will accelerate the skin process of renewal and BRONZE, which stimulates the body's natural bronzing.

This was also an opportunity to re-set of the social strategy and start an Instagram account for cosmetics (CLINUVEL DNA). Since the launch in June, we have reached over 7 million people with our

brand story, with a following increase of over 100%. Reaching our desired target audience and building an audience will be the key focus of the next year with social, aided by our ambassador programme (CUVAs).

May 2024 also saw the launch of our global e-commerce site for our PhotoCosmetic products, available in five languages, which sets the foundation for our global launches. All this communication work has been done with the work of a growing in-house creative and marketing team, which will continue to grow to fulfill the mission ahead.

## 4 – FINANCIAL REVIEW

CLINUVEL's financial performance for fiscal year 2024 marked another successful period of revenue growth and sustained profitability for the Company. This continued success is a testament to our team and their strategic focus to build a high-performing life sciences company and delivering year-on-year returns.

The results that stem from the deliberate strategy to push the organisation forward in this way has resulted in CLINUVEL delivering its largest before and after-tax profit to date.

CLINUVEL's ongoing expansion is evident as we continue to grow our primary revenue stream by reaching more patients across more trained and accredited centres. Simultaneously we are investing strategically in the foundations of the future through key personnel, clinical programs, and infrastructure that will enable us to diversify a revenue base to support long-term stability and growth.

A commitment to retaining and investing in our most critical asset - our people

- remains a priority. Over the past 12 months, we have bolstered the teams across several critical areas including operations, clinical development, and communications, marketing, and branding. This expansion is integral to supporting the Company's ongoing growth and reinforces our strategic initiatives which includes reaching new and wider audiences with current and future products.

### REVENUE PERFORMANCE

CLINUVEL achieved a 15% increase in Total Revenues including other income this year, marking an eighth consecutive year of growth. Since the launch of our SCENESSE® program in 2016, we have maintained strong revenues with a CAGR of 38%, reflecting the program's sustained global success and robust performance. To date, we have facilitated the administration of over 17,000 SCENESSE® implants worldwide, both clinically and commercially, reflecting our commitment to advancing patient care globally.

Commercial sales plus special access scheme reimbursements grew by 12.6% to \$88.2 million.

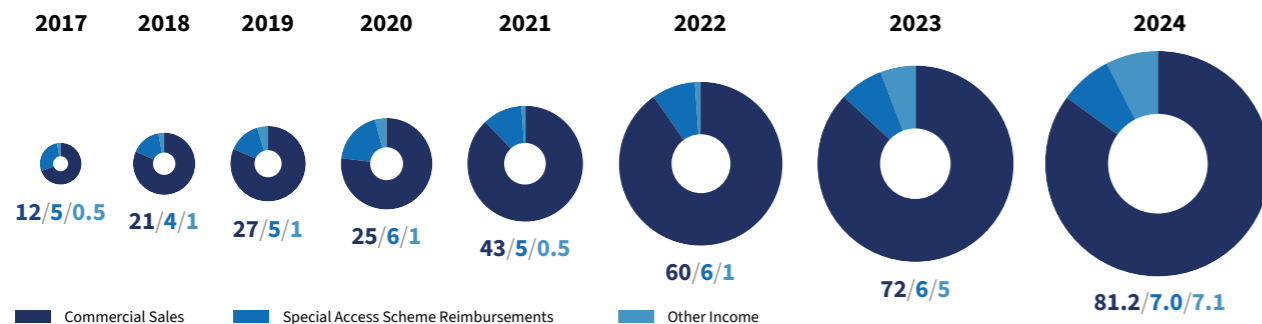
Total Revenues for the Company including interest and other income for FY2024 totalled \$95.3 million, an increase of \$12.3 million (15%) from FY2023.

### SCENESSE® Market Expansion

Successful revenue growth and increase product uptake from known and newly diagnosed patients can be attributed to the establishment of a dedicated team of professionals specialising in patient liaison, compliance, distribution, and finance. Market access and an assistance team have been instrumental for our European and North American expansion, utilising a lean model that has proven effective for the treatment of erythropoietic protoporphyria (EPP) patients.

We are in the middle of a second phase of increasing the number of trained and accredited Specialty Centres across North America from 87 across 33 states to 120 centres across 48 states and Canada by 2025, targeting experienced sites. We are confident that this expansion will provide treatment access in due course for vitiligo patients while clinical studies are ongoing and regulatory submissions are made.

## GROWING REVENUES SINCE INITIAL LAUNCH (A\$m)



## CLINUVEL ACHIEVED SEVERAL SIGNIFICANT FINANCIAL MILESTONES THIS FINANCIAL YEAR







#### OTHER INCOME

CLINUVEL has maintained a robust cash reserves position, with Cash and Cash Equivalents and Cash Held in Term Deposits increasing by \$27 million (17%) to \$183.9 million. This increase has enabled us to benefit from strong interest rate yields through Australian dollar and US dollar denominated term deposits, generating revenue of \$7.3 million an increase of \$3.4 million (88%) compared to the previous year.

Given forecasts of potential interest rate declines in Australia and the US, we have elected to lengthen the maturity periods of our term deposits to a weighted average of 276 days, with a weighted average yield of 5.22%.

#### EXPENSES MANAGEMENT

Total Expenses during the FY2024 year rose by \$7.2 million (19%) to \$44.6 million in direct support of the planned expansion of activities across the Group. As has been the case historically, expenses will continue to be tightly controlled and closely measured against the returns these provide monitoring alignment with the strategic objectives for the coming period.

#### Personnel Expenses

Personnel expenses rose by \$5.3 million, or 39%, primarily due to an increase in headcount, particularly within the Clinical and Regulatory teams with an emphasis on attracting specialists and expertise across specific domains. To remain

competitive in the global employment market we implemented targeted cost-of-living remuneration adjustments supporting our 87% staff retention rate this year.

#### Materials and Related Expenses

Materials and related expenses totalled \$5.2 million, reflecting a 57% decrease from FY2023.

Our Singapore RD&I Centre continues to advance innovation in formulations and delivery methods for existing products. The RD&I Centre site will undergo an expansion to its size and capacity in the coming year to increase both its capacity and capability to support the site's ongoing work on NEURACTHEL®, PRÉNUMBRA® and the range of PhotoCosmetics.

#### Commercial Distribution Expenses

Increased sales naturally resulted in higher distribution costs, up 16% on the prior year to \$3.6 million encompassing storage, freight, and related regulatory and monitoring services.

#### Finance, Corporate & General Expenses

We remain committed to minimising the environmental impact of travel and restrict travel whenever possible. Nonetheless, post-COVID in-person attendance at essential regulatory, clinical site, and operational meetings was unavoidable. Rising travel costs – particularly in air travel – were a significant factor in the increase in this reporting period's expenses.

#### Legal, Insurance, and Intellectual Property Expenses

Insurance costs increased due to expanded coverage for clinical trials. Legal expenses rose during the year due to increased activities not the least of which were the negotiations with the European Medicines Agency (EMA) regarding SCENESSE® to seek authorisation for adolescent use and Orphan Drug Designations for variegate porphyria and xeroderma pigmentosum (XP).

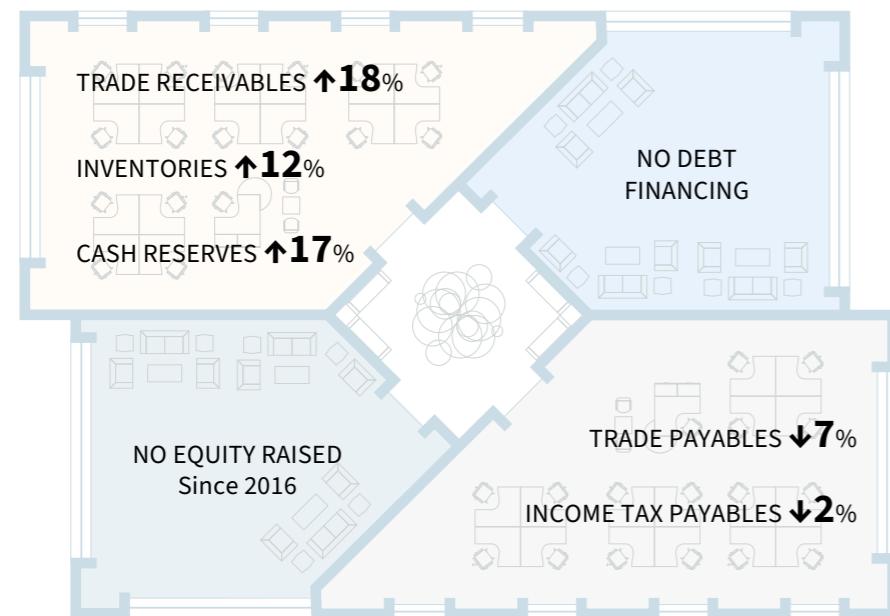
#### Communications, Branding & Marketing (CBM) Expenses

Expenses in CBM totalled \$2.2 million, a 191% increase from FY2023 as we systematically build the foundations of a market presence and seeking higher visibility with a wider global audience.

CLINUVEL is moving to distinguish itself from traditional pharmaceutical companies by translating its core pharmaceuticals technology in melanocortins to PhotoCosmetics, creating synergistic revenue opportunities. Translating medical technology into consumer markets is relatively rare for pharmaceutical companies but can be highly strategic particularly when analysing the potential applications for its molecules.

To support our drive for market visibility, we are building a specialised CBM team of professionals from the luxury retail and marketing sectors. The CBM team is being formed to enhance CLINUVEL's exposure through

## BALANCE SHEET HIGHLIGHTS



social media and international event platforms which, in conjunction with the Investor Relations team, will ensure communication of all key developments reaches our stakeholder groups. The Investor Relations team has been leading this strategic shift holding targeted investor events in Monaco, Sydney, Malibu and Düsseldorf, non-deal roadshows and the Capital Markets Briefing in Sydney. Refer to the Investor Relations feature in this Annual Report for further detail.

CLINUVEL recently announced the re-launch of its e-commerce platform, [www.cyacelle.com](http://www.cyacelle.com), and introduced the CYACÉLLE Radiant Gold and CYACÉLLE Radiant Bronze polychromatic screens as part of a soft pre-launch phase. This initial pre-launch pilot program is designed to gather insights to refine our market strategy for the launch of the wider CYACÉLLE range.

### Clinical and Non-Clinical Development Expenses

Clinical and non-clinical development expenses totalled \$2.3 million, an 85% increase from FY2023 which reflects on our strategic focus on advancing our various clinical programs to establish future revenue streams. Whilst our

clinical trials costs are expected to fluctuate as patients move through the various trial periods culminating with an increase in costs from sites close outs, we will be closely monitoring the expenditure against budget cross all sites.

Our core programs in vitiligo, DNA Repair/XP, VP, and stroke continue to progress whilst we diligently monitor all expenditures and processes ensuring efficient and effective results are being delivered. Concurrently we are advancing preclinical work on melanocortins such as PRÉNUMBRA® and NEURACTHEL® in seeking to diversify risks by preparing multiple future revenue opportunities.

Through research, development and innovation, we are committed to advancing the use of afamelanotide in new formulations targeting multiple therapeutic outcomes addressing high unmet patient needs beyond EPP.

### PROFIT OUTCOMES

For the fiscal year, the Company reported a Net Profit Before Tax of \$50.7 million, an increase of \$5.1 million or 11% on the prior year. This growth underscores the effective financial stewardship and success in

achieving strategic growth objectives whilst maintaining stringent controls on expenditure.

The Net Profit After Tax of \$35.6 million reflects an increase of \$5 million or 16% compared to FY2023. This is also reflective of - deemed organisation wide - an improved 3% average tax rate from 33% down to 30% during the current year.

Under non-IFRS reporting standards, and viewing the net impact on the cash statement, and excluding non-cash and unrealised expenses, the Net Profit After Tax would be reported at \$42.1 million, an improvement of \$3.8 million (10%), compared to \$37.8 million in FY2023.

Throughout the year, the Company has scaled its operations significantly enhancing its workforce, infrastructure, and capacity to support ongoing expansion through progress in revenue growth, clinical programs, new R&D innovations, and advancements in manufacturing and formulation. The continued operational scale up over the past 12 months is in line with the five-year strategy outlined to the market and shareholders in 2021.

### BALANCE SHEET

#### Cash Reserves and Liquidity Position

During the financial year, our combined cash reserves balance, comprising cash and cash equivalents and cash held in term deposits, increased by \$27 million (17%) to \$183.9 million compared to FY2023. This growth was achieved through operational activities and the strategic decision to increase the average yield of Term Deposits from surplus funds held, with no inflows from debt or equity financing. This financial year marks the 19th consecutive year that the Company has remained debt-free.

We strategically chose to take advantage of favourable term deposit rates yielding a weighted average return of 5.22% over an average term of 276 days. The returns from prudent liquidity management aims to support future extensive commercial, clinical, and pharmaceutical programs and facilitates expansion into new revenue streams with consumer-focused PhotoCosmetic products.

#### Balance Sheet and Financial Strength

Maintaining a robust Balance Sheet remains of strategic priority for CLINUVEL. This is evidenced by a \$37.4 million increase in total assets

and a \$0.97 million reduction in total liabilities, resulting in a \$38.4 million (23%) improved net asset position to \$203 million and an improved debt-to-equity ratio from 18% in FY2023 down to 14% in 2024.

We took the opportunity to reinvest in the business through the acquisition of a UK office building which currently accommodates more than 40 employees. Balance Sheet strength not only provides CLINUVEL with resilience against unforeseen events and economic volatility but also offers the opportunity of flexibility to pursue strategic acquisitions or investments which align with growth and diversification objectives.

#### OPERATING CASH FLOWS

Operating cash inflows were primarily driven by global receipts from SCENESSE® distribution, totalling \$84 million, up 12% from \$74.9 million in FY2023. Interest income from cash deposits also increased to \$7.6 million, up 180% from \$2.7 million in FY2023 reflecting the higher yields we're obtaining from increased cash reserves.

Operating cash outflows included payments to suppliers and employees

totalling \$39.7 million, an increase from \$33.2 million in FY2023. Taxes paid amounted to \$15.7 million, compared to \$7.7 million in FY2023.

#### Returning Value to Shareholders

In FY2024, we distributed \$2.47 million in dividends to shareholders, compared to \$1.98 million in FY2023 an increase of \$0.5 million (25%). Adding to this in FY2024, \$0.742 million was allocated to a Share Buy-Back program resulting in the repurchase of 49,490 shares to enhance shareholder value by reducing dilution. The dividend and share buy-back program underscores a commitment to deliver longer-term returns to our shareholders. FY2024 also sees CLINUVEL declare its seventh consecutive annual dividend which this year will be \$0.05 per share, fully franked.

#### SUMMARY

In summary, CLINUVEL remains focused on driving innovation, expanding its market presence, and optimising its financial position in the pursuit of advancing patient care whilst enhancing shareholder value through strategic initiatives and investments into future revenue streams. 🏡

# PLANS 2025 AND BEYOND

### Building a global pharmaceutical group

CLINUVEL commenced the third phase of its evolution in September 2020 with the announcement of the DNA Repair Program, focused initially on evaluating SCENESSE® as the first ever treatment for xeroderma pigmentosum (XP). An important precursor to this was the opening of a new bespoke, state-of-the-art Research, Development & Innovation (RD&I) Centre in Singapore, in August 2020.

The Company has since established a broad new product development pipeline encompassing:

- new pharmaceutical products - PRÉNUMBRA® and NEURACTHEL®;
- three PhotoCosmetic product ranges – polychromatic protection (PROTECT), DNA repair (PRESERVE) and melanogenesis (BRONZE); and

- new clinical studies and programs – vitiligo, XP, VP, stroke, and most recently, Parkinson's disease.

The Company's expansion is enabled by the success of the strategy formed in FY2006 to focus on one drug (SCENESSE®) for one indication (EPP). The first phase of the Company's evolution was the period spanning FY2006 to FY2019 which involved drug development, clinical studies, and regulatory approvals. The second phase was the commercialisation of SCENESSE® to treat EPP patients – this commenced in the EU in 2016 and the US in 2020. There is some overlap between the milestones of each phase. Collectively, these phases have established a strong foundation for FY2025 and beyond. Specifically, annual revenues growth and controlled expense management has resulted in rising profitability over the FY2017 to FY2024 period and the

accumulation of sufficient cash reserves to fund all our development programs simultaneously, without resorting to dilutive capital raisings.

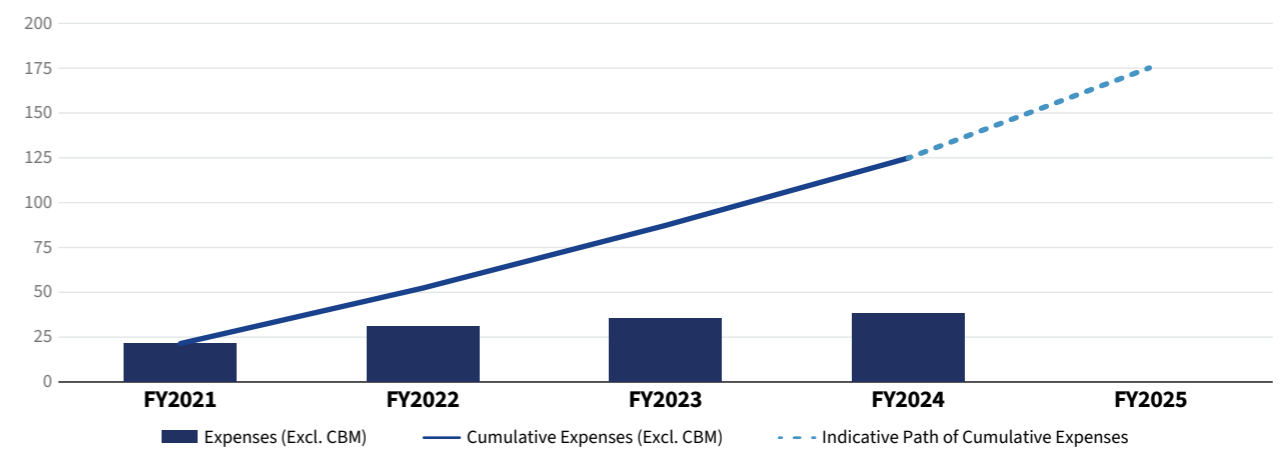
This feature highlights the Company's activities and key objectives over the next three years.

