

CLINUVEL PHARMACEUTICALS LTD

A.B.N. 88 089 644 119

1. Reporting period: 1 July 2022 to 30 June 2023.

Previous corresponding period: 1 July 2021 to 30 June 2022.

2. Results for announcement to the market.	Percentage change to 2022	Amount (A\$)
2.1 Revenues from ordinary activities.	Increased 19%	To 78,321,318
2.2 Profit from ordinary activities before tax attributable to members.	Profit has increased 33%	To 45,578,723
2.3 Net profit for the period attributable to members.	Profit has increased 47%	To 30,604,566
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: 06 September 2023.		
2.6 The CLINUVEL PHARMACEUTICALS LTD audited Annual Report for the year ended 30 June 2023 accompanies this announcement. Additional Appendix 4E disclosure requirements, including the Review of Operations and Financial Condition 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:		

3. Refer to the Attachment to Appendix 4E for the Statement of Profit or Loss and Other Comprehensive Income together with notes to the statement.

4. Refer to the Attachment to Appendix 4E for the Statement of Financial Position together with notes to the statement.

5. Refer to the Attachment to Appendix 4E for the Statement of Cash Flows together with notes to the statement.

6. Refer to the Attachment to Appendix 4E for the Statement of Changes in Equity together with notes to the statement.

7. The Directors have declared a fully franked final dividend of \$0.05 per ordinary share to be paid on 20 September 2023.

8. No dividend reinvestment plan.

9. Net Tangible Assets per Security for Year Ended	Net Tangible Assets per Security for Year Ended
30 June 2023: \$3.290	30 June 2022: \$2.504

10. The control of entities which had control gained or lost: N/A

11. N/A

12. No other significant information.

13. Foreign entities: 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)

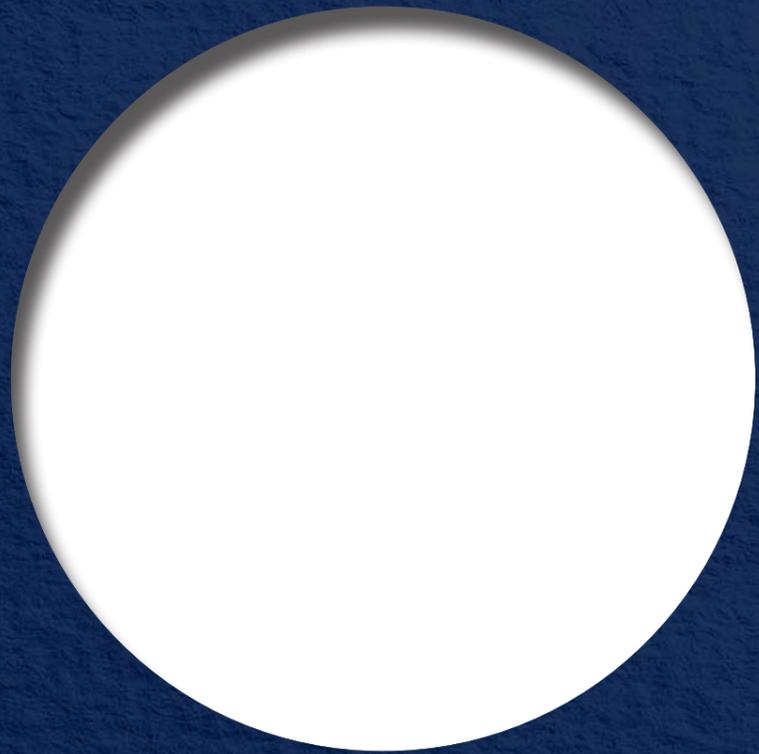
14. COMMENTARY OF RESULTS: Commentary in respect of the financial results is provided in the Operating and Financial Review of the attached Annual Report.

ANNUAL REPORT 2023



CLINUVEL

PHARMACEUTICALS LTD



“A smooth sea never made
a skilled sailor”

Franklin D Roosevelt



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NAVIGATING DIVERSIFICATION ON TURBULENT WATERS

The ocean is vast and unpredictable, yet it supports a diverse array of life. CLINUVEL is navigating turbulent waters with a committed team to diversify the Group in reaching multiple patient groups, and underserved populations.

During the financial year ending 30 June 2023 (FY2023), CLINUVEL continued to steer a defined course to maintain the commercial distribution of SCENESSE® (afamelanotide 16mg) for patients with erythropoietic protoporphyria (EPP). The Company's melanocortin drug portfolio has expanded, to include PRÉNUMBRA® Instant and NEURACTHEL® Instant, to provide new treatment options for a range of central diseases. The expanded clinical program was advanced, specifically in DNA Repair, vitiligo, variegate porphyria, and arterial ischaemic stroke.

CLINUVEL also started translation of its technological know-how to a non-pharmaceutical sector. The first PhotoCosmetic product CYACËLLE, was launched in a pilot setting to targeted audiences in need of polychromatic protection from Ultraviolet (UV) and High Energy Visible (HEV) light. The overall plan is to launch a number of product ranges belonging to PhotoCosmetics, with the innovative melanocortin based products to assist DNA repair and MSH-response for risk-free bronzing.

FY2023 marks the seventh consecutive year of positive revenues growth, net cash inflow and profitability, and the declaration of a sixth consecutive annual dividend. The balance sheet has been bolstered by the highest cash reserves achieved in the history of the Company. Like the directional movement of a strong ocean current, this dynamic financial performance underpins CLINUVEL's ability to advance its diversification initiatives. The Company's expansion trajectory will continue into FY2024 and beyond to advance our objective to become an integrated, diversified, and sustainable pharmaceutical group.



KEY ACHIEVEMENTS



More SCENESSE® treatment access changing lives

Ongoing supply of SCENESSE® to EPP patients

Growth in treatment centres, patients, prescriptions filled

Special access program launched in Canada

Application submitted for label expansion to treat adolescent EPP patients (aged 12–17 years)

Start of adolescent patients treated



Melanocortin portfolio

PRÉNUMBRA® Instant
Developed, first use in second stroke study

NEURACTHEL® Instant
Instant formulation of ACTH progressed to cGMP manufacture of validation batches and preparation of Drug Master File



Afamelanotide in the clinic

DNA Repair

- Control study of healthy volunteers completed
- Two studies in xeroderma pigmentosum (XP) underway
- Initial results of one XP study presented at the 2023 American Academy of Dermatology Meeting (reduction in key markers of photodamage)

Arterial Ischaemic Stroke

- PRÉNUMBRA® study underway

Repigmentation

- Vitiligo monotherapy study underway
- Large combination therapy study in planning

Variegate Porphyria

- Study underway



PhotoCosmetics

First polychromatic product CYACÉLLE, pilot launched 1 March (EU)

Focus on highest risk audiences

Three product ranges in development – radiant polychromatic protection, DNA-Repair and melanogenesis



Financial performance

24% growth in revenues

Seventh consecutive annual profit

Sixth consecutive annual dividend declared

Controlled increase in expenses

Continued increase in cash reserves



Active communication of CLINUVEL's story

57 company announcements

6 Soirées and Investor Briefings

6 Investor Conferences

2 Strategic Updates – V and VI

CUVA and CUVIP campaigns launched

Targeted social media posts

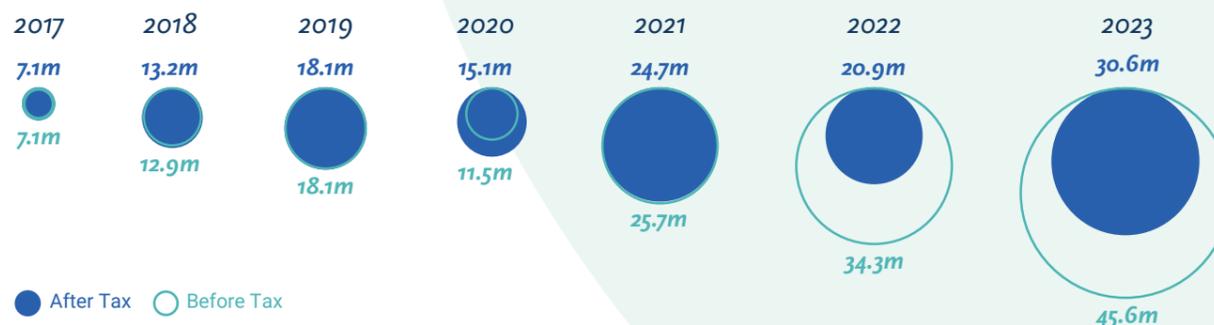
FINANCIAL HIGHLIGHTS

Seven years of consecutive annual growth in revenues, profit, and cash reserves



Revenues & expenses (A\$m)

Revenues grew by 24% whilst expenses rose by 15% in FY2023. The seven year compound annual growth rate of revenues of 42% exceeded by more than doubled growth of expenses of 20%.

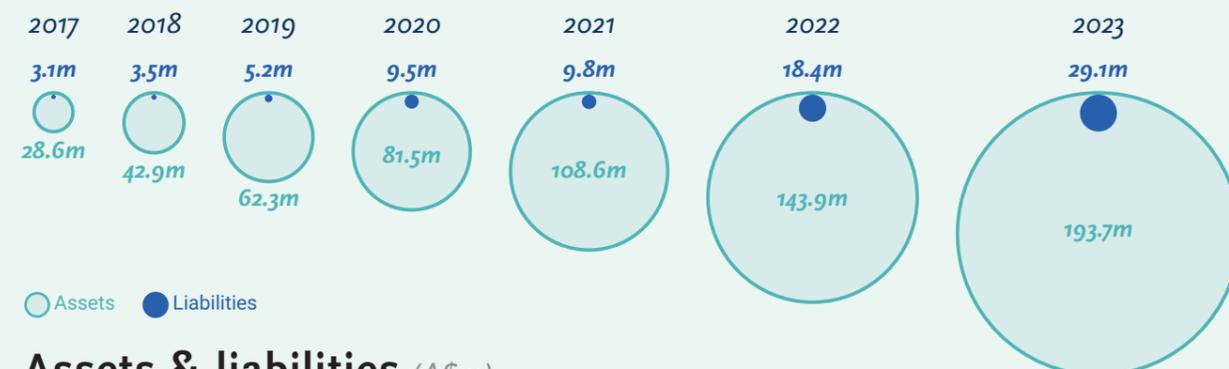


Net profit (A\$m)

Profits increased before and after tax by 33% (to A\$45.6 million) and 47% (to A\$30.6 million). The seventh consecutive annual profit is the highest achieved to date.

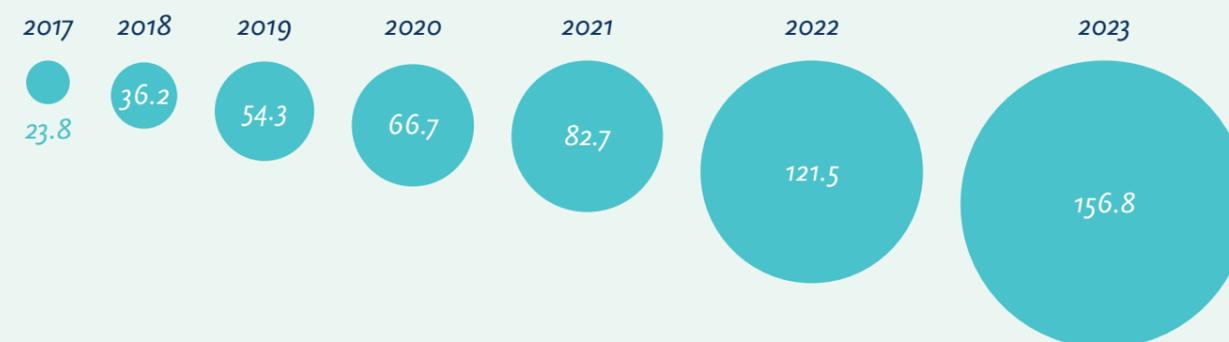


Key indicators of high performance



Assets & liabilities (A\$m)

The balance sheet strengthened again in FY2023, with an increase of 31% in net assets.



Cash & cash equivalents (A\$m)

A solid rise of 29% in cash reserves to A\$157 million, further consolidating the capacity to self-finance the Group's initiatives.

LETTER FROM THE CHAIR

CLINUVEL is staying the course to diversify the business with self-reliance and determination in the face of ‘stormy conditions’.

Dear Shareholders

Charting the Course

At times that the Company is performing, one can only be proud to Chair the CLINUVEL Group as it continues to navigate a pre-planned strategic course with full commitment from all teams.

A difficult operating environment continued to challenge most life science companies during the past year, and it is possible that we will face more ‘stormy conditions’. Inflation remained higher than the range targeted by monetary authorities, seeing interest rates increase with a consequent impact on the pace of economic growth around the world. Ongoing global tensions contributed to uncertainty in the markets, as securing timely supply remained challenging.

Expansion Strategy Achieving Results

CLINUVEL entered a phase of expansion – growing the distribution of SCENESSE® for EPP patients, expanding a melanocortin product portfolio, expanding a clinical program, and carefully treading the field of PhotoCosmetics. By doing so, we launched a rare initiative amongst pharmaceutical companies. We are transforming the business to a diverse pharmaceutical with multiple products for a range of patient and general population needs. This strategy is an exciting one and it is unfolding in front of us.

The year has been marked by advances in the development of new products, particularly PRÉNUMBRA® Instant, which is first being evaluated in the second clinical study in arterial ischaemic stroke, and the pilot launch in March 2023 of CYACÉLLE, the Group’s first PhotoCosmetic product. Given the relevance of the DNA Repair program to people with a deficiency in their natural skin repair processes, I was pleased to see the initial results in xeroderma pigmentosum, showing a reduction in key markers of photodamage; these were presented by expert opinion leaders at the 2023 American Academy of Dermatology Meeting.

The financial result for the year is excellent, with continued growth of revenues, net cash flow, and profit. The diligence and work by Mr Keamy and the finance team in the management and support of controlled fiscal operations should be acknowledged and received with appreciation. It is also my pleasure as Chair of the Board to declare the sixth consecutive annual dividend providing returns to shareholders. In parallel, we continue to increase our financial position, enabling us to pursue long-term plans for the business while shielding the Company from short-term tumult.

Governance of the Board

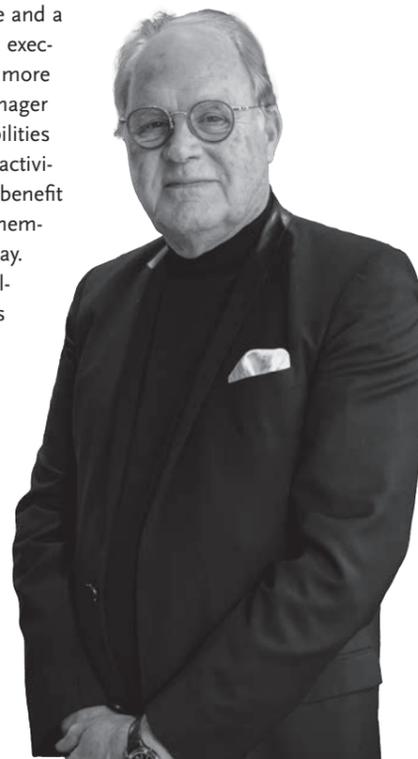
The Board governs the adherence of the Group to its defined strategy and, as intimated above, we are very satisfied with progress. The Board is also accountable to ensure CLINUVEL exhibits responsible and ethical conduct in the pursuit of its wide ranging activities. As Chair, I provide keen support to CLINUVEL’s Environmental, Social and Governance (ESG) agenda and can report that we maintained positive metrics and advanced key initiatives in this area during the year. Whilst this is detailed in a feature on this report, I can highlight:

- the ongoing safety profile of our products remains positive;
- no breaches of the Group’s code of conduct or whistleblower reports;
- maintenance of peer leadership on multiple measures of diversity; and
- initiation of a new process to assess the adherence of key suppliers to responsible ESG conduct.

Management

CLINUVEL distinguishes itself by an executive management team that has developed together over a long period. It is testament to Dr Wolgen’s leadership that the core team of executives has been kept in place for more than a decade and a half, while he has overseen the executive expansion to nine, with more to come. Each executive manager is allocated specific responsibilities which collectively embrace all activities of the Group. I regard the benefit of the growing tenure of the members of the Board in a similar way. The Directors’ intimate knowledge of the Group’s activities and joint view on building the Group for the future gives us the backbone of success.

Despite intense competition for talent, we have been able to build out our team across several global offices in the UK, Europe, USA, Singapore, and Aus-



‘The financial result for the year is excellent, with continued growth of revenues, net cash flow, and profit.’



tralia. We offer a balanced mix of remuneration and workforce conditions to prevailing candidates. We have found that talented people are interested in playing a role in the fulfilment of CLINUVEL’s mission and developing their careers in ways not readily available in other larger organisations. I witness a focused, motivated, and well co-ordinated team, notwithstanding the fast growth.

Executive Remuneration

I specifically want to mention that the Board is acutely aware that executive agreements with Mr Keamy and Dr Wolgen expire on 30 June 2024 and 2025, respectively. The executive remuneration outlined in this report is designed to hold and incentivise executives to this term.

With regard to retaining all executives, a new performance rights plan is due at the end of a four-year cycle and seen as essential. The Board is conscious of the need to search globally to secure a new CEO post 30 June 2025 and wishes to assure shareholders that we and Dr Wolgen are committed to an orderly and thorough transition to a new CEO in the 2026 financial year, such that no disruption will take place.

Our view is that it would be a real loss to the business if both executives would leave before the Group would have achieved its diversification plan of multiple products, markets, and communication strategies; therefore, I am spending much time seeking wider consultation on what is best for CLINUVEL to take away any uncertainty our existing and new shareholders may have on succession.

Outlook

Comment is due first on the operating environment and then on the Group’s initiatives. We look at markets exhibiting increasingly positive sentiments as the rate of inflation and interest rates

abate, and the pace of economic growth starts to improve. The improved conditions will benefit CLINUVEL’s continued advance of key initiatives underway. The positive plans for 2024 and beyond are outlined in this report and contribute collectively to the ongoing transformation of the Group. The effective and wider communication of CLINUVEL’s story and trajectory is the mission of the Communications, Branding & Marketing team, as well as Investor Relations.

Appreciation

I am conscious of the support from fellow shareholders. I hope the dividend you will receive in September 2023 is welcomed in this spirit. As a shareholder, I take encouragement from the rise of 20% in the Company’s share price over the year, and over 60% in the five years, to 30 June 2023. I remain optimistic that the foundations of incremental value will ultimately be reflected in the share price.

I wish to also thank all stakeholders for their support. I especially want to comment on our patients: your response to our treatments is the sole reason we continue to operate, while your support is a driving motivation for the CLINUVEL team. The past year, we demonstrated that our commitment to ensure uninterrupted treatment is firm and unwavering.

Finally, I thank members of the Board for their support during the year, and the management and entire CLINUVEL team for their diligence and achievements.

I wish you all well as we continue navigate towards 2024 and beyond to achieve our objectives.

Willem Blijdorp
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 2023, 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/people/#corporate-governance>.

VISION

Delivering innovative solutions for unmet patient and healthcare needs.



MISSION

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 practise. 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 of 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

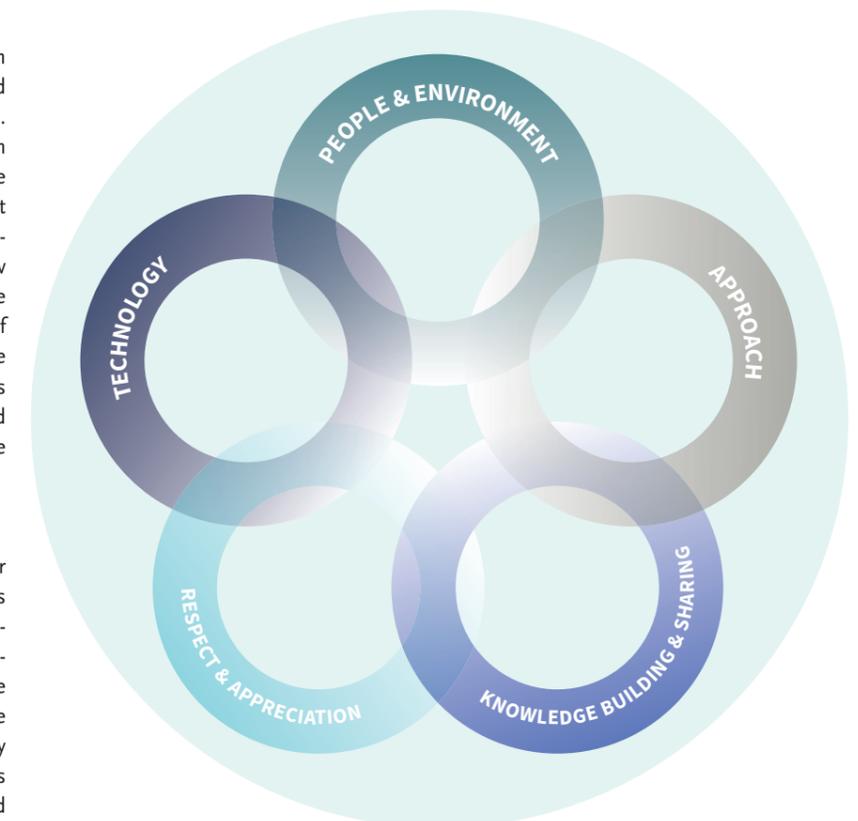
We create, develop, advance, and offer pharmaceutical and healthcare products which are driven by medical need, consumer demand, and a lack of available solutions. Our technologies aim to add value beyond existing offerings. We acknowledge that new technologies require regulatory environments to be primed 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 knowhow continuously and establish a learned community. Collaboratively we seek to excel in a multifaceted field to arrive at scientific breakthroughs.

Respect & Appreciation

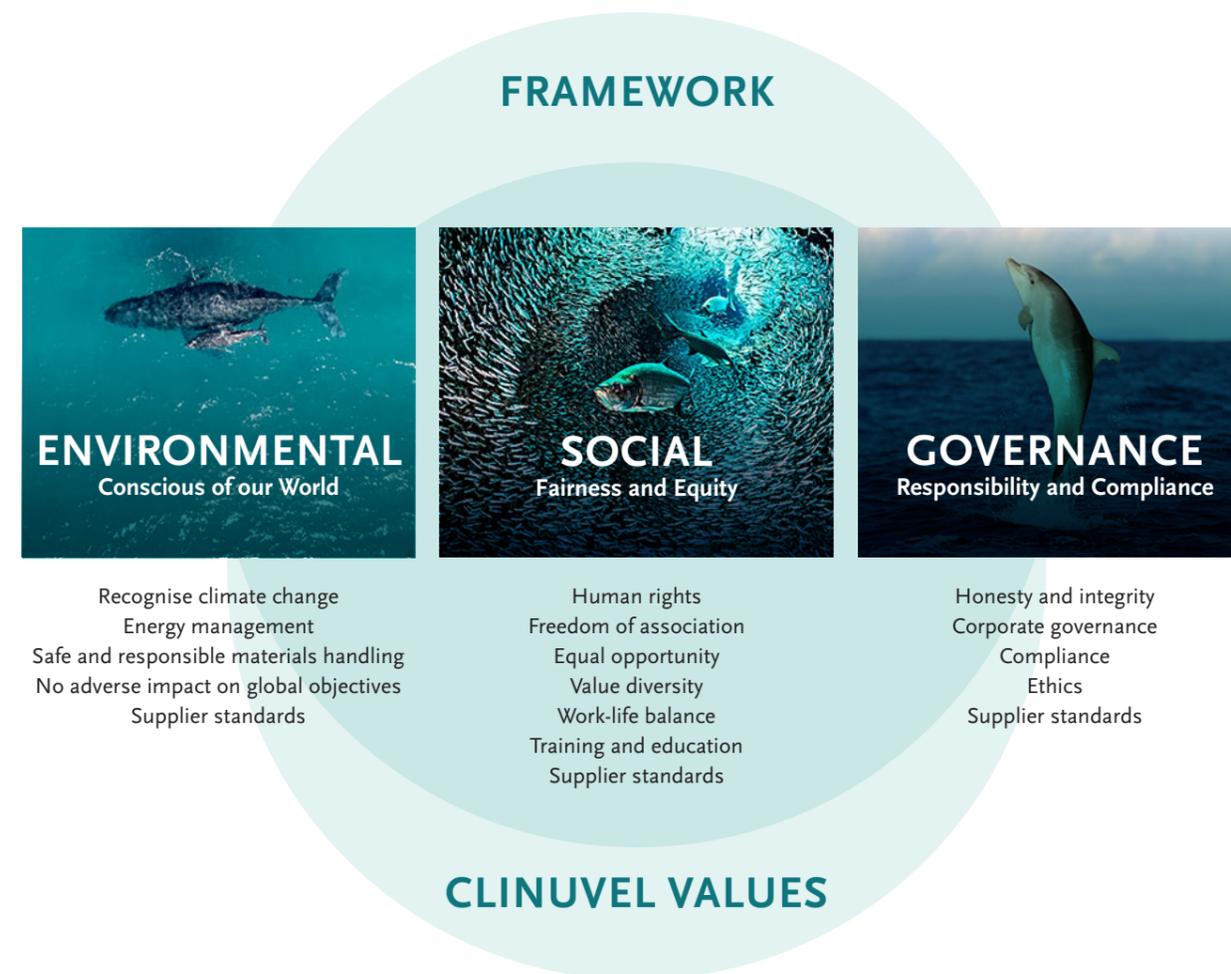
We are conscious of the privilege to be productive during our professional lives. We appreciate the significance of being able to function in good health and we value this gift every day. We aim to be sincere in our approach and represent data and facts. We act respectfully and do not harm others. We 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.



