Appendix 4E: Preliminary Final Report

Lodged with the ASX under Listing Rule 4.3A

CLINUVEL PHARMACEUTICALS LTD

A.B.N. 88 089 644 119

1.	**Reporting period:**	**1 July 2021 to 30 June 2022.**		
	Previous corresponding period:	1 July 2020 to 30 June 2021.		

2.	**Results for announcement to the market.**	**Percentage change to 2021**		**Amount** (AUD)
2.1	Revenues from ordinary activities.	**Increased 37%**	**To**	**65,722,292**
2.2	Profit from ordinary activities before tax attributable to members.	**Profit has increased 33%**	**To**	**34,320,915**
2.3	Net profit for the period attributable to members.	**Profit has decreased 16%**	**To**	**20,878,465**

2.4 A fully franked final dividend of $0.04 per ordinary share has been declared.

2.5 Record date for determining entitlements for the final dividend: 07 September 2022.

2.6 The CLINUVEL Pharmaceuticals Ltd audited Annual Report for the year ended 30 June 2022 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 16 below:

3. Refer to the attached Annual Report for the Statement of Profit or Loss and Other Comprehensive Income together with notes to the statement.

4. Refer to the attached Annual Report for the Statement of Financial Position together with notes to the statement.

5. Refer to the attached Annual Report for the Statement of Cash Flows together with notes to the statement.

6. Refer to the attached Annual Report for the Statement of Changes in Equity together with notes to the statement.

7. The Directors have declared a fully franked final dividend of $0.04 per ordinary share to be paid on 21 September 2022.

8. There is no dividend reinvestment plan.

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

Net Tangible Assets per Security for Year Ended 30 June 2021: $1.911

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

11. Details of associates and joint venture entities: 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 Review of Operations and Financial Condition in the attached Annual Report.

CLINUVEL
Pharmaceuticals
2022
Annual Report

CLINUVEL

DIVERSIFICATION

Diversifying towards a sustainable pharmaceutical group. Balancing growth and expansion in a challenging operating environment.

The approval of SCENESSE® (afamelanotide 16mg) for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP) by the US Food and Drug Administration (FDA) in October 2019 was a significant milestone for CLINUVEL. It satisfied a desire for regulatory endorsement that had been expressed 42 years ago. It enabled the negotiations with US insurers allowing reimbursement and distribution of SCENESSE® (started April 2020), which has contributed to further growth in revenues and profit.

The FDA's outcome – foremost – opened the doors for CLINUVEL to expand the application of its expertise and know-how on the melanocortin family of molecules in key functions of the body.

In FY2021, CLINUVEL commenced to expand the product portfolio and develop an active clinical program aimed at the treatment of multiple indications with unmet or underserved needs and continued this strategy in FY2022. CLINUVEL has balanced the growth of commercial operations and the expansion of the drug portfolio and clinical program during the most challenging operating environment seen for decades. The achievement of a sixth consecutive annual profit in FY2022 and a strong balance sheet, reflects the value of the proven strategy and integrated business model, the commitment and longevity of management and led by an effective Board.

CLINUVEL will continue in FY2023 and beyond to balance the objectives of growth and expansion to diversify towards a sustainable specialised melanocortin pharmaceutical group to create long-term value for the benefit of all stakeholders.

CLINUVEL Pharmaceuticals | **2022** Annual Report

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Vision

Delivering innovative solutions for unmet patient and healthcare needs.

Mission

The CLINUVEL Group works to translate scientific concepts and breakthroughs into commercial products.

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

The CLINUVEL Group puts much emphasis on 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 solutions. Our products seek to prevent or treat acute and chronic medical conditions where no alternatives exist.

Values

The CLINUVEL Group pledges to adhere to a principal set of values, which reflect how we operate and expand our business.

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.

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 all 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.

People & Environment

We work for those who have no alternatives: patients, physicians, and at-risk individuals. We are selective 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.

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 are proficient in our understanding of acute, rare, and complex disorders, and skin care. 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.

KEY 2022 ACHIEVEMENTS

The focus during the financial year ended 30 June 2022 has been to progress the growth and expansion strategy to diversify towards a sustainable pharmaceutical group.

Distribution of SCENESSE®

- Continued growth in patient access in the EEA, the USA and Israel
- Reimbursement of SCENESSE® agreed with State and Private insurers in Germany

Expansion of Melanocortin Drug Portfolio

- Introduced ACTH formulation, NEURACTHEL® for acute neurological, endocrinological and degenerative disorders

Healthcare Solutions Progressed

- Ongoing development of a dermatocosmetic product range
- Digital marketing campaign commenced ahead of first product launch

Frequent and Diverse Communications Maintained

71 ASX Announcements

2 Strategic Updates – III (November 2021) and IV (May 2022)

6 News Communiqués issued

5 Presentations to Investor Conferences

3 Investor Briefings – webinar/webcast/face-to-face

Weekly Social Media Posts

Expanded Clinical Programs Advanced

- First stroke study commenced, completed and results announced
- Three studies commenced in DNA Repair Program
- Design of new vitiligo study agreed; SCENESSE® to be evaluated as monotherapy

Strong Financial Performance

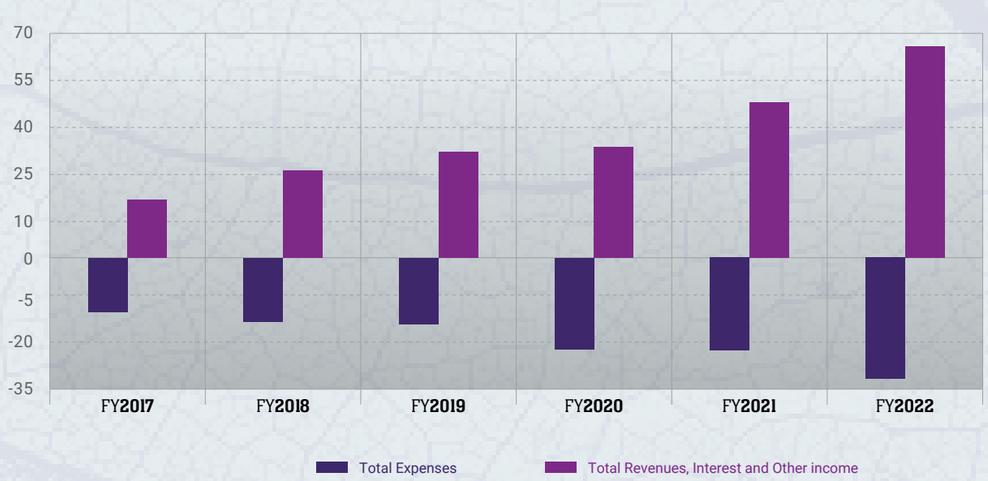
- Growth reflected in record operating profit, half year to 31 December 2021 and full year to 30 June 2022
- Sixth consecutive annual profit delivered
- Highest cash receipts for a September, December, March, and June quarter achieved throughout the year
- Fifth consecutive annual dividend declared
- Cash balances rose to over A$121 million to enable self-financing of key initiatives

FINANCIAL HIGHLIGHTS 2022

A summary of the key financial highlights for the financial year ended 30 June 2022 and key trends over the six years since the commencement of commercial operations is provided below.

Growth in Revenues and Controlled Management of Expenses

CLINUVEL increased total revenues, interest and other income by 38% in FY2022, continuing the trend of growth from the commencement of commercial operations in June 2016. Expenses grew by 44% in the year to support the Company's strategic initiatives. The Company has delivered six consecutive years of revenue growth, whilst expenses have been well controlled.



Strong Performance Indicators

CLINUVEL has high liquidity, no debt and achieved positive returns to shareholders in the past year.

10:1
Quick Ratio

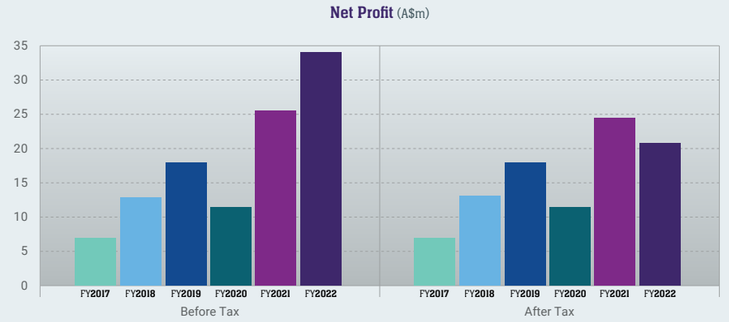
Nil
Debt

17%
Return on Equity

A$ 0.42
Earnings per Share

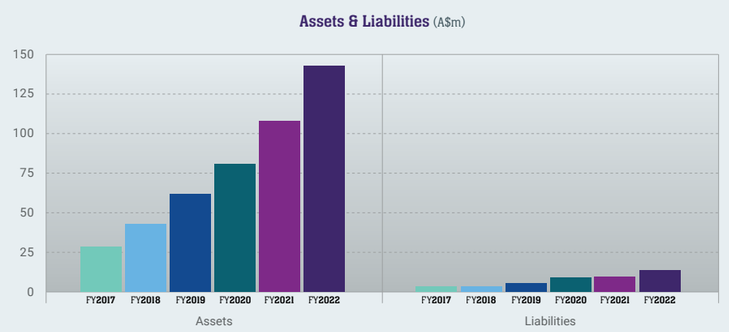
Strong Net Profit Outcomes

Growth in revenues, coupled with careful management of expenses, has underpinned the net profit outcomes achieved. FY2022 showed an excellent operating profit.



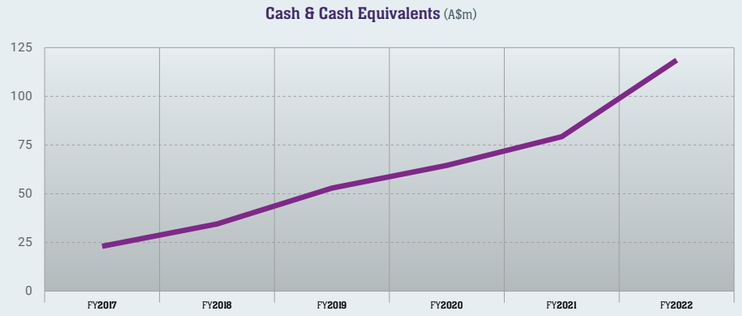
Improved Balance Sheet

Assets have increased steadily over past six years in relation to a more modest increase in short-term liabilities which are largely composed of trade creditors and income taxes payable.



Strong Cash Generation and Rise in Cash Reserves

The net increase in cash held in the year was more than double the amount of the increase seen in the previous year. This resulted in a substantial increase in cash and cash equivalents on the balance sheet, from A$82.7 million to A$121.5 million.



Letter from the Chair

Dear Shareholders,

Well Positioned in Turbulent Times

The turbulence seen the past 12 months ended with CLINUVEL posting better than expected financial results, the best the Company has ever booked in its history. We are building a diversified pharmaceutical business, and the road is long and full of challenges.

In April 2022, in a letter to shareholders, I discussed the deterioration in the geopolitical environment, and our perseverance to fulfil a long-term strategy. The basis of every company I have led is its financial household, 'the till needs to be in order' to realise ambitions, and to stay away from financiers. Since then, the operating environment has worsened with a rapid rise in inflation, and interest rates rising. Whilst monetary policies are put in place to dampen inflation, economic growth is expected to slow down, and a global recession cannot be ruled out. There have been further adverse market reactions to these developments and – despite the continued progress of our company across financial, operational, and clinical parameters – our share price has been adversely affected, along with most other companies operating in public markets.

As Chairman of the Board, and a long-term investor, I empathise with shareholders as they have seen the decline in share price in FY2022. However, for those with a long-term view, the prospects for incremental value are positive based on our consistent strategy. Now, I draw the balance and see a viable business with no debt, and cash reserves sufficient to finance our multi-pronged strategy. In brief, the goal is to optimise further commercial operations and expand the pharmaceutical and non-pharmaceutical product portfolio. CLINUVEL stands out from many other biotechnology firms by its consistency and long view. As a shareholder, I take heart in the prospects of CLINUVEL.

The Managing Director expands on the developments in the operating environment and how we are managing the challenges of it in his letter to shareholders (refer pages 22 to 30). I share opposite some other important issues.

Shareholder Communications

As a Board, we assess also how and when the Company communicates with existing shareholders and new audiences. In recent years, CLINUVEL has purposely delivered an increase in the frequency and variety of communications to stakeholders. Of course, this has been enabled by the increase in our activities since the US Food and Drug Administration (FDA) approved the distribution of SCENESSE® in October 2019.

We regularly communicate on mandatory company news items, but in addition, issue bi-monthly news communiqués (also translated to German), scientific communiqués, Chair and MD Letters. As we have said in the past, we are not obliged to issue quarterly activity and cash flow reports, but the appreciation by shareholders drives us to continue this courtesy. Finally, we issue progress reports across the full range of the Company's activities.

Many of the overseas shareholders comment positively on the frequency and consistency of the news published by the Company. The trend in the number of ASX announcements is shown below:

Number of CLINUVEL Announcements

712022 | **69**2021 | **68**2020 | **59**2019

We have complemented these announcements with more webinars, webcasts, and videos and a wide range of social media posts. I have received positive feedback on the increased communication channels.

The Board and management have reflected on shareholder feedback on executive remuneration and governance and formulated a plan of action to explain the Company's remuneration approach. We encourage broader participation for members to vote at Annual General Meetings. In addition, we also have had direct interactions with remuneration consultants, legal experts in remuneration matters and shareholders.

The challenge in reaching shareholders is to navigate through layers of custodians to be able to contact beneficial shareholders located around the world. Many custodians, however, do not allow the Company to contact their clients directly. Meetings were also held with proxy advisors, who review our remuneration policies and issue recommendations on voting for the remuneration report to shareholders. Finally, we had already enhanced the explanation of executive remuneration in the 2021 Annual Report to Shareholders.

The outcome of the Annual General Meeting of Shareholders in November 2021 was pleasing with more shareholders voting than ever before with the majority supporting the Company to pass the resolutions recommended by the Board. Over twenty million shares were voted on the Remuneration Report, compared to a range of 14.26 to 17.29 million per annum in the 2016-2020 period.

Importantly, this support enabled the Board and management to progress the Group's strategic objectives and operations during the difficult operating environment in FY2022. Although the outcome of the voting on the remuneration report is not binding, we take the outcome as an important measure for the way forward. We appreciate all shareholders who voted and supported the Board's approach.

We maintained this highly communicative approach to shareholders in FY2022. The return to face-to-face interactions with shareholders across the world has been announced by our CEO, Dr Wolgen. We will continue to meet with shareholders and proxy advisors to clarify our approach to growth, financial management, remuneration and ESG related matters.

In the coming months, we will communicate the Board's rationale of the resolutions put forward to the members at the 2022 Annual General Meeting.

Expansion of the Team

The CLINUVEL team has expanded in recent years to meet the new business challenges: in FY2022 we have seen growth of 16% in our worldwide staff. Recruitment is a challenge in the competitive global market searching for specialised talent, but we have managed to attract high quality talent and enhance the Company's positive and tenacious culture. The commitment and determination of the expanded team across the wide range of activities and geographic points of operation has underpinned the strong performance we have achieved.

Maintenance of a positive culture within the Group of Companies is not only important to retain talent, but also to allow for development, and productivity. Equality and fairness underpin our diversity and I am proud of the positive measures of diversity presented in the Spotlight on CLINUVEL's Approach to ESG Issues which follows my letter. We recognise ESG is increasingly important in this world, not just to investors, and as responsible corporate citizens we are conscious of the various social and green measures falling within evolving ESG practices.

Board Activity and Expansion

During the year, the Board had input to, and provided guidance on, key initiatives of the expansion strategy of the Group. I am pleased with the progress achieved, but as our Managing Director has said, much more could have been achieved with the same pool of people we work with.

The growth of commercial operations supported a sixth consecutive annual profit. The operating profit before tax of A$34.3 million is excellent, while adjusting for non-cash expenses the net profit after tax (non-IFRS) is equivalent to last year's.

We have expanded the melanocortin-based product portfolio and progressed the clinical program. During the year, we reported:

- positive results of the first study using afamelanotide in the treatment of arterial ischaemic stroke (AIS);
- the commencement of studies to assist DNA Repair of the skin (xeroderma pigmentosum [XP]); and
- meeting consensus on a new vitiligo study with the US FDA.

We continued to work towards the launch of the Company's first non-pharmaceutical photoprotective product, and as part of our overall online strategies the initial launch of the Light Skin Science was made allowing for the first campaigns from our CLINUVEL Ambassadors. Features in this year's Annual Report provide more detail on the progress of the clinical studies and the dermatocosmetic product range.

An important outcome during the year was to extend the employment contracts of CEO Dr Wolgen and CFO Mr Keamy to July 2025 and July 2024, respectively. Dr Wolgen has proven his worth, and the Board is pleased he finally agreed to add another three years to lead the Company through the current growth and expansion phase. We could not lightly accept a disruption of the realisation of our long-term goals, and we appreciate his continued commitment. Mr Keamy provides the ongoing surety of discipline to financial controls and management of our funds, which is the basis we operate from.

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 2022, 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

Whilst shareholders reacted positively to the extension of Dr Wolgen's tenure, I am frequently asked what will happen beyond July 2025. The Board takes its responsibility to ensure the best possible executive talent succeeds at the helm. We have given ourselves time to identify and secure the services of a suitable executive team moving forwards. In the meantime, we will await how the Group develops the next three years under executive leadership.

To support the growth and expansion of the Group, the Board has increased from five members in 2019, to six in 2020, and to seven in April 2022 with the appointment of Sir Andrew Likierman. Sir Andrew enhances the skills and capabilities of the Board to achieve its strategic objectives.

The Board maintained its governance oversight of the Company over the past year. I can report there were no material issues that needed to be addressed on adherence to Company policies during the year. The initiative was also taken to formalise ESG issues in management's regular reports to the Board. A link to the Company's Corporate Governance Statement for FY2022 is provided on the previous page.

Summary and Acknowledgements

The financial and operational outcome achieved in FY2022 is very positive and the outlook, despite a challenging economic environment, is reason for optimism. Our sound foundation has become stronger over the past year, and I expect the diversification strategy to continue. Melanocortins remain our mainstay, but more initiatives may come to boiling point.

I thank all stakeholders who have supported the Company during the past year; in the current environment, your loyalty is highly appreciated. In recent meetings, including the Basel discussion in May 2022, many long-term shareholders expressed their support and, in doing so, have stated they want to see management's focus on key objectives continue.

I thank all employees of CLINUVEL, management and the executive team. Finally, but by no means least, I wish to thank my colleagues on the Board for their counsel and collaboration on the key issues we have reviewed and decided on during the year.

I remain committed to continue to steer the Company forward through the difficult operating environment to achieve its long-term objectives.

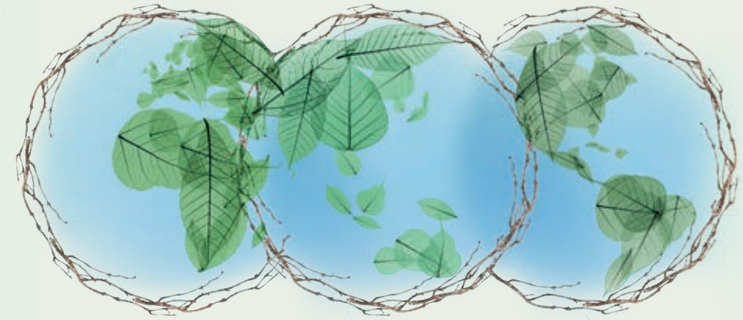
Willem Blijdorp
Chair
CLINUVEL Group

Spotlight on CLINUVEL's *Approach to* ESG Issues

As the Group grows and diversifies, CLINUVEL is conscious of its responsibilities towards Environmental, Social and Governance (ESG), plus measures of sustainability.

Our approach is informed by the United Nations (UN) Global Compact and tenets on ESG issues and sustainability. The UN's ten universal principles span the key areas of human rights, labour standards, environmental responsibility, and anti-corruption. CLINUVEL's approach to ESG was discussed in the 2019 and 2020 Annual Reports (and thereafter on the Company's website). It is timely to affirm our approach to ESG and identify some of the key ESG issues that are relevant and of particular focus to CLINUVEL. We also provide insight on how our approach is working in practice and plans to further enhance our effectiveness in ESG management as part of our focus on ongoing continuous improvement.

ESG framework



Environment

Conscious of our World

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

Social

Fairness & Equity

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

Governance

Responsibility & Compliance

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

CLINUVEL's VALUES

CLINUVEL's values are intentionally placed at the base of the ESG framework to signify the foundation they provide to our ethical and responsible approach to ESG issues and more broadly, how we govern our behaviours and conduct our business in all of the activities we undertake. CLINUVEL's values are detailed on pages 4 and 5 of this report.

Key ESG Issues

The UN's ten universal principles on ESG are contained within four categories:

Human Rights

1) respect internationally proclaimed human rights.
2) to not become complicit in abuses of human rights.

Labour

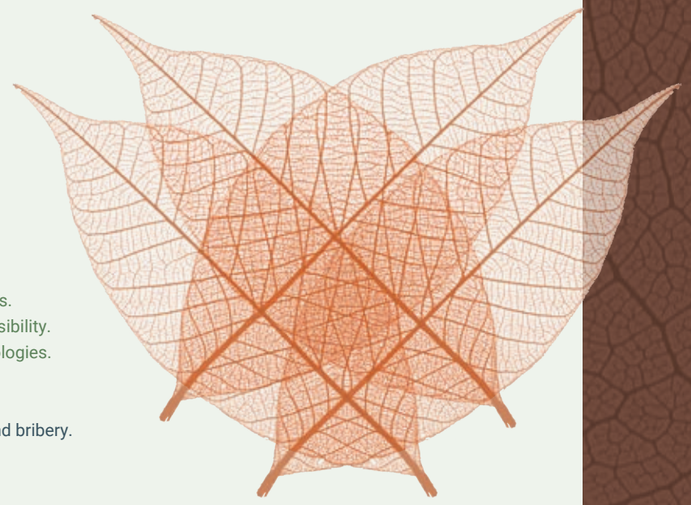
3) freedom of association and the right to collective bargaining.
4) elimination of all forms of forced and compulsory labour.
5) abolition of child labour.
6) elimination of discrimination in employment and occupation.

Environment

7) exercise a precautionary approach to environmental challenges.
8) undertake initiatives to promote greater environmental responsibility.
9) encourage the development of environmentally friendly technologies.

Anti-Corruption

10) work against corruption in all its forms, including extortion and bribery.



CLINUVEL also acknowledges the charter of the Task Force on Climate-related Financial Disclosure (TCFD) and its objectives to increase climate transparency in financial markets though the disclosure by companies of their climate practices across the areas of governance, strategy, risk management and metrics and targets.

We set out below the key ESG issues which are the focus of CLINUVEL and the performance measures that reflect the effectiveness of our approach. These measures are qualitative and/or quantitative, depending on the ESG issue.

Environment

CLINUVEL recognises the adverse impact of mankind's activities on the global climate and environment and is supportive of actions that address the causes of these impacts for the benefit of future generations. This concords with the UN definition of sustainability to meet the needs of the present without compromising the ability of future generations to meet their own needs.

There are rising expectations that public companies set targets across a range of environmental criteria and monitor their performance against those targets. Common targets relate to reduced CO_2 omissions, energy and water usage and waste. In this regard, it is important to recognise that CLINUVEL outsources the manufacture of its key inputs and products to strategic suppliers and has less than 100 employees working across modest offices worldwide, and a laboratory focussed on molecular research and product formulation. The impact of our direct activities on the environment are relatively modest and we consider the setting of metricated targets on environmental criteria to be more practical for larger companies with a relatively larger direct impact on the environment. We therefore take a practical qualitative approach to consciously seek to minimise CO_2 emissions, resource use and waste and to maximise recycling across our activities. It is incumbent on our management team to maintain this approach as we continue to grow and re-assess the need for formal targets from time to time.

The ways in which we perform against our qualitative environmental objectives are reflected in:

- The practice across all offices of daily conservation of energy, powering down computers and turning off lights not related to essential security.
- Our vision to achieve paperless offices. For example, during recent investor roadshows information on CLINUVEL was issued via a QR code linked to a briefing on the Company's website instead of multiple bound coloured paper information packs.
- The Singapore based Research, Development & Innovation Centre has a conscious practice to responsible materials handling and waste minimisation.
- CLINUVEL's Remote Working Policy is positive for the environment as it conserves resources otherwise used by employees to travel to and from the office.
- In the same vein, when interstate or international travel is proposed to maintain stakeholder relationships, senior management approval is required which is subject to the satisfaction of a minimum quantum of meeting and expected outcomes to justify the use of scarce resources.
- CLINUVEL's focus to ensure as best as practicable that its key inputs and products are manufactured in an environmentally responsible way utilising suppliers who adhere to World Health Organization (WHO) Good Laboratory Practice (GLP), the principles of Good Manufacturing Practice (GMP), and UN tenets on ESG.

Social

CLINUVEL has no adverse impact on UN social objectives and makes a positive contribution through its development and distribution of products for unmet patient and healthcare needs. CLINUVEL's key focus is on the quality and safety of its products. CLINUVEL works with key suppliers who adhere to global regulatory standards (including GLP and GMP standards) to ensure the quality of its products. The lead compound, SCENESSE® (afamelanotide 16mg), has a positive safety profile based on over 11,000 administrations in clinical trial, special access, compassionate use, and commercial distribution programs over more than one and a half decades. A rigorous pharmacovigilance program is maintained and reported to global regulatory authorities to confirm the real-world experience treating adult EPP patients with SCENESSE®.

CLINUVEL's research and development program is highly ethical and undertakes the minimum studies necessary to obtain the regulatory approvals required to distribute its treatments. We are 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. The focus of past clinical studies and the current clinical studies of the Company's expanded clinical program is on safety.

The most important social issues to CLINUVEL are labour standards and equality of opportunity to support fairness and enable all CLINUVEL employees to achieve their professional and life objectives.

Labour Standards

On labour standards, CLINUVEL supports a safe and flexible workplace and a positive work-life balance in which motivated and committed employees can excel in their professional and personal development. Good working conditions at home and in the office or laboratory, with fair employment terms and conditions, including remuneration and a range of leave benefits, are essential to this objective.

During FY2022 employee benefits were enhanced to provide a greater range of leave options and flexibility with amends to healthcare and pensions benefits in select regions. The Company's Remote Working Policy also assists work-life balance, whilst active individual training and development plans support professional fulfillment and job satisfaction. Reflecting the safe working environment provided, injuries and time lost from workplace accidents were nil in FY2022.

The effectiveness of this approach to fairness and positive working conditions is reflected in the employee tenure data and growth in new employees achieved in a competitive global market for talented people. The growth in employees has been strong over FY2020-22 to support the growth and expansion strategy of the Group. This has influenced the employee tenure data with an increase in employees with tenure of up to five years. In the last year, however, there was a rise in the proportion of employees with tenure with CLINUVEL of over ten years.

Measure, Year Ended 30 June	2022	2021	2020
Employee Tenure, % of total employees			
Up to 2 Years	60	56	67
+2 and up to 5 Years	26	28	14
+5 and up to 10 Years	3	3	4
Over 10 years	11	13	15
Growth in Employees, % change year on year	**16**	**17**	**41**

Equality

Equality in opportunity is defined to apply 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 is proud of its commitment and track record in treating all employees with equality and this extends to its interactions with external stakeholders.

Diversity is a key indicator of an equitable and fair approach to employees. CLINUVEL aims to recruit from as diverse a pool of candidates as possible, provide the opportunity for positive career development, ensure succession planning has a focus on diversity, and adopts and supports flexible work practices to suit the broadest diversity possible. Diversity is monitored by the Board and is a key performance responsibility of the Managing Director.

Measure, Year Ended 30 June	2022	2021	2020
Gender Diversity % Female / Male of total employees			
Board	43/57	50/50	50/50
Top 7 Salaried Employees	57/43	57/43	57/43
All Employees	68/32	62/38	60/40
Number of Nationalities	**16**	**19**	**15**
Employees with more than one language % of total	**51**	**54**	**40**
Age Composition % of total employees			
Generation Z (born 1997-2012)	10	8	3
Generation Y, Millennials (born 1981-1996)	59	61	65
Generation X (born 1965-1980)	24	23	22
Baby Boomers (born 1946-1964)	7	8	10

CLINUVEL is a leader in its sector in securing gender diversity, exceeding the Australian Securities Exchange (ASX) minimum expectation of females at Board level of 30% (applicable to all listed companies in the ASX300 Index) and having more female than male employees amongst the highest salaried and all employees. The number of females in the top seven salaried employees (excluding the Chief Executive Officer) exceeds the 40% minimum expected by the ASX. Multiple nationalities and linguistic abilities underlie CLINUVEL's diversity beyond gender. The aged composition of employees further highlights the diversity of the CLINUVEL team across seasoned and younger personnel at various stages of their career. All are committed to develop their skills and work together in a highly collaborative way to achieve the objectives of the Company, noting the ongoing stewardship of the Company is provided by Generation X and Baby Boomers, along with the more experienced of the Millennial generation.

CLINUVEL is committed to maintain the high level of diversity represented in the table above.

Governance

The Board of Directors are responsible for the governance of CLINUVEL, and this extends to oversight of ESG issues. The Board has endorsed the Company's ESG Framework which is underpinned by the Group's values (detailed on pages 4 and 5 of this report) and incorporated throughout a suite of corporate governance policies. These ensure CLINUVEL operates ethically and responsibly, fairly, and within the law of the jurisdictions in which it operates, consistent with ESG standards. More specifically, 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. Employees are also supported (through the Whistleblower Protection Policy) to report any breaches in the Company's values, ethics, policies on acceptable conduct and the laws and regulations to which we are committed to adhere.

CLINUVEL expects its suppliers to adhere to ESG standards. This is assessed and reviewed on a regular basis by managers and executives of the Company. Any negative issues are reported to senior management for attention, discussion, and decision on ongoing engagement.

In the past, CLINUVEL's management has reported ESG issues to the Board for guidance and decision. Based on feedback from proxy advisors, a more formal reporting practice was commenced during FY2022 in which ESG issues are part of management's regular briefing reports to the Board. For the year ended 30 June 2022, there were no material issues reported to the Board on ESG issues; and more generally, no material breaches of policies on conduct and non-adherence to CLINUVEL's values and laws, and no protected whistleblower reports.