### Investment

The Company provided a projection of the expenses that would be incurred during the five-year period from FY2021 to FY2025 to reassure stakeholders of the continued focus on controlled expenses to support its expansion initiatives. The expenses plan of A\$175.0 million for the five-year period was set before the onset of the increase in global inflation and did not include capital expenditures or the expenses to be incurred by the Communications, Branding & Marketing Division (CBM) on the PhotoCosmetic product ranges. The chart below shows

## EXPENSES PLAN

Five Years to 30 June 2025 (A\$m)



Expenses FY2021, FY2022, FY2023 and FY2024, exclude expenses associated with Communications, Branding & Marketing (CBM). Indicative path of cumulative expenses, excluding CBM expenses, is shown to projected expenses of A\$175.0 million to 30 June 2025.

the expenses, excluding CBM expenses, that have been incurred. At the end of the fourth year of the plan, expenses of A\$125.2 million (or 72% of the plan) have been accumulated.

When the expenses plan was set, it was expected that the Company's cash reserves would be fully utilised to finance it. However, the strong performance of the Company has resulted in annual net cash inflows which have replenished what has been expended on growth initiatives. This has resulted in a rise in cash reserves which underpin the Company's self-financing capability. Had the Company not followed its long-term strategic path and instead resorted to issuing shares to finance the A\$175.0 million expenses plan, the ownership of existing shareholders would have been significantly diluted. From certain assumptions on capital raisings of A\$50 million on 30 June 2022 and 30 June 2023 and A\$75.0 million on 30 June 2024, the potential dilution of shareholder ownership is estimated to be around 20%. The fact that this course of action was not required reinforces the value of the Company's strategy and effective cost management of its expansion.

**Distribution of SCENESSE® for EPP**  
We are committed to ensuring the ongoing supply of SCENESSE® and

increased treatment centres and reimbursement arrangements to support expected growth in patient demand. The demand of EPP patients for SCENESSE® was robust in FY2024 and is expected to continue over the next three years. Step-up growth may come from access to new countries, including Latin America through our partnership with Valentech, and regulatory approval, following the completion of CUV052 and re-submission to the EMA, to treat adolescent patients.

In the USA we have expanded our independent network of Specialty Centers to 85 and are well on track to reach 120 centres by the end of 2025. This network will be capable of treating both EPP and other patients, with an initial focus on vitiligo.

**Pharmaceutical products**  
PRÉNUMBRA® has been developed and its use is to be expanded in the clinic from stroke to Parkinson's.

NEURACTHEL® in instant and modified-release formulations will continue to be developed. An update on manufacturing will be provided during FY2025. The objective is to seek approval of an Abbreviated New Drug Application (ANDA) to treat Infantile Spasms and Multiple

Sclerosis which are underserved in the current market.

**PhotoCosmetics**  
CLINUVEL is looking to breakthrough into the industry by being the first company to launch a line of cosmetics based on melanocortin technology. Melanogenesis is the action of our category defining product, which comes from the knowledge and translation of the technology that is delivering breakthrough therapies for vitiligo. The objective is to safely enhance the natural process of bronzing.

Our desire is global, and so are our campaigns; please join us on the journey in the next year, we will focus on medical channels, starting with dermatologists and medical practitioners. This will work as a catalyst for everything to come in the next two years. Influencers in the beauty industry, beauty editors and industry publications will come to our briefings and become aware of CLINUVEL's evolution into cosmetics. Exciting plans of scale are underway, and the CLINUVEL team is growing at a rapid pace to accommodate an inevitable shift towards global visibility. Who wouldn't respond to the call of a bronzed skin, not only without the solar risk, but as a means of protection?

## CLINICAL PROGRAMS

Clinical programs are expected to progress through typical study phases to support compelling dossiers to obtain the approval of regulatory authorities. It is important to note that clinical and regulatory timelines are subject to change according to a range of internal and external factors.

PROGRAM	FY2025	FY2026–FY2027
Vitiligo	<ul style="list-style-type: none"> <li>• CUV105 Phase III recruitment completed</li> <li>• CUV107 Phase III recruitment commenced</li> </ul>	<ul style="list-style-type: none"> <li>• CUV105 Phase III first results</li> <li>• CUV107 Phase III first results</li> <li>• FDA meeting</li> <li>• Submission FDA</li> </ul>
DNA Repair – XP	<ul style="list-style-type: none"> <li>• CUV152 and 156 Phase II results</li> <li>• Commence CUV154, late-stage study</li> </ul>	<ul style="list-style-type: none"> <li>• New Phase II study results</li> <li>• Regulatory approval, label expansion</li> </ul>
VP	<ul style="list-style-type: none"> <li>• Further clinical studies to commence</li> </ul>	<ul style="list-style-type: none"> <li>• Further study results</li> </ul>
Arterial Ischaemic Stroke	<ul style="list-style-type: none"> <li>• CUV803 Phase II study first results</li> </ul>	<ul style="list-style-type: none"> <li>• Further clinical development</li> </ul>
Parkinson's Disease	<ul style="list-style-type: none"> <li>• CUV901 Phase IIa study to commence patient treatment</li> </ul>	<ul style="list-style-type: none"> <li>• CUV901 Phase IIa study first results</li> <li>• Further clinical development</li> </ul>

Or to preserve our biggest organ, the skin. Our objective is clear; to become a household name by 2026.

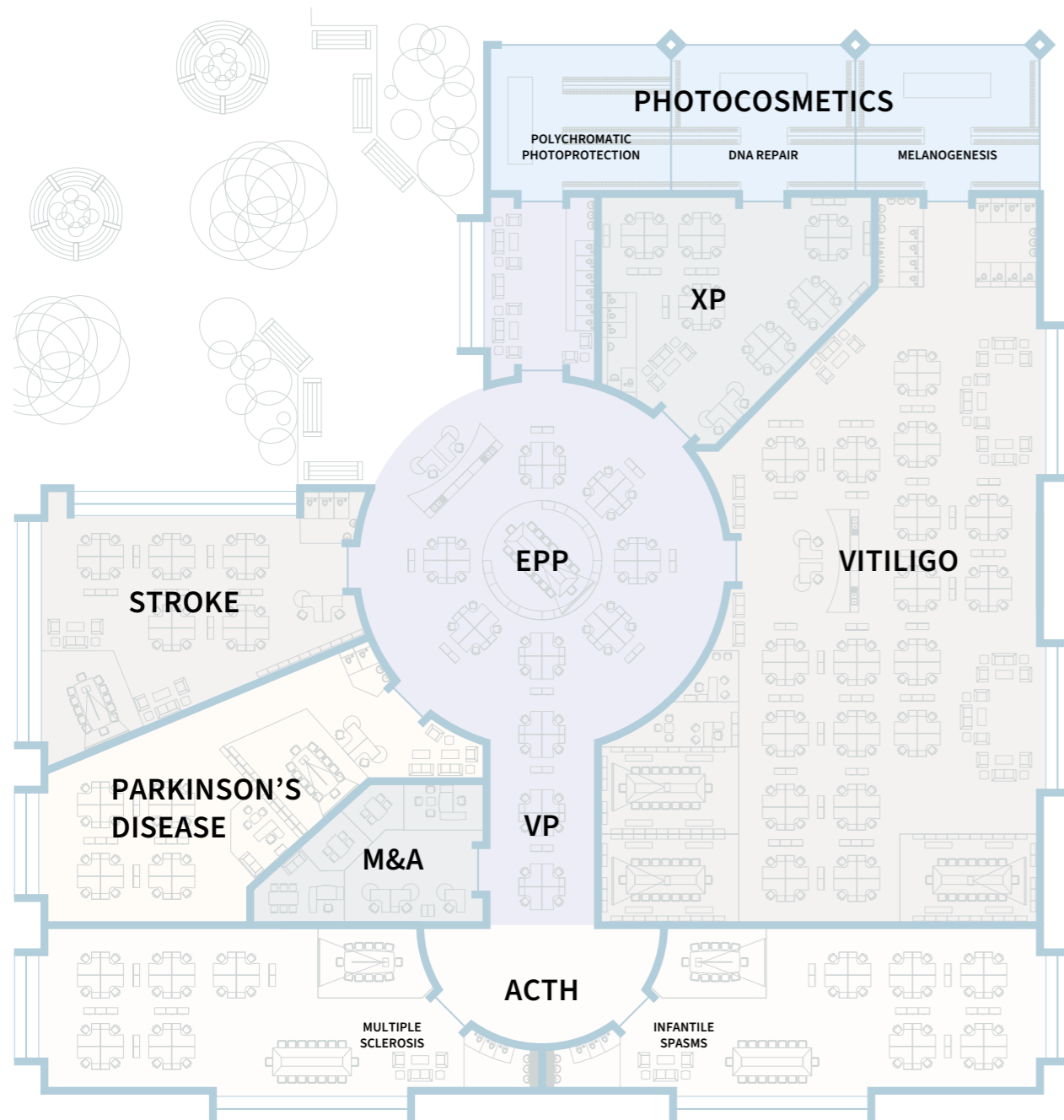
In 2025 we will initiate global product launches of the PROTECT range, in preparation of the M-lines, the melanocortin-containing topical formulations. Subject to formulation and manufacturing development work, the first products of the melanocortin product lines are expected to be launched in calendar

year 2026. This next generation product will be the first of its kind, putting CLINUVEL at centre stage of a total addressable market of US\$6.2 billion.

This will be the time for the wider world to know CLINUVEL's PhotoCosmetic offerings. We will have global events, launching around the world in locations synonymous with sunshine and luxury: Cannes, Ibiza, Saint-Tropez, Malibu, Venice Beach,

St Morritz & Aspen, as well as key urban cities. This will be amplified by a global media program, focusing on magazines, digital media and brand partnerships. Our launch will be targeted to specific audiences via luxury stockists, digital media and specialised digital clientele. We will foster a global ambassador programme, amplifying the knowledge and experience of survivors, experts and athletes who effortlessly align with CLINUVEL. Exciting times lie ahead.

## THE MELANOCORTIN HOUSE PLAN



### Acquisition plans

We continue to assess inorganic growth opportunities and have a keen eye out for assets that add value to the Group, whether they be at late clinical stage or involved in the manufacture of healthcare products. The intention is to complete a revenue adding acquisition over the coming few years. By the end of FY2027 we expect to have achieved our product objectives and progressed

the conditions to be treated. Whilst stroke and Parkinson's are medium-to long-term programs, the vitiligo program is expected to have progressed towards FDA approval. The treatment of vitiligo offers the prospect of revenues of US\$490 - 570 million in the first two years of distribution from the treatment of approximately 6,000 patients. This will transform the financial profile of the Company.

The Company may also have completed the acquisition of a new asset, thus adding to sustainable future earnings.

This is an exciting time to be a CLINUVEL shareholder and witness the incremental long-term value being added. We expect the market to reflect the advances being made on these initiatives and step-up demand for CUV accordingly. 🏠

## SUMMARY

WE ARE WORKING TOWARDS A DIVERSIFIED BIOPHARMACEUTICAL FOR LONG-TERM SUSTAINABILITY BASED ON:

**3**

**PHARMACEUTICAL PRODUCTS**

**8**

**CONDITIONS TREATED**

**3**

**PHOTOCOSMETIC PRODUCT LINES**

# INVESTOR RELATIONS PROGRAM

**Introduction**

The key objectives and achievements of Investor Relations over the past five years are summarised below:

**Approach**

Investor Relations maintains open and interactive communications with shareholders. We are focused on assisting existing and potential shareholders and other stakeholders such as analysts, investment banks, financial planners, wealth managers and brokers, to understand the Company's history, performance, strategy, business model, and progress towards key

objectives. The vision of a diversified and sustainable biopharmaceutical group and the progress being made in product and clinical programs are central to our message.

**Review of FY2024**

The Investor Relations team conducted a wide variety of activities during FY2024, engaging a broader stakeholder group than ever before. In addition to presentations and participation at global investment conferences, the team hosted non-deal roadshows (NDRs) around these conferences, following the release of the Company's

half year and full year financial results, after the Annual General Meeting, and at other times in conjunction with our program of Investor Briefings. Webinars were also held on financial results with periodic webcasts on key issues, such as the Managing Director's webcast on the share buy-back initiated in March 2024.

A number of new institutional shareholders entered the register during the year. They provided feedback that they were attracted by the Company's record of revenues, profitability and build-up of cash reserves. They also value the pipeline of opportunities and

**KEY OBJECTIVES AND ACHIEVEMENTS**

OBJECTIVE	ACHIEVEMENT
Increase institutional shareholding	Increased from 25% March 2019 to 35% June 2024
Maintain diversity of geographical ownership	Achieved: June 2024 holdings as % of issued capital: <ul style="list-style-type: none"> <li>• Europe, 36%</li> <li>• Australia, 34%</li> <li>• USA, 28%</li> <li>• Other, 2%</li> </ul>
Increase research analyst coverage	Increased from one (in June 2019) to seven (in June 2024), with an eighth added post reporting date
Improve range, depth of communications and audiences	Communications span conference presentations, non-deal roadshows, one-on-one and group meetings, investor briefings, webcasts and webinars, company communiqués, announcements and videos, and social media
Increase participation and votes at Annual General Meeting	Nearly 10 million additional shares voted: <ul style="list-style-type: none"> <li>• 29.8% of issued capital November 2018</li> <li>• 47.8% of issued capital October 2023</li> </ul>



Professor Rosenfeld addresses the attendees of the inaugural Capital Markets Briefing.



An attentive audience viewed the panel discussion at the Düsseldorf Investor Briefing.

overall, see CLINUVEL as good value in the current market. Existing institutional shareholders have also stepped-up their holding in CLINUVEL and some have done so after interacting with us at conferences and NDRs.

It was a successful year to increase the number of independent research analysts of CLINUVEL from four to a record high of seven. An eighth German research analyst was added after the reporting date. We now reach more investors across institutional and retail segments than ever before.

A major event for the year was the Capital Markets Briefing, held in Sydney in May. Professor Rosenfeld commenced the briefing with a Chair's address, followed by several executives on the distribution of SCENESSE® and progress of clinical programs, including vitiligo. It was beneficial for the analysts and institutions who attended to hear from CLINUVEL's executives on the depth of the product development and clinical pipeline. We appreciated the suggestions of analysts as we formed the agenda for the briefing and their engagement on the day. Webcasts on key presentations were issued following the event to communicate the briefing to a wider audience.

Investor Briefings are a non-traditional investor relations event in which CLINUVEL Executives brief multiple

audiences on the Company. These briefings are delivered to a variety of audiences, including existing and potential institutional, family office and high net worth shareholders, analysts, bankers and brokers, advocates and influencers.

Two investor briefings stood out in FY2024:

- the introduction of CLINUVEL to an audience of influencers and potential investors at the residence of Ms Stefani Germanotta (Lady Gaga) and Mr Michael Polansky in Malibu in the USA in February. This event facilitated a wider social media audience for our PhotoCosmetic products.
- the investor briefing in Düsseldorf in March where attendees heard from EPP patients and doctors on the benefits of SCENESSE® treatment and provided encouraging feedback on CLINUVEL's strategy and progress.

Also noteworthy is the NDR held in Germany and Switzerland in March which resulted in over 25 meetings with new potential investors across the institutional, family office and high net worth individual segments who continue to be engaged.

**Expansion of the Investor Relations team**  
CLINUVEL's Investor Relations team

was formed in January 2019 with the appointment of Mr Malcolm Bull. Working closely with Dr Wolgen, Mr Hay and Mr Keamy, he has driven the achievements of the past five years.

Given the diversity of share ownership in key regions of the world, the Investor Relations team is expanding.

Mr Myles Clouston joined the Company in April 2024 to head investor relations in the United States. This is an important region for the Company given its activities are building through the distribution of SCENESSE® for EPP and the Phase III clinical studies needed to extend the use of SCENESSE® to the treatment of vitiligo. Based in New York, Mr Clouston is well positioned to extend and develop new relationships with institutional investors, investment banks, and analysts.



Myles Clouston  
Head of Investor Relations (US)

CLINUVEL's highest concentration of shareholders is in Europe and the intention is to appoint a new European-based investor relations professional to support Mr Bull to maintain existing and gain new shareholder relationships, particularly in German speaking countries. We have also engaged investor relations consultants to assist us to build relationships with new potential investors in Europe.

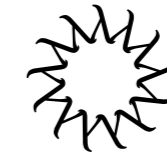
#### Plans FY2025

The key objective in FY2025 is to tell our story to more shareholders and potential investors with a specific focus on institutional investors. Investor Relations will continue to be active on the ground in key geographic regions and communicate with stakeholders through a wide range of channels.

The first NDR of FY2025 will be on the results for FY2024 which will be conducted in Melbourne and Sydney (29-30 August) and then Switzerland and Germany (2-6 September). Another NDR is planned in Europe in March/April 2025.

We will also work to enhance relationships with the custodians who hold shares on behalf of beneficial shareholders and encourage both new and ongoing analyst coverage of CLINUVEL. 📌

# THE PHOTOMEDICINE FOUNDATION



PhotoMedicine  
FOUNDATION

*SUPPORT / AWARENESS / HOPE*



Having established itself as the world leader in photomedicine – understanding the interaction of light and human biology – CLINUVEL has continuously supported the patient, academic, clinical and research communities intersecting with our work. As part of the Company's growth, CLINUVEL's management and Board have, for a long time, supported the plans to formalise this work through a charitable foundation. In FY2024, these plans have crystallised, with the Photomedicine Foundation established as a private foundation in California.

The Photomedicine Foundation has three overarching objectives, to:

1. Support individuals most severely affected by ultraviolet and visible light through access to equipment, medical care, treatments, or other means to improve individuals' health;
2. Improve awareness of, and research towards, diseases affected by ultraviolet and visible light; and
3. Promote leadership in photomedicine by supporting projects focused on knowledge sharing, professional trainings, and development.

Initial work is being focused on supporting three key projects across the globe. The first is working to provide photoprotective products and equipment to patients with xeroderma pigmentosum and albinism in Africa, the Middle East and South America. Having engaged with physicians and patient communities in each of these regions, CLINUVEL's teams have recognised the unique challenges of acquiring suitable photoprotection and the Foundation will work to overcome these hurdles. Initial test shipments of CYACËLLE polychromatic screens have been well received, while the Foundation will aim to work with existing formal and informal networks to widen resource access.

The second project will work with leading global photodermatologists to facilitate access to tele dermatology clinics to enable world-class consultancy access. Tele dermatology has been largely pioneered from Europe and Australia – such as providing skin cancer consultation support to isolated communities in the Australian outback – and the diagnostic and treatment tools well established for photomedicine. As access to mobile internet and videoconferencing increases in remote communities, the

Foundation will work to enable greater access to tele dermatological services.

Finally, the Foundation will support work – both ongoing and new – to establish global patient registries relevant to photomedicine. Registries have the ability to connect researchers and patients, expediting research and spurring innovation.

The work of the Photomedicine Foundation will be supported through a donation of 5% of the net proceeds of sales of CLINUVEL's PhotoCosmetic lines, as well as with in-kind and practical support from CLINUVEL's teams.