CLINUVEL'S ESG PRACTICES

CLINUVEL is committed to an annual statement of its Environmental, Social, and Governance (ESG) practices. In order to provide all stakeholders insights as to the Company's approach to and management of ESG issues, this feature covers:

- the Company's ESG framework;
- performance against a range of ESG measures, particularly in the social and governance fields; and
- a new initiative to assess the ESG practices of key suppliers.



CLINUVEL is a responsible adherent to the United Nations (UN) tenets on ESG practices. The UN's ten universal principles guide our approach to ESG in the areas of human rights, labour standards, environmental responsibility, and anti-corruption'. CLINUVEL's ESG framework is detailed above, noting the key focus in each of the ESG fields are underpinned by CLINUVEL's values, as detailed on page 13.

Environment

CLINUVEL is conscious of the impact of the activities of humanity on the environment and takes a responsible approach to managing its impact on the environment. CLINUVEL embraces the UN definition of sustainability to meet the needs of the present without compromising the ability of future generations to meet their own needs.

Currently, CLINUVEL's activities are conducted by a workforce of less than 100 and does not manufacture its products. The direct impact of CLINUVEL's activities on the environment is therefore assessed as low. Reflecting this, CLINUVEL's focus is on qualitative initiatives to manage its impact on the environment. Management is accountable to ensure environmental responsibility across all activities and specifically:

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

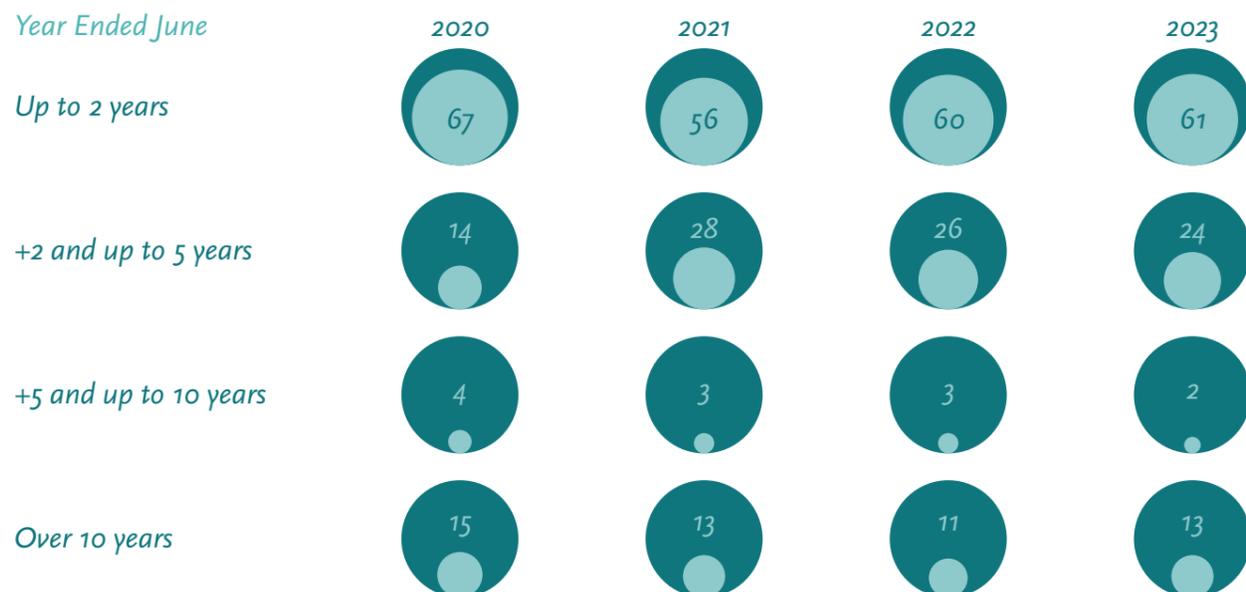
- of current Good Manufacturing Practice (cGMP), and responsible ESG practices in general;
- conservation of resource and energy use in each of our offices;
- minimisation and management of waste, particularly in our Singapore based Research, Development & Innovation Centre; and
- responsible product packaging.

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

In addition to these initiatives, a split home / office working week in most locations serves to minimise the carbon footprint of employees. Whilst we are now travelling more frequently to see stakeholders in person, responsibility is vested in senior management to review and approve travel within countries of operation and internationally, to ensure sufficient tangible benefits are realised.

Quantitative measures or metricated targets are not set at this time but will be assessed and introduced as the scale and size of the business increases in the future. Given its low environmental

Year Ended June



Employee tenure (% of total employees)

impact, CLINUVEL has received support for this approach from a range of investors, including those institutions with an ESG focus. We are aware of plans for mandatory climate-related financial disclosure requirements by companies in Australia. If implemented, they would be phased-in from 2024/25 to 2027/28 based on three groupings of companies meeting different reporting thresholds (two out of three measures of size of employees, assets and revenues)².

Social

CLINUVEL has no adverse impact on UN social objectives. Its key social contribution is the development and distribution of products for unmet patient and healthcare needs. The paramount focus of CLINUVEL in terms of social responsibility is on the safety of its products and the wellbeing of patients and personnel.

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

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

Afamelanotide, the active pharmaceutical ingredient in SCENESSE®, the Company's first therapeutic, has a positive safety record from over 14,500 administrations over more than one and

a half decades. A rigorous pharmacovigilance program is also maintained and reported to global regulatory authorities to confirm the real-world experience treating adult erythropoietic protoporphyria (EPP) patients with SCENESSE®.

CLINUVEL respects the human rights of employees and freedom of association and exceeds the minimum labour standards expected of an employer. The Company's focus is to provide employees with

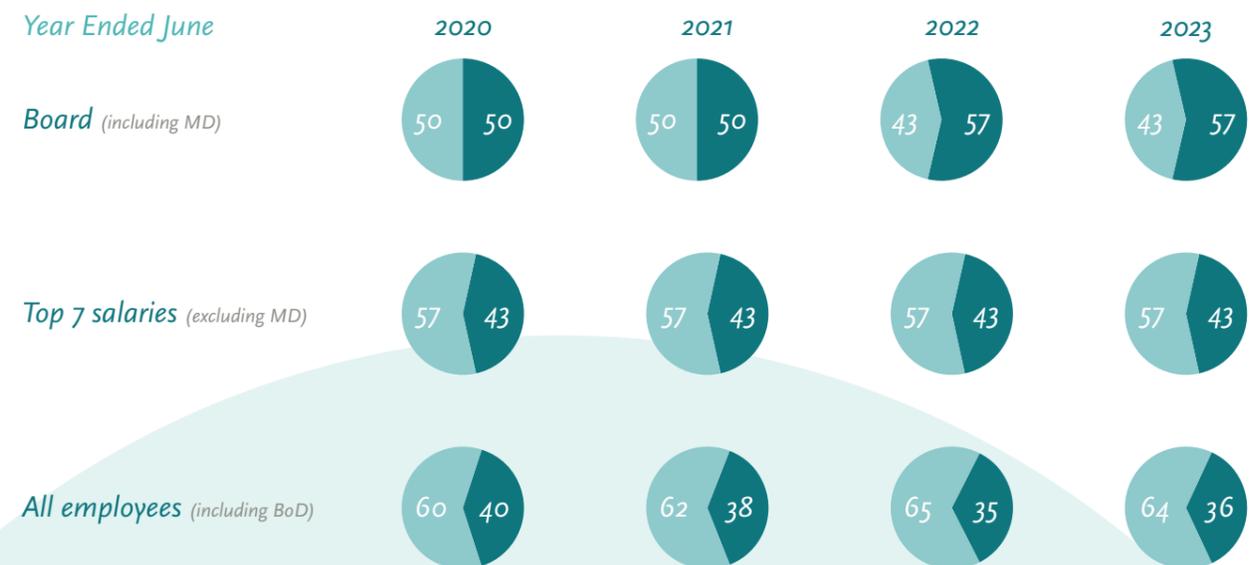
- 1) a safe, positive, and flexible working environment to support wellbeing, active interaction and productivity, and
- 2) competitive performance-based remuneration and employment benefits that enable financial independence and acceptable living standards. In addition, CLINUVEL provides the opportunity for positive career development, ensuring succession planning rewards performance and endeavour.

Reflecting the safe working environment provided, there was one minor injury and no time lost from workplace accidents in FY2023 (Nil in FY2022).

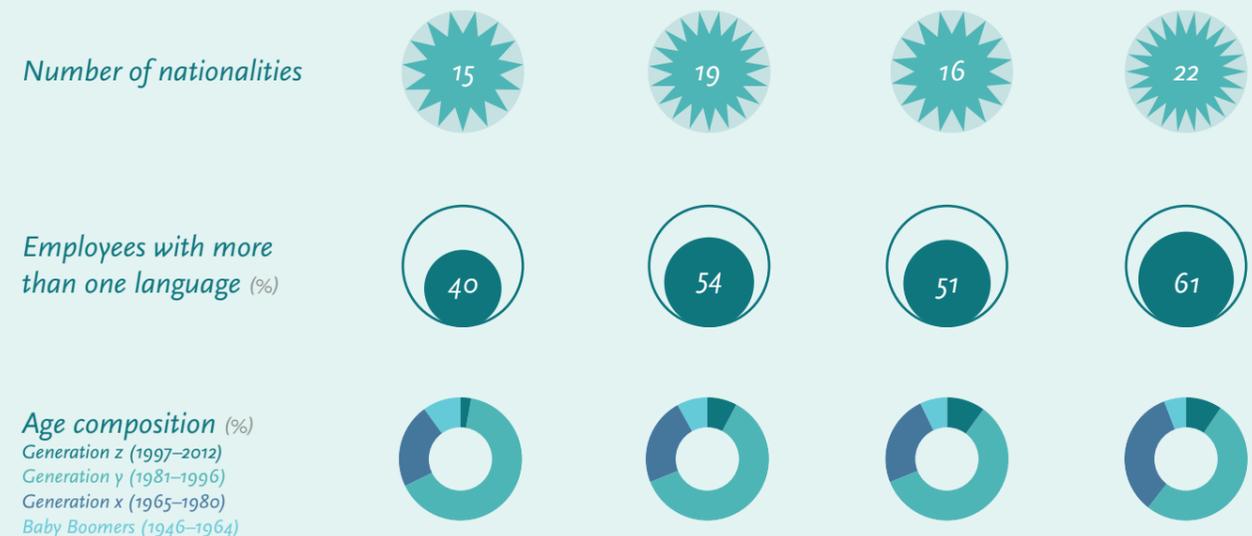
CLINUVEL has been able to attract new employees in a competitive market for talented people to support its growth and expansion. The number of employees has increased by 95% over the past four years. Reflecting the growth in employees, the proportion of employees with tenure of less than 2 and 5 years has averaged around 60% and 25%, respectively, over the past two years, with most of the remainder of employees being with the Company for more than 10 years.

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

Year Ended June



Diversity (% female/male)



external stakeholders. Diversity in the workforce is a key indicator of an equitable and fair approach to employees. Diversity is monitored by the Board and is a key performance responsibility of the Managing Director. CLINUVEL takes pride in its leadership on diversity which is represented in gender, age, nationality, and use of languages.

CLINUVEL recruits new employees from as diverse a pool of candidates as possible and has been able to maintain its diversity as it grows and expands.

- The Company's leadership in gender diversity is clear with:
- the 43% female quotient of the Board of Directors exceeding the Australian Securities Exchange (ASX) minimum expectation of women at Board level of 30% (applicable to all listed companies in the ASX300 Index);

- the majority of the top seven salaried employees (excluding the Chief Executive Officer) are females, exceeding the 40% minimum expected by the ASX; and
- nearly two-thirds of all employees are females.

Multiple nationalities and linguistic abilities underly CLINUVEL's diversity beyond gender. The age composition of employees further highlights the diversity of the CLINUVEL team across seasoned and younger personnel at various stages of their careers. All are committed to develop their skills and work together in a highly collaborative way to achieve the objectives of the Company, noting the ongoing stewardship of the Company is provided by Generation X and Baby Boomers and the more experienced of the Millennial generation.



Governance

The Board endorses the Company's ESG framework and plays a key governance role to ensure ongoing compliance with ESG standards. Monthly reporting of ESG issues by management to the Board was formalised in 2022. This complemented the already heightened appreciation of ESG issues at Board level.

As mentioned above, the Group's values (outlined on page 13) underpin the practices of the Company and its employees and align to key ESG tenets. CLINUVEL has several formal policies which support its adherence to responsible ESG practices. The Corporate Governance Protocol and the annual Corporate Governance Statement set out the code of conduct and ethics and other policies to ensure conflicts of interest are avoided and a culture of honesty and integrity is maintained which concords with the expectation of responsible management of ESG issues.

To extend this point, CLINUVEL adheres to a policy of adequate and correct communication within the Group, stipulating earnest and direct interaction with its staff and management. Human Resource policies provide guidance on conflict resolution and communication strategies to be deployed. CLINUVEL adheres to communication guidelines which promote open dialogue with those who seek to interact with CLINUVEL on relevant matters of business, and those who act fairly and openly. However, to protect the interest of CLINUVEL and the wellbeing of its staff and management, the Group reserves its rights to prosecute to the fullest extent permitted by law those who intend harm and disseminate falsified and untrue statements about the Company and its officers.

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

ture. There were no breaches in the Company's Code of Conduct or Whistleblower reports submitted in FY2023 and up to the date of this Annual Report. CLINUVEL adheres to Disclosure UK, a searchable database which records annual payments and benefits in kind made by pharmaceutical companies to doctors, nurses, and other health professionals, as part of a Europe-wide initiative to increase transparency in the pharmaceutical-health sector.

Assessment of Key Suppliers

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

CLINUVEL's suppliers are considered responsible and active in their practice of ESG. CLINUVEL's practice has been to assess this on an ongoing basis from regular interactions and reviews of relationships. During the past financial year, CLINUVEL initiated a project to develop a new formal process to assess the adherence of our key suppliers to responsible ESG practices. The initial focus is on the largest 25 suppliers based on their ranking in CLINUVEL's annual expenses budget. The process has been finalised and involves scheduled annual reviews by date by management with senior executive sign-off and provision of regular briefings of issues to the Board, in line with the monthly reporting practice formalised in 2022. If the assessment finds areas to rectify or improve, actions are undertaken to discuss them with the supplier and resolve, with formal sign-off by senior executives. This process is effective from 1 July 2023.

1. For details on the UN's ten principles and approach to ESG and sustainability, access to the United Nations website and particularly refer to United Nations Global Compact (2017), Progress Report: Business Solutions to Sustainable Development, and United Nations Global Compact (2014), Guide to Corporate Sustainable Development.

2. Per the Australian Government - Treasury - Government ESG Consultation Paper, June 2023, reporting would commence from 2024/25 for large companies meeting two of three thresholds (over 500 employees, gross assets of at least A\$1 billion or revenue of at least A\$500 million); from 2026/27 for a second group of companies (meeting two of three thresholds - over 250 employees, gross assets of at least A\$500 million or revenue of at least A\$200 million); and from 2027/28 for a third group of companies (meeting two of three thresholds - over 100 employees, gross assets of at least A\$25 million or revenue of at least A\$50 million).

SUMMARY

The Company's ESG practices are responsible and sound. Performance in ESG management, particularly against key social and governance measures, has been maintained in FY2023. The new initiative to assess the adherence of key suppliers to ESG practices is a significant step forward to encourage and support wider responsibility in each of the ESG fields. The Company's commitment is to continue to evolve and improve ESG practices as an integral part of its focus on continuous improvement and in line with the Company's growth and expansion.



LETTER FROM THE MANAGING DIRECTOR

The most successful financial year in CLINUVEL's history has drawn to a close, and it is apparent that our team's steadfast resolve to advance has not been in vain. Step by step, we are laying the foundation for further growth, independence, and sustainability; our key objectives.

Dear Shareholders

On Course with a Clear Growth Strategy

The business relationship with hospitals and medical centres, our customers, is a central element that has been the constant to the Group's progress. The direct distribution model maintained both in Europe and the United States continued to provide benefits in terms of just-in-time distribution and consistency of supply terms, while direct interface with healthcare customers lay the foundation for future markets we aim to establish.

I must acknowledge the resourcefulness, tenacity, and exceptional efforts of our team, held together by a drive and passion to succeed in uncertain macro environments. The past year, we enhanced our capacity and capabilities, and realised significant growth of personnel. The Group remained on course with a clear growth strategy to become a specialist in the development and use of melanocortins. The Group's strengthened balance sheet indicates that we are well positioned to create further longer-term value for our shareholders.

However, most revealing has been that more patients, and an increasing number of centres, have gained access to SCENESSE®, whereby demand for ongoing treatment remained a key parameter we monitored. We managed to train more medical centres and healthcare providers, providing direct access to drug to our patients, shortening travel time. Feedback from prescribers remained excellent, both on ease of administration of the drug product, efficacy, and safety. In working towards one clinical goal of making medical innovation available, I wish all patients and their families a symptom-free existence enjoying full physical and psychological freedom.

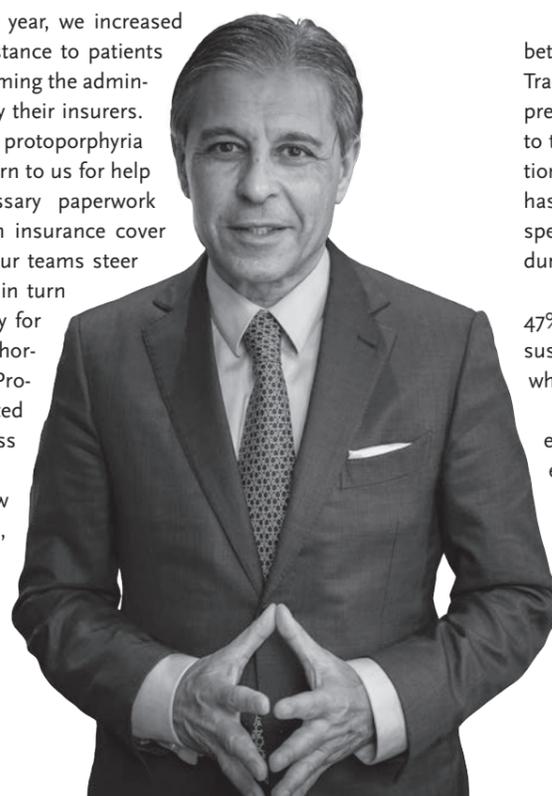
CLINUVEL's future is crystal clear as we are establishing a melanocortin specialty group, based on a core pharmaceutical and a branch into PhotoCosmetics, a specialised consumer market. Our research & development spans three pharmaceutical prod-

ucts (SCENESSE®, PRÉNUMBRA® Instant, and NEURACTHEL® Instant), two formulations (controlled-release, immediate release) to be administered in at least five diseases, and three product lines to consumer markets, specialising in PhotoCosmetics (CYACÉLLE, DNA-assisted repair, MSH-response). As the Group increases in size and functions, the aim is to make each of the new divisions profitable on their own merits, as products and services are added.

Financial Year 2023

At the beginning of the year, we increased the US team, lending assistance to patients who had difficulty in overcoming the administrative burden imposed by their insurers. Since many erythropoietic protoporphyria (EPP) patients frequently turn to us for help in wading through necessary paperwork as a requirement to obtain insurance cover under their existing plan, our teams steer them such that physicians in turn are properly set-up to apply for treatment under Prior Authorization. The Assistance Program in the US has supported US patients in gaining access to a life-altering treatment.

Equally in Europe, we saw a rise in patient numbers, frequency of drug doses, and new centres being trained. In both continents, and without excep-



tion, prescribers are enthused about the drug since their patients benefit from their effective care. At each bimonthly visit, patients, partners, and families give a detailed description of newly found lives, of the ability to participate in daily activities which had been unimaginable. Concurrently, from data obtained we see that the distribution of EPP patients shows a skewness, whereby the pool of longer-term treated patients, between 10 and 15 years, increases year on year. I have particular sympathy for our group of patients, who have literally lived in the dark for the majority of their existence. Facilitating "a full life in the light" for patients is a reward to our entire team, it is the kind of motivation to keep doing what we set out to.

All in all, clinical expansion and increased demand led to a better than anticipated result of 24% increase in global revenues. Tracking annual orders for SCENESSE®, we continued to see US prescribers placing orders during the winter months. In contrast to the belief of payors, porphyria patients need outdoors protection all year round, as the use of the drug in real world conditions has shown, since light source exposure (including the visible spectrum) will trigger phototoxic reactions. Therefore, coverage during winter months appears necessary.

Profits before tax grew by 33%, while net profits after tax by 47%, results far exceeding our expectations, and beating consensus. The Group remained debt free. Net assets increased by 31% while cash reserves rose by 29%.

In keeping with our own projections shared in 2021 of expenses up to A\$175 million over 5 years, we steadily and deliberately increased the rate of reinvestments year on year. For the year, overall expenses increased by 15%, while capital expenditures were made towards facilities at the Singapore RDI Centre. Resources have been made available towards new talent, clinical studies, drug product and research activities.

Among many new staff, I mention the addition of several engineers, a talented medically trained manager, the

Group's first in-house lawyer, new financial staff, a new head of scientific affairs, scientific staff, and an assistant to investor relations in Europe. The Group grew by 19% over the past 12 months, facing difficult labour markets.

Under guidance of Drs Wright and Bilbao, clinical progress was made in the XP-DNA repair program, where first human biopsy results showed novel and promising results. We started a variegate porphyria program, evaluating the effects of afamelanotide in a group of patients with a different variant of porphyria but akin to EPP, but who suffer from high degrees of skin fragility, seen as incapacitating wounds and blisters triggered by light exposure.

With PRÉNUMBRA® Instant, we entered the second afamelanotide product in clinical trials, part of deliberate life cycle management. As we obtained good results from the first clinical trial in ischaemic stroke (CUV801), we introduced this product in a further study (CUV803) exposing mild to moderate, and moderate to severe stroke patients. Our pharmacovigilance team reviewed the first data on safe use of the product, the prerequisite of CLINUVEL's ongoing success, and we are enthused by the clinical reports on the patients.

The scientific team led by Chief Scientific Officer (CSO), Dr Wright and Dr Rizzitelli progressed the manufacturing of NEURACTHEL® Instant, the ACTH product, adding to our suite of melanocortins. Under Good Manufacturing Practices, we manufacture NEURACTHEL® batches for use in a clinical setting.

The backstop was provided by Dr Hamila and her quality and pharmacovigilance team, ensuring that each porphyria patient worldwide was followed up and data captured in a global registry.

Further advancements were made in formulation development at VALLAURIX, our Singaporean facilities, and the first pilot batch of our test product CYACÉLLE, a polychromatic screen, was released on 1st March. Feedback was obtained before engaging in scaled-up commercial manufacturing of a chosen formula-





tion. Aiming to serve high risk populations, we start to realise the ambition to establish a PhotoCosmetic market.

The CBM team grew in number and quality with Mrs Arrom Bibiloni heading the division, providing guidance on global branding and marketing activities for the years to come. While Investor Relations is a separate discipline, we harmonised our communications strategy such that similar messages and news flow to various stakeholders would be ensured; Mr Bull continued the efforts to address domestic and international investors, joined by Mrs Hardy.

The overall responsibility of the global operations was well handled by Mr Hay, while local operations were presided by Mrs Colucci and Dr Teng.

The Immediate Future: 2024-2026

Direction. Often, I am asked to provide more colour on the future of CLINUVEL, its direction and expectations. On various occasions, I have expressed our strategy to build a sustainable and diversified group, containing multiple divisions and attracting diverse skills, turning CLINUVEL into an independent firm. Actually, answers as to the chosen path are found in facts and history, while business execution is multi-pronged and planned for the long haul. Our approach is not axiomatic, but one which has been contemplated for more than a decade of analyses, and one that is within the realm of possibility. It is also apparent that CLINUVEL will be the world's first to launch a PhotoCosmetics product range based on melanocortins.

The prospect of building a house from the brink of bankruptcy to the status of being able to withstand the challenges of time is exciting; many of us see this business case unfolding as a once-in-a-lifetime opportunity, one created out of a unique long-term strategy. What was once a dream has gradually turned into reality.

Let's go back to the start. Mass demand for melanocortins was provoked from 1980 onwards, and markets started to realise the potential to chemically activate skin pigmentation by injection.

Various attempts by venture capitalists and pharmaceutical executives failed, which led to the Company facing insolvency in 2005. The rest is known.

Nevertheless, insistence for melanogenesis, humans' unique defence mechanism to solar radiation, remained high among the widest imaginable audiences, individual and professional investors, banks, and consumers. However, the only strategy to exhaust a regulatory authorisation for afamelanotide – the first systemic photoprotective drug worldwide – and create value had been via a pharmaceutical program spanning nearly two decades of Phase I, II and III trials. We religiously followed a plan based on compelling technology, while preparing for the second part of the business to unfold.

There always remained the realisation that melanocortins, expressed both in brain and skin, actually share neuroendocrine end targets, in simpler terms both organs showing similar cellular responses to these hormones. Logically, our CSO, Dr Wright and technical staff followed a course of developing melanocortins for brain diseases (acute stroke), as well as metabolic afflictions characterised by severe light intolerance, phototoxicity, such as seen in porphyria, and depigmentation – called vitiligo.

