CLINUVEL
Pharmaceuticals
Annual Report 2021

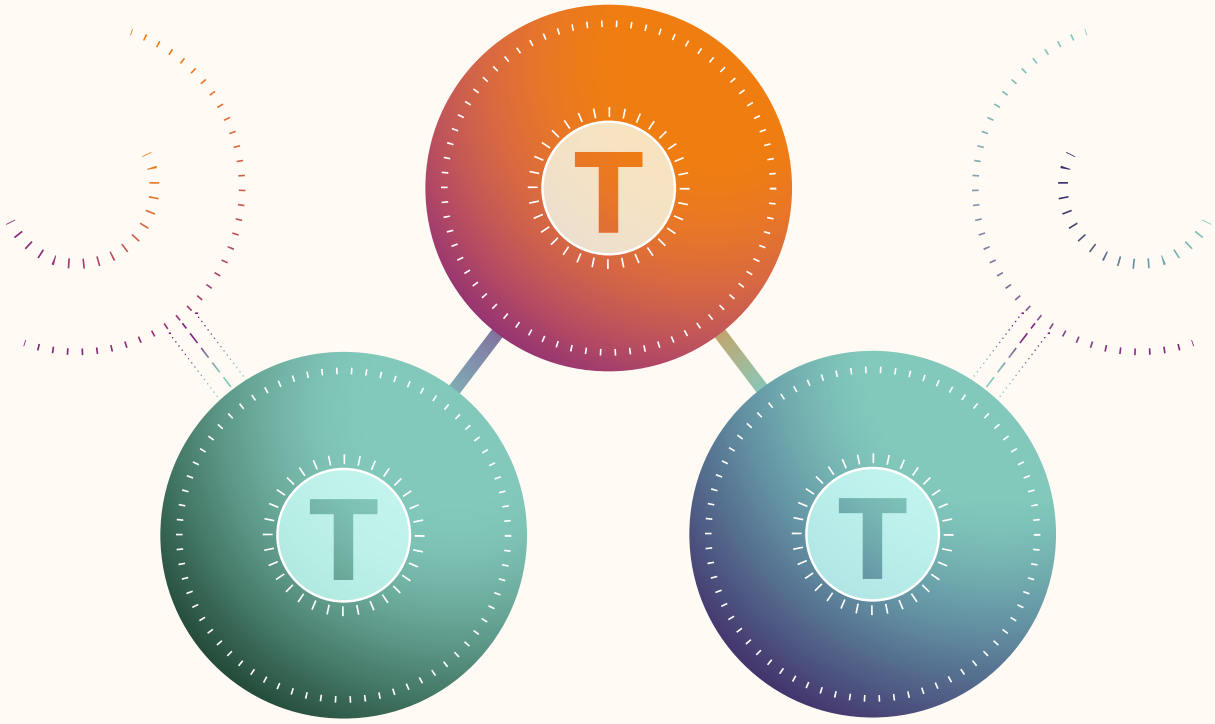
CLINUVEL

Targeted Technology Translation

As 2005 drew to a close, avenues were limited and prospects were at a bare minimum; this point in time marks the birth of CLINUVEL, the Company as we know it today. Twenty-five years wasted on execution and intellectual property; a new reset was needed.

Fast forward, and the October 2019 approval of SCENESSE® (afamelanotide 16mg) by the US Food and Drug Administration (FDA) has been a catalyst to 'unlock the door' for CLINUVEL to justify expansion of its research and development (R&D) programs in melanocortins. The regulatory endorsement of the concept of systemic photoprotection and use of melanocortins has followed decades of unsuccessful attempts. The emphasis on the safety of SCENESSE® provides the basis to translate CLINUVEL's technology to multiple technologies, new formulations, and new indications.

The 2021 financial year saw an expansion in R&D as part of the overall strategy to make CLINUVEL's proven technology available for more patients with unmet medical needs, as well as broader targeted groups at high risk from exposure to ultraviolet and high energy visible light.



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Key Events 2021

Constructing CLINUVEL's Future: the Next Phase

The past year witnessed multiple key events in CLINUVEL's commercial operations, research and development program, financial performance, communications and analyst coverage, and advanced strategy which collectively, are forming the future of the Group.

Since the end of the financial year, and in addition to the 2021 financial results and dividend announced in August 2021, we have achieved further progress in the R&D program.

Continued Strong Financial Performance

5th consecutive
Annual Profit Delivered

4th consecutive
Annual Dividend Declared

5th consecutive
Annual Positive Cashflow

Wider Engagement with the Investor Community

Jefferies Australia Initiates Research Coverage of CUV
First Virtual AGM
Operations Update Webinar I
Wilsons Initiates Research Coverage of CUV
Strategic Update I
Strategic Update II
Chair's Interview Series

Growth of CLINUVEL

Four Divisions Announced

Enabling Patients to Access Treatment

Australian TGA Approves SCENESSE® for EPP

SCENESSE® Granted Market Access Israel

First Full Year of Distribution of SCENESSE® in the USA

Expanding R&D

PRENUMBRA® Second Afamelanotide Formulation

Opening of VALLAURIX RD&I Facility in Singapore

DNA Repair Program Announced

First XP Patient Dosed in DNA Repair Program

First Global Human Trial in an XP-C Patient, Evaluating the Effects on DNA Repair

Arterial Ischaemic Stroke Program Announced

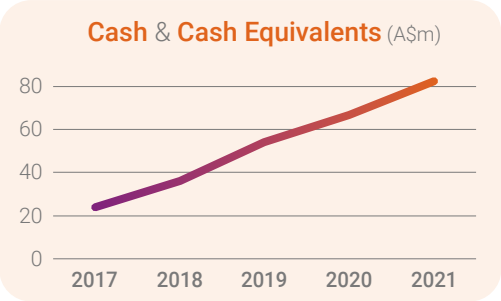
SCENESSE® in DNA Repair Approved for Healthy Volunteers

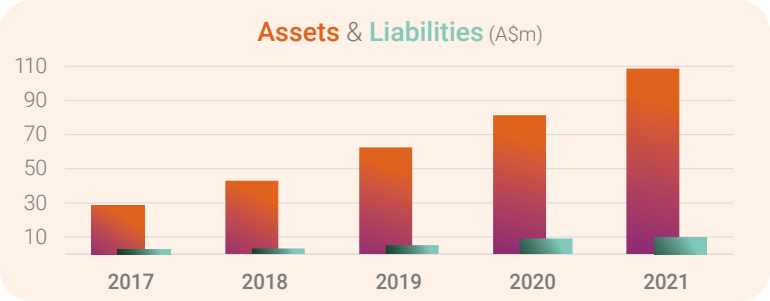
DNA Repair Program Extended to XP-V Variant Patients

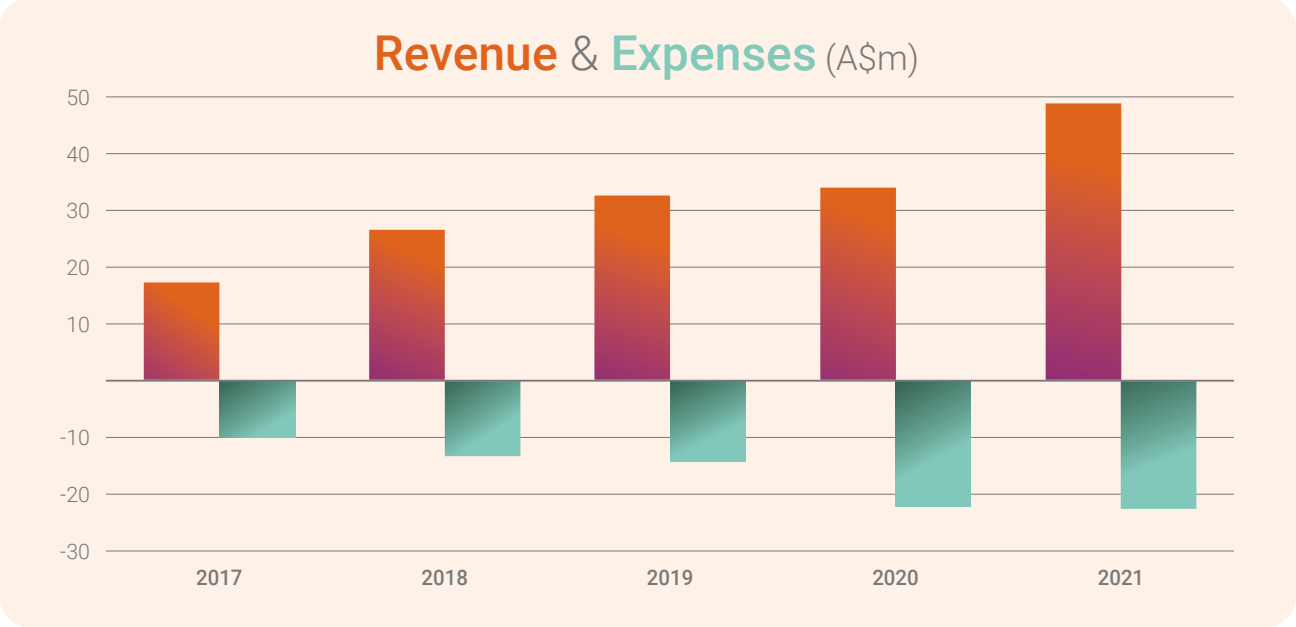
First Stroke Patient Treated with Afamelanotide