CLINUVEL's investor briefings have, in part, focused on the potential of the Photomedicine Foundation to assist many individuals worldwide. As a result, the Foundation has quickly garnered support from many of the Company's stakeholders, with the following agreeing in principle to act as trustees: Dr Daudi Mavura of the Regional Dermatology Training Center in Moshi, Tanzania; Ms Perla Azouri, a Monaco-based entrepreneur and philanthropist; and Mr Michael Polansky, a Silicon Valley based entrepreneur and head of the Parker Institute for Cancer Immunotherapy. ■



# ANNUAL RESULTS

FINANCIAL YEAR ENDING 30 JUNE 2024

*"Throughout the financial year, our team has maintained a sharp focus on executing CLINUVEL's expansion strategy. Despite the increased operational complexity, we have remained aligned with long-term objectives and successfully achieved our annual targets. Key financial metrics — including revenue, profit, investment, and asset growth — continue to show consistent year-on-year increases whilst expanding the ability to provide SCENESSE® treatment to an increasing number of patients."*

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 2024 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; Member 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.

#### **BRENDA SHANAHAN**, AO, BComm, FAICD, ASIA

Non-Executive Director

Appointed Non-Executive Director 6 Feb 2007.

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

**Current Directorships and Other Interests:** Chair of the Aikenhead Centre for Medical Discovery, Melbourne; Director of SG Hiscock Ltd; Chair, SG Hiscock Medtech; Advisory Board Director of DMP Asset Management Ltd; Director of Rock Art Australia.

**Other Listed Company Directorships (last 3 years):** Phoslock Water Solutions Ltd (ASX: PHK, since 2017–2023).

**Relevant Interest in Shares and Performance Rights:** Shares 196,577; 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 5,500; 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.**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.**WILLEM BLIJDORP**, Fama

Non-Executive Director

Served as Non-Executive Director 21 Jan 2015 to 21 Feb 2024

Served as Chair of Board 30 Nov 2019 – 31 Dec 2023.

**Committee Membership:** Chair of the Remuneration Committee until 21 Feb 2024; Chair of the Nomination Committee until 21 Feb 2024; Member of the Audit and Risk Committee until 21 Feb 2024.**Current Directorships and Other Interests:** None.**Other Listed Company Directorships (last 3 years):** None.**Relevant Interest in Shares and Performance Rights:** Shares 1,743,118; Performance Rights – NIL.**SIR ANDREW LIKIERMAN**, MA, FCMA, FCCA

Non-Executive Director

Served as Non-Executive Director 4 Apr 2022 to 31 Oct 2023.

**Committee Membership:** Member of the Nomination Committee until 31 Oct 2023.**Current Directorships and Other Interests:** Professor of Management Practice at the London Business School.**Other Listed Company Directorships (last 3 years):** Beazleys PLC (London Stock Exchange) to 2021.**Relevant Interest in Shares and Performance Rights:** Shares – Nil; Performance Rights – NIL.

More information on the relevant skills and biography of the Directors is provided in the feature on pages 36–41 of this Annual Report.

**Information on Company Secretaries****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 1 July 2024 to 6 August 2024

Appointed: Chief Financial Officer 1 July 2024

**Darren Keamy**, (BComm, CPA, GradDip ACG)

Company Secretary and Chief Financial Officer

Appointed: Company Secretary 7 December 2005 to 1 July 2024

Appointed: Chief Financial Officer 28 February 2006 to 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	
	A	B	A	B	A	B	A	B
Mrs. B. M. Shanahan	9	9	2	2	-	-	1	1
Dr. P. J. Wolgen	9	9	-	-	-	-	-	-
Mr. W. Blijdorp	6	5	2	2	4	4	1	1
Dr. K. A. Agersborg	9	9	-	-	6	6	1	1
Mrs. S. E. Smith	9	9	-	-	6	6	1	1
Prof J. V. Rosenfeld	9	9	2	2	2	2	1	1
Prof. J. A. Likierman	3	2	-	-	-	-	1	1

Column A indicates the number of meetings held during the period the Director was a member of the Board and/or Board Committee.  
Column B indicates the number of meetings attended during the period the Director was a member of the Board and/or Board Committee.  
Note: The Managing Director is not a voting member of the Remuneration or Nomination Committee 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 USA, Israel and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP).

The principal activities of the Group during the 12 months to 30 June 2024 (FY2024) were to:

- manufacture and commercially distribute its prescription pharmaceutical SCENESSE® in the European Union and the USA 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 a range of severe disorders, including vitiligo, variegate porphyria, xeroderma pigmentosum, arterial ischaemic stroke, DNA repair, Parkinson's disease and other disorders;
- 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

- Increased number of patients treated, more implants administered, and expert treatment centre network expanded.
- April 2024 marked the fourth anniversary of treatment of EPP patients in the USA.
- Uniform pricing per jurisdiction maintained.
- Partnership with Valentech Pharma commenced to extend treatment of EPP patients to Latin America.
- Adolescent study CUV052 expanded and underway to support proposal to European Medicines Agency to extend the approved label of SCENESSE® to treat adolescent patients.

### Clinical Programs – Advanced

- DNA Repair with focus on xeroderma pigmentosum (XP):
  - Study CUV152 (n=6) and CUV156 (n=6) ongoing.
  - XP granted European Orphan Drug Designation status.
  - Study CUV151 (n=9) completed, results announced.
- Variegate Porphyria (VP):
  - Study CUV040 (n=6) completed March 2024.
  - VP granted European Orphan Drug Designation status.
- Vitiligo:
  - Monotherapy study CUV104 (n=6) ongoing.
  - Combined treatment study CUV105 (n=200) commenced recruitment October 2023 and subsequently, treatment.
- Arterial Ischaemic Stroke (AIS):
  - Study CUV803 (n=12), continued using PRÉNUMBRA® Instant.
- Parkinson's disease (PD):
  - Study CUV901 (n=6), announced June 2024.

### Melanocortin – Drug Pipeline

- PRÉNUMBRA® Instant (afamelanotide):
  - Developed to offer flexibility to personalise treatment and achieve faster clinical responses.
  - First use in the second clinical study in stroke patients, CUV803.
- Development of NEURACTHEL®, adrenocorticotrophic hormone (ACTH) continued as Instant and Modified-Release products.
  - The initial focus is on treatment of adult Multiple Sclerosis and Infantile Spasms.
  - Work continued with partner to validate batches of NEURACTHEL® manufactured under current Good Manufacturing Practice (cGMP) and prepare Drug Master File for submission to the US Food & Drug Administration.

### PhotoCosmetic – Products

- New polychromatic screen CYACËLLE Radiant, launched May 2024, supported by new website and e-commerce platform.
- Wider audiences reached on the benefits of photoprotection and skin care through briefings to target audiences, social media campaigns, and activities of CUVAs and CUVIPs.
- Development of the second and third product lines, DNA Repair and melanogenesis, continued at the Singapore Research, Development & Innovation Centre.

The financial highlights of the Company for the year ended 30 June 2024 are presented in the following table:

Consolidated Entity	A\$ millions	Change
Total Revenues, Interest and Other Income	95.306	Up 15%
Total Expenses	44.627	Up 19%
Net Profit Before Income Tax	50.679	Up 11%
Net Profit After Income Tax Expense	35.636	Up 16%
Cash and Cash Equivalent & Cash Held in Term Deposits	183.868	Up 17%
Basic Earnings per Share (dollars per share)	0.72	Up 15%
Net Tangible Assets backing per Share (dollars per share)	4.02	Up 22%
Dividend distribution per Share (dollars per share)	0.05	-

A review of the Company's operations and information on the financial results is contained in the feature on pages 50–65 of this Annual Report.

## Reconciliation of Net Profit after Tax with Adjusted Net Profit after tax

The Group's net profit after tax and earnings per share are prepared in accordance with Australian Accounting Standards. The Group has prepared a financial measure titled "Adjusted Net Profit after Tax" which provides for a number of non-International Financial Reporting Standard ("non-IFRS") financial measures including "Adjusted Total Revenue, Interest and Other Income", "Adjusted Expenses", "Adjusted Net Profit Before Tax" and "Adjusted Net Profit After tax".

The Directors believe in providing additional meaningful information characterised as non-IFRS financial measures, for instance on,

- the performance of the business, and
- period-to-period comparability,

by adjusting for non-recurring, non-cash or unrealised items that may be of a material nature which may affect the Group's statutory results.

Non-IFRS financial measures should be viewed in addition to, and not as a substitute for, the Group's statutory results. These measures may also differ from non-IFRS measures used by other companies.

Non-IFRS financial measures are not subject to audit or review. The Group's non-IFRS financial measures are presented with reference to the Australian Securities & Investment Commission ("ASIC") Regulatory Guide 230 *Disclosing non-IFRS financial information*.

The Group's statutory net profit after tax for FY2024 was \$35.6 million, up 16% from FY2023 of \$30.6 million. The Group's adjusted net profit after tax for FY2024 was \$42.1 million, up 11% from FY2023 of \$37.8 million. The adjusted result considers various non-cash and unrealised items, including the non-cash charge for share-based payments attached to the prior grant of performance rights to the Managing Director and other staff which are typically valued at their grant dates and expensed over time, even if certain performance conditions attached to the performance rights are unmet.

	30 June 2024		30 June 2023	
	Statutory	Non-IFRS	Statutory	Non-IFRS
	\$	\$	\$	\$
Total Revenues	88,178,308	88,178,308	78,321,318	78,321,318
Total Interest Income	7,324,871	7,324,871	3,905,856	3,905,856
Total Other Income	(197,442)	(197,442)	763,082	763,082
<b>Total Revenue, Interest Income and Other Income</b>	<b>95,305,737</b>	<b>95,305,737</b>	<b>82,990,256</b>	<b>82,990,256</b>
<i>Adjust for:</i>				
Unrealised (loss)/gain on restating foreign currency balances and currencies held	-	745,764	-	(659,901)
Adjusted Total Revenue, Interest Income and Other Income	-	96,051,501	-	82,330,355
<b>Total Expenses</b>	<b>44,626,759</b>	<b>44,626,759</b>	<b>37,411,533</b>	<b>37,411,533</b>
<i>Adjust for:</i>				
Share-based payments	-	(6,107,272)	-	(8,989,788)
Adjusted Expenses	-	38,519,487	-	28,421,746
<b>Net Profit before Tax</b>	<b>50,678,978</b>		<b>45,578,723</b>	
Adjusted Net Profit before Tax		57,532,014		53,908,609
Income Tax	15,042,619	15,042,619	14,974,157	14,974,157
<i>Adjust for:</i>				
Tax on above adjustments		258,438	-	(167,070)
Tax on Unrealised gains/losses including loans to subsidiaries		139,676	-	1,263,081
<b>Net Profit after Tax</b>	<b>35,636,359</b>		<b>30,604,566</b>	
Adjusted Net Profit after tax		42,091,281		37,838,442

## 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 <sup>®</sup> . 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. In FY2024 the Company increased its inventory levels to meet pending demand and to ensure supply chain risk is managed.
<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 FY2024, less reliance on third-party providers was sought 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.	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 22 to the financial statements. 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.
<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.	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. The Board has instituted a CLINUVEL Academy, providing and sponsoring advanced training and learning opportunities to eligible talent within the Company.
<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 2023/24	Cents per Share	Amount	Date of Payment
Final	5.00	\$2,470,227	20 September 2023

On 28 August 2024, the Board of Directors declared a fully-franked dividend of \$0.05 per ordinary share in relation to the full year ended 30 June 2024.

## 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 28 August 2024, 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 pharmaceutical 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, 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 and Financial Review" (on pages 50–65) in this Annual Report details the type of developments and outcomes that occurred in FY2024 as the Company advanced its expansion plans. The feature on "Plans 2025 and Beyond" (on pages 66–71) in this Annual Report sets out in greater detail the likely developments and outcomes expected in FY2025 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 20–25 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 and Insurance of Directors and Officers

During or since the end of the financial year the Group has given or agreed to indemnify, or paid or agreed to pay, insurance premiums to insure each of the Directors against liabilities for costs and expenses incurred by them in defending any legal proceedings arising from their conduct while acting in the capacity of Director of the Group, other than conduct involving wilful breach of duty in relation to the Group. Details of the amount of the premium paid in respect of insurance policies are not disclosed as such disclosure is prohibited under the terms of the contract.

## Directors' Benefits and Interest in Contracts

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

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

# 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 2024.

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. Executive Key Management Personnel
- C. Governance Policies & Practices
  - 1) Remuneration Committee
  - 2) Remuneration Recommendations
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## A. INTRODUCTION BY THE CHAIR OF THE REMUNERATION COMMITTEE

### Chairman 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 2024. This introduction covers:

- The 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 strike received against the 2023 Remuneration Report at the 2023 Annual General Meeting (AGM);
- Key achievements of the past year and discussion of specific factors determining pay for performance;
- The remuneration outcomes for FY2024; and
- Remuneration intentions FY2025 and beyond.



#### 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 KMP (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 earning all revenues outside Australia with over 82% of its employees now also located outside Australia. We recruit and retain talented staff in the highly competitive global market. Our objective is to deliver competitive remuneration packages and employment benefits on par with international levels of remuneration that encourage longevity of tenure.

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) (for all eligible staff, except the MD). 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 through conditional Performance Rights (PRs).

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 FY2024, the comparable peer group has been expanded to 34 companies, of which 22 are US listed and the rest (12) are approximated to mirror CLINUVEL's business and are listed in Australia. Refer section F, pages 100–104 for details.

#### Responding to first strike 2023

At the 2023 Annual General Meeting (AGM), the Company's FY2023 Remuneration Report received a First Strike with 39.7% of the votes cast voting against the Report – this equated to 16.3% of issued capital. Our first response was to consult with shareholders and advisors. Based on the feedback received, the Company resolved to provide additional detail on its approach to executive remuneration, its practices and remuneration structure, comparison of remuneration to comparable peers, and improve disclosure of the STI and LTI awarded. In addition, the MD's remuneration structure was simplified during the year with the cessation of an LTI. Following the expiration of the MD's last LTI in November 2023, the MD will no longer be eligible to receive a LTI for the remainder of his Employment Agreement to 30 June 2026.

As required by the Corporations Act, if there is a Second Strike (of more than 25% of the issued shares voted) against the FY2024 Remuneration Report at this year's AGM, a spill resolution will need to be put to the Meeting. If more than 50% of votes are cast in favour of a spill resolution, an Extraordinary General Meeting will need to be held to elect a new Board of Directors, excluding the MD. The disruption and distraction that such a process would cause to this successful and high

performing company, its staff, shareholders and stakeholders, should not be understated; the continuity of the Company could be jeopardized by this process.

#### Key achievements of the past year

During FY2024, CLINUVEL faced an uncertain global economic environment but again achieved an excellent outcome. We advanced the expansion of melanocortin products and clinical development for conditions of unmet need and achieved an eighth year of consecutive growth in revenues, profit and net cash inflows.

We expanded the CLINUVEL team, attracting more professionals in the fields of product development, clinical research, regulatory affairs and quality assurance, communications and marketing, finance, and investor relations. This in no small part reflects the quality of CLINUVEL's reputation in the labour market and the competitive remuneration and employment benefits we offer.

In addition to expansion of the erythropoietic protoporphyria market, we progressed our product development and clinical programs. Key highlights are on pages 14-15 and pages 18-19 of the Annual Report, but specifically included:

- Clinical programs advanced: results from the variegate porphyria and DNA Repair programs, commencement of vitiligo Phase III study and announcement of a new program in Parkinson's Disease.
- PhotoCosmetics: prelaunch of CYACÉLLE Radiant and new audiences reached.

#### Financial achievements for FY2024 are summarised below:

<b>Total Revenues</b>	Up 15% to \$95.306 million
<b>NPBT</b>	Up 11% to \$50.679 million
<b>NPAT</b>	Up 16% to \$35.636 million
<b>Assets</b>	Up 19% to \$231.123 million
<b>Cash and Cash Equivalent &amp; Cash Held in Term Deposits</b>	Up 17% to \$183.868 million
<b>EPS</b>	Up 15% to 72 cents
<b>ROE</b>	Decreased from 18.6% to 17.6%
<b>Dividend</b>	0.05 cents per share, the 7 <sup>th</sup> consecutive year of distribution

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 underpinning a 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 needs.

We firmly believe that the share price trend alone should not result in remuneration packages being reduced, given the otherwise strong performance of the Company and strategic milestone achievements, while market value on the Australian Securities Exchange seems not to have reflected the value built over the past year. We are building a business for the future and must maintain competitive executive remuneration packages based on the outcome focused performance criteria detailed above to ensure longevity of tenure in our talent and continuity of the business. Downward adjustment of remuneration packages 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 FY2024

The tables in Section J of this report set out the remuneration outcomes for the MD, KMP and NED for FY2024.

For FY2024, the MD received:

- Gross FBR of €1,069,930; and a
- STI award of 60% of the maximum opportunity based on the achievement of KPIs outlined in Section D.

A total of 1,929,441 PRs were awarded to KMP, including the MD, in 2019 of which a total of 517,365 (26.8%) vested and were exercised in November 2023, having partially met performance criteria against a suite of eight performance conditions. An amount of 1,412,075 (73.2%) lapsed and expired due to the performance conditions not having been achieved. Full details of the vesting outcomes for the MD are in Section K. The conditions of the PRs have been set to maximum stretch, explaining the relatively low percentage of PRs achieved and vested (26.8%).

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.**
- Only 20% of the PRs of the MD were achieved and vested, 80% were forfeited.
- The MD's remuneration package has only comprised of a FBR, including non-monetary benefits, and an STI component since November 2023.

It is not market practice to award the MD further equity incentives, given the relatively short length remaining of his Employment Agreement to 30 June 2026. 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.

### Beyond 2024

We announced on 28 June this year that the MD's Employment Agreement of 2022, which was due to expire on 30 June 2025, had been extended for a further year to 30 June 2026. This result means we have successfully secured the services of our MD for a maximum of two years to facilitate and complete the Company's strategic transition to a diversified biopharmaceutical. The MD's extended tenure will provide the continuity of leadership needed to solidify the executive team and staff to drive towards the objectives outlined in this Annual Report.

The Board has been able to secure the extension based on the MD's existing FBR and STI remuneration components without a further LTI for the years remaining under the MD's extended Employment Agreement, and therefore will not seek shareholder approval for a further LTI. To provide the Board ample time to search for a suitable successor as MD to Dr Wolgen and to enable a seamless transition, a retention award of up to the equivalent of 200% of FBR, subject to satisfaction of certain conditions, will be payable to the MD within the final year of his tenure.

### Summary

As Chairperson of the Remuneration Committee, I am pleased to present the Remuneration Report for the financial year ended 30 June 2024 in the pages that follow. The Report will be considered by shareholders at the 2024 AGM, to be held later this year.