Vision. We had long formed the vision to make melanocortins available for broader populations, aiding the repair of DNA-skin damage provoked by UV. Data obtained earlier in the programs drove us to sequentially execute a complex strategy. Besides, the use of melanocortins as a DNA protective agent had always remained a talking point for those seeking bronzing without UV damage. To be able to 'close the scientific loop', we all too well understood that safety of melanocortins used systemically would be the requisite for its later translation into PhotoCosmetic products, hence our decades-long public emphasis on safety, vigilance, and analyses, all pre-empting our greater plans. Regulatory authorities required confirmation from abundant data sets to quell their anxiety about the safety of melanocortins. We are nearing the moment of silencing any longer-term concern of safety

with more than 14,500 doses of SCENESSE® administered, and patients followed-up for 17 consecutive years.

A successful establishment of a cosmetic business within a core pharmaceutical one is unconventional, but in our case makes much sense to progress. Therefore, as a first step, we explored and engaged marketing consultants, advertising agencies, branding and creative professionals, marketers and came to the conclusion that the unique PhotoCosmetic products would be better served by an in-house team of professionals coming from the luxury goods sector, as well as experts in digital analytics. In 2021, we started to form the Communications, Branding & Marketing (CBM) team in anticipation of the launch of PhotoCosmetics. In the year past, we attracted our preferred head of creative, professionals in digital marketing, branding, and social media managers, as well commercial and marketing specialists with a background in cosmetics.

XP-DNA damage repair and skin cancer prevention. It is beyond question that from all factors contributing to skin cancers and melanoma, solar radiation is a dominant one. The absence of photodamage will seldom lead to any of the dermal cancers, hence our mission to innovate in this area. Melanocortins have long been shown to optimise the cellular signals needed to effectively protect against UV-radiation, and enhancing these signals gave us the ability to commercially launch the first melanocortin afamelanotide as a systemic photoprotectant.

The unravelling of the puzzle came as it was discovered that enhancement of cellular signalling in skin tissues led to assistance in DNA reparative processes following UV radiation. To effectively protect against solar damage, effective processes are needed to mobilise complementation factors to recognise, excise and replace DNA-damaged fragments. Melanocortins assist in these processes, and our clinical studies in xeroderma pigmentosum and healthy controls aim to demonstrate the magnitude of the role of these peptides.

The origin of photodamage is found in the formation of chem-

ical bonds distorting DNA strands, and replication of defective nucleotides increases the risk of skin cancers. This is even more problematic in the highest risk populations, XP patients, who develop multiple skin cancers per year due to the lack of DNA-reparative processes.

Our teams are evaluating the extent of benefit melanocortins provide to these XP patients, the percentage reduction of CPDs. In the past year, we shared the first results of CUV156, and most recently from CUV151 in healthy volunteers.

Vitiligo. The North American and European market for vitiligo opened-up with the introduction of the first topical drug in July 2022, while US Food and Drug Administration (FDA) had made a u-turn change in its views in March 2021. Since then, we have answered the FDA's request to conduct a small trial using afamelanotide as monotherapy (CUV104), while we prepare a larger vitiligo trial using the optimum combination of narrowband UVB and afamelanotide. We had already shown the supremacy of the combination therapy in 2014 (CUV102) and it had always been clear that this combination would provide pigment thrust for thrust for those who had lost skin colour. It has taken years of debate with regulatory authorities for their representatives to understand the effect of vitiligo on patients with darker skin complexion, and after they had come around the necessity to prioritise these patients, CLINUVEL's pathway unfolded. The CUV105 trial will be the largest held with 150 vitiligo patients to be recruited.

Brain disorders. A further arm of our pharmaceutical program is the use of melanocortins in brain disorders. Since these hormones are expressed both in skin and brain, the function of melanocortins in neuroprotection is one long described by various research groups, spanning decades. Our first neuro-program targets an unaddressed population of stroke patients, those who are ineligible to receive clot dissolution and clot removal therapy. The results from study CUV801 were published during the past 12 months. These results provided the signal to advance the program to CUV803, currently ongoing.

For diversification of the stroke program, we developed a second afamelanotide formulation in PRÉNUMBRA® Instant, giving physicians the option to increase acute doses. The results of CUV803 will ultimately determine the design of a larger randomised clinical trial in stroke. The ability to assist patients who suffered a stroke is a privilege and summarises our quest to develop novel solutions.

PhotoCosmetics. The ability to translate pharmaceutical technologies to consumer products is in itself a rare opportunity, but one that beckons from the specialty in melanocortins. Peptide technology enables one to enter galenic research to arrive at user-friendly products. However, many obstacles lay ahead to even contemplate entry into consumer markets. The main one was human safety of melanocortins. Here, we left no stone unturned, and comprehensive analyses from 14,500 doses of SCENESSE®, and longer-term monitoring of patients gave us the comfort in 2021 that regulatory authorities would no longer be able to object to wider use. Since then, we have focused on the advancement of the product lines containing melanocortins serving populations in highest need of skin repair and protection.

With the two M-lines, we expect to change the way we think and speak about solar damage, regeneration, and DNA-assisted repair. We also intend to rewrite the notion of MSH-response following UV exposure, as melanocortin-containing formulations aim to accelerate the bronzing effect, melanisation of the skin to reduce and prevent solar damage. In essence, we are closing the circle, we are delivering on an expectation that came with the birth of melanocortins, as these had first been introduced in 1980.

The circle came in three parts. Our pharmaceutical programs in photo-induced diseases, patients characterised by absolute

light-intolerance, such as porphyria (EPP), showed the ability to provide photoprotection. Second, clinical trials in XP and healthy controls gave the scope to show reduction in photoproducts, cyclobutane pyrimidine dimers (CPDs). Last, the vitiligo trials (depigmentation), demonstrated our ability to use melanocortins to repigment skin when exposed to UV-radiation. This triptych is being translated in parallel in three PhotoCosmetic lines, one P-line and two M-lines. The P-line offers new products providing polychromatic (multiple wavelengths) protection under extreme conditions, while the M-Lines contain the melanocortins. The pilot launch of CYACÉLLE started on 1st March this year.

As far as our research has uncovered, there is no other pharmaceutical company which has endeavoured to translate its pharmaceutical programs from core technology into consumer focused products. However, being first and novel has never daunted our teams, someone has to do it. For this, we need a professional team solely focussed on preparing global digital campaigns to give visibility to our cause, preventing photodamage and skin cancers in using melanocortins and thorough education.

Future expansion. The near-term goals are to advance manufacturing of NEURACTHEL® Instant, complete the marketing programs for PhotoCosmetics, and expand through an acquisition. In the short-term, we will initiate manufacturing plans, bringing in-house capacity to manufacture the next generation of products. We aim for all our divisions, pharmaceuticals, healthcare solutions, and manufacturing to become profitable in time. For this to occur, during the next period we will further invest in R&D facilities, new formulation development at scale, and capital equipment such that our research efforts be accelerated.



Summary

The clock is running to complete an ambitious program, since I wish to see through the launch of several products before the end of my engagement with CLINUVEL in 2025. My immediate goals are aligned with the rest of our staff, and these are defined as launching two new pharmaceuticals PRÉNUMBRA® Instant, NEURACTHEL® Instant and a PhotoCosmetic range of three product lines. Thereby, our Board's objectives are to establish a strong, independent group versed in many disciplines, and one standing out in its management of personnel and intercompany culture.

I place most emphasis on the true assets of this Group, its people and therefore the longer-term careers we can offer. Although we are doing well in this respect, it will improve to such standards that CLINUVEL will position itself in the market as an academy, able to outperform its peers in retention and attraction of unique talent, and career development.

At the beginning of the calendar year, we shared our enthusiasm for the months ahead, and while we tend not to provide financial guidance, there are no immediate reasons why CLINUVEL would not continue to grow at its current pace. In staying with our own projections, we certainly prepare ourselves for this by putting in place infrastructure and new systems, to spur further growth. We plan for increase of staff in all disciplines, back-office, finance, clinical, regulatory, investor relations, quality, research, CBM, and business development; positions across all functions will be added to the Group to a level of 120 over the next 12 months.

In the next 12 months, we foresee that organic growth will be complemented by acquisition(s) with an aim to turn these cash neutral the first year. It is quite clear that to succeed in these ambitions, we need discipline and focus across the Group. Guidelines and policies and clear operating procedures are maintained while we expand at high pace.

Against the ongoing successes, there are a number of business domains we are turning our attention to, such that we can say next year at the same time that we master not a number but all disciplines of the decathlon.

My appreciation goes to all our physicians in Europe, Switzerland, Israel and North-America for their devoted attention to patients, and the independent analysts of CLINUVEL – Dr Stanton and Mrs Thomson at Jefferies Australia, Mrs Mann at MA Moelis Australia, Dr Benson, Dr Storey and Ms Williams at Wilsons Advisory, and last, but not least, the Bioshares team led by Mark Pachacz – for their efforts and long hours of work put to analyse CLINUVEL.

Philippe Wolgen
Managing Director
CLINUVEL Group

OPERATING AND FINANCIAL REVIEW

CLINUVEL is established to address unmet medical needs, with a particular focus on patients with brain and skin disorders. One of the specialties of the firm is photomedicine, serving populations at highest risk from UV and light exposure.

The Company's key operating activities encompass:

- the distribution of its novel pharmaceutical photoprotective SCENESSE® (afamelanotide 16mg) for patients with erythropoietic protoporphyria (EPP);
- the development of pharmaceutical products, including SCENESSE®, PRÉNUMBRA® and NEURACTHEL®, and the conduct of clinical programs for patients who require medical solutions; and
- the commercialisation of a range of PhotoCosmetic products to provide healthcare solutions for people at highest risk of UV and light, DNA-damage and requiring MSH-response as melanogenic (bronzing) protectant.

The review of operations details the key activities and developments in each of these areas over the year ending 30 June 2023 (FY2023).



DISTRIBUTION OF SCENESSE®

Only Approved Therapy for EPP

SCENESSE® is distributed for the treatment of adult EPP patients in Europe, Switzerland, the USA, and Israel. During the past year, access to Canadian patients was granted under a special access program. The number of EPP patients receiving treatment, total doses of SCENESSE®, and treatment centres facilitating treatment all increased over the year.

In Europe, the number of EPP Expert Centres has increased, with new centres opened in several countries, including Germany, Italy, and Scotland. During the year, the English National Institute for Health and Care and Excellence (NICE) decided not to recommend SCENESSE® for use on the English National Health Service, despite NICE being twice found by its own Appeal Panel to have breached the Equality Act and having acted unfairly in its review of the drug. This decision has resulted in an ongoing asymmetry of access for EPP patients in the UK, with Scottish patients continuing to receive SCENESSE® treatment under a patient access scheme.

April 2023 marked the third anniversary of the commencement of commercial distribution of SCENESSE® for EPP patients in the USA. CLINUVEL has established a network of over 50 Specialty Centers to facilitate patient treatment across 39 states as of 30 June 2023. This advances CLINUVEL's goal to reduce the time and distance patients need to travel to receive their bi-monthly treatment, with a network of 120 centers planned. Over 100 national and local private insurers are reimbursing SCENESSE®. Following the conclusion of FY2023, in July 2023, the US Department of Veterans Affairs agreed to reimburse SCENESSE®.



Canadian patients were first treated with SCENESSE® under a Special Access Program in May 2023. CLINUVEL can supply up to six doses of SCENESSE® per annum to adult EPP patients through accredited Specialty Centers under insurance coverage.

Peer Reviewed Publications

During FY2023, a number of peer reviewed publications were seen on the use of SCENESSE®. The medical publications reported ongoing clinical benefit under real world conditions – which was greater than that seen in clinical trials. Importantly, during the year we saw the first analyses of the drug showing a possible hepatoprotective effect, further investigations are following.

Uniform Pricing

Uniquely, CLINUVEL maintained a uniform net price for SCENESSE® per jurisdiction, treating payors equally and in full transparency.

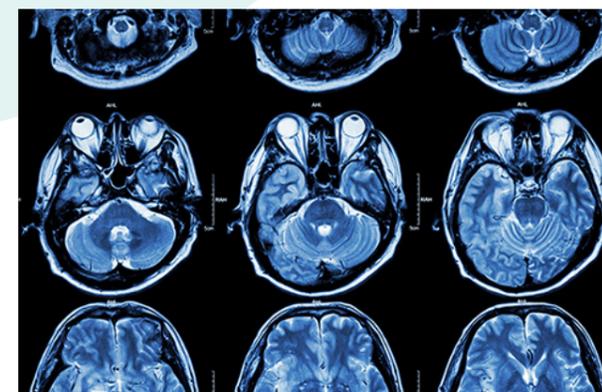
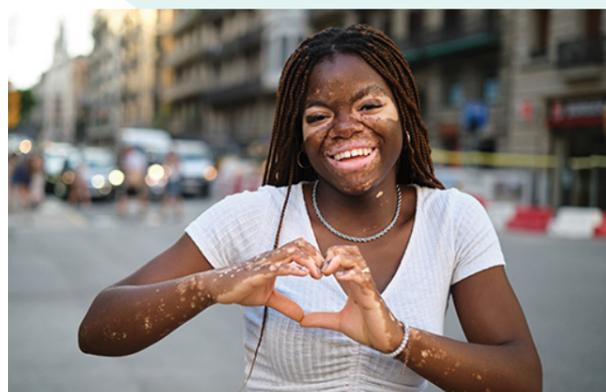
SCENESSE® for Adolescents

CLINUVEL submitted a formal application to the European Medicines Agency (EMA) in September 2022 to expand the approved indication for SCENESSE® (afamelanotide 16mg) to include the treatment of adolescent patients aged 12-17. As part of global pharmacovigilance, CLINUVEL has been closely monitoring the effects of the drug in the adolescent patient population. Based on the data received, the safety profile and clinical benefit of SCENESSE® in these patients has been consistent with that seen in adults. CLINUVEL continues to liaise with the EMA on the submission.



...AND CLINICAL PROGRAMS

CLINUVEL's expertise in the role of melanocortins in the function of the human body underpins the Company's expanded clinical development program. Specific mention of each program is made below:



DNA Repair

- Deffective DNA skin repair in >2 billion individuals.
- Initial focus on 1,000 xeroderma pigmentosum (XP) patients.
- Results CUV151 (n = 9), showed reduced skin damage, statistically decreased UV-erythema dose response, increased minimal erythema dose and skin pigmentation (one dose of SCENESSE® following UV irradiation in disease free individuals).
- Initial results CUV156 (n = 6), presented to the 32nd Meeting of the Photodermatology Society as part of the 2023 American Academy of Dermatology (AAD) Meeting, showed afamelanotide reduced DNA photodamage.
- CUV152 (n = 6), ongoing.

Vitiligo

- Skin depigmentation disorder.
- Prevalence between 0.1-2% of global population.
- >250K darker skin type (IV-VI) patients in North America.
- Positive repigmentation in past studies CUV102 and CUV103.
- CUV104 (n = 6) underway with focus on SCENESSE® as a monotherapy.
- CUV105 (n = 150) with combination NB-UVB and SCENESSE® therapy in design.

Arterial Ischaemic Stroke (AIS)

- 15 million strokes annually, 80% ineligible for treatment.
- First study (CUV801) results (n=6) showed no safety concerns and improved neurological function.
- Second study (CUV803) commenced March 2023 (n=12).
- Initial results of CUV803 showed improvement in three patients administered PRÉNUMBRA® Instant.
- Study extended in May 2023 from patients with mild and moderate strokes to patients with moderate-to-severe and severe strokes.

Variegate Porphyria (VP)

- Light exposure causes skin fragility.
- No existing treatment.
- 3,000-4,000 patients US/EU.
- Study CUVo40 (n = 6) commenced May 2023.
- SCENESSE® to reduce severity of phototoxicity and skin disease.

Refer to the feature on "Plans 2024 and Beyond" on page 34 for the timelines to regulatory approval of each of these indications.



3

PHOTOCOSMETIC PRODUCTS

CLINUVEL is translating its expertise and know-how in photomedicine and melanocortins, accumulated over more than two decades. It aims to assist the wellbeing of those at higher risk from UV and HEV light exposure. The Company's first PhotoCosmetic product line, the polychromatic screen CYACELLE, was launched as part of a pilot in March 2023 in six European countries. Second generation polychromatic screens and lines for DNA repair and melanogenesis are under development at the Group's Singapore Research, Development & Innovation Centre.

The key focus in FY2023 was to complete the development and initial limited launch of CYACELLE, which offers polychromatic photoprotection to a wider range of light – incorporating UV and HEV light – than currently provided by products in the market. CYACELLE is also the Company's second commercial product, and it marks a milestone in the diversification of the Company's product range.

Prior to the initial pilot launch of CYACELLE on 1 March 2023, the focus of the Communications, Branding & Marketing Division (CBM) Division to raise awareness of the need for photoprotection. The CBM team started campaigns through digital marketing, reaching new audiences. CLINUVEL Ambassadors (CUVAs) were identified and engaged to progressively build awareness of the need for photoprotection. CUVAs are leading and influential individuals from each of the target audiences – fair skinned individuals with a history of skin cancer in their family, immunocompromised organ transplant patients, and people exposed under extreme outdoors conditions due to their profession or recreational pursuits.

Two Intriguing Personalities (CUVIPs) were first engaged during the year, as they shared common audiences. The two CUVIPS aimed to first time raise CLINUVEL's mission and story.

'We raise awareness of photageing, photodamage and skin cancer. Combat their effects with a truly new skincare category. And will become a household name by 2026.'

Marga Bibiloni, Director - Brand Strategy & Creative

CUVAs

Outdoor extreme



Paula Novotna: What is my daily routine to protect my skin? I try to wear UV protective clothes to cover my skin, and apply sunscreen to my exposed parts of my body.



Greta Hoeller: Living on the oceans means we are constantly exposed to the sun. When @clinuveldna reached out to ask us to be their ambassador and raise awareness of the damaging effects of UV radiation on our skin, it was a clear yes. It gives us access to scientific knowledge like the Fitzpatrick skin types to protect ourselves and all of you from unintentionally damaging our skin while sailing.

Immunocompromised



Jonathan Ferguson: Through my partnership with Clinuvel, we're trying to raise awareness about skin cancer. Our team is fuelled by passionate outdoor athletes, skin cancer survivors and high risk groups with autoimmune diseases like me, who need to be extra careful around the sun. I've learned so much from these ambassadors.



Jacqueline Fraser: Organ transplantation isn't a cure either. It's merely swapping one set of medical issues for another. Along with a lifetime of anti rejection medications which come with their own side effects. One being the increased risk of skin cancer. There's a high mortality rate around the 7 to 8 year mark post transplant as a result.

Skin Cancer susceptible



Kate Fitzpatrick: Sometimes remembering to apply sunscreen is annoying. Sometimes wearing long-sleeved swim shirts is annoying. Who wouldn't rather be in a cuter suit at the beach or pool? But you know what? Skin cancer surgery is annoying too, to say the least. And it only takes 21 days to develop a habit, for better or for worse.



Matt Heywood: I've learnt that there is always more to learn, through my relationship with sun/light and the team @clinuveldna, I have very much realised that we are only at the very start of a journey, the individuals that are protecting their skin are a minority in comparison.

CUVIPs



Jaap van Zweden
@JaapVanZwedenOfficial
During my most recent trips I ensured that I was adequately protected from the sun when exploring the city. Working with @clinuveldna has highlighted the importance of solar protection in order to minimise the risk of skin cancer.



Cristina Ramos
@cristinaramos_ofc
Summer is coming and taking advantage of the fact that May is Skin Cancer Awareness Month, I encourage you to protect yourselves, because the sun at certain hours and for a long time is harmful. Take care of your skin with care to prevent diseases and its premature deterioration.

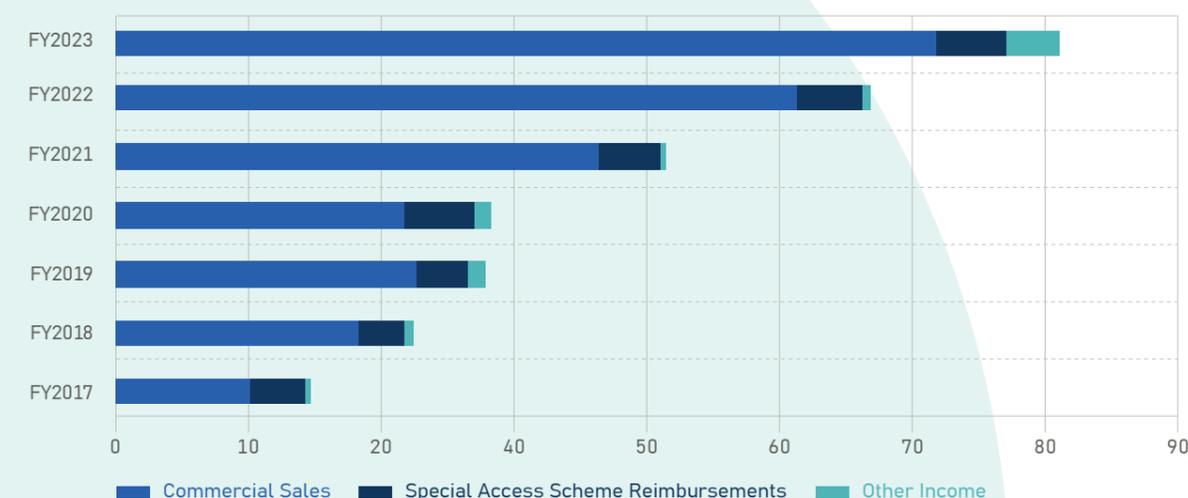


FINANCIAL REVIEW

The highlights of the Group's financial result for the 12 months ended 30 June 2023 are summarised below:

Consolidated Entity	A\$ million	Change
Total Revenues, Interest and Other Income	\$82,990	Up 24%
Total Expenses	\$37.412	Up 15%
Net Profit before income tax	\$45.579	Up 33%
Profit after income tax expense	\$30.605	Up 47%
Cash and Cash Equivalents	\$156.814	Up 29%
Basic Earnings per Share	\$0.62	Up 46%
Net Tangible Assets backing per Share	\$3.29	Up 31%
Dividend distribution per Share	\$0.05	Up 25%

Growing revenues since initial launch (A\$m)



The year saw the Group increasing the number of specialist treatment centres to facilitate higher patient access and further engagement with existing centres delivering a significant 19% reported increase in revenue.

The compound annual growth rate in revenues from time of first product launch in 2016 is 42%, clearly demonstrating the sustained demand for the SCENESSE® implant over the long term. On a constant currency basis, total revenues increased 13.75%. A weaker Australian dollar resulted in a \$3.562 million positive impact to the reported Total Revenue result for the year.

Total revenues include the initial pilot launch in March 2023 of CYACELLE, the Group's first over-the-counter PhotoCosmetic product. Distributed firstly free-of-charge, through hospitals to patients suffering from EPP and XP¹ as an adjuvant to SCENESSE®, and secondly, through a dedicated e-commerce platform to targeted audiences in six European countries. Sales from the initial pilot launch was \$0.009m.

US Revenues have grown through greater patient outreach from expansion of the number of new treatment centers able to administer SCENESSE® now exceeding 50 in number. Improved geographic dispersion of centres is facilitating higher sales orders. European orders have remained robust, reflecting ongoing patient demand and more timely ordering earlier in the year having a positive impact to current year revenues.

Total revenues, including interest and other income increased by 24% in FY2023 to \$83.0 million.

The growth in cash balances held throughout FY2023 were complemented by an increasing interest rate yield earned on holding interest bearing term deposits consistently throughout the year, averaging 268 basis points higher year-on-year, resulting in a robust increase in interest received from funds held in bank accounts and term deposits from \$0.44 million in FY2022 to \$3.90 million in FY2023.

Expenditures increased to drive R&D pipeline development, new product development; Net operating profit continues to grow

Net profit after tax of \$30.6 million (FY2022: \$20.9 million) reflects the performance of the Group in executing its objective to provide its novel key pharmaceutical product in an underserved market.

Adjusted for various non-cash and unrealised items, the non-International Financial Reporting Standard ("non-IFRS") financial metric of adjusted net profit after tax was \$37.8 million (FY2022 \$27.9 million) – refer to the reconciliation of statutory net profit after tax with adjusted net profit after tax on page 53.

Return on sales improved during the year to 58% in FY2023 (52% in FY2022) reflecting an improved rate of profitability. The stronger financial performance has been achieved despite the Group increasing expenditures to expand its product development and clinical pipeline.

Internal resource capacity has been boosted to provide the platform to support entering new markets with new products and to prepare for future operational expansion.

The Group is now three years into its five-year business expansion plan where it anticipated to commit to re-invest in its activities and to spend \$175.0 million over the five years to 30 June 2025. The Total Expense result for the Group for FY2023 of \$37.4

	Commercial Sales, incl. OTC	SAS Reimbursements, Switzerland and Other	Total
	A\$ million		
FY2023 Reported	72.179	6.142	78.321
FY2023 Constant*	69.027	5.732	74.759
FY2022 Reported	60.002	5.720	65.722
% change (Constant)	15.04%	0.21%	13.75%
% change (Reported)	20.29%	7.38%	19.17%

*FY2023 revenues converted to A\$ monthly at the average conversion rate of the same month of FY2022

million is a 15% increase to FY2022's total expense result of \$32.7 million and is aligned with the anticipated financial commitments of the five-year plan – (refer to Plans 2024 and Beyond on page 36 for more detail).

Key expenditure items:

Personnel-related expenses were \$13.58 million (FY2022: \$11.59 million). Average headcount was 7% higher than last year, new roles created in Quality Assurance, in supply chain management and to bolster the newly formed Communications, Branding and Marketing division with the goal to drive the continued expansion of the business. Increases in remuneration rates were implemented to maintain market competitiveness, reflected in the employee turnover rate improving by 13% compared to FY2022.