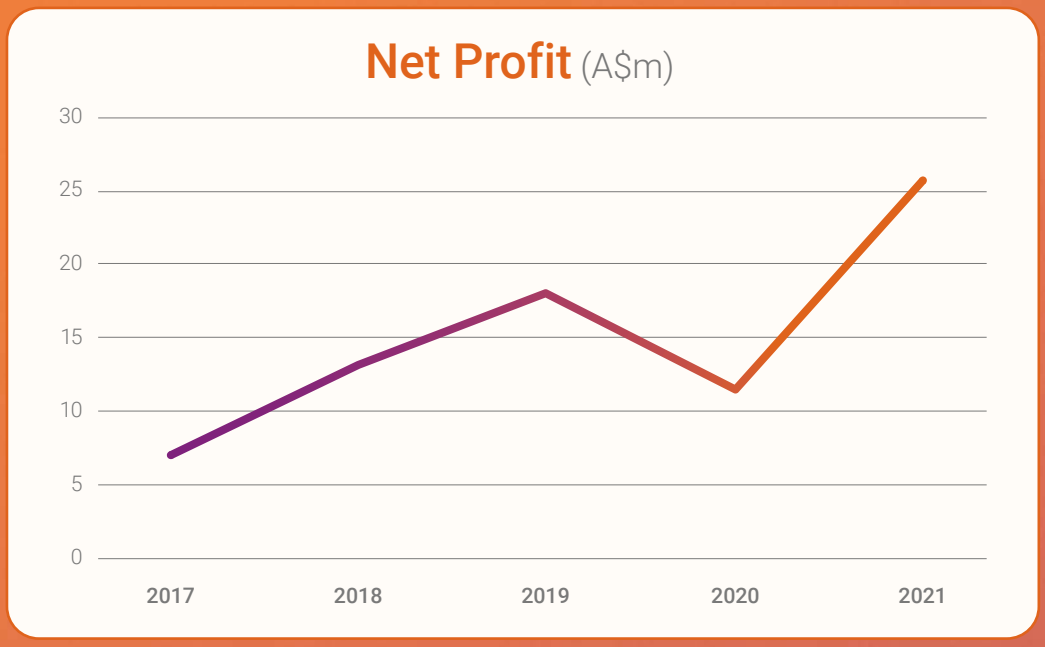
Advancement OTC Product Lines

Financial Highlights 2021









Strong Foundation for Growth:

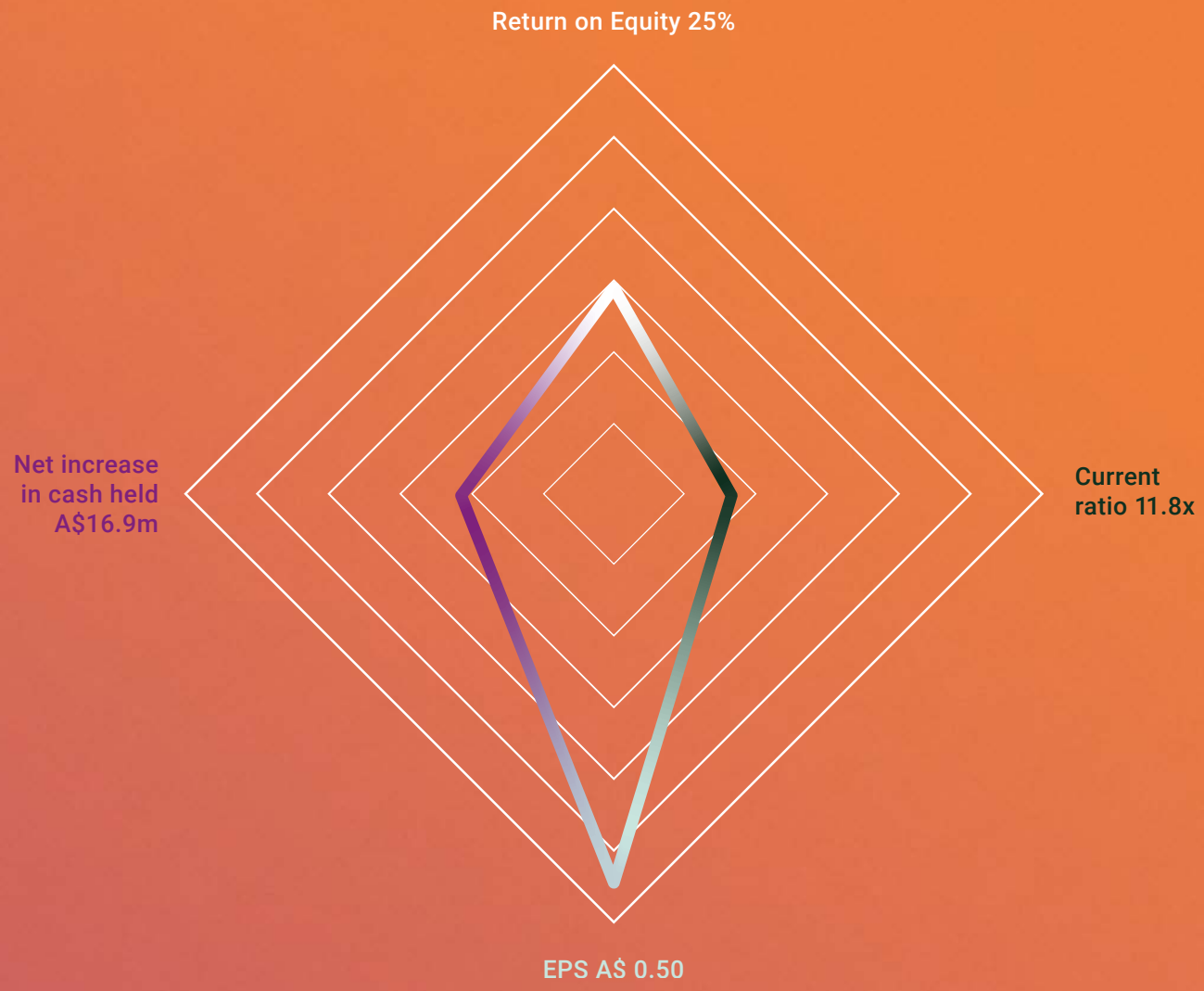
Five Consecutive Years of Positive Cash and Profit

Commercial operations commenced in June 2016 with the first post-authorisation distribution of SCENESSE® in Europe. CLINUVEL's direct distribution model has been implemented effectively with cautious cost control. We have established a track record of positive cash flow and profitable outcomes over five consecutive years to provide a strong foundation to support the growth and sustainability of the Group.

Revenues have grown over the last five years with the start of sales in the USA reflected in the 2021 outcome. Expenses have been well controlled, rising in 2020 to support key growth initiatives with an abatement of growth in 2021 due to the timing of planned expenditures on the expansion of the research and development program. A net profit for the fifth consecutive year in a difficult operating environment points to the sustainability of commercial operations.

Assets have grown strongly with the accumulation of cash reserves sufficient to finance planned organic growth. Liabilities are at a minimum and are composed of trade payables and leases of operating assets.

Key Indicators FY 2021

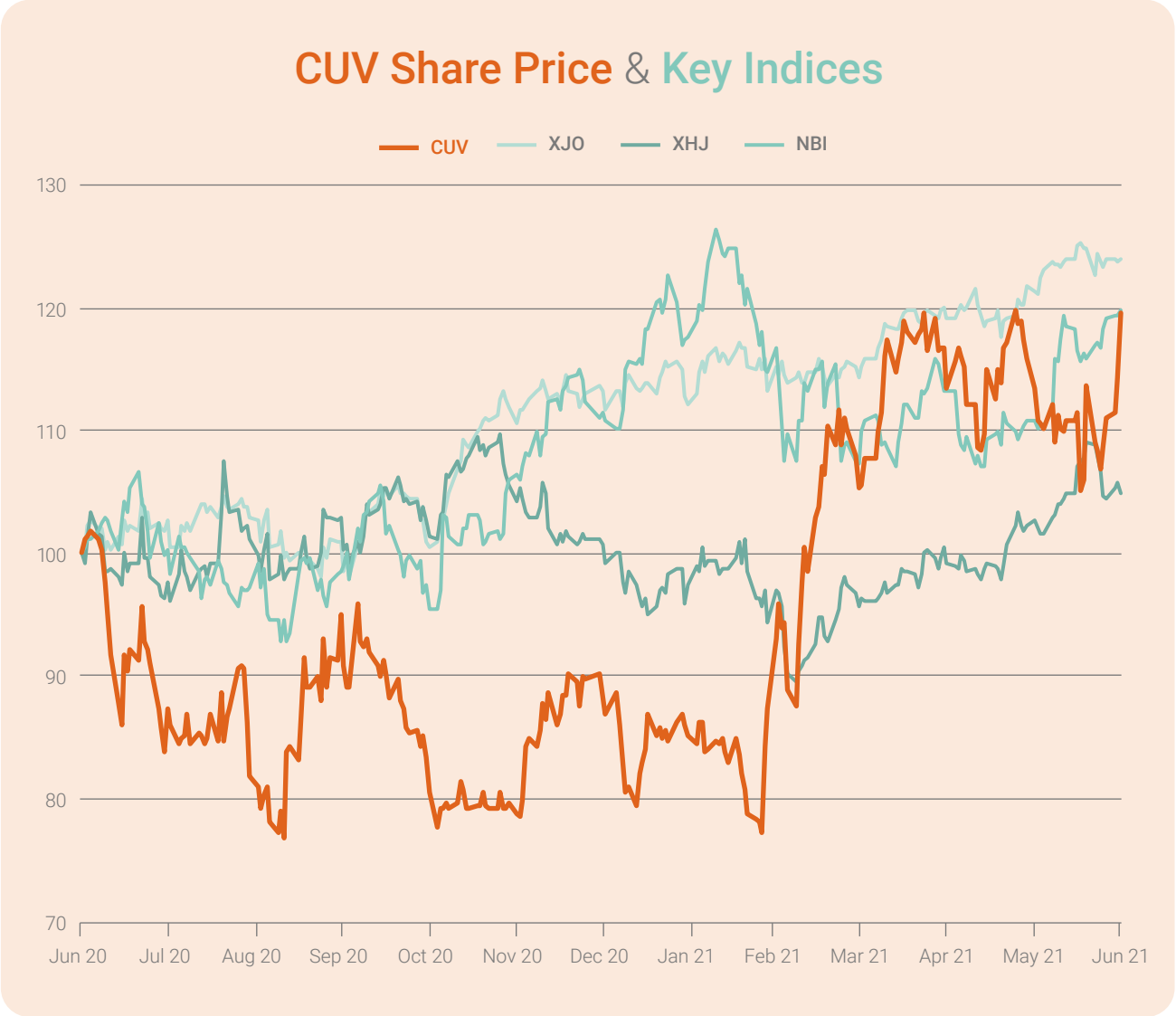


KEY INDICATORS

CLINUVEL's liquidity is very strong due to high cash reserves (which make up most of the current assets), relative to modest liabilities, mainly composed of trade creditors.