We strongly encourage shareholders to support the Remuneration Report and vote in favour of its adoption on the following grounds:

- The Company has continued to perform successfully, achieving excellent operational and financial outcomes;
- Based on recommendations received, the MD's remuneration package has abolished any LTI component; and
- The Company has continued to outperform the mean of its comparable industry peer group in 7-year TSR and Revenues growth and 5-year EPS growth.

Your support to adopt the FY2024 Remuneration Report will enable the Company to proceed without disruption to achieve its strategic objectives under Dr Wolgen's ongoing leadership.

Yours sincerely,



Sue Smith

Chair of the Remuneration Committee

## B. EXECUTIVE 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
<b>Non-Executive Directors</b>		
<b>Mrs. B. M. Shanahan</b>	Non-Executive Director	Full Year
<b>Mr. W. A. Blijdorp</b>	Non-Executive Director	1 Jul 2023 - 21 Feb 2024
<b>Dr. K. A. Agersborg</b>	Non-Executive Director	Full Year
<b>Mrs. S. E. Smith</b>	Non-Executive Director	Full Year
<b>Prof. J. V. Rosenfeld</b>	Non-Executive Director	Full Year
<b>Prof. J. A. Likierman</b>	Non-Executive Director	1 Jul 2023 - 31 Oct 2023
<b>Executive KMP</b>		
<b>Dr. P. J. Wolgen</b>	Managing Director and Chief Executive Officer (CEO)	Full Year
<b>Dr. D. J. Wright</b>	Chief Scientific Officer (CSO)	Full Year
<b>Mr. D. M. Keamy*</b>	Chief Financial Officer and Company Secretary (CFO)	Full Year

\* Mr Keamy resigned as Chief Financial Officer and Company Secretary on 1 July 2024 and was replaced by Peter Vaughan as Chief Financial Officer and Claire Newstead-Sinclair as Company Secretary.

## 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 is 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.

For the year ended 30 June 2024, the Remuneration Committee secured the services of remuneration advisors to provide comparable peer company market data and advice on remuneration structure, mix and short and longer-term incentive options. However, under the definition of the Corporations Act, no remuneration recommendations were obtained during the financial year.

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

At the 2023 Annual General Meeting (AGM), 60.3% of the votes cast (including votes at the proxy's discretion) voted in favour of adopting the 2022/23 Remuneration Report with the other 39.7% voting against its adoption. The resolution was carried, but as the vote against the Remuneration Report was greater than 25% of the votes cast, this constituted a First Strike under the Corporations Act, 2001.

Following the AGM, the Board consulted with shareholders, proxy advisors and remuneration consultants. Reflecting on the feedback received, the Company has improved its emphasis in this report to explain its approach to KMP and executive remuneration to recruit, retain and reward high performing executives of the Company in the competitive international labour market, benchmark KPM remuneration against that offered by relevant industry peers, simplify the remuneration structure, and improve the disclosure of the remuneration structures, particularly with regard to the STI and LTI awarded to KMP. Following the feedback received, the MD's remuneration structure has been simplified during the financial year ended 30 June 2024 and beyond, with the cessation of any further LTI.

## 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 high level of failure-rate in the sector (bio-pharmaceuticals), 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 key 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 by others to develop melanocortin technologies for commercial use. To mitigate the risk and provide a strong platform to achieve meaningful progress, the Board of Directors has followed 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 continued or sustainable profitability and or growth, the Committee strives to award its KMP for continuing to build a strong and robust Balance Sheet.

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 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 Value generation aligned with shareholders' interest</b>	i) long term incentives	non-cash based	Performance Rights awarded annually <sup>1</sup> , with a vesting period of 3 years, conditional upon continuous employment up to vesting date or risk forfeiture
<b>v 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 competitive 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 2024 financial year, CPI increases were implemented to all staff FBR rates reflective of the CPI increases in their respective regions of employment. For the FY2025 financial year, a flat CPI increase will be passed onto all staff FBR rates to assist CLINUVEL to remain competitive in the market to retain our employees and to 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 bio-pharmaceutical peers in establishing profitable ventures, as well as the desire to avoid dilution of shareholders’ interests.

FBR is tested annually for market competitiveness through comparison to appropriate benchmarks recommended and provided by external consultants and comparing to industry-relevant local and international 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		
b) Profit Growth	20%-30%	High
c) Organisational Structuring Optimisation		
<b>2. Growth &amp; expansion</b>		
a) Organic growth		
– R&D output, decision making	15%-25%	High
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		
– advancement, read-outs		
– application and formulation enhancements	10%-20%	High
– regulatory outcomes, work-arounds,		
– Solutions		
<b>5. General Management, Value</b>		
a) People management		
– staff recruitment,		
– staff retention		
– skills mix and diversity composition	1%-10%	Medium
– 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, for KMP, the first variable part of 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.

<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: 20% 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 105-107.

For the year ended 30 June 2024, the Remuneration Committee assessed overall performance for the 2023/24 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 Scientific Officer – 80%.
- Chief Financial Officer – 60%.

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 FY2024, 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 the supply chain.

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.

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

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

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 (34: 22 American and 12 Australian companies).

CEO Key Performance Indicators			
Financial year 2024	Performance Metric	Weighting	Assessed
<b>Finance Management</b>	Revenue - Consecutive growth		10%
	Profit - Consecutive growth	30%	10%
	Optimise group tax structuring		5%
<b>Growth Expansion</b>	Organic Growth – Further expansion of delivery pipelines	25%	12.5%
	Inorganic Growth – M&A of complementary business or revenue stream		0%
<b>Investor Relations</b>	Increase footprint among investors	15%	5%
	>5% new institutional investors attracted		5%
<b>R&amp;D Pipeline Development</b>	Vitiligo CUV105 - 75% Recruitment		0%
	DNA repair – Full Recruitment of XP CUV152-156	20%	0%
	Stroke – Full Results in CUV803		0%
	New indication announced		5%
<b>General Management Initiatives</b>	Recruit Key Personnel in R&D		2.5%
	Recruit Key Personnel in Operations	10%	2.5%
	Initiatives to expand/add value to Clinuvel		2.5%
<b>TOTAL</b>		<b>100%</b>	<b>60%</b>

The Remuneration Committee determined that 60% of the maximum potential opportunity for the MD was achieved for FY2024 (FY2023: 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 2-year minimum period, a claw back provision to recoup 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 shareholder's interest

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 4 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 three years from grant date whereby risk of forfeiture exists until the last day of employment at the end of the 36 months.

During the FY2024 financial year, only the Group's CFO was eligible to receive retention awards, payable in cash and conditional to having remained employed at the last day of the respective employment terms. The Group CFO, Mr Darren Keamy, received a long-term retention award of \$28,198 during the FY2024 financial period.

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

KMP receive periodically receive equity awards in the form of PRs every four years assessed upon value-generating performance conditions. The most recent PRs were awarded to KMP in November 2019 and vested or expired in November 2023.

As of 1 January 2024, newly employed KMP are annually awarded PRs on tenure of service set to secure retention for time served. In contrast, existing KMP were eligible to receive PRs with a vesting period of four years.

For the CFO (Darren Keamy resigned 1 July 2024) and CSO, the relative percentage of LTIs are highlighted in the table below:

Executive KMP	# Performance Rights on Issue 1 July 2023	# Performance Rights Vested and Exercises	# Performance Rights Lapsed and Expired	Deemed Achieved at Vesting Date
CSO	75,813	31,938	43,875	42%
CFO	339,875	184,302	155,575	54.2%

During the financial year ended 30 June 2024, a total of 216,240 of the potential 415,688 PRs issued to KMP in the 30 June 2022 financial year were deemed to have been achieved by 20 November 2023 and were subsequently converted to shares on 27 November 2023. No PRs were issued to KMP during the financial year ended 30 June 2024.

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

PRs were last awarded to the MD in 2019 where at the 2019 AGM, shareholders approved the grant of 1,513,750 PR to the MD and these PRs were offered and granted to the MD, who accepted the offer on 26 August 2020. These PRs had a vesting period of up to four years from date of shareholder approval. Several of the performance conditions were deemed to have been achieved which amounted to an issuance of 301,125 shares (20%) with the remaining performance conditions not achieved by 20 November 2023 amounting to 1,212,625 PRs (80%) being forfeited and lapsed. As at 30 June 2024, the MD has no PRs outstanding.

Whilst the employment agreement of the MD has been extended by one further year to 30 June 2026 (refer ASX announcement 28 June 2024), following advice from external remuneration consultants, proxy advisors, and counsel, the Remuneration Committee has deemed to not award the MD any new PRs or equity incentives beyond the expiry of the existing PRs in November 2023. Accordingly, the MD has not received any equity incentives in FY2024 and will currently not receive PRs in either of the next two financial years, FY2025 and FY2026.

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, may entitle him 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 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:

- the CLINUVEL Conditional Performance Rights Scheme (2009); and
- 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 2024, 29,082 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 NED 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.

Of the 2,591,860 Performance Rights on issue on 1 July 2023 which had been previously issued under the 2014 Performance Rights Plan to both KMP and non-KMP employees, 716,932 (27.7%) PRs were deemed to have achieved the performance conditions by the 20 November 2023 vesting date and were exercised. 1,637,678 (63.2%) performance rights were deemed to have not achieved the performance criteria by the vesting date and lapsed. It indicates how the Committee has set performance conditions at maximum stretch.

At the Company's Annual General Meeting held on 31<sup>st</sup> October 2023, shareholders approved the renewal of the 2014 Performance Rights Plan for a further 3 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 2024, 237,250 PRs issued under the 2014 Performance Right Plan remain outstanding, of which an estimated 200,854 of the PRs (85%) 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.

## 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.

A 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 82% 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>Bio-pharmaceuticals</b>	Bio-pharmaceutical 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 bio-pharmaceutical 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 bio-pharmaceutical 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 3 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 22 US life science peer companies with different profiles, since there are few profitable bio-technology 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	US 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

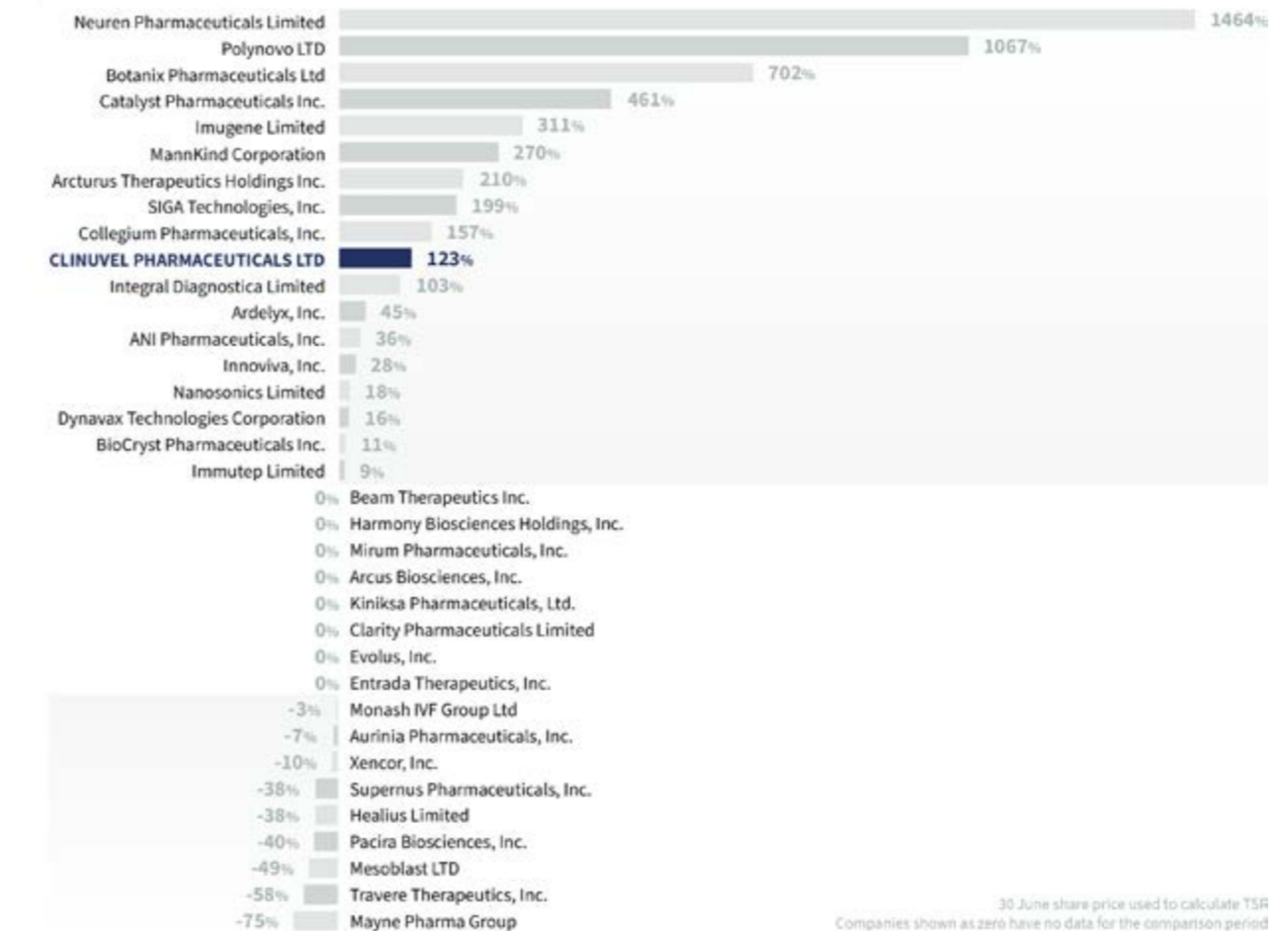
The financial performance of the Company measured against this peer group ranks strongly on TSR, EPS and revenues growth, and ROE criteria. The Company ranks:

- 10th amongst its peers for TSR performance over 7 years;
- 8th among its peers for growth in earnings per share over 5 years;
- 5th among its peers in the compound annual growth of total revenues over 7 years; and
- 6th amongst its peers for ROE performance.

### PEER GROUP RANKINGS



### 7 Year TSR- Time from First Commercial Launch (1 Jul 2017 to 30 Jun 2024)



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

**5 Year EPS Growth Rankings**  
(2019 to 2024)



**7 Year Revenue Growth Rankings**  
(2017 to 2024)



Companies shown as zero have no data for the comparison period

**ROE Rankings**

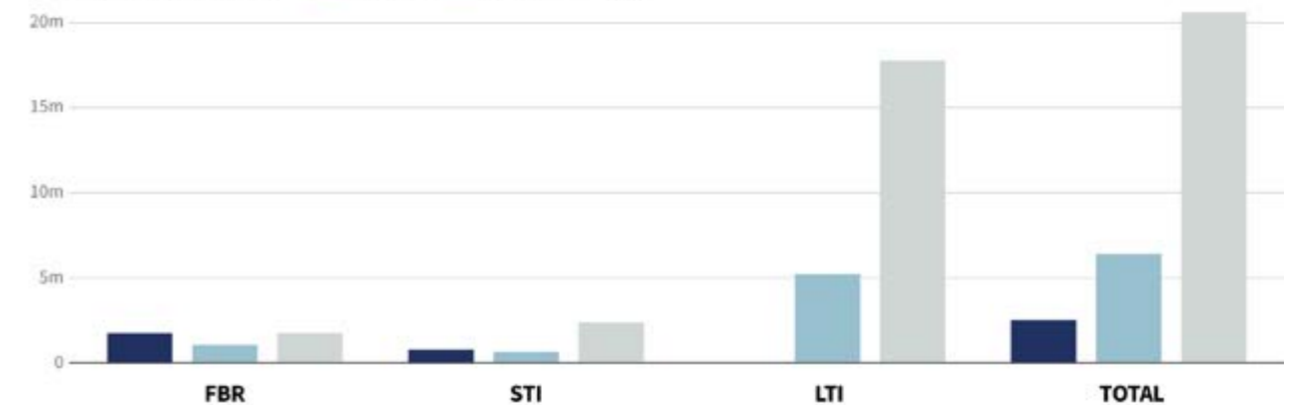


Companies shown as zero have no data for the comparison period

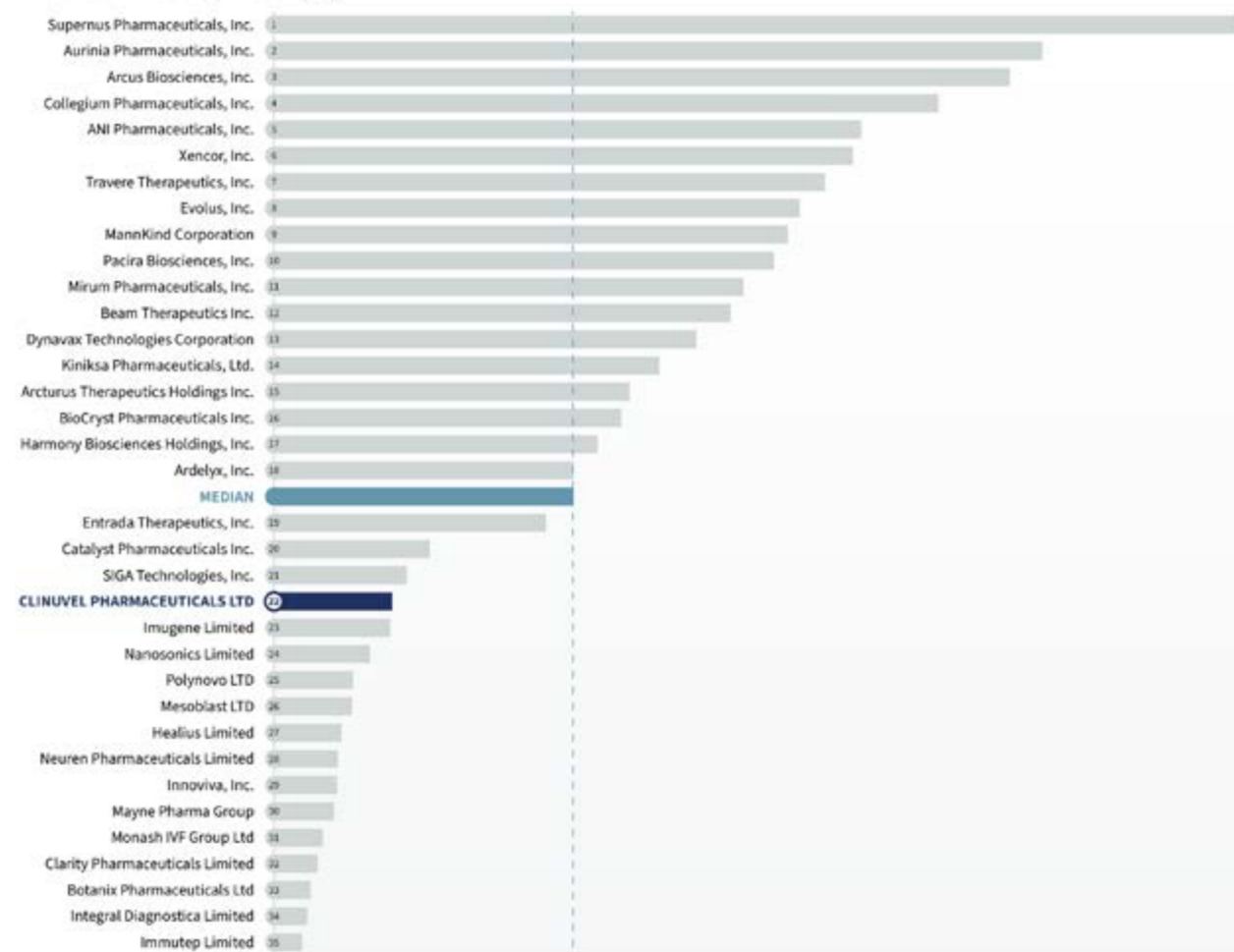
In comparing FY2024 KMP remuneration to the peer group remuneration for FY2023, the MD's FBR was found to be positioned above the median level, whereas the overall remuneration package was below the median level. The Board considers the level of FBR to be appropriate, considering the long-term outperformance 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 high shareholder returns.