Materials and related expenses were \$12.06 million (FY2022: \$5.40 million). In FY2023 a series of manufacturing campaigns were undertaken with the Group's contract manufacturer of the SCENESSE® implant to meet imminent clinical, and term commercial demand, resulting in a significant investment in associated materials. Investment in the development and manufacture of product formulations by the Healthcare Solutions Division, in the expanded formulation development programs targeting NEURACTHEL® and PRÉNUMBRA® Instant, along with supplies and materials for the Singapore RDI Centre to progress their development of other formulations, were incurred to ensure the Group continued its path of becoming the global melanocortin leader.

Increases across commercial distribution, finance and administration, legal and insurance, and Communications, Branding & Marketing (CBM) were incurred in FY2023:

- 1) Commercial distribution expenses were \$3.15 million (FY2022: \$2.49 million)
- 2) Legal, Insurance and IP expenses were \$1.32 million (FY2022: \$1.15 million)
- 3) Finance, Corporate and General expenses were \$3.19 million (FY2022: \$2.27 million)
- 4) CBM expenses were \$0.75 million (FY2022: \$0.29 million)

The Group saw the cost of several essential activities increase throughout FY2023 as the business pursues its growth objectives. It experienced increased regulatory interaction connected to dossier changes and regulatory audits and inspections of systems including the use of external assistance to support these activities. There was increased freight, manufacturing royalties, product handling and distribution of product from higher volumes to support commercial sales and special access arrangements.

Lower insurance costs from risk protection were offset legal

assistance to address several matters throughout FY2023, including the Group's responses to various pricing negotiations in the UK, and Europe, as well as the protracted legal proceedings surrounding the breach by University of Muenster filing patent applications on technology and knowledge proprietary to the Group. The impact of heightened international staff travel across the Group, higher professional services fees, and a first-time recognition for expected credit losses arising from the US commercial distribution market, were all important factors during FY2023.

The Group has invested in resources to expand its visibility and to engage with new audiences and some of these activities included developing promotional content for the PhotoCosmetic product lines, engaging with selected ambassadors to build awareness for the need for photoprotection across digital marketing channels and conducting roadshow presentations and investor soirées to select stakeholders.

The non-cash accounting charge for share-based payments was \$8.99 million (FY2022: \$6.12 million). Performance rights are an effective tool in promoting employee retention and to encourage participants be aligned with the interests of the owners of the Group. In early FY2022, the Group issued 743,174 unlisted performance rights to staff of the CLINUVEL group of companies and at the end of FY2023 a further 255,750 unlisted performance rights were issued to staff. The FY2023 result reflects:

- the first full year of expensing of the FY2022 issue of performance rights, and
- reassessing the probability of achieving certain non-market conditions for performance rights held by certain staff previously considered unlikely to be met as the vesting date draws nearer.

Clinical and non-clinical development fees were \$1.27 million (FY2022: \$1.23 million). The deliberate increase reflects the Group's strategy to advance its research and development initiatives into new products and new formulations as well as expanding the use of afamelanotide using new and existing formulations as a potentially new therapy for indications beyond EPP. Expense towards the DNA Repair program, investigating afamelanotide as a potential first-line therapy for XP, and the vitiligo program to evaluate the safety and efficacy of afamelanotide as a monotherapy in vitiligo patients with darker skin complexions (CUV104), were largely offset by temporary reductions in the cost of pre-clinical studies to support the Group's strategic focus to develop new and alternative formulations and in regulatory-related fees to prepare dossier applications for review in new jurisdictions that was incurred in FY2022.



Income tax expense was \$14.97 million (FY2022: \$13.44 million) reflecting the impact on corporate taxes from the growth in taxable profit year-on-year. The result was aided by movements in the deferred tax position of the Australian business along with benefits received from utilising unused tax losses.

Significant growth in cash balance, maintained consistent annual spend in operating activities

Cash and cash equivalents of \$156.81 million as at June 2023 (FY2022: \$121.51 million), the 29% growth in cash held exclusively generated from operations and without reliance on debt or equity financing activities.

Operating cash inflows primarily consisted of receipts from the global distribution of SCENESSE® under relevant market authorisations and access arrangements of \$74.88 million (FY2022: \$66.4 million). Cash inflows also comprise \$2.73 million from interest earned on cash held, reflecting higher yields earned from higher cash deposits throughout the financial year.

Operating cash outflows included payments to suppliers and employees of \$33.23 million (FY2022: \$27.35 million) and taxes paid of \$7.74 million (FY2022: \$Nil).

Net cash used in investing activities was \$1.03 million to strengthen the infrastructure of the Group's Singapore RDI Centre to develop novel PhotoCosmetic and pharmaceutical formulations.

Dividends distributed to shareholders during FY2023 was \$1.98 million, an increase in dividends per share from \$0.025 on FY2021 earnings to \$0.04 on FY2022 earnings, reflecting the commitment of the Company to return value to shareholders.

Highly liquid balance sheet, free of debt financing

A key objective of the Group is to ensure a financially strong Balance Sheet, allowing the optionality for future re-investing in the business and/or to acquire new assets and businesses to be absorbed within the Group. Additionally, a robust Balance Sheet with liquid assets provides a financial buffer to withstand unexpected adverse events. The Company has been successful to both grow and preserve its cash and cash equivalents without needing to seek further funding, and in doing so diluting shareholder returns, nor has it raised debt capital.

The increasing financial strength of the Group is reflected in the growth of its net assets to \$164.6 million (FY2022: \$125.56 million). The Company continues to hold no long-term debt. The ratio of the Company's overall debt to equity increased to 18% (FY2022: 15%).

Trade and other receivables at 30 June 2023 of \$22.21 million (FY2022: \$16.20 million), reflect the overall growth in distribution.

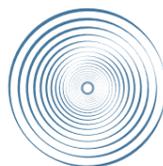
Inventories increased to \$9.52 million (FY2022: \$1.83 million) to meet expected commercial demand and imminent clinical demand.

Trade and other payables of \$7.65 million (FY2022: \$3.28 million), with the increase driven by timing of payments to support product manufacturing initiatives and supply chain commitments.

Income taxes payable increased to \$16.09 million (FY2022: \$7.28 million), driven by a higher taxable profit result to meet Australian corporate income tax obligations as well as tax obligations in other relevant jurisdictions.



Balance Sheet Highlights



PLANS 2024 AND BEYOND

CLINUVEL's strategic objective is to transform into a sustainable pharmaceutical group and diversify its activities establishing an integrated business.

Long-term Value of Integration and Diversification

CLINUVEL's business model strives to build and retain key pharmaceutical functions in-house, rather than outsource to external business partners and suppliers. The overall aim is to further integrate functions while diversifying revenue streams. The rationale of this approach is found in the Company's objectives for independence with self-determination and control of quality, costs and supply, reflecting the Company's resourceful culture. CLINUVEL undertakes several functions in-house:

- Formulation R&D, including select pre-clinical development;
- Design and conduct of clinical studies;
- Regulatory affairs, pharmacovigilance and quality assurance activities, including key manufacturing activities;
- Direct distribution of SCENESSE® to European EPP Expert Centres and US Specialty Centers;
- Pricing and reimbursement functions, including patient support and the SCENESSE® Assistance Program in the USA;
- Finance, facilitated by preservation of cash balances to allow for planned organic and inorganic growth and expansion; and
- Communications, branding and marketing, and investor relations.

Plans to diversify the Company are being executed and aim to result in new revenue streams as treatments are provided for indications with larger patient populations than EPP. In other words, the firm's efforts go towards spreading the Company's activities, products and markets. This strategy is one to diversity revenue streams, part of a risk management plan. The risk of the chosen strategy lies in its implementation, which is mitigated by a deliberate and thorough approach of the Company to expand its activities based on its existing expertise in melanocortins



and photomedicine, and central nervous system. The Group has increased its workforce to support its activities accordingly.

Infrastructure and Know-How to Support Expansion

CLINUVEL has built enhanced infrastructure and know-how in support of its expansion plans.

With this overview of CLINUVEL's strategic approach in mind, more specific plans in EPP patient treatment, drug development and indications, and PhotoCosmetics, are outlined below.

Enabling EPP Patient Treatment

CLINUVEL continues to focus on the distribution of SCENESSE® for EPP patients in existing jurisdictions to meet patient and physician demand. In this regard, work with external contract manufacturers and raw material suppliers continues to ensure product supply at current Good Manufacturing Practice standard.

Europe

As part of the conditions attached to European marketing authorisation, CLINUVEL will maintain its commitment to the European EPP Disease Registry to monitor the long-term safety of SCENESSE®.

The Company recognises the impact of EPP on patients under the age of 18 and the potential for SCENESSE® as a treatment for adolescent patients. CLINUVEL subsequently proposed an expansion of the drug's label to the European Medicines Agency (EMA) to include adolescent patients and expect to provide an update later in 2023.

USA

CLINUVEL aims to establish a network of 120 Specialty Centers across the US to provide greater treatment access for EPP patients. This network may also play a role in the clinical development of

SCENESSE® for other indications. Work continues to provide treatment access for all US EPP patients.

Other Jurisdictions

The Company is committed to gaining market access for SCENESSE® in other jurisdictions around the world.

Melanocortin Drug Development

CLINUVEL is a world leader in melanocortins, evaluating a number of melanocortin-based pharmaceuticals for a range of patient groups with unmet need.

CLINUVEL expects progress across several clinical programs with afamelanotide:

- DNA Repair Program – results of the first two XP studies (CUV156 and CUV152) and the study on healthy volunteers (CUV151) are expected in FY2024. Subject to these results, additional studies will be undertaken with the objective of completing a dossier of patient results of sufficient gravitas to present to the EMA to extend the approved label of SCENESSE® to XP patients.
- Vitiligo – the results of CUV104 will be available in FY2024 and CUV105, a new, larger study, using SCENESSE® in combination with NB-UVB phototherapy, will commence as soon as design and ethics approvals are received. The objective is to submit a dossier to the US FDA to consider approval to extend the label of SCENESSE® to vitiligo patients.
- Variegated porphyria – first efficacy results of CUV040 are expected in 2024. After assessing the results, the next steps will be determined, including the need for another study, with a view to substantiate a submission to the EMA to extend the label of SCENESSE® to VP patients in Europe.
- Stroke – first efficacy results of CUV803 are expected in

FY2024. The path to regulatory approval of afamelanotide for Stroke is a longer term one. Additional and larger studies will need to be undertaken before regulatory approvals can be sought and a timeframe to commercialisation of at least 5 years is considered likely.

Clinical studies in other indications are planned to be announced in 2024 and 2025.

PhotoCosmetic Products

CLINUVEL is establishing a new category of products as PhotoCosmetics, with the objective of making the brand a household name by 2026.

CYACËLLE is planned for wider launch in new jurisdictions, particularly the USA. The PhotoCosmetic products for DNA repair and melanogenesis will continue to be developed by the Research, Development & Innovation Centre in Singapore, for planned launch in 2024 and 2025, respectively.

Regular Bulletins from the CBM team, addressing different aspects of CLINUVEL's brand architecture, will be issued to provide updates to stakeholders.

Cumulative Expenses Plan

We have provided a five-year projection of expenses we expect to incur to aim for our objectives. Excluding capital expenditures and marketing expenses on the PhotoCosmetics initiative, expenses of \$175.0 million are planned over the five years to the end of FY2025. To date, expenses incurred in FY2021 to FY2023 total \$92.8 million, or 53% of the expenses plan. The chart below shows the indicative path to achieve this projection.

Acquisitions

CLINUVEL has long expressed an interest in acquiring assets to augment the planned organic growth of the Company. An acquisition needs to fit several criteria:

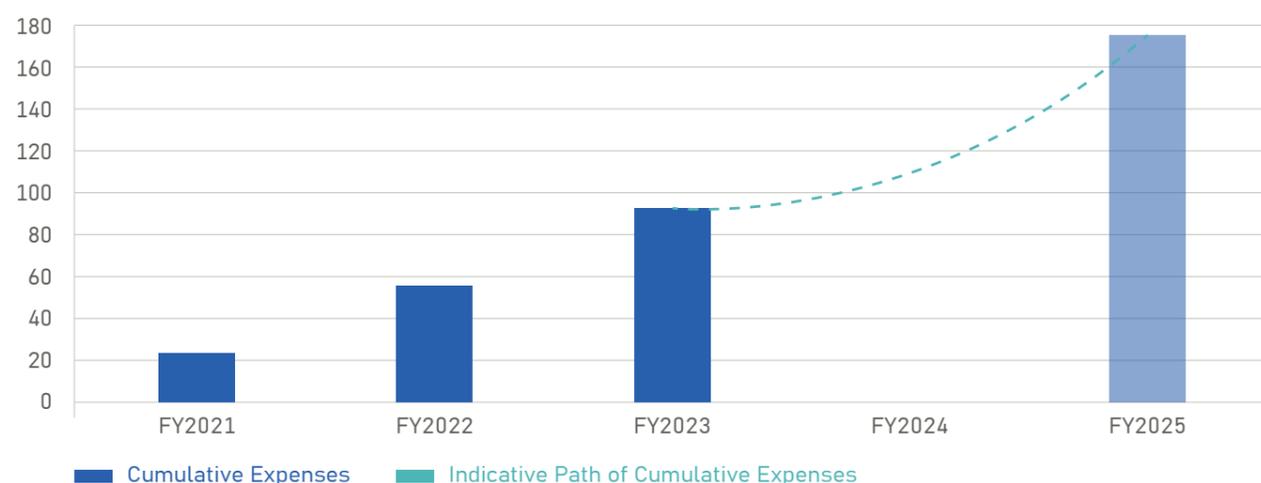
- An existing management team with complementary skills and willingness to integrate within the Group;
- Scope to add value from its experience and expertise;
- Complement or add to our activities;
- In either a late clinical stage biotech; and/or a
- Manufacturer that advances our objectives.

CLINUVEL does not rule out recourse to external finance – whether this be bank debt and/or a capital raising – to accelerate or complete one or more acquisitions. The option to secure finance to allow for an acquisition is one of several avenues to grow the Group inorganically. The ongoing monitoring and assessment of opportunities does not engage more management time and effort than warranted by the potential value add of the appropriate incorporation.

Primary Listing of the Company

The primary listing of CLINUVEL is the Australian Securities Exchange (ASX) – since 2001. We have made it explicit in our recent communications that consideration would be given to a primary listing elsewhere if the benefits to the Group and stakeholders are compelling. We have also stated that we are not inclined to a dual listing due to the duplication of compliance and reporting costs, and dilution of trading volume. Therefore, our approach is to either remain on the ASX or move to a listing in another country, if opportunities are sufficiently compelling. The implications of a change in listing will be thoroughly assessed such that shareholders benefit and do not lose out or suffer negative consequences.

Five-year Expenses Plan to 30 June 2025 (A\$m)



Actual expenses FY2021, FY2022 and FY2023. Indicative path of expenses FY2024 and FY2025 to planned cumulative expenses of A\$175.0m.

SUMMARY

CLINUVEL is on the path towards a highly integrated and diversified pharmaceutical company. Its transformation will be reflected in four pharmaceutical products for eight indications – four in photomedicine and four in CNS conditions – and three PhotoCosmetic product lines which will make CLINUVEL a household name. CLINUVEL will be recognised as an expert in melanocortins and their therapeutic role in managing conditions of the skin and brain. The benefit of this integration and diversity will be a sustainable business able to perform with resilience and dynamism over the long-term.

ANNUAL RESULTS

Financial Year Ending 30 June 2023

“Since the launch of SCENESSE® in 2016, we have pursued clear and ambitious objectives for CLINUVEL, with a strong financial foundation and consistent performance being central. It is undeniable that – with seven years of growing revenues and profitability, continued R&D investment, and a formidable balance sheet to navigate uncertainty – we are meeting our long-term objectives and setting a standard for the future of the Group.

In parallel, strong cash inflows have enabled the Board to declare a sixth consecutive annual dividend for shareholders, recognising their long-term support. We will continue the strategy to translate our technology to the benefit of patients and the general population at high risk of DNA damage.”

Mr Darren Keamy, Chief Financial Officer, CLINUVEL Group

Directors' Report

The Directors of the Board present their report on the Company for the financial year ended 30 June 2023 and the Auditor's Independence Declaration thereon.



WILLEM BLIJDORP

Non-Executive Director, Chair since 30 November 2019, Funda Appointed 21 January 2015

Committee Membership

Chair of the Remuneration Committee
Chair of the Nomination Committee
Member of the Audit and Risk Committee

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 –

Relevant Skills

- entrepreneurship, commercial prowess
- general management
- financial management
- experienced in listed company Directorships

Background

Mr Blijdorp is an entrepreneur recognised for having established the B&S Group, one of the largest global trading houses, in a period spanning three decades. Mr Blijdorp has led B&S's growth, with the Dutch group focused on specialty distribution services to serve markets. The B&S Group has worldwide reach and is a leader in its market sector. Formerly B&S Group's CEO, and former member of its Supervisory Board, Mr Blijdorp is a majority shareholder of B&S, focussing on the Group's development and expansion strategy. He led and oversaw the Group's initial public offering on Euronext Amsterdam in March 2018.

In 2014 Mr Blijdorp received acknowledgment for his expertise in mergers and acquisitions and commercial leadership as the Ernst & Young Entrepreneur of the Year in the Netherlands, and runner-up in its European Union awards.

Since becoming a director of CLINUVEL in 2015, Mr Blijdorp has provided valuable knowhow and contributed by setting the Group's long-term strategy for product commercialisation, growth, and plans to diversify CLINUVEL. He provides guidance on business and tax restructuring of the Company, as well as assist in setting up distribution channels for CLINUVEL's business in photocosmetic products serving a specialised consumer market



PHILIPPE WOLGEN

Chief Executive Officer, MBA, MD

Appointed to Board 1 October 2005, appointed Chief Executive Officer 28 November 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 3,122,247 Performance Rights 1,513,750

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® (afamelanotide 16mg) 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

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)

Relevant Interest in Shares and Performance Rights

Shares 196,577 Performance Rights -

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

Committee Membership

Member of the Remuneration Committee
 Member of the Nomination Committee

Current Directorships and Other Interests

Fellow of the American Association of Clinical Endocrinologists

Other Listed Company Directorships (last 3 years)

None

Relevant Interest in Shares and Performance Rights

Shares 5,500 Performance Rights –

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

Committee Membership

Member of the Remuneration Committee
 Member of the Nomination Committee

Current Directorships and Other Interests

Director of HCA Hope Fund UK
 Board Chair of The Ewell Group Ltd

Other Listed Company Directorships (last 3 years)

None

Relevant Interest in Shares and Performance Rights

Shares 420 Performance Rights –

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.



JEFFREY ROSENFELD, AC, OBE

Non-Executive Director MBBS MS MD FRACS
Appointed 26 November 2019

Committee Membership

Member of the Audit and Risk 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 –

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.



SIR ANDREW LIKIERMAN

Non-Executive Director, MA, FCMA, FCCA
Appointed 4 April 2022

Committee Membership

Member of the Nomination Committee

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 1,000 Performance Rights –

Relevant Skills

- cross-border financial and commercial acumen
- public sector experience
- board and committee oversight and governance
- leadership and management

Background

Sir Andrew's long and accomplished career sees him alternating between public, private and academic positions.

Sir Andrew is Professor of Management Practice at the London Business School and was its Dean from 2009 to 2017. He is currently working on the role of good judgement in management, with his work used extensively by many organisations and recently incorporated in guidance issued by the UK financial regulator.

In the private sector, Sir Andrew served as non-executive Director of Times Newspaper Holdings Ltd, Monument Bank, Barclays Bank plc, quoted insurance Lloyds underwriter Beazley plc, Applied Intellectual Capital plc, and market research firm MORI Ltd.

Among many roles in the public sector, Sir Andrew worked in the UK Cabinet Office, and spent 11 years as Head of the UK Government Financial Management Service, during five of which he was also the Chief Financial Officer of the UK Treasury (Finance Ministry). In this period, he led the nine-year project which changed the basis of government planning, control, and reporting. He was knighted for public service in 2001. He has also served as non-executive Director at the Bank of England and non-executive Chair of the (UK) National Audit Office.

Information on Company Secretary



DARREN KEAMY

Company Secretary, Chief Financial Officer, BComm, CPA, GradDip ACG.

Mr Keamy, a Certified Practising Accountant and Company Secretary, joined CLINUVEL in November 2005 and became Chief Financial Officer of the Group in 2006. He has previously worked in key management accounting and commercial roles in Amcor Limited and has experience working in Europe in financial regulation and control within the banking and retail pharmaceutical industries.

He has overseen the financial management of the Group since 2005, played a role in raising A\$95 million in capital, and assisted the steering of the Group from a loss-making, pre-revenue position to a commercially focussed profitable enterprise, recording six consecutive years of growth.

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 Committee		Remuneration Committee		Nomination Committee	
	A	B	A	B	A	B	A	B
Mrs. B. M. Shanahan	7	7	2	2			2	2
Dr. P. J. Wolgen	7	7						
Mr. W. Blijdorp	7	7	2	2	5	5	2	2
Dr. K. A. Agersborg	7	7			5	5	2	2
Mrs. S. E. Smith	7	7			5	5	2	2
Prof J. V. Rosenfeld	7	7	2	2			2	2
Prof. J. A. Likierman	7	7					2	2

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.

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 peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute 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 2023 (FY2023) were to:

- manufacture and commercially distribute its leading drug candidate SCENESSE® in the European Union (EU) and the USA for the treatment of the rare, genetic metabolic disorder, erythropoietic protoporphyria (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 (XP), acute arterial ischaemic stroke (AIS), DNA repair and other disorders;
- develop and manufacture NEURACTHEL® (adrenocorticotrophic hormone; ACTH) in different formulations, to target neurological, endocrinological, and degenerative disorders;
- research, develop, manufacture and commercialise 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 new pharmaceutical formulations containing afamelanotide and melanocortin analogues for the treatment of a range of disorders;
- research and develop various pharmaceutical formulations of melanocortin analogues for the treatment of a range of disorders.

There was 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 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 research and development of a portfolio of assets centred around its key drug candidate SCENESSE® and its melanocortin derivatives; their successful commercialisation, manufacture, and distribution; and the maintenance of ongoing 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

- More patients treated, more implants administered and expanded expert treatment centre network.
- April 2023 marked the third anniversary of treatment of EPP patients in the USA.
- Uniform pricing per jurisdiction maintained.
- First treatment of EPP patient in Canada in May 2023 under special access arrangements.
- Application to EMA to treat adolescents submitted September 2022 and is under ongoing consideration.

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 on stroke, commenced March 2023.
- NEURACTHEL® (ACTH)
 - Adrenocorticotrophic hormone (ACTH) being developed as Instant and Modified-Release products.
- Initial focus on treatment of adult Multiple Sclerosis and Infantile Spasms.
- Ongoing work with partner to validate batches of NEURACTHEL® manufactured under current Good Manufacturing Practice (cGMP) and prepare Drug Master File for submission to the US FDA.

Clinical Programs – Advanced

- DNA Repair with focus on xeroderma pigmentosum (XP):
 - Study CUV156 (n=6) ongoing, positive preliminary results reported, presented at global conferences.
 - Study CUV152 (n=6) ongoing.
 - Study CUV151 (n=9) in disease free volunteers reduced DNA photodamage.
- Variegate Porphyria (VP):
 - Study CUV040 (n=6) commenced May 2023.
- Vitiligo:
 - Monotherapy study CUV104 (n=6) commenced.
 - Combined treatment with narrow-band UVB study CUV105 (n=150) being designed.
- Arterial Ischaemic Stroke (AIS):
 - Study CUV803 (n=12), commenced March 2023, using

PhotoCosmetic – Products

- First polychromatic screen product CYACËLLE launched in pilot phase in March 2023, initial distribution limited to hospitals and people at highest risk through e-commerce in Europe.
- CUVA and CUVIPs engaging targeted highest risk communities on the impact of UV exposure and the benefits of photoprotection.
- Three product lines communicated:
 - Polychromatic photoprotection;
 - DNA Repair;
 - Melanogenesis.
- Development of the second and third product lines continued at the Singapore Research, Development & Innovation Centre.