Company debt is minimal, consisting of leased operating assets. There is no long-term debt.

Due to ongoing profitability, the Company's return on equity and earnings per share are positive and are rising year on year.



SHARE PRICE

CUV's share price trended downwards in the first half of the 2021 financial year. Following the announcement of the December 2020 half year results in February 2021, the share price rose strongly and ended the year with a rise of 19.7%. This is in line with the 19.8% rise in the Nasdaq Biotech Index (NBI) and exceeds the 5% increase in the S&P/ASX 200 Healthcare Index (XHJ). The broader S&P/ASX 200 Index of the largest capitalised listed companies in Australia rose 24% in the 2021 financial year.

The indices above are based as at 30 June 2020 = 100 to show their absolute and comparative movements during the 2021 financial year.

Mission Vision & Values

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 places 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

- Technology
- Approach
- People & Environment
- Knowledge Building & Sharing
- Respect & Appreciation

CLINUVEL's Values

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

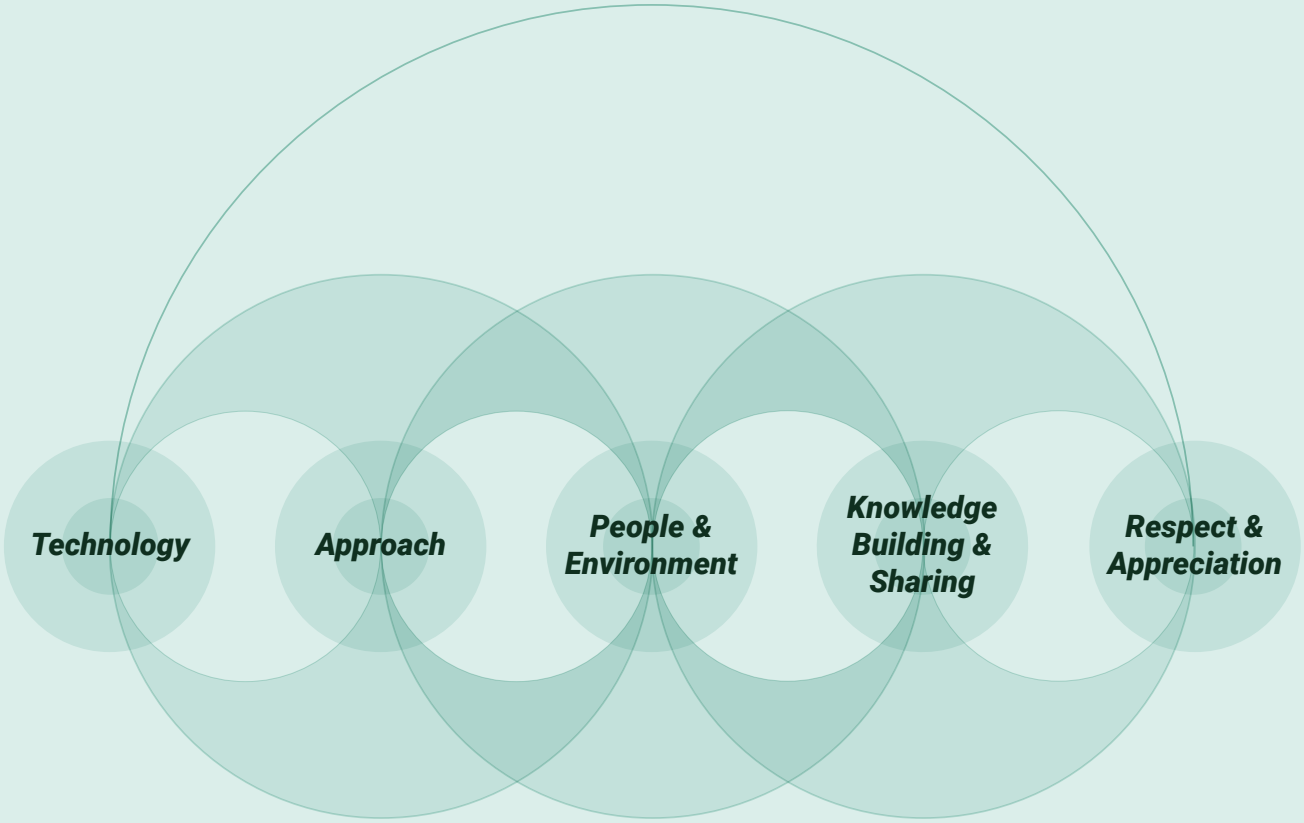
These fall into five main categories; **Technology, Approach, People and Environment, Knowledge Building and Sharing,** and **Respect and Appreciation**.

Technology

We create, develop, advance, and offer 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 are vigilant not to become complacent and recognise that success can only come from the identification and mastering of obstacles. Our staff are optimistic and focused.



People & Environment

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

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

Respect & Appreciation

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

Chair's Letter

Dear Shareholders,

Strategy Drives Value

CLINUVEL's history demonstrates that a long vision will eventually lead to value for society and shareholders. The CLINUVEL Board has long supported an often difficult strategy to reach its goals, and the plan is just starting to unwind as new shareholders are discovering our consistent approach to the business. I am positive that further focus will lead to more growth and results and my task is to see that we can keep and add to our existing team of managers. This is CLINUVEL's story where many successes and even some setbacks have taken us to present successes.

As Chair, my mandate is to guide the turnaround and viability of the Company, and since the strategic reset from late 2005 our primary focus has shifted to growth and expansion of skills, services and products. As we progressed the Company's strategy, there were many problems that needed to be solved and many errors that have been avoided. The successful progression of our strategic path required an entrepreneurial mindset, being prepared to take calculated risks to benefit patients and shareholders.

As a Board, we are united by the desire to contribute to society in particular to patients who have an unmet medical need. The commercialisation of the drug over the past five financial years and the track record of the team has driven performance that is enviable amongst life-science companies. The Board have overseen critical decisions taken by a committed team of professionals. Now, we find ourselves again at a decision moment after a difficult but successful year.

An Excellent Financial Year

The financial year ending June 2021 is a record year for total revenues and the achievement of profit under the most demanding COVID conditions. Top revenues of A$48.451 million and profit before tax of A$25.713 million are excellent outcomes and marks the Company's fifth consecutive year of profit and growth.

During the past financial year, the CLINUVEL team in various locations around the world have had to communicate, co-ordinate and progress their work remotely and worked in scheduled shifts in the laboratories. We saw an increase in the number of EPP patients receiving care and prudently managed our supply chain to meet rising patient demand. We have advanced our research and development initiatives to underpin the diversification and sustainability of the Company for the future. In addition, we have excelled in capital and financial management, maintaining our share capital. We have no debt and have declared the payment of a dividend four years in a row to again show our appreciation of shareholders, particularly those who directly funded the development of the Company over many years.

New Divisions to Support Expanded Operations

We now maintain operations in seven countries. Operations in Australia, the United States, United Kingdom, Switzerland, and Singapore have been enhanced by new operations in Ireland, and following Brexit most recently, Monaco. During the year, we positioned our Company for the future with four divisions:

- Pharmaceuticals, the core of our business;
- Healthcare Solutions, for dermatocosmetic non-prescription products;
- Communications, Branding & Marketing, to communicate our activities and reach new audiences; and
- Manufacturing, to improve our self-reliance.

These Divisions are underpinned by the Singapore based Research, Development & Innovation Centre, commissioned in August 2020 to progress new product development opportunities for the Group.

Pipeline & Development

CLINUVEL has expanded its research and development program over the past year:

- We have commenced a clinical study in acute stroke, specifically arterial ischaemic stroke (AIS), which has a high unmet need;
- The DNA Repair Program is underway with clinical studies in xeroderma pigmentosum (XP) patients set to commence;
- A new topical product is under development to add to our medical product portfolio;
- We continue the development of a formulation of afamelanotide for the treatment of children; and
- PRÉNUMBRA®, a liquid formulation of afamelanotide, is in development.

Incremental Value

Many of us have invested in CLINUVEL because we want to see something good for particular patient groups who have no other medical choice. The pursuit of this objective has resulted in significant incremental value to shareholders over the years and, in many ways, FY2021 has been an important year to commence the next phase of CLINUVEL's progress.

In staying with a specific strategy, we have seen CLINUVEL's market performance improve over the years. **Shareholder returns based on the change in the CUV share price are impressive.**

Shareholder returns	
15 years	692%
10 years	1,487%
5 years	591%
1 year	28%

The increase over the last five years (30 June 2016 to 30 June 2021) in CLINUVEL's market capitalisation is 645.8%.

To continue this performance, I believe it is critical that we retain the people who have proven their worth in building the business over the years and in continuing to attract new talent. We have increased our staff significantly over the last few years to support the expanding activities of the Group. A very high percentage of our staff become integrated and perform at high standard. Despite some attrition with a demanding workload, we generally select personnel with a positive attitude to winning, consistent with CLINUVEL's culture. The best talent requires not just a positive environment and inspirational objectives, they also see their remuneration and incentives grow over the years as they contribute meaningfully to the Company's success.

CLINUVEL has taken a lead in setting incentives at the executive leadership level to encourage entrepreneurship, measured risk taking at highest level, a behaviour close to my heart, and one which, I believe, enables the best and most effective results. **I cannot be clearer that the retention of key personnel from the CEO and senior executives, through to personnel of the Company at all levels, is essential for this Company to come through the lows and achieve the highs.** The Board, through the Remuneration Committee, which I continue to lead as Chair, have reviewed and improved further the Company's remuneration arrangements. Together with remuneration consultants and the legal team, we undertake annually analysis of peer groups of comparative companies resulting in the remuneration of executive management detailed in the Remuneration Report.