From ESG to Sustainability

ESG issues are intrinsically linked to sustainability. CLINUVEL is committed to build a diverse and sustainable pharmaceutical group based on its specialised knowledge of melanocortins and is committed to achieve this concurrently with a sustainable environment, economy, and society. This means CLINUVEL is committed to support balanced ecological, human, and economic health and vitality to meet present needs without compromising the ability of future generations to achieve the right ongoing balance. During the 2023 financial year, CLINUVEL will continue its work in this area and report progress to stakeholders.

CLINUVEL Pharmaceuticals | **2022** Annual Report

Summary

CLINUVEL is a responsible corporate citizen. It has a clear and active ESG framework that is aligned to recognised UN tenets and charters on ESG and sustainability. This feature has reiterated CLINUVEL's approach to the management of ESG issues and provided insights to key performance measures used to govern responsible outcomes, particularly in the social area. More work is planned on policies and metrics to enhance its management of ESG issues in FY2023.

Letter from the MD

Dear loyal shareholders, friends,

It is a great honour to serve this company, each single day starts with the acute awareness of establishing a company based on beliefs and people's discipline to devote a great part of their career turning concepts to practical healthcare solutions. CLINUVEL is not unique in this, but where our teams differ is in their ability to search, find and conceptualise. Our teams develop new formulations, new applications, translate technology to larger markets and open new communication channels. Working for CLINUVEL is voluntarily embracing 'pain' and uncertainty, with ever-changing risks, threats, and dynamic environments, and in spite of all this, at the end of financial year 2022 we arrived at the Group's strongest financial position. Analogous to any business, performing arts, or cinematography, there is no guarantee that the next film will be a box office hit, however, my belief is that the current pool of management teams executing plans stand a much greater chance of prolonging the Company's success, based on their ability to find solutions for complex problems.

Surrounded by a generation of managers and many new staff members, we climbed a summit to expand the Company in the middle of a pandemic, as we witnessed the birth of a new employment market. We see it as a primary task to provide shareholders financial strength and business capability to sustain continued prosperity. Put very simply, predicting a downpour doesn't hold, building an ark does.

The pharmaceutical sector is undergoing a deeper transformation, spurred by three major forces of change: technological advancements, growing negotiating powers by payors, and lower barriers to entry. Each brings challenges and opportunities for CLINUVEL.

In this brief, I will address this year's financial performance, the current operating climate, and how we aim to adapt and grow our products and services to wider audiences. At the very end, I will elaborate on the ancillary objective to ensure a larger visibility for the Group.

CLINUVEL's Business Model

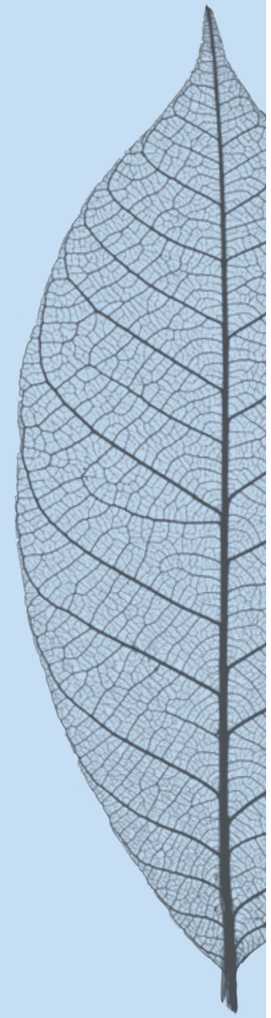
We emerged as an Australian domiciled company, but with all commercial operations having shifted to the European Economic Area, Asia, and North America. In establishing functional business units, teams are led to work cross-functionally, and seek daily communications with overseas counterparts, sharing our main currency: knowledge and experience. We do not support the notion of isolated business functions within a larger Group, and actively stimulate cross-border communication imparting critical information. We do this by seconding management, rotating staff, establishing international collaboration, and allocating specific tasks and functions per country. This year, integration has proven more difficult than any other, since staff had grown accustomed to working remotely, but also since we added a greater number of new talents to our teams. In general, there is no magic to corporate integration, it all hinges on the time one devotes to management and newly recruited staff. A single clear vision, discipline, and passion are the commonalities we share to get to the finishing line.

Among our executive team we have seen zero attrition or turn-over the past three years, and a median 16 years of continuity. I attribute this unusual longevity at the top of the organisation to a single factor, the collective wish to see the completion of a journey started. Among our senior management team, the retention of personnel is a median six years, while at managerial level currently three years. We put much effort to assimilate senior management swiftly, as they are adapting to a varying working environment and structure compared to that of pre-pandemic. In turn, we learn from the newly recruited managers that accountability is higher within CLINUVEL compared to peers in our sector.

We adopted a universal model necessitated by the Company's history. The construct has worked for CLINUVEL, and as environment, regulatory demands and commercial arena are changing, we periodically pose the question where and when we need to change. The Board's reasoning goes as follows, what worked 15 years ago may not be applicable today, therefore adjustments and changes may be needed to arrive at a diversified pharmaceutical and healthcare business. I expect that many of our current activities will converge and be made public in the coming 12 months.

I always remind myself of the perverse tension in bio-pharmaceutical companies, on the one hand the ultimate attempt to alleviate consequences of human disease, while on the other, simultaneously satisfying our owners with growing returns. In thinking about this paradox, the challenge is to maintain a justifiable balance, while serving multiple stakeholders. We also pay close heed to our specific role in society, making sure that those who have remained unattended, untreated, and not cared for, receive our assiduity and lastly, products. This is a thread running through the Company, stretching to the way we communicate, operate and recruit.

Another theme which richly deserves our attention, and where we make incremental steps, is the quest for an integrated but independent group of companies, covering the value chain from start to the end. Here, we made progress, but I would have wanted to see more from the past year; in FY2022 we did not fully live up to our own expectation. I expect that we will expand our services and products in the coming year, thereby gradually transforming the Company. We established the Communications, Branding and Marketing (CBM) Division, found experienced managers leading the teams, engaged in new activities, opened communication channels to reach new audiences. Many of our shareholders commented in FY2022 on the calibre, and change of our communications, feedback that has been appreciated.



ESG Reporting, Governance Risk Review

In FY2022, we continued to strengthen our governance policies, as the Board implemented several important measures.

I have often stated in public that CLINUVEL's Risk Register is the single most important document influencing our thinking, and changes in strategies. So to speak, an indelible checklist which is quarterly reviewed, keeping us alert and flexible. We strive for gender and cultural diversity, with key metrics showing that we are achieving well above our peers. With 43% female representatives on the Board, 57% of the top salaried personnel, and an overall 68% of employees female, we are readdressing societal imbalances.

We are selecting new talent on a number of criteria, but we have truly accomplished a Group diversified in 16 different nationalities, with 51% of us speaking more than one language. In total, 31% of our staff is born prior to 1981, while 69% after. Keeping the balance while filling the vacancies for specialised professionals is a discipline in itself, and one of current and future challenges, no doubt.

We continued to limit preclinical studies as part of R&D investments, however, within the confounds of our sector and in order to satisfy regulatory authorities, we completed two studies in 2022. We remain conscious on preserving biology and life, where we can.

In 2022, we welcomed Sir Andrew Likierman to the Board of Directors, and after years of having followed CLINUVEL at a distance, the moment was chosen for him to join in the capacity as non-executive director. His attention to decision making is well published, and I am sure we will enjoy his leadership on this very discipline. In financial year 2022, we continued Board exchange, whereby constructive critique and relevant questions allowed for the formation of new thoughts, viewpoints and guidance influencing our current strategy. The diversity of skills on this Board has worked well over the past year.

Last, in FY2022, we aimed to reduce the use of fossil fuels, emphasising renewable energy, and reversing the post-industrial growth in greenhouse gas emissions. We continue to do this by monitoring our global travel policies, and suppliers' and vendors' reports on CO_2.

Financial Year 2022

The near-term objective is to turn our operations into stand-alone and profitable units within our Group. Each subsidiary has its own operating procedures and targets, however together they comprise a resilient and balanced Group, which has delivered unexpected levels of profitability in financial year 2022. Following our growth plan disclosed in 2021, we have seen a number of our subsidiaries meeting our internal financial criterion.

In focusing our attention on supply during the second and third COVID wave, we have seen the efforts translated into a 37% increase in revenues. In the past year we faced several critical moments, where decisions on manufacturing, supply and actual patient treatment needed to be taken. Cross functional teams led by Drs Wright and Hamila, Mr Hay, Mrs Colucci, Dr Teng and Dr Quadbeck-Diel were committed during the wee hours to see to continuation and growth. We attribute the FY2022 results to all CLINUVEL cogs inter-digiting. During crises, one learns the true make-up of its teams, its verism to objectives, managers devoting the lion share of their career to see ambitions come to fruition. The total research & development costs are found in various line items of our financial reporting, but for the past year we succeeded to reinvest more than 49% of our revenues in research, development, new specialised personnel, and production.

The Group's Profit Before Tax for 2022 was A$34.3 million, a rise of 33% year on year, and marking the sixth consecutive year posting positive results.

The Net Profit After Tax was A$20.9 million, a decline of 16%, however, this financial metric requires closer attention. In following the financial reporting standards as laid out by the AASB, one is required to expense unvested performance rights valued at the time of grant to the entire staff. In setting a high bar, the majority of these performance conditions had not been met in FY2022, nevertheless we saw A$6.121 million as a non-cash charge affecting the NPAT, compared to A$2.602 million in FY2021. Taking into account these non-cash expenses, growth of profitability of the Company has been linear and well meeting expectations.

After utilisation of the previous years' available carry forward tax losses, we saw a current tax expense of A$7.370 million on FY2022 taxable income, further affecting the bottom line. For the past financial year, we utilised further carry forward tax losses under the deferred tax asset allowance, resulting in a debit to income tax expense of A$6.075 million and the recognition of a deferred tax liability.

Total Assets increased by 33% from A$108.568 million to A$143.950 million and cash reserves rose by 47%, to a new level of A$121.509 million. In line with our communicated strategy, the intention is to grow the Group while maintaining countercyclical liquidity during low conjuncture, providing optionality to procure capital equipment, and integrate products and new businesses.

Importantly, and heeding the numerous lessons taught by equity markets, our fiscal discipline has taken away anticipation of further equity or debt finance, most frequently putting companies in a longer-term value spiral. The strong profitability helped us withstand periodic fluctuations in patients' treatments, dictated by hospital capacity during and post pandemic.

The Company's return on equity for FY2022 is 17% with both our EU and US operations delivering double-digit returns.

The Board has thoughtfully decided to increase our dividend in 2021-2022 by 60% with our long-term shareholders in mind, some of you holding CUV common stock since 2005. In total, we enjoy approximately 35% longer term investors in support of the Company's direction, and I would like once more to wholeheartedly thank you all for the words of encouragement during COVID. The total net cost of redistribution is approximately A$2.1 million, while we have refrained from a share buy-back plan.

Finally, my own reminder on the projections made, we continuously review and track our budgets set against five-year projections made in 2021. Total expense was for the Group A$32.667 million (+44%) compared to FY2021. In sum, the two years yield a total expense of A$55.405 million, leaving A$119.6 million in projected expenditures for the remaining three years of the plan, expiring in June 2025. In continuing to invest in the next generation of managers, we aim to establish a stronger and diversified group.

In line with the global biotechnology sector, CLINUVEL's share price declined heavily with a low of A$13.16 and high of A$44.67. The decline follows the drop in key life-sciences indices like the XBI over the same timeframe. The current reality is that multiple factors play a role and impact a company's share price, short selling, lack of buyers and uncertainty about the sector are some of the main reasons found. However, the Company's continued growth within a sector where the majority of bio-pharmaceutical companies are not posting revenues or profits, will eventually distinguish as markets seek value.

My observations underscore the necessity of maintaining financial performance, increasing the visibility of the Group's mission, while expanding target audiences. Our performance over the last five years, certainly compared to other peers with platform technologies, is evidence that the chosen approach has provided strength and stability and a foundation to build from.

Pipeline Value

Periodically, we hold a mirror to ourselves, and discern whether we are achieving our objectives, and whether we need to adjust. Equally, we are conscious of time, and in a rear view assess whether our teams are on course. To reiterate our objectives for growth of the pipeline; the intent is to expand the Company on different fronts:

i. clinical expansion of afamelanotide: new indications, persisting unmet patients' need,
ii. new formulations of afamelanotide, providing dosing flexibility,
iii. new melanocortin molecules (ACTH, CUV9900),
iv. new formulations, delivery methods, and
v. translation of technology and knowhow to over-the-counter (non-prescriptive) products for specialised populations (Highest Risk of photodamage).

These five targets will establish the Company as an integrated melanocortin house, with drug products for a variety of patient populations, while occupying a sub-specialty in photomedicine.

In terms of clinical development, the breakthrough consensus with the US FDA's Division of Dental and Dermatology Products to test afamelanotide as monotherapy in darker skin populations is welcome, timely and most exciting. Our teams see the development of afamelanotide for a select group of vitiligo patients as a commercially viable avenue. With SCENESSE®, as a non-immune-modulatory repigmentation therapy, we target parts of the vitiligo market, patients with the strongest visible contrast of depigmented skin and at highest need. One can argue that any loss of pigmentation occurring establishes a medical need, however other factors determine the clinical necessity to treat, such as affected surface area, visibility (head and limbs), age, and skin complexion.

The trial CUV104 will start in Q3 2022, as the American hospital is going through its screening process to find suitable darker skinned patients affected by generalised vitiligo. The trial size is small, since administering SCENESSE® as a single therapy will rapidly reveal whether visible pigmentation re-emerges or not; a systemic treatment (a drug transported through our circulation) for generalised – spread over one's body surface – vitiligo needs to show rapid and visible response. We have looked forward to this trial and patients' reactions, worldwide it would be a first to see a melanocortin being administered as a monotherapy, that is without narrowband UVB (light therapy).

Significantly, as the medical community states, afamelanotide would be a natural human hormone not affecting the immune system in contrast to JAK inhibitors in development which suppress immune response long-term. Whereas the systemic treatment has seen in CUV102 and CUV103 first signs of repigmentation after weeks, topical treatments take months to exert a beneficial effect, such as the topical JAK inhibitor approved recently by the US FDA.

Xeroderma pigmentosum (XP) is a disease with highest impact on patients' lives and morbidity. As a pharmaceutical company, being the only one doing something for these patients is a humbling experience, and one can only truly appreciate the worthwhile mission of developing and testing a drug when one sees and hears the XP patients, their families and healthcare professionals.

Our clinical team started the CUV156 study (which had been numerated CUV150 before a new therapeutic parameter was added), CUV152, CUV152 and CUV151, the latter acting as a control study in fair-skinned disease-free subjects. The study aims are to evaluate the properties of afamelanotide in providing photoprotection and DNA-assisted repair of skin cells. The Company had to overcome more than a decade of hurdles to compel the medical community, decision makers and importantly patients and their families to collaborate in clinical trials. The challenge to subject patients to a new drug therapy has been immense, mainly due to the grave nature of XP. In 2022, our teams advanced the studies, and at present the first data are being analysed, while completion of the studies is next.

Our stroke program using afamelanotide started with CUV801, whereby six patients were evaluated on safety. Given the acute nature of arterial ischaemic stroke, long dialogues with hospitals and leading physicians were needed. The specialists and their institutions had to arrive at a point willing to take the responsibility for subjecting their patients to a new drug therapy. In 2022, we posted better-than-expected results in all patients, while unfortunately one patient suffered a second stroke during the trial and passed away.

Safety and neurological functionality were evaluated, and the results led to the unanimous decision to prepare the second trial CUV803, when afamelanotide will be dosed higher and more frequently. It is hypothesised that afamelanotide has a positive effect in stroke patients, providing benefits to the vascular circulation and oxygen-deprived brain tissue. Here, we are aware that the medical need is vast.

The expansion continued with the development of PRÉNUMBRA® Instant, the flexible dosing alternative of afamelanotide. The R&D teams secured contract manufacturing for the exclusive production of this second product, to be tested first in CUV803, and later in other undisclosed indications.

The past year, we also saw the new direction taken by investing in ACTH, a well-known molecule with multiple applications. Historically, the distribution of ACTH in easy-to-use formulations had been dominated by Novartis and Mallinckrodt, however development and supply had stagnated in recent years. New market entrants with generic versions concentrated on the US market for ACTH, while our teams identified new opportunities for unserved populations. As the approved list of diseases for ACTH nears 20, our scientific teams believe that there is an untapped potential for new generations of the drug product. The production of ACTH is ongoing, and we expect to see first clinical testing in 2023.

In CUV9900, we hold one of our smaller molecules, with the intent to make the melanocortin derivative available for topical use (administered to the skin surface). Here, we received new positive data giving us direction for its final applicability.

Taken together, afamelanotide, ACTH and CUV9900 provide CLINUVEL a differentiated position, grouped around specific hormones, members of the same family.

The final piece of the photomedicine jigsaw is found in our specialised consumer product lines. Here, progress was made with the first formulations produced for commercial distribution, whereby our marketing team are collecting expectations and preferred product profiles from specialised groups. Data sets, qualitative information will be used by our newly formed CBM team to translate these in the 2nd, 3rd and 4th product lines to be launched. Further expansion on the role and objectives of the CBM division is gradually given as the products near launch.

We made the decision to increase investments in the new afamelanotide formulation, PRÉNUMBRA® Instant, the next generation of melanocortins, the development of ACTH, NEURACTHEL® (larger melanocortin molecule), and enter production of the first over-the-counter product. Although, I wish to see faster progress, the past 12 months has seen valuable addition to the Group's pipeline.

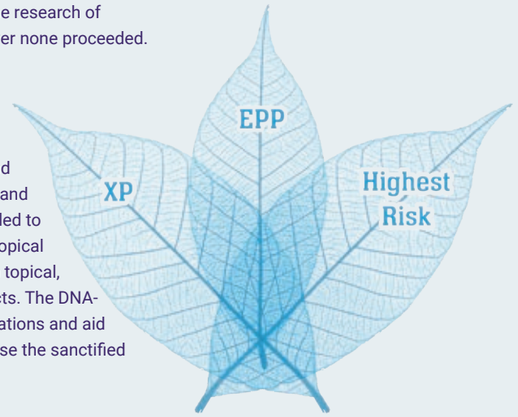
I am grateful that our teams can benefit further from the current CSO, Dr Wright's deep knowledge, and dedication. He is a unique talent understanding in-depth all aspects of new drug development to commercial stage. Surrounded by a scientific team of seasoned and new managers, he is passing on his experience and managing a complex program. However, there is unity and desire among the team to see multiple applications of afamelanotide on market, as well as new generations of melanocortin developed into commercial prescriptive products. At the same, the team around Dr Wright is equally engaged to achieve success with our healthcare products for specialised user groups.

Communication With New Audiences

There is a strong opinion among our stakeholders for us to continue our pharmaceutical strategy, but in 2022 we have shifted our focus to a wider range of activities to globally increase visibility of CLINUVEL. I have no doubt that a diversified model will become the bedrock of the Company's success for many years.

I see many opportunities of opening new communication channels with wider audiences, and these new routes will go beyond those one may expect from a pharmaceutical company. Our current social media activities, and planning are the results of longer thoughts, discussions, and exploration. With the decision to establish a CBM team, we are stepping once again away from what is regarded as conventional in pharmaceuticals, however there is a good reason to go this avenue. Two main factors underlie our communications strategy, a growth story, and the relevance of our specialised healthcare products to wider audiences ('at risk populations').

In 1980, the quest for the 'holy grail' to develop a self-tanning solution started. Based on flawed technological and commercial assumptions, although led by a group of seasoned pharmaceutical executives, the treasure was never to be found. Many companies followed suit, larger cosmetic players such as L'Oréal, Johnson and Johnson, but around the millennium also dermato-cosmetically focussed Galderma and Allergan dabbled in the research of melanocortins and other compounds as a topical tanning solution, however none proceeded. The mission proved too challenging, too costly, too long, and uncertain.



As CLINUVEL focussed on the use of afamelanotide, analyses of pharmacology, photoprotection and anti-oxidation were made while other valuable properties had been identified for wider use. Objectives and definitions changed, applicability in dermato-cosmetics became feasible, and new and more data were generated. The new observations and learnings led to investments in developing a number of new melanocortin molecules for topical use. My personal aim is to see the first melanocortin being marketed as a topical, skincare product with multiple photoprotective and photo-reparative effects. The DNA-assisted repair program aims to provide further data in highest risk populations and aid the launch of a successful melanocortin topical product. This would finalise the sanctified journey started 42 years ago.

For our journey to successfully come to completion, a conducive environment needs to be developed, new audiences are to be reached; in 2022, we started to implement some parts of this global communications strategy, and the first response from the audiences on our mission is better than expected.

In FY2022, a new comprehensive communication strategy was implemented involving CLINUVEL Ambassadors ('CUVAs') to disseminate our mission and objectives to 'prevent photodamage induced by UV-HEV and reduce skin cancers and melanoma'. Simultaneously, we are engaging multiple individuals with a large public exposure, such as performing artists, TV personalities, those affected by skin cancers, and politicians aligned with our mission and objectives and reaching wider audiences.

Communications also span the dialogue with new institutions, investment funds and family offices. Here, our head of investor relations, Mr Malcolm Bull, has made important strides. Both through the more traditional participation in investment conferences, follow ups and by directly meeting private investors, we see a steady pool of new investors on our register.

Going back to CLINUVEL's mores of organising in major capital cities gatherings with funds, private investors, investment banks and firms, we receive positive response on this initiative. Actually, this is how the Company had started off in November 2005, organising luncheons in Frankfurt, Vienna, Paris, Sydney, London, and New York. We discontinued these face-to-face presentations in 2007 as the GFC shattered market confidence.

In May 2022, we organised the first of a series of 13 meetings in Basel, the pharmaceutical hub, attended by 60 people. The aim is to increase visibility on CLINUVEL's mission, ambitions, and commercial plans. In the coming months, several meetings are being organised in Monaco, Sydney, and New York. This avenue of communication needs to be viewed as part of a wider program, and in parallel to the traditional bank-led non-deal roadshows, webinars, public meetings with retail investors' associations and upon request from investment funds. We will review the impact in 12 months, but so far, the response is excellent.

Prospects 2023

We typically refrain from making predictions, timelines or giving guidance, since the sector engenders too much uncertainty, too much dependency and unexpected events urging for a change in strategies. However, I am of the belief that 2022-2023 will see larger activities taking place in the Company, since the foundation for more aggressive growth has been laid the past years.

In 2021, we stepped out and shared the commitment to taking the Group towards becoming the high performing business that CLINUVEL should be. Through biannual Strategic Updates, we share progress, laying out the steps that we need to take to complete our restructuring and improve our performance. I remain confident that our decisions allow us to become a Group which can maintain returns to our shareholders, who have been patient and deserve ongoing success. However, I also make a proviso that in today's economic climate we carefully need to redefine the notion of 'deserve'. Let's say, thus far, our stakeholders have benefited from the contorted roads we needed to travel.

In completing the restructuring of the Group, we focus on our core pharmaceutical business, while establishing a non-core healthcare franchise. We will continue to operate as an integrated international business, straddling these two new divisions.

The question of the timing of new developments and specialised consumer products often comes up with our head of investors relations, Mr Malcolm Bull and equally, we are often asked as to the rationale of diversifying the Group. The latter question is relevant, as we hold that intense focus at an early stage is necessary to maximise chances of regulatory and commercial success. As the business reaches maturity, focus is replaced by controlled expansion from within. That implies strengthening the skill set of one's management team, before going to inorganic expansion. I view this final stage as critical since the majority of mergers fail due to the lack of ability to integrate with the acquirer. I believe we are reaching the point where CLINUVEL can diversify its efforts without losing attention to the ongoing research, and commercial activities. The ultimate objective is not only to diversify the revenue stream but also the markets we operate in. With a sibling market, we will maintain our foothold in pharmaceuticals, while entering a specialised consumer market.

As to the timing, we have been analysing many public and private opportunities in FY2022, which deserve each thorough understanding of cost synergies, market opportunities and commercial risks. As progress is made in financial and operational diligence, it is clear that we will not retreat from being focused only on the family of melanocortins. We are seeking for value-driven organisations complementing our business strategies.

Summary

I entered pharmaceuticals 25 years ago, and I was excited to be a part of a respected profession doing good at large scale. CLINUVEL posed an entire new set of challenges. Part of our current mission has already succeeded, in that we have established an organisation in which the commitment and longevity of our employees do not hinge on the size of their remuneration package, but where they join to be part of unique venture trying to play a role in society to develop innovative technology for unaddressed and attended populations. All our staff hold in common the wish to overcome adversity in their operations.

For the next 12 months, I wish to see CLINUVEL as a diversified Group, where our employees choose to work because they believe in the mission, challenges, and opportunities to express themselves. As the employees grow, develop, and become accountable, they are becoming co-owners, taking responsibility for the growth of the Company. Along this vein, in FY2023 we will maintain the most important key performance indicator found across all staff levels, 'an annual demonstration of new initiatives taken to add value to the Group'.

En résumé, I hold all reasons to be optimistic about the future, while unmistakably new challenges will befall our teams. I am privy to their ability and resilience to solve problems at the right time, and there is no reason why this attitude will not continue in FY2023. As the foundation of the house, under the guidance of Mr Keamy and Mr Lim, the finances of the Group remain in safe hands. Therefore, I believe that FY2023 will become the year of expansion transforming the Group.

My appreciation goes out to all new employees who joined our forces in FY2022, all the work performed by our staff often behind the scenes and at irregular hours as the boundaries between professional and private life working from home became blurred in FY2021-2022. You have all contributed to CLINUVEL's successful year, excellent under difficult circumstances!

Philippe Wolgen
Managing Director
CLINUVEL Group

Review of Commercial Operations USA

From Regulatory Approval to First Treatment

In October 2019, the US Food and Drug Administration (FDA) granted CLINUVEL approval to distribute SCENESSE® as the first ever treatment for adult erythropoietic protoporphyria (EPP) patients. This was a significant milestone for the Company and its stakeholders, as it culminated many years of focus and effort to develop the drug, complete clinical studies, and liaise with the FDA to gain approval. CLINUVEL's US team and supporting personnel proceeded swiftly to put the distribution arrangements in place to enable the treatment of the first EPP patient in April 2020. Upon release of this Annual Report, CLINUVEL will have been distributing SCENESSE® in the USA for just under two and a half years and it is timely to outline the initial plans and achievements in the USA in the critical past implementation period.

Key Features of the Plan

The plan to commence commercial operations in the US was extensive and set aggressive targets for the team. Some of the key objectives were to:

- establish a patient registry, build a network of Specialty Centers across the United States to treat EPP patients;
- work with insurers on arrangements to reimburse the cost of treatment;
- establish a savings program to assist EPP patients in need of financial assistance;
- establish new and unique drug and treatment codes to smooth the reimbursement process; and
- establish a distribution facility for efficient distribution of the drug in the US.

CLINUVEL's Commercial Operations in the USA

Item	Planned	Achieved	Comment
Patient Registry	Establish an EPP patient registry	The Company promptly established and continues to rapidly expand the registry	This information is confidential for insurance purposes
Specialty Centers	30 Specialty Centers by end of 2021	30 Centers were trained and accredited by mid-2021 40 Centers were trained by the end of 2021	We are maintaining over 40 Centers across the USA, with the goal of enabling patients to get access close to home
Insurers	Build a network of private and public insurers making SCENESSE® available, initially through Prior Authorization (PA) then on formulary	Over 100 national and state insurers are reimbursing the cost of treatment Government health insurers are also providing treatment coverage	The reception of insurers has been positive and new insurance providers continue to include SCENESSE® into their drug policy/formulary
Savings Program	Establish a savings program to assist patients with out-of-pocket costs of treatment	Established and operational	This supports patients in need of financial assistance to ensure equitable access to healthcare
Codes	Initiate unique codes for the drug and treatment	Drug J-Code (HCPCS II) for SCENESSE® J7352 x 16 units "Afamelanotide implant, 1 mg", became effective January 2021 Procedural CPT Code (HCPCS I) for administration of the drug since CPT11981, became effective January 2022	The unique codes have enabled smoother reimbursement of costs of treatment
Distribution Facility	Establish a drug distribution facility with a partner in the US by the end of 2021	The US distribution facility was established in Q2 2021	The domestic distribution facility has increased efficiency and shortened the time from order to delivery of the medication

Patient registry

The patient registry was the first objective met. Data collected is protocolised, stored, and only used with patients' consent, exclusively for insurance purposes, ensuring compliance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA). After an initial foundation period, the registry grew rapidly in 2021 and continues to expand.

An extensive network of Specialty Centers

The initial plan of 30 Specialty Centers across the United States was to provide a manageable travel time for patients to receive treatment (no greater than five hours' travel). A more extensive network of over 40 Specialty Centers has now been established, well in advance of our planned roll out. This means the average travel time for patients to receive treatment has further decreased, while patients have greater choice of Specialty Center for their treatment.

Each Specialty Center has been trained and accredited by CLINUVEL. The CLINUVEL team maintains close communication with the Centers to solve any problems or issues in the management and administration of patient treatment, particularly to ensure that insurance qualification and approval of coverage are obtained, and treatment is provided efficiently.

As CLINUVEL registers new EPP patients on the registry, the US team continues to identify and train physicians nationwide that are within the proximity of the EPP patients' residences. Several Centers have included more healthcare professionals and support staff to administer SCENESSE® and care for EPP patients, further expanding their Center's EPP program and the value they add to their patients.

The range and number of insurers reimbursing the cost of treatment

The CLINUVEL team was very active early-on in the implementation period to engage a large number of insurers and educate them on EPP and its treatment with SCENESSE®, in order to facilitate treatment coverage for their EPP patients. It was pleasing that the insurers progressively approved coverage under Prior Authorization, where each patient needs to be approved for treatment by their insurer based on their medical history. As insurers have become more familiar with the treatment and patients' individual needs, the process has become faster and smoother, particularly to reduce the burden on new patients seeking treatment.

Today there are over 100 private/commercial health plan insurance companies across the US providing coverage for the cost of SCENESSE® treatment. Government health insurance plans (e.g., Medicare and Medicaid) are also providing coverage to a small number of EPP patients in the US.

Savings Program

The CLINUVEL team works closely with each EPP patient to assist them in navigating the complexities of their health care plan coverage, billings, and reimbursements. The Company established the SCENESSE® Savings Program to provide support to EPP patients in need of financial assistance, in order to facilitate equitable access to healthcare. The Program is designed to cover out-of-pocket expenses for treatment, based on proven individual patient need. Eligible EPP patients have received assistance through the SCENESSE® Savings Program since 2020.

Drug and treatment codes

The healthcare reimbursement landscape in the US is complex and requires administrative procedures to be established for both insurers and healthcare providers. Unique drug and treatment codes enable much smoother patient treatment and reimbursement processes, essentially expediting the overall access for patient access to treatment. As part of establishing the commercial infrastructure for SCENESSE® the US team worked to facilitate the approval and listing of these codes.