The financial highlights of the Company for the year ended 30 June 2023 are presented in the following table:

Consolidated Entity	A\$ million	Change
Total Revenues, Interest and Other Income	\$82,990	Up 24%
Total Expenses	\$37,411	Up 14%
Net Profit before income tax	\$45,578	Up 33%
Profit after income tax expense	\$30,605	Up 47%
Cash and Cash Equivalents	\$156,814	Up 47%
Basic Earnings per Share	\$0.619	Up 47%
Net Tangible Assets backing per Share	\$3.29	Up 31%
Dividend distribution per Share	\$0.05	Up 25%

A review of the Company's operations and information on the financial results is contained in the feature on pages 26-37 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 non-IFRS financial measures assist in providing meaningful information about,

- 1) the performance of the business, and
- 2) 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 FY2023 was \$30.605 million, up 47% from FY2022. The Group's adjusted net profit after tax for FY2023 was \$37.838 million, up 36% from FY2022's adjusted net profit after tax result. 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 2023		30 June 2022	
	Statutory	Non-IFRS	Statutory	Non-IFRS
	\$	\$	\$	\$
Total Revenues	78,321,318	78,321,318	65,722,292	65,722,292
Total Interest Income	3,905,856	3,905,856	444,071	444,071
Total Other Income	763,082	763,082	821,152	821,152
Total Revenue, Interest Income and Other Income	82,990,256	82,990,256	66,987,515	66,987,515
Adjust for:				
Unrealised gain on restating foreign currency balances and currencies held	-	(659,901)	-	(604,317)
Adjusted Total Revenue, Interest Income and Other Income	-	82,330,355	-	66,383,197
Total Expenses	37,411,533	37,411,533	32,666,600	32,666,600
Adjust for:				
Share-based payments	-	(8,989,788)	-	(6,120,977)
Unrealised loss on restating foreign currency balances and currencies held	-	-	-	-
Adjusted Expenses	-	28,421,745	-	26,545,623
Net Profit before Tax	45,578,723		34,320,915	
Adjusted Net Profit before Tax	-	53,908,610	-	39,837,574
Income Tax	14,974,157	14,974,157	13,442,450	13,442,450
Adjust for:				
tax on above adjustments	-	(167,070)	-	(179,454)
tax on Unrealised gains/losses including loans to subsidiaries	-	1,263,081	-	(1,284,691)
Net Profit after Tax	30,604,566		20,878,465	
Adjusted Net Profit after tax	-	37,838,442	-	27,859,269

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
Technology	Despite obtaining marketing authorisations, the approved products may ultimately prove not to be safe and/or of clinical or other benefit.	The Company has established a comprehensive pharmacovigilance system and conducts intense and continuous safety monitoring, evidenced by the risk management commitments agreed with the European Medicines Agency for the long-term follow-up of patients treated with SCENESSE®. The Group works with key opinion leaders to ensure it responds to any evidence supporting a change to the clinical relevance or change to the safety profile.
Supply	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 nor non-supply of product and/or adverse regulatory outcomes.	This risk has a high degree of non-controllability, and the switching costs comes 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 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 FY2023 the Company increased its inventory levels to meet pending demand and to ensure supply chain risk is managed.
Clinical & Regulatory	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 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 FY2023, less reliance on third-party providers was sought by bringing data analytical functions in-house.
Market Competition	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.
Drug Pricing	Third-party payors may not provide insurance coverage or not be willing to accept the prices agreed with other third-party payors, adversely affecting 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.
Intellectual Property	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. Also, 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 a relatively strong IP protection. It works closely with experienced specialists and advisors internationally over many years and it continues to fortify its portfolio through applying for new patents arising from new knowledge gained during its research and development.
Funding	Cash outflows from its operations over the long-term may be higher than cash inflows over the long-term. Therefore, the ability of the Group to successfully bring its products to market and achieve consistent positive cash flow is dependent on its ability to maintain a revenue stream and to access sources of funding 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 believe additional funding could be obtained if 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.
Management	The corporate strategy could be impacted adversely if the Group was not able to retain its specialised knowledge and areas of expertise, key management, members of staff and/or Board.	The Company continually reviews its remuneration, reward, and training to ensure it is a competitive employer in a tight labour market, and an attractive place to work. Strategies to promote staff retention include eligibility to participate in LTI Plans after a period of service has passed, and specialist training programs are available to career develop performing staff. Staff benefits are constantly reviewed to ensure market competitiveness.
Cyber Security	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.

Dividends Paid or Recommended

Declared & paid in 2022/23	Cents per Share	Amount	Date of Payment
Final	4.00	\$1,976,414	21 September 2022
On 28 August 2023, the Board of Directors declared a fully-franked dividend of \$0.05 per ordinary share in relation to the full year ended 30 June 2023.			

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:

- In July 2023, the Group purchased a commercial property located in Egham, UK to support its expanding European-based workforce for a cash consideration, net of fees, of £2,500,000; and
- On 28 August 2023, 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 26-37) in this Annual Report details the type of developments and outcomes that occurred in FY2023 as the Company advanced its expansion plans. The feature on the "Plans 2024 and Beyond" (on pages 38-41) in this Annual Report sets out in greater detail the likely developments and outcomes expected in FY2024 and beyond as the 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 is 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 14-19 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 20 to the financial statements.

Remuneration Report

The Remuneration Report, which forms part of the Directors' Report, provides information about the remuneration of the Directors of CLINUVEL PHARMACEUTICALS LTD and Other Key Management Personnel for the year ended 30 June 2023.

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

Name	Position	Term as KMP
Non-Executive Directors		
Mrs. B. M. Shanahan	Non-Executive Director	Full Year
Mr. W. A. Blijdorp	Non-Executive Director	Full Year
Dr. K. A. Agersborg	Non-Executive Director	Full Year
Mrs. S. E. Smith	Non-Executive Director	Full Year
Prof. J. V. Rosenfeld	Non-Executive Director	Full Year
Prof. J. A. Likierman	Non-Executive Director	Full Year
Executive KMP		
Dr. P. J. Wolgen	Managing Director and Chief Executive Officer (CEO)	Full Year
Dr. D. J. Wright	Chief Scientific Officer (CSO)	Full Year
Mr. D. M. Keamy	Chief Financial Officer and Company Secretary (CFO)	Full Year

The remuneration report is set out under the following main headings:

- A. Introduction by the Chair of the Remuneration Committee
- B. Remuneration Governance
- C. Executive Remuneration
- D. Non-Executive Remuneration
- E. Service Agreements FY2023
- F. Share Based Remuneration
- G. Details of Remuneration
- H. Description of Performance Conditions to Performance Rights expiring 20 November 2023

A. Introduction by the Chair of the Remuneration Committee

Chairman of the Remuneration Committee

Dear Shareholder,

On behalf of the Remuneration Committee (Committee), I am pleased to present the Remuneration Report for the year ended 30 June 2023. This introduction to the Report covers:

- the Company's approach to remuneration of Executive KMP and Directors;
- key achievements of the past year, and CLINUVEL's longer-term objectives;
- FY2023 remuneration outcomes for Executive KMP and Directors; and
- our intentions on remuneration into FY2024 and beyond.



Remuneration framework

As part of our remuneration framework, we strive to be and remain an attractive group to work for. We place high emphasis on keeping skills and talent under one roof. Since we invest resources and time on improving specialized professionals, retention has become key.

In a global talent market, and given the maturity of the Company, it is more important than ever to offer competitive remuneration packages. As a company operating on several continents, and being aware of an ever-changing working environment, luring specialized talent in the pharmaceutical sector has become a global aspiration of many.

Competitors in the sector are seeking similar skills, and in a unique working environment, we intend to balance financial and non-financial benefits, and provide a long-term career path. Fundamental to our current success remain our strong values, which have proven a definite factor the past year in attracting employees. With an increase of 95% of staff numbers over the four financial years to 30 June 2023, we have been able to build around a core executive team of new professionals. Retention of skills has equally proven beneficial to shareholders, with the executive team showing an average tenure of 16 years.

The value of having an experienced team, replenished with new managers coming through, is immense and cannot be overplayed.

In Section C of the Report, the remuneration framework links the Group's mission and strategy to executive remuneration, and contains the following key components:

- fixed base remuneration, and non-monetary benefits (health insurance, accommodation, relocation, travel and statutory benefits);
- short-term incentives (STIs); and
- long-term incentives (LTIs, equity participation through conditional performance rights).

As an international company commercially operating outside Australia, limiting its peer benchmarking of its executive remuneration to Australian peers only is not considered to be a fair comparison. For this reason, the Committee commissions annually analyses of its executive remuneration, benchmarking against comparable peers in terms of complexity and innovative focus, scope and scale, technical and specialised skills, market capitalisation, achievements, and risk profile, operating on either an Australian or UK market exchange. For FY2023, the peer group consists of 26 companies, 22 which are US-listed, and four listed in Australia – refer to pages 66-69. The CEO's total remuneration package is lower than the median of peers, albeit higher on fixed remuneration and percentage potential on STI, but much lower on long term incentives, whilst the reverse is the case for the CFO. The variation in the components is assessed by the Remuneration Committee to be reasonable based on the leading performance and achievements of the business.

Key achievements of the past year

In an environment of increasing inflationary pressures globally, CLINUVEL entered the financial year in a strong financial position. It joined a select group of biopharmaceuticals companies who avoided the need to rely on external funding. The ability to access both capital and credit markets had changed dramatically the past year, and we witnessed the phenomena midway through the year of more than 180 US listed companies trading below cash levels.

It became clear that consistent financial management had given us the opportunity to focus on the diversification of activities, on further research and preparing the new consumer focussed business, PhotoCosmetics. As the year passed, the Group continued to increase its profitability through this uncertain environment, demonstrated by the release of the December half year results, reporting a 93.9% increase to after-tax profit.

We reinvested in 2023 in further highly skilled personnel, we expanded the EPP market in Europe and US, and progressed new pharmaceutical products. Specifically, we saw news on:

- PRÉNUMBRA® Instant, completed development, and administered for the first time in the clinic;
- the development of NEURACHTEL®;
- key clinical programs advanced – XP and DNA Repair, variegate porphyria, vitiligo and acute ischaemic stroke; and
- the first PhotoCosmetic product, CYACÉLLE, entered its pilot phase (first polychromatic screen).

At the end of book year 2023, the Company had enhanced its financial position, the highlights are:

Total Revenues & Other Income:	Up 24% to A\$83.0 million
NPBT:	Up 33% to A\$45.6 million
NPAT:	Up 47% to A\$30.6 million
EPS:	Up 47% to 62 cents
ROE:	Increased from 16.6% to 18.6%
Dividend	5.0 cents per share, 6th consecutive year of distribution

The Board is closely involved in the Company's operations, its developments and is across the unique challenges posed on innovation in melanocortins. It therefore greatly appreciates the work our teams have delivered over the past year. These outcomes overall have exceeded our expectations set at the beginning of the financial year, and do not come without considerable commitment and effort from all involved. Keeping a team of professionals together and highly motivated has made a real difference to patients' lives. From the many stories of families and caretakers, we know how much we are improving the lives of patients.

Overseeing this year, I owe all Clinuvelians a big "thank you" for what has been achieved the past year.

Remuneration outcomes FY2023

The tables in Section G of the Report set out the remuneration outcomes for Executive KMP and non-executive Directors for FY2023.

The lower Australian dollar affected components of the total remuneration reported, for those executives who reside outside Australia and are paid in non-Australian dollar currency. Inflationary adjustments had an impact to salaries in FY2023 and this was combined with an average headcount increase of 7% when compared to the FY2022 average headcount for the Company.

For the financial year, the Managing Director received:

- gross fixed base remuneration of \$1,593,117 - a modest increase of 6.9% compared to FY2022;
- STI – award is 60% of the maximum opportunity;
- LTI. As of 30 June 2023, 15% of the maximum number of the 1,513,750 performance rights granted to the CEO have been assessed to have hit their performance condition, and we are anticipating up to 21% to be achieved by their vesting date.

I must add that the relatively low number of performance conditions achieved truly reflects the significant 'stretch targets' embodied in the performance rights plan designed and set by the Committee in 2019. The 15% percent performance conditions achieved by the Managing Director is also well below the expectations of those who expressed concerns at the time of grant of the performance rights, and who may have voted against the grant.

The Committee sets ambitious objectives for the performance conditions such that these are at "highest threshold"; the challenging objectives at the time of grant in November 2019 was considered a novel approach in Australia at the time. Ahead of the next AGM, we expect to inform our shareholders as to the future challenges we have set for our executives.

Yours sincerely,

Willem Blijdorp
Chairman of the Remuneration Committee

B. Remuneration Governance

(i) Remuneration Committee

The Board has provided a mandate to 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 objectives of the Remunerations Committee's responsibilities are to ensure that:

- remuneration of the Company's KMP is aligned with the interests of the Company and its shareholders within an appropriate control framework, taking into account the Company's strategies but also its risks.
- the level and composition of remuneration attract, motivate and retain professionals of high calibre and with unique specialist industry knowledge to work towards the long-term growth and success of the Company.
- the role that total fixed remuneration and short- and long-term incentives play is clearly defined and provides a clear relationship between performance and remuneration.
- the levels and structure of remuneration are benchmarked against relevant international peers and considered against global employment market conditions.
- the Company gives due consideration to applicable legal requirements and appropriate standards of governance.

The methods used by the Remuneration Committee to assess Board performance is disclosed in the Corporate Governance Protocol.

(ii) 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 and 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 2023, the Remuneration Committee secured the services of remuneration advisors to provide comparable peer company market data and advice on LTI plans. However, under the definition of the Corporations Act, no remuneration recommendations were obtained during the financial year.

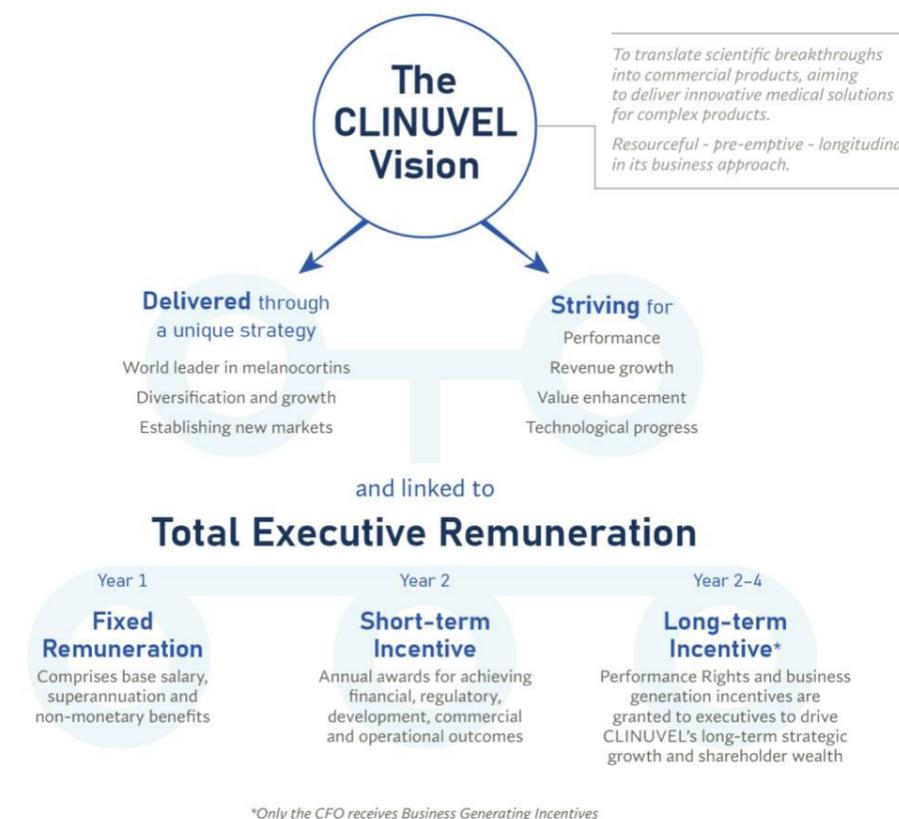
(iii) Voting and feedback at the Company's last Annual General Meeting

In the 2022 Annual General Meeting (AGM), the Company obtained 81.47% of the proxy votes (including votes at the proxy's discretion) in favour of adopting the 2021/22 Remuneration Report, and this resolution was carried in favour by poll with 81.46% of votes cast. A question was raised regarding the vesting of performance rights held by the Managing Director, otherwise the Company did not receive any further specific feedback at the AGM on its remuneration practices.

C. Executive Remuneration

(iv) Executive Remuneration Framework

The following diagram links each of the executive remuneration components to the Company's mission and strategy.



The Company's reward framework has historically provided for a mix of fixed and variable pay. The variable pay is structured to incentivise:

- **short-term** generally payments in the form of performance-based incentives awarded as a percentage of base salary.
- **long-term** generally based upon the issuance of performance rights to acquire shares in the Company to secure and recognise ongoing commitment.

The inherent risk of failure within pharmaceutical development and innovation is high and this risk is amplified for the Company due to its history of implementing a specialised and narrow focus on developing and commercialising novel, first-in-class and first-in-line therapies in diseases where there is an unmet clinical need.

The current progress and success of the Company needs to be set against previously unsuccessful managerial attempts to develop melanocortin technologies for commercial use. To mitigate risk and to provide a strong platform to achieve meaningful progress, the Board has followed a distinct business model where most operational skills are retained in-house, where possible, and many management responsibilities are concentrated between the Managing Director, the CSO, and the CFO. The Managing Director has the responsibility of guiding and overseeing the execution of the overall corporate strategy and has global responsibility for the safety aspects of the lead's drug technology.

The CSO is responsible for pre-clinical programs, toxicology, the manufacturing of the drug delivery program, clinical programs and setting the regulatory strategies in close coordination with the Board of Directors. As the business evolves and progresses through its development path, this centralised management model will continue to evolve, and key management responsibilities are being shared across existing and new senior management who have been brought into the Company.

The CFO is responsible for the overall financial management and administration of the Group. The CFO is critical in assisting the Board and Managing Director in its resource allocation and reinvestment decisions of cash and working capital, while representing the Company to existing and new investors.

The Board recognizes that experience, processes and the unique interaction between the three executive KMP and its executive staff, as critical factors underlying the financial performance of the Company.

The Managing Director's remuneration structure is reviewed every three years to ensure:

- a maximum level of incentivisation is in place to lead and advance the Company's programs from its current stages of development and commercial growth, in taking into account the unique risk and complexity of the chosen business model; and
- it is competitive in international markets to attract and retain specific skillsets.

In 2021/22 the Managing Director's service agreement was renewed for a further three years, from 1 July 2022 to 30 June 2025. In determining the level and structure of the remuneration agreed with the Managing Director, the Remuneration Committee considered the following criteria:

- longevity of his 17+ years of service as CEO compared against the average tenure of local and international peers;
- track record, integrity, and professional qualifications to excel in the role;
- the enterprise value created since first employment;
- capability to sustain the Company's focus to maximise profitability following market access;
- the demonstrated ability to maintain the solidarity of the business and management team over the long term; and
- communication of a longer-term vision to establish a diversified Group.

(v) Executive Remuneration Structure Financial year 2023

1. Fixed Base Remuneration Salary and Non-Monetary Benefits

Fixed base remuneration (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 on CLINUVEL's objectives, taking into account a range of factors including, seniority, qualifications, skill, experience, length of service, leadership, industry knowledge and level of strategic oversight.

FBR is tested annually for market competitiveness by reference 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. Any adjustments above CPI are in response to individual performance or change in job scope and reviewed by the Remuneration Committee.

2. Short-Term Incentives

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.

Details of the STI arrangements are as follows:

	Managing Director	Other Executive KMP
Setting and Assessment	Are reset at the start of each financial year by the Remuneration Committee and are assessed at the end of the financial year.	Are reset at the start of each financial year by the Managing Director and are recommended to the Remuneration Committee for their review and approval.
Maximum Opportunity	100% of Fixed Base Remuneration	Chief Financial Officer: 20.5% of Fixed Base Remuneration Chief Scientific Officer: 9% of Fixed Base Remuneration
Cessation of employment	STIs will be evaluated for the current performance period on a pro-rata basis.	Must be employed by the Company and not serving a period of notice prior to the end of the relevant financial year. It will not be paid pro-rata should the other KMP leave employment during the relevant financial year.
Performance hurdles	Can 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.	Can 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.
Payment	In the year following the year of achievement.	In the year following the year of achievement.
Disclosure of Performance	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 69 and 70.	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 69 and 70.

In assessing the Managing Director's STI for FY2023, the Remuneration Committee considered a variety of factors that impacted the reporting period, and Dr Wolgen's guidance was shown to navigate critical issues and challenges facing the Company. The Remuneration Committee considered such factors including rising supply constraints and costs, inflationary pressures, as well as the re-rating of 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, investigational settings. It viewed the overall progress of research, clinical and regulatory development, and the start of a photocosmetic consumer-oriented business.

Additional objectives were taken into consideration when assessing other executive KMP performance by the Remuneration Committee, which were considered an essential element of achieving individual performance.

However, some of these are considered commercially sensitive and are not disclosed.

The Managing Director's STI performance outcomes for FY2023 are tabled below, as aligned with the CLINUVEL strategy. An STI rating of 60.0% of the maximum potential opportunity for the Managing Director was achieved for FY2023 (FY2022: 42.5%).

STI Outcomes	Year Ended 30 June 2023		
STIs summarised into Strategic Grouping for Year	Managing Director		
	Weighting	Rating	Outcome
R&D, Manufacturing	30%	Medium	Development of the second afamelanotide formulation PRÉNUMBRA® INSTANT, completed and now in clinical use Progress in new pharmaceutically targeted formulations at pre-clinical stage Advancement in NEURACTHEL manufacturing Progress in establishing centres for clinical trial participation across multiple studies, first results announced
Growth	25%	Low	Diligence conducted on a range of potential targets, public and private company opportunities Pilot launch of first dermatocosmetic product Maintained strength in intellectual property protection; IP patent position defended
Financial Performance	30%	High	Increased total revenues in both major markets, complemented by disciplined, controlled growth in expenditure base Generated positive cash flows to increase cash reserves, enabling further reinvestment Continued avoidance of external funding sources Ongoing optimisation program to support future expansion
General Management & New Initiatives	15%	Medium	Increased the size of the executive team reduction to employee turnover rate Progress made to receive approval to expand the use of SCENESSE® in adolescents
Total	100%	60.0%	

Ratings Legend, Low = STIs are not met or marginally met, Medium = STIs are partially met, High = STIs are largely or wholly met

For the year ended 30 June 2023, the Remuneration Committee assessed overall performance for the 2022/23 year against the Short-Term Incentives, which were recommended by the Managing Director, and who approved following assessments against the maximum Short-Term Incentives:

Chief Scientific Officer – 100%

Chief Financial Officer – 85%

3. Long Term Incentives (equity-based incentives)

Long term incentives (LTIs) are generally offered in the form of performance rights, being an option to acquire ordinary shares of CLINUVEL PHARMACEUTICALS LTD. Since 2010, the Company has issued LTIs to the Managing Director and to other Executive KMPs on only three occasions. At the risk of forfeiting the performance rights, executives are generally required to remain employed during the entire length of the vesting term before the performance rights can be exercised into ordinary shares.

The LTIs are acquired at nil exercise price, and are offered to executive KMP and to staff from time to time to:

- support, attract and retain key executives;

- align their interests with CLINUVEL’s business strategy and maturity; and
- reward executives from improving long-term business performance and shareholder returns, and
- considering international and Australian best practices.

The Company does not issue LTIs annually to the Managing Director and executive KMPS, unlike many peer companies, but instead sets longer-term objectives to align executives within the group to predetermined objectives. Due to setting these long-term objectives, performance conditions have historically been based on a mix of financial and commercial objectives, and operational targets strongly linked to shareholder value, such as, revenue growth and regulatory approvals.

Under the existing performance rights plan of 2014, and applicable to the performance rights issued to the Managing Director in 2020, to other executive KMP in 2021, performance rights have a vesting end date of 20 November 2023. The achievement of a performance condition is assessed and approved by the Board when it is considered satisfied, or the condition has otherwise been waived by the Board. To date, no condition has been waived by the Board.

The Company may, at the sole discretion of the Board, determine that any ordinary shares exercised from vested performance rights be acquired by a Plan Trustee and then, from time to time, transferred to the Executive KMP and other participants of the Performance Rights Plan. The Company may determine and conclude agreements with the Plan Trustee and enforce or prosecute any rights and obligations under such agreements, without reference or recourse to a participant under the Plan.

The performance conditions attached to performance rights previously issued to executive KMPS which are unvested at any time during 2022/23 relate to long-term (multi-year) strategic, non-financial objectives.

At the 2019 Annual General Meeting, shareholders approved the grant of 1,513,750 Performance Rights to the Managing Director and these Performance Rights were offered and issued to the Managing Director, who accepted the offer on 26 August 2020. Prior to this, the Managing Director was last issued Performance Rights five years previously, in the 2014/15 financial year.

These performance rights have a vesting period of up to four years from date of shareholder approval. If the performance conditions are not achieved by 20 November 2023, these shall be forfeited and will lapse. On the reporting date the Group has assessed the probability of the underlying performance conditions attached to the performance rights being achieved by their vesting date to be 21% of the 1,513,750 performance rights granted to the Managing Director

Maximum LTI Opportunity

The Remuneration Committee outlines in its framework an annual maximum LTI opportunity as a percentage of fixed base remuneration for executives. The maximum annual LTI opportunity for the Managing Director is assessed in context of two factors:

- the relative weightings between fixed base remuneration, STI and LTI as part of the overall package
- desired positioning of each element relative to international markets.

Maximum LTI Opportunity



*Based on the value of the share price at issue date of 26 August 2020, LTI maximum opportunity is divided over 4 years being the length of the vesting period and compared with current year FBR.

The underlying conditions for the performance rights issued to the Managing Director and other Executive KMP are presented in the “Description of Performance Conditions”, and tabled below:

Performance Condition	Rationale
PC1	• to promote growth in Company value
PC2	• to diversify the Group whilst maintaining profitability
PC3	• to ensure conscious and risk-free financial management for further Company growth • to provide for financial stability to protect Shareholder value and to act as a counter cyclical buffer during adverse economic conditions
PC4	• to increase the revenue base
PC5	• to build further value from internal product development
PC6	• to expand its existing pharmaceutical product into a new market and increase commercial opportunities
PC7	• to expand new products in new or existing markets and increase potential revenue base
PC8	• to incentivise and reward for unanticipated commercial opportunities which are demonstrably value accretive

The market capitalisation targets defined in PC (i) to (v) continue to apply and were not replaced with performance targets in case of a recession for 2 consecutive quarters during the vesting period.
A summary of the performance conditions granted to the Managing Director in respect of the Performance Rights approved by shareholders at the 2019 AGM are set out in pages 80 to 81.