We also recognise and accept as a Board that the minority voting can influence the direction of the Company with the majority of shareholders not taking the time to vote for resolutions proposed to them. In the worst case, the voting outcome can have an impact on the longevity of management and the stability of the Company. During the year, the Board has supported initiatives to communicate in more varied ways, to reach more shareholders, and to assist a broader understanding of the Company. The Chair's Letters, issued in November 2020, March 2021, and May 2021, provided insights into the Company's plans, the role of entrepreneurship and how this links to our approach to executive retention and remuneration. Regular and more detailed News Communiqués were issued on the progress

of the Company on its many initiatives, and these continued to be translated to German for shareholders in Switzerland, Austria, and Germany. We also launched new initiatives in public communications during the year to assist general understanding of the Company. We provided shareholders the opportunity to learn about the Company through:

- An Operations Update Webinar hosted by Mr Bull of investor relations, engaging Mr Keamy and Mr Hay on financial and operational issues;
- Strategic Updates I and II with the CEO's video in the second update attracting much positive comment; and
- A series of video interviews I gave in Amsterdam.

In addition to many meetings and conversations with shareholders, we also made an effort to connect with shareholders who hold their shares through one or more custodians; time will tell how effective this process has been.

Vision

As Chair, my role is to oversee the Company and its financial independence. I am very pleased how the CLINUVEL team has consistently driven the progress of our strategy and objectives, and found solutions in situations and times where there were none to be found. We are an innovative company, and more is coming, noting that patience is required in this industry and in the prevailing operating environment. FY2021 has shown the resilience and sustainability of the Company's operations, and as I said many times the performance of the company is dependent on our managers. The Board is planning for succession of some of our key managers and personnel so that the Company will continue to thrive on from its current basis.

Based on the well performing and growing commercial operations and the potential being built in the R&D pipeline, I am very optimistic for the future of CLINUVEL and the benefit this will confer to all stakeholders, including our valued shareholders.

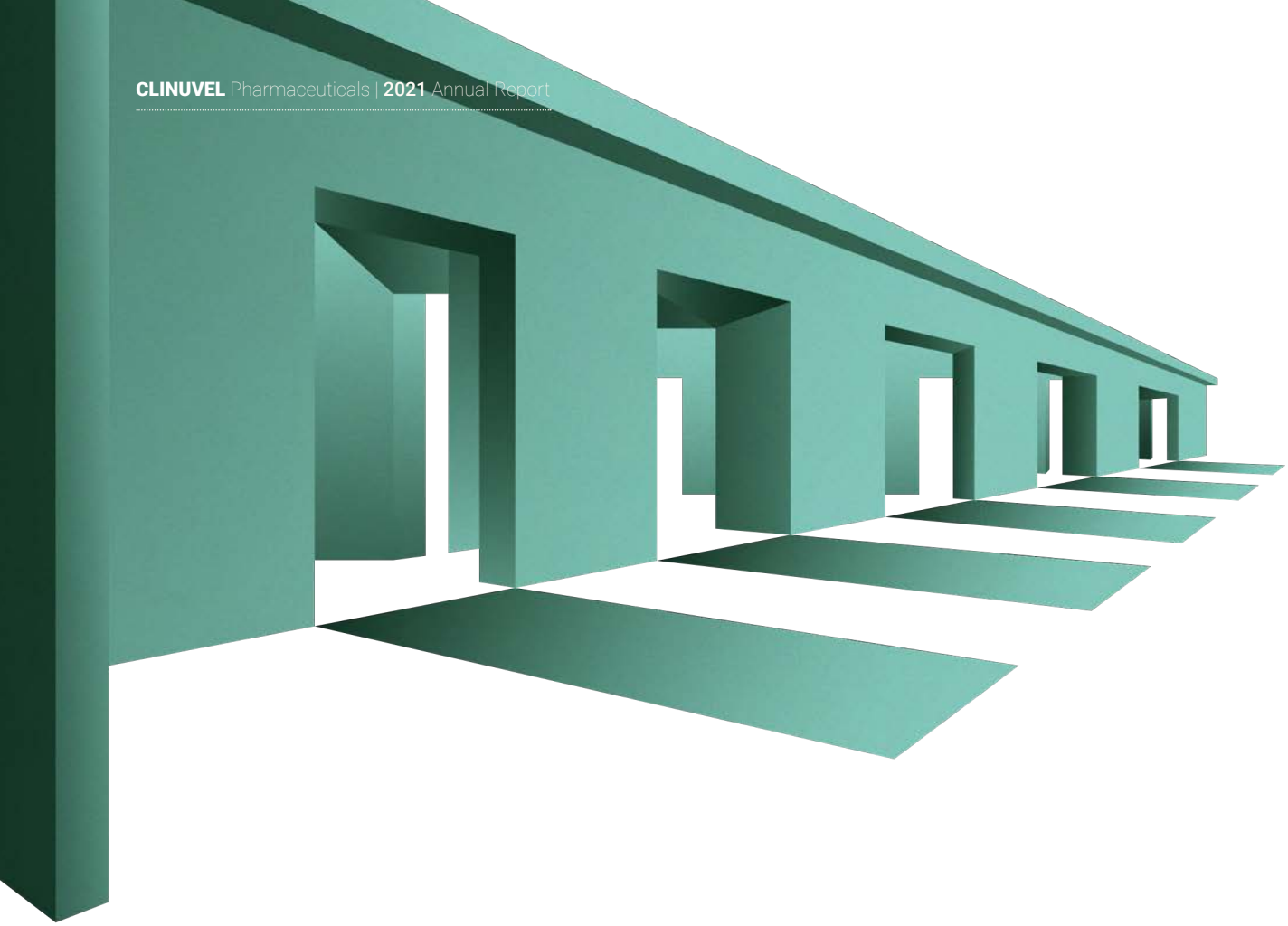
I thank the leadership and drive of our Managing Director, Dr Wolgen, our CSO Dr Wright and CFO Mr Keamy, and the entire global staff of CLINUVEL for their efforts over the past year. This is also the place to thank the Board of Directors for the work, passion and various insights they have brought the past year to progress the Company.

I look forward with optimism to update you on our progress during FY2022.

Willem Blijdorp
Chairman, CLINUVEL Group

CORPORATE GOVERNANCE

CLINUVEL Pharmaceuticals Ltd and its Board are committed to establishing and achieving the highest standards of corporate governance. The Company's Corporate Governance Statement for the year ending 30 June 2021, based on the Australian Securities Exchange Corporate Governance Council's (ASXCGC) Corporate Governance Principles and Recommendations, 4th Edition, can be found on our website at https://www.clinuvel.com/clinuvel/company-overview/corporate-governance



Managing Director's Letter

Dear Shareholders,

Review of 2020-2021

I look back on a year marked by several distinct highlights within our Group, and it is fair to state that it has been far from easy to operate under the worldwide conditions. **Despite the restrictions our teams faced, 2021 will go into our history as one with unforgettable moments to cheer our teams' performances in serving targeted patient populations.**

The zenith was undoubtedly our team's ability to overcome the numerous delays occurring in the supply chain and drug distribution to hospitals under the COVID-19 conditions. We appointed new EU and US facilities providing cold storage for our hormonal therapy, we succeeded in overcoming stricter import criteria and managed to distribute, despite hospital restrictions. In categorising our treatment as innovative medical care administered within secondary care facilities, the greatest challenge had been to prolong the supply of SCENESSE® to selected hospitals, which were all operating under very limited schedules.

Additionally, we faced restricted schedules of (EPP) patients' appointments as critical care patients had obtained priority status within hospitals.

As our teams navigated barrier nursing and protective isolation in university centres and specialised centres, we spent most nights through various time zones finding novel solutions for problems nobody had ever faced before. There are quite a number of senior managers who deserve public acknowledgement for their mammoth achievements over the past 12 months, but I would risk short-changing all others in the Group who have equally pulled their weight behind the scenes and made 2021 the most successful year in the Company's history. It is one not to forget.

Another critical observation is that **the silent credit our team has built over the years vis a vis regulatory authorities, the EMA, HPRA and FDA, has led this year to a remarkable degree of collaboration and support in assisting CLINUVEL to operate a just-in-time drug supply in both continents**. The intangible currency our team has accrued during two decades of dialogue with the three leading agencies had become quite apparent from the exchanges with the regulatory authorities, who are holding the final card when it comes to drug supply. I witnessed first-hand how longstanding relationships between our managers and regulatory decision makers in Silver Spring (USA) and Amsterdam (Netherlands) has led to constructive dialogues in seeking solutions to serve patient populations with a chronic disease, i.e., porphyria. The unscheduled by-product of longer term adherence to strict plans (namely risk management plans, and quality systems), but also the consistency of our lead managers, is a surprising working relationship between our technical staff and these three agencies, particularly at times when it really mattered.

This year, we disclosed how the Company has gradually balanced its clinical research attention between brain and genetic diseases. As part of our planning, we treated the first three patients with ischaemic stroke, a condition affecting large swaths of society. With great satisfaction, we observed how the first stroke patients with a history of heart disease responded to treatment as part of trial CUV801. Although early days, we recorded first safety data from this new population at risk. The COVID-19 restrictions caused delay in recruitment and, as the site was working with limited staff, clinical studies became secondary to clinical care of stroke patients.

We treated the first xeroderma pigmentosum (XP) patient, while Ethics Committees and National Competent Authorities deliberated at length and with great care so as not to expose XP patients too early to a novel hormonal treatment. At the time of writing, the first Ethics Committee has provided a green light for the first study in XP patients. The mid-term goal is to evaluate the effect of afamelanotide on photoproducts affecting the DNA helix of these patients. The scientific data generated in XP trials will further assist CLINUVEL's scientific team in their innovative work on topical products, with the aim of demonstrating beneficial effects on UV-provoked damage on DNA.

Another highlight was the fifth consecutive commercial year, when we adhered to the uniform drug pricing policy in Europe, while setting a first and similar equitable standards across all US states. The response from insurers and healthcare providers has been undividedly positive, providing us with further affirmation of CLINUVEL's differing approach to pharmaceutical markets. In addition, the first market access obtained in Israel was an unexpected event led by Mrs Colucci and her team, while discussions with the Ministry of Health and individual insurers had been encouraging throughout 2020 and 2021. As we obtained the green light from the National Committee for Healthcare ("Healthcare Basket"), we put the framework in place to import SCENESSE® into Israel. In the meantime, the first Israeli EPP patients have received the drug.

A milestone was undoubtedly the 10,000th SCENESSE® implant administered, equating to 70,000 drug exposure days. This remarkable billboard requires a longer discussion about the product's consistency concerning its safety profile and future implications for our programs; we will come back to this on another occasion. However, the statistics of safe drug administration allows for further developments of melanocortin drug candidates in humans.