**FY2024 CEO Remuneration**

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



**Total REM comparison (A\$)**



**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 such that they are focussed 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, where 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.

The table shows the development progress made during the year:

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

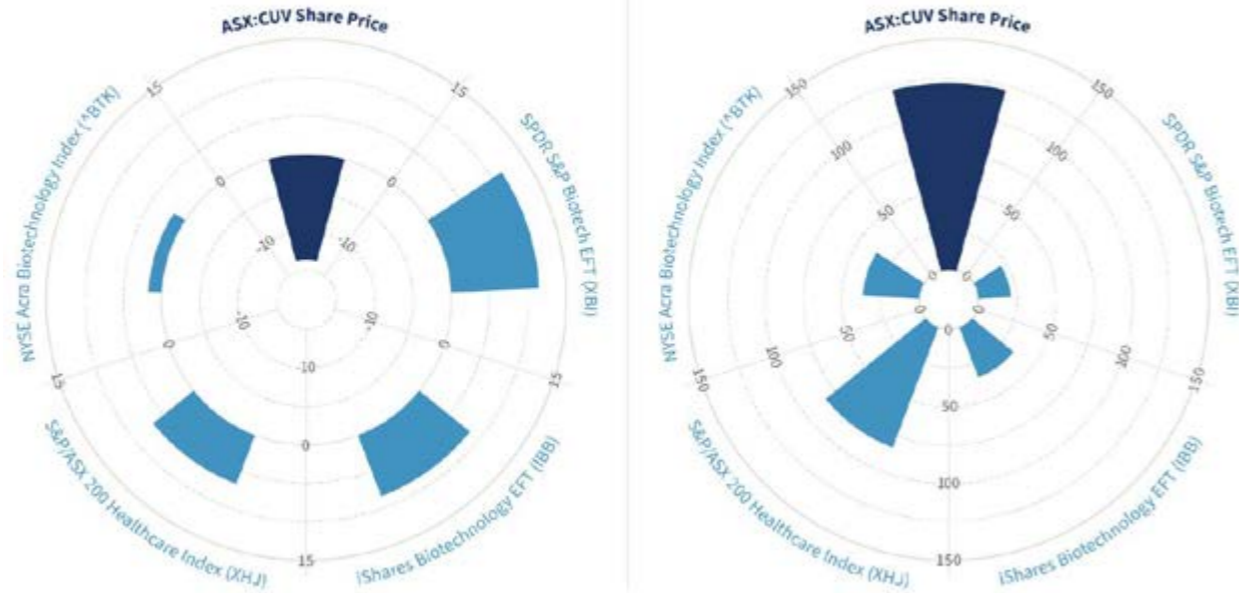
Analysis of CLINUVEL’s share price performance against main life science indices shows an equally positive outcome over the long-term (the past seven years). However, the Board is cognisant that there may not be a relation between CLINUVEL’s volume weighted average share price (VWAP) and performance of the Company, as has been frequently seen. This was the case in FY2024 as CLINUVEL’s share price declined by 14.5%, whilst the Company has grown and some recovery was evident in key biotech indices.

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

**ASX:CUV Share Price and Key Indices**

(% change, year to June 2024)

(% change, seven years to 30 June 2024)



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



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

The Board believes the remuneration mix aligns the other executive KMP and MD to shareholder interest. The remuneration mix for 2023/24 is demonstrated in the table below.

The Board intends to award PR, or LTIs, to the KMP (except the current MD) in the coming financial year. The current CFO is eligible to receive PRs at the end of the vesting period.

Position	Fixed Remuneration	STI Cash	LTI Cash1	LTI Equity
Managing Director	100%	46% of Base Salary	None	None
<b>Other Executive KMP</b>				
CFO	100%	7% of Base Salary	None	None
CSO	100%	7% 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 NED 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**

NED 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 NED fees (inclusive of superannuation):**

	Board Fees	Audit & Risk Committee	Remuneration Committee	Nomination Committee
Chair	115,000	-	-	-
Non-Executive Director	70,000	-	-	-
Committee Chair	-	15,000	15,000	-
Committee Member	-	5,000	5,000	-

\* The Chair of the Board is a member of all Committees but does not receive any additional Committee fees in addition to the base fee.  
 \*\* The CEO does not receive Board fees for his membership as director.

Under the Company’s Constitution, the maximum aggregate remuneration available for division among the NEDs is to be determined by the shareholders in a General Meeting and was set at \$700,000 at the 2019 AGM. This amount (or some part of it) is to be allocated to NEDs as determined by the Board. The aggregate amount paid to NEDs for the year ended 30 June 2024 was \$437,084 (2023: \$495,000).

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

Long-term equity remuneration was formerly provided to NEDs via the CLINUVEL Conditional Rights Plan and the Performance Rights Plan. Any issue of PRs to NEDs requires shareholder approval. It is not planned for NEDs to participate in long-term equity compensation plans. No NED holds PRs as of 30 June 2024.

## 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.

Due to the resignation of Mr Keamy, effective from 1 July 2024, his service agreement for the roles of Company Secretary and CFO were not renewed beyond the 1 July 2024 expiration date.

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

Name	Dr Philippe Wolgen	Dr Dennis Wright
Duration of contract	24 months (terminating 30 June 2026)	No fixed term
Notice Period (from Company)	12 months	3 months
Notice Period (from Managing Director)	12 months	-
Notice Period (from Executive KMP)	-	3 months
Termination Payment without Cause	12 months	3 months
Termination Payment with Cause	None	None
Contract End Date	30 June 2026	not applicable

## J. DETAILS OF REMUNERATION

### 1) KMP remuneration of the Company for the years ended 30 June 2024 and 30 June 2023 – Cash Based Benefits

	Year	Gross Salary <sup>3</sup>	Short Term Incentive	Retention Award	Other <sup>1</sup>	Superannuation/ Pension Fund	Total (Excluding Share-Based Payments)
		\$	\$	\$	\$	\$	\$
Dr. P. J. Wolgen <sup>2</sup>	2024	1,765,068	941,046	-	283,454	-	2,989,568
	2023	1,593,117	898,244	-	286,314	-	2,777,675
Mrs. B. M. Shanahan	2024	76,577	-	-	-	8,424	85,001
	2023	76,923	-	-	-	8,077	85,000
Mr. W. A. Blijdorp	2024	82,083	-	-	-	-	82,083
	2023	115,000	-	-	-	-	115,000
Dr. K. A. Agersborg	2024	75,000	-	-	-	-	75,000
	2023	75,000	-	-	-	-	75,000
Mrs. S. E. Smith	2024	80,000	-	-	-	-	80,000
	2023	75,000	-	-	-	-	75,000
Prof. J. V. Rosenfeld	2024	82,583	-	-	-	9,084	91,667
	2023	67,874	-	-	-	7,126	75,000
Prof J. A. Likierman	2024	23,333	-	-	-	-	23,333
	2023	70,000	-	-	-	-	70,000
Dr. D. J. Wright	2024	305,086	21,966	-	-	27,399	354,451
	2023	289,182	26,026	-	-	25,292	340,500
Mr. D. M. Keamy	2024	361,594	26,035	30,736	-	27,399	445,764
	2023	331,737	58,054	-	-	25,292	415,083
Total	2024	2,851,324	989,047	30,736	283,454	72,305	4,226,867
	2023	2,693,833	982,324	-	286,314	65,787	4,028,258

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

2. Dr Wolgen's salary is paid in Euro currency.

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

For Mr Keamy and Dr Wright, the movement in their annual leave and long service leave entitlements was \$22,519 accretive and \$28,447 accretive respectively (year ending 30 June 2023: \$11,206 accretive and \$24,693 reduction respectively).

For Dr Wolgen, the movement in his aggregate annual leave and long service leave entitlements for year ending 30 June 2024 decreased by \$11,787 (2023: \$232,054).



### 3) KMP remuneration of the Company for the years ended 30 June 2024 and 30 June 2023 – Non-Cash Benefits

Share-based payments (accounting charge only) <sup>1</sup>					
	Year	Total (Excluding Share- Based Payments)	Performance Rights (for accounting purposes only)	Total (Including Share- Based Payments, for accounting purposes only)	Performance- based
		\$	\$	\$	%
<b>Dr. P. J. Wolgen</b>	2024	2,989,568	752,844 <sup>2</sup>	3,742,412	20%
	2023	2,777,675	3,612,426	<b>6,390,101</b>	57%
<b>Mrs. B. M. Shanahan</b>	2024	85,001	-	<b>85,001</b>	-
	2023	85,000	-	<b>85,000</b>	-
<b>Mr. W. A. Blijdorp</b>	2024	82,083	-	<b>82,083</b>	-
	2023	115,000	-	<b>115,000</b>	-
<b>Dr. K. A. Agersborg</b>	2024	75,000	-	<b>75,000</b>	-
	2023	75,000	-	<b>75,000</b>	-
<b>Mrs. S. E. Smith</b>	2024	80,000	-	<b>80,000</b>	-
	2023	75,000	-	<b>75,000</b>	-
<b>Prof. J. V. Rosenfeld</b>	2024	91,667	-	<b>91,667</b>	-
	2023	75,000	-	<b>75,000</b>	-
<b>Prof J. A. Likierman</b>	2024	23,333	-	<b>23,333</b>	-
	2023	70,000	-	<b>70,000</b>	-
<b>Dr. D. J. Wright</b>	2024	354,451	428,162	<b>782,613</b>	55%
	2023	340,500	296,352	<b>636,852</b>	47%
<b>Mr. D. M. Keamy</b>	2024	445,764	2,218,120	<b>2,663,884</b>	83%
	2023	415,083	2,674,581	<b>3,089,664</b>	87%
<b>Total</b>	<b>2024</b>	<b>4,226,867</b>	<b>3,399,126</b>	<b>7,625,993</b>	-
	<b>2023</b>	<b>4,028,258</b>	<b>6,583,359</b>	<b>10,611,617</b>	-

<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>The value of the PRs assigned to the MD, as awarded on achieving 20% of the PRs granted at the AGM 2019. Dr Wolgen is no longer eligible for PR or any form of equity.

### 4) Remuneration Performance Rights holdings of KMP – 2024

	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. J. Wolgen	1,513,750*	-	(301,125)	(1,212,625)	-	-
Mrs. B. M. Shanahan	-	-	-	-	-	-
Mr. W. A. Blijdorp	-	-	-	-	-	-
Dr. K. A. Agersborg	-	-	-	-	-	-
Mrs. S. E. Smith	-	-	-	-	-	-
Prof. J. V. Rosenfeld	-	-	-	-	-	-
Prof. J. A. Likierman	-	-	-	-	-	-
<b>Other KMP</b>						
Dr. D. J. Wright	93,938	-	(31,938)	(43,875)	18,125	-
Mr. D.M. Keamy	347,235	-	(184,302)	(155,575)	7,358	-

\* A listing of the Performance Conditions for the Performance Rights vested and exercised are shown at section XXX.

### 5) Shares held by KMP

The number of ordinary shares in the Company during the 2023/24 reporting period held by each of the Group's KMP, including their related parties, is set out below:

Year Ended 30 June 2024						
Personnel	Balance at Start of Year	Granted as Remuneration	Received on Exercise	Other Changes	Held at the End of Reporting Period	
Dr. P. J. Wolgen	3,122,247	-	301,125	1,850	3,425,222	
Mrs. B. M. Shanahan	196,577	-	-	-	196,577	
Mr. W. A. Blijdorp	1,743,118	-	-	-	1,743,118	
Dr. K. A. Agersborg	5,500	-	-	-	5,500	
Mrs. S. E. Smith	420	-	-	-	420	
Prof. J. V. Rosenfeld	3,148	-	-	-	3,148	
Prof. J. A. Likierman	1,000	-	-	(1,000)	-	
<b>Other KMP</b>						
Dr. D. J. Wright	156,874	-	31,938	-	188,812	
Mr. D. M. Keamy	178,588	-	184,302	-	362,890	

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

Entity	Number of Rights Granted	Value per Right on Grant Date	Class	Grant Date	Issue date	Expiry Date	Perform Condition met, not exercisable until end Vesting Period	Exercisable Date
CLINUVEL	7,500	\$12.87	Ordinary	05/05/2022	05/05/2022	20/12/2024	-	20/12/2024

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

## 7) 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. J. Wolgen	-	-	-	-	-
Mrs. B. M. Shanahan	-	-	-	-	-
Mr. W. A. Blijdorp	-	-	-	-	-
Dr. K. A. Agersborg	-	-	-	-	-
Mrs. S. E. Smith	-	-	-	-	-
Prof. J. V. Rosenfeld	-	-	-	-	-
Prof J. A. Likierman	-	-	-	-	-
Other KMP					
Dr. D. J. Wright	2011/12	no limitation	-	-	\$12,853
Mr. D. M. Keamy	2011/12	no limitation	-	-	\$5,219

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 between in 2010/11 was \$Nil.

## 8) Remuneration details of cash incentives

Cash Incentives				
Name	Max Potential Opportunity (%)	STI Awarded (%)*	STI Forfeited (%)	Total Granted (\$)
Dr. P. J. Wolgen	100%	53%	47%	941,046
Dr. D. J. Wright	9%	80%	20%	21,966
Mr. D. M. Keamy	20.5%	35%	65%	26,035

\* For the MD, the STI Awarded in the functional currency on his base salary was 60.0%

## Loans to Directors and Executives

No loans were granted to Directors or executives for the years ended 30 June 2024 and 30 June 2023.

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

## K. DETAILS OF PERFORMANCE RIGHTS

## 1) Managing Director Performance Rights Vested on 20 November 2023

Details of Performance Rights issued to Managing Director	Performance Condition Met	Number of Rights Vested
<b>PC1 Performance Rights granted to Managing Director – 450,000</b>		
<b>Executive management and staff succeeding in steering the Company to a:</b>		
(i) Market capitalisation of a minimum A\$1,700,000,000 - as measured by a minimum of 15 trading days during the vesting period - 10% of the performance rights under PC1 shall vest,	✓	45,000
(ii) Market capitalisation of a minimum A\$2,100,000,000 - as measured by a minimum of 15 trading days during the vesting period - 15% of the performance rights under PC1 shall vest,	X	-
(iii) Market capitalisation of a minimum A\$2,700,000,000 - as measured by a minimum of 15 trading days during the vesting period - 25% of the performance rights under PC1 shall vest,	X	-
(iv) Market capitalisation of a minimum A\$5,000,000,000 - as measured by a minimum of 15 trading days during the vesting period - 25% of the performance rights under PC1 shall vest,	X	-
(v) Market capitalisation of a minimum A\$7,500,000,000 - as measured by a minimum of 15 trading days during the vesting period - 25% of the performance rights under PC1 shall vest.	X	-
Only in case of a recession in the country of the Company's primary market exchange (recession defined by a contraction of gross domestic product for 2 consecutive quarters) when the Company's market capitalisation may be adversely impacted by conditions outside management control, that the market capitalisation targets defined in PC1 (i) to (v) above will be replaced by the following performance targets:		
(i) The Company's growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 3.0%, 10% of the performance rights under PC1 shall vest,		
(ii) The Company's growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 4.0%, 15% of the performance rights under PC1 shall vest,		
(iii) The Company's growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 5.0%, 25% of the performance rights under PC1 shall vest,		
(iv) The Company's growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 7.0%, 25% of the performance rights under PC1 shall vest,		
(v) The Company's growth in share price outperforms either the Nasdaq Biotech Index or ASX Healthcare Index for 1 quarter - after the country has entered a recession - by more than 9.0%, 25% of the performance rights under PC1 shall vest.		
When the country of the Company's primary market exchange is no longer in recession, this performance condition reverts back to the original market capitalisation conditions.		
<b>PC2 Performance Rights granted to Managing Director – 105,000</b>		
(i) Upon quarterly reporting of A\$60 million in cash and cash equivalents* held for 2 consecutive quarters, 15% of PC2 shall vest,	✓	15,750
(ii) Upon quarterly reporting of A\$70 million in cash and cash equivalents* held for 2 consecutive quarters, a further 20% of PC2 shall vest,	✓	21,000
(iii) Upon quarterly reporting of A\$80 million in cash and cash equivalents* held for 2 consecutive quarters, a further 30% of PC2 shall vest,	✓	31,500
(iv) Upon quarterly reporting of more than A\$150 million in cash and cash equivalents* held for 2 consecutive quarters, a further 35% of PC2 will be achieved.	✓	36,750
* The Board ad Remuneration Committee deemed Cash and Cash Equivalents to pertain to cash assets of the business held in Cash and Cash Equivalents together with Cash Held in Term Deposits. Dividends paid out during the vesting period shall be added back to the calculation of the cash reserves. At any time during the vesting period, the ratio between cash and cash equivalents internally generated from the Company's operations and any debt and/or equity financing which increases cash and cash equivalents must be at minimum 2:3 ratio for any of the 5 performance targets under PC2 to be achieved.		
<b>PC3 Performance Rights granted to Managing Director – 105,000</b>		
Successful acquisition of a business entity, defined by:		
(i) The acquired entity must have generated sales revenue within 6 months of transaction, 50% of PC3 shall vest,	X	-
(ii) CUV Group becomes or remains profitable within 3 years (plus variability of one year) of transaction as measured by two successive quarters reporting profitability of the two or more combined entities, 50% of PC3 shall vest.	X	-
For PC3 to be achieved, the acquisition must be considered synergistic to the Company's business operations at the time of acquisition.		