The Board regarded each performance hurdle for the performance conditions at the time of issue to be extremely challenging and this is now widely recognised by remuneration consultants, proxy advisors, and shareholders. This is currently demonstrated in the number of Performance Rights whose underlying performance conditions have not yet been met since their date of grant at the 2019 AGM. As at 30 June 2023, of the 1,513,750 granted to the Managing Director at the 2019 AGM, 1,197,500 performance rights, or 79% of the amount granted, are currently assessed as **not likely** to be probable of meeting their underlying performance condition by the date of vesting of 20 November 2023. Overall, the Managing Director is expected to meet just 21% of the performance hurdles set in 2019, indicating that these thresholds were set at ‘maximum stretch’.

The performance conditions attached to the Performance Rights granted to the other executive KMP are a mix of the same performance conditions attached to performance rights granted to the Managing Director at the 2019 AGM, ensuring total alignment with the Group’s long-term strategy, as well as role-specific performance conditions which are also linked to enhancing corporate value and to promoting longer term retention of skills and knowledge.

For CFO and CSO, the relative percentage of LTIs awarded during the past four years and their probability of vesting is highlighted in the table below:

Other Executive KMP	# Performance Rights	PC1-8	Role Specific PCs	Likely to be met by Vesting Date
CSO	75,813	69%	31%	26%
CFO	339,875	60%	40%	39%

No performance rights were issued to other executive KMP for the financial year ended 30 June 2023. For the financial year ended 30 June 2022, the other executive KMP were issued in total 415,688 Performance Rights, to vest 20 November 2023, as part of the remuneration reward framework to further align their interests with shareholders, to act as a key retention tool for and to provide further incentivisation to build company value. Prior to the 2021/22 year, the other executive KMP were last issued performance rights in the 2015/16 financial year.

4. Long Term Incentives - Future Issues to Executive KMP

The performance rights currently held by the executive KMP, including the Managing Director, vest on 20 November 2023. After this date, the remuneration structure for the executive KMP will no longer contain a long-term, equity-based component intended to provide the requisite level of motivation and incentivisation for the executive KMP to work towards the long-term growth and success of the Company. After this date, the absence of equity-based LTI’s will not be in alignment with the reward framework set by the Committee.

In consultation with proxy advisors, remuneration and legal specialists, the Committee is designing a new long-term incentive plan, in the form of performance rights that in the near term will be offered to the executive KMP, and in relation to the Managing Director, will require shareholder approval prior to granting. Consistent with prior issues of performance rights, to encourage retention, the next issue of performance rights will have a multi-year vesting period and will only be exercisable upon the holder of the performance rights remaining in employment at the expiration of the vesting period. Various factors will be considered when setting the amount of performance rights to be granted to the executive KMP, including:

- length of time served;
- volume weighted average share price (VWAP) at time of issue;
- the level of fixed base remuneration;
- market trends among international peer companies;
- responsibility within the Group;
- potential impact on share dilution; and
- characterisation of vesting conditions attached to the issue of performance rights.

Given the context of the Company’s distinct operations, as well as the practices of its peers, the nature of the performance conditions attached to future grants of performance rights to executive KMP, including the Managing Director, is expected to be a mix of market and non-market conditions. The Committee acknowledges a change to the Company’s share price is not solely determined by the financial performance achieved by management but can be influenced by the achievement of key strategic objectives, and a mix of financial and strategic targets linked to the long-term reward structure would be the best fit for the Company. The performance conditions could be linked to share price or other financial performance, clinical and regulatory outcomes, business expansion, the growth in the photocosmetic consumer line and achievements not foreseen at the time of grant due to a change in business direction. The Committee acknowledges the risk of changing business circumstances during a long-term vesting period which may result in a deviation away from those performance conditions based on strategic and operational outcomes. Accordingly, a future issue of performance rights will most likely have a discretionary element attached to it to reward the participant in the event a change in business strategy that was unforeseen at the time of grant is assessed as creating value.

Future issues of performance rights which may extend beyond the executive KMP and to be offered to other staff and management will most likely incorporate common elements aligning the global team i with achieving its objectives.

5. Business Generation Incentive (BGI)* and Discretionary Payments

Since 2021, the Company no longer includes cash-based BGIs in executive service agreements, and it considers LTIs a better instrument to ensure longer term value for shareholders.

BGIs are Individual longer-term cash incentive components based on specified performance-based targets which remain for the term of an executive’s service agreement. BGIs had aimed to:

- 1) reward exceptional business outcomes that contribute to creating significant corporate value without shareholder dilution through equity remuneration; and
- 2) to act as a key retention tool.

The Managing Director does not receive BGIs, no BGIs form part of the Managing Director’s service agreement. Only the CFO has currently two BGIs remaining in his current service agreement, linked to:

- 1) expansion of the Company through acquisition and integration of a new entity with demonstrated positive cash flows of the acquired entity post-acquisition; and
- 2) participation in an equity or debt funding event if deemed necessary to meet the business needs of the Company.

No BGIs were achieved by the Chief Financial Officer for the years ended 30 June 2023, or 30 June 2022

The Managing Director may be eligible to receive a discretionary cash payment only in the event of exceptional performance, innovation, expansion, acquisitions, manufacturing and business development which do not form part of the STI or not otherwise anticipated at the time of execution of the service agreement.

No discretionary payments have been made in 2023 or 2022.

(vi) Executive Remuneration – Peer Benchmarking

One of the Remuneration Committee’s responsibilities is to ensure that the level and structure of remuneration of staff are benchmarked against relevant peers and considered against global employment market conditions. CLINUVEL refers to a select group of publicly listed companies on the ASX and, more relevant, to international securities exchanges for the purpose of peer group analyses.

CLINUVEL is a company operating globally with all commercial activities taking place outside Australia, and the bulk of its operations and financial exposure falling within North America and the European Economic Area. 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. 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.

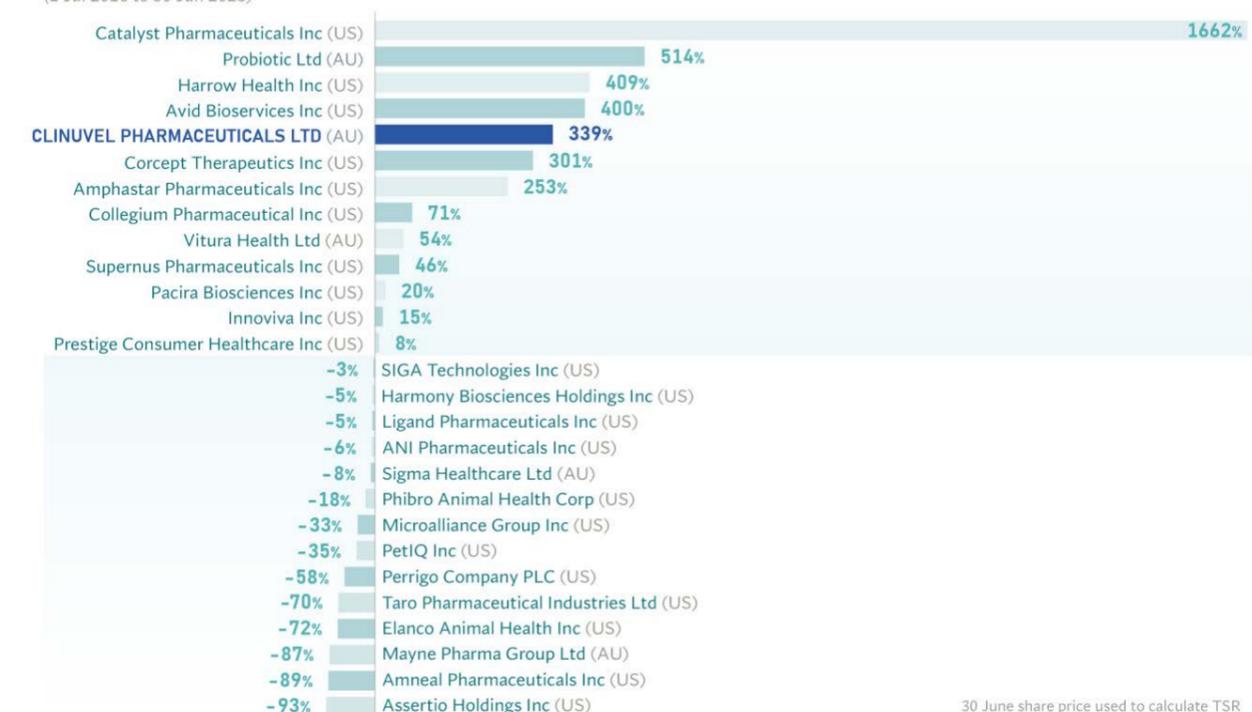
During the year the Managing Director’s remuneration was benchmarked against four Australian and 22 US life science peer companies with different profiles, since there are few profitable bio-technology companies globally serving as benchmark, (except for the mix of medical device, human and animal health prescriptive and over-the-counter pharmaceutical product, healthcare solutions and diagnostic focussed companies) using the following criteria:

Benchmarking Criteria	Australian Companies	US Companies
Market Capitalisation:	Between A\$100 million and A\$3 billion	Between US\$300 million and US\$5 billion
Generating Product Revenues:	Yes	Yes
Financial Status:	Positive EBITDA	Positive EBITDA

The financial performance of the Company measured over 7 consecutive years, being the time from first commercial product launch of its approved drug SCENESSE® has seen it rank strongly against revenue growth, EPS, and TSR amongst its peers.

7 Year TSR– Time from First Commercial Launch

(1 Jul 2016 to 30 Jun 2023)



30 June share price used to calculate TSR

Analyses of CLINUVEL’s share price performance against main life science indices shows an equally positive outcome, both in the shorter term (for the 12 months to 30 June 2023) and across the long-term (for the past seven years, consistent with the period of time from first commercial product launch). However, the Board is cognizant that there may not always be a relation between CLINUVEL’s volume weighted average share price (VWAP) and performance of the Company, as has been frequently demonstrated.

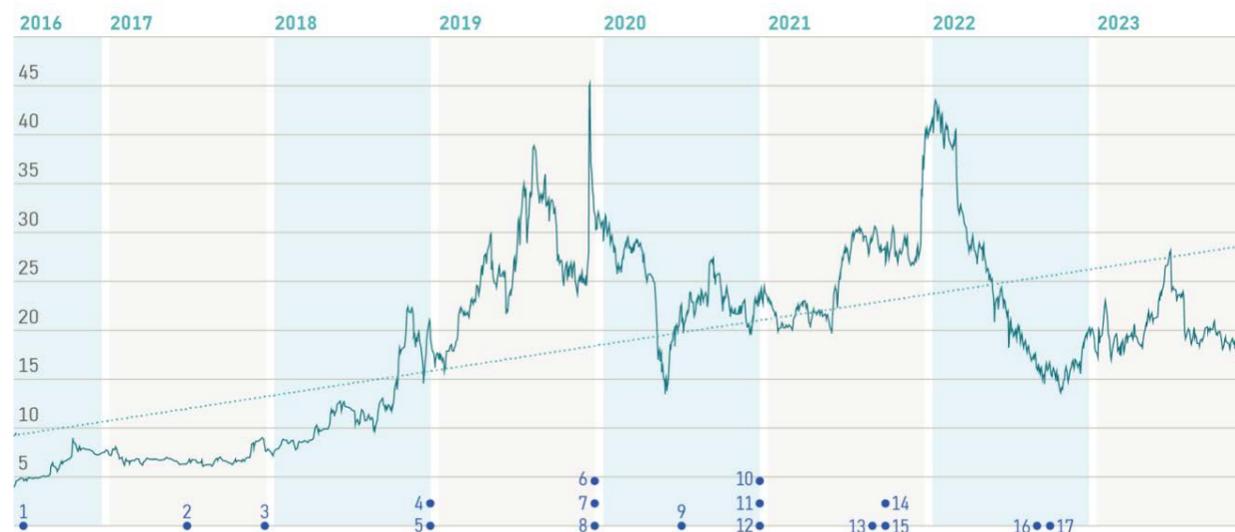


CUV Share Price and Key Indices

(% change year to June 2023)

(% change over seven years to 30 June 2023)

The table below shows the share price and some of the key milestones the past year.



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

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

6. Executive Remuneration Pay Mix

The Board believes the remuneration mix aligns the other executive KMP and Managing Director to shareholder interest. The remuneration mix for 2022/23 is demonstrated as follows:

Position	Fixed Remuneration	STI Cash	LTI Cash ¹	LTI Equity ¹
Managing Director	100%	47% of Base Salary	None	191% of Base Salary
Other Executive KMP				
CFO	100%	17.5% of Base Salary	None	633% of Base Salary
CSO	100%	9% of Base Salary	None	89% of Base Salary

1. Shown as total value of performance rights calculated under AASB2 divided by 4 years (CEO) and 2.4 years (CFO and CSO) being the vesting period of the performance rights held during the year.

D. Non-Executive Remuneration

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

7. Non-Executive Director Fees

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

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

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

	Board Fees	Audit & Risk Committee	Remuneration Committee	Nomination Committee
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 Non-Executive Directors 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 divided among the Non-Executive Directors as determined by the Board. The aggregate amount paid to Non-Executive Directors for the year ended 30 June 2023 was \$495,000.

8. Non-Executive Director Long-Term Incentive – Equity Compensation

The long-term equity remuneration was formerly provided to Non-Executive Directors via the CLINUVEL Conditional Rights Plan and the Performance Rights Plan. Any issue of Performance Rights to Non-Executive Directors requires shareholder approval.

It is not planned for Non-Executive Directors to participate in long-term equity compensation plans. No Non-Executive Director holds performance rights as at 30 June 2023.

E. Service Agreements FY2023

Remuneration and other terms of employment for the Managing Director and executive KMP are formalised by a service agreement determined by the Remuneration Committee and accepted by the Board of Directors. The agreement provides for fixed base remuneration, short- and long-term incentives, other benefits and participation, when eligible, in the CLINUVEL Performance Rights Plan.

The Managing Director, in consultation with the Remuneration Committee, oversees the service agreements entered into with other executive KMP, providing for base salary, incentives, other benefits and participation, when eligible, in the CLINUVEL Performance Rights Plan.

On appointment to the Board, all Non-Executive Directors enter into a service agreement with the Company in the form of a letter of appointment. The letter summarises the Board's policies, the Director's responsibilities and compensation for holding office.

In the prior financial year 2022 the service agreements for key Executives Dr Wolgen and Mr Keamy were extended for a further three years and two years respectively.

The details of the service agreements to the Managing Director and Executive KMP are:

Name	Dr Philippe Wolgen	Dr Dennis Wright	Mr Darren Keamy
Duration of contract	3 years	No fixed term	2 years
Notice Period (from Company)	12 months	3 months	12 months
Notice Period (from Managing Director)	12 months	-	-
Notice Period (from Executive KMP)	-	3 months	12 months
Termination Payment without Cause	12 months	3 months	12 months
Termination Payment with Cause	None	None	None
Contract End Date	30 June 2025	not applicable	30 June 2024

F. Equity-Based Awards

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.

9. Performance Rights:

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

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

a) 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 Performance Rights convert to one ordinary share of the Group and are issued for nil consideration, have no voting rights, are non-transferable and are not listed on the ASX. These can be converted to ordinary shares at any time once the vesting conditions attached to the rights have been achieved, whereby these will be held in a Scheme Trust 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. It is no longer intended to issue Performance Rights under the 2009 Plan.

As at 30 June 2023, 38,333 Performance Rights issued under the 2009 Scheme remain unvested.

b) 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. Since 2020, the Company policy is for Non-Executive Directors to **not** receive performance rights or other equity securities in the Company. All rights convert to one ordinary share of the Group and 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 performance rights be acquired by a Plan Trustee and then, from time to time, transferred to participants to the Performance Rights Plan. Unless the performance rights are granted with a shorter vesting period, performance rights under this plan lapse after seven years from grant date.

Performance rights 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 performance rights may or may not receive a benefit from these amounts, either in the current or future reporting periods. The value of all performance rights granted, exercised and lapsed during the financial year is detailed in the tables within the Remuneration Report.

On June 29, 2023, the Company issued 255,750 performance rights to non-Key Management Personnel. Each performance right entitles the holder to receive one fully paid ordinary share in CLINUVEL, subject to achieving certain time-served and company performance-based vesting conditions. Unless the Board determines otherwise, each staff member must be employed by CLINUVEL on the expiry date in order to exercise those performance rights that have met their performance conditions.

2,591,860 performance rights are issued under the 2014 Performance Rights Plan. 420,607 (16.3%) performance rights have met their underlying performance condition but will not vest until the end of their vesting period.

G. Details of Remuneration

10.KMP remuneration of the Company for the years ended 30 June 2023 and 30 June 2022 – Cash Based Benefits

	Year	Gross Salary ¹	Short Term Incentive	Retention Award ⁴	Other ¹	Superannuation/ Pension Fund	Subtotal	Leave Entitlements Paid Out, (Exceptional)	Total (Excluding Share-Based Payments)
		\$	\$	\$	\$	\$	\$	\$	\$
Dr. P. J. Wolgen ²	2023	1,593,117	898,244	-	286,314	-	2,777,675	-	2,777,675
	2022	1,490,048	560,113	101,731	198,128	-	2,350,020	1,314,157	3,664,177
Mrs. B. M. Shanahan	2023	76,923	-	-	-	8,077	85,000	-	85,000
	2022	77,273	-	-	-	7,727	85,000	-	85,000
Mr. W. A. Blijdorp	2023	115,000	-	-	-	-	115,000	-	115,000
	2022	115,000	-	-	-	-	115,000	-	115,000
Dr. K. A. Agersborg	2023	75,000	-	-	-	-	75,000	-	75,000
	2022	75,000	-	-	-	-	75,000	-	75,000
Mrs. S. E. Smith	2023	75,000	-	-	-	-	75,000	-	75,000
	2022	75,000	-	-	-	-	75,000	-	75,000
Prof. J. V. Rosenfeld	2023	67,874	-	-	-	7,126	75,000	-	75,000
	2022	68,182	-	-	-	6,818	75,000	-	75,000
Prof J. A. Likierman	2023	70,000	-	-	-	-	70,000	-	70,000
	2022	17,051	-	-	-	-	17,051	-	17,051
Dr. D. J. Wright	2023	289,182	26,026	-	-	25,292	340,500	-	340,500
	2022	278,059	25,025	-	-	23,568	326,652	-	326,652
Mr. D. M. Keamy	2023	331,737	58,054	-	-	25,292	415,083	-	415,083
	2022	331,737	46,443	12,000	-	23,568	413,748	-	413,748
Total	2023	2,693,833	982,324	-	286,314	65,787	4,028,258	-	4,028,258
	2022	2,527,350	631,581	113,731	198,128	61,681	3,532,471	1,314,157	4,846,628

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.

4) In FY2022 Retention Awards were removed from executive service agreements.

For Mr Keamy and Dr Wright, the movement to their aggregate annual leave and long service leave entitlements was \$11,206 accretive and \$24,693 reduction respectively (year ending 30 June 2022: \$39,991 and \$9,698 increase respectively).

For Dr Wolgen the accretive movement to his aggregate annual leave and long service leave entitlements for year ending 30 June 2023 was \$149,280.

FY2022 Leave Entitlements Paid Out

Paid annual leave and long-service leave are considered compensation as defined by Australian Accounting Standards Board AASB 119 Employee Benefits and the Corporations Regulations 2001 - REG 2M.3.03. During the year a management review was undertaken to address the increase in the Group's current and non-current employee provisions over time. As a result of the review, to assist in reducing the value of employee entitlements appearing on the Group Balance Sheet, the Board of Directors approved the payment of all unused, accrued annual leave and long service leave owed to the Managing Director from employment start in November 2005 up to 30 June 2021. The payout was made in lieu of the Managing Director consuming the employee entitlements through taking an enforced, extended leave of absence from his duties as Chief Executive Officer and Managing Director.

KMP remuneration of the Company for the years ended 30 June 2023 and 30 June 2022 – Non-Cash Benefits

Share-based payments (accounting charge only) ¹					
	Year	Total (Excluding Share-Based Payments)	Performance Rights (for accounting purposes only)	Total (Including Share-Based Payments, for accounting purposes only)	% Performance-based
		\$	\$	\$	
Dr. P. J. Wolgen	2023	2,777,675	3,612,426	6,390,101	71%
	2022	3,664,177	3,448,463	7,112,640	56%
Mrs. B. M. Shanahan	2023	85,000	-	85,000	-
	2022	85,000	-	85,000	-
Mr. W. A. Blijdorp	2023	115,000	-	115,000	-
	2022	115,000	-	115,000	-
Dr. K. A. Agersborg	2023	75,000	-	75,000	-
	2022	75,000	-	75,000	-
Mrs. S. E. Smith	2023	75,000	-	75,000	-
	2022	75,000	-	75,000	-
Prof. J. V. Rosenfeld	2023	75,000	-	75,000	-
	2022	75,000	-	75,000	-
Prof. J. A. Likierman	2023	70,000	-	70,000	-
	2022	17,051	-	17,051	-
Dr. D. J. Wright	2023	340,500	296,352	636,852	51%
	2022	326,652	176,165	502,817	40%
Mr. D. M. Keamy	2023	415,083	2,674,581	3,089,664	88%
	2022	413,748	1,196,205	1,609,953	77%
Total	2023	4,028,258	6,583,359	10,611,617	-
	2022	4,846,628	4,820,833	9,667,461	-

1. 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 performance rights and share options granted, exercised and lapsed during the financial year is detailed in the following tables within the Remuneration Report. Performance rights 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.

Remuneration Performance Rights holdings of KMP – 2023

	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*
Directors						
Dr. P. J. Wolgen	1,513,750	-	-	-	1,513,750	227,000
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	93,938	-	-	-	93,938	11,328
Mr. D.M. Keamy	347,235	-	-	-	347,235	86,400
*The underlying performance-based conditions have been met, but performance rights will not vest until the end of the vesting period. All Performance Rights held at the end of the year are unvested.						

Shares held by KMP

The number of ordinary shares in the Company during the 2022/23 reporting period held by each of the Group's KMP, including their related parties, is set out below:

Year Ended 30 June 2023					
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	3,120,715	-	-	1,532	3,122,247
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	2,848	-	-	300	3,148
Prof. J. A. Likierman	1,000	-	-	-	1,000
Other KMP					
Dr. D. J. Wright	256,874	-	-	(100,000)	156,874
Mr. D. M. Keamy	313,588	-	-	(135,000)	178,588

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	450,000	\$10.86	Ordinary	20/11/2019	26/08/2020	20/11/2023	45,000	20/11/2023
CLINUVEL	1,063,750	\$26.87	Ordinary	20/11/2019	26/08/2020	20/11/2023	182,000	20/11/2023
CLINUVEL	37,976	\$8.97	Ordinary	24/12/2020	24/12/2020	20/11/2023	3,798	20/11/2023
CLINUVEL	94,524	\$20.73	Ordinary	24/12/2020	24/12/2020	20/11/2023	31,543	20/11/2023
CLINUVEL	133,440	\$18.74	Ordinary	26/08/2021	26/08/2021	20/11/2023	24,901	20/11/2023
CLINUVEL	598,484	\$26.22	Ordinary	26/08/2021	26/08/2021	20/11/2023	123,566	20/11/2023
CLINUVEL	22,500	\$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.

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	2019/20 *	2023/24	-	-	8,226,311	
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	
	2021/22	2023/24	-	-	466,723	
Mr. D. M. Keamy	2011/12	no limitation	-	-	5,219	
	2021/22	2023/24	-	-	3,169,166	

On exercise, each Performance Right 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 performance rights is \$Nil. The exercise price for those Rights granted between 2010/11 and 2021/22 was \$Nil.

* At the 2019 Annual General Meeting, shareholders approved the grant of 1,513,750 performance rights to the Managing Director and these performance rights were issued on 26 August 2020. At 30 June 2023, it is assessed that 21% of these performance rights are considered probable to be met by their vesting date of 20 November 2023.

Remuneration details of cash incentives

Cash Incentives				
Name	Max Potential Opportunity (%)	STI Awarded (%)*	STI Forfeited (%)	Total Granted (\$)
Dr. P. J. Wolgen	100%	56%	53%	898,244
Dr. D. J. Wright	9%	100%	0%	26,026
Mr. D. M. Keamy	20.5%	85%	15%	58,054

* For the Managing Director, 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 2023 and 30 June 2022.

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

H. APPENDIX

Details of performance rights issued to Managing Director, expiring 20 November 2023	Performance Condition met, not exercisable until end Vesting Period (20 November 2023)
PC1 Performance Rights granted to Managing Director – 450,000	
Executive management and staff succeeding in steering the Company to a:	
(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,	✓
(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,	
(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,	
(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,	
(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.	
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.	
PC2 Performance Rights granted to Managing Director – 105,000	
(i) Upon quarterly reporting of A\$60 million in cash and cash equivalents held for 2 consecutive quarters, 15% of PC2 shall vest,	✓
(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,	✓
(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,	✓
(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.	
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.	

PC3 Performance Rights granted to Managing Director – 105,000	
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,	
(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.	
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®, 34% of PC4 shall vest,	✓
(ii) US revenues in year 3 to exceed revenues by a minimum of 10% in year 2, a further 33% of PC4 shall vest,	✓
(iii) US revenues greater than US\$10,000,000 in a 12-month period leads to vesting of 33% of PC4.	✓
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,	✓
(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,	
(iii) First topical melanogenic formulation to be used either in animal or in human testing, a further 25% of PC5 shall vest,	
(iv) Upon the completion of the first clinical study of a SCENESSE® paediatric formulation (being the completion of a final clinical study report), a further 30% of PC5 shall vest.	
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,	
(ii) Upon disclosure to the securities exchange of the results to the Phase IIb vitiligo study in North America, 20% of PC6 shall vest,	
(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,	
(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,	
(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.	
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® or any other molecule or product enhancing the pharmaceutical product line-only offerings of the Company, 25% of PC7 shall vest,	
(ii) Upon the regulatory approval by either of EMA, FDA, TGA, PMDA and Swissmedic of SCENESSE® or any other molecule constituting a successful evaluation of a scientific dossier, a further 75% of PC7 shall vest.	
PC8 Performance Rights granted to Managing Director – 116,250	
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.	
These corporate events shall include, but are not limited to, business generation in new markets without the Company engaging in merger and acquisition activity.	