The recommended Healthcare Common Procedure Coding System (HCPCS) codes for SCENESSE® treatment include:

- Code: E80.0 “Erythropoietic protoporphyria”, assigned under the World Health Organization’s International Statistical Classification of Diseases and Related Health Problems (ICD-10);
- National Drug Code (NDC) Code: 73372-0116-1 or 73372-0116-01;
- (HCPCS I) CPT 11981: “Insertion, drug delivery implant (i.e., bioresorbable, biodegradable, non-biodegradable)”; and
- J-Code (HCPCS II): J7352 Afamelanotide implant, 1 mg; 1 billable unit = 1 mg.

The Level II HCPCS unique J-code (J7352) for SCENESSE® was approved and listed, effective from January 2021 while the Category I CPT Code® (CPT11981) for the administration of SCENESSE® was approved and listed, effective from January 2022. These codes have significantly expedited the approval of administration of treatment for patients and simplified the medical billing and reimbursement for the Speciality Centers.

Establishment of a distribution facility

The Company had planned to establish a US distribution centre to support the network of Specialty Centers across the country by the end of 2021. The rapid development of the Specialty Center network necessitated this being brought forward, and a distribution facility was established with a partner in Florida in Q2 2021. This immediately improved the logistical management associated with distribution and reduced the time from order to delivery.

Patient Feedback

CLINUVEL has worked closely to build relationships with the US EPP community since the commencement of our EPP program in 2006. Many patients and their families have followed our program closely (including volunteering to participate in clinical trials and joining the first ever FDA public workshop on EPP in October 2017) and have welcomed the approval of the first ever treatment for EPP. Our long-standing relationship with the community has allowed the Company to keep patients informed and, ultimately, facilitate their treatment, with many enthusiastically referring their physicians to the CLINUVEL team to consider adding their clinics as Speciality Centers.

Consistent with the experience in Europe, patient retention in the US is high, which we take as a measure of overall effectiveness of, and satisfaction with, the treatment. The team regularly receives constructive feedback from EPP patients regarding their treatment experience. The positive feedback provided expressing appreciation and gratitude is encouraging to the entire CLINUVEL team and EPP Specialty Centers. Excerpts from the feedback of two patients, representative of many we receive, are highlighted.

“

EPP Patient I

The doctors in my Center have been absolutely wonderful to work with. They seem truly invested and so caring in the process. I have done a lot on the phone with their team and their response time has been great.

“

EPP Patient 2

This is truly a life changing experience for me and my family. The doctor has a tremendous amount of knowledge about the medicine and the process, and under his care, I have seen an outstanding improvement in my quality of life outdoors.

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Summary

CLINUVEL’s commercial distribution in the US has been established ahead of plan and in an effective and timely manner. The US team’s dedication and perseverance have been instrumental in assisting both Specialty Centers and patients with PA submissions, liaising with the Centers and insurers in confirming contractual rates and reimbursement claims, and providing general support. The speed and thoroughness of the establishment of commercial operations in the USA is now part of CLINUVEL history and serves as internal model to duplicate and indeed, surpass in other jurisdictions. The CLINUVEL team has established positive rapport with Specialty Centers, patients, and insurers. They will extend its support to new Centers and patients of the EPP community to continue to build commercial distribution in the years ahead to meet growing demand from patients for treatment with SCENESSE®.

Clinical Programs Gather Pace

CLINUVEL has built unique expertise in the development of a novel class of peptides – melanocortins and their analogues – as therapies for patient groups with high unmet medical need.

Pre-Conditions for Clinical Expansion

Several key criteria needed to be satisfied before CLINUVEL aggressively expanded its clinical program to treat new patient groups with afamelanotide and other melanocortins. The most critical criteria were the:

- US FDA approval of SCENESSE® (afamelanotide 16mg) for the treatment of adult EPP patients in the US, which 'unlocked the door' to CLINUVEL's growth and expansion;
- long-term safety record of SCENESSE®; and
- accumulated expertise in the family of melanocortins and their role in key functions of the body.

The opening of the Group's state-of-the-art Research, Development & Innovation Centre in Singapore in August 2020 was also an important pre-requisite to support more intensive molecular profiling, peptide chemistry, and polymer and formulation sciences.

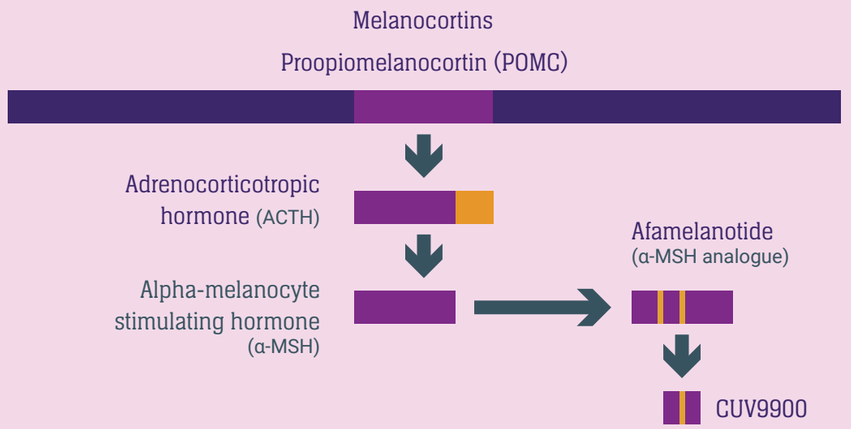
It is notable, particularly in the current environment, that the Group is self-financing its growth and expansion with the cash reserves accumulated and the ongoing net cash being generated from commercial operations. The Company has not needed to raise funds from capital markets and/or financiers to enable the expansion of the clinical program.

About Melanocortins

Melanocortins are bioactive human hormones which act on cells throughout the body and can play a role in regulating the central nervous system, energy balance, appetite, photoprotection and DNA repair, as well sexual function. They bind with different melanocortin receptors (MC1R to MC5R) throughout the body to influence different functions.

Melanocortin hormones are derived from the precursor peptide proopiomelanocortin (POMC) which is produced in both the pituitary gland and in peripheral tissues and skin. ACTH is derived from POMC and is essential to produce cortisol, enabling the combat of stress and regulation of immune responses, maintenance of blood pressure, moderation of blood sugar, and the regulation of metabolism. The alpha-melanocyte stimulating hormone (α-MSH) is a derivative of ACTH. Both ACTH and α-MSH are shorter than POMC.

CLINUVEL has commercialised the novel drug afamelanotide, an analogue of α-MSH, as the controlled release injectable implant SCENESSE® and has developed PRÉNUMBRA® Instant as a liquid formulation to enter late-stage clinical trials.



Clinical Expansion – Step by Step

CLINUVEL is progressing clinical programs in the following key indications: DNA Repair, with an initial focus on xeroderma pigmentosum (XP); vitiligo; and arterial ischaemic stroke (AIS).

DNA Repair Program

The expanded clinical program commenced with the announcement of the DNA Repair Program in September 2020. This program is of significance to two billion people worldwide who have an impairment in their natural DNA repair processes. The initial focus of CLINUVEL's DNA Repair Program is on XP. People with this rare and hereditary disorder are unable to repair the cellular damage to their skin caused by exposure to UV and sunlight, which is known as photodamage. This results in the mutation of their skin which leads to skin cancer at an early age. Their risk of skin cancer is over 1,000 times that of the general population, with patient life expectancy tragically around 30 years.

CLINUVEL's DNA Repair Program initially encompasses five clinical studies involving XP patients with the XP-C and XP-V complementation, who are at the highest risk of exposure to UV and high energy visible (HEV) light, as well as disease-free individuals who serve as a control group. Three clinical studies commenced in FY2022, focusing on the safety of afamelanotide as a DNA regenerative therapy:

- CUV156 in adult XP-C patients;
- CUV151, a mechanistic study in disease free adults; and
- CUV152 in adult XP-V and XP-C patients.

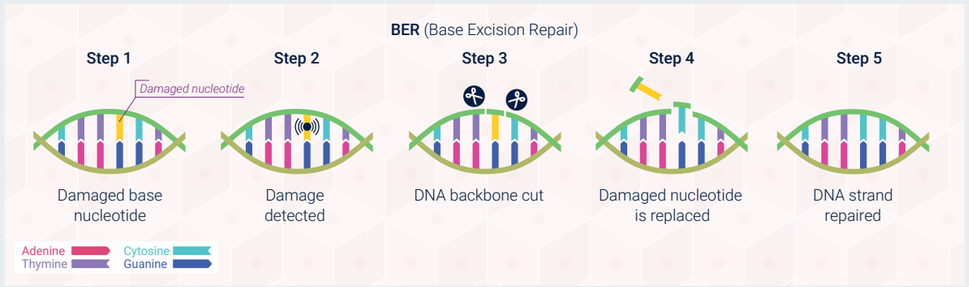
These studies involve taking samples (biopsies) of exposed skin areas for laboratory analyses of DNA damage before and after drug administration. CLINUVEL has collaborated with expert physicians to develop global assessment tools and patient reported outcomes for use in the studies. In addition to confirmation of the safety of SCENESSE® in these cohorts, the objective of the studies is to see a reduction in oxidative damage in the skin biopsies after drug administration.

Read outs of these studies are expected to issue later in 2022, subject to full recruitment and completion of treatment. Pending the results of these initial studies, two further studies are planned, CUV153 and CUV154. The adjacent table summarises the studies.

When completed, the five studies are expected to collectively enrol 38 XP patients and 10 disease-free control subjects. The results will be analysed and if favourable, discussions will take place with regulatory authorities on the filing of a dossier to seek marketing authorisation on for the product for the treatment of XP. The Company will announce key milestones as the studies progress.

A proven therapy, which safely offers protection and assists DNA repair, would reduce the overall burden of the disease for XP patients and their families and could dramatically improve quality of life and life expectancy. Beyond this critical milestone for XP patients, CLINUVEL will assess other clinical indications with a view to extending the benefit of melanocortin therapy to other groups with deficient DNA repair processes. The learnings from the DNA Repair Program are also expected to be translated to the dermatocosmetic products under development for broader populations and specifically, three targeted audiences of highest risk. To learn more about this initiative, read the next feature of the Annual Report.

CLINUVEL has learnt how the impact of the disease is greatest for these patients and understands from our earlier studies that they may see the greatest therapeutic response to the monotherapy treatment. Following the completion of CUV104, we will assess the results and plan the next phase of studies.



Summary of CLINUVEL DNA Repair Program

Study	Patients	n =	Commenced	Objectives	First results
CUV156	XP-C	6	October 2021	Safety and reduction in oxidative damage	2022
CUV151	Disease-free subjects	10	December 2021	Reduction in oxidative damage	2022
CUV152	XP-V and XP-C	6	February 2022	Safety and reduction in oxidative damage	2022
CUV153	XP-V and XP-C	6	Planned	Safety, assist DNA repair, quality of life	Not yet disclosed
CUV154	XP-V and XP-C	20	Planned	Safety, assist DNA repair, quality of life	Not yet disclosed

How does afamelanotide repair DNA damage caused by ultraviolet radiation (UVR) and lower the risk of skin cancers?

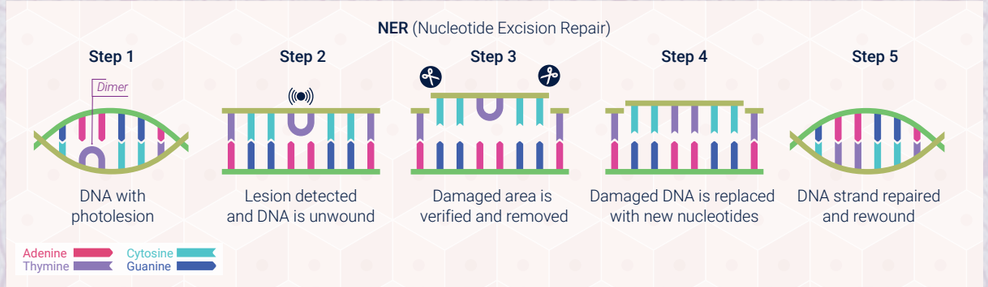
In summary, UVR leads to skin cell damage, expression of genes, proteins, and degradation of surrounding structures. If this damage is not repaired, the chances increase that DNA damaged cells are replicated, leading to skin cancer(s), including melanomas. Afamelanotide has been shown to reduce DNA damage caused by the sun's energy by activating melanin, which can absorb UVB and UVA rays, and reduced free radical formation.

In more scientific terms, afamelanotide:

- acts as a physical barrier to UVR;
- optimises melanocortin 1 receptor (MC1R) and ET-1 signalling;
- reduces oxidative stress after exposure to UVR;
- reduces photoproducts caused by UVR;
- increases the activity of key proteins XPC-XPA; and
- increases Nucleotide Excision Repair (NER) and Base Excision Repair (BER), key DNA repair mechanisms.

Thus afamelanotide assists and expedites DNA repair in damaged skin by activating repair genes and proteins, and removing damaged DNA and replacing it with new DNA fragments to stabilise the cell and its surrounding tissues. This reduces the chances of malignant transformation following UV and sun exposure and sunburns.

For a detailed diagram on the seventeen ways afamelanotide is understood to play a role in DNA Repair, refer to the 2020 Annual Report.



Vitiligo

Vitiligo is a common skin disorder in which the pigment producing cells of the skin (melanocytes) are absent or demonstrate a lack of activity. As a result, lighter depigmented patches of skin (vitiliginous lesions) appear on different sites across the body due the lack of melanin (pigment). The precise cause of vitiligo remains unknown. Vitiligo also causes significant psychological and emotional distress. A high disease burden is experienced by patients with Fitzpatrick Skin Types IV-VI (darker skin), where the contrasting loss of skin colour can lead to a profound sense of loss of identity.

On 8 March 2021, the FDA hosted a patient-focused vitiligo meeting for the first time, when testimonies were given of the impact of vitiligo in patients of darker skin colour, and its effect on their quality of life. The FDA acknowledged that "(t)his forum is important to the FDA, drug companies, researchers and other medical product developers that were in attendance on the day. The Agency hopes that the information provided to the FDA will help advance the science and development of new treatments for patients who would like to have them."

What is vitiligo?

Vitiligo is traditionally separated into two clinical forms: generalised vitiligo and segmental vitiligo (SV), which present with distinctive clinical features and natural histories.

Generalised vitiligo (or just 'vitiligo', previously referred to as 'nonsegmental vitiligo') is the most common form of the disease, accounting for 72-95% of the cases. The vitiliginous lesions are usually symmetrically distributed and new patches may appear throughout the patient's life. The disease is progressive with flare-ups. Vitiligo is frequently associated with personal or family history of autoimmunity.

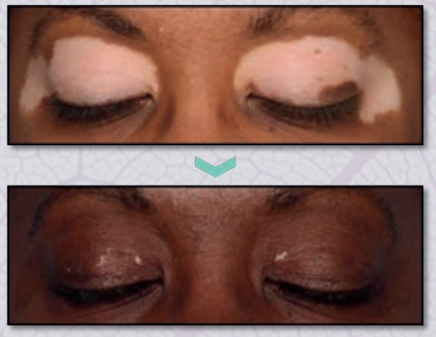
SV is characterised by a unilateral distribution that may totally or partially match a dermatome (area of skin with innervation from a single spinal nerve) and has an earlier onset and a rapid spread. SV occurs in a minority of patients and is thought to be more frequent in paediatric patients; it may account for 30% of childhood cases. Autoimmune association is rare with SV.

The main goal of treating vitiligo is to arrest depigmentation and then achieve repigmentation of the unpigmented lesions. Many treatment options exist but clinical challenges persist, as not all patients respond to available therapies and relapse is common.

CLINUVEL has demonstrated its commitment to develop a therapy focussed on the systemic repigmentation of the skin of vitiligo patients. Earlier studies, CUV102 (in the US in 2011) and CUV103 (in Singapore in 2014), have shown that treatment with afamelanotide in combination with narrowband ultraviolet B (NB-UVB) phototherapy can achieve faster and deeper repigmentation than NB-UVB as monotherapy, currently the most common treatment in vitiligo. The studies individually showed that the combination treatment led to follicular repigmentation and meaningful clinical results within six months. In the larger CUV102 study of 41 vitiligo patients, the repigmentation achieved was significant (p=0.025); refer to the picture below.

In December 2021, agreement was reached agreement with the FDA on a new Phase II study, CUV104, to evaluate SCENESSE® as a monotherapy for adult vitiligo patients. Approval to proceed with the study was received from the Institutional Review Board (IRB; ethics committee) in May 2022. CUV104 is now scheduled to commence at an expert centre in North America with the recruitment of up to six patients in the second half of 2022. The study will assess the efficacy of afamelanotide to repigmentation the face and body and improve the quality of life of adult vitiligo patients. More specifically, the endpoints of the study will be the extent and speed of repigment seen in patients as measured by the Vitiligo Area Scoring Index (VASI) tool, as well as the impact of the treatment with validated disease-specific quality of life tools. The focus of the study is on patients with darker skin types (Fitzpatrick IV-VI), more than half a million of whom are estimated to live in Europe and North America. CLINUVEL has learnt how the impact of the disease is greatest for these patients and understands from our earlier studies that they may see the greatest therapeutic response to the monotherapy treatment. Following the completion of CUV104, we will assess the results and implement the next phase of studies.

Repigmentation in vitiligo (CUV102)
p=0.025 (VASI)

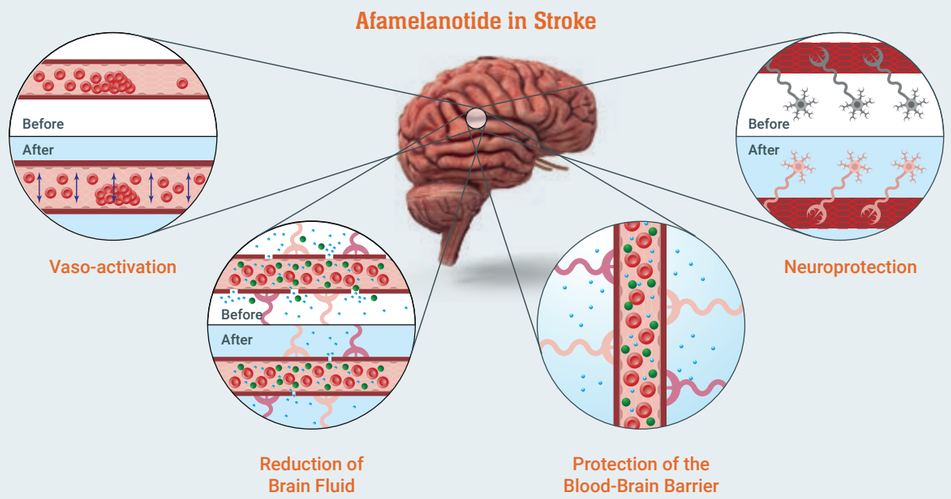


Arterial Ischaemic Stroke (AIS)

In June 2021 the Company commenced the first study of afamelanotide in AIS patients, evaluating the safety and efficacy of interventional treatment in six adult patients. Afamelanotide was administered up to four times over ten days following the stroke. The final results of the study, announced in May 2022, showed afamelanotide was well tolerated with five of the six patients experiencing considerable clinical and functional recovery up to 42 days after treatment. Specifically, National Institutes of Health Stroke Scale (NIHSS) scores improved in five patients and brain scans (MRI-FLAIR) in all patients showed a reduction in affected tissue.

The role of afamelanotide in the treatment of AIS

CLINUVEL's expertise incorporates a deep understanding of the role of melanocortins in the functions throughout the body. Scientific progress has demonstrated melanocortins, including afamelanotide, provide a positive effect on the central nervous system (CNS). Afamelanotide is known to offer neuroprotection and function as a potent antioxidative hormone. The drug possesses further therapeutic benefits, activating blood vessels, reducing fluid formation, protecting critical nerve and brain tissue, and restoring the blood brain barrier (BBB), a critical defence mechanism protecting the brain. The drug therapy is expected to affect the blood flow and oxygen to deprived brain tissue.



Following the positive results of CUV801, CLINUVEL is commencing a new study in AIS patients, CUV803. The Company has identified stroke as the first target indication for its PRÉNUMBRA® Instant formulation, which will be used in the CUV803 study. Patient enrolment is expected to commence in the second half of 2022 pending regulatory and ethics approvals. CUV803 will maintain a focus on safety with neurological function and extent of damage, while evaluating a flexible and higher dosing regimen to CUV801. PRÉNUMBRA® Instant provides a flexible, fast-acting dosage form of afamelanotide as a subcutaneous liquid injectable.

Addressable Market of Indications

The addressable market of each of the indications being assessed is summarised below:

Indication	Addressable Market
DNA Repair XP*	• XP is rare with an estimated 1,000 patients in Europe-USA-Latin America, with no approved therapy
Vitiligo	• Prevalence between 0.1 – 2.0% of the global population • Estimated 563,000 vitiligo patients in Europe-UK-North America with Fitzpatrick Skin Types IV-VI
AIS	• 15 million stokes occur worldwide, of which 85% are AIS • Estimates vary, but up to 80% of ischaemic stroke patients are ineligible for treatment with existing therapies

* Two billion people have inefficient DNA repair processes, putting them at risk of skin cancer(s) and melanoma. There are an estimated 19.3 million skin cancer cases globally.

The size of the addressable markets of the indications for which CLINUVEL is progressing treatments varies from ultra-rare to large. XP is ultra-rare, but the relevance of testing afamelanotide as an assisting agent for cellular DNA-damage repair is high, since many 'high risk' populations eventually develop skin cancers. Vitiligo is a sizeable problem to patients, specifically for those with a darker skin type. Collectively, the addressable markets of the clinical programs underway are large, and warrant our attempt to develop commercial solutions.

Expansion of the Drug Portfolio

The starting point of CLINUVEL's pharmaceutical portfolio is SCENESSE®, a controlled-release formulation of the melanocortin analogue afamelanotide. It is administered as a subcutaneous, solid injectable which dissolves under the skin. With its expertise in melanocortin drug development, CLINUVEL is following a program to commercialise other formulations and products to add to dosing and treatment flexibility of an expanded range of indications with unmet needs.

PRÉNUMBRA®

In July 2020, we announced the development of PRÉNUMBRA®, liquid formulations of afamelanotide to provide dosing flexibility as part of the life-cycle management of afamelanotide and to address clinical needs in critical disorders. This is the second formulation of the active pharmaceutical ingredient afamelanotide developed by CLINUVEL. PRÉNUMBRA® is being advanced as a potent haemodynamic, vasoactive (acting on blood vessels) and anti-oncotic (counteracting fluid formation in tissues) therapeutic agent, initially in adult patients.

Product development has progressed and working under an exclusive agreement, the PRÉNUMBRA® Instant presentation is being manufactured according to current Good Manufacturing Practice (cGMP) guidelines for use in clinical studies. In July 2022 we announced that PRÉNUMBRA® Instant will be administered in the CUV803 study as a treatment for stroke (AIS), with the study expected to commence in the second half of 2022. CLINUVEL is also developing the PRÉNUMBRA® Modified-release formulation. Other potential target indications are under evaluation for PRÉNUMBRA®, including disorders of the central nervous system, and are to be announced.

NEURACTHEL®

In November 2021, we announced the addition of the adrenocorticotropic hormone (ACTH) drug substance to CLINUVEL's melanocortin drug portfolio. To be developed as NEURACTHEL® in Instant and Modified-release formulations with application to neurological, endocrinological and degenerative diseases. In March 2022, we reported that the ACTH drug substance was being manufactured for CLINUVEL under cGMP and the development and validation work for the product formulations are ongoing.

The expanded melanocortin drug portfolio is summarised below.

Afamelanotide – photoprotective, repigmentation, anti-oxidative, anti-oncotic, DNA repair			
SCENESSE® (afamelanotide 16mg)	Implant	Adults – EPP, XP, vitiligo, stroke	Commercial, In development
SCENESSE® Enfance	Liquid	Paediatric 12-17– EPP, XP, vitiligo	In development
PRÉNUMBRA® Instant	Liquid	All ages – stroke, XP, CNS disorders	Developed for clinical use in stroke
PRÉNUMBRA® Modified-release	Liquid	Adults – stroke, CNS disorders	In development
Adrenocorticotropic hormone (ACTH) – anti-oxidative, anti-oncotic, neurotrophic			
NEURACTHEL® Instant	Liquid	Adults – acute neurological, endocrinological, degenerative disorders	Update expected Q3
NEURACTHEL® Modified-release	Liquid		In development
Next generation melanocortins – enhancing DNA repair and assisting re-pigmentation			
CUV9900	Topical, leave on	Adults – anti-oxidative, DNA repair	In development
Phimelanotide	Topical, leave on	Adults – repigmentation	In development
Parvysmelanotide	Topical, leave on	Adults – repigmentation	In development

The expansion of the melanocortin drug portfolio is integral to, and supports, CLINUVEL's clinical program.

Summary

CLINUVEL's clinical programs generate data on the safety and efficacy of our melanocortin drugs in specific medical indications. The expansion of both the melanocortin drug portfolio and the clinical program is well advanced. This is a critical part of the Company's growth and expansion strategy towards a diversified and sustainable pharmaceutical group.

Progress Towards OTC Product Launch

Developing Healthcare Solutions

Deliberately and carefully over more than two decades, CLINUVEL has become a global leader in photomedicine, devoting its scientists to understanding the impact of the full spectrum of light exposure on human biology.

CLINUVEL is founded upon a culture of exploration, and knowledge building, and sharing. This enriches each of our technical and scientific teams, and often sparks novel solutions and ideas based on data and sound information.

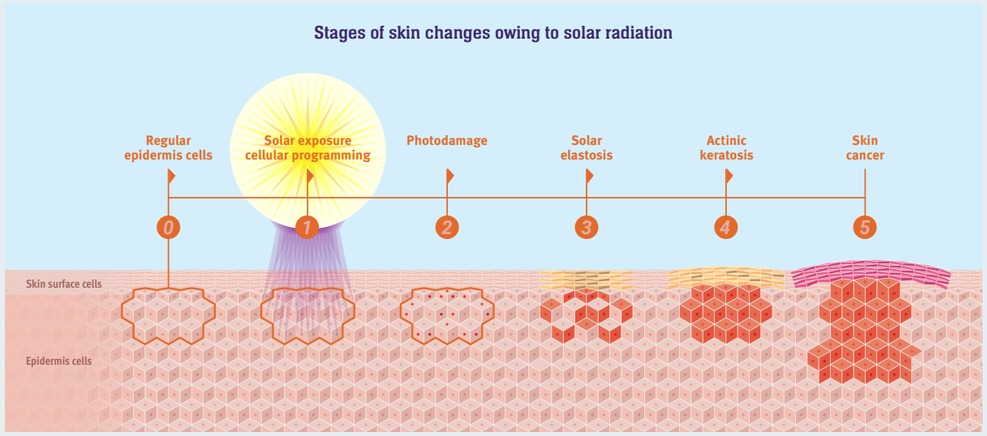
One of our core principles is to act responsibly and for the betterment of human health worldwide. The time has now come for us to share our knowledge, offering the same enrichment to new audiences, as with our leading scientists. Introducing a new language, our science-based approach will encourage audiences to reassess their relationship with solar light and, ultimately, offer healthcare solutions.

Defining the Challenge

Exposure to solar light (also referred to as solar radiation) is the single most important factor contributing to the risk of skin damage (photodamage), actinic changes (elastosis) and, eventually, skin cancer(s).

From the first moment of sun exposure as children, we incur biological and skin reactions which may impact our health later in life. As we age, our genetic make-up and cumulative solar exposure compound our risk for developing the three most frequent skin cancers: basal cell carcinoma, squamous cell carcinoma and melanoma. Common to each of these skin cancers is a certain dose exposure to polychromatic light (light of multiple wavelengths). Protecting skin from light is essential to reducing the risk of skin cancer.

For decades, CLINUVEL's research & development teams have focused on the effects of UV and high energy visible (HEV) light on human health, centred around skin and photoprotection.



The impact of HEV on skin is only just beginning to be widely understood, yet it affects us all. HEV exposure leads to the generation of reactive oxygen species (ROS) which damage cellular skin structures, as well as increased skin pigmentation, and – in certain populations – to irreparable severe burns.

CLINUVEL's expertise in HEV is founded on our experience developing and delivering the first and only treatment for erythropoietic protoporphyria (EPP) patients, who are prone to intolerable skin burns, reactions, due to visible wavelengths of light. We pioneered the world's first systemic photoprotective drug, SCENESSE®, to successfully protect these patients against polychromatic light. With extensive and unique expertise, we are now deploying our specific technologies for wider populations at Highest Risk of skin cancer, translating complex subjects and data into understandable knowledge, and a range of skin protective and reparative products.

Targeted Audiences

Global skin cancer rates are increasing, with environmental changes playing a role. Each of us is at risk of photodamage, but there are populations at Highest Risk. Individuals with minimum pigmentation (or fair skin complexion), and those who burn easily following sun exposure are at higher risk of photodamage.

There are three further groups in the world, however, who are regarded as being at the Highest Risk of photodamage and skin cancer:

- immunocompromised;
- personal or family history of skin cancer; and
- extreme outdoor athletes and professionals.

Immunocompromised

Around 3% of the global population have a weakened or compromised immune system, placing them at higher risk of photodamage and skin cancers. A compromised immune system can result from genetic diseases, acquired illness, or the use of immune suppressive drugs to combat an illness or to preserve a new organ after receiving a transplant. In all these cases, the suppression of the natural immune system leads to an increased and high risk of photodamage and developing skin cancer, and warrants extra skin protection for life.

Unfortunately, the unintended postliminary effects of suppressing the immune system, such as photodamage and skin cancers, only become apparent years or decades later. Many people are not aware of this risk. In some instances, there may be short-term care, but long-term attention is often missing.

Personal or family history of skin cancer

Individuals with a previous history of skin cancer and, or a family history are at much higher risk of photodamage. Often this higher susceptibility to photodamage is due to genetics, and the additional longer-term exposure to polychromatic light sources emitted by the sun, increasing the chances of developing skin cancer.

The risk of recurrent skin cancer is stark. Approximately 60% of people who have one skin cancer will have another within ten years. Those who have had two or more squamous or basal cell carcinomas have a 61.5% chance of another within two years.

Genetics and family history of skin cancer also plays a role. Up to 10% of melanoma patients have a close family member with the disease and there is a strong association between a family history of skin cancer and early-onset basal cell carcinoma.

All this research recognises, however, that the lead risk factor for photodamage and skin cancer remains solar and ultraviolet exposure.