Overall, we saw our headcount increase with professionals adding new skills to our existing teams. Working remotely brought out the advantages of saving time from commuting, while accentuating the frustration of working from home, deprived of human interaction. The lockdowns required from each staff member in our seven offices, longer term discipline and focus to communicate on-screen.

Other highlights were the progress of the PRÉNUMBRA® program, the performance of the Singapore team and the innovation driven by leading managers Mr Choy, Ms Yu and Dr Ng and their loyal staff. All in all, our team in Singapore, led by senior managers to get through the circuit breaker, displayed a high level of discipline.

In staying with high-risk populations, albeit in a non-medical market, our division of Healthcare Solutions advanced the development of product lines to mitigate solar skin damage and skin cancers. With this total focus on the wellbeing of patients and selected populations, we expanded our company with scientific talent, a Communications, Branding and Marketing team, and additional professionals with expertise in chemistry, manufacturing, and control.

Quarter on quarter, we recorded better than expected revenues and higher net profits. We managed to expand our operations and investments in research-development-innovation, while restricting other variable costs to see the Group eventually increase total costs by a marginal 2%. **Our financial management remained scrupulous when it concerned the overall profitability of the Group**.

Our finance team expanded. New accountants and managers fitted in well, setting out to work on the financial households of our subsidiaries. We adopted a uniform accounting practice using new systems easing the consolidation of our financial reporting. Our finance team passed a 16th year of biannual audits, and it has been obvious that its accomplished leadership is one of the main reasons behind CLINUVEL's performance. I have shared my views on the importance of having a robust finance team at various occasions during our frequent News Communiqués.

First-rate in execution, the excellent financial performance of FYE 2021 provides the Company with future choices and a basis for further growth. **Our consistency in financial management answers my personal views to establish a Group able to withstand unexpected oscillations, not rendering the Company dependent on either equity or debt financing**. While we remain aware of the cyclical nature and risks in our sector, we prolong our chosen course by investing wisely in people and technologies.

Common Thread

Our company's operations are centred around the unaddressed needs of patients, and our overall success hinges on patients' response to our therapies as well as physicians' assessment of efficacy. As a pharmaceutical group entirely committed to improving the lives of patients, all our corporate functions are aligned to serve primarily medical communities. This year, we have added wider populations at risk; we now focus part of our efforts to serve populations at high risk of incurring a second fatal stroke, as well as XP patients incurring debilitating and fatal skin cancers.

Throughout all our work and all divisions runs a red line, longitudinal care. Our mission is to communicate and engage long term with our patient community, medical community, researchers, stakeholders, regulatory authorities and shareholders. Our management team has been together a long time, in some cases fifteen years, and part of our business is to follow up, manage and monitor the relationships we have built over time with all forementioned stakeholders. I regard tremendous clinical and therefore business value in longitudinal management of key protagonists. **Patients who have remained on SCENESSE® therapy deserve a consistent and long-term communication with and from the Company, and we take the same approach to other stakeholders**.

I look back at a fundamental discussion which took place in March. German-speaking shareholders posed questions about CLINUVEL's mission and its broader position

within the pharmaceutical sector. Here, my views remained unwavering, as I believe CLINUVEL is here to serve the needs of unattended patients and populations at risk.

By communicating and fulfilling this clear mission, we stay true to a common and recognisable course of developing and commercialising unique products. Central to our objectives are the various unaddressed medical populations and individuals prone to incurring cerebral damage, but also those in danger of incurring multiple often fatal skin cancers as a consequence of the genetic disorder XP. This clear mission has already provided value to first end-users, porphyria patients.

A pertinent question was why CLINUVEL had pursued the current strategy?

As commented on at previous occasions, this Board and managers take strategic decisions based on a variety of criteria which remain unique to CLINUVEL and befit our group of professionals. Our strategy could be interpreted as perhaps differing from that of peers, however in general there is little point of comparing with motives that apply uniquely to others. So why then this strategy?

In the case of porphyria patients, we had identified a group of individuals who had remained unattended; no other company in the history of drug development had bothered to pay medical attention to these patients. Having introduced the first systemic photoprotective therapy to these patients has doubtlessly been a meaningful cause, as we learn day to day from their families and caretakers.

In 2006, we first analysed XP and its impact on patients. It became our main objective to treat this population using a systemically-targeted melanocortin. For those who had followed CLINUVEL closely, a long road has been travelled to gain access to these patients who are highly prone to develop and succumb to four types of skin cancers. Unaffected by the passing of time, our quest to become the first company globally to offer a systemic therapy to XP patients had never faded. However, we were driven to execute a clinical and regulatory plan to gather necessary safety data "beyond reasonable doubt". In selecting EPP, a condition characterised by absolute light intolerance, we started our journey towards XP. In simple terms, in EPP we first provide systemic photoprotection, while in XP we not only aim to achieve effective systemic photoprotection to slow down or mitigate the development of skin cancers, but we are on our way to prove the effect of melanocortins on photoproducts (DNA lesions) caused by UV and loss of cellular integrity.

When progressing the use of afamelanotide in brain diseases, in the stroke population, we had identified the life-threatening nature and dramatic impact a brain blockage (clot) has on patients and their immediate family. We realised that the majority of patients suffering a cerebral infarct do not receive therapy. Empathy, and the desire to do something about the problem, coupled with technological opportunity, drove our decision to take on this clinical challenge.

We selected a further indication for SCENESSE® and are overcoming various hurdles to extract and retain value of the use of afamelanotide. As we progress with regulatory authorities, Institutional Review Boards and expert physicians, we plan the start of an innovative trial. We are aware of the risk of translating the use of afamelanotide, but collectively our teams assessed the long-term benefit being greater than the numerous risks.

Furthering our line of thoughts, by grouping the three addressable populations for our first over the counter (OTC) product line, we had strongly identified untreated and unattended groups in the general population. Immune compromised patients, patients with a history of skin cancer(s) and outdoors professional sportspeople at risk of chronic UV and HEV exposure are all populations poorly addressed by the dermatocosmetics sector. Armed with our expertise, understanding of the risks these three groups share and the long-term effects of UV and HEV exposure, it was only natural to focus on these populations.

In numerous past News Communiqués and corporate communications, we have highlighted the insidious enemy of CLINUVEL, its ongoing success and risk of complacency. With that, we try to instil in our managers and staff, but also at Board level, a continuous hunger to improve the business, vary our approach and sharpen decision making. We work on the basis of common objectives, and this cry to remain agile at all times is by no means sufficient to guarantee growth and success, but at least it eliminates a silent factor one seldom wishes to address in companies.

The ongoing analyses of the CUV business, the anticipation of unknown risks, the repetitive modelling scenarios, and courage to play out unthinkable options helps to deliberate extreme projections. This practice triggers discussions among Board members on dramatic scenarios one would most likely not contemplate if one would not push each other to fathom the unthinkable scenarios, both favourable and unfavourable.

When balancing CLINUVEL's risks versus commercial present and future rewards, I use my experience and analyses of available information while surrounding myself with voices, minds and professionals one has come to respect owing to their ability to adopt unexpected viewpoints. I have exchanged with great minds, business leaders, entrepreneurs and analysts and have concluded that a sustainable business not only hinges on one's ability to take risks, but equally on the ability to analyse and frame risks in such a manner that the execution of the adopted plan becomes measurable and segmented. The segmentation then offers frequent evaluation of direction and performance at set timepoints. It is a formulaic approach which has worked well for us thus far. In summary, CLINUVEL selects its direction and course of development, both for pharmaceutical products and OTC lines, on the basis of compassion for those in society who are left unattended, untreated and unheard.

Vision 2022

The new world, post-COVID-19, will not resemble the old one. Staff will operate in shifts, coming to the office once per week while working remotely the next. The time of large office spaces, all working under one roof every day of the week, seems to have fleeted and is not destined to return. We are already selecting staff, setting up people to work at distance while coming in for office meetings at short notice. In 2022, off-sites will be more frequent, while flexibility will be required from employer and employee.

In this company, we are all driven to fulfil this one common mission: we share a deep empathy for the patients and individuals at risk, who are not attended in society. Some of us are personally affected by these conditions, some of us have family members in our immediate environment and some of us deeply relate to these patients and selected groups. Under this roof, without a single exception, we are all connected by doing something meaningful for others, fulfilling a worthwhile cause for patients – and individuals at high risk – by restoring for them a balance to resume a normal life, one free of restrictions. In pursuing this mission, I dare to think that the first successes CLINUVEL has attained have already brought the medical community therapeutic advantage, relief and satisfaction. CLINUVEL will continue this journey with authority, empathy and passion.

In 2022, we are looking to further our Board's views on the macroeconomic issues affecting the Company, whereby we generally seek to invite the most diverse and contradictory viewpoints asking for a healthy dissent to arrive at higher quality decisions.

This attitude to seek unorthodox discussions can be regarded somehow as counterintuitive to build value and it certainly requires much energy. As a Board, however, we will continue to operate from the principle that past decisions may have been sound to bring the Company to its present level of operational success, but that the constantly changing dynamics in the markets and tension within the sector require us to challenge each other frequently to take adequate decisions to generate incremental value.

The foundation and legacy of a company play indelible roles in taking decisions, and the first mandate to rebuild the Company's ramparts may have been fulfilled, however the second part has been looming ever since the management team had shown commercial progress: how to build a sustainable company based on a variety of products and services.

Conclusion

Among all the euphoria of the recent increase in CLINUVEL's value, I see the markets' reaction as the consequence of a series of decisions our team has taken over the decades, rather than a short-term reaction to our financial performance. Management decisions led to a tenacious attitude to the development of a new drug product, and to a series of choices to independently distribute the innovative pharmaceutical among selected hospitals worldwide. During the first quarter of 2021, we saw how CUV as a

momentum stock attracted many retail shareholders (>500) from Germany, Switzerland and Austria.