PC4 Performance Rights granted to Managing Director – 87,500		
(i) Upon receipt of first US revenues under the US post-marketing authorization for SCENESSE <sup>®</sup> , 34% of PC4 shall vest,	✓	29,750
(ii) US revenues in year 3 to exceed revenues by a minimum of 10% in year 2, a further 33% of PC4 shall vest,	✓	28,875
(iii) US revenues greater than US\$10,000,000 in a 12-month period leads to vesting of 33% of PC4.	✓	28,875
PC5 Performance Rights granted to Managing Director – 175,000		
(i) Market launch of first non-pharmaceutical ('OTC') product(s) line developed by the VALLAURIX subsidiary entity, 15% of PC5 shall vest,	X	-
(ii) Total revenues from OTC product lines developed by the VALLAURIX subsidiary entity achieving greater than A\$250,000 in accumulated gross sales, a further 30% of PC5 shall vest,	X	-
(iii) First topical melanogenic formulation to be used either in animal or in human testing, a further 25% of PC5 shall vest,	X	-
(iv) Upon the completion of the first clinical study of a SCENESSE <sup>®</sup> paediatric formulation (being the completion of a final clinical study report), a further 30% of PC5 shall vest.	X	-
PC6 Performance Rights granted to Managing Director – 262,500		
(i) Upon start (being the closure of recruitment period) of a Phase IIb vitiligo study in North America, 20% of PC6 shall vest,	✓	5,500 (10.5% of full target)
(ii) Upon disclosure to the securities exchange of the results to the Phase IIb vitiligo study in North America, 20% of PC6 shall vest,	X	-
(iii) After the completion of the Phase IIb vitiligo study in North America and prior to the subsequent Phase IIb/III study, upon holding a Type-C meeting (FDA) and acceptance of study protocol for the Phase IIb/III vitiligo study in North America, a further 20% of PC6 shall vest,	X	-
(iv) Upon start (being the closure of recruitment period) of the subsequent Phase IIb/III vitiligo study in North America, a further 20% of PC6 shall vest,	X	-
(v) Upon disclosure to the securities exchange of the results to the subsequent Phase IIb/III vitiligo study in North America, 20% of PC6 shall vest.	X	-
PC7 Performance Rights granted to Managing Director – 212,500		
(i) Upon the regulatory submission to either of EMA, FDA, TGA, PMDA and Swissmedic to approve SCENESSE <sup>®</sup> or any other molecule or product enhancing the pharmaceutical product line-only offerings of the Company, 25% of PC7 shall vest,	X	-
(i) Upon the regulatory approval by either of EMA, FDA, TGA, PMDA and Swissmedic of SCENESSE <sup>®</sup> or any other molecule constituting a successful evaluation of a scientific dossier, a further 75% of PC7 shall vest.	X	-
PC8 Performance Rights granted to Managing Director – 116,250		
(i) The Board to use its discretion to award performance rights depending on the extraordinary nature of the corporate event(s) achieved and the significant impact on the Company's value. It is not certain that these performance rights will be issued during the fixed term of the Conditional Rights Plan, and hence these need to be regarded as a reserve pool enabling the Company to grant in the event of exceptional and unexpected performances which was unanticipated at the time of business planning.	✓	58,125 (50% of full target)
<small>These corporate events shall include, but are not limited to, business generation in new markets without the Company engaging in merger and acquisition activity.</small>		
<b>Total Performance Rights Vested and Exercised by Managing Director</b>		<b>301,125</b>

– 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	716,932	Nil\$	Ordinary

### Unissued shares under option

Entity	Number of Shares under Rights	Exercise Price	Class	Expiry Date
CLINUVEL PHARMACEUTICALS LTD	266,332	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>266,332</b>			

### Auditor's Independence Declaration

The auditor's independence declaration as required by s.307C of the Corporations Act 2001 is included on page 151 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

Director

Dated this 29<sup>th</sup> day of August, 2024

## Statement of Profit and Other Comprehensive Income for the year ended 30 June 2024

		Consolidated Entity	
		2024	2023
		\$	\$
<b>Revenues</b>			
Commercial sales of goods	19	81,218,146	72,179,047
Sales reimbursements	19	6,960,162	6,142,271
<b>Total revenues</b>		<b>88,178,308</b>	<b>78,321,318</b>
Interest income		7,324,871	3,905,856
<b>Total interest income</b>		<b>7,324,871</b>	<b>3,905,856</b>
<b>Other income</b>			
Unrealised (loss)/gain on restating foreign currency balances and currencies held		(745,764)	659,901
Government grants and other income		562,936	23,817
Realised foreign currency (loss)/ gain on transactions		(14,614)	79,364
<b>Total other income (loss)</b>		<b>(197,442)</b>	<b>763,082</b>
<b>Total revenues, interest and other income</b>		<b>95,305,737</b>	<b>82,990,256</b>
<b>Expenses</b>			
Personnel-related		18,917,924	13,576,951
Share-based payments		6,107,272	8,989,788
Materials and related expenses		5,201,364	12,063,281
Finance, corporate and general		4,454,292	3,192,713
Commercial distribution		3,638,897	3,145,355
Clinical and non-clinical development		2,348,296	1,268,456
Communication, branding and marketing		2,180,489	749,769
Legal, insurance and IP		1,743,050	1,323,383
Depreciation and amortisation		1,142,326	789,408
Changes in inventories of raw materials, work in progress and finished goods		(1,107,151)	(7,687,571)
<b>Total expenses</b>		<b>44,626,759</b>	<b>37,411,533</b>
Profit before income tax		50,678,978	45,578,723
<b>Income tax</b>			
Current	3(a)	15,532,461	16,382,733
Deferred	3(a)	(489,842)	(1,408,576)
<b>Income tax expense</b>	3(a)	<b>15,042,619</b>	<b>14,974,157</b>
Operating profit after income tax	15(b)	35,636,359	30,604,566
<b>Net profit for the year</b>		<b>35,636,359</b>	<b>30,604,566</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		138,945	(1,454,160)
<b>Other comprehensive loss for the period, net of income tax</b>		<b>138,945</b>	<b>(1,454,160)</b>
<b>Total comprehensive income for the period</b>		<b>35,775,304</b>	<b>29,150,406</b>
Basic earnings per share - cents per share	14	71.5	61.9
Diluted earnings per share - cents per share	14	69.8	59.1

The accompanying notes form part of these financial statements.

## Statement of Financial Position as at 30 June 2024

	Note	Consolidated Entity	
		2024	2023 Restated
		\$	\$
<b>Current assets</b>			
Cash and cash equivalents	1(e) and 15(a)	35,200,751	31,893,021
Cash held in term deposits	1(f)	148,667,720	124,920,516
Trade and other receivables	4	26,238,297	22,214,646
Inventories	5	10,626,613	9,519,462
Other current assets		1,330,461	1,070,153
<b>Total current assets</b>		<b>222,063,842</b>	<b>189,617,798</b>
<b>Non-current assets</b>			
Property, plant and equipment	6	6,982,337	2,017,861
Right-Of-Use assets	7	737,788	833,326
Intangible asset		185,030	185,030
Deferred tax assets	3(c)	1,020,344	1,059,541
Lease bonds		134,208	-
<b>Total non-current assets</b>		<b>9,059,707</b>	<b>4,095,758</b>
<b>Total assets</b>		<b>231,123,549</b>	<b>193,713,556</b>
<b>Current liabilities</b>			
Trade and other payables	9	7,109,053	7,649,572
Income tax payables		15,851,385	16,094,178
Provisions	10	1,881,898	1,450,120
Lease liabilities	7	369,861	300,843
<b>Total current liabilities</b>		<b>25,212,197</b>	<b>25,494,713</b>
<b>Non-current liabilities</b>			
Deferred tax liabilities	3(d)	2,226,104	2,757,516
Lease liabilities	7	509,923	699,022
Provisions	10	163,959	131,162
<b>Total non-current liabilities</b>		<b>2,899,986</b>	<b>3,587,700</b>
<b>Total liabilities</b>		<b>28,112,183</b>	<b>29,082,413</b>
<b>Net assets</b>		<b>203,011,366</b>	<b>164,631,143</b>
<b>Equity</b>			
Contributed equity	11	168,802,368	151,849,375
Reserves	12	4,245,371	22,556,044
Retained earnings/(accumulated losses)		29,963,627	(9,774,276)
<b>Total equity</b>		<b>203,011,366</b>	<b>164,631,143</b>

The accompanying notes form part of these financial statements.

## Statement of Cash Flows for the Year Ended 30 June 2024

	Note	2024 \$	Consolidated Entity 2023 Restated \$
<b>Cash flows from operating activities</b>			
Receipts from customers		84,020,937	74,877,720
Payments to suppliers and employees		(39,749,125)	(33,230,793)
Income taxes paid		(15,648,111)	(7,744,922)
Interest received		7,633,046	2,727,126
Government grants		344,394	22,009
GST and VAT refunds		244,147	260,923
Proceeds from insurance claims		208,594	-
<b>Net cash provided by operating activities</b>	15(b)	<b>37,053,882</b>	<b>36,912,063</b>
<b>Cash flows from investing activities</b>			
Investments in cash held in term deposits		(23,457,711)	(30,820,516)
Payments for property, plant and equipment		(5,576,215)	(1,027,532)
<b>Net cash used in investing activities</b>		<b>(29,033,926)</b>	<b>(31,848,048)</b>
<b>Cash flows from financing activities</b>			
Issuance of shares related to employee share schemes		4,155,010	-
Payments related to employee share schemes		(4,155,010)	-
Dividends paid		(2,470,227)	(1,976,414)
Payments for share buy back		(754,236)	-
Payments of lease liabilities		(347,344)	(263,718)
<b>Net cash used in financing activities</b>		<b>(3,571,807)</b>	<b>(2,240,132)</b>
<b>Net increase in cash held</b>		<b>4,448,149</b>	<b>2,823,883</b>
<b>Cash and cash equivalents at beginning of the year</b>		<b>31,893,021</b>	<b>27,409,282</b>
Effects of exchange rate changes on foreign currency held		(1,140,419)	1,659,856
<b>Cash and cash equivalents at end of the year</b>	15(a)	<b>35,200,751</b>	<b>31,893,021</b>

The accompanying notes form part of these financial statements.

## Statement of Changes in Equity for the Year Ended 30 June 2024

	Share Capital \$	Performance Rights Reserve \$	Foreign Currency Translation Reserve \$	Retained Earnings/ (Accumulated Losses) \$	Total Equity \$
<b>Balance at 30 June 2022</b>	<b>151,849,375</b>	<b>10,380,258</b>	<b>1,731,838</b>	<b>(38,402,428)</b>	<b>125,559,043</b>
Employee share-based payment options	-	8,989,788	-	-	<b>8,989,788</b>
Dividends paid	-	-	-	(1,976,414)	<b>(1,976,414)</b>
Exercise of performance rights under share-based payment	-	-	-	-	-
<b>Transactions with owners</b>	<b>151,849,375</b>	<b>19,370,046</b>	<b>1,731,838</b>	<b>(40,378,842)</b>	<b>132,572,417</b>
Profit for the year	-	-	-	30,604,566	<b>30,604,566</b>
<b>Other comprehensive income:</b>					
Exchange differences of foreign exchange translation of foreign operations	-	-	1,454,160	-	<b>1,454,160</b>
<b>Total other comprehensive income</b>	<b>-</b>	<b>-</b>	<b>1,454,160</b>	<b>-</b>	<b>1,454,160</b>
<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>
Share buy back	(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>

# Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2024

## 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 complies 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 material 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 factors 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 material 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 material 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.

## 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 2024 and 30 June 2023 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;
- An increase to consolidated entity revenues are expected in the near term from making SCENESSE® available in the USA 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.

### Private Tax Ruling

During the 2024 financial year, Clinuvel applied for, and received, a Private Tax Ruling from the Australian Taxation Office (ATO) to affirm its entitlement to deduct an amount under section 8-1 of the Income Tax Assessment Act 1997 (Cth) (ITAA 1997) for irretrievable cash contributions it makes to CPU Share Plans Pty Limited (the Trustee) of the Clinuvel Pharmaceuticals Limited Employee Share Plan Warehouse Trust (the Trust) to fund the subscription for, or acquisition on-

market of, fully paid ordinary shares in the Company (Shares), to satisfy employee share scheme (ESS) interests issued pursuant to the 2014 Performance Rights Plan as updated in September 2023 and renewed by the Company's shareholders at the 2023 Annual General Meeting.

### 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 include cash in term deposits with banks or financial institutions. The Company's policy is to place surplus cash in term deposits to earn competitive interest income while maintaining liquidity. As of 30 June 2024, the term deposits are readily convertible to cash upon Clinuvel providing 31 days' prior notice to the institution following which a market-related rate reduction to the interest payable for the early withdrawal is applied.

The average effective interest rate on cash held in term deposits was 5.28% (2023: 3.33%). These deposits have an average maturity date of 251 days (2023: 252 days).

#### Reclassification of comparative amounts

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

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

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

The comparative amount for the consolidated Statement of Cash Flows for the year ended 30 June 2023 has been restated to present the movement of cash into cash in term deposits as a net cash flow from investing activity.

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

Statement of Cash Flows (extract)	30 June 2023	Increase/ (Decrease)	30 June 2023 (Restated)
Investments in cash held in term deposits	-	(30,820,516)	(30,820,516)
Net cash used in investing activities	(1,027,532)	(30,820,516)	(31,848,048)
Net increase in cash held	33,644,399	(30,820,516)	2,823,883
Cash and cash equivalents at beginning of the year	121,509,282	(94,100,000)	27,409,282
Effects of exchange rate changes on foreign currency held	1,659,856	-	1,659,856
<b>Cash and cash equivalents at end of the year</b>	<b>156,813,537</b>	<b>(124,920,516)</b>	<b>31,893,021</b>

### 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) Property, Plant and Equipment

Property, 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.

Building is depreciated using the straight-line method over the estimated useful lives of assets up to 50 years. Land is not depreciated.

Plant and equipment depreciation is calculated on diminishing value so as to write off the net cost of each asset over its expected useful life to its estimated residual value. The estimated useful lives, residual values and depreciation method are reviewed at the end of each annual reporting period and adjusted if appropriate. An asset's carrying amount is written off immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

The following percentages are used in the calculation of depreciation:

- Computers and software: 40%
- Leasehold improvement: 40%
- All other assets: 7.5% to 33.3%

Gains and losses on disposal of assets are determined by comparing proceeds upon disposal with the asset's carrying amount. These are included in the Profit or Loss.

### i) 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.

### j) 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).

#### 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.

### k) 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.

### l) 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.

### m) Employee Benefits

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

### n) 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.

### o) 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.

### p) 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.

### q) Revenue And Other Income

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

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

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

- Identifying supply conditions laid down in a contract with a customer;
- 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 markets.

#### Interest

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

#### Government R&D Tax Incentive

The Company formerly received other income through a refundable tax offset as part of the Australian government R&D tax incentive program. Other income would be recognised when it has been established that the conditions of the tax incentive have been met and that the expected amount of tax incentive can be reliably measured.

#### Government Grant

Government grants represent the Research Incentive Scheme for Companies provided by the Singapore Economic Development Board, along with the Job Growth Incentive 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.

#### r) 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 US product the above criteria have not been fully satisfied to support the recognition and generation of an internally generated intangible asset.

#### s) Comparatives

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

#### t) Foreign Currency Transactions And Balances

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

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

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

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

#### u) 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.

#### v) 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 entity's 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).

### w) Segment Reporting

A segment is a component of the consolidated entity that earns revenues or incurs expenses whose results are regularly reviewed by the chief operating decision makers and for which discrete financial information is prepared.

The Group has identified its operating segments based on the internal reports that are reviewed and used by the Chief Executive Officer (the Chief Operating Decision Maker) in assessing performance and in determining the allocation of resources. The 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.

### x) New Australian Accounting Standards Issued But Not Yet Effective

The Group has not adopted any new accounting standards or interpretations that are issued but not yet effective. The Group is yet to undertake a detailed assessment of the impact of any new accounting standards or interpretation. 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 2024.

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

Profit/(loss) before income tax includes the following specific expenses	Consolidated Entity	
	2024	2023
Employee benefits expense	17,861,812	12,960,543
Depreciation on property, plant & equipment	753,184	397,260
Operating lease expense – minimum lease payments	339,011	306,830
Amortisation of right-of-use assets	331,932	343,642
Bank charges	41,562	38,671

## 3. Income Tax Expense

	Consolidated Entity	
	2024	2023
	\$	\$
<b>(a) Income tax expense</b>		
Current	15,532,461	16,382,733
Deferred	(489,842)	(1,408,576)
<b>Income tax expense</b>	<b>15,042,619</b>	<b>14,974,157</b>
<b>Deferred tax included in income tax benefit comprises:</b>		
Decrease/(Increase) in deferred tax assets	(110,542)	497,571
Increase/(Decrease) in deferred tax liabilities	(379,300)	911,005
	<b>(489,842)</b>	<b>1,408,576</b>
<b>(b) Numerical</b>		
Profit before income tax expense	50,678,977	45,578,723
Tax at the statutory tax rates of 30% in 2023 and 2022	15,203,693	13,673,617
<i>Tax effect amounts which are not deductible/(taxable) in calculating taxable income:</i>		
Other non-deductible (deductible) expenses for tax purposes	(161,074)	71,075
Non-deductible share-based payments	-	1,229,465
<b>Income tax expense</b>	<b>15,042,619</b>	<b>14,974,157</b>
<b>Tax losses not recognised</b>		
Unused tax losses for which no deferred tax asset has been recognised	18,301,957	18,899,558
<b>(c) Deferred tax assets</b>		
Carry forward tax losses	856,768	1,011,871
Intangibles	572,581	553,282
Provisions	256,668	233,280
Accrued Expenses	225,869	61,700
Lease liabilities	71,804	10,642
	<b>1,983,690</b>	<b>1,870,775</b>
<b>Reconciliation to the Statement of Financial Position</b>		
Total deferred tax assets	1,983,690	1,870,775
Set-off of deferred tax liabilities that are expected to reverse in the same period	(963,346)	(811,234)
	<b>1,020,344</b>	<b>1,059,541</b>
<b>Movements</b>		
Opening balance	1,870,775	1,346,074
Carry forward tax losses	(155,103)	630,821
Intangibles	19,299	39,813
Lease liabilities	61,162	(23,314)
Accrued Expenses	164,169	(84,030)
Provisions	23,388	(38,589)
	<b>1,983,690</b>	<b>1,870,775</b>
<b>(d) Deferred tax liabilities</b>		
Unrealised foreign exchange gains	(2,744,331)	(3,142,445)
Accrued income	(339,133)	(420,888)
Right-of-use assets	(124,435)	(10,108)
Intangibles	18,449	4,691
	<b>(3,189,450)</b>	<b>(3,568,750)</b>
<b>Reconciliation to the Statement of Financial Position</b>		
Total deferred tax liabilities	(3,189,450)	(3,568,750)
Set-off of deferred tax assets that are expected to reverse in the same period	963,346	811,234
	<b>(2,226,104)</b>	<b>(2,757,516)</b>
<b>Movements</b>		
Opening balance	(3,568,750)	(4,479,755)
Unrealised foreign exchange gains	398,113	1,096,011
Right-of-use assets	(114,327)	23,167
Accrued income	81,756	(202,247)
Intangibles	13,758	(5,926)
	<b>(3,189,450)</b>	<b>(3,568,750)</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 2024 and 2023, income tax rate of 21% for US entity in 2024 and 2023 and income tax rate of 25% for UK entity in 2024 and 2023.