Extreme outdoors

Our desire to take on challenges, compete, and experience new environments leads us to spending more and more time in the great outdoors.

But our environment has a direct impact upon our health. At altitude, solar light is more intense. Reflective surfaces, such as snow, sand, water, and ice amplify radiation exposure. Extensive time in these environments dramatically increases the risk of photodamage, even though it may not be visible initially.

All of us engaging in these extreme outdoor activities increase our risk of photodamage as time goes on.

Information, solar protection, and longitudinal care are the only remedies to decrease the rate of photodamage in extreme outdoor athletes and professionals, and to secure improved health.

CLINUVEL has taken on the challenge to accompany these audiences on a journey of polychromatic solar protection, assisted DNA repair while providing information and longitudinal care to people at highest risk of photodamage and skin cancer.

Healthcare Solutions Product Lines

CLINUVEL is advancing the development of next generation leave-on products for skin care. The following product lines are planned in sequence:

I. a polychromatic skin protection product line;
II. a product line to stabilise melanogenesis; and
III. a product line to assist cellular DNA repair.

These product lines will be revealed progressively over time.

The first product will contain active ingredients and chromophores to offer polychromatic protection over a wider-spectrum of wavelengths compared to existing solar protection products. In addition to the UVB and UVA protection offered by a broad-spectrum sunscreen, CLINUVEL's Polychromatic Screens will also provide effective protection against HEV light, a wavelength band responsible for the higher oxidative stress in the human skin. Thus, the polychromatic product will serve to reduce total light exposure through high protection.

The second product line aims to stabilise pigmentation, while providing anti-oxidative effects and polychromatic protection.

The third melanocortin-based product lines aim to enhance protective properties and repair of the skin. They will offer differentiating and specialised care to users, by enhancing all the major pathways that our skin activates to reduce photodamage early in the process:

- enhance melanogenesis to reduce photo exposure to both UV and HEV;
- induce antioxidative enzymes activities to reduce oxidative stress; and
- enhance DNA repair to help reduce or prevent mutation and carcinogenesis.

The Path to Product Launch is Building Audiences

CLINUVEL is preparing the first product line for launch in 2022, with an extensive digital outreach campaign to engage the identified three targeted audiences. The Company has selected a team of CLINUVEL Ambassadors (CUVAs): members of each of the Highest Risk communities who have committed to help raise awareness of the risks and damage caused by UV and HEV light across various social media platforms. More specifically, the CUVAs will communicate information on solar radiation, DNA damage and skin cancer risks. The Company has commenced the first of three initial campaigns to evaluate content generation, adherence, and subscription rates. Complementing this is the dedicated platform, lightskinscience.clinuvel.com.

We are continuing to build connections with the targeted audiences. Our objective is to build a connected community through digital marketing of 25 million people over the five years to 2027, driven by the Communications, Branding & Marketing Division.

Plans 2023 and Beyond

Objective and Focus

CLINUVEL is building a diversified and sustainable pharmaceutical company based on the specialisation in melanocortins. Both the Board and management believe this will generate significant incremental long-term value.

Integrated Business Model

A key factor in CLINUVEL's success to date has been the integrated business model employed to manage the diversity of its activities. This means the conduct of key functions of the business are undertaken 'in-house' where practical. These functions are typically outsourced by other pharmaceutical companies.

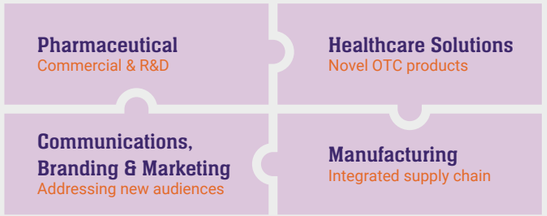
This approach has been beneficial to shareholders. CLINUVEL's direct distribution of SCENESSE® to EPP Expert Centres in Europe and Specialty Centers in the USA means margins are kept intact by our self-distribution model. Other activities managed 'in-house' – such as formulation R&D, regulatory affairs, and quality assurance – also result in better control of outcomes and costs. The integrated business model is also reflected in the establishment of the Communications, Branding & Marketing Division to reach the targeted audiences at highest risk of exposure to UV and HEV light.

An integrated business model also fits with CLINUVEL's culture of self-determination, resourcefulness, and persistence, and serves to provide an internal environment in which supports the development of well rounded, highly skilled, and capable professionals.

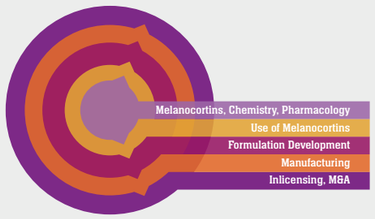
Following the easing of restrictions imposed at the height of the COVID-19 pandemic, we can reflect on supply arrangements and determine that independence of operation has many advantages compared to a broader model based on outsourcing and consequent dependence on suppliers. This is also the rationale for the establishment of the Manufacturing Division in which CLINUVEL will manufacture its own products and, in time, offer its manufacturing capabilities to other pharmaceutical enterprises. The divisional structure of CLINUVEL has evolved to support the integrated business model and as shown below; this encompasses the Pharmaceutical and Healthcare Solutions Divisions, as well as divisions focussed on Communications, Branding and Marketing and Manufacturing. The research and development activities of the Group are undertaken by the VALLAURIX Research, Development and Innovation Centre in Singapore.

We will continue to develop this integrated business model to support the ongoing and future activities of the Group.

Divisional Structure



Building the Business



Plans

Our plans for FY2023 and beyond in each functional area of the business are shown below:

Growth and Expansion

1. Afamelanotide in Multiple Indications
2. Portfolio of Melanocortins
3. Targeted Technology Translation
4. Integration of business functions, including manufacturing

Increase EPP patient access to SCENESSE® treatment
In existing jurisdictions (Europe, USA, Israel) and new jurisdictions (refer text box) and extend the use of afamelanotide to adolescent EPP patients.

Expand the product range
This encompasses the expanded pharmaceutical drug portfolio, as well as the translation of our melanocortin expertise and know-how to dermatocosmetic products, as detailed in the preceding feature of the Annual Report.

Continue to progress the clinical program
We will continue the existing studies already outlined through 2022 and into 2023. We also expect to announce new indications that will result in further expansion of the clinical program.

Progress the Manufacturing Division
Plans to establish self-manufacturing are at an early stage and developments will be shared with stakeholders as they progress.

In addition to the above, the Group will consider opportunities for inorganic growth that add value to the Group's capabilities and achievement of its objectives.

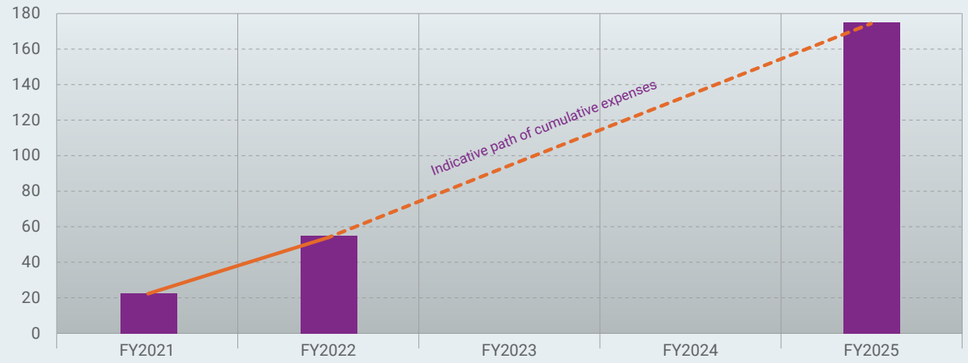
New jurisdictions planned for distribution of SCENESSE® for EPP

- Australia – we are progressing an application to have SCENESSE® listed on the Pharmaceutical Benefits Scheme for reimbursement of the cost of treatment of Australian EPP adult patients.
- China – we are collaborating with a local partner to treat EPP patients as part of a named patient program. This will provide Chinese patient data to combine with European and US patient data to submit to Chinese authorities for consideration of approval to distribute SCENESSE® to EPP patients in China.
- Japan – we are assessing the dossier that the authorities require to assess approval of the distribution of SCENESSE® to EPP patients in Japan.

Expenditures to Rise to Support Growth

We have provided a five-year guide of the expenses expected to achieve our plans. Excluding capital expenditures, expenses of A$175 million are planned over the five years to the end of FY2025. To date, the expenses incurred in FY2021 (A$22.738 million) and FY2022 (A$32.667 million) put us on track to achieve this projection.

Cumulative Expenses: Five Years to FY2025 (A$m)

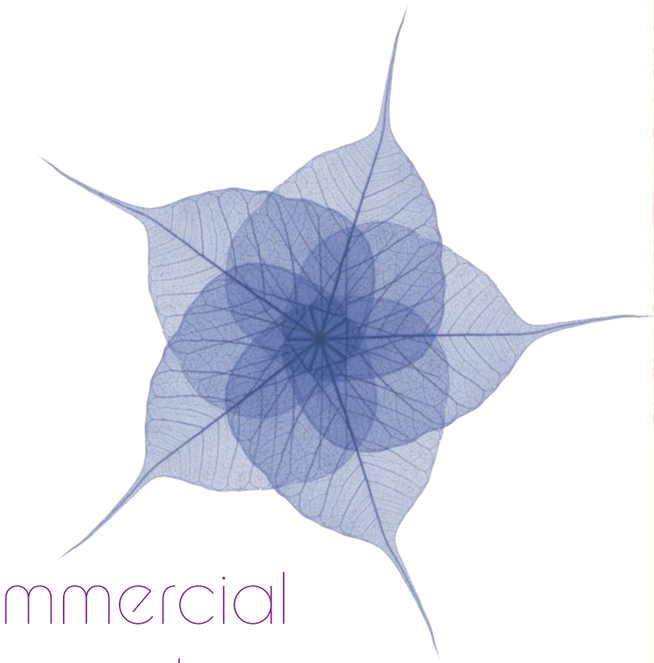


Note: Actual expenses FY2021 and FY2022. Indicative path of expenses FY2023 and FY2024 to planned cummulative level of expenses in FY2025

Summary

These plans detail a clear and deliberate growth strategy to add significant long-term value to the Group. We are persistent and determined and believe in the ability of the melanocortin family of hormones to have influence on the quality of the lives of many people, whether this be through pharmaceutical drug treatments or dermatocosmetic products. This is the course we at CLINUVEL have embarked upon and we welcome all existing and potential stakeholders to this journey.

CLINUVEL Pharmaceuticals | **2022** Annual Report



> CLINUVEL's commercial operations are scaling up to meet treatment demand worldwide, while the Group is pursuing R&D projects which aim to add value over the long-term.
>
> Our FY2022 results show a fundamentally strong business to date, allowing us to invest for future growth.

Mr Darren Keamy, Chief Financial Officer, CLINUVEL Group

CLINUVEL

Annual Results

Financial Year Ending 30 June 2022

Directors' Report

The Directors of the Board present their report on the Company for the financial year ended 30 June 2022 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
Director of the Supervisory Board of the B&S Group (The Netherlands)

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 internationally recognised entrepreneur who has helped build 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 difficult to serve markets. The B&S Group has global reach and is a leader in its market sector.

Formerly B&S Group's CEO, Mr Blijdorp now serves on its Supervisory Board and is a majority shareholder, 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 was recognised 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 a valuable contribution to setting the Group's long-term strategy for product commercialisation, growth, and plans to further diversify CLINUVEL. He provides guidance on business and tax restructuring of the Company, as well as setting distribution channels for future intended sales of dermato-cosmetic products in 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 3,120,715 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 since late 2005, 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 first melanocortin 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.

Dr Wolgen is currently leading the Group's expansion, with an immediate focus on the US and the further development of the product pipeline for various market segments. His focus has been to establish a professional management team to execute the corporate objectives set as well as to prepare the next generation of managers. 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
Fellow of the American College of Osteopathic Internists.
Doctorate of Osteopathic Medicine

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 Evewell 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 and in 2021 formed SSJ Partnership Ltd, a consultancy specialising in providing regulatory governance support in the healthcare sector. Mrs Smith has led a distinguished career, serving for 14 years as Chief Executive Officer of The Princess Grace Hospital, London, and 11 years as the Chief Executive Officer of The Portland Hospital for Women and Children, London. Mrs Smith's specific expertise is in the implementation of operational strategies within complex and acute care environments, and in the interaction with healthcare authorities and UK regulators. Her most recent role was as the Chief Executive Officer of the Independent Doctors Federation, a membership organisation representing practising physicians within the UK independent healthcare sector.

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

JEFFREY ROSENFELD, AC, OBE

Non-Executive Director
Appointed 26 November 2019

Committee Membership
Member of the Audit and Risk Committee
Member of the Nomination Committee

Current Directorships and Other Interests
Director, Connectivity TBI Ltd
Scientific Advisor, HitIQ Ltd
Representative Honorary Colonel, Royal Australian Army Medical Corps

Other Listed Company Directorships (last 3 years)
None

Relevant Interest in Shares and Performance Rights
Shares 2,848 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 also became an Emeritus Professor at Monash University in January 2021.

SIR ANDREW LIKIERMAN

Non-Executive Director
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)

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 Qualifications: BComm, CPA, GradDip ACG.

Mr Keamy, a Certified Practicing 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	8	8	2	2			2	2
Dr. P. J. Wolgen	8	8						
Mr. W. Blijdorp	8	8	2	2	3	3	2	2
Dr. K. A. Agersborg	8	8			3	3	2	2
Mrs. S. E. Smith	8	8			3	3	2	2
Prof J. V. Rosenfeld	8	8	2	2			2	2
Prof. J. A. Likierman	2	2					0	0

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

Principal Objectives and Activities

Objectives

CLINUVEL PHARMACEUTICALS LTD (CLINUVEL) is a global biopharmaceutical company focussed on developing and delivering treatments for patients with genetic, metabolic, and life-threatening disorders, as well as healthcare solutions for the general population. CLINUVEL's pioneering work in melanocortins aims to translate scientific breakthroughs to innovative medical solutions for complex problems and thus deliver lifelong care through novel products to patient groups and individuals at high risk of exposure to light and solar radiation.

CLINUVEL's expertise in understanding the interaction of the melanocortin family of hormones and human biology is focussed on developing treatments for patients with genetic and acute diseases who lack therapy.

CLINUVEL has developed and launched the world's first systemic photoprotective drug, SCENESSE® (afamelanotide 16mg), in Europe, the USA and Israel. CLINUVEL is also progressing an expanded research and development program into the role of afamelanotide and melanocortin hormones in general, for the treatment of a wide range of indications of unmet need, including:

- severe light and UV-related disorders;
- depigmentation of the skin;
- acute disorders and vascular anomalies; and
- diseases of the Central Nervous System.

The patient populations in these diseases range in size from 5,000 to 45 million worldwide.

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, 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 maintaining financial discipline and stability.

Performance Indicators

Management and the Board monitor the overall performance of the Group in the achievement of its objectives in relation to a defined strategic plan and annual operating and financial budgets.

The Board, with management, have identified a range of key performance indicators (KPIs) that are used annually to monitor performance. Key managers monitor performance against these KPIs and provide regular reports to the Board for review, feedback, and guidance, as necessary. This enables the Board to actively monitor and guide the Group's performance.

Activities

The principal activities of the Group during the 12 months to 30 June 2022 (FY2022) were to:

- manage and expand commercial distribution of its leading drug candidate SCENESSE® in the European Union (EU) and the USA for the treatment of a rare, genetic metabolic disorder, erythropoietic protoporphyria (EPP);
- progress the ongoing research and development of the Pharmaceutical Division's product pipeline for a range of severe disorders, including:
    - SCENESSE® and various pharmaceutical formulations of melanocortin analogues for the treatment of a range of disorders;
    - topical based pharmaceutical formulations for photoprotection of the skin;
    - medicinal photoprotection and assisted DNA repair of the skin, initiating the first studies in the genetic disorder, xeroderma pigmentosum (XP);
    - completing the first pilot study to investigate the use of SCENESSE® as a medicinal therapy for acute arterial ischaemic stroke (AIS);
    - preparing for further clinical study to investigate the use of SCENESSE® as a medicinal therapy in the depigmentary disorder vitiligo, focussing on affected darker-skin populations;
    - the ongoing development of PRÉNUMBRA®, a new liquid formulation of afamelanotide for the treatment of acute disorders and vascular anomalies; and
    - the development of a new product, NEURACTHEL® in different formulations, based on the adrenocorticotropic hormone (ACTH), for neurological, endocrinological, and degenerative disorders.
- progress the development of a range of non-prescription, dermatocosmetic products for individuals and populations at high risk of exposure to ultraviolet (UV) and high energy visible (HEV) light.

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

Review of Operations and Financial Condition

Key Features of Business Operations

There are several key features of CLINUVEL's business operations:

- The commercial operations of the Group are undertaken in the EU and the USA.
    - Since June 2016, CLINUVEL has distributed SCENESSE® to EPP patients through accredited EPP Expert Centres, working within the commitments agreed with the European Medicines Agency (EMA) as a condition for continuous marketing authorisation.
    - Since April 2020, CLINUVEL has been distributing treatment for patients with EPP through accredited Specialty Centers in the USA, in accordance with the approval of the FDA, granted in October 2019.
- CLINUVEL has distributed SCENESSE® to EPP patients under a Special Access Scheme in Switzerland since 2012, and in Israel since February 2021, in accordance with the approval of Israeli Ministry of Health.
- The net price per unit of SCENESSE® is uniform across the jurisdictions in which it operates.
    - Manufacturing and distribution costs specific to each jurisdiction determines the gross price of SCENESSE®.
    - This approach reflects the Group's values of fairness and equitable access to treatment to all patients, thereby providing transparency to all payors in North-America the European Union, and Israel.
- SCENESSE® is manufactured in the USA by a sole contract manufacturer and is distributed by the Group directly to accredited EPP Expert Centres in Europe and Israel and Specialty Centers in the USA.
- CLINUVEL's cash receipts in Europe and to a lesser extent in the USA and Israel are markedly higher in the northern hemisphere from spring to autumn when ambient light is more intense and demand for treatment from EPP patients is higher.
- The Group has an ongoing clinical interest to further develop SCENESSE® and its derivatives with a focus on vitiligo, a skin depigmentation disorder; DNA repair of the skin, with initial clinical studies commenced in xeroderma pigmentosum (XP); acute arterial ischaemic stoke (AIS); and additional indications to be disclosed.
- New products are being developed to enhance the melanocortin based treatment options for a wider range of indications.
    - A second formulation of afamelanotide, PRÉNUMBRA®, is being developed to focus on acute disorders and vascular anomalies.
    - NEURACTHEL® in different formulations, based on adrenocorticotropic hormone (ACTH), is being developed for neurological, endocrinological, and degenerative disorders.
- The Group's product development program is conducted through its fully owned Singaporean subsidiary, VALLAURIX PTE LTD (VALLAURIX) with a focus on developing pharmaceutical topical products and other formulations, as well as a non-prescriptive, over-the-counter, dermatocosmetic product range.
- The Melbourne headquarters of the Group covers the key regulatory affairs, scientific programme, accounting and finance, and investor relations functions. The United Kingdom office co-ordinates global operations, communications, branding and marketing, while the US office oversees the distribution of SCENESSE® in North America and clinical programs undertaken in the USA. Strategic management and other marketing and investor relations takes place from the Monaco office. The Irish and Swiss offices provide regulatory and quality guidance, serving management functions for EU distribution of SCENESSE®.

Review of Operations

The review of operations for FY2022 focuses on:

- the distribution of SCENESSE® in Europe and the USA;
- ongoing work in new jurisdictions to obtain regulatory approval of SCENESSE® and/or agreement on the reimbursement of the cost of treatment of SCENESSE®;
- the expansion of the Group's research and development program to develop SCENESSE® and its analogues for the treatment of patients with a range of severe metabolic and vascular disorders; and
- the development of a range of non-prescription, dermatocosmetic products aimed at the highest risk groups among the general population.

Distribution of SCENESSE® in Europe and USA

The supply of SCENESSE® to EPP Expert Centres in key European countries, including under a special access scheme to Switzerland, continued in FY2022. During the COVID-19 pandemic, the majority of EPP Expert Centres have continued to prescribe SCENESSE® due to strong clinical demand. A small number of Centres either deferred orders or reduced order sizes in the initial months of the COVID-19 pandemic in the second half of FY2020. These few Centres were not able to provide treatment access to patients, or patients were unable to attend Centres. Despite ongoing uncertainty surrounding the pandemic, patient demand for SCENESSE® largely normalised in FY2021. With the increase in vaccination rates and less restricted mobility, demand strengthened in FY2022.

In January 2022, after lengthy negotiations we arrived at a second agreement with the German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband or GKV-SV) for the ongoing treatment and reimbursement of SCENESSE® in Germany. The new negotiation was necessitated by the fixed review period imposed by the German Federal Joint Committee (GB-A) in 2016 in relation to the first agreement reached in March 2017. Over 19 months of extensive discussion the CLINUVEL team argued the benefit of treatment to German EPP patients, and the perseverance of negotiations led to the acceptance by GKV-SV. The continuation of treatment in Germany also has significance to other countries in Europe, as Germany is an important reference country for other reimbursement decisions being made. The second agreement impacts the ongoing treatment of adult EPP patients in Europe.

On 8 October 2019, the US FDA approved SCENESSE® to increase pain free light exposure in adult patients with a history of phototoxic reactions from EPP. This was a milestone approval for the Group after 15 years of research and development of SCENESSE® for EPP. Following the FDA's approval, the Group activated its implementation plan for US operations and, within six months of approval, completed the key pre-distribution logistics to commence treatment. These logistics included establishing the business infrastructure, securing correct reimbursement codes for the drug and administration of treatment ensuring seamless operations and reimbursement. Initial insurer discussions took place and agreements were reached to obtain reimbursement of treatment, and our teams worked towards identification of initial Specialty Centers which were then trained and accredited by CLINUVEL.

In April 2022, CLINUVEL recorded its second anniversary of distributing SCENESSE® for adult EPP patients in the USA. The Company's plan was to accredit up to 30 Specialty Centers across the USA over a phased period by the end of calendar year 2021. CLINUVEL achieved this objective mid-2021 and by the end of 2021 had trained and accredited 40 Specialty Centers. This engagement with Specialty Centers is well ahead of planning, and a network of over 40 prescribers continues to be maintained.

Over 100 insurance companies are actively involved in the reimbursement of the cost of treatment, mainly under Prior Authorization (PA). CLINUVEL continues to operate a Savings Program to assist with the out-of-pocket expenses of patients and provides a dedicated patient and healthcare professional website to facilitate patient access to treatment. CLINUVEL actively supports patients and Specialty Centers which are required to contact insurance companies to obtain approvals for reimbursement of the cost of treatment.

The first cash receipts from the supply of SCENESSE® to US markets were received in FY2021. The Company's experience is that payment cycles are longer in the US than the 30 to 60 days average length of payment terms in Europe. The terms of payment are improving as the Specialty Centers are becoming more experienced in the administrative reimbursement process.

After revenues were recorded from first-adoption prior to 30 June 2020, orders rose steadily throughout FY2021, underpinned by the progress achieved to train and accredit more Specialty Centers. This trend continued in FY2022.

SCENESSE® in New Jurisdictions

The Group continues to work towards gaining regulatory approval for SCENESSE® for EPP patients in other important markets. This reflects our commitment to provide EPP patients worldwide with access to SCENESSE®.

In October 2020, the Australian Therapeutic Goods Administration (TGA) approved the registration of SCENESSE® for the prevention of phototoxicity in adult patients with EPP, after a nine-month review of the SCENESSE® scientific dossier. This is the first treatment approved for EPP in Australia. Following the TGA approval, SCENESSE® was registered on the Australian Register of Therapeutic Goods (ARTG) and subject to the agreement of the Pharmaceutical Benefits Advisory Committee, will be made available on the Pharmaceutical Benefit Scheme (PBS) in Australia. It is expected that the drug will be administered by specialists in an outpatient setting through speciality centres.

In February 2021, the Israeli Ministry of Health approved SCENESSE® as a first-line treatment for the prevention of phototoxicity to all adult patients diagnosed with EPP. It is anticipated this first approval of national reimbursement in the Middle East opens the pathway to other countries in the region.

The Collaboration Agreement to treat EPP patients with SCENESSE® under a Named Patient Program (NPP) in the People's Republic of China continues. The collaboration with the local distribution partner focuses on facilitating early access for Chinese EPP patients while collecting data to compile a dossier to submit a new drug application (NDA) to the Chinese National Medical Products Administration (NMPA). CLINUVEL and its distribution partner is working with prominent hospitals in China to facilitate EPP patient treatment. It is planned that the NPP will include up to 10 Chinese EPP patients – treated according to US and EU protocols – who will be evaluated during a defined period. Local subsidies are available to enable eligible EPP patients to receive treatment. Following treatment with SCENESSE® under the NPP, CLINUVEL and its partner will evaluate the drug's safety and effectiveness in Chinese EPP patients. The collaboration will also focus on subsequent registration of SCENESSE® on the National Drug Reimbursement List. On a prevalence basis, an estimated 5,000 Chinese residents suffer from EPP, for which there is no approved therapy in China.

CLINUVEL plans to seek regulatory approval to distribute SCENESSE® in other countries, including European countries not in the EU, the Middle East, Japan, and Latin America.

Activities of the Singapore Laboratory

Commissioned in August 2020, the Company's Research, Development & Innovation (RDI) Centre, based in Singapore, are state-of-the-art expanded laboratories with a larger and skilled team, and specialised technical laboratory equipment. The RDI Centre is leading the Group's R&D effort on novel melanocortins, and prescription and over-the-counter products to further enhance the progress of its product pipeline and underlies the Group's divisional structure (refer below).

The RDI Centre is operated by the Group's wholly owned subsidiary, VALLAURIX Pte Ltd. The Singapore Economic Development Board (EDB) is supporting the facility with an award under their Research Incentive Scheme for Companies (RISC). This is part of the Government of Singapore's incentives to assist Singaporean businesses to develop their research capacity to advance high valued technologies. The EDB award is up to S$500,000 (A$547,000) over three years, subject to ongoing conditions being met.

CLINUVEL's Organisational Structure

To support the strategic objectives and initiatives of the Group, the Group has maintained the organisational structure of four divisions implemented in FY2021:

- the Pharmaceuticals Division, CLINUVEL's core business focussed on developing and delivering products for patients with unmet medical need;
- the Healthcare Solutions Division, concentrated on non-prescription products derived from the know-how and active ingredients used in the Pharmaceuticals Division, aiming to serve populations with highest risk of solar damage and skin cancers;
- the Communications, Branding and Marketing Division is established to communicate to wider differentiated audiences, positioning the Group for broader engagement; and the
- Manufacturing Division is focussed on novel formulations and products for CLINUVEL, while it aims to set up facilities concentrated on research, development and production for third parties, and companies, research organisations in the biopharmaceutical sector.

Underlying the divisional structure is the RDI Centre in Singapore, researching molecular science, biology, and follow-on formulations.

Product Pipeline

The Group has expanded its product development pipeline that encompasses the application of SCENESSE®, PRÉNUMBRA®, CUV9900, parvysmelanotide and other novel treatments for patients with severe genetic, skin, and vascular disorders which lack therapeutic alternatives.

The pipeline includes research and development into:

- a paediatric formulation of SCENESSE® for EPP;
- SCENESSE® for adult vitiligo patients;
- next generation products based on melanocortin analogues CUV9900 and parvysmelanotide, currently being evaluated as an adjuvant maintenance therapy in vitiligo, with the intention of developing these analogues for medicinal purposes;
- a range of over-the-counter products for general photoprotective use;
- the use of melanocortins in assisted DNA repair of UV-damaged skin;
- the role of afamelanotide in treatment of acute stroke (AIS); and
- the application of a newly developed second formulation of afamelanotide, PRÉNUMBRA®, a non-solid controlled-release formulation, to be evaluated in clinical studies for acute disorders and vascular anomalies.
- Developing NEURACTHEL®, based on adrenocorticotropic hormone (ACTH), for neurological, endocrinological, and degenerative disorders.

Vitiligo Program

The Group has undertaken Phase II studies (in the USA in 2011 and in Singapore in 2014) to evaluate the effectiveness of SCENESSE® to activate and repopulate melanocytes within vitiliginous lesions (depigmented skin areas) and achieve repigmentation in combination with NB-UVB phototherapy in patients with vitiligo.

Following the approval of SCENESSE® for EPP patients in the USA, CLINUVEL has discussed with the FDA the design of a new study in vitiligo to commercially develop a first systemic repigmentation agent in North America, that is without the use of narrowband UVB therapy. The focus of discussions has been on SCENESSE® as part of a combination therapy versus a monotherapy, and targeting populations with Fitzpatrick Skin Types (IV, V, VI) to be included in the new study, CUV104.

During this period of liaison, the FDA held a virtual public meeting on patient-focussed drug development for vitiligo in March 2021 which attracted 1,155 participants. The recognition of vitiligo as a disease requiring treatment for darker skin populations was encouraging, as were the majority of patients who advised in the meeting that they may or would use a treatment if it provided up to 50% repigmentation with modest side-effects.

In December 2021, the FDA consented to a new Phase II study, CUV104, to evaluate SCENESSE® as a monotherapy for vitiligo adult patients. In May 2022, approval to proceed with the study was received from the Institutional Review Board (IRB). Based in the United States, the IRB is responsible for the ethical oversight of studies involving human participants. CUV104 is now scheduled to commence at a North American expert centre with the recruitment of up to six patients in the second half of 2022. The study will assess the efficacy of afamelanotide to activate repigmentation of the face, and body, and to improve the quality of life of adult vitiligo patients.

More specifically, the endpoints of the study will be the extent and speed of repigmentation as measured by the Vitiligo Area Scoring Index (VASI) tool, as well as the impact of the treatment with validated disease-specific quality of life tools. The focus of the study is on patients with darker skin types (Fitzpatrick IV-VI), more than half a million of whom are estimated to live in Europe and North America. CLINUVEL has learnt how the impact of the disease is greatest for these patients, and understands from earlier studies that a therapeutic response to monotherapy may be expected. Following the completion of CUV104, we will assess the results and plan the next phase of studies.

Following acceptable results on the safety and efficacy in its vitiligo program, CLINUVEL would seek to file a supplemental New Drug Application (sNDA) filing for SCENESSE® in vitiligo. Referred to as an “efficacy supplement”, this is required to add a new indication to the labelling of an approved drug in the USA, with the submission consisting of clinical data supporting the new indication and any additional studies which may be required to support the efficacy and safety in the new indication.