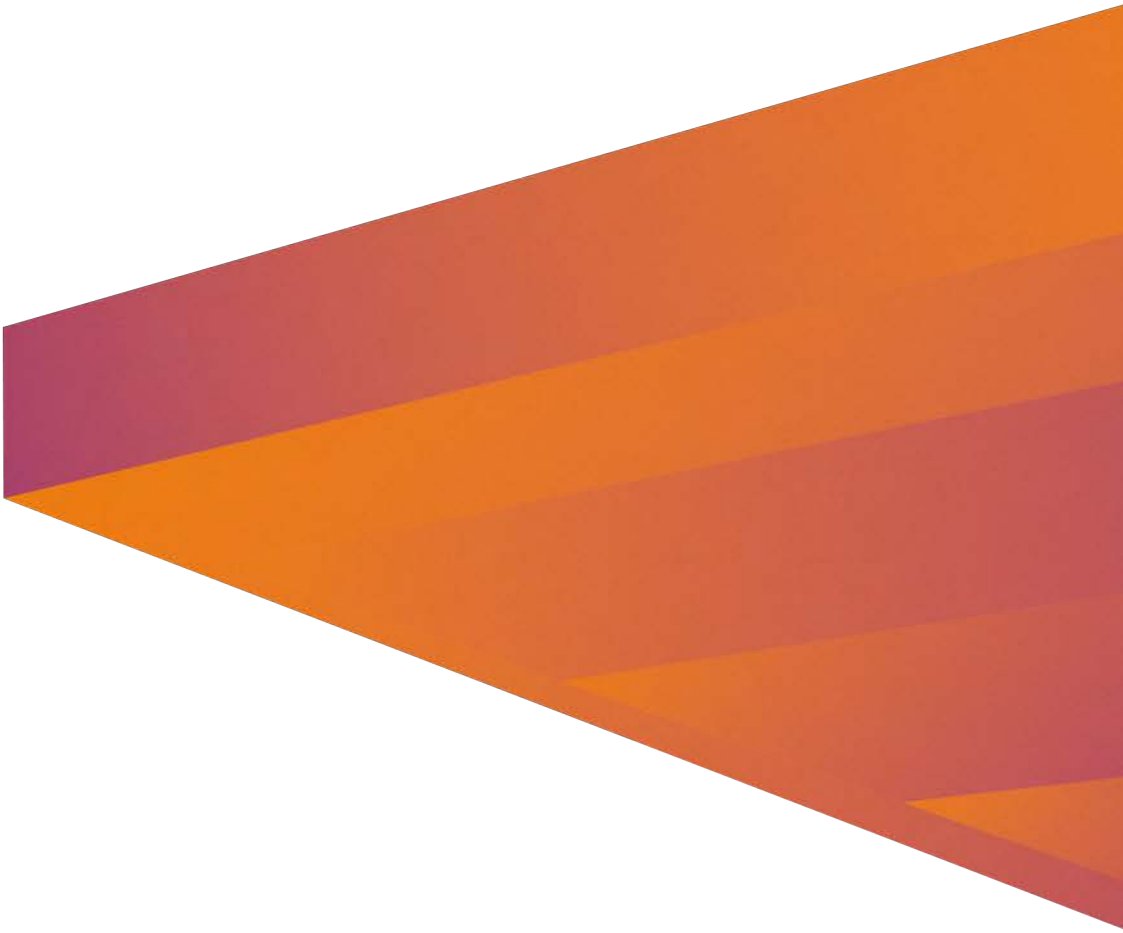
The biggest gain of 2021, however, lies in the direct corollary of these continuous decisions, since we witnessed how porphyria patients demanded continuation of treatment in spite of the travel to which they needed to commit under restricted conditions, but foremost the risk of nosocomial infections they were prepared to take in seeking treatment in hospitals. As far as I can try to be objective in my position, reflecting on 2021, I cannot see the patients' response to treatment under the most severe travel restrictions other than as the best real-world evidence of efficacy of our lead product.

Without doubt, there will be many more challenges coming CLINUVEL's way, nevertheless I place full trust in our current team. I see the ensemble as well equipped and trained to tackle the unforeseen and uncalculated events which may befall us, while this group of professionals has the stamina and vision to further develop programs and products for a variety of unattended populations.

I regard 2022 as a pivotal year when we enter non-medical distribution, expand our pipeline of pharmaceutical products and – pending the hospital restrictions due to COVID-19 – will see results in XP, AIS and arrive at agreements with FDA, institutions and National Competent Authorities to add another indication for the use of afamelanotide to our portfolio.

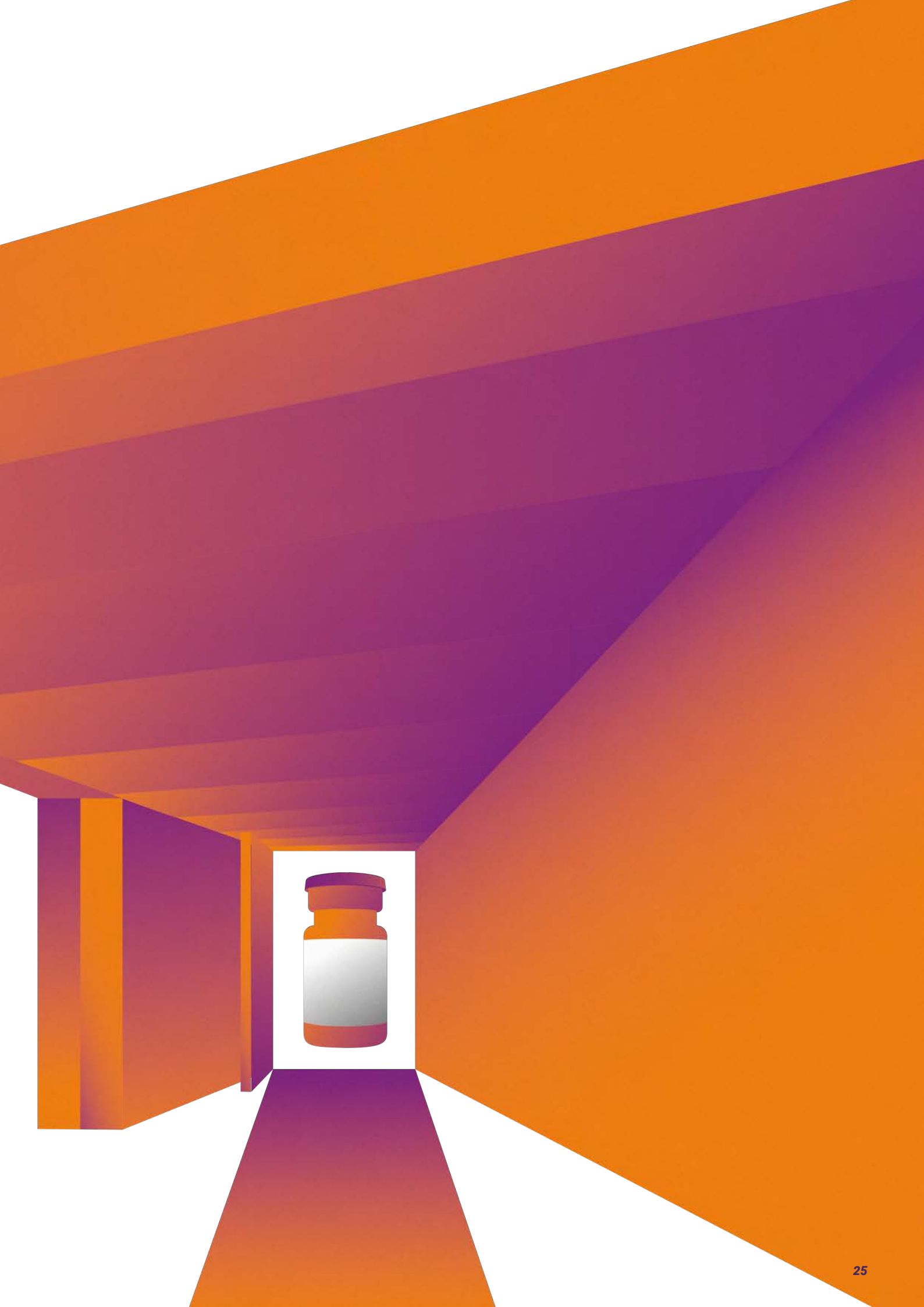
While progress requires much patience from all of us, I am confident that further benefit will be generated and received by all stakeholders. On behalf of the Board of Directors and management, I thank you for your continued support.

Philippe Wolgen
Managing Director, CLINUVEL Group



The Door Opens

for CLINUVEL's Expansion



The Door Ope

for CLINUVEL's Expansion

The door to CLINUVEL's expansion towards a diversified and sustainable healthcare company was opened by the approval of SCENESSE® (afamelanotide 16mg) in October 2019 by the US Food and Drug Administration (FDA) for adult erythropoietic protoporphyria (EPP) patients. After decades of misfortune, CLINUVEL's reviewed strategy to develop a novel melanocortin for an unmet medical need had then been validated by the two leading regulatory bodies of the world in 2014 and 2019, enabling the Group to evaluate how it could expand its operations and address broader audiences.

Strategy Reset

The initial unsuccessful strategy of the Company to the end of 2005 was to develop a drug to assist tanning of the skin as a lifestyle product. Whilst a large recreational market was receptive to such a drug, its more cosmetic than medicinal purpose was never going to be supported by the regulators and CLINUVEL thus had to come up with a brand new strategy.

In November 2005, Dr Philippe Wolgen was appointed CEO of CLINUVEL. Together with the support of the Board and a revitalised management team, the Company's strategy was reset to focus on the development and commercialisation of one drug for one indication with a high unmet medical need. This strategy met numerous obstacles and was implemented over 15 years by one homogenous team. A number of indications were researched before the genetic metabolic disorder EPP was selected as the lead indication with which to prove the novel concept of systemic photoprotection. CLINUVEL completed clinical studies over several years and built expertise in melanocortins and their role in the human body, as well as the impact of light on human biology.

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"The door not only opened for SCENESSE® to treat EPP patients in the USA in October 2019, but also unlocked the opportunity to expand the research and development program to assess the application of SCENESSE® to other indications."