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	Nil	\$Nil	Ordinary

Unissued shares under option

Entity	Number of Shares under Rights	Exercise Price	Class	Expiry Date
CLINUVEL PHARMACEUTICALS LTD	2,630,193	\$Nil	Ordinary	Upon achievement of specific performance and time-based milestones or upon cessation of employment
Total as at date of Directors Report				
	2,630,193			

Auditor's Independence Declaration

The auditor's independence declaration as required by s.307C of the Corporations Act 2001 is included in page 115 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 29th day of August, 2023

Statement of Profit and Other Comprehensive Income for the Year Ended 30 June 2023

	Note	Consolidated Entity	
		2023 \$	2022 \$
Revenues			
Commercial sales of goods	21	72,179,047	60,002,220
Sales reimbursements	21	6,142,271	5,720,072
Total revenues		78,321,318	65,722,292
Interest income		3,905,856	444,071
Total interest income		3,905,856	444,071
Other income			
Unrealised gain on restating foreign currency balances and currencies held		659,901	604,317
Realised foreign currency gain on transactions		79,364	-
Government grants and other income		23,817	216,835
Total other income		763,082	821,152
Total expenses			
Personnel-related		13,576,951	11,590,661
Materials and related expenses		12,063,281	5,401,679
Share-based payments		8,989,788	6,120,977
Finance, corporate and general		3,192,713	2,274,357
Commercial distribution		3,145,355	2,494,361
Legal, insurance and IP		1,323,383	1,147,199
Clinical and non-clinical development		1,268,456	1,232,989
Depreciation and amortisation		789,408	757,826
Communication, branding and marketing		749,769	291,772
Changes in inventories of raw materials, work in progress and finished goods		(7,687,571)	1,354,779
Total expenses		37,411,533	32,666,600
Profit before income tax		45,578,723	34,320,915
Income tax on income		-	-
Current	3(a)	16,382,733	7,367,889
Deferred	3(a)	(1,408,576)	6,074,561
Income tax expense	3(a)	14,974,157	13,442,450
Operating profit after income tax	17(b)	30,604,566	20,878,465
Net profit for the year		30,604,566	20,878,465
Other comprehensive income			
Items that may be re-classified subsequently to profit or loss		-	-
Exchange differences of foreign exchange translation of foreign operations		(1,454,160)	(1,057,433)
Other comprehensive loss for the period, net of income tax		(1,454,160)	(1,057,433)
Total comprehensive income for the period		29,150,406	19,821,032
Basic earnings per share - cents per share	16	61.9	42.3
Diluted earnings per share - cents per share	16	59.1	40.3
The accompanying notes form part of these financial statements.			

Statement of Financial Position as at 30 June 2023

	Note	Consolidated Entity	
		2023	2022
		\$	\$
Current assets			
Cash and cash equivalents	17(a)	156,813,537	121,509,282
Trade and other receivables	4	22,214,646	16,201,937
Inventories	5	9,519,462	1,831,891
Other assets	6	1,070,153	1,039,453
Total current assets		189,617,798	140,582,563
Non-current assets			
Property, plant and equipment	7	2,017,861	1,540,702
Right-of-use assets	8	833,326	1,159,642
Intangible asset	9	185,030	185,030
Deferred tax assets	3(c)	1,059,541	481,600
Total non-current assets		4,095,758	3,366,974
Total assets		193,713,556	143,949,537
Current liabilities			
Trade and other payables	11	7,649,572	3,277,857
Income tax payables		16,094,178	7,279,449
Provisions	12	1,450,120	2,859,828
Lease Liabilities	8	300,843	315,068
Total current liabilities		25,494,713	13,732,202
Non-current liabilities			
Deferred tax liabilities	3(c)	2,757,516	3,615,281
Lease Liabilities	8	699,022	941,463
Provisions	12	131,162	101,548
Total non-current liabilities		3,587,700	4,658,292
Total liabilities		29,082,413	18,390,494
Net assets		164,631,143	125,559,043
Equity			
Contributed equity	13	151,849,375	151,849,375
Reserves	14	22,556,044	12,112,096
Accumulated losses		(9,774,276)	(38,402,428)
Total equity		164,631,143	125,559,043

The accompanying notes form part of these financial statements.

Statement of Cash Flows for the Year Ended 30 June 2023

	Note	Consolidated Entity	
		2023	2022
		\$	\$
Cash flows from operating activities			
Receipts from customers		74,877,720	66,399,524
Payments to suppliers and employees		(33,230,793)	(27,352,186)
Income taxes paid		(7,744,922)	-
Interest received		2,727,126	248,999
GST and VAT refunds		260,923	358,687
Government grants		22,009	217,258
Net cash provided by operating activities	17(b)	36,912,063	39,872,282
Cash flows from investing activities			
Payments for property, plant and equipment		(1,027,532)	(434,438)
Net cash used in investing activities		(1,027,532)	(434,438)
Cash flows from financing activities			
Dividends paid		(1,976,414)	(1,235,265)
Payment of lease liabilities		(263,718)	(268,492)
Payment of interest		-	-
Net cash used in financing activities		(2,240,132)	(1,503,757)
Net increase in cash held		33,644,399	37,934,087
Cash and cash equivalents at beginning of the year		121,509,282	82,690,982
Effects of exchange rate changes on foreign currency held		1,659,856	884,213
Cash and cash equivalents at end of the year	17(a)	156,813,537	121,509,282

The accompanying notes form part of these financial statements.

Statement of Changes in Equity for the Year Ended 30 June 2023

	Share Capital	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
	\$	\$	\$	\$	\$
Balance at 30 June 2021	151,849,375	4,343,422	674,405	(58,129,768)	98,737,434
Exercise of performance rights under share-based payment	-	-	-	-	-
Employee share-based payment options	-	6,036,836	-	84,141	6,120,977
Dividends paid	-	-	-	(1,235,266)	(1,235,266)
Transactions with owners	151,849,375	10,380,258	674,405	(59,280,893)	103,623,145
Profit for the year	-	-	-	20,878,465	20,878,465
<i>Other comprehensive income:</i>					
Exchange differences of foreign exchange translation of foreign operations	-	-	1,057,433	-	1,057,433
Total other comprehensive income	-	-	1,057,433	-	1,057,433
Balance at 30 June 2022	151,849,375	10,380,258	1,731,838	(38,402,428)	125,559,043
Exercise of performance rights under share-based payment	-	-	-	-	-
Employee share-based payment options	-	8,989,788	-	-	8,989,788
Dividends paid	-	-	-	(1,976,414)	(1,976,414)
Transactions with owners	151,849,375	19,370,046	1,731,838	(40,378,842)	132,572,417
Profit for the year	-	-	-	30,604,566	30,604,566
<i>Other comprehensive income:</i>					
Exchange differences of foreign exchange translation of foreign operations	-	-	1,454,160	-	1,454,160
Total other comprehensive income	-	-	1,454,160	-	1,454,160
Balance at 30 June 2023	151,849,375	19,370,046	3,185,998	(9,774,276)	164,631,143

Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2023

1. Basis Of Preparation

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

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

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

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

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

a) Principles Of Consolidation

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

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

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

b) Going Concern

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

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

c) 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.

The deferred tax asset has been recognised as at 30 June 2023 and 30 June 2022 after management judgement was applied to assess whether its unused tax losses and tax offsets could be utilised by future taxable profits. It was determined:

- The consolidated entity has experienced consecutive years of profitability and revenue growth;
- Current pricing agreements with European and US payors are not expected to change in the next financial year;
- 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.

d) Cash And Cash Equivalents

Cash and cash equivalents comprise of cash on hand, at call and term deposits with banks or financial institutions, bank bills and investments in money market instruments where it is easily convertible to a known amount of cash and subject to an insignificant risk of change in value.

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

e) 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.

f) Other Current Assets

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

g) Property, Plant And Equipment

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

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 diminishing value 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.

h) 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.

i) Intangible Assets – Trademarks And Patents

Trademarks and patents have a finite useful life and are recorded at cost less accumulated amortisation and impairment losses. Amortisation is charged on a straight-line basis over the shorter of the relevant agreement or useful life. The trademarks and patents had been fully amortised.

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).

Subsequent Measurement Of Financial Assets

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

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

Classifications are determined by both:

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

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

Financial Assets At Amortised Cost

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

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

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

Impairment Of Financial Assets - Trade And Other Receivables

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

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

Classification And Measurement of Financial Liabilities

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

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

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

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

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, loyalty payment, annual leave and long service leave when it is probable that settlement will be required and they are capable of being measured reliably.

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

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

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:

- 1) identifying the contract with a customer;
- 2) identifying the performance obligations;
- 3) determining the transaction price;
- 4) allocating the transaction price to the performance obligations; and
- 5) 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 21 provides additional disclosures disaggregating revenue by geographical market.

Interest

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

Government 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 represents 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) Goods And Services Tax/Value Added Tax (GST)

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

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

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

t) Comparatives

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

u) 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.

v) 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.

w) 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 23. The total expense is brought to account over the vesting period which for some instruments requires the group to form judgements associated with the timing and probability of vesting conditions.

Key Judgements – Trade Debtors

In applying the Group's accounting policy to trade debtors, significant judgement is involved in assessing the expected credit loss of trade debtors amounts. The Group uses ageing of trade debtors and use judgement to assess the expected credit loss of

trade debtors taking into account historical loss experience and other forward-looking factors specific to the debtors and the economic environment. The value of trade debtors is included in Note 4.

Key Judgements – Tax Losses

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

Uncertainty Over Income Tax Treatments

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

x) 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 21.

y) 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 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 2023.

2. Profit/(Loss) From Continuing Operations

Profit/(loss) before income tax includes the following specific expenses	Consolidated Entity	
	2023	2022
Employee benefits expense	12,960,543	10,825,178
Operating lease expense – minimum lease payments	306,830	324,124
Amortisation of right-of-use assets	343,642	289,888
Depreciation on property, plant & equipment	397,260	426,700
Bank charges	38,671	38,069
Loss on sale of property, plant and equipment	-	27,380

3. Income Tax Expense

	Consolidated Entity	
	2023	2022
	\$	\$
(a) Income tax expense		
Current	16,382,733	7,367,889
Deferred	(1,408,576)	6,074,561
Income tax expense	14,974,157	13,442,450
Deferred tax included in income tax expense (benefit) comprises:		
Increase/Decrease in deferred tax assets	(497,571)	4,425,880
Increase/Decrease in deferred tax liabilities	(911,005)	1,648,682
	(1,408,576)	6,074,562
(b) Numerical		
Profit before income tax expense	45,578,723	34,320,915
Tax at the statutory tax rates of 30% in 2023 and 2022	13,673,617	10,296,275
<i>Tax effect amounts which are not deductible/(taxable) in calculating taxable income:</i>		
Non-deductible share-based payments	1,229,465	1,836,293
Other non-deductible expenses for tax purposes	71,075	1,735,845
	14,974,157	13,868,413
Recognition of DTA on carry forward tax losses at year end	-	(425,963)
Income tax expense	14,974,157	13,442,450
Tax losses not recognised		
Unused tax losses for which no deferred tax asset has been recognised	18,899,558	20,325,477
(c) Deferred tax assets		
Carry forward tax losses	1,011,871	381,050
Intangibles	553,282	513,469
Provisions	233,280	271,869
Accrued Expenses	61,700	145,729
Lease liabilities	10,642	33,957
	1,870,775	1,346,074
Reconciliation to the Statement of Financial Position		
Total deferred tax assets	1,870,775	1,346,074
Set-off of deferred tax liabilities that are expected to reverse in the same period	(811,234)	(864,474)
	1,059,541	481,600
Movements		
Opening balance	1,346,074	5,762,262
Deferred tax assets utilised	-	(5,042,930)
Carry forward tax losses	630,821	381,050
Intangibles	39,813	79,747
Lease liabilities	(23,314)	(14,763)
Accrued Expenses	(84,030)	118,933
Provisions	(38,589)	61,775
	1,870,775	1,346,074
(c) Deferred tax liabilities		
Unrealised foreign exchange gains	(3,142,445)	(4,238,456)
Accrued income	(420,888)	(218,641)
Right-of-use assets	(10,108)	(33,275)
Intangibles	4,691	10,617
	(3,568,750)	(4,479,755)
Reconciliation to the Statement of Financial Position		
Total deferred tax liabilities	(3,568,750)	(4,479,755)
Set-off of deferred tax assets that are expected to reverse in the same period	811,234	864,474
	(2,757,516)	(3,615,281)

Movements		
Opening balance	(4,479,755)	(2,831,074)
Unrealised foreign exchange gains	1,096,011	(1,464,144)
Right-of-use assets	23,167	15,920
Accrued income	(202,247)	(201,854)
Intangibles	(5,926)	1,397
	(3,568,750)	(4,479,755)

Deferred tax assets include US and UK 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 2023 and 2022, income tax rate of 21% for US entity in 2023 and 2022 and income tax rate of 25% for UK entity in 2023.

4. Trade and Other Receivables

	Consolidated Entity	
	2023	2022
	\$	\$
Current		
Trade debtors	20,807,909	15,898,020
Interest receivables	1,438,696	259,633
Sundry debtors	134,199	44,284
Less: Provision for expected credit losses	(166,158)	-
Total	22,214,646	16,201,937

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 2023, the Group had a provision for expected credit loss of \$166,158 (2022: \$Nil).

	Consolidated Entity	
	2023	2022
	\$	\$
Opening balance as at 1 July 2022	-	-
Provision for expected credit losses	166,158	-
Closing balance at 30 June 2023	166,158	-

5. Inventories

	Consolidated Entity	
	2023	2022
	\$	\$
Current		
Raw materials – at cost	514,812	519,393
Less: Provision for obsolescence – raw materials	(51,655)	(159,712)
Work in progress – at cost	7,466,396	1,176,227
Finished goods – at cost	1,589,909	295,983
Total	9,519,462	1,831,891

A provision for obsolescence of \$108,057 was written off in 2023 (2022: \$Nil).

6. Other Assets

	Consolidated Entity	
	2023	2022
	\$	\$
Prepayments	1,070,153	1,039,453
Total	1,070,153	1,039,453

7. Property, Plant and Equipment

	Consolidated Entity	
	2023	2022
	\$	\$
Plant and equipment		
At cost	1,487,388	1,289,490
Less: accumulated depreciation	(490,012)	(343,245)
Sub-total	997,376	946,245
Furniture and fittings		
At cost	45,603	41,935
Less: accumulated depreciation	(26,387)	(22,575)
Sub-total	19,216	19,360
Leasehold improvements		
At cost	1,888,048	1,253,373
Less: accumulated amortisation	(886,779)	(678,276)
Sub-total	1,001,269	575,097
Total property, plant and equipment	2,017,861	1,540,702

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			
	Plant And Equipment	Furniture And Fittings	Leasehold Improvements	Total
	\$	\$	\$	\$
Carrying amount at 30 June 2021	483,267	22,448	878,707	1,384,422
Additions	615,183	1,306	-	616,489
Disposals	(101,018)	-	-	(101,018)
Depreciation written back on disposals	72,464	-	-	72,464
Depreciations expense	(123,651)	(4,394)	(303,610)	(431,655)
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)
Carrying amount at 30 June 2023	997,376	19,216	1,001,269	2,017,861

8. Right-of-Use Assets and Lease Liabilities

	Consolidated Entity	
	2023	2022
	\$	\$
Right-of-use assets		
At cost	1,782,946	1,775,894
Less: accumulated depreciation	(949,620)	(616,252)
Total right-of-use assets	833,326	1,159,642

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 2021	1,218,721	
Additions	236,965	
Amortisation	(289,888)	
Currency translation differences	(6,156)	
Carrying amount at 30 June 2022	1,159,642	
Additions	7,052	
Amortisation	(343,642)	
Currency translation differences	10,274	
Carrying amount at 30 June 2023	833,326	

	Consolidated Entity	
	2023	2022
	\$	\$
Lease liabilities		
Lease liabilities - Current	300,843	315,068
Lease liabilities - Non-current	699,022	941,463
Total lease liabilities	999,865	1,256,531

The Group has leases primarily in relation to offices and laboratory facility ranging from 3 to 6 years. 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 6.4% in 2023 and 5.5% in 2022. Please refer to Note 22 for a maturity analysis of the Group's lease liabilities.

9. Intangible asset

	Consolidated Entity	
	2023	2022
	\$	\$
Goodwill		
At cost	185,030	185,030
Less: impairment	-	-
Total	185,030	185,030

Goodwill is not amortised but is measured at cost less any accumulated impairment losses. Impairment occurs when a cash-generating unit's recoverable amount falls below the carrying value of its net assets. The results of the impairment test show that the cash-generating unit's recoverable amount exceeds the carrying value of its net assets, inclusive of goodwill. Consequently, there is no goodwill impairment as at 30 June 2023.

10. Interests in Subsidiaries

Name of Entity	Country of Incorporation	Ownership Interest	
		2023	2022
Parent entity			
CLINUVEL PHARMACEUTICALS LTD	Australia		
Controlled entities			
A.C.N. 108 768 896 PTY LTD	Australia	100%	100%
CLINUVEL (UK) LTD	United Kingdom	100%	100%
CLINUVEL, INC.	United States of America	100%	100%
CLINUVEL AG	Switzerland	100%	100%
CLINUVEL SINGAPORE PTE LTD	Singapore	100%	100%
VALLAURIX PTE LTD	Singapore	100%	100%
CLINUVEL EUROPE LIMITED	Ireland	100%	100%
VALLAURIX MC SARL	Monaco	100%	100%

All transactions with subsidiaries have been eliminated on consolidation.

11. Trade and Other Payables

	Consolidated Entity	
	2023	2022
	\$	\$
Current		
Unsecured trade creditors	2,791,672	259,199
Sundry creditors and accrued expenses	4,857,900	3,018,658
Total	7,649,572	3,277,857
(a) Aggregate amounts payable to:		
Directors and Director-related entities	910,574	564,667
(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged by natural hedges and included in Trade and Sundry creditors:		
Danish Krona	-	42
Canadian dollars	16,791	-
Other	-	-
Total	16,791	42

For an analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 22.

(c) Terms and conditions: Trade and sundry creditors are non-interest bearing and normally settled on 30 day terms.

12. Provisions

	Consolidated Entity	
	2023	2022
	\$	\$
Current		
Employee benefits	1,450,120	2,859,828
Total	1,450,120	2,859,828
Non-current		
Employee benefits	56,573	31,643
Other provisions	74,589	69,905
Total	131,162	101,548

13. Contributed Equity

(a) Issued And Paid Up Capital

	Consolidated Entity	
	2023	2022
	\$	\$
49,410,338 fully paid ordinary shares (2022: 49,410,338)	151,849,375	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			
	2023		2022	
	No.	\$	No.	\$
At the beginning of the financial year	49,410,338	151,849,375	49,410,338	151,849,375
Issued during the year	-	-	-	-
Conditional rights issues and transferred from conditional rights reserve	-	-	-	-
Less: transaction costs	-	-	-	-
Balance at the end of the financial year	49,410,338	151,849,375	49,410,338	151,849,375

(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
Upon achievement of various performance milestones	\$Nil	-
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
Upon achievement of various performance milestones	\$Nil	2,630,193

14. Reserves

	Consolidated Entity	
	2023	2022
	\$	\$
Conditional Performance Rights reserve:		
Balance at the beginning of period	10,380,258	4,343,422
Share-based payment	8,989,788	6,120,977
Transfer to share capital	-	-
Lapsed, forfeited rights	-	(84,141)
Balance at the end of period	19,370,046	10,380,258
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.		
Foreign currency translation reserve:		
Balance at the beginning of period	1,731,838	674,405
Translating foreign subsidiary to current rate at reporting date	1,454,160	1,057,433
Balance at the end of period	3,185,998	1,731,838
Total reserves	22,556,044	12,112,096

15. Short-Term Lease Commitments

	Consolidated Entity	
	2023	2022
	\$	\$
Operating lease commitments		
Non-cancellable operating leases contracted for but not capitalised under AASB 16 as they are short-term or low value and are payable as follows:		
not later than 1 year	43,207	27,867
Low value item later than 1 year but not later than 5 years	1,350	2,731
Total	44,557	30,598
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.		

16. Earnings Per Share (EPS)

	Consolidated Entity	
	2023	2022
	\$	\$
(a) Basic earnings per share (cents per share)	61.9	42.3
(a) Diluted earnings per share (cents per share)	59.1	40.3
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	49,410,338	49,410,338
(b) Weighted average number of performance rights on issue in respect of share based payments during the year	2,405,659	2,366,106
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	51,815,997	51,776,444
(c) The numerator used in the calculation of basic earnings per share (\$)	30,604,566	20,878,465
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.		

17. Cash Flow Information

	Consolidated Entity	
	2023	2022
	\$	\$
(a) Reconciliation of cash		
<i>Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled to the related items in the balance sheet as follows:</i>		
Cash at bank	22,883,205	22,849,846
Cash on hand	774	259
Deposits on call	617,759	4,215,543
Term deposits	132,946,316	94,100,000
Security bonds	365,483	343,634
Total cash and cash equivalents	156,813,537	121,509,282
(b) Reconciliation of cash flows from operating activities with operating profit (loss)		
Operating profit after income tax	30,604,566	20,878,465
<i>Non cash flows in operating profit after income tax:</i>		
Depreciation expense on property, plant & equipment	397,260	426,700
Amortisation expense on right-of-use assets	343,642	289,888
Exchange rate effect on foreign currencies held	(1,659,855)	(884,213)
Share-based payment expense	8,989,788	6,120,977
Unrealised loss (gain) on foreign exchange translation	1,454,160	1,057,434
Loss on sale of non-current assets	-	27,379
<i>Changes in assets and liabilities:</i>		
(Increase)/decrease in receivables	(6,012,709)	(113,410)
(Increase)/decrease in inventories	(7,687,571)	1,354,779
Increase in other assets	(30,700)	(157,418)
(Increase)/decrease in deferred tax assets	(577,941)	2,449,588
Increase/(decrease) in payables	4,514,552	(1,563,412)
Increase in income tax payables	8,814,729	7,184,398
Decrease in provisions	(1,380,093)	(814,154)
Increase/(decrease) in deferred tax liabilities	(857,765)	3,615,281
Net cash used in operating activities	36,912,063	39,872,282
Cash at bank earns floating rates based on daily bank deposit rates. The carrying amounts of cash and cash equivalents represent fair value. The effective interest rate on short-term deposits was 3.33% (2022: 0.64%). These deposits have an average maturity date of 252 days (2022: 249 days).		

18. Key Management Personnel

	Consolidated Entity	
	2023	2022
	\$	\$
Short-term employee benefits	3,962,471	4,225,617
Post-employment benefits	65,787	61,681
Long-term benefits	-	559,330
Share-based payments	6,583,359	4,820,833
Total	10,611,617	9,667,461
No loans or other transactions existed with key management personnel.		

19. Auditor's Remuneration

	Consolidated Entity	
	2023	2022
	\$	\$
<i>Amounts received or due and receivable by Grant Thornton for:</i>		
Audit services and review	246,154	179,000
Total	246,154	179,000
No non-audit services were provided by Grant Thornton during the year (FY2022\$Nil).		

20. 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 2023 is \$0 (2022: \$4,370,640).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL, INC. is interest bearing at average of 4.6% in 2023 and 2.1% in 2022. 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 2023 is \$21,681,805 (2022: \$23,381,365).

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 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 2023 is \$188,531 (2022: \$13,985,963).

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 2023 is \$625,133 (2022: \$629,876).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL (UK) is interest bearing at average of 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 2023 is \$2,053,783 (2022: \$7,383,677).

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 2023 is \$10,475,621 (2022: \$7,127,994).

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 (from) VALLAURIX MC SARL as at 30 June 2023 is \$6,339,501 (2022: \$2,958,807 payable).

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 2023 is \$9,675,165 (2022: \$1,984,059).

Director Related And Key Management Personnel Transactions And Entities:

There are no loan transactions and relationships in existence as at 30 June 2023 between Directors and the Company and its related entities.

21. Segment Information

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

The Group has identified its operating segments based on the internal reports that are reviewed and used by the Chief Executive Officer (the Chief Operating Decision Maker) in assessing performance and in determining the allocation of resources. The Group operates in a single operating segment, being the biopharmaceutical sector, and the majority of its activities are concentrated on researching, developing and commercialising a sole asset, being its leading drug candidate. Accordingly, the Group's consolidated total assets are the total reportable assets of the operating segment.

The Group has established entities in more than one geographical area. The non-current assets that are not held within Australia are immaterial to the Group. The revenues earned from external customers by geographical location is detailed below. The consolidated entity has one operating segment within the definition of AASB 8.

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

	FY2023			FY2022		
	Commercial sales of goods \$'000	Sales reimbursements \$'000	Total \$'000	Commercial sales of goods \$'000	Sales reimbursements \$'000	Total \$'000
Europe & USA	72,179	104	72,283	60,002	139	60,141
Switzerland, Others	-	6,038	6,038	-	5,581	5,581
Total	72,179	6,142	78,321	60,002	5,720	65,722

The Group has a number of customers to which it provides its leading drug candidate. Two customers each comprise 15% and 13% of external total revenue (2022: Two customers each comprising 12% of external total revenue).