DNA Repair Program

Scientific advancements on melanocortins and CLINUVEL’s programs have shown that afamelanotide can assist in the repair of cellular DNA damage caused by exposure to ultraviolet radiation. In September 2020, CLINUVEL announced the commencement of work to evaluate the possible therapeutic effect in humans, with an initial focus on xeroderma pigmentosum (XP), thereby acknowledging a problem of skin’s DNA-damage due to a deficiency in natural DNA repair processes, affecting millions of fair-skinned populations.

There has been understandable caution by authorities and decision makers of the impact of conducting clinical trials with novel compounds and therapies in XP patients. CLINUVEL was finally able to convince decision makers, owing to the long-term safety results generated over more than a decade The first patient with the XP-C variant dosed with SCENESSE® tolerated the treatment well and work proceeded to the design and approvals necessary to commence formal clinical studies. In June 2021, CLINUVEL reached agreement with clinical and academic experts to proceed with clinical studies focusing on patients with the XP-C and XP-V variants. In FY2022, CLINUVEL commenced three studies:

- CUV156, in up to 6 XP-C patients;
- CUV151, in up to 10 disease-free subjects, as a control group; and
- CUV152, in up to 6 XP-V and XP-C patients.

These studies involve the taking of skin samples (biopsies) of exposed skin areas for laboratory analyses of DNA damage before and after drug administration. CLINUVEL has collaborated with expert physicians to develop global assessment tools and patient reported outcomes for use in the studies. In addition to confirmation of the safety of SCENESSE®, the objective is to see a reduction in oxidative damage in the skin biopsies taken after drug administration. Read outs of these studies are expected to issue later in 2022, subject to full recruitment and completion of treatment. Pending the results of these initial studies, two further studies, CUV153 and CUV154, are planned.

Acute Stroke Program

CLINUVEL announced its research program into the role of afamelanotide in the treatment of acute arterial ischaemic stroke (AIS) in October 2020. Stroke is the second most common cause of death and a leading cause of disability worldwide. Of 15 million strokes worldwide, 85% are AIS cases. Existing therapies can treat around 15% to 20% of these cases due to the accessible location of the clot in the M1 (or first branch) region of the main cerebral artery. In the bulk of cases, the clot is in the smaller arteries in the mid or upper regions of the brain and, therefore not eligible for existing clot removing and clot dissolving treatments. Hence, CLINUVEL is seeking to develop a treatment for a significant unmet medical need, namely for clots occurring in these brain areas.

Due to the COVID-19 pandemic, the start of the clinical study in stroke patients (CUV801) incurred a delay, but the first AIS patient was treated with afamelanotide in June 2021. In August 2021 a preliminary update was provided on the treatment of the first three AIS patients. Treatment was well tolerated with two patients showing improvement in neurological deficit while one patient showed no improvement. Enrolment and treatment of all six patients of the study was completed in January 2022.

Preliminary results of the study were announced in March 2022, followed by the final results of the study in May 2022. The latter results showed afamelanotide was well tolerated with five of the six patients experiencing considerable clinical and functional recovery up to 42 days after treatment. Specifically, National Institutes of Health Stroke Scale (NIHSS) scores improved in five patients and brain scans (MRI-FLAIR) in all patients showed a reduction in affected tissue.

Based on these promising results, the next study, CUV803, is well advanced in planning. The enrolment of patients is expected to commence in the second half of 2022, pending regulatory and ethics approvals. CUV803 will maintain a focus on safety with neurological function and extent of damage, while evaluating a different dosing regimen to CUV801. PRÉNUMBRA® Instant which provides flexible dosage of afamelanotide through a subcutaneous liquid injectable, will be administered in the study.

Development of the Melanocortin Drug Portfolio

The development of SCENESSE® and ongoing research on drug formulations by the Singapore RDI Centre has enabled CLINUVEL to build its expertise in melanocortin drug development. CLINUVEL has implemented a program to commercialise new melanocortin based formulations and other protective products to add to dosing and treatment flexibility of an expanded range of indications with unmet needs. Key product developments during FY2022 are summarised below.

PRÉNUMBRA®

At the start of FY2021, the Group announced the development of a second formulation of afamelanotide, PRÉNUMBRA®. Managed by the RDI Centre in Singapore, PRÉNUMBRA® is a non-solid controlled-release formulation which provides dosing flexibility as part of the active life-cycle management of afamelanotide to address clinical needs in acute disorders and vascular anomalies. The Group has secured the intellectual property rights for the dosage form in identified indications, as well as the international trademarks for PRÉNUMBRA®.

Product development progressed during FY2022. In July 202 we announced that working under an exclusive agreement, the PRÉNUMBRA® Instant presentation is being manufactured according to current Good Manufacturing Practice (cGMP) guidelines for use in clinical studies. PRÉNUMBRA® Instant will first be administered in the CUV803 stroke study to commence in the second half of 2022.

NEURACTHEL®

In November 2021, CLINUVEL announced the addition of the adrenocorticotropic hormone (ACTH) drug substance to its melanocortin drug portfolio, to be developed as NEURACTHEL® in Instant and Modified-release formulations with application to neurological, endocrinological and degenerative diseases. In March 2022, we reported that the ACTH drug substance was being manufactured for CLINUVEL under current Good Manufacturing Practice (cGMP) with ongoing development and validation work for the product formulations.

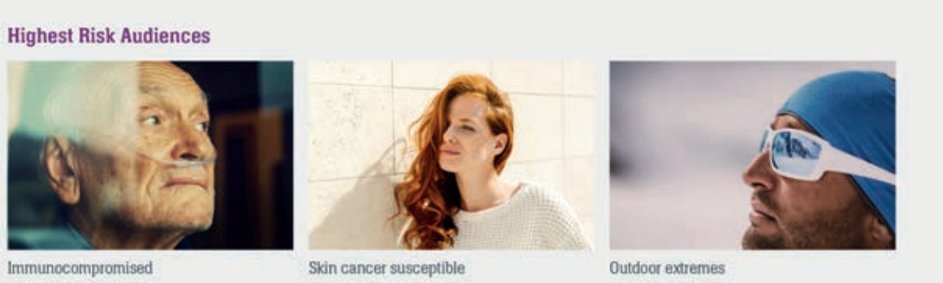
Non-Pharmaceutical Healthcare Products

CLINUVEL is developing a range of non-pharmaceutical products for individuals in the general population at the 'Highest Risk' of photodamage from exposure to UV and HEV light. The Highest Risk groups are:

- those who have a personal or family history of skin cancer;
- immune-suppressed populations; and
- extreme outdoor populations such as farmers, construction workers and professional sportspeople.

These specialised groups are being addressed by CLINUVEL as they remain underserved by the products currently available in the dermatocosmetic market.

Work on the launch of the first product proceeded in FY2022. In May 2022, CLINUVEL commenced an extensive digital outreach campaign to engage the addressable audiences. A team of CLINUVEL Ambassadors comprised of members of the highest risk groups have been appointed to actively communicate information on solar radiation, DNA damage and skin cancer risks though social media channels to build a following. Once the series of campaigns have been completed and data from the campaigns are evaluated, a pilot launch of the first product will take place. This is planned for later in 2022. The first product line will provide polychromatic protection from a wider spectrum of wavelengths than existing solar protection products. This will be followed by other product lines that provide protective benefits.



Financial Review

The financial year ended 30 June 2022 marks another successful year for the Group, with double-digit annual increases achieved in key financial categories: total revenues (37% increase); before tax profit (33%); and cash flows generated from operating activities (107%).

The result for the Group for FY2022 was a $34.321 million profit before tax, compared to $25.713 million for FY2021, a 33% increase.

Profit after tax was $20.878 million, a 16% decline on the FY2021 result of $24.728 million. The decline in profit after tax was due to a $13.442 million income tax expense (FY2021: $0.984 million). Of this, $6.075 million is a deferred tax expense charge resulting from utilising unused tax losses previously recognised as a deferred tax asset and temporary differences primarily stemming from unrealised gains in exchange rate movements over financial assets, increasing the deferred tax liability position.

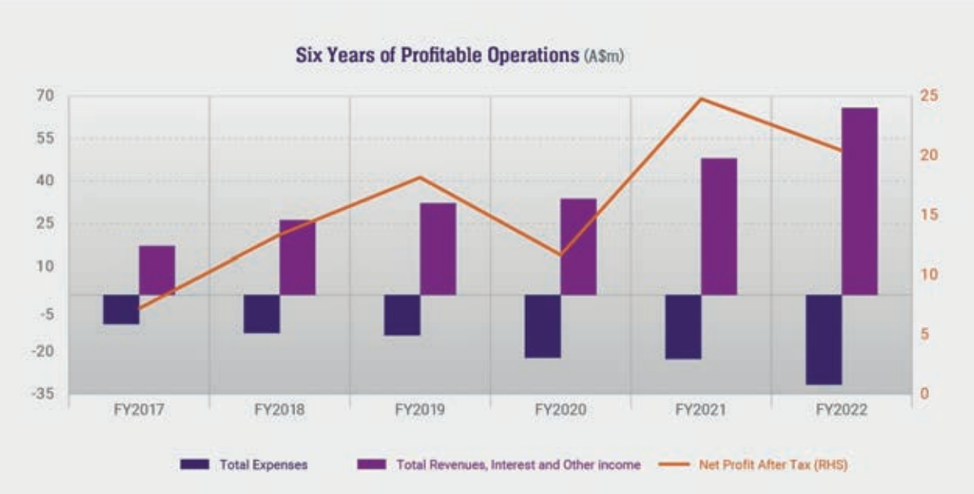
The result reinforces the Group's success in pursuing a strategy to maintain and grow its commercial operations of SCENESSE® in the EU and the US whilst expanding its existing activities to support product development to place the Company in the best possible position to maximise future cash flows. Total expenses increased 44% year-on-year in support of the expansion in activities.

Importantly, Net Cash provided by Operating Activities into the Group was strong at $39.872 million for FY2022, compared to the positive result of $19.262 million in FY2021. After the deployment of cash in investing and financing activities, including a dividend distribution to shareholders, net cash added $38.818 million to cash and cash equivalents on the balance sheet after accounting for exchange rate adjustments on foreign currencies held. Cash reserves have increased steadily since the commencement of commercial operations in June 2016 without reliance on debt or equity funding, from $13.845 million at 30 June 2016 to the 30 June 2022 level of $121.509 million.

The results are summarised in the table below and the following graph which shows CLINUVEL's six years of profitable operations.

Summary Financials FY2022				
Consolidated Entity	FY2022		FY2021	
	$		$	
Revenues and Other Income	66,987,515	+38%	48,450,599	+43%
Net Profit before income tax	34,320,915	+33%	25,712,644	+123%
Profit after income tax expense	20,878,465	-16%	24,728,247	+64%
Basic earnings per share	0.423	-16%	0.500	+64%
Net tangible assets backing per share	2.504	+31%	1.911	+41%
Dividends	4.0 cents	+60%	2.5 cents	unchanged

Note: CLINUVEL has one operating segment for reporting purposes.



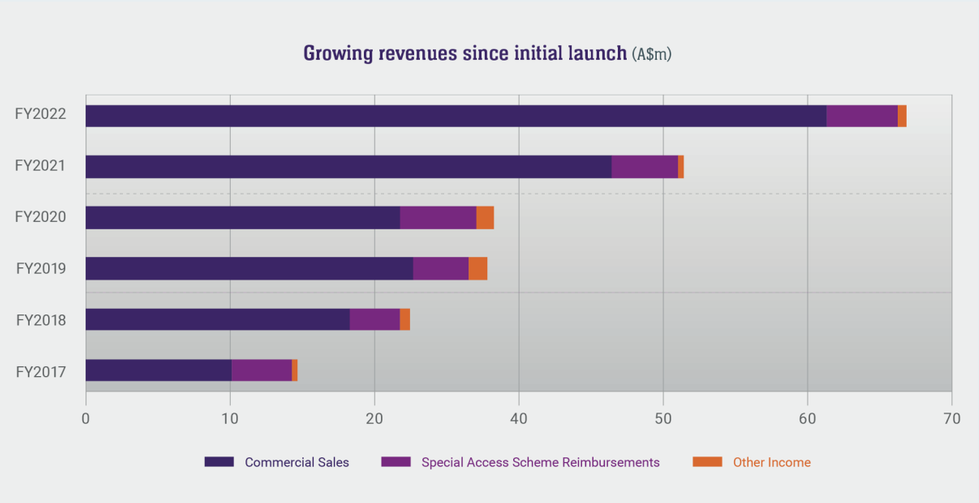
Revenues

The Group achieved a Total Revenue result of $65.722 million for FY2022. This strong top line result is a 37.0% increase on the prior year of $47.976 million which in turn was a 47.3% increase to FY2020 of $32.565 million.

Total revenues have continued to grow year on year since initial launch of SCENESSE® in FY2016, reflecting the progress made from achieving marketing authorisation in two major markets and the subsequent agreements to establish a price for the lead medicinal product. The graph below depicts the growth in Total Revenues year on year since FY2017.

A comparison of the FY2022 reported and constant currency results against the FY2021 reported results for Commercial Sales and Special Access Scheme Reimbursements is shown in the table on the following page.

Throughout FY2022, the Australian dollar currency averaged weaker relative to most other currencies the Group had an exposure to when compared to FY2021. As a result, movements in foreign exchange rates against the Australian dollar presentation currency resulted in a $1.234 million positive impact to the reported Total Revenue result for the year.



	Commercial Sales	SAS Reimbursements Switzerland, Other	Total
A$ million			
FY2022 Reported	60.002	5.720	65.722
FY2022 Constant*	58.786	5.702	64.488
FY2021 Reported	42.603	5.373	47.976
% change (Constant)	37.99%	6.12%	34.42%
% change (Reported)	40.84%	6.46%	36.99%

* FY2022 revenues converted to A$ monthly at the average conversion rate of the same month of FY2021

Commercial Sales

Commercial sales for FY2022 were $60.002 million, a 40.8% increase to the commercial sales result for FY2021 ($42.603 million). On a constant currency basis, commercial sales revenues of SCENESSE® increased 38.0% for the year. The Group views its commercial sales as a single operating segment however further insights across its key markets follow.

Commercial sales in the USA have gone from strength-to-strength, with sales steadily increasing throughout FY2022. At the end of its second full year of recorded sales, more than one hundred insurance companies had agreed to reimburse SCENESSE® either via Prior Authorization (PA) or through acceptance of the drug on individual formularies. The number of Specialty Centers participating in the distribution program who are trained and accredited has now grown to over 40 and the US operations continues to approach new centres for program enrolment to serve first-time patients. The medication and treatment codes for SCENESSE® are now well established for insurance reimbursement purposes, facilitating a more timely patient start-up from time of program enrolment. A patient savings program is implemented and provides financial assistance to those patients who are in financial need. Year-round demand continues with largely consistent ordering patterns throughout the year in the US. This indicates a level of year-round demand for SCENESSE® in the US.

Commercial sales in Europe continued to grow year-on-year. Those expert centres who have been treating patients since product launch and who have reached their treatment capacity have retained their patient base, whilst other centres were able to grow the number of patients they treat. Further patient access was aided from market access reimbursement arrangements being established with regional pricing authorities in several countries, who agreed to reimburse the uniform drug price set across the EU.

Reimbursements – Special Access Schemes

The distribution of SCENESSE® under Special Access Schemes continued to provide a preventative treatment for adult EPP patients, primarily to Switzerland. SCENESSE® was also supplied outside Switzerland to select countries under a special access arrangement whereby CLINUVEL received full cost compensation, linked to the uniform price of SCENESSE® sold in the European Economic Area under the marketing authorisation.

On a constant currency basis, sales reimbursements from special access schemes increased 6.5% for the year. The result was driven by a slight increase in new patients seeking treatment in Switzerland.

Interest Revenue and Other Income

Interest received from funds held in bank accounts and term deposits for FY2022 was $0.444 million compared to $0.342 million for FY2021, a 30% increase to interest revenue.

Cash and cash equivalents increased by 47% over the course of the twelve months to 30 June 2022 reflecting the strong financial performance of the Group. The Group's policy of holding cash reserves in fixed interest bearing term deposits saw an increase of 54% of the average amount of cash held in interest-bearing term deposits. For the majority of the year, the higher cash balances were offset by a lower interest rate yield earned on holding interest bearing term deposits, averaging 13 basis points less year-on-year. Increases to the cash rate from Australian government monetary policy decisions have only taken effect from May 2022. The Group's policy to maintain lower-yielding foreign currencies to cover working capital requirements is reflected in this result, whereby funds held in non-Australian dollar currency providing a natural hedge against downward movement on the Australian dollar. The average amount of funds held in non-Australian dollar currency in FY2022 has remained stable, decreasing 4% on average when compared to FY2021.

The Group recorded other income of $0.217 million in government grants and incentives received in Singapore. Of this, $0.191 million was a grant received the Singapore Economic Development Board under their Research Incentive Scheme for Companies to support the expansion of the Group's RDI Centre. The award is up to S$500,000 over three years. The remainder was part of the Singaporean Government's assistance for local companies to respond to the economic impact of the COVID-19 pandemic.

The presentation currency of the Group is Australian dollars. The Group invoices its commercial sales and special access reimbursement invoices in non-Australian dollar currency. Trade debtors are recognised in non-Australian currency and cash receipts are received in non-Australian dollar currency. Non-Australian dollar currencies are held to meet ongoing working capital requirements which become payable in those currencies. Unrealised adjustments are brought to account to restate trade debtors, trade creditors and foreign currencies held into Australian dollar currency as at 30 June each year.

As a result of the downward movement in the Australian dollar against those currencies the Group has an exposure to over the course of the year to 30 June 2022, the Group recorded a $0.604 million gain (30 June 2021: $1.368 million loss).

Expenditures

In 2021 the Group outlined a growth strategy to expand into four divisions: (a) Pharmaceutical, (b) Healthcare Solutions, (c) Communications, Branding & Marketing, and (d) Manufacturing, supported by the RDI Centre. The expansion of the business into four divisions requires a significant commitment to re-invest in its activities and it is anticipated the Group would spend $175 million over five years to 30 June 2025. The Total Expense result for the Group for FY2022 of $32.667 million is a 44% increase to FY2021's total expense result of $22.738 million and is congruent to this long-term strategy. The two years combined show expenditures of $55.4 million, keeping management well on track to achieve its projected target over five years.

An explanation of the Total Expense result by expense groupings follows.

Clinical & non-Clinical Development

Clinical & non-clinical development expenses reflect the direct investment of the Group in its clinical trial and analytical programs targeting the expanded use of SCENESSE® beyond the field of EPP, along with the paediatric and alternative formulations, including PRÉNUMBRA® and NEURACTHEL®. This category includes analytical testing, pre-clinical and non-clinical activities.

Clinical and non-clinical development fees increased 125% from $0.548 million in FY2021 to $1.233 million in FY2022. The increase reflects the Group's strategy to advance its research and development initiatives, led by the VALLAURIX operations, after a sustained period of focus on the commercialisation activities following European and US regulatory approval in 2014 and 2019, respectively.

This expense result for FY2022 was driven by:

- Development costs incurred towards the new dosage forms;
- Further pre-clinical studies to support the Group's strategic focus to develop new and alternative formulations;
- Progress in the clinical trials forming part of the Group's DNA Repair Program:
  - Clinical trial set up and conduct toward the single-site XP study CUV156:
  - Clinical trial set up and conduct toward the multi-centre-site XP study CUV152:
  - Clinical trial set up and conduct toward the single-site disease-free control study CUV151;
- Statistical management service fees toward the stroke study CUV801; and
- Regulatory-related fees to prepare dossier applications for review in new jurisdictions.

Commercial Distribution

Commercial distribution expenditures ensure our product is provided to end users under Good Distribution Practice and to satisfy our risk management commitments with regulatory agencies. As well as freighting and general distribution, these activities include pharmacovigilance, quality systems, safety reporting, PASS Registry data capture and dossier updates.

There was a modest 3% increase to Commercial distribution expenditures in FY2022, from $2.421 million in FY2021 to $2.494 million, noting:

- Less external assistance was required to support pricing, market access, pharmacovigilance and other post-marketing regulatory affairs activities;
- Reduced regulatory interaction connected to dossier changes, offset by;
- Improved efficiencies in the freight, product handling and distribution of product in the US as part of the contracting in of a new distribution centre in the prior year, despite higher transportation volumes;
- Higher manufacturing royalty expenses from increased more product volume; and
- Increased expenditures towards data collection, handling and processing of information generated from the post-authorisation safety study in Europe which forms a critical role in the risk management commitments agreed with the European Medicines Agency.

Materials Expense

Materials and related expenses primarily reflect purchases to support the acquisition of materials used in the production of finished product by the Group's contract manufacturer, along with other materials purchases connected to the various product development and formulation programs.

The Group continues to prepare for future sales growth and also to manufacture new products and formulations from testing and prototype stage through to a final dosage form. The Group engaged its contract manufacturer during the reporting period to undertake a number of batch manufacturing campaigns to meet longer term commercial demand, as well as to meet the clinical supply needs of those clinical trials which commenced in FY2022 as part of the expanded R&D program. Materials, supplies and related conversion expenses were incurred as part of the expanded formulation development program in the Pharmaceutical Division, targeting NEURACTHEL® and PRÈNUMBRA® Instant. Materials and related expenses also included purchases towards the development and initial manufacture of the first products by the Healthcare Solutions Division, with the first of these products expected to be launched in FY2023.

Expenditures on essential materials increased 48%, from $3.650 million in FY2021 to $5.402 million in FY2022. The increase reflects both an increase in both the volume and cost of materials required to support manufacture to meet product requirements.

Communication, Branding and Marketing

Communication, Branding and Marketing fees decreased 7% to $0.292 million for FY2022 (FY2021: $0.314 million).

The Group has invested in resources to expand its visibility and to engage with new audiences. It has established a team of professionals experienced in, and capable of, expanding the Company's reach using various media tools and channels to prepare for new product launches whilst communicating the CLINUVEL corporate brand. During the year work continued to create a brand presence through digital and other channels. Some functions where outside assistance was previously sought were brought in-house such as development, design and maintenance of websites. The reduction in these fees were offset by fees towards market research, publication support and roadshow presentation activities.

Legal, Insurance and IP

Legal, insurance and IP-related fees increased 5% from $1.095 million in FY2021 to $1.147 million in FY2022.

Expenditures towards external legal support, patent & trademark expenses and various insurances play an extremely important role in the Group's risk management framework. It contributes towards protecting the Group's most important assets from many forms of loss and affords a competitive advantage in the market.

This expense result was driven by increases to essential annual insurances triggered by the revenue growth within the Group's commercial operations. Overall IP, trademark and general legal fees was stable year-on-year. Third party legal assistance was received on a range of matters including the Group's responses to various pricing negotiations in Europe.

Personnel

People and Environment is one of the Group's five principal values, central to all of the Group's working practices. The Group aspires to create an environment where our people able to develop and excel in their careers and in turn, drive the growth and expansion strategy of the business.

The personnel expense result for FY2022 was $11.591 million, a 14% increase from FY2021 of $10.158 million.

In FY2022 we expanded the size of our international teams amid an increasingly competitive global employment market, with an emphasis on growing personnel resources within the Communications, Branding and Marketing Division. Increased costs to source new hires more than doubled recruitment fees and this contributed to a personnel-related expense result which saw a total average headcount increase of 13% between the two reporting periods. In FY2022, the Group implemented a structured benefits program for its global workforce, aiming to promote market competitiveness and to encourage a positive working environment.

Share Based Payment

The non-cash share-based payment charge increased 135% from $2.602 million in FY2021 to $6.121 million in FY2022. This is a non-cash accounting charge for share-based payments provided to the Managing Director and other staff and are typically valued at the time of grant. For those share-based payments affecting the reporting period attached to the prior grant of performance rights to the Managing Director, their value at grant date was between $10.86 and $26.87 per performance right.

During FY2022, the Group issued 743,174 unlisted performance rights to staff of the CLINUVEL group of companies (their value at grant date between $18.73 and $26.22 per performance right) and the increase in the accounting charge for share-based payments reflects the recent issue of performance rights. These unlisted performance rights have an expiry date of 20 November 2023 and each staff member who has been granted performance rights must be employed by CLINUVEL on the expiry date in order to exercise those performance rights, provided the underlying performance condition attached to each right may have otherwise been met. A further 22,500 unlisted performance rights were issued to staff in May 2022.

As at 30 June 2022, of the 1,513,750 granted to the Managing Director at the 2019 AGM, 1,313,000 performance rights, or 87% of the amount granted have not yet met their underlying performance condition.

Finance, Corporate and General

Finance, corporate and general costs are reflective of the support function necessary to ensure the execution of the Company's demanding near-term and long-term expansion strategy. The Group operates in seven different locations, with a workforce across four different continents who require the infrastructure and support to execute their important functions. Examples of expenditures include IT, corporate support, listing and registry fees, travel and short-term rents.

Expenditures from finance, corporate and general activities increased 41% from $1.618 million in FY2021 to $2.274 million in FY2022. Factors contributing to this expense result include:

- The lifting of travel restrictions in COVID-19 affected countries saw a return to local and international staff travel where active in-person engagement with various stakeholders resumed. This activity contributed to over half of the 40% increase in this expense result;
- An increase in professional services fees, reflecting the need for specialist services to support the company's growth as it expands and the complexity of the Company increases; and
- Expanded short-term office space to accommodate increasing staff numbers.

Depreciation and Amortisation

Depreciation and amortisation decreased 12% by $0.104 million, from $0.861 million in FY2021 to $0.758 million. The decrease is attributable to fixed assets deployed within the RDI Centre in Singapore whose value is consumed over time at a diminishing rate.

Changes in Inventories of Raw Materials, Work in Progress and Finished Goods

Changes in inventories of raw materials, work in progress and finished goods represents the adjustment to inventory acquisition expenditures in excess of adjustments to inventory from commercial sales. For FY2022, a net adjustment of $1.355 million was recorded to account for a reduction in the value of inventory held since 30 June 2021. For FY2021, the result was a $1.899 million gain in the expense result, reflecting an increase to the value of inventory held.

Income Tax and Deferred Tax Asset

FY2022 marks the sixth consecutive year of the Company yielding a before-tax profit. Notably, after utilisation of available carry forward tax losses, the Company incurred a current tax expense of $7.368 million on FY2022 taxable income.

In FY2020, the Group brought to account a deferred tax asset (DTA) relating to previously unrecognised prior period tax losses, resulting in a credit to income tax benefit of $3.510 million. In FY2021, the Group utilised carry forward tax losses in the DTA, resulting in a debit to income tax expense of $0.984 million. In FY2022, the Group utilised further carry forward tax losses in the DTA, resulting in a debit to income tax expense of $6.075 million and the recognition of a deferred tax liability (DTL).

The reduction in the DTA account reflects:

- the benefit received from utilising unused tax losses;
- increases in temporary differences primarily related to exchange rate movements that result in increases to deferred tax liability for the business; partly offset by
- the expected utilisation of unused tax losses against probable near term taxable profits for subsidiaries recording positive earnings.

Further information on the income tax expense and movements on net deferred tax assets and liabilities are detailed in Note 3.

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,

a) the performance of the business, and

b) 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 FY2022 was $20.878 million, down 16% from FY2021 The Group's adjusted net profit after tax for FY2022 was $27.859 million, compared to $27.948 million for FY2021, a 0.3% decrease. 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 2022		30 June 2021	
	Statutory	Non-IFRS	Statutory	Non-IFRS
	$	$	$	$
Total Revenues	65,722,292	65,722,292	47,975,583	47,975,583
Total Interest Income	444,071	444,071	342,203	342,203
Total Other Income	821,152	821,152	132,813	132,813
Total Revenue, Interest Income and Other Income	**66,987,515**	**66,987,515**	**48,450,599**	**48,450,599**
Adjust for:				
Unrealised gain on restating foreign currency balances and currencies held		(604,317)		0
Adjusted Total Revenue, Interest Income and Other Income		66,383,197		48,450,599
Total Expenses	**32,666,600**	**32,666,600**	**22,737,955**	**22,737,955**
Adjust for:				
Share-based payments		(6,120,977)		(2,602,393)
Unrealised loss on restating foreign currency balances and currencies held		0		(1,368,369)
Adjusted Expenses		26,545,623		18,767,193
Net Profit before Tax	**34,320,915**		**25,712,644**	
Adjusted Net Profit before Tax		39,837,574		29,683,406
Income Tax	13,442,450	13,442,450	984,397	984,397
Adjust for:				
tax on above adjustments		(179,454)		182,324
tax on Unrealised gains/losses including loans to subsidiaries		(1,284,691)		569,002
Net Profit after Tax	**20,878,465**		**24,728,247**	
Adjusted Net Profit after tax		27,859,269		27,947,683

Balance Sheet

One of the key objectives of the Company is to ensure its Balance Sheet is sufficiently robust and positioned to allow investment in future assets, with a financial buffer to withstand unexpected adverse events. The Company has continued to preserve cash and cash equivalents held, without needing to raise capital, and without diminishing shareholder returns, nor has it raised debt capital and increased the debt leverage of the Group.

The cash position has enabled the Group to meet anticipated increases to short term liabilities in support of the business growth, and navigate adverse economic conditions, as seen the past two years. The financial management remains part of a deliberate and planned strategy, reflecting CLINUVEL's approach to risk management. The strong balance sheet enables the Company to consider and execute on any opportunities presented to expand the business through acquisitions

Key Balance Sheet Highlights of the Year

The positive cash flows generated by the Company's commercial distribution programs drove the key changes to the balance sheet, increasing cash reserves by 47% from $82.691 million in FY2021 to $121.509 million in FY2022.

Trade and other receivables rose by 0.7% from $16.089 million in FY2021 to $16.202 million in FY2022. This modest increase compared to the increase of 143% in FY2021 reflects more prompt payment by US Specialty Centers during the year as they have become more experienced with the administrative processes for reimbursement of treatment which is also facilitated by use of new drug and treatment codes.

Total Assets increased 33% from $108.568 million to $143.950 million.

Total liabilities increased 87%, from $9.830 million to $18.390 million. Trade payables including income tax payables increased 122%. The Company has utilised unused tax losses during the year which were available and recognised, resulting in a tax payable on current year earnings.

The Company continues to hold no long-term debt. The ratio of the Company's overall debt to equity is 14% (FY2021: 10%).

Total Equity increased 27% during the year, largely due to the impact of the positive net profit on Accumulated Losses.