The Company had commenced first distribution of SCENESSE® for EPP patients in Italy in 2010 and Switzerland in 2012 under special access programs, while in 2014 the European Medicines Agency (EMA) approved SCENESSE® for adult EPP patients. Commercial operations began in the European Union in June 2016 after agreement was reached on a rigorous risk management plan to monitor and report the patient experience with SCENESSE®. Liaison continued with the FDA on regulatory approval in the USA, with the FDA seeking real world evidence from the European programs. In October 2019, the FDA granted approval to CLINUVEL to distribute SCENESSE® in the USA and commercial operations commenced in April 2020.

Success of the strategic reset of 2005, is reflected by:

a) the increasing number of EPP patients being treated who report a positive safety experience over time; and
b) the financial performance of the Company, achieving record revenues and profit in June 2021, in the fifth consecutive year of positive cashflow and profit.

The Company has been and remains focused on the safety of the melanocortin first-in-class drug. The positive real-world patient experience builds confidence as to the implemented strategy and together with the expertise built in melanocortins, enables the expansion of research and development activities to treat a much wider range of indications and broader audiences..

Regulatory Approvals Unlock CLINUVEL's Expansion

The key regulatory approvals that have been granted reflect the acceptable safety profile of SCENESSE®, the world's first systemic photoprotective drug. This position was reached after many years of hard work to build credibility as a pharmaceutical company with expertise in melanocortins. Subsequent to the EMA and FDA approvals, the Australian Therapeutic Goods Administration and Israeli Ministry of Health granted approval to SCENESSE® for adult EPP patients in October 2020 and February 2021, respectively.

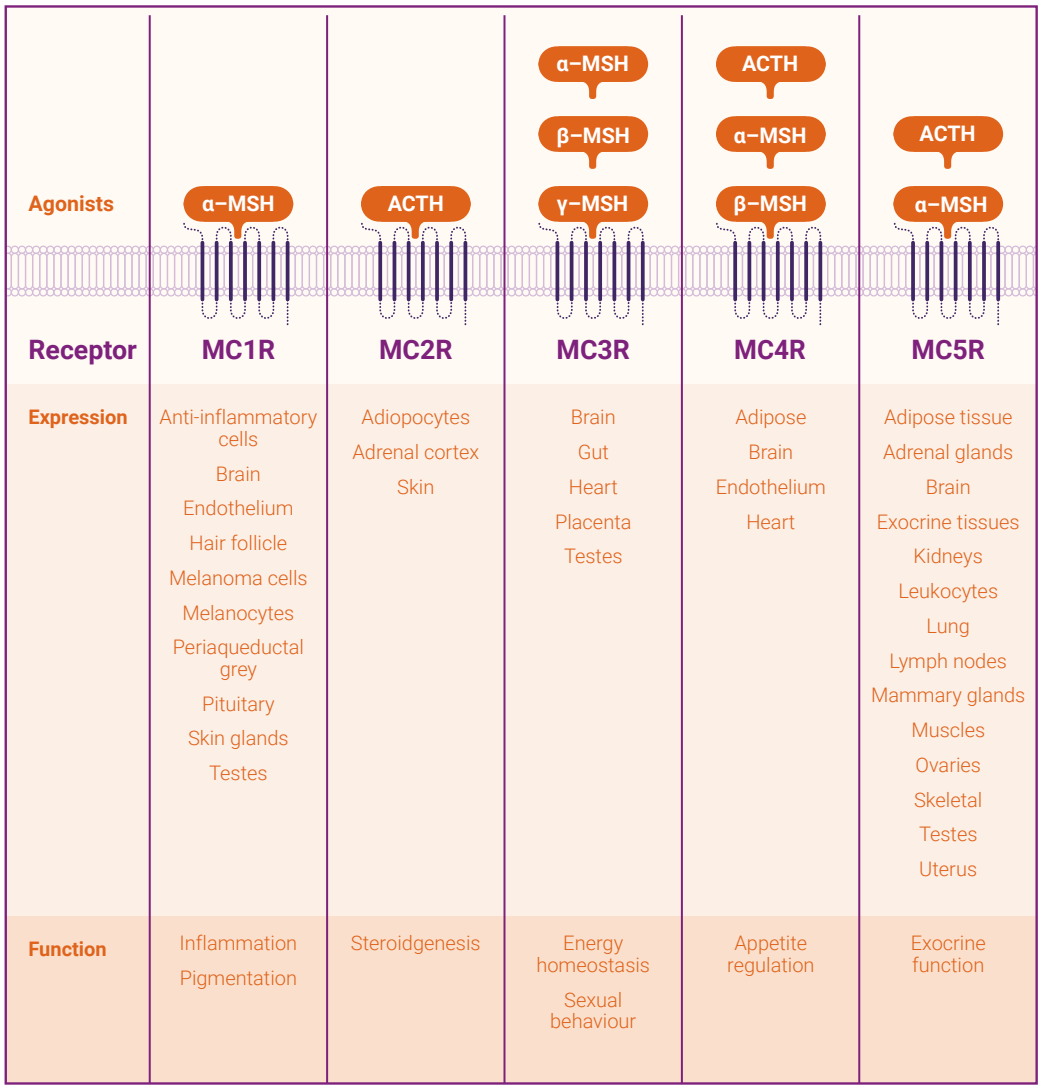
The door was not only unbolted for SCENESSE® to treat EPP patients in the USA in October 2019, but also unlocked the opportunity to expand the research and development program to assess the application of SCENESSE® to other indications.

We know from our own work, and an increasing dossier of worldwide research, that melanocortins can play a multifactorial role in the body, binding with one or more of the five melanocortin receptors (MC1R to MC5R) to influence a range of physiological activities. These range from photoprotection, repigmentation and DNA repair of the skin, to inflammation, energy homoestasis, appetite and sexual function. The table shows a global snapshot of the distribution of the five melanocortin receptors and the functions they influence.

From a foundation built on expertise and experience, CLINUVEL has progressed to allocate resources to target other unmet medical needs. The intention is to assess the ability of afamelanotide to bind with different melanocortin receptors and assist different functions of the human body. Afamelanotide is a synthetic hormone of the naturally occurring alpha-melanocyte stimulating hormone (α-MSH), which binds to receptors showing affinities to MC1R, MC3R, MC4R and MC5R. In addition to progressing our commitment to develop a repigmentation treatment for vitiligo, we have expanded the research and development program to DNA Repair – with an initial focus on xeroderma pigmentosum (XP) – and to stroke. These indications provide the opportunity to treat more patients and build upon our commercial success. The Company's focus on the research and development, regulatory approval, and commercialisation of treatments for these indications is justified based on the acceptance and status of SCENESSE® as a safe treatment for EPP.

The expertise developed in melanocortins will also be extended to non-pharmaceutical products for broader audiences within the general population at risk from ultraviolet (UV) and high energy visible (HEV) light. We assess that dermatocosmetic products are needed by these underserved groups.

"…melanocortins can play a multifactorial role in the body, binding with one or more of the five melanocortin receptors (MC1R to MC5R) to influence a range of physiological activities."



The next article covers how we are organising the Company to meet the challenges of the future. In subsequent articles of the Annual Report, we round out the activities and initiatives to build a diversified and sustainable group of companies with:

- an update on the growth of commercial operations based on SCENESSE® for EPP;
- details of the expansion of the research and development program and translation of our technology to targeted indications; and
- outline the rationale and plans for a dermatocosmetic product range to assist individuals at high risk of exposure to light.

Divisional Expansion

The 'hinges' to the expansion of CLINUVEL's research and development program have been unscrewed and how we organise our company to capitalise on the opportunities ahead is critical.

A new organisational structure has been established in four divisions.

The Focus of Each Division

- The Pharmaceuticals Division is the core of the Group, focused on developing and delivering treatments for patients with unmet medical needs.
- The Healthcare Solutions Division is concentrated on non-prescription products derived from the know-how and active ingredients used in the Pharmaceuticals Division for targeted audiences at high risk of exposure to UV and HEV light.
- The CBM Division prepares communications to wider and differentiated audiences, positioning the Group for broader engagement and is now fully resourced and active.
- The Manufacturing Division will manufacture novel formulations and products for CLINUVEL and for other operators in relevant sectors.

The Divisions are supported by the Research, Development & Innovation (RDI) Centre based in Singapore which opened in August 2020 and was featured in last year's Annual Report.

The Purpose and Objectives of the Singapore RDI Centre are to:

- undertake a research program focused on molecular profiling, peptide chemistry and polymer and formulation sciences; and
- commercialise innovative pharmaceuticals and new over-the-counter product lines.

Growth of Commercial Operations– SCENESSE® for EPP

The commercial operations based on the distribution of SCENESSE® for adult patients with erythropoietic protoporphyria (EPP) continued to progress in the 2021 financial year. The key developments and achievements in key jurisdictions are outlined here.

In Europe

- Demand for SCENESSE® near normalised during the 2021 financial year after an initial adverse impact of the coronavirus pandemic in the 2020 financial year
- Patient continuation on treatment remains above 94% in the European Economic Area
- Progress has been made in extending distribution of SCENESSE® to patients in more European countries
- Expert physicians have published data on the use of SCENESSE® to treat EPP patients

In the USA

- April 2021 marked the first anniversary of the commencement of treatment in the USA
- Over 40 Specialty Centers have been trained and accredited to provide treatment to patients across the USA
- The number of private and national insurers agreeing to reimburse the cost of treatment exceeds 60
- Considerable effort has been exerted to obtain a set of codes for the drug and the treatment to smooth the administrative process of reimbursement

Global Treatment Progress

Australia

- The Therapeutic Goods Administration (TGA) granted approval to prescribe SCENESSE® to adult patients with EPP in October 2020
- We are working with the Pharmaceutical Benefits Advisory Committee to make the drug available on the Pharmaceutical Benefits Scheme to enable access to the treatment for patients

Israel

- The Ministry of Health granted access to distribute SCENESSE® to adult patients with EPP in February 2021

Others

- Collaboration with our partner in China continues to focus on treating a small number of EPP patients to establish a database of Chinese patients to enable discussions on the path of regulatory approval to distribute SCENESSE® with Chinese authorities
- Assessment of the regulatory process in Japan is ongoing
- CLINUVEL is committed to extend the distribution of SCENESSE® for EPP to other jurisdictions

Targeted Technology Translation

CLINUVEL's expanded pharmaceutical research and development program is aimed at the translation of its technology and know-how developed and gained over the last decades, to serve wider populations. The medical needs of these patient populations have remained unmet, implying that no current therapy exists for these patients and no products have been developed for broader target populations. CLINUVEL frequently reports on the direction and clinical opportunities in which it seeks to test its drug candidates. In brief, a number of indications are reviewed below.