## 4. Trade and Other Receivables

	Consolidated Entity	
	2024	2023
	\$	\$
<b>Current</b>		
Trade debtors	25,162,556	20,807,909
Interest receivables	1,130,444	1,438,696
Sundry debtors	94,803	134,199
Expected credit losses	(149,506)	(166,158)
<b>Total</b>	<b>26,238,297</b>	<b>22,214,646</b>

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 2024, the Group had a provision for expected credit loss of \$149,506 (2023 \$166,158)

	Consolidated Entity	
	2024	2023
	\$	\$
Opening balance as at 1 July	(166,158)	-
Reversal of/(provision for) expected credit losses	16,652	(166,158)
<b>Closing balance as at 30 June 2024</b>	<b>(149,506)</b>	<b>(166,158)</b>

## 5. Inventories

	Consolidated Entity	
	2024	2023
	\$	\$
<b>Current</b>		
Raw materials – at cost	571,169	514,812
Provision for obsolescence – raw materials	-	(51,655)
Work in progress – at cost	7,026,835	7,466,396
Finished goods – at cost	3,028,609	1,589,909
<b>Total</b>	<b>10,626,613</b>	<b>9,519,462</b>

A provision for obsolescence of \$51,655 was written off in 2024 (2023 : \$108,057)

## 6. Property, Plant and Equipment

	Consolidated Entity	
	2024	2023
	\$	\$
<b>Land</b>	<b>347,744</b>	<b>-</b>
<b>Building</b>		
At cost	4,620,025	-
Less: accumulated depreciation	(76,327)	-
<b>Sub-total</b>	<b>4,543,698</b>	<b>-</b>
<b>Plant and equipment</b>		
At cost	1,849,823	1,487,388
Less: accumulated depreciation	(758,157)	(490,012)
<b>Sub-total</b>	<b>1,091,666</b>	<b>997,376</b>
<b>Furniture and fittings</b>		
At cost	92,293	45,603
Less: accumulated depreciation	(35,639)	(26,387)
<b>Sub-total</b>	<b>56,654</b>	<b>19,216</b>
<b>Leasehold improvements</b>		
At cost	1,987,000	1,888,048
Less: accumulated amortisation	(1,044,425)	(886,779)
<b>Sub-total</b>	<b>942,575</b>	<b>1,001,269</b>
<b>Total property, plant and equipment</b>	<b>6,982,337</b>	<b>2,017,861</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.

	Consolidated Entity					Total
	Land	Building	Plant And Equipment	Furniture And Fittings	Leasehold Improvements	
	\$	\$	\$	\$	\$	\$
Carrying amount at 30 June 2022	-	-	946,245	19,360	575,097	1,540,702
Additions	-	-	197,898	3,668	634,675	836,241
Disposals	-	-	-	-	-	-
Depreciation written back on disposals	-	-	-	-	-	-
Depreciations expense	-	-	(146,767)	(3,812)	(208,503)	(359,082)
<b>Carrying amount at 30 June 2023</b>	<b>-</b>	<b>-</b>	<b>997,376</b>	<b>19,216</b>	<b>1,001,269</b>	<b>2,017,861</b>
Additions	347,744	4,620,025	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>347,744</b>	<b>4,543,698</b>	<b>1,091,666</b>	<b>56,654</b>	<b>942,575</b>	<b>6,982,337</b>

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

	Consolidated Entity	
	2024	2023
	\$	\$
<b>Right-of-use assets</b>		
At cost	1,762,660	1,782,946
Less: accumulated depreciation	(1,024,872)	(949,620)
<b>Total right-of-use assets</b>	<b>737,788</b>	<b>833,326</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 30 June 2022	1,159,642	
Additions	7,052	
Amortisation	(343,642)	
Currency translation differences	10,274	
<b>Carrying amount at 30 June 2023</b>	<b>833,326</b>	
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>	

	Consolidated Entity	
	2024	2023
	\$	\$
<b>Lease liabilities</b>		
Lease liabilities - Current	369,861	300,843
Lease liabilities - Non-current	509,923	699,022
<b>Total lease liabilities</b>	<b>879,784</b>	<b>999,865</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 6.26 % in 2024 and 6.4% in 2023.

## 8. Interests in Subsidiaries

Name of Entity	Type of Entity	Ownership Interest		Country of Incorporation
		2024	2023	
<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%	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

## 9. Trade and Other Payables

	Consolidated Entity		
	2024	2023	
	\$	\$	
<b>Current</b>			
Unsecured trade creditors	2,345,436	2,791,672	
Sundry creditors and accrued expenses	4,763,617	4,857,900	
<b>Total</b>	<b>7,109,053</b>	<b>7,649,572</b>	
(a) Aggregate amounts payable to:			
<b>Directors and Director-related entities</b>	<b>952,653</b>	<b>910,574</b>	
(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade and Sundry creditors:			
	British Pounds	85,880	-
	Canadian dollars	3,750	16,791
	Other	603	-
<b>Total</b>	<b>90,233</b>	<b>16,791</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	
	2024	2023
	\$	\$
<b>Current</b>		
Employee benefits	1,881,898	1,450,120
<b>Total</b>	<b>1,881,898</b>	<b>1,450,120</b>
<b>Non-current</b>		
Employee benefits	84,721	56,573
Other provisions	79,238	74,589
<b>Total</b>	<b>163,959</b>	<b>131,162</b>

## 11. Contributed Equity

### (a) Issued And Paid Up Capital

	Consolidated Entity	
	2024	2023
	\$	\$
50,077,780 fully paid ordinary shares (2023: 49,410,338)	168,802,368	151,849,375

Ordinary shares have the right to receive dividends as declared and, in the event of winding up the Company, to participate in the proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held. Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company. The Company does not have a limited amount of authorised capital and issued shares do not have a par value.

### (b) Movements In Ordinary Share Capital

	Consolidated Entity			
	2024		2023	
	No.	\$	No.	\$
<b>At the beginning of the financial year</b>	<b>49,410,338</b>	<b>151,849,375</b>	<b>49,410,338</b>	<b>151,849,375</b>
Issued during the year	-	-	-	-
Conditional rights issues and transferred from conditional rights reserve	716,932	17,707,229	-	-
Share buy back <sup>1</sup>	(49,490)	(754,236)	-	-
Less: transaction costs	-	-	-	-
<b>Balance at the end 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>

<sup>1</sup> During the year ended 30 June 2024, shares purchased under the share buy back program were cancelled.

### (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>716,932</b>

As at 30 June 2023, 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>266,332</b>

## 12. Reserves

	Consolidated Entity	
	2024	2023
	\$	\$
<b>Conditional Performance Rights reserve:</b>		
<b>Balance at the beginning of period</b>	<b>19,370,046</b>	<b>10,380,258</b>
Share-based payment	6,107,272	8,989,788
Transfer to share capital	(17,707,229)	-
Lapsed, forfeited rights	(6,571,771)	-
<b>Balance at the end of period</b>	<b>1,198,318</b>	<b>19,370,046</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>3,185,998</b>	<b>1,731,838</b>
Translating foreign subsidiary to current rate at reporting date	(138,945)	1,454,160
<b>Balance at the end of period</b>	<b>3,047,053</b>	<b>3,185,998</b>
<b>Total reserves</b>	<b>4,245,371</b>	<b>22,556,044</b>

## 13. Short-Term Lease Commitments

	Consolidated Entity	
	2024	2023
	\$	\$
<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	66,942	43,207
later than 1 year but not later than 5 years	-	1,350
<b>Total</b>	<b>66,942</b>	<b>44,557</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	
	2024	2023
	\$	\$
(a) Basic earnings per share (cents per share)	71.5	61.9
(a) Diluted earnings per share (cents per share)	69.8	59.1
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	49,834,035	49,410,338
(b) Weighted average number of performance rights on issue in respect of share based payments during the year	1,192,679	2,405,659
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	51,026,713	51,815,997
(c) The numerator used in the calculation of basic earnings per share (\$)	35,636,359	30,604,566

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	
	2024	2023 Restated
	\$	\$
<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 Statement of Financial Position as follows:</i>		
Cash at bank	18,102,718	22,883,205
Cash on hand	1,818	774
Deposits on call	16,874,047	617,759
Term deposits	-	8,025,800
Security bonds	222,168	365,483
<b>Total cash and cash equivalents</b>	<b>35,200,751</b>	<b>31,893,021</b>
<b>(b) Reconciliation of cash flows from operating activities with operating profit (loss)</b>		
<b>Operating profit after income tax</b>	<b>35,636,359</b>	<b>30,604,566</b>
<b>Non cash flows in operating profit after income tax:</b>		
Executive share option expense	6,107,272	8,989,788
Exchange rate effect on foreign currencies held	808,148	(1,659,855)
Depreciation expense on property, plant & equipment	753,184	397,260
Amortisation expense on right-of-use assets	331,932	343,642
Unrealised loss (gain) on foreign exchange translation	(138,945)	1,454,160
<b>Changes in assets and liabilities:</b>		
(Increase)/decrease in receivables	(4,023,652)	(6,012,709)
(Increase)/decrease in inventories	(1,107,151)	(7,687,571)
(Increase)/decrease in other current assets	(260,308)	(30,700)
(Increase)/decrease in deferred tax assets	39,197	(577,941)
(Increase)/decrease in lease bonds	(134,208)	-
Increase/(decrease) in payables	(648,316)	4,514,552
Increase/(decrease) in income tax payables	(242,793)	8,814,729
Increase/(decrease) in provisions	464,574	(1,380,093)
Increase/(decrease) in deferred tax liabilities	(531,411)	(857,765)
<b>Net cash used in operating activities</b>	<b>37,053,882</b>	<b>36,912,063</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	
	2024	2023
	\$	\$
Short-term employee benefits	4,123,825	3,962,471
Post-employment benefits	72,306	65,787
Long-term benefits	30,736	-
Share-based payments	3,399,126	6,583,359
<b>Total</b>	<b>7,625,993</b>	<b>10,611,617</b>
No loans or other transactions existed with key management personnel.		

## 17. Auditor's Remuneration

	Consolidated Entity	
	2024	2023
	\$	\$
<b>Amounts received or due and receivable by Grant Thornton Audit Pty Ltd for:</b>		
Audit services and review	249,126	246,154
<b>Total</b>	<b>249,126</b>	<b>246,154</b>

## 18. Related Party Disclosures

### Wholly-Owned Group Transactions

#### Loans

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from A.C.N. 108 768 896 Pty Ltd is non-interest bearing. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in A.C.N. 108 768 896 Pty Ltd. On 1 July 2022, CLINUVEL PHARMACEUTICALS LTD issued a Deed of Loan Forgiveness to A.C.N. 108 768 896 Pty Ltd. The loan to A.C.N. 108 768 896 Pty Ltd as at 30 June 2024 is \$Nil (2023: \$Nil).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL, INC. is interest bearing at average of 5.81% in 2024 and was 4.6% in 2023. Repayment of the loan has commenced upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in CLINUVEL, INC. The loan to CLINUVEL, INC. as at 30 June 2024 is \$20,499,042 (2023: \$21,681,805).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL AG is non-interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in CLINUVEL AG. During the 2023 financial year, CLINUVEL PHARMACEUTICALS LTD entered into a Deed of Loan Forgiveness to CLINUVEL AG effective 1 July 2022. The loan to CLINUVEL AG as at 30 June 2024 is \$91,828 (2023: \$188,531).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL SINGAPORE PTE LTD is non-interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in CLINUVEL SINGAPORE PTE LTD. The loan to CLINUVEL SINGAPORE PTE LTD as at 30 June 2024 is \$503,705 (2023: \$625,133).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL (UK) is interest bearing at average of 5.81% in 2024 and was 4.6% in 2023. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in CLINUVEL (UK) LTD. The loan to CLINUVEL (UK) LTD as at 30 June 2024 is \$3,753,911 (2023: \$2,053,783).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from VALLAURIX PTE LTD is non-interest bearing. Repayment of the loan will commence upon commercialisation of VALLAURIX PTE LTD's product(s). A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in VALLAURIX PTE LTD. The loan to VALLAURIX PTE LTD as at 30 June 2024 is \$13,333,126 (2023: \$10,475,621).

The loan receivable by (payable by) CLINUVEL PHARMACEUTICALS LTD from VALLAURIX MC SARL is non-interest bearing. Repayment of the loan will commence upon commercialisation of the Company's drug candidate. A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in VALLAURIX MC SARL. The loan to VALLAURIX MC SARL as at 30 June 2024 is \$5,208,319 (2023: \$6,339,501).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL EUROPE LIMITED is non-interest bearing. Repayment of the loan will commence upon commercialisation of CLINUVEL EUROPE LIMITED's product(s). A provision for non-recovery has been raised in the accounts of CLINUVEL PHARMACEUTICALS LTD where a deficiency in net assets exists in CLINUVEL EUROPE LIMITED. The loan to CLINUVEL EUROPE LIMITED as at 30 June 2024 is \$9,205,322 (2023: \$9,675,165).

#### Foundation

The Photomedicine Foundation (Foundation), a Not For Profit entity, was incorporated on 7 February 2024 under the State of California USA. The purpose of the Foundation is to support individuals affected by ultraviolet and visible light through access

to equipment, medical care, treatments or other means to improve the individual's health. The Foundation is currently dormant and not actively engaged in any activities.

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

There are no loan transactions and relationships in existence as at 30 June 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:

	FY2024			FY2023		
	Europe & USA	Switzerland, Others	Total	Europe & USA	Switzerland, Others	Total
	(\$'000)	(\$'000)	(\$'000)	(\$'000)	(\$'000)	(\$'000)
Commercial sales of goods	81,218	-	81,218	72,179	-	72,179
Sales reimbursements	265	6,695	6,960	104	6,038	6,142
<b>Total revenues</b>	<b>81,483</b>	<b>6,695</b>	<b>88,178</b>	<b>72,283</b>	<b>6,038</b>	<b>78,321</b>
<b>Total expenses</b>			<b>(44,627)</b>			<b>(37,412)</b>
<b>Net profit before tax</b>			<b>50,679</b>			<b>45,579</b>
<b>Income tax</b>			<b>(15,043)</b>			<b>(14,974)</b>
<b>Net profit after tax</b>			<b>35,636</b>			<b>30,605</b>
<b>Total asset</b>			<b>231,124</b>			<b>193,714</b>
<b>Total liability</b>			<b>28,112</b>			<b>29,082</b>

The Group has a number of customers to which it provides its leading drug candidate. Two customers each comprise 12% of external total revenue (2023: Two customers each comprise 15% and 13% 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 2024 and as at 30 June 2023.

#### The Consolidated Entities Exposure To Foreign Currency Risk At 30 June 2024

	Consolidated Entity									
	2024					2023 Restated				
	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	1,600,443	20,000,000	9,213,442	(1,588,919)	<b>29,224,966</b>	3,516,211	8,500,000	7,719,647	(2,249,199)	<b>17,486,659</b>
EUR	4,907,251	-	6,755,698	(2,458,873)	<b>9,204,076</b>	7,658,588	2,000,000	5,157,824	(2,403,905)	<b>12,412,507</b>
SEK	-	-	971,172	-	<b>971,172</b>	-	-	-	-	<b>-</b>
CHF	1,016,656	-	28,451	(122,923)	<b>922,184</b>	1,406,750	-	-	(93,231)	<b>1,313,519</b>
SGD	527,674	-	155,324	(272,159)	<b>410,839</b>	558,588	-	-	(241,557)	<b>317,031</b>
GBP	376,258	-	211,781	(574,237)	<b>13,802</b>	1,184,729	-	-	(396,064)	<b>788,665</b>
CAD	-	-	-	(3,433)	<b>(3,433)</b>	-	-	-	(14,744)	<b>(14,744)</b>
BRL	-	-	-	(2,114)	<b>(2,114)</b>	-	-	-	-	<b>-</b>
ILS	-	-	-	(89)	<b>(89)</b>	-	-	-	-	<b>-</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, a 2.2% appreciation of the Australian dollar against the Euro currency would have decreased profit and loss and equity by \$622,563 for the year ended 30 June 2024 (2023: \$2,147,985 decrease), on the basis that all other variables remain constant. 2.2% 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 2024, if interest rates had changed by +/- 325 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 \$5,234,216 higher/lower (2023: \$4,564,433 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, US and other medical institutions who are reimbursed by government or private insurance payors.

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

### c) Liquidity Risk

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

### Fair Value Estimation

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

The fair value of financial instruments traded in active markets is based on quoted market prices at reporting date. The quoted market price for the consolidated entity is the bid price. For longer-term debt instruments held by the consolidated entity, dealer quotes are used to determine fair value. The 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 2024

	2024	Consolidated Entity 2023
	\$	\$
<b>Trade and other payables</b>		
Carrying amount	7,109,053	7,649,572
6 months or less	7,082,494	7,645,178
Greater than 6 months	26,559	4,394
<b>Total</b>	<b>7,109,053</b>	<b>7,649,572</b>
<b>Lease liabilities</b>		
Carrying amount	879,784	999,865
6 months or less	178,694	161,018
Greater than 6 months	701,090	838,847
<b>Total</b>	<b>879,784</b>	<b>999,865</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 Canada and from commercial sales currently in the European Economic Area and USA. 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 2024

	2024	Consolidated Entity 2023 Restated
	\$	\$
<b>Cash and cash equivalents</b>		
Carrying amount	35,200,751	31,893,021
6 months or less	35,200,751	31,893,021
<b>Total</b>	<b>35,200,751</b>	<b>31,893,021</b>
<b>Cash held in term deposits</b>		
Carrying amount	148,667,720	124,920,516
6 months or less	65,125,316	77,320,516
Greater than 6 months	83,542,404	47,600,000
<b>Total</b>	<b>148,667,720</b>	<b>124,920,516</b>
<b>Other financial assets (includes trade and other receivables)</b>		
Carrying amount	26,238,297	22,214,646
6 months or less	25,799,352	20,959,240
Greater than 6 months	438,945	1,255,406
<b>Total</b>	<b>26,238,297</b>	<b>22,214,646</b>

Cash at bank and cash held in term deposits 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.

## 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 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. Since 2020, the Company policy is for NED 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.