Returns on Equity

	FY2022	FY2021	FY2020 Restated	FY2019	FY2018	FY2017
Profit attributable to owners of parent (A$m)	$20.878	$24.728	$15.051*	$18.134	$13.224	$7.180
Basic EPS	42.3 cents	50.0 cents	30.6 cents*	37.6 cents	27.7 cents	14.9 cents
Dividends Paid in Year (A$m)	$1.235	$1.235	$1.224	$0.957	-	-
Dividends per Share Declared	4.0 cents	2.5 cents	2.5 cents	2.5 cents	2.0 cents	-
Change in Share Price YoY	(52%)	20%	(24%)	206%	58%	62%
Return on Equity	17%	25%	21%*	32%	34%	28%

Investments for Future Performance

The Group's key objectives are to progress CLINUVEL as a world leader in medicinal photoprotection and repigmentation and to support the expansion into other, similar genetic, metabolic and severe disorders, such as acute vascular anomalies. In addition to the ongoing development of its active and expanded product pipeline, the Group is actively considering the integration of new functions and capabilities through one or more selective acquisitions.

The Group has deployed working capital throughout the year to prepare for future performance across the following areas:

People	Created new roles across all management levels and business functions Continued to attract talented staff to fill positions Attract and mentor senior management as part of succession planning
Research & Development	Maintained operations of the Singapore RDI Centre (opened August 2020) Non-solid dosage formulation development Non-clinical development
Clinical	Expanded program progressed with new clinical studies to pursue potential new markets for SCENESSE® and its derivatives in: • Vitiligo • DNA Repair, focussed on XP • Acute Stroke (AIS) • Other indication(s) to be announced
Manufacturing	Program to manufacture raw material peptide via a process change to support future scale-up Management of product inventory levels to meet expected commercial and clinical demand
IP	Continued to renew and maintain existing and new patents to strengthen the Company's intellectual property position

Capital Structure

The Group is debt-free and has a consistent capital structure of ordinary shares on issue plus unlisted securities in the form of conditional performance rights, which will vest on certain performance and/or time-based conditions being met.

CLINUVEL's outstanding shares on issue remained at 49,410,338 shares to 30 June 2022. There was no issue of new shares through the exercise of performance rights under the Group's performance rights plans or from capital raising.

Dividends Paid or Recommended

Declared & paid in 2020/21	Cents per Share	Amount	Date of Payment
Final	2.50	$1,235,266	17 September 2021

On 29 August 2022, the Board of Directors declared a fully-franked dividend of $0.04 per ordinary share in relation to the full year ended 30 June 2022.

Cash from Operations and Other Sources of Cash

Overall, the Company generated cash from its operating activities by $39.872 million in FY2022 (FY2021: $19.262 million).

Cash inflows from customer receipts increased 71% to $66.400 million in FY2022, compared to $38.724 million for FY2021.

Cash outflows for payments to suppliers and employees increased by 37%, from $20.032 million to $27.352 million.

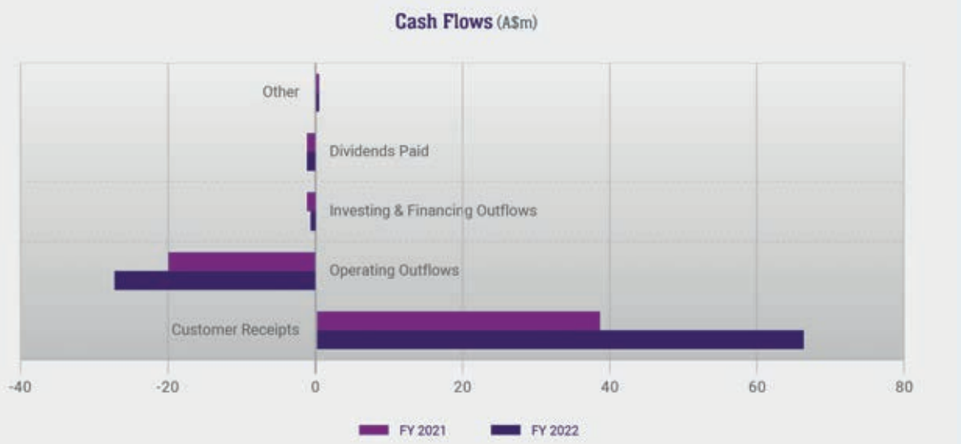
There were also cash outflows of $0.434 million for the acquisition of property, plant and equipment, $0.268 million of repayment of borrowing and leasing liabilities, and $1.235 million for the payment of an unfranked dividend to shareholders in relation to FY2022.

The Groups' policy towards cash management is to:

- Hold cash in at-call bank accounts and place additional cash in short-term term deposits providing favourable rates of interest; and
- Actively manage foreign currency exposure, taking account of recent and expected currency trends, holding foreign currencies as a natural hedge, using market orders, foreign exchange forward contracts and other foreign exchange risk management products, as considered appropriate.

The Group's financial liquidity as at 30 June 2022 is reflected in:

- A quick ratio of 10:1 (30 June 2021 11:1); and
- Cash and cash equivalents of $121.509 million, accounting for 86.4% of total current assets (FY2021: $82.691 million, 88.8% of total current assets).



Material Business Risks

The following specific business risks are reviewed periodically by the Board and management, as these have the potential to affect the Group's achievement of the business goals detailed above. This list is not exhaustive.

Technology	Despite obtaining marketing authorisations, those products may ultimately prove not to be safe and/or of clinical or other benefit.
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.
Clinical & Regulatory	Clinical trials may not yield the expected and desired results for the investigational medicinal product(s) to obtain further regulatory approvals.
Drug Pricing	Third-party payors may not provide insurance coverage or will not be willing to accept the prices agreed with other third-party payors, adversely affecting revenues and profitability. Furthermore, reductions in government insurance programs may result in lower prices for our products and could materially adversely affect our ability to operate profitably.
Intellectual Property	Future sales could be impacted to the extent that there is not sufficiently robust patent protection across the Group's product portfolio that will prevent competitors from entering the marketplace to compete with 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.
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 a state of consistent positive cash flow is dependent on its ability to maintain a revenue stream and to access sources of funding while containing its expenditures.
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.
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.

Impact of the COVID-19 Pandemic on CLINUVEL's Business

The coronavirus pandemic continues to adversely impact both people's health and global economic activity. Many countries have made progress to achieve high levels of vaccination of the populations to provide ongoing protection from the variants of the virus and enable free mobility and less restriction on movement. However, the impact and consequences on how we live, work, and interact will be felt for years.

CLINUVEL is no exception to being impacted by the coronavirus pandemic. However, CLINUVEL's business has proven resilient and is relatively well positioned to manage the difficult operating environment and progress its strategic initiatives.

Demand for SCENESSE®

Access for patients seeking treatment in hospitals was affected during the initial months of the pandemic when population lockdowns across Europe were first instituted in the latter months of FY2020. EPP Expert Centres either deferred orders or reduced order sizes in the initial months of the COVID-19 infections, because they were unable to provide treatment access to patients. Notwithstanding the uncertainty surrounding the pandemic, patient demand for SCENESSE® in Europe remained strong, with existing patients continuing to seek treatment and new patients receiving therapy for the first time. CLINUVEL is conscious of the patient community it serves, as well as the anxiety and uncertainty they faced during the COVID-19 pandemic, and therefore has worked conscientiously to continue to meet demand for SCENESSE®.

Research and Development

CLINUVEL's research and development program continued to progress in FY2022. The operations of the laboratory facilities in Singapore were restricted during the circuit-breaker period which overlapped FY2020 to FY2021, with some remote working required. The circuit-breaker also resulted in minor delays to the laboratory expansion project, which was completed in August 2020.

In the context of CLINUVEL's expanded clinical program, we have managed to commence clinical studies at a time when the expert centres and their physicians have a natural concern with the potential disruption to clinical studies caused by the coronavirus. The concern, shared by CLINUVEL, is that repetitive outbreaks and new strains could cause either capacity constraints disrupting clinical studies and/or restrictions on movements of patients. Time and effort were spent to monitor conditions and liaise with all parties involved to commence new clinical studies in FY2022.

Supply of SCENESSE®

The sourcing, manufacturing, and controlled distribution of SCENESSE® has continued without material disruption or delay due to the COVID-19 pandemic. Raw material sourcing, manufacturing activities and movement of goods were able to be conducted without materially adversely impacting timeframes. CLINUVEL continuously reviews its operations to assess ongoing supply of SCENESSE® which may be impacted by COVID-19.

CLINUVEL's People

CLINUVEL has played a responsible role to assist a global effort to manage the spread of the virus. At the height of the pandemic, CLINUVEL personnel adapted to work largely remotely, attending the office only as necessary and when permitted under government regulations. Video-based technology has been maximised, particularly during peak periods of the virus, when local and international travel was restricted.

During FY2022, increased vaccination rates provided greater protection, as we saw restrictions on movement gradually being relaxed. As a result, CLINUVEL personnel resumed responsible face-to-face interaction with stakeholders, and now operates on the basis of two to three days working in the office per week, noting that laboratory staff in the Singapore RDI Centre generally work five days a week. The safety and well-being of our people is of paramount importance to the Group and our practices are under constant review in relation to developments in local healthcare, and each of the jurisdictions we operate in. Diligence and adaptation under a difficult operating environment by the entire CLINUVEL team has seen productivity and focus remain largely unaffected.

Changes in The State of Affairs

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

Significant Events after the Reporting Date

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

- On 29 August 2022, the Board of Directors declared a franked dividend of $0.04 per ordinary share.

Likely Developments and Expected Results

The Group launched SCENESSE® in Europe in June 2016. As part of the conditions attached to the European marketing authorisation, the Group operates an agreed long-term risk management plan under the supervision of the EMA. The Group has been assisted by third parties to support the European EPP Disease Registry to monitor long-term safety and it will continue to invest in existing and new personnel with the appropriate skills and expertise to maintain the ongoing requirements of the post-authorisation program in Europe. The ongoing requirements will remain in place until such time the EMA decides these are no longer necessary.

The Group has established a reference price for SCENESSE® as part of its uniform pricing strategy in Europe and has entered into pricing agreements with several European countries, and state and private insurance groups. The Group has established a distribution-focused workforce in Europe to support the increase in product volumes and will continue to increase staff numbers to respond to newly trained and accredited treatment centres to treat new patients, when pricing agreements per country are established with payors, and as the required pharmacovigilance activities continue to expand.

The Group continues to focus on ongoing drug manufacturing requirements by working with its contract manufacturer and raw material suppliers to meet commercial product supply in line with its timing expectations and to pursue ongoing process improvement initiatives to support future increases in supply. These initiatives are part of continuous process improvement and will form part of the Group's expenditure base moving forward. The contract manufacturer bare responsibility for the manufacturing standards of the commercial drug product along with timely supply. The Group announced in March 2021 it will establish a Manufacturing Division where it will manufacture own products to reduce external dependencies and evolve into a contract manufacturer for other pharmaceutical companies and research groups.

SCENESSE® was launched in the US in April 2020. The Group is focussed on expanding agreements on reimbursement of SCENESSE® with both state and private insurers to make SCENESSE® available to all US patients seeking treatment. The Group will continue to increase its resources and activities to support to progress of its entry to the US market which includes operating a risk management plan, similar to what has been instituted in Europe.

The Group will continue to pursue a research and development program to investigate expanding the use of SCENESSE® and other drug formulations based on the melanocortin family of hormones in other indications where there is an unmet clinical need. The Group will continue its North American clinical program to evaluate the effectiveness of its lead product to activate repigmentation of vitiliginous lesions (depigmented skin areas) in patients with vitiligo. This program includes advancing through phases of clinical studies to demonstrate the efficacy and long-term safety of SCENESSE® in the treatment of vitiligo.

The Group also intends to further progress its clinical program with SCENESSE® in other indications, such as in DNA Repair with a focus on treating patients with XP, in AIS, in VP, and in other yet to be disclosed indications. To support this likely development, CLINUVEL is advancing PRÉNUMBRA®, a non-solid dosage form of afamelanotide as a potent haemodynamic, vasoactive, and anti-oncotic therapeutic agent, initially in adult patients. The first clinical use of PRÉNUMBRA® is planned for the next study in AIS, expected to commence in the second half of 2022.

The Group expects to advance its product pipeline, progressing the development of the molecules CUV9900 and VLRX001 through the various development phases which may include formulation development, non-clinical and human testing. In addition, complementary OTC products are being developed and manufactured for distribution to targeted audiences at the highest risk of exposure to UV and HEV light. The Group has increased its resources and expanded its capabilities to progress these projects underway at VALLAURIX.

In November 2021, the Group announced that adrenocorticotropic hormone (ACTH) would be added to the melanocortin drug portfolio under the tradename, NEURACTHEL®, in Instant and Modified-release formulations, for patients with neurological, endocrinological, and degenerative disorders. Since then, the drug substance has been manufactured by a strategic partner under current Good Manufacturing Practice and product development and validation work is progressing.

Ultimately, the long-term financial objective of the Group is to build a sustainable commercial enterprise serving the needs of unattended populations. Key to longer-term profitability is not only continuing the successful research and development of its portfolio of assets but also their successful commercialisation, manufacturing and distribution, and the ability to attract additional funding to support these activities should the need arise.

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.

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 2022.

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	Since 4 April 2022
Executive KMP		
Dr. P. J. Wolgen	Managing Director and Chief Executive Officer	Full Year
Dr. D. J. Wright	Chief Scientific Officer	Full Year
Mr. D. M. Keamy	Chief Financial Officer and Company Secretary	Full Year

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

A. Introduction by the Chair of the Remuneration Committee

Chairman of the Remuneration Committee

Mr Willem Blijdorp

Dear Shareholder,

On behalf of the Remuneration Committee (Committee), I am pleased to present to you our Remuneration Report for the year ended 30 June 2022 (FY2022). The FY2022 Remuneration Report details our remuneration policy for our Executive KMP and Directors and explains how FY2022 remuneration outcomes for Executive KMP align with CLINUVEL's performance, long-term objectives, and shareholder outcomes.

The past year

First, in providing background to CLINUVEL'S performance, I'll share some reflections on the past year. The challenges of the operating environment increased in FY2022 due to heighted macroeconomic and geopolitical tensions. The impact of COVID-19 on life sciences has been sufficiently reported, the consequences of Russia's unwarranted invasion of Ukraine is now being felt, as global suppliers are rapidly increasing their prices. We now know that these events have exacerbated worldwide inflation. The consequent higher interest rates have added to overall uncertainty which regrettably, is expected to continue. The outlook is for lower economic growth, potential recession, and I note that the International Monetary Fund considers the risks are weighted more to the downside than the upside.

As in past years, FY2022 demonstrates again the tenacity of CLINUVEL's team and the viability of the commercial operations established in the distribution of SCENESSE®. We view the sixth consecutive year of profitability, ongoing growth in revenues and moderated growth in expenses supporting the expanding activities of the Group, as an outstanding achievement. The self-sufficiency we have achieved to finance our clinical program is a definite advantage of our strategy compared to other companies, which are distracted from their objectives to look for finance in need to survive. We are in a strong financial position to continue our clinical program and launch non-pharmaceutical products. Together these two directions will transform the Group into a diversified and sustainable specialised pharmaceutical. As a Board we take the view that this takes time, like all pharmaceutical and new developments.

I look back on some specific financial outcomes for the year:

- Total Revenues – up 37% to A$65.7 million;
- NPAT – down 16% to A$20.9 million, compared to A$24.7 million in FY2021. This is the sixth consecutive year of NPAT;
- NPBT – up 33% to A$34.3 million and compared to A$25.7 million in FY2021;
- Dividend – declared for the fifth consecutive year at A$0.04 per share in relation to FY2022 earnings;
- EPS of A$0.42 compared to A$0.50 in FY2021;
- ROE of 17% compared to 25% in FY2021; and in addition to these financial metrics,
- Positive progress in product development and clinical programs.

As the entire sector saw a strong correction in shareholder returns, as measured by the 30 June share price, have been negative over the last year. Taking a perspective over the past five years, CLINUVEL compares well to other companies and life-science key indices. CLINUVEL's share price change over the five years to 30 June 2022 was 113.6% compared to a range of -3.2% to 19.9% in key US life-science indices and to 64% in the S&P/ASX 200 Healthcare Index.

Remuneration outcomes

The continued commercial performance of the business as well as the strategies followed, defined as business metrics, influences our approach to executive remuneration in the face of a significant decline in the share price. Over the past year biotech companies around the world have experienced significant declines in their share prices and CLINUVEL has not been immune to this.

However, we take into account all circumstances in evaluating CLINUVEL's executives, and we place appropriate weight on their work to

1) build a strong foundation while managing uncertain economic environments,

2) progress growth and expansion plans, and

3) strive for commercial progress.

We all benefit and recognise the strong financial position of the Company that enables us to endure the current economic turbulence. The Board appreciates that the chosen strategy is a key factor which facilitates the ongoing progress towards the achievement of our long-term objectives.

Another key factor in assessing key executives is their ability to develop people within the organisation. We place much value in building an organization that cares about its people, and help them develop a career in the sector. As Chairman, I recognise the efforts made by the executives, whereas we also see the results of the programs in place for managers, executives.

The Executive team has completed another creditable year in terms of financial performance, risk management, distribution to patients in need, progress of clinical programs, and the development of new products to the benefit of new populations, but most importantly, patients.

I also see some points where the executive team can improve, speed of execution to drive projects forward ensuring that all managers deliver, filling the pipeline with even greater number of potential products. However, in general and under global circumstances, my colleagues on the Board and I are of the opinion that we could not have asked more from the executive team.

As an international company with operations in several countries around the world, we seek to attract and retain talented people in an increasingly competitive labour market. Not only must we offer attractive remuneration packages, we also need to offer a career path, and a work-life balance. But we see that the teams managed to recruit new specialists, pharmacists, an MD, personnel for scientific development and financial specialists. It is in all our interests to continue this path, such that people across all three management layers become a recognisable asset.

One incentive allowing CLINUVEL to offer the right people is an equity-based remuneration. This is part of a remuneration framework, not only for key executives, but for the next generation of executives across the management structure. The Board wishes to continue incentivising those staff members who have shown to be integral to CLINUVEL achieving its future goals.

As an example, in retaining talented professionals who have contributed to the recent success of the Company and to preserve the level of know-how accumulated across our workforce, the Board agreed to issue a total of 765,674 performance rights over the past year. The performance rights are not entitlements, but an incentive to achieve predetermined milestones. In the past year, 26% of staff were awarded these incentives. We introduced a long time ago an entrepreneurial mindset and culture, in which all staff are encouraged to think and act as business owners striving for successful outcomes. The performance conditions attached to the issue of performance rights reflects a blend of conditions which are set across all employees of the company and also giving the flexibility to be tailored to the employee's role and responsibilities. This approach has led to value generation for shareholders.

As announced during the past financial year, the Managing Director and Chief Financial Officer agreed to extend their employment agreements for a further three years to 30 June 2025 and two years to 30 June 2024, respectively. In doing so, we considered feedback received from shareholders and advisors and acted concertedly to simplify the executive agreements to the extent that the long-term retention awards were removed from the executive agreements. In the case of the Managing Director, we additionally removed Business Generation incentives. This ensures a framework where long-term incentives are limited to equity remuneration and not a mix of cash and equity. The CEO's fixed pay was maintained at the same level (CPI adjustments notwithstanding).

In reference to FY2022 for the Managing Director, the Board determined to award a short-term incentive (STI) of 42.5% of the maximum opportunity of 100%. In FY2021, the award was 70%, but capped at 53%. In the previous year, FY2020, the award of 70% was waived by the Managing Director out of affinity with those affected by the COVID-19 pandemic to see the funds deployed on the Company's initiatives for the long-term benefit of patients in need of treatment.

To give context to the performance rights awarded to the Managing Director in 2020, and vesting period terminating by November 2023, modest progress has been made towards the very challenging performance conditions. On 30 June 2022, only 13% of the underlying performance conditions attached to the 1,513,750 shares had been achieved.

We simplified the Executive employment agreements by removing most of the long-term cash incentives. On the other hand, we are conscious that the overall package of our executives may no longer be in keeping with international benchmarks when the LIT's reach their end dates. The Remuneration Committee and Board will reassess our executive package offered in the first half of 2023, as the current performance rights plan nears expiry. Thus far, we get positive feedback from the proxy advisors for having harmonised Executive and senior management contracts and they have noted our concerns on being able to remain competitive.

Shareholder engagement

I am pleased to have seen greater engagement with shareholders over the past year through our frequent and diverse communication channels, direct meetings. Interactions with new shareholder groups, Australian but also American institutional investors provide clear feedback on the impression of the Company. Proxy advisors provide commentary not only on executive remuneration, but also on our approach and policies, and governance. All in all, the changes we have seen to remuneration reports, explanations, standards and governance are well received.

In conclusion, I see a clear and challenging path forward for the Company. I also see many struggling companies, those in constant need of cash and those with an uncertain future ahead. On behalf of the Board, I state my gratitude for another terrific year, and we have much respect for the work our team and executives are doing to bring this company forward. I have no doubt that we will face more difficulties ahead, we would not want to see other crew leading the times ahead.

I wish to thank you all for your feedback and encourage you to maintain active engagement with us as we will with you.

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 appropriate remuneration 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 non-executive director fees and advice on setting salaries and fees, short- and long-term incentives and employment terms and conditions for its key executives.

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 and risks.
- The level and composition of remuneration attract, retain and motivate people 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 advisors. To ensure that any recommendations made by remuneration consultants are provided without undue influence being exerted by Executives, external remuneration consultants deliver their advice directly to members of the Committee.

In the year ended 30 June 2022, the Remuneration Committee engaged the services of remuneration advisors to provide comparable peer company market data. No remuneration recommendations as defined by the Corporations Act were received from external consultants during the financial year.

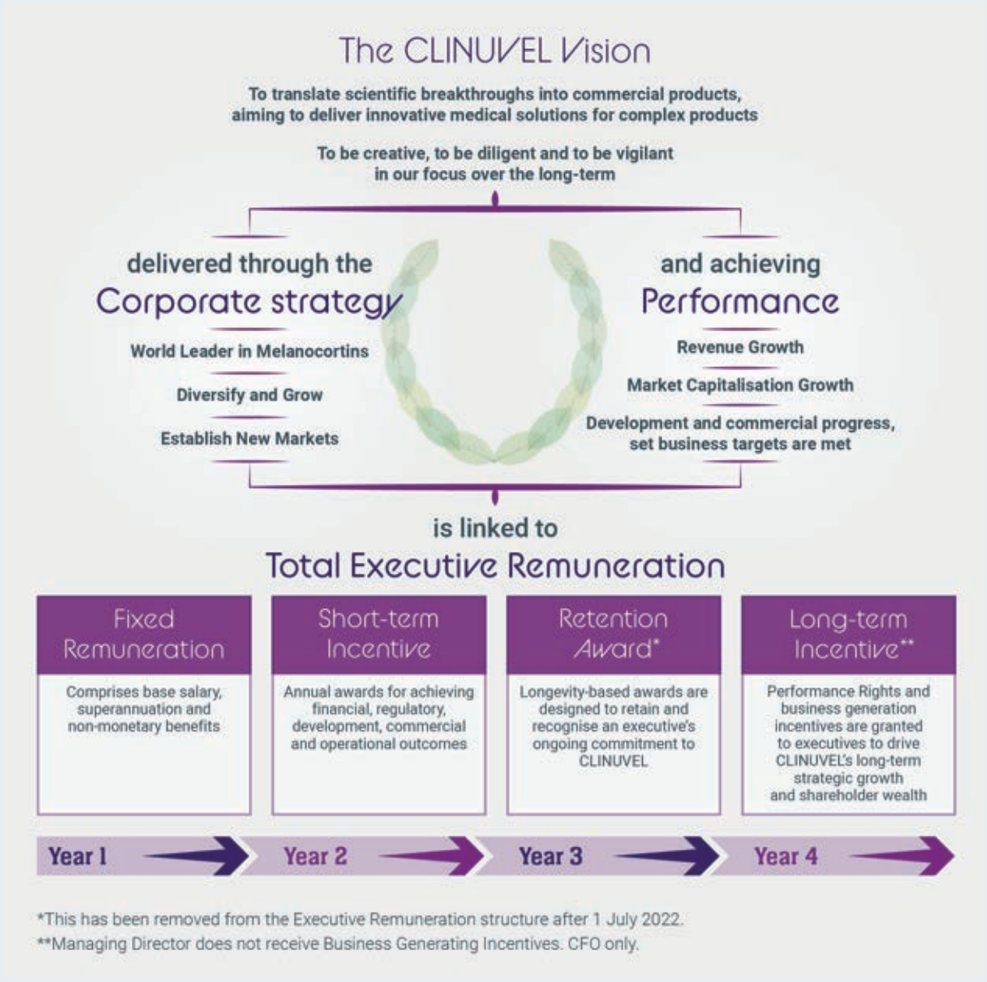
(iii) Voting and feedback at the Company's last Annual General Meeting

In the 2021 Annual General Meeting (AGM), the Company obtained 79.02% of the proxy votes (including votes at the proxy's discretion) in favour of adopting the 2020/21 Remuneration Report, and this resolution was carried in favour by poll with 78.02% of votes cast. Aside from general questions on market and non-market performance conditions attached to issued performance rights, 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 pay and variable pay. The variable pay is structured to incentivise:

- Short-term (generally payments in the form of performance-based incentives awarded at a fixed amount or as a percentage of base salary).
- Long-term (generally based upon the issue of performance rights to acquire shares in the Company, and in relation to the Managing Director and to the Chief Financial Officer and only up to 1 July 2022, other fixed amount cash incentives, including retention awards to recognise ongoing commitment to the Company).

(v) Executive Remuneration Structure 2021-22

1. Fixed Base Remuneration Salary and Non-Monetary Benefits

Fixed base remuneration (FBR) comprises base salary, superannuation and 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 regularly tested for market competitiveness by reference to appropriate benchmarks sourced externally 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 and approved by the Remuneration Committee.

2. Short-Term Incentive

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 shareholder value.

Details of the STI arrangements are as follows:

	Managing Director	Other 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: 17% 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	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.	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 94 to 96.	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 94 to 96.

For the year ended 30 June 2022, the Remuneration Committee assessed the Managing Director's performance targets which form his Short-Term Incentive and awarded a 42.50% assessment against the targets.

For the year ended 30 June 2022 the Managing Director assessed overall performance for the 2021/22 year against the Short-Term Incentives and recommended to the Remuneration Committee and who approved the following assessments against the maximum Short-Term Incentives:

Chief Scientific Officer – 100%

Chief Financial Officer – 82%

3. Long-Term Retention Award –Removed from Executive Remuneration Structure in 2022/23

Longevity-based awards are remuneration payments to encourage key management retention in an increasingly competitive global talent pool and to recognise an ongoing commitment to the Company.

In 2019/20 the Managing Director and Chief Financial Officer entered into new service agreements with the Company which included longevity-based award payments as part of overall remuneration. The executives are entitled to receive the following payments for each full month of service to CLINUVEL and its subsidiaries since their original employment start in November 2005.

Managing Director – €5,025 (Long Term Retention Award has ceased as of 1 July 2022)

Chief Financial Officer – A$1,000 (Long Term Retention Award has ceased as of 1 July 2022)

The longevity-based awards were at risk of forfeiture for the first 12 months following the 1 July 2019 Effective Date if the executives had provided a notice of termination during this period. The longevity-based award shall be paid to the executives no less than 36 months following the 1 July 2019 Effective Date of the service agreement.

The Remuneration Committee considered feedback received on Long-Term Retention Awards after receiving a 'first strike' on the remuneration resolution at the 2020 Annual General Meeting. In renewing the service agreements with the Managing Director and the Chief Financial Officer, from 1 July 2022 these awards have been removed from their respective remuneration packages.

4. Long Term Incentives

a) Equity - Performance Rights

Performance Rights, being an option to acquire ordinary shares of CLINUVEL PHARMACEUTICALS LTD for nil exercise price, are offered to Executive KMP and to staff from time to time to:

- retain and motivate staff and Executive KMP to drive the long-term growth and success of the Company;
- to align their interests with increased shareholder wealth over the longer term.

Unlike other equity remuneration plans internationally, performance rights are **not granted to Executives annually**.

Historically, by virtue of the nature of the Company being primarily focussed on business expansion through ongoing research and development, the Performance Conditions attached to Performance Rights have been based on a mix of financial and commercial objectives and non-financial operational targets strongly linked to shareholder value, such as enterprise value and revenue growth.

The Remuneration Committee assesses and recommends to the Board the quantum of Performance Rights amounts based on:

- length of time served prior to issue of Performance Rights;
- weighted average share price levels at time of issue;
- responsibility levels within the Group;
- current base pay including variable short-term incentive levels;
- industry trends;
- impact on share dilution; and
- nature of vesting (time and/or performance) conditions attached to the issue of Performance Rights.

Performance Rights have vesting periods either up to nearly three years, four years, or undated in duration whereby when the performance conditions are not met by the vesting date, the Performance Rights will lapse. Performance Rights will generally only vest if the Executive remains in employment within the CLINUVEL group of entities at the time of vesting.

The Performance Rights for the key Executives have a vesting end date of 20 November 2023.

The achievement of the Performance Condition is assessed and approved by the Board when it is considered satisfied, or the condition has otherwise been waived by the Board.

Prior to 2020/21, the Performance Rights were exercised into new Shares and are acquired by a Plan Trustee and then, from time to time, transferred to the beneficiary, but generally only when the beneficiary ceases employment (or Directorship). 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. For current and future issues of Performance Rights, it is intended for new Shares to be transferred directly to the participant upon successful achievement of time and performance-based vesting conditions.

The Performance Conditions attached to Performance Rights previously issued to Executives (and to Non-Executive Directors in previous years) issued and unvested at any time during 2021/22 relate to long-term (multi-year) strategic, non-financial objectives and they were chosen because they are considered to be significant for long-term sustainability of the Group and longer-term value creating in nature.

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Managing Director

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 grant. If the Performance Conditions are not achieved by 20 November 2023, they shall be forfeited and will lapse.

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 shareholders. This is currently demonstrated in the number of Performance Rights whose underlying performance conditions have not yet been meet since their date of grant at the 2019 AGM. As at 30 June 2022, of the 1,513,750 granted to the Managing Director at the 2019 AGM, 1,313,000 performance rights, or 87% of the amount granted, have not yet met their underlying performance condition.

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 90 to 91.

Other Executive KMP

For the financial years ended 30 June 2022, the Other Executive KMP were issued 415,688 Performance Rights 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. No Performance Rights were granted to the Other Executive KMP for the financial year ended 30 June 2021. The Other Executive KMP were last issued performance rights in the 2015/16 financial year.