22. 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 2023 and as at 30 June 2022.

The Consolidated Entities Exposure To Foreign Currency Risk At 30 June 2023

	Consolidated Entity							
	2023				2022			
	Cash and Cash Equivalents	Trade Debtors and Other Assets	Trade, Other Payables and Provisions	TOTAL	Cash and Cash Equivalents	Trade Debtors and Other Assets	Trade, Other Payables and Provisions	TOTAL
USD	12,016,211	7,719,647	(2,249,199)	17,486,659	7,932,297	7,452,124	(422,710)	14,961,711
EUR	9,658,588	5,157,824	(2,403,905)	12,412,507	5,876,623	2,650,122	(2,252,650)	6,274,095
CHF	1,406,750	-	(93,231)	1,313,519	554,736	579,272	(128,874)	1,005,134
GBP	1,184,729	-	(396,064)	788,665	297,972	149,530	(258,288)	189,214
SGD	558,588	-	(241,557)	317,031	989,697	238,264	(302,720)	925,241
CAD	-	-	(14,744)	(14,744)	-	-	-	-
DKK	-	-	-	-	-	-	(206)	(206)
SEK	-	-	-	-	-	429,225	-	429,225
ILS	-	-	-	-	-	-	(100)	(100)

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 8.7% appreciation of the Australian dollar against the Euro currency would have decreased profit and loss and equity by \$2,147,985 for the year ended 30 June 2023 (2022: \$1,661,459 decrease), on the basis that all other variables remain constant. 8.7% 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 2023, 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 \$4,564,433 higher/lower (2022: \$3,247,999 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 2023

	Consolidated Entity	
	2023	2022
	\$	\$
Trade and other payables		
Carrying amount	7,649,572	3,277,857
6 months or less	7,645,178	3,273,492
Greater than 6 months	4,394	4,365
Total	7,649,572	3,277,857
Lease liabilities		
Carrying amount	999,865	1,358,214
6 months or less	161,018	170,979
Greater than 6 months	838,847	1,187,235
Total	999,865	1,358,214

Capital Risk Management

The consolidated entity's equity is limited to shareholder contributions, supported by the cash inflows received from providing SCENESSE® to EPP patients under both the full cost special access reimbursement programs such as in Switzerland and from commercial sales currently in the European Economic Area and 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 2023

	Consolidated Entity	
	2023	2022
	\$	\$
Cash and cash equivalents		
Carrying amount	156,813,537	121,509,282
6 months or less	109,213,537	84,709,282
Greater than 6 months	47,600,000	36,800,000
Total	156,813,537	121,509,282
Other financial assets (includes trade and other receivables)		
Carrying amount	22,214,646	16,201,937
6 months or less	20,959,240	15,142,670
Greater than 6 months	1,255,406	1,059,267
Total	22,214,646	16,201,937

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

23. Share-Based Payments

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

Conditional Performance Rights Plan (2009)

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

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

Performance Rights Plan (2014)

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

As at 30 June 2023, the Company via its wholly owned subsidiary A.C.N. 108768896 Pty Ltd acting in its capacity as trustee for the 2009 Scheme Trust and the 2014 Plan Trust, holds Nil shares (2022: 2,214,810 shares).

The Following Share-Based Payment Arrangements Were In Existence At 30 June 2023

Performance Rights Series	Number	Grant date	Expiry Date	Exercise Price	Fair Value at Grant Date
Issued 16/09/2011	38,333	16/09/2011	The earlier of achievement of specific performance milestones and cessation of employment/directorship	\$ Nil	between \$0.55 and \$0.72
Issued 26/08/2020	1,513,750	20/11/2019	20/11/2023	\$ Nil	between \$10.86 & \$26.87 *
Issued 24/12/2020	132,500	24/12/2020	20/11/2023	\$ Nil	between \$8.98 & \$20.74 *
Issued 26/08/2021	682,360	26/08/2021	20/11/2023	\$ Nil	between \$18.73 & \$26.22
Issued 5/05/2022	7,500	5/05/2022	20/12/2024	\$ Nil	\$12.87
Issued 29/06/2023	111,500	29/06/2023	30/06/2025	\$ Nil	between \$9.16 & \$14.26 *
Issued 29/06/2023	144,250	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 – 2023

Performance Rights Series	Balance at Start of Year	Granted as Compensation	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
Total	2,439,007	255,750	(64,564)	2,630,193	418,431	2,211,762
Weighted average exercise price	\$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 – 2022

Performance Rights Series	Balance at Start of Year	Granted as Compensation	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	113,335	-	(75,002)	38,333	-	38,333
Issued	25,000	-	(25,000)	-	-	-
Issued	1,513,750	-	-	1,513,750	200,750	1,313,000
Issued	132,500	-	-	132,500	11,731	120,769
Issued	-	743,174	(11,250)	731,924	63,942	667,982
Issued	-	22,500	-	22,500	-	22,500
Total	1,784,585	765,674	(111,252)	2,439,007	276,423	2,162,584
Weighted average exercise price	\$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 2022

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.

24. CLINUVEL PHARMACEUTICALS LTD

Parent Company Information

	CLINUVEL PHARMACEUTICALS LTD	
	2023	2022
	\$	\$
Assets		
Current assets	152,351,411	117,142,670
Non-current assets	47,683,856	29,199,431
Total assets	200,035,267	146,342,101
Liabilities		
Current liabilities	19,899,692	9,010,574
Non-current liabilities	2,785,053	3,667,875
Total liabilities	22,684,745	12,678,449
Equity		
Issued equity	151,849,375	151,849,375
Share-based payments reserve	19,370,046	10,380,258
Accumulated losses	6,131,101	(28,565,981)
Total equity	177,350,522	133,663,652
Financial performance		
Net profit for the year	32,720,668	22,294,578
Total comprehensive income	32,720,668	22,294,578

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 2023 and 2022.

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 2023 and 2022.

25. 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 28th August 2023, the Board of Directors declared an unfranked dividend of \$0.05 per ordinary share; and
- In July 2023, the Group purchased a commercial property located in Egham, UK to support its expanding European-based workforce for a cash consideration, net of fees, of £2,500,000.

26. Additional Company Information

CLINUVEL PHARMACEUTICALS LTD is a listed public company incorporated and operating in Australia.

The Registered office is:

Level 11, 535 Bourke Street
Melbourne VIC 3000
Ph: (03) 9660 4900

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 2023 and of its performance for the year ended on that date;
 - b) complying with Accounting Standards; and
 - c) complying with International Financial Reporting Standards as disclosed in Note 1.
- 2) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable; and
- 3) the audited remuneration disclosures set out in pages 57 to 82 of the Directors' Report comply with Section 300A of the Corporations Act 2001.

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.



Dr. Philippe Wolgen, MBA MD
Director

Dated this 29th day of August, 2023



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 Melbourne VIC 3008
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Independent Auditor's Report

To the Members of Clinuvell Pharmaceuticals Limited

Report on the audit of the financial report

Opinion

We have audited the financial report of Clinuvell Pharmaceuticals Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 30 June 2023, 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 a summary of significant accounting policies, 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 2023 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

Income taxes (Note 3)

The Group holds significant tax balances at 30 June 2023, including deferred tax assets of \$1,059,541, deferred tax liabilities of \$2,757,516, and income tax payable of \$16,094,178.

There are also \$18,899,558 of unused carry-forward tax losses from its foreign subsidiaries not recognised on the balance sheet.

Deferred tax assets are recognised to the extent that there are sufficient taxable profits relating to the same taxation authority against which the unused tax losses can be utilised. The Group also operates globally and is therefore subject to tax regimes and legislation administered by tax authorities in a number of jurisdictions.

This area is a key audit matter due to:

- The degree of judgement required in assessing Management's estimates of future taxable profits to enable the asset to be realised;
- The Group undertaking transactions in a number of tax jurisdictions which require the Group to make significant judgments about the interpretation of tax legislation and the application of accounting standards; and
- The nature of cross-border tax arrangements and our need to involve taxation specialists with cross-border transactions experience and expertise in transfer pricing in key jurisdictions.

Share-based payments (Note 14 & Note 23)

The Group has material share-based payment arrangements in place for key management and employees, with the expense for the year being \$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, 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.

How our audit addressed the key audit matter

Our procedures included, amongst others:

- Holding discussions with Management to obtain an understanding of the policy applied for the recognition of deferred tax and assessment of profitability of the group in the near future;
- Evaluating Management's forecast of future taxable income by assessing the key underlying assumptions such as future taxable income against historic performance and market trends;
- Assessing the competence and objectivity of Management's tax expert used, to assist in the preparation of the valuation of the tax balances;
- Utilising our internal taxation specialists to assess that carry-forward losses are available for use;
- Checking the accuracy of input data and evaluate formulas and assumptions applied in the computation of the deferred tax asset;
- Utilising our transfer pricing specialists to assist in our assessment of the cross-border transactions made between Group entities in different tax jurisdictions;
- Utilising our internal taxation specialists to assist in the assessment of the determination of the tax bases; and
- Assessing the adequacy of the group's disclosure in relation to the carrying value of deferred tax assets.

Our procedures included, amongst others:

- 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;
- Holding discussions with Management to understand the share-based payment arrangements in place;
- Assessing the allocation of the share-based payment expense over the relevant vesting period (assessing appropriateness of the vesting period);
- Evaluating Management's forecasts, holding discussions with management and corroborating achievement of performance conditions attached to the share-based payments to external evidence to validate consistency and appropriateness of vesting dates for performance conditions; 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 2023, but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report, or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Directors for the financial report

The Directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 and for such internal control as the Directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material 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. 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 57 to 82 of the Directors' report for the year ended 30 June 2023.

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Limited, for the year ended 30 June 2023 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 2023

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 2023, I declare that, to the best of my knowledge and belief, there have been:

- no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and
- 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 2023

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SHAREHOLDER INFORMATION

As at 15 August 2023

Additional information as at 15 August 2023 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	4,381	1,249,177	2.53
1,001-5,000	951	2,164,496	4.38
5,001-10,000	152	1,111,802	2.25
10,001-100,000	163	4,297,291	8.70
100,001 & Over	25	40,587,572	82.14
Total	5,672	49,410,338	100.00

b) Shareholdings held in less than marketable parcels

Total	Minimum parcel size	Holders	Units
Minimum \$500.00 parcel at \$20.32 per unit	25	422	3,709

c) Substantial shareholdings

Name	No. Ordinary shares & American Depository Receipts
The Bank of New York Mellon Corporation ¹	4,296,472
Dr Philippe Wolgen ²	3,122,247
Ender 1 LLC ³	2,340,824

1. As disclosed in substantial holder notice dated 24 May 2022.
 2. As disclosed in director's interest notice dated 28 June 2023. Actual shareholding on 15 August 2023 is 3,122,247.
 3. As disclosed in substantial holder notice dated 16 September 2013. Actual shareholding on 15 August 2023 is 2,590,824.

d) Voting rights

The voting rights attaching to each class of equity securities are set out below:

(i) **Ordinary shares:** Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company.

(i) **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	11,280,990	22.83
2.	BNP Paribas Nominees Pty Ltd ACF Clearstream	5,679,762	11.50
3.	BNP Paribas Nominees Pty Ltd	5,312,764	10.75
4.	J P Morgan Nominees Australia Pty Ltd	4,390,776	8.89
5.	Dr Philippe Jacques Wolgen	3,122,247	6.32
6.	Citicorp Nominees Pty Ltd	3,014,759	6.10
7.	Ender 1 LLC	2,590,824	5.24
8.	BNP Paribas Nominees Pty Ltd	1,482,356	3.00
9.	Emilino Group Pty Ltd	603,447	1.22
10.	National Nominees Ltd	548,371	1.11
11.	Dr Mark Edwin Badcock	440,085	0.89
12.	Mr David William Trevorrow	229,600	0.46
13.	Mr David John Lewis	187,000	0.38
14.	HSBC Custody Nominees (Australia) Ltd - a/c 2	180,199	0.36
15.	Mr Trent Sheldon Redding	179,480	0.36
16.	Mr Darren Michael Keamy	178,588	0.36
17.	Rusty Hammer Pty Ltd	156,892	0.32
18.	Dr Dennis Wright	156,874	0.32
19.	Mr Simon John Bown	146,000	0.30
20.	BNP Paribas Noms (NZ) Ltd	130,710	0.26
Totals: Top 20 holders of ordinary fully paid shares (total)		40,011,724	80.97
Total remaining holders balance		9,398,614	19.03

2. Company Secretary

The name of the Company Secretary is: Darren Keamy

3. Registered Office

The principle registered office in Australia is:

Level 11, 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 depository bank for CLVLY.

6. Restricted Securities

Restricted securities on issue at 30 June, 2023: Nil.

7. Directory

Non-Executive Chair

Willem Blijdorp

Non-Executive Directors

Brenda Shanahan, Dr Karen Agersborg, Susan Smith,
Prof Jeffrey Rosenfeld, Sir Andrew Likierman

Managing Director And Chief Executive Officer

Dr Philippe Wolgen

Chief Scientific Officer

Dr Dennis Wright

Chief Financial Officer And Company Secretary

Darren Keamy

Auditor

Grant Thornton Audit Pty Ltd
Collins Square, Tower 5, Level 22, 727 Collins Street, Melbourne,
VIC 3008, Australia

Banker

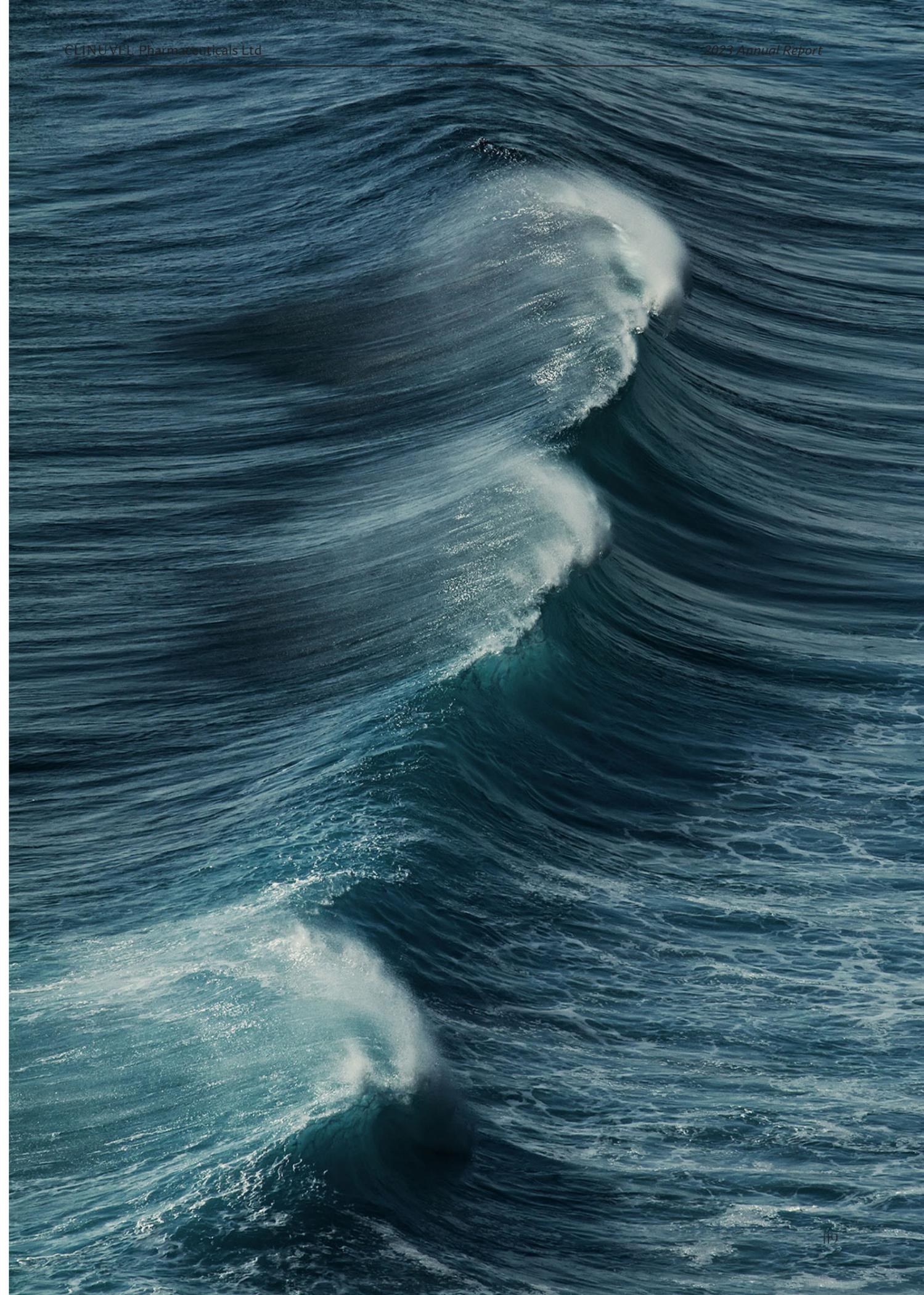
National Australia Bank (NAB)
Western Branch, 460 Collins St, Melbourne, VIC 3000, Australia

Legal Counsel

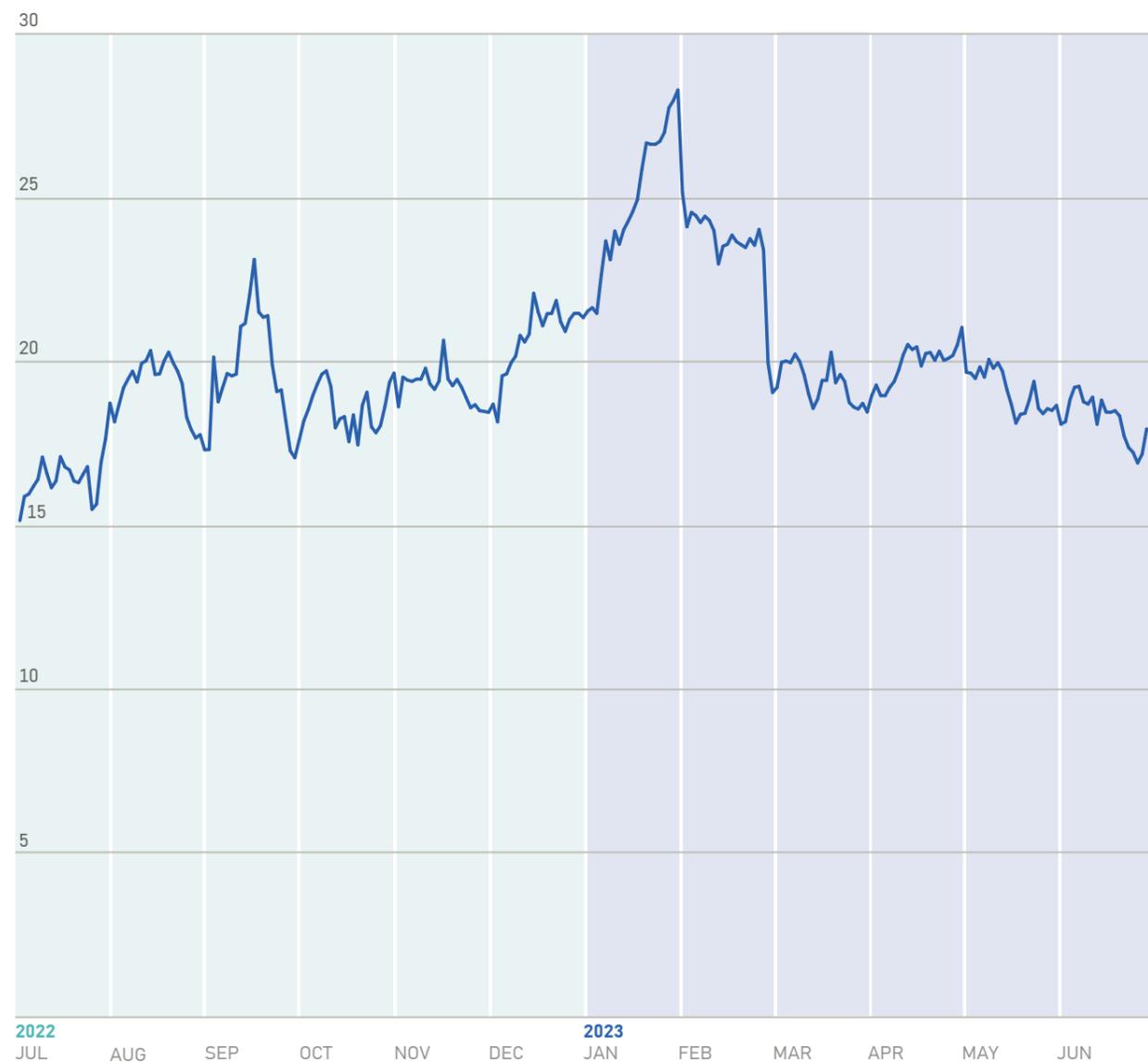
Arnold Bloch Leibler
Level 21, 333 Collins St, Melbourne, VIC 3000, Australia
Sidley Austin LLP
Woolgate Exchange, 25 Basinghall Street, London, EC2V 5HA,
United Kingdom

IP Lawyer

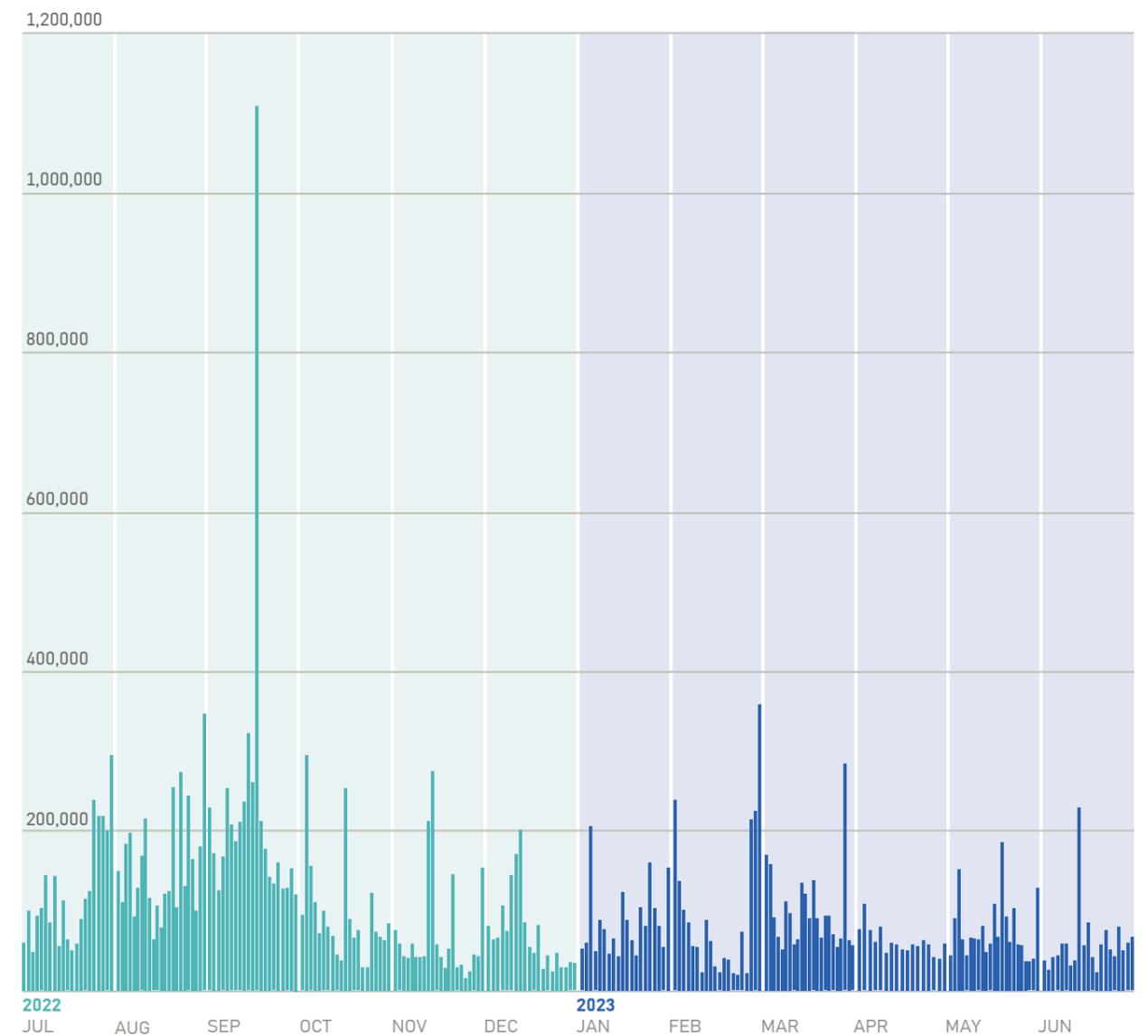
Dipl.-Ing Peter Farago
Baadestr 3, Munich 80, Germany



MARKET PERFORMANCE



ASX:CUV – Share Price (A\$)



ASX:CUV – Daily Trading Volume (No.)

GLOSSARY

Alpha-melanocyte stimulating hormone (α -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-aging, 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). α -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 450 to 450 nm in the visible light spectrum. HEV generates oxidative stress, accelerates skin aging 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), α -melanocyte stimulating hormone (α -MSH), beta-melanocyte-stimulating hormone (β -MSH), and gamma-melanocyte-stimulating hormone (γ -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 (MC_{1R} to MC_{5R}) 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.