Of the 2,591,860 Performance Rights on issue on 1 July 2023 which had been previously issued under the 2014 Performance Rights Plan to both KMP and non-KMP employees, 716,932 (27.6%) PRs were deemed to have achieved the performance conditions by the 20 November 2023 vesting date and were exercised. 1,611,678 (72.4%) performance rights were deemed to have not achieved the performance criteria by the vesting date and lapsed.

At the Company's Annual General Meeting held on 31st October 2023, shareholder approved the renewal of the 2014 Performance Rights Plan for a further 3 years. Under the renewed plan, up to a maximum of 2.25% of the Company's issued share capital may be issued as new Performance Rights, 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 at 30 June 2024, 237,250 performance rights issued under the 2014 Performance Right Plan remain outstanding, of which and estimated 200,854 of the PRs (85%) are likely to achieve the underlying performance condition but will not vest until the end of their respecting vesting dates if the employee is still employed at that time by the Company.

The Company, via its wholly owned subsidiary A.C.N. 108 768 896 Pty Ltd, previously acted as trustee for the 2009 Scheme Trust and the 2014 Plan Trust. The entity currently holds NIL shares (2023: NIL shares).

#### The Following Share-Based Payment Arrangements Were In Existence At 30 June 2024

Performance Rights Series	Number	Grant date	Expiry Date	Exercise Price	Fair Value at Grant Date
Issued 16/09/2011	29,082	16/09/2011	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	Between \$0.55 and \$0.72
Issued 5/05/2022	7,500	5/05/2022	20/12/2024	\$ Nil	\$12.87
Issued 29/06/2023	94,500	29/06/2023	30/06/2025	\$ Nil	Between \$9.16 & \$14.26 *
Issued 29/06/2023	135,250	29/06/2023	30/06/2026	\$ Nil	Between \$9.16 & \$14.26 *

\* 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 – 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 05/05/2022	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 option, and the risk free rate used in the pricing model is assumed to be the yield on ranging from 1 year to 10 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

**For Performance Rights Issued in 2020 to 2023** 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 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 – 2023**

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	-	-	-	38,333	-	38,333
Issued 26/08/2020	1,513,750	-	-	-	1,513,750	227,000	1,286,750
Issued 24/12/2020	132,500	-	-	-	132,500	35,341	97,159
Issued 26/08/2021	731,924	-	-	(49,564)	682,360	156,090	526,270
Issued 05/05/2022	22,500	-	-	(15,000)	7,500	-	7,500
Issued 29/06/2023	-	255,750	-	-	255,750	-	255,750
<b>Total</b>	<b>2,439,007</b>	<b>255,750</b>	<b>-</b>	<b>(64,564)</b>	<b>2,630,193</b>	<b>418,431</b>	<b>2,211,762</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 option, and the risk free rate used in the pricing model is assumed to be the yield on ranging from 1 year to 10 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

**For Performance Rights Issued in 2020 to 2023** 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 the 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	
	2024	2023
	\$	\$
<b>Assets</b>		
Current assets	184,283,878	152,351,411
Non-current assets	55,207,108	47,683,856
<b>Total assets</b>	<b>239,490,986</b>	<b>200,035,267</b>
<b>Liabilities</b>		
Current liabilities	18,960,091	19,899,692
Non-current liabilities	2,420,996	2,785,053
<b>Total liabilities</b>	<b>21,381,087</b>	<b>22,684,745</b>
<b>Equity</b>		
Issued equity	168,802,380	151,849,375
Share-based payments reserve	1,198,628	19,370,046
Accumulated losses	48,108,891	6,131,101
<b>Total equity</b>	<b>218,109,899</b>	<b>177,350,522</b>
<b>Financial performance</b>		
Net profit for the year	39,507,563	32,720,668
<b>Total comprehensive income</b>	<b>39,507,563</b>	<b>32,720,668</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 2024 and 2023.

**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 2024 and 2023.

**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 28<sup>th</sup> August 2024, the Board of Directors declared a fully franked dividend of \$0.05 per ordinary share; and

**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 2024

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 year commencing on or after 1 July 2023:

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	-	100%	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

### 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 (AASB10).

#### 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 2024 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.
- 3) the audited remuneration disclosures set out in pages 87 to 114 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 2001.
- 5) the consolidated entity disclosure statement on page 146 is true and correct.

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



Dr. Philippe Wolgen, MBA, MD

Director

Dated this 29<sup>th</sup> day of August, 2024



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## 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 2024, 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 2024 and of its performance for the year ended on that date; and
- b complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

### Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report of the current period. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

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### Key audit matter

### How our audit addressed the key audit matter

#### Share-Based Payments (Note 21)

The Group has material share-based payment arrangements in place for key management and employees, with the expense for the year being \$6,107,272 (2023: \$8,989,788).

These arrangements include a combination of both market and non-market conditions, with the expense being incurred during the year being heavily impacted by the probabilities determined by management of the specific performance milestones being met, which contain a high degree of judgement.

Under AASB 2 *Share-Based Payments*, management are required to value the performance rights and assess the expected vesting date for achievements of the milestones.

This area is a key audit matter due to the degree of judgement required in valuing the performance rights, as well as determining estimates of the vesting dates, relating to both the probability and likely timing of achieving specific non-market conditions.

Our procedures included, amongst others:

For newly issued performance rights:

- Reviewing the relevant agreements to obtain an understanding of the contractual nature of the share-based payment arrangements;
- Obtaining management's option valuations and associated share-based payment support;
- Utilising our internal valuation specialist to review the valuation performed by management's expert;
- Reviewing management's determination of fair value of the share-based payments issued, considering the appropriateness of the valuation model used and assessing the valuation inputs; and
- Holding discussions with management to understand the share-based payment arrangements in place.

For both newly issued and existing performance rights:

- Evaluating management's assessment of the likelihood of meeting the performance conditions attached to the share-based payments;
- Assessing the allocation of the share-based payment expense over the relevant vesting period (and the appropriateness of the vesting period);
- Evaluating management's forecasts to validate consistency of vesting dates for performance milestones;
- Determining whether performance rights cancelled or lapsed during the year have been correctly accounted for; and
- Assessing the adequacy of the disclosures in the financial report.

### Information other than the financial report and auditor's report thereon

The Directors are responsible for the other information. The other information comprises the information included in the Group's annual report for the year ended 30 June 2024 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.

Grant Thornton Audit Pty Ltd

#### 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: [http://www.auasb.gov.au/auditors\\_responsibilities/ar1\\_2020.pdf](http://www.auasb.gov.au/auditors_responsibilities/ar1_2020.pdf). This description forms part of our auditor's report.

#### Report on the remuneration report

##### Opinion on the remuneration report

We have audited the Remuneration Report included in pages 87 to 114 of the Directors' report for the year ended 30 June 2024.

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Limited, for the year 30 June 2024 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, 29 August 2024

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 2024, I declare that, to the best of my knowledge and belief, there have been:

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

Grant Thornton Audit Pty Ltd  
Chartered Accountants

M A Cunningham  
Partner – Audit & Assurance  
Melbourne, 29 August 2024

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# SHAREHOLDER INFORMATION

AS AT 15 AUGUST 2024

Additional information as at 15 August 2024 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	4,282	1,273,323	2.54
1,001-5,000	1,024	2,336,641	4.67
5,001-10,000	160	1,188,167	2.37
10,001-100,000	170	4,316,697	8.62
100,001 & Over	26	40,962,952	81.80
Total	5,662	50,077,780	100.00

### B. SHAREHOLDINGS HELD IN LESS THAN MARKETABLE PARCELS

Total	Minimum parcel size	Holders	Units
Minimum \$500.00 parcel at \$13.96 per unit	36	627	11,049

### C. SUBSTANTIAL SHAREHOLDINGS

Name	No. Ordinary shares & American Depository Receipts
The Bank of New York Mellon Corporation <sup>1</sup>	4,296,472
Dr Philippe Wolgen <sup>2</sup>	3,425,222
Ender 1 LLC <sup>3</sup>	2,340,824

- As disclosed in substantial holder notice dated 24 May 2022.
- As disclosed in director's interest notice dated 27 November 2023. Actual shareholding on 15 August 2024 is 3,425,222.
- As disclosed in substantial holder notice dated 16 September 2013. Actual shareholding on 15 August 2024 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) Ltd	10,225,972	20.42
2.	BNP Paribas Nominees Pty Ltd ACF (Clearstream)	5,685,193	11.35
3.	BNP Paribas Nominees Pty Ltd	4,988,645	9.96
4.	J P Morgan Nominees Australia Pty Limited	3,629,550	7.25
5.	Dr Philippe Jacques Wolgen	3,425,222	6.84
6.	Citicorp Nominees Pty Limited	3,416,310	6.82
7.	Ender 1 LLC	2,590,824	5.17
8.	BNP Paribas Nominees Pty Ltd (IB AU Noms Retail Client)	2,207,904	4.41
9.	HSBC Custody Nominees (Australia) Ltd A/C2	922,480	1.84
10.	Emilino Group Pty Ltd (Emilino Super Fund)	601,447	1.20
11.	National Nominees Limited	548,778	1.10
12.	Mr Darren Michael Keamy	362,890	0.72
13.	Dr Mark Edwin Badcock	346,772	0.69
14.	Mr David William Trevorrow	229,600	0.46
15.	BNP Paribas Nominees Pty Ltd (Agency Lending A/C)	229,044	0.46
16.	Dr Dennis Wright	188,812	0.38
17.	Mr David John Lewis	185,000	0.37
18.	Mr Trent Sheldon Redding	177,370	0.35
19.	Rusty Hammer Pty Ltd (Archipelago Holdings SF A/C)	150,722	0.30
20.	Mr Simon John Bown	146,000	0.29
<b>Totals: Top 20 holders of ordinary fully paid shares (total)</b>		<b>40,258,535</b>	<b>80.39</b>
<b>Total remaining holders balance</b>		<b>9,819,245</b>	<b>19.61</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, 2024:

Nil.

**7 – DIRECTORY**

**Non-Executive Chair**

Prof. Jeffrey Rosenfeld.

**Non-Executive Directors**

Brenda Shanahan, Dr Karen Agersborg, Susan Smith.

**Managing Director And Chief Executive Officer**

Dr Philippe Wolgen.

**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

**8 – ANNUAL GENERAL MEETING**

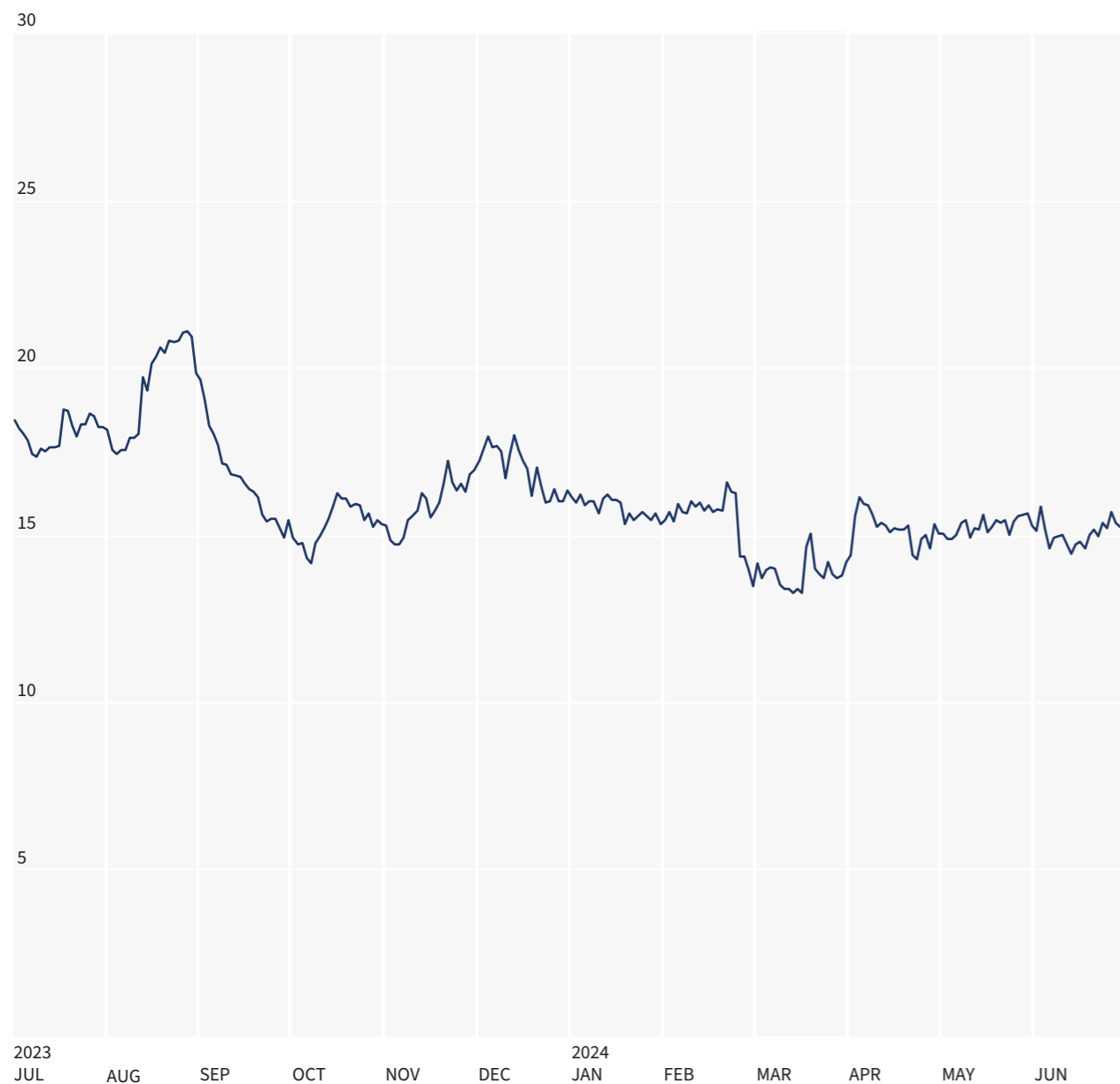
CLINUVEL PHARMACEUTICALS LTD (“Company”) provides notice for its 2024 Annual General Meeting (AGM) of shareholders, which is scheduled to take place on Wednesday 16 October 2024 commencing at 10.00 am (AEDT).

The Notice of Meeting will be lodged with the ASX no later than Friday 13 September 2024. Details in relation to the AGM, including shareholder participation, will be included in the Notice of Meeting and accompanying materials.

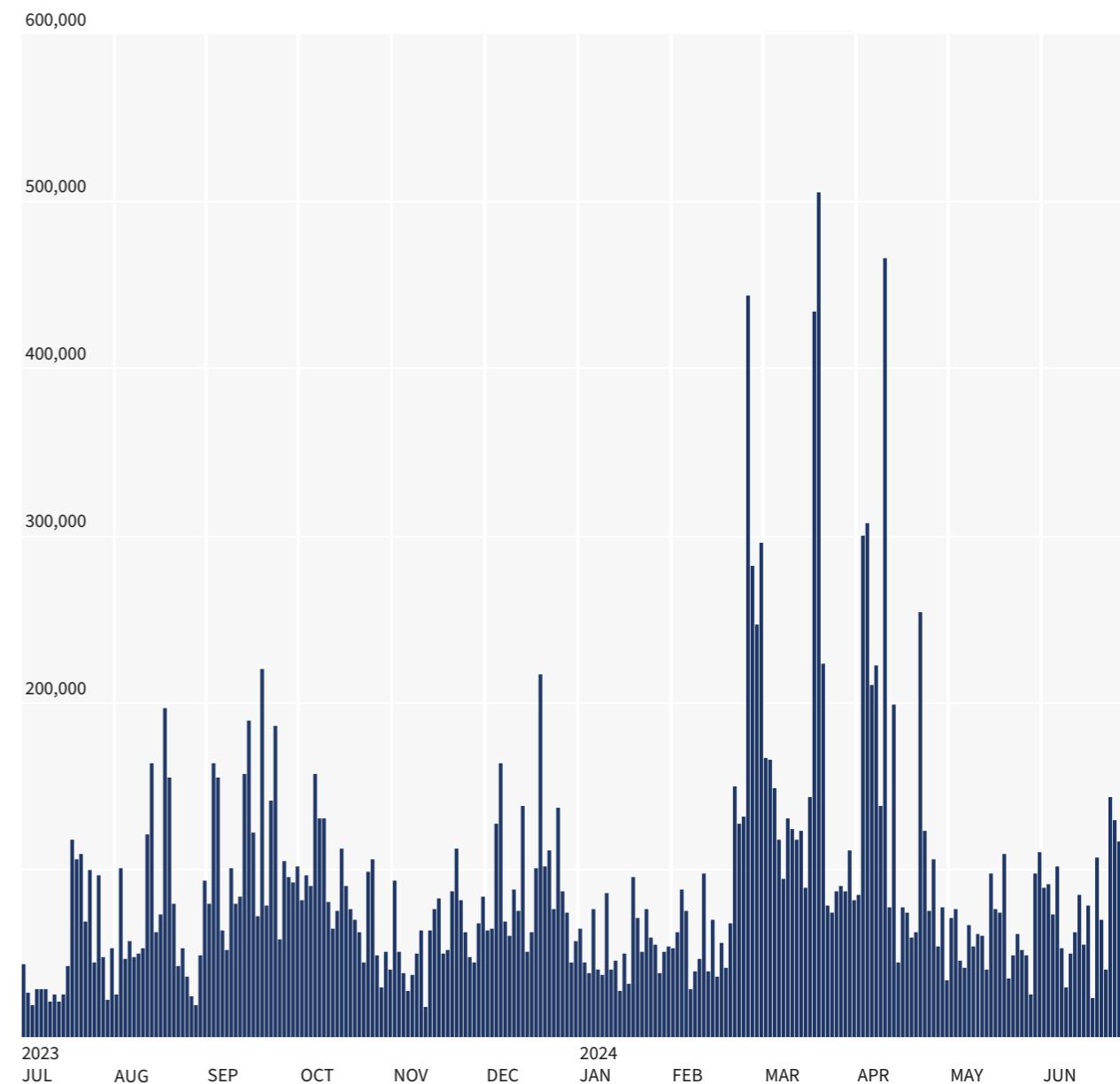
In accordance with ASX Listing Rule 3.13.1, the Closing Date for receipt of Director nominations is Thursday 5 September 2024.

# MARKET PERFORMANCE

ASX:CUV – Share Price (A\$)



ASX:CUV – Daily Trading Volume (No.)





# GLOSSARY

## Alpha-melanocyte stimulating hormone ( $\alpha$ -MSH)

A peptide hormone which activates or stimulates the production and release of (eu)melanin in the skin (melanogenesis).

## Dermatocosmetics

Specially formulated products designed to assist skin health with a focus on anti-ageing, and repair and regeneration of the skin. Dermatocosmetics 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 USA'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 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.



“Each new situation requires  
a new architecture.”

*Jean Nouvel*

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