The Performance Conditions attached to these Performance Rights are a mix of the same Performance Conditions attached to Performance Rights granted to the Managing Director at the 2019 AGM, ensuring alignment with the long-term Group strategy, as well as role-specific Performance Conditions that are also linked to building company value and to promoting retention. The mix is comprised as follows:

Other Executive KMP	# Performance Rights	PC1-8	Role Specific PCs
CSO	75,813	69%	31%
CFO	339,875	60%	40%

The rationale behind the issue of the performance rights issued to the Managing Director and Other Executive KMP presented in the "Description of Performance Conditions" are 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

Description of Performance Conditions

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.

The Performance Rights awarded to the Managing Director carry a vesting period of four years (vesting date 20 November 2023), after which all Performance Rights attached to the Performance Conditions not achieved, will expire. As of 30 June 2022, 13% of the Performance Rights awarded to the Managing Director have had their underlying Performance Conditions met.

b) Cash - Business Generation Incentive* and Discretionary Payments

Business Generation Incentives (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 are aimed to:

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

The Remuneration Committee reviews existing BGIs and considers new BGIs each time there is a renewal to a service agreement to ensure these incentives are linked to the Company's longer-term strategies it considers most likely to achieve the best possible outcomes for the Company and its shareholders.

Managing Director: ***The Remuneration Committee considered feedback received on Long-Term Retention Awards after receiving a 'first strike' on the remuneration resolution at the 2020 Annual General Meeting. In renewing the service agreements with the Managing Director, from 1 July 2022 Business Generation Incentives has been removed from the service agreement.***

Other Executives: Upon a change to the Chief Financial Officer's service agreement from 1 July 2019, BGI targets which form part of the overall remuneration package were amended. These longer-term incentives are based on set performance targets which must be achieved before 30 June 2022 and are linked to the Company achieving exceptional business outcomes that contribute to creating corporate value and to act as a key retention tool.

The remaining BGIs for the Chief Financial Officer vary between $30,000 and $60,000 per BGI, linked to:

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

For the 2021/22 financial year, no BGIs were achieved by the Chief Financial Officer.

Discretionary Payment - Managing Director Only: The Managing Director can 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 payment was awarded to the Managing Director for the years ended 30 June 2022 or 30 June 2021.

(vi) Managing Director Remuneration – Further Information

The inherent risk of failure within pharmaceutical development is high and this risk is amplified for the Company due to its 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 the previous managerial attempts to develop a melanocortin for commercial use, and which had posed insurmountable operational, regulatory and financial challenges. To mitigate the risk and to provide a strong platform to achieve meaningful progress, the Board has followed a business model where most operational skills are retained in-house, where possible, and many management responsibilities are concentrated between the Managing Director and the Chief Scientific Officer. 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 drug (including pharmacovigilance and quality management). The Chief Scientific Officer is responsible for pre-clinical programs, toxicology, the manufacturing of the drug delivery program, clinical program 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 new and existing senior management throughout the Group.

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

- a maximum level of incentivisation to lead and advance the Company's program from its current stages of development and commercial growth to serve the long-term interest of the Company, taking into account the unique risk and complexity of the business model; and
- It is competitive in international markets, industry and related fields of expertise and providing for specific skillsets.

In the 2021/22 year 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 local and international peers;
- track record, integrity and professional qualifications to excel in the role;
- the enterprise value created over the past decade and since first employment;
- capability to sustain the Company's focus to maximise profitability following market access; and
- the demonstrated ability to maintain the solidarity of the business and management team over the long term.

(vii) Executive Remuneration – Peer Benchmarking

One of the objectives of the Remuneration Committee's responsibilities is to ensure that the levels and structure of remuneration 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, on 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.

Its remuneration structure requires to be competitive to international benchmarks to attract and retain existing executive talent at the highest management levels. The Board firmly contends it cannot limit its benchmarking and consequent setting of the level and structure of its executive remuneration to local Australian companies only.

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

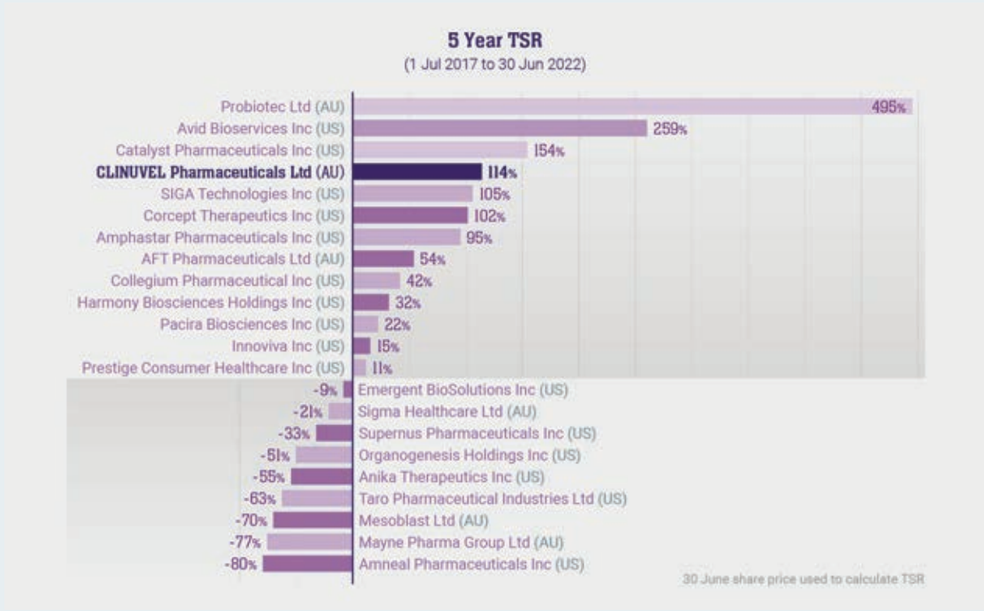
During the year the Managing Director's remuneration was benchmarked against five Australian and 16 US life science peer companies (being a mix of medical device, prescriptive and over-the-counter pharmaceutical product, healthcare solutions and diagnostic focussed companies) using the following criteria:

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

Headline results of the peer analyses concluded that in the past five years, CLINUVEL:

Throughout FY2022 CLINUVEL was trading at significantly higher P/E multiples than all its Australian and the majority of its US peers, indicating shareholder expectation that CLINUVEL will deliver superior growth than its peers, a reflection of shareholders' confidence in management executing on the stated strategy. A decline in the share price was seen as of September 2021 mirroring the decline in the share price of most peer companies, whereas financial performance of the Company increased each quarter.

In comparing FY2022 Managing Director remuneration to the peer group remuneration for FY2021, the fixed base remuneration and short-term remuneration was positioned above the median level, whereas the long-term remuneration level was positioned slightly below the median level. The Board considers the level of fixed base remuneration to be appropriate, considering the long-term outperformance of the Company and the relatively unusual long-term tenure of the Managing Director who has led the restructure of the Company since 2005, building a profitable and sustainable business whilst delivering higher shareholder return.



(viii) Relationship Between Remuneration and Performance

The Group has solely dedicated its resources to the research, development and commercialisation of its unique and medically beneficial technology. The remuneration and incentive framework, which has been put in place by the Board, has ensured executive personnel are remunerated to ensure they are focussed on both maximising short-term operating performance and long-term strategic growth that will need to lead to shareholder value. The focus on growth in shareholder value has been centred on achievement of regulatory, development, commercial and operational outcomes, where financial metrics are not necessarily an appropriate measure of executive performance and is commonly expected in other market segments.

In recent years the Board has recognised that both financial and non-financial performance measures have been a key link to driving share price performance, and these have been reflected in various performance conditions attached to the long-term equity incentives. The performance outcomes tabled in the following page, as aligned with the CLINUVEL strategy, were achieved resulting in a performance based STI incentive rating of 42.5% of the maximum potential opportunity for the Managing Director. This STI incentive rating is significantly lower than in recent years.

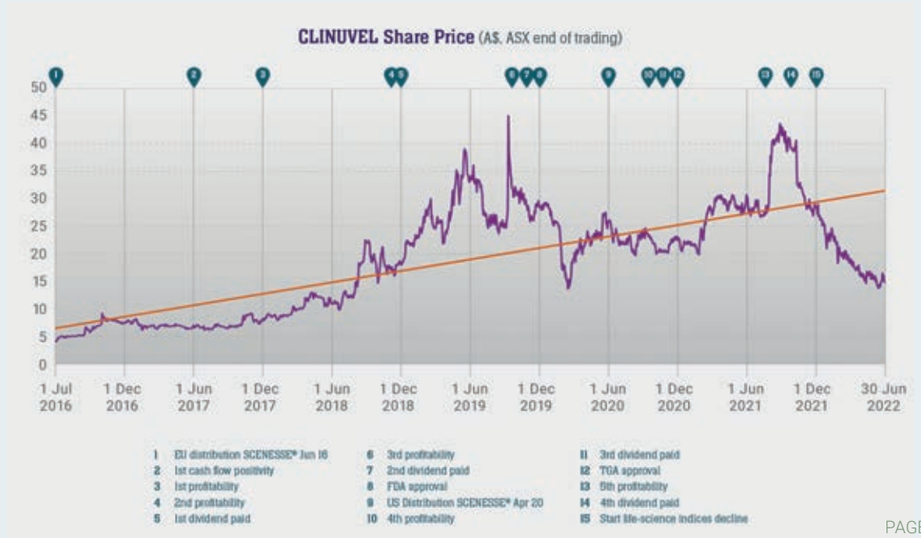
In assessing the KPIs, the Board considered a variety of factors that impacted the reporting period, and where leadership was required to navigate critical issues and challenges facing the Company, including the COVID-19 pandemic, rising supply constraints and inflationary pressures, as well as the re-rating of life science companies globally. The Board assessed the supply of treatment centres across Europe and the United States with uninterrupted supply, working with the centres to access patients and to prepare centres to treat new patients under pending clinical, investigational settings.

Additional objectives were taken into consideration when assessing Other KMP performance by the Board, which were considered an essential element of achieving individual performance. However, some of these are considered commercially sensitive.

STI Outcomes	Year Ended 30 June 2022		
STIs summarised into Strategic Grouping for Year	**Managing Director**		
	Weighting	Rating	Outcome
Product Development	35%	Low	• Progress made in the development of the PRÉNUMBRA® INSTANT, the second afamelanotide formulation • Formulations developed for non-pharmaceutical topicals, preparing for commercial scale manufacture amid challenging supply chain environment
Manufacturing	20%	Low	• Targeted alternative manufacturing solutions to allow eventual vertical integration of supply chain within the Group • Commenced manufacturing program for new NEURACTHEL® formulations, part of the expanded melanocortin product portfolio • Sourcing opportunities to establish in-house infrastructure
Consolidation & Growth	10%	Medium	• Attracting new shareholders • Continued financial discipline, generating cash reserves to facilitate further reinvestment • Maintained uniform pricing after re-negotiation with EU reference payors
Clinical	15%	High	• Final results of first stroke study, proceeding to second study • DNA Repair program progressed into three studies; patients dosed • Final consensus on vitiligo, proceeding to patient recruitment of monotherapy study CUV104
New Initiatives	20%	High	• Expanding the pharmaceutical development portfolio to develop new formulations of the ACTH melanocortin to evaluate its use in patients with neurological, endocrinological, and degenerative disorders, who lack alternative therapy
Total	100%	42.5%	

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

Long-term share price performance has largely followed achievement of key regulatory, development, commercial and operational outcomes:

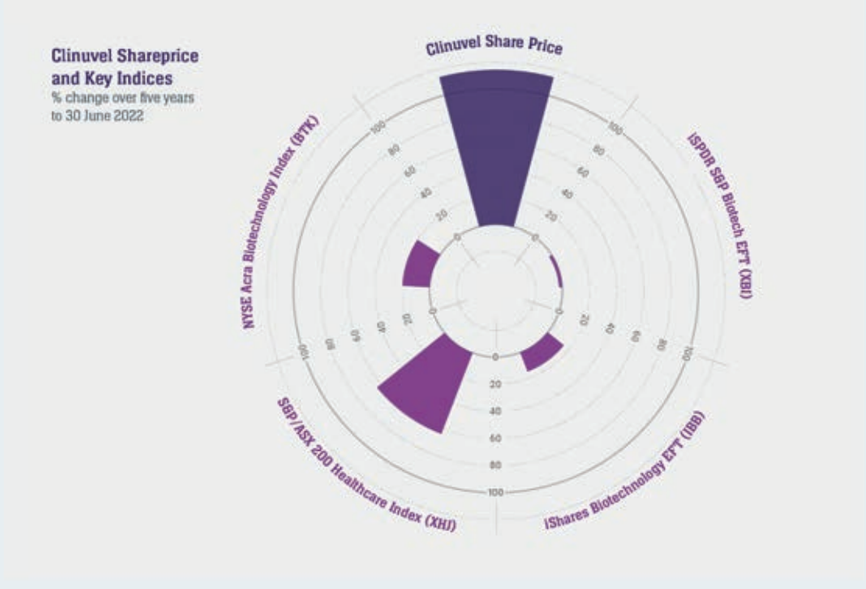


The table below shows the progress made in moving through the clinical pathway and into the commercialisation pathway, reflecting the performance of executive management under the leadership of the Managing Director. The table also links to share price performance.

Clinical Development Pathway

Regulatory, Clinical & Commercial Milestones	Year Ended 30 June				
	2018	2019	2020	2021	2022
Ph II Vitiligo Study – Singapore					
VALLAURIX PTE LTD – Formulation & melanocortin development					
First commercial sales in EU					
Submission and subsequent approval for Marketing Authorisation – US FDA					
Submission and subsequent approval for Marketing Authorisation – Australian TGA					
First commercial sales in US					
Ph II Arterial Ischaemic Stroke Study – Melbourne					
Ph II DNA Repair Studies – Europe					
Ph II Vitiligo Study – USA					
Market capitalisation (A$m)	527	1,649	1,267	1,517	734
Share Price High ($)	13.52	39.85	45.88	31.23	44.67
Share Price Low ($)	5.91	9.43	12.92	19.53	13.16
Closing Share Price ($)	11.0	33.68	25.65	30.70	14.65
Change in Share Price over 1 Year (%)	58	206	(24)	20	(52)
Change in Share Price over 3 Years (%)	288	680	268	179	(56)
Change in Share Price over 5 Years (%)	508	1881	803	611	113
Dividend Paid (cents)	–	2.0	2.5	2.5	2.5
EBIT (A$m)	12.942	18.115	13.136	25.713	34.321
NPAT (A$m)	13.224	18.134	16.647	24.728	20.878

CLINUVEL's strong share price performance compares favourably against the performance of broader key life-science and healthcare indices over the five years to 30 June 2022.



(ix) Executive Remuneration Pay Mix

The Board believes the remuneration mix aligns the Managing Director and Other Executive KMP to shareholder interest. The remuneration mix for 2021/22 is demonstrated as follows:

Position	Fixed Remuneration	STI Cash	LTI Cash[1]	LTI Equity[2]
Managing Director	100%	100% of Base Salary	6.8% of Base Salary	188% of Base Salary
Other Executive KMP				
CFO	100%	17% of Base Salary	3.6% of Base Salary	136% of Base Salary
CSO	100%	9% of Base Salary	-	16% of Base Salary

1. Retention Award earned during 2021/22.
2. Shown as total value of performance rights calculated under AASB2 divided by 4 years being the vesting period of the performance rights granted in the year

D. Non-Executive Remuneration

The Board seeks an appropriate mix of skill, diversity, experience and specific expertise 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 aforementioned attributes, having regard to global employment market conditions and consultation with specialist remuneration consultants with experience in the healthcare and biotechnology industries.

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.

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 2022 was $442,051.

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 no longer planned for Non-Executive Directors to participate in long-term equity compensation plans. No Non-Executive Director holds Performance Rights as at 30 June 2022.

E. Service Agreements FY2022

Remuneration and other terms of employment for the Managing Director 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.

During FY2022 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[1]	No fixed term	2 years[2]
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

1. Expiry Date 30 June 2025
2. Expiry Date 30 June 2024

F. Share Based Remuneration

The Group has an ownership-based scheme for Directors, Other Executive KMP, employees and select consultants of the Company which is designed to provide long-term incentives to deliver long-term value.

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

a. the CLINUVEL Conditional Performance Rights Scheme (2009); and

b. the CLINUVEL Performance Rights Plan (2014).

1,513,750 Performance rights were approved by shareholders to grant to the Managing Director at the 2019 AGM.

a. Conditional Performance Rights Scheme (2009)
The Conditional Performance Rights Scheme (2009) is 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.

38,333 Performance Rights issued under the 2009 Scheme remain unvested as at 30 June 2022.

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 the vesting conditions attached to the rights have been achieved, whereby, at the discretion of the Board, they will be held in a Plan Trust on behalf of the eligible person.

If shares are held in trust, the eligible person cannot trade the shares held by the Plan Trustee without prior written Board consent until the earlier of seven years from grant date of Performance Rights, when the eligible person ceases employment or when all transfer restrictions are satisfied or waived by the Board in its discretion. 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 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.

2,400,674 Performance Rights are issued under the 2014 Performance Rights Plan and 2,117,016 or 88.2%, remain unvested. 283,659 Performance Rights have met their underlying performance condition but will not vest until the end of their vesting period.

G. Details of Remuneration

KMP remuneration of the Company for the years ended 30 June 2022 and 30 June 2021 – Cash Based Benefits

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. An amount of accrued, unused annual leave was last paid out to the Managing Director in the year ended 30 June 2012 ($152,026).

People & Environment is one of the company's principal set of values. The Board acknowledges that in order to promote a work environment where all professionals can maintain a positive work-life balance that will support work productivity, staff morale and good health, all staff must be encouraged to consume the employee entitlements available to them.

	Year	Gross Salary [3]	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]	2022	1,490,048	560,113	101,731	198,128		**2,350,020**	1,314,157	**3,664,177**
	2021	1,532,499	732,976	105,152	296,911		**2,667,538**		**2,667,538**
Mrs. B. M. Shanahan	2022	77,273				7,727	-		**85,000**
	2021	75,343				7,157	-		**82,500**
Mr. W. A. Blijdorp	2022	115,000					-		**115,000**
	2021	112,500					-		**112,500**
Dr. K. A. Agersborg	2022	75,000					-		**75,000**
	2021	72,500					-		**72,500**
Mrs. S. E. Smith	2022	75,000					-		**75,000**
	2021	72,500					-		**72,500**
Prof. J. V. Rosenfeld	2022	68,182				6,818	-		**75,000**
	2021	66,210				6,290	-		**72,500**
Prof J. A. Likierman Appointed 4 April 2022	2022	17,051					-		**17,051**
	2021	0				-	-		**0**
Dr. D. J. Wright	2022	278,059	25,025			23,568	-		**326,652**
	2021	264,818	15,492			21,694	-		**302,004**
Mr. D. M. Keamy	2022	331,737	46,443	12,000		23,568	-		**413,748**
	2021	288,468	40,386	13,331		21,694	-		**363,879**
Total	**2022**	**2,527,350**	**631,581**	**113,731**	**198,128**	**61,681**	**2,350,020**	**1,314,157**	**4,846,628**
	2021	**2,484,838**	**788,853**	**118,483**	**296,911**	**56,835**	**2,667,538**	**-**	**3,745,920**

1) 'Other' includes health insurance, housing and other allowances that may be subject to fringe benefits tax.
2) Dr Wolgen's salary is paid in Euro currency
3) Does not include movement in annual leave and long service leave provisions.

For Mr Keamy and Dr Wright, the accretive movement to their aggregate annual leave and long service leave entitlements was $39,991 and $9,698 respectively (year ending 30 June 2021: $11,172 and $20,223 increase respectively)

4) The retention award shall be paid to the executives no less than 1 July 2022 unless their service agreement is terminated sooner. See page 88 for further information.

KMP remuneration of the Company for the years ended 30 June 2022 and 30 June 2021 – Non-Cash Benefits

Share-based payments (accounting charge only)[1]	Year	Total (Excluding Share-Based Payments)	Performance Rights	Total (Including Share-Based Payments)	% Performance-based
		$	$	$	
Dr. P. J. Wolgen	2022	3,664,117	3,448,463	7,112,640	56%
	2021	2,667,538	2,312,308	4,979,846	61%
Mrs. B. M. Shanahan	2022	85,000	-	85,000	
	2021	82,500	-	82,500	
Mr. W. A. Blijdorp	2022	115,000	-	115,000	
	2021	112,500	-	112,500	
Dr. K. A. Agersborg	2022	75,000	-	75,000	
	2021	72,500	-	72,500	
Mrs. S. E. Smith	2022	75,000	-	75,000	
	2021	72,500	-	72,500	
Prof. J. V. Rosenfeld	2022	75,000	-	75,000	
	2021	72,500	-	72,500	
Prof J. A. Likierman Appointed 4 April 2022	2022	17,051	-	17,051	
	2021	0	-	0	
Dr. D. J. Wright	2022	326,652	176,165	502,817	40%
	2021	302,004	-	302,004	5%
Mr. D. M. Keamy	2022	413,748	1,196,205	1,609,953	77%
	2021	363,879	0	363,879	11%
Total	**2022**	**4,846,628**	**4,820,833**	**9,667,461**	
	2021	**3,745,920**	**2,312,308**	**6,058,228**	

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 – 2022

	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						
Mrs. B. M. Shanahan	25,000	-	-	(25,000)	-	-
Dr. P. J. Wolgen	1,513,750*	-	-	-	1,513,750	200,750
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	18,125	75,813	-	-	93,938	2,828
Mr. D.M. Keamy	32,360	339,875	-	(25,000)	347,235	35,950

*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 2021/22 reporting period held by each of the Group's KMP, including their related parties, is set out below:

Year Ended 30 June 2022 **Personnel**	Balance at Start of Year	Granted as Remuneration	Received on Exercise	Other Changes	Held at the End of Reporting Period
Mrs. B. M. Shanahan	233,969	-	-	(37,392)	196,577
Dr. P. J. Wolgen	3,175,321	-	-	(54,606)	3,120,715
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	2,363	-	-	485	2,848
Prof. J. A. Likierman	-	-	-	1,000	1,000
Other KMP					
Dr. D. J. Wright	256,874	-	-	-	256,874
Mr. D. M. Keamy	313,588	-	-	-	313,588

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	155,750	20/11/2023
CLINUVEL	37,976	$8.97	Ordinary	24/12/2020	24/12/2020	20/11/2023	3,738	20/11/2023
CLINUVEL	94,524	$20.73	Ordinary	24/12/2020	24/12/2020	20/11/2023	7,993	20/11/2023
CLINUVEL	134,690	$18.74	Ordinary	26/08/2021	26/08/2021	20/11/2023	26,749	20/11/2023
CLINUVEL	608,484	$26.22	Ordinary	26/08/2021	26/08/2021	20/11/2023	37,193	20/11/2023
CLINUVEL	22,500	$12.87	Ordinary	05/05/2022	05/05/2022	20/12/2024	-	--

For each cash incentive and right granted, the percentage of the available grant or cash incentive that was paid or vested in the financial year, and the percentage forfeited due to unmet milestones (including service length), is set out below. Cash incentives 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	2011/12	no limitation	-	100%	-
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	-	78%	5,219
	2021/22	2023/24	-	-	3,169,166

The maximum value of outstanding Performance Rights is unable to be estimated. 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.

Remuneration details of cash incentives

Cash Incentives				
Name	Max Potential Opportunity (%)	STI Awarded (%)*	STI Forfeited (%)	Total Granted ($)
Dr. P. J. Wolgen	100%	38%	62%	560,113
Dr. D. J. Wright	9%	100%	0%	25,025
Mr. D. M. Keamy	17%	82%	18%	46,443

* For the Managing Director, the STI Awarded in the functional currency equates to 42.5%

Loans to Directors and Executives

No loans were granted to Directors or executives for the years ended 30 June 2022 and 30 June 2021.

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

Details of shares transferred during the year to employees from the 2009 scheme trust and the 2014 plan trust

Entity	Number of shares issued[1]	Issue Price for Shares	Class
CLINUVEL PHARMACEUTICALS LTD	565,230	Nil$	Ordinary

[1] These shares were issued by the Trustee to the 2009 Scheme and the 2014 Plan to departing employees who resigned from the Group during the year or to existing employees who had their transfer restrictions waived by the Board in their discretion.

Unissued shares under option

Entity	Number of Shares under Rights	Exercise Price	Class	Expiry Date
CLINUVEL PHARMACEUTICALS LTD	2,439,007	$Nil	Ordinary	Upon achievement of specific performance and time-based milestones or upon cessation of employment
Total as at date of Directors Report	**2,439,007**			

Auditor's Independence Declaration

The auditor's independence declaration as required by s.307C of the Corporations Act 2001 is included in page 138 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.

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

Dr. Philippe Wolgen, MBA MD

Director

Dated this 29th day of August, 2022

Statement of Profit and Other Comprehensive Income for the Year Ended 30 June 2022

		Consolidated Entity	
	Note	2022	2021
		$	$
Revenues			
Commercial sales of goods	21	60,002,220	42,602,594
Sales reimbursements	21	5,720,072	5,372,989
Total revenues		**65,722,292**	**47,975,583**
Interest income		444,071	342,203
Total interest income		**444,071**	**342,203**
Other income			
Unrealised gain on restating foreign currency balances and currencies held		604,317	-
Government grants		216,835	129,734
Realised foreign currency gain on transactions		-	3,079
Total other income		**821,152**	**132,813**
Total expenses			
Personnel-related		11,590,661	10,157,625
Share-based payments		6,120,977	2,602,393
Materials and related expenses		5,401,679	3,650,304
Commercial distribution		2,494,361	2,421,204
Finance, corporate and general		2,274,357	1,618,430
Changes in inventories of raw materials, work in progress and finished goods		1,354,779	(1,898,756)
Clinical and non-clinical development		1,232,989	547,553
Legal, insurance and IP		1,147,199	1,095,415
Depreciation and amortisation		757,826	861,432
Communication, branding and marketing		291,772	313,986
Unrealised loss on restating foreign currency balances and currencies held		-	1,368,369
Total expenses		**32,666,600**	**22,737,955**
Profit before income tax		34,320,915	25,712,644
Income tax on income			
Current	3(a)	7,367,889	104,085
Deferred	3(a)	6,074,561	880,312
Income tax expense	3(a)	13,442,450	984,397
Operating profit after income tax	17(b)	20,878,465	24,728,247
Net profit for the year		**20,878,465**	**24,728,247**
Other comprehensive income			
Items that may be re-classified subsequently to profit or loss			
Exchange differences of foreign exchange translation of foreign operations		(1,057,433)	(575,253)
Other comprehensive income/(loss) for the period, net of income tax		(1,057,433)	(575,253)
Total comprehensive income for the period		**19,821,032**	**24,152,994**
Basic earnings per share - cents per share	16	42.3	50.0
Diluted earnings per share - cents per share	16	40.3	48.4

The accompanying notes form part of these financial statements.

Statement of Financial Position as at 30 June 2022

	Note	Consolidated Entity 2022 $	2021 $
Current assets			
Cash and cash equivalents	17(a)	121,509,282	82,690,982
Trade and other receivables	4	16,201,937	16,088,527
Inventories	5	1,831,891	3,186,670
Other assets	6	1,039,453	882,034
Total current assets		**140,582,563**	**102,848,213**
Non-current assets			
Property, plant and equipment	7	1,540,702	1,384,422
Right-Of-Use assets	8	1,159,642	1,218,721
Intangible asset	9	185,030	185,030
Deferred tax assets	3(c)	481,600	2,931,188
Total non-current assets		**3,366,974**	**5,719,361**
Total assets		**143,949,537**	**108,567,574**
Current liabilities			
Trade and other payables	11	3,277,857	4,656,087
Income tax payables		7,279,449	95,051
Lease liabilities	8	315,068	258,236
Provisions	12	2,859,828	3,697,579
Total current liabilities		**13,732,202**	**8,706,953**
Non-current liabilities			
Lease liabilities	8	941,463	1,045,236
Provisions	12	101,548	77,951
Deferred tax liabilities	3(c)	3,615,281	-
Total non-current liabilities		**4,658,292**	**1,123,187**
Total liabilities		**18,390,494**	**9,830,140**
Net assets		**125,559,043**	**98,737,434**
Equity			
Contributed equity	13	151,849,375	151,849,375
Reserves	14	12,112,096	5,017,827
Accumulated losses		(38,402,428)	(58,129,768)
Total equity		**125,559,043**	**98,737,434**

The accompanying notes form part of these financial statements.

Statement of Cash Flows for the Year Ended 30 June 2022

	Note	Consolidated Entity 2022 $	2021 $
Cash flows from operating activities			
Receipts from customers		66,399,524	38,723,858
Payments to suppliers and employees		(27,352,186)	(20,031,810)
Interest received		248,999	390,970
GST and VAT refunds		358,687	79,684
Government grants		217,258	99,359
Net cash provided by operating activities	**17(b)**	**39,872,282**	**19,262,061**
Cash flows from investing activities			
Payments for property, plant and equipment		(434,438)	(854,325)
Net cash used in investing activities		**(434,438)**	**(854,325)**
Cash flows from financing activities			
Dividends paid		(1,235,265)	(1,235,266)
Payment of lease liabilities		(268,492)	(200,280)
Payment of interest		-	(44,405)
Net cash provided by financing activities		**(1,503,757)**	**(1,479,951)**
Net increase in cash held		**37,934,087**	**16,927,785**
Cash and cash equivalents at beginning of the year		**82,690,982**	**66,746,521**
Effects of exchange rate changes on foreign currency held		884,213	(983,324)
Cash and cash equivalents at end of the year	**17(a)**	**121,509,282**	**82,690,982**

The accompanying notes form part of these financial statements.

Statement of Changes in Equity for the Year Ended 30 June 2022

	Share Capital	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
	$	$	$	$	$
Balance at 30 June 2020	**151,849,375**	**1,751,223**	**99,152**	**(81,632,943)**	**72,066,807**
Exercise of performance rights under share-based payment	-	-	-	-	**-**
Employee share-based payment options	-	2,592,199	-	10,194	**2,602,393**
Dividends paid	-	-	-	(1,235,266)	**(1,235,266)**
Transactions with owners	**151,849,375**	**4,343,422**	**99,152**	**(82,858,015)**	**73,433,934**
Profit for the year	-	-	-	24,728,247	**24,728,247**
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	575,253	-	**575,253**
Total other comprehensive income	**-**	**-**	**575,253**	**-**	**575,253**
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**
Other comprehensive income:					
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**

Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2022

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 judgments 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 Accounting Standard AASB 10 Consolidated Financial Statements. 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.

The Company does not consider the impact of COVID-19 produced a material adverse impact on its consolidated financial position, consolidated results of operations, and consolidated cash flows in the financial year 2022, and it does not expect it to materially impact the financial results in the near future.

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 (or asset) to the extent it is unpaid (or refundable).

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 given 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 2022 and 30 June 2021 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 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;
- 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) 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.

f) 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 other 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.

g) Inventories

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

h) 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 judgment 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.

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) 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.

k) 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.

l) 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 a single patient on a case-by-case basis.

To determine whether to recognise revenue, the Group follows a 5-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 as earned when performance obligations are satisfied at a point in time, which is when control of the product passes to the customer, or generally upon receipt of shipment.

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 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, Job Support Scheme, Property Tax Rebate and the Boosting Cash Flow for Employer schemes from Australian and Singaporean governments in response to the COVID-19 pandemic. 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.

m) 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.

n) 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.

o) 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.

p) 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.

q) 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.

r) Comparatives

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

s) 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.

t) Foreign Currency Transactions And Balances

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

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

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

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

u) 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.

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 Judgment

The Directors evaluate estimates and judgments 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 Operating Segments. 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.

2. Profit/(Loss) From Continuing Operations

	Consolidated Entity	
Profit/(loss) before income tax includes the following specific expenses	**2022**	**2021**
Employee benefits expense	10,825,178	9,630,783
Operating lease expense – minimum lease payments	324,124	241,385
Amortisation of right-of-use assets	289,888	319,962
Depreciation on property, plant & equipment	426,700	499,625
Bank charges	38,069	34,621
Loss on sale of property, plant and equipment	27,380	90,136

3. Income Tax Expense

	Consolidated Entity	
	2022	**2021**
	$	**$**
(a) Income tax expense		
Current	7,367,889	104,085
Deferred	6,074,561	880,312
Income tax expense	**13,442,450**	**984,397**
Deferred tax included in income tax benefit comprises:		
Decrease in deferred tax assets	4,425,880	1,612,242
Increase (decrease) in deferred tax liabilities	1,648,682	(731,930)
	6,074,562	880,312
(b) Numerical		
Profit before income tax expense	34,320,915	25,712,644
Tax at the statutory tax rates of 30% in 2022 and 26.0% in 2021	10,296,275	6,685,287
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Non-deductible share-based payments	1,836,293	417,537
Other non-deductible expenses	1,735,845	-
	13,868,413	7,102,824
Recognition of DTA on carry forward tax losses at year end	(425,963)	(5,042,930)
Recognition of DTA on carry forward tax losses in year	-	(1,075,497)
Income tax expense	**13,442,450**	**984,397**
Tax losses not recognised		
Unused tax losses for which no deferred tax asset has been recognised	20,325,477	25,737,879
(c) Deferred tax assets		
Carry forward tax losses	381,050	5,042,930
Intangibles	513,469	433,722
Provisions	271,869	210,094
Accrued Expenses	145,729	26,797
Lease liabilities	33,957	48,719
	1,346,074	**5,762,262**

Reconciliation to the Statement of Financial Position		
Total deferred tax assets	1,346,074	5,762,262
Set-off of deferred tax liabilities that are expected to reverse in the same period	(864,474)	(2,831,074)
	481,600	**2,931,188**
Movements		
Opening balance	5,762,262	7,374,504
Deferred tax assets utilised	(5,042,930)	(7,818,490)
Carry forward tax losses	381,050	6,118,426
Intangibles	79,747	(15,343)
Lease liabilities	(14,763)	32,823
Accrued Expenses	118,933	(12,821)
Provisions	61,775	83,163
	1,346,074	**5,762,262**

(c) Deferred tax liabilities		
Unrealised foreign exchange gains	(4,238,456)	(2,774,312)
Accrued income	(218,641)	(16,787)
Right-of-use assets	(33,275)	(49,195)
Intangibles	10,617	9,220
	(4,479,755)	**(2,831,074)**
Reconciliation to the Statement of Financial Position		
Total deferred tax liabilities	(4,479,755)	(2,831,074)
Set-off of deferred tax assets that are expected to reverse in the same period	864,474	2,831,074
	(3,615,281)	**-**
Movements		
Opening balance	(2,831,074)	(3,563,004)
Unrealised foreign exchange gains	(1,464,144)	751,326
Right-of-use assets	15,920	(34,053)
Accrued income	(201,854)	15,642
Intangibles	1,397	(985)
	(4,479,755)	**(2,831,074)**

Deferred tax assets include US deferred tax assets that cannot be offset with Australian deferred tax liabilities. The tax rates used in this report are the Australian corporate tax rate of 30% in 2022 and 26% in 2021, and income tax rate of 21% for US entity in 2022.

4. Trade and Other Receivables

	Consolidated	
	2022	**2021**
	$	**$**
Current		
Trade debtors	15,898,020	15,811,629
Interest receivables	259,633	64,565
Sundry debtors	44,284	212,333
Total	**16,201,937**	**16,088,527**

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.

5. Inventories

	Consolidated Entity	
	2022	**2021**
	$	**$**
Current		
Raw materials – at cost	519,393	504,565
Provision for obsolescence – raw materials	(159,712)	(159,712)
Work in progress – at cost	1,176,227	2,637,386
Finished goods – at cost	295,983	204,431
Total	**1,831,891**	**3,186,670**

6. Other Assets

	Consolidated Entity	
	2022	**2021**
	$	**$**
Current		
Prepaid supplies	596,103	472,184
Other prepayments	443,350	409,850
Total	**1,039,453**	**882,034**

7. Property, Plant and Equipment

	Consolidated Entity	
	2022	**2021**
	$	**$**
Plant and equipment		
At cost	1,289,490	775,324
Less: accumulated depreciation	(343,245)	(292,057)
Sub-total	**946,245**	**483,267**
Furniture and fittings		
At cost	41,935	40,629
Less: accumulated depreciation	(22,575)	(18,181)
Sub-total	**19,360**	**22,448**
Leasehold improvements		
At cost	1,253,373	1,253,373
Less: accumulated amortisation	(678,276)	(374,666)
Sub-total	**575,097**	**878,707**
Total property, plant and equipment	**1,540,702**	**1,384,422**

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 2020	**343,840**	**39,639**	**691,962**	**1,075,441**
Additions	260,291	7,944	623,356	891,591
Disposals	(45,450)	(89,871)	(128,282)	(263,603)
Depreciation written back on disposals	37,279	70,680	69,552	177,511
Depreciations expense	(112,693)	(5,944)	(377,881)	(496,518)
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**

8. Right-of-Use Assets and Lease Liabilities

	Consolidated Entity	
	2022 $	2021 $
Right-of-use assets		
At cost	1,775,894	1,538,929
Less: accumulated depreciation	(616,252)	(320,208)
Total right-of-use assets	**1,159,642**	**1,218,721**

	Consolidated Entity	
	2022 $	2021 $
Lease liabilities		
Lease liabilities - Current	315,068	258,236
Lease liabilities - Non-current	941,463	1,045,236
Total lease liabilities	**1,256,531**	**1,303,472**

Lease liability is measured at the present value of the lease payments unpaid at that date, discounted using the interest rate implicit in the lease if that rate is readily available or the Group's incremental average borrowing rate of 5.5% in 2022 and 3.5% in 2021.

9. Intangible asset

	Consolidated Entity	
	2022 $	2021 $
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 business unit's recoverable amount falls below the carrying value of its net assets. The results of impairment testing during the year show that the relevant business 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 2022.

10. Interests in Subsidiaries

Name Of Entity	Country Of Incorporation	Ownership Interest	
		2022	2021
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%

11. Trade and Other Payables

	Consolidated Entity	
	2022 $	2021 $
Current		
Unsecured trade creditors	259,199	2,323,560
Sundry creditors and accrued expenses	3,018,658	2,332,527
Total	**3,277,857**	**4,656,087**
(a) Aggregate amounts payable to:		
Directors and Director-related entities	564,667	735,701

(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade and Sundry creditors:

DKK	42	271
Israeli Shekel	-	105
Total	**42**	**376**

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	
	2022 $	2021 $
Current		
Employee benefits	2,859,828	3,697,579
Total	**2,859,828**	**3,697,579**
Non-current		
Employee benefits	31,643	13,166
Other provisions	69,905	64,785
Total	**101,548**	**77,951**

13. Contributed Equity

(a) Issued and Paid Up Capital

	Consolidated Entity	
	2022	2021
	$	$
49,410,338 fully paid ordinary shares (2021: 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			
		2022		2021
	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	-	-	-	-
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 2022, the following conditional Performance Rights existed which if exercised, resulting in the issue of fully paid ordinary shares:

Expiry date	Exercise Price	Number of Performance Rights
Upon achievement of various performance milestones	**Nil$**	**2,439,007**

14. Reserves

	Consolidated Entity	
	2022	2021
	$	$
Conditional Performance Rights reserve:		
Balance at the beginning of period	4,343,422	1,751,223
Share-based payment	6,120,977	2,602,393
Transfer to share capital	-	-
Lapsed, forfeited rights	(84,141)	(10,194)
Balance at the end of period	10,380,258	4,343,422

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	674,405	99,152
Translating foreign subsidiary to current rate at reporting date	1,057,433	575,253
Balance at the end of period	1,731,838	674,405
Total reserves	**12,112,096**	**5,017,827**

15. Short-Term Lease Commitments

	Consolidated Entity	
	2022	2021
	$	$
Operating lease commitments		
Non-cancellable operating leases contracted for but not capitalised under AASB 16 as they are short-term and are payable as follows:		
not later than 1 year	27,867	111,817
later than 1 year but not later than 5 years	2,731	17,177
Total	**30,598**	**128,994**

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	
	2022	2021
	$	$
(a) Basic earnings per share (cents per share)	42.3	50.0
(a) Diluted earnings per share (cents per share)	40.3	48.4
(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	2,366,106	1,720,732
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	51,776,444	51,131,070
(c) The numerator used in the calculation of basic earnings per share ($)	20,878,465	24,728,247

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	
	2022	2021
	$	$
(a) Reconciliation of cash		
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:		
Cash at bank	22,849,846	34,572,626
Cash on hand	259	1,317
Deposits on call	4,215,543	2,241,903
Term deposits	94,100,000	45,550,000
Security bonds	343,634	325,136
Total cash and cash equivalents	**121,509,282**	**82,690,982**
(b) Reconciliation of cash flows from operating activities with operating profit (loss)		
Operating profit after income tax	**20,878,465**	**24,728,247**
Non cash flows in operating profit after income tax:		
Depreciation expense on property, plant & equipment	426,700	499,625
Amortisation expense on right-of-use assets	289,888	319,962
Exchange rate effect on foreign currencies held	(884,213)	983,325
Executive share option expense	6,120,977	2,602,393
Unrealised loss (gain) on foreign exchange translation	1,057,434	575,253
Loss on sale of non-current assets	27,379	90,136
Changes in assets and liabilities:		
Increase in receivables	(113,410)	(9,475,843)
(Increase)/decrease in inventories	1,354,779	(1,898,756)
Increase in other assets	(157,418)	(413,782)
Decrease in deferred tax assets	2,449,588	880,312
Decrease in payables	(1,563,412)	(115,494)
Increase in income tax payables	7,184,398	95,051
Increase/(decrease) in provisions	(814,154)	391,632
Increase in deferred tax liabilities	3,615,281	-
Net cash used in operating activities	**39,872,282**	**19,262,061**

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.

The effective interest rate on short-term deposits was 0.64% (2021: 0.70%). These deposits have an average maturity date of 249 days (2021: 233 days).

18. Key Management Personnel

	Consolidated Entity	
	2022	2021
	$	$
Short-term employee benefits	4,225,617	3,570,602
Post-employment benefits	61,681	56,835
Long-term benefits	559,330	118,483
Share-based payments	4,820,833	2,312,308
Total	**9,667,461**	**6,058,228**

No loans or other transactions existed with key management personnel.

19. Auditor's Remuneration

	Consolidated Entity	
	2022	2021
	$	$
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	179,000	113,000
tax and advisory services	-	10,000
Total	**179,000**	**123,000**

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. The loan to A.C.N. 108 768 896 Pty Ltd as at 30 June 2022 is $4,370,640 (2021: $4,370,640).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL, INC. is interest bearing at 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 2022 is $23,381,365 (2021: $21,780,429).

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. The loan to CLINUVEL AG as at 30 June 2022 is $13,985,963 (2021: $13,972,152).

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 2022 is $629,876 (2021: $642,292).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL (UK) 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 (UK) LTD. The loan to CLINUVEL (UK) LTD as at 30 June 2022 is $7,383,677 (2021: $13,900,471).

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 2022 is $7,127,994 (2021: $5,752,040).

The loan payable by CLINUVEL PHARMACEUTICALS LTD to 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 from VALLAURIX MC SARL as at 30 June 2022 is -$2,958,807 (2021: -$3,973,021).

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 2022 is $1,984,059 (2021: $5,039,479).

Director related and Key Management Personnel transactions and entities:

There are no loan transactions and relationships in existence as at 30 June 2022 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 Operating Segments.

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

	FY2022			FY2021		
	Commercial sales of goods	Sales reimbursements	Total	Commercial sales of goods	Sales reimbursements	Total
	$'000	$'000	$'000	$'000	$'000	$'000
Europe & USA	60,002	139	60,141	42,603	139	42,742
Switzerland, Others	-	5,581	5,581	-	5,234	5,234
Total	**60,002**	**5,720**	**65,722**	**42,603**	**5,373**	**47,976**

The Group has a number of customers to which it provides its leading drug candidate. Two customers each comprise 12% of external total revenue (2021: 18% and 15% respectively).

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 2022 and as at 30 June 2021.

The consolidated entities exposure to foreign currency risk at 30 June 2022

	Consolidated Entity							
	2022				2021			
	Cash & Cash Equivalents	Trade Debtors & Other Assets	Trade, Other Payables & Provisions	TOTAL	Cash & Cash Equivalents	Trade Debtors & Other Assets	Trade, Other Payables & Provisions	TOTAL
USD	7,932,297	7,452,124	(422,710)	**14,961,711**	5,089,237	6,829,485	(1,888,178)	**10,030,544**
EUR	5,876,623	2,650,122	(2,252,650)	**6,274,095**	9,330,841	3,709,227	(2,956,578)	**10,083,490**
CHF	554,736	579,272	(128,874)	**1,005,134**	1,623,549	664,643	(137,695)	**2,150,497**
GBP	297,972	149,530	(258,288)	**189,213**	420,266	100,453	(205,788)	**314,931**
SGD	989,697	238,264	(302,720)	**925,241**	521,309	233,263	(283,017)	**471,555**
SEK	-	429,225	-	**429,226**	-	-	-	**-**
DKK	-	-	(206)	**(206)**	-	-	(1,272)	**(1,272)**
ILS	-	-	(100)	**(99)**	-	214,500	(255)	**214,245**

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 7.2% appreciation of the Australian dollar against the Euro currency would have decreased profit and loss and equity by $1,661,459 for the year ended 30 June 2022 (2021: $1,144,073 decrease), on the basis that all other variables remain constant. 7.2% is considered representative of the market volatility in the Australian dollar/Euro rate for the period.

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

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

Interest Rate Risk

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

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

Sensitivity Analysis
For the consolidated entity, at 30 June 2022, if interest rates had changed by +/- 75 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 $749,539 higher/lower (2021: $532,001 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 meets its financial obligations when they fall due. It is the policy of the consolidated entity to ensure there is sufficient liquidity to meet is 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 2022

	Consolidated Entity	
	2022	2021
	$	$
Trade and other payables		
Carrying amount	3,277,857	4,751,138
6 months or less	3,273,492	4,737,110
Greater than 6 months	4,366	14,028
Total	**3,277,857**	**4,751,138**
Lease liabilities		
Carrying amount	1,358,214	1,303,472
6 months or less	170,979	147,447
Greater than 6 months	1,187,235	1,156,025
Total	**1,358,214**	**1,303,472**

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 2022

	Consolidated Entity	
	2022	2021
	$	$
Cash and cash equivalents		
Carrying amount	121,509,282	82,690,982
6 months or less	84,709,282	69,053,415
Greater than 6 months	36,800,000	13,637,567
Total	**121,509,282**	**82,690,982**
Other financial assets (includes trade and other receivables)		
Carrying amount	16,201,937	16,088,527
6 months or less	15,142,670	15,619,400
Greater than 6 months	1,059,267	469,127
Total	**16,201,937**	**16,088,527**

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 2022, the Company via its wholly owned subsidiary ACN 108768896 Pty Ltd acting in its capacity as trustee for the 2009 Scheme Trust and the 2014 Plan Trust, holds 2,214,810 shares (2021: 2,780,840 shares).

The following share-based payment arrangements were in existence at 30 June 2022

Performance Rights Series		Number	Grant date	Expiry Date	Exercise Price	Fair Value at Grant Date
Issued	16/09/2011	38,335	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	731,924	26/08/2021	20/11/2023	$ Nil	Between $18.73 & $26.22
Issued	05/05/2022	22,500	05/05/2022	20/12/2024	$ Nil	$12.87

*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 – 2022

Performance Rights Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Performance Condition Met, not exercisable until end Vest Period	Performance Condition Not Met, not exercisable until end Vest Period
Issued 16/09/2011	113,335	-		(75,002)	38,333	-	38,333
Issued 16/11/2011	25,000	-	-	(25,000)	-	-	-
Issued 26/08/2020	1,513,750	-	-	-	1,513,750	200,750	1,313,000
Issued 24/12/2020	132,500	-			132,500	11,731	120,769
Issued 26/08/2021		743,174		(11,250)	731,924	63,942	667,982
Issued 05/05/2022		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	$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 7seven years from date of grant of rights or at its designated end date of vesting, set at the time of issue of rights. 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 after 24 December 2020, an illiquidity discount was applied to the pricing model.

Holdings of All Issued Conditional Performance Rights – 2021

Performance Rights Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Performance Condition Met, not exercisable until end Vest Period	Performance Condition Not Met, not exercisable until end Vest Period
Issued 16/09/2011	127,710	-		(14,375)	113,335	-	113,335
Issued 16/11/2011	25,000	-	-		25,000	-	25,000
Issued 26/08/2020	-	1,513,750	-	-	1,513,750	95,375	1,418,375
Issued 24/12/2020	-	132,500			132,500	-	132,500
Total	**152,710**	**1,646,250**	**-**	**(14,375)**	**1,784,585**	**95,375**	**1,689,210**
Weighted average exercise price	$Nil	$Nil	$Nil	$Nil	$Nil	$Nil	$Nil

For Performance Rights issued in 2011
Performance Rights were priced using either a binomial or trinomial pricing model. There is no limitation on the life of the right. Expected volatility of each right is based on the historical share price for the approximate length of time for the expected life of the rights. It is assumed that the consolidated entity will not pay any dividends during the life of the option, and the risk free rate used in the pricing model is assumed to be the yield on ranging from 1 year to 10 year Government bonds. The exercise conditions are non-marketable and a discount for lack of marketability was applied to the pricing model.

For Performance Rights issued in 2020
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 20 November 2023. 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 24 December 2020, an illiquidity discount was applied to the pricing model.

24. CLINUVEL PHARMACEUTICALS LTD Parent Company Information

	CLINUVEL PHARMACEUTICALS LTD	
	2022	2021
	$	$
Assets		
Current assets	117,142,670	73,061,479
Non-current assets	29,199,431	34,530,668
Total assets	**146,342,101**	**107,592,147**
Liabilities		
Current liabilities	9,010,574	3,284,678
Non-current liabilities	3,667,875	126,355
Total liabilities	**12,678,449**	**3,411,033**
Equity		
Issued equity	151,849,375	151,849,375
Share–based payments reserve	10,380,258	4,343,422
Accumulated losses	(28,565,981)	(52,011,683)
Total equity	**133,663,652**	**104,181,114**
Financial performance		
Net profit for the year	22,294,578	23,741,882
Total comprehensive income	**22,294,578**	**23,741,882**

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 29th August 2022, the Board of Directors declared an unfranked dividend of $0.04 per ordinary share

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 2022 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 82 to 103 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, 2022

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Independent Auditor's Report

To the Directors of Clinuvel Pharmaceuticals Limited

Report on the audit of the financial report

Opinion

We have audited the financial report of Clinuvel Pharmaceuticals Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 30 June 2022, 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 2022 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.

Key audit matter	How our audit addressed the key audit matter
Income taxes (Note 3)	
The Group holds significant tax balances at 30 June 2022, including deferred tax assets of $1,346,074 (2021: $5,762,262), deferred tax liabilities of $4,479,755 (2021: $2,831,074) and income tax payable of $7,279,449 (2021: $nil). There are $20,325,477 (2021: $25,737,879) 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 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.	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 the 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; • Utilising our internal taxation specialists to assess that carry-forward losses are available for use; • Assessing the competence, capability and objectivity of management's tax expert used, to assist in the preparation of the valuation of the tax balances; • Checking the accuracy of input data and evaluating 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.
Share-based payments (Note 23)	
The Group has material share-based payment arrangements for key management and employees. The following transactions occurred during the current financial year: • In August 2021, the Group issued 743,174 rights to 16 employees, valued at $6,682,162; and • In May 2022, 22,500 rights were issued to two employees, valued at $241,273. Both sets of rights issued during the year were valued for accounting and reporting purposes using the Monte-Carlo simulation and Binomial Options Valuation method. The value will be expensed over the vesting period.	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; • Utilising our internal valuation specialist to assist in our review of the valuation performed by management's expert; • Holding discussions with management to understand the share-based payment arrangements in place and, where applicable, evaluating management's assessment of the likelihood of meeting the performance conditions attached to the share-based payments;

Key audit matter	How our audit addressed the key audit matter
Under AASB 2 *Share-Based Payments*, management is 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 and determining estimates of the vesting dates relating to the probability and likely timing of achieving specific non-market conditions.	• Reviewing management's determination of the fair value of the share-based payments issued, considering the appropriateness of the valuation model used and assessing the valuation inputs; • Assessing the allocation of the share-based payment expense over the relevant vesting period, including assessing the appropriateness of the vesting period; • Evaluating management's forecasts to evaluate the consistency of vesting dates for performance milestones; 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 2022, 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 82 to 103 of the Directors' report for the year ended 30 June 2022.

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Limited, for the year ended 30 June 2022 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 2022

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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 2022, I declare that, to the best of my knowledge and belief, there have been:

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

b no contraventions of any applicable code of professional conduct in relation to the audit.

Grant Thornton Audit Pty Ltd
Chartered Accountants

M A Cunningham
Partner – Audit & Assurance

Melbourne, 29 August 2022

Shareholder Information

AS AT 15 AUGUST 2022

1. SHAREHOLDING

A) DISTRIBUTION OF SHAREHOLDER NUMBERS

		ORDINARY FULLY PAID SHARES	
CATEGORY (SIZE OF HOLDING)	TOTAL HOLDERS	UNITS	% OF ISSUED CAPITAL
1-1,000	4,312	1,344,387	2.72
1,001-5,000	988	2,223,164	4.50
5,001-10,000	160	1,172,570	2.37
10,001-100,000	170	4,471,926	9.05
100,001 & Over	27	40,198,291	81.36
TOTAL	5,657	49,410,338	100.00

B) SHAREHOLDINGS HELD IN LESS THAN MARKETABLE PARCELS

TOTAL	MINIMUM PARCEL SIZE	HOLDERS	UNITS
Minimum $500.00 parcel at $19.66 per unit	26	472	4,945

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]	3,120,715
Ender 1 LLC[3]	2,340,824

1. As disclosed in substantial holder notice dated 24 May 2022.
2. As disclosed in substantial holder notice dated 12 May 2022 which includes the relevant interest of Dr Philippe Wolgen, for 2,199,810 quoted ordinary shares, held in the CLINUVEL Conditional Performance Rights Scheme Trust and the Performance Rights Plan Trust by ACN 108 768 896 Pty Ltd. Actual shareholding as at 15 August 2022 is 3,120,715.
3. As disclosed in substantial holder notice dated 16 September 2013. Actual shareholding as at 15 August 2022 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.

(ii) PERFORMANCE RIGHTS

Performance Rights have no voting rights.

E) LARGEST SHAREHOLDERS

POSITION	NAME	NUMBER OF ORDINARY FULLY PAID SHARES HELD	
1.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	10,891,392	22.04
2.	BNP PARIBAS NOMINEES PTY LTD ACF CLEARSTREAM	6,185,931	12.52
3.	BNP PARIBAS NOMINEES PTY LTD <DRP>	5,852,767	11.85
4.	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	3,337,853	6.76
5.	ENDER 1 LLC	2,590,824	5.24
6.	CITICORP NOMINEES PTY LIMITED	2,298,420	4.65
7.	ACN 108 768 896 PTY LTD	2,214,810	4.48
8.	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAIL CLIENT DRP>	1,468,183	2.97
9.	DR PHILIPPE JACQUES WOLGEN	920,905	1.86
10.	NATIONAL NOMINEES LIMITED	647,883	1.31
11.	M BADCOCK AND P CHU SUPERANNUATION FUND PTY LTD	633,447	1.28
12.	DR MARK EDWIN BADCOCK	499,502	1.01
13.	MR DARREN MICHAEL KEAMY	313,588	0.63
14.	MR DENNIS WRIGHT	256,874	0.52
15.	MR DAVID WILLIAM TREVORROW	229,600	0.46
16.	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	218,256	0.44
17.	MR DAVID JOHN LEWIS	187,000	0.38
18.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	184,069	0.37
19.	MR TRENT SHELDON REDDING	181,250	0.37
20.	TRUEBELL CAPITAL PTY LTD <TRUBELL INVESTMENT FUND>	180,000	0.36
TOTALS: TOP 20 HOLDERS OF ORDINARY FULLY PAID SHARES (TOTAL)		39,292,554	79.52
TOTAL REMAINING HOLDERS BALANCE		10,117,784	20.48

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: http://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

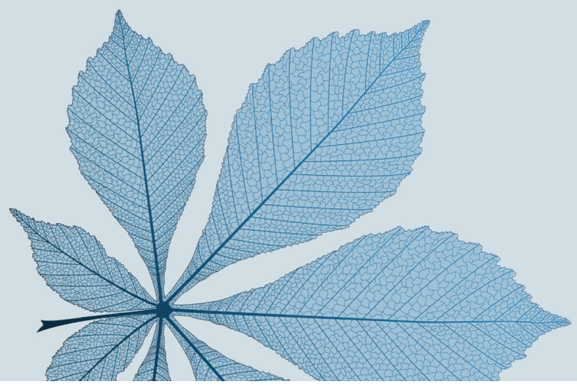
5. AUSTRALIAN SECURITIES EXCHANGE LIMITED

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 XETRA, an electronic trading system, based in Frankfurt, Germany, under the code UR9.

In the USA, the Company's Level 1, American Depositary Receipts (ADRs), trade under the code CLVLY. Each ADR of the Company is equivalent to one ordinary share of the Company, as traded on the ASX. The Bank of New York Mellon is the depositary bank.



6. RESTRICTED SECURITIES

Restricted securities on issue at June 30, 2021: Nil.

7. DIRECTORY

NON-EXECUTIVE CHAIR
Willem Blijdorp

NON-EXECUTIVE DIRECTORS
Brenda Shanahan, Dr Karen Agersborg, Susan Smith, Dr 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 Australia Limited
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

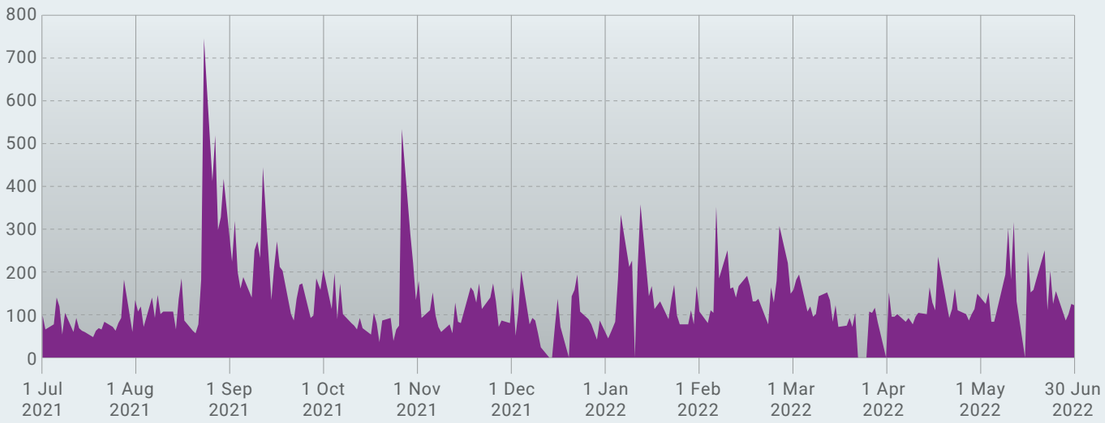
LEGAL COUNSEL
Arnold Bloch Leibler
Level 21, 333 Collins St, Melbourne, VIC 3000, Australia
Sidley Austin LLP
Woolgate Exchange, 25 Basinghall Street, London, EC2V 5HA,
United Kingdom

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

Market Performance

ASX CUV – Share Price (A$)

ASX CUV – Daily Trading Volume (No.)



CLINUVEL Pharmaceuticals | **2022** Annual Report

Glossary

ALPHA-MvELANOCYTE 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 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 (MC1R to MC5R) seven-transmembrane G-protein coupled receptors (GPCRs) that affect different body functions. The receptors are widespread throughout the body, exhibiting myriad ligand affinities, tissue and cell distribution, and downstream effects.

MELANOGENESIS
The process whereby melanin is produced in the body

NARROWBAND ULTRAVIOLET B (NB-UVB) PHOTOTHERAPY
Therapy which utilises an ultraviolet B light source to activate melanin in vitiliginous lesions of the skin.

PHASE I
The first trials of a new drug candidate in humans, Phase I trials are designed to evaluate how a new drug candidate should be administered, to identify the highest tolerable dose and to evaluate the way the body absorbs, metabolises and eliminates the drug.

PHASE II
A Phase II trial is designed to continue to test the safety of the drug candidate, and begins to evaluate whether, and how well, the new drug candidate works (efficacy). Phase II trials often involve larger numbers of patients.

PHASE IIB/PHASE III
Advanced-stage clinical trials that should conclusively demonstrate how well a therapy based on a drug candidate works. Phase III trials can be longer and typically much larger than Phase II trials, and frequently involve multiple test sites. The goal is statistically determining whether a therapy clinically improves the health of patients undergoing treatment while remaining safe and well tolerated.

PHARMACODYNAMICS
The study of the time course of a drug's actions in the body.

PHARMACOKINETICS
The part of pharmacology that studies the release and availability of a molecule and drug in the human body.

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.

An extensive glossary of terms relevant to CLINUVEL's work can be found at https://www.clinuvel.com/glossary.


CLINUVEL