Erythropoietic Protoporphyria and SCENESSE® Enfance

We continue to develop the application of an afamelanotide formulation for paediatric patients diagnosed with the rare metabolic disorder, erythropoietic protoporphyria (EPP). A focus of the research is the assessment of different formulations of SCENESSE® based on four age groups. The research in the Singapore based Research, Development & Innovation Centre (RDI) is being conducted by senior managers under the direction of the Chief Scientific Officer.

Vitiligo

Vitiligo is a common skin depigmentation disorder which affects between 0.1-2% of the world's population. The pigment producing cells of the skin (melanocytes) are either

no longer functional or in some cases absent as a result of a variety of factors. As a result, the human skin - over time - starts to develop lighter depigmented patches of skin (vitiligous lesions) which appear across the surface of the body. The disease is resistant to treatment and has an intense psychological and social impact on these patients. Its devastating effect is most pronounced for patients of darker skin complexion.

CLINUVEL has successfully evaluated the efficacy of SCENESSE® in conjunction with narrowband ultraviolet B (NB-UVB) phototherapy as a systemic treatment for the repigmentation of darker skin types. Also being developed through the Singapore RDI are topical pharmaceutical formulations of melanocortin analogues (such as CUV9900) for the treatment of vitiligo and various other conditions.

CLINUVEL has undertaken studies in the past (Phase II CUV102 in 2011 and Phase IIb CUV103 in 2014) which produced encouraging results on repigmentation with SCENESSE® in conjunction with NB-UVB phototherapy. These results are accessible through the CLINUVEL website. As a next step in the drug development path, CLINUVEL plans to commence a Phase II study in North America with a focus on people with Fitzpatrick skin types IV-VI whose need for repigmentation is greatest. Their darker skin pigmentation shows the most distinct improvement, and therefore benefit, from treatment.

We have continued to liaise with the US Food and Drug Administration (FDA) on an agreed design of the study.

Of importance was that in March 2021, for the first time in its history, the FDA held a public meeting on patient-focused drug development for vitiligo with 1,155 participants. The focus on the disorder is welcomed and indicated the demand for novel treatments, only 24% of the participants stated that they would not use a daily topical treatment that provided only up to 50% repigmentation.

A global update on the stages of the development progress to take SCENESSE® to a prospective vitiligo market is provided below:

- Agreement on design;
- Recruitment of centers and participants;
- Undertake and complete the study ;
- Post study analysis and sharing of results with the FDA;
- Completion of additional research considered necessary;
- Submission and assessment of a Supplementary New Drug Application;
- Regulatory decision;
- Establishment of distribution and reimbursement arrangements; and then,
- First treatment.

A minimum time frame of three years is a realistic expectation to travel this path to first treatment but depends on the clinical results and regulatory authorities; the Company will provide periodic updates on its progress for the information of stakeholders.

DNA Repair and XP

Due to the frequency and length of UV exposure, large groups of the global population are at risk of permanent skin damage, called photodamage, and high percentages progress to solar skin damage and first stages of skin cancers. The risk of skin cancers following UV exposure is the highest in those who are deficient in their natural DNA repair processes, specifically base-excision repair (BER), and nucleotide-excision repair (NER).

Going deeper in the subject, UV and HEV light impacts cellular DNA, causing chemical alterations to DNA - the preliminary step in cancer formation.

In clinical testing, afamelanotide has been shown to reduce DNA damage caused by UV radiation and visible light (oxidative damage and pyrimidine dimers). Further research has shown the ability of afamelanotide and other melanocortin molecules to assist skin cells in DNA repair mechanisms (such as NER).

The Company announced the DNA Repair Program in September 2020 with an initial focus on xeroderma pigmentosum (XP) patients who are >1,000 times more susceptible to skin cancers than the general population.

The prevalence of XP ranges from 1:250,000 to 1,100,000 in western populations.

The fist XP-C variant patient in the world was treated in September 2020 and tolerated the drug well during a 42 day observation period, thus providing the basis to progress to the planned study. This study is the first-ever to have been approved by Ethics Committee(s) in western countries, as – due to the fatal course of the disease - the concern has been to protect XP patients from human medicinal trials and experiments.

The scope of the XP study was subsequently extended in 2021 to XP-V variant patients.

A number of studies have been designed in collaboration with expert physicians. We share three of these at this stage – CUV150, 151 and 152 – while reviews are performed by regulatory authorities and Ethics Committees. Individual patients have provided consent for the studies to commence.

Clinical trial	Phase	Target population	Participants
CUV150	Phase IIb	XP-C	n = 6
CUV151	Phase II	Healthy volunteers	n =10
CUV152	Phase IIb	XP-C and XP-V	n = 6

The global objectives are to evaluate afamelanotide, a first-in-class melanocortin - in XP-C and XP-V patients in relation to safety, the effect on the integrity of the skin, photoproducts, NER and overall, as a systemic photoprotective drug.

These involve the administration of the drug over four months, skin biopsies to assess UV damage, and the administration of ultraviolent radiation to assess the effect of erythemal exposure.

Stroke – AIS

Stroke impacts 15 million people worldwide each year. Of these, 85% (12.75 million) are arterial ischemic stroke (AIS), around 85% (10.84 million) of which are untreatable due to the blood clot prevailing in narrow and inoperable blood vessels of the brain.

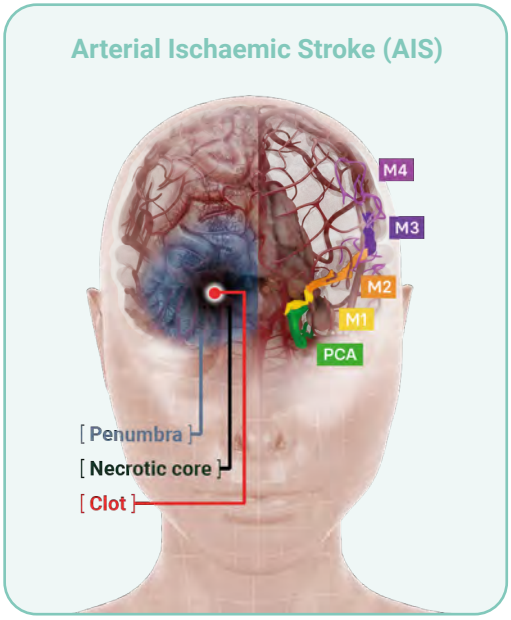
Afamelanotide assists blood vessels to stimulate blood flow and oxygen to the penumbra, the brain tissue at risk; it also provides protection of the brain cells.

A Phase II study - CUV801 has been designed and approved by clinical decision makers and ethical committees and commenced.

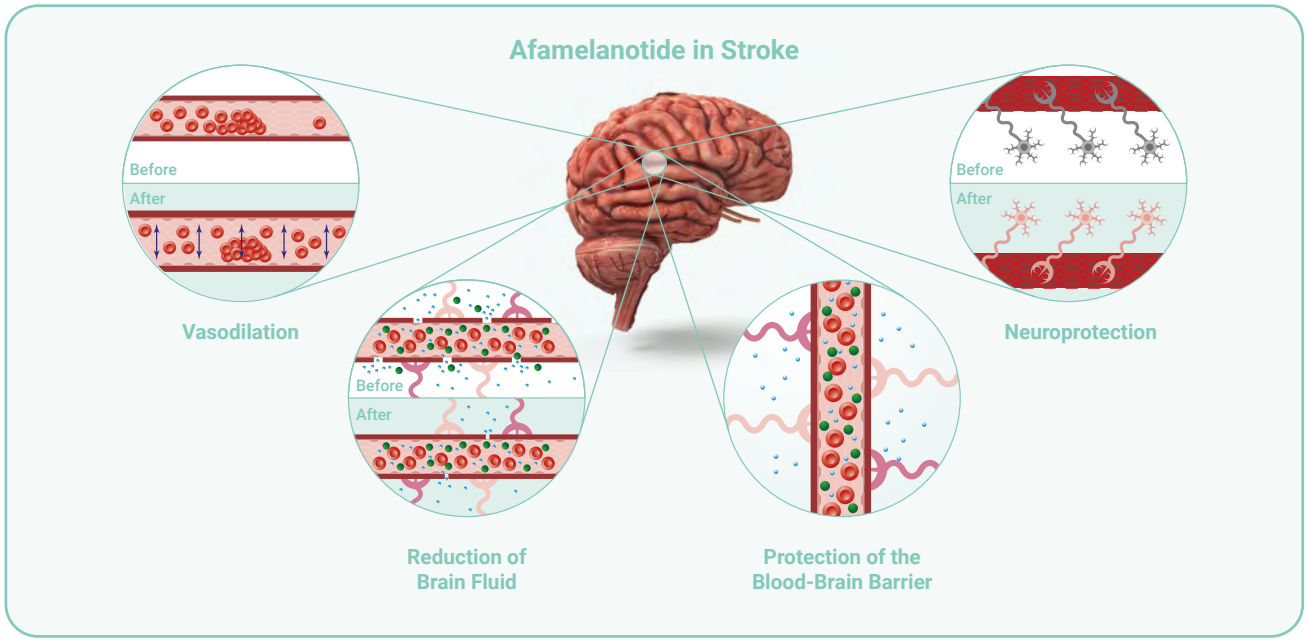
The first of six AIS patients was treated in June 2021, conducting the world's first human study of a systemic melanocortin in the treatment of a life-threatening condition.

The objective is to assess whether afamelanotide's intervention provides a benefit to the arterial supply of the brain as measured by Computed Tomography Perfusion and Magnetic Resonance Imaging of the brain.

Progress of the study will be advised.



A sudden clot lodged in a brain vessel causes an acute stroke leading to a zone of dead brain tissue, known as the necrotic core. The area surrounding the core is at immediate risk of further tissue death and is called the penumbra: brain tissue which can be returned to normal function if immediate intervention can be offered. The right side of the image shows the middle cerebral artery (MCA) sections M1–M4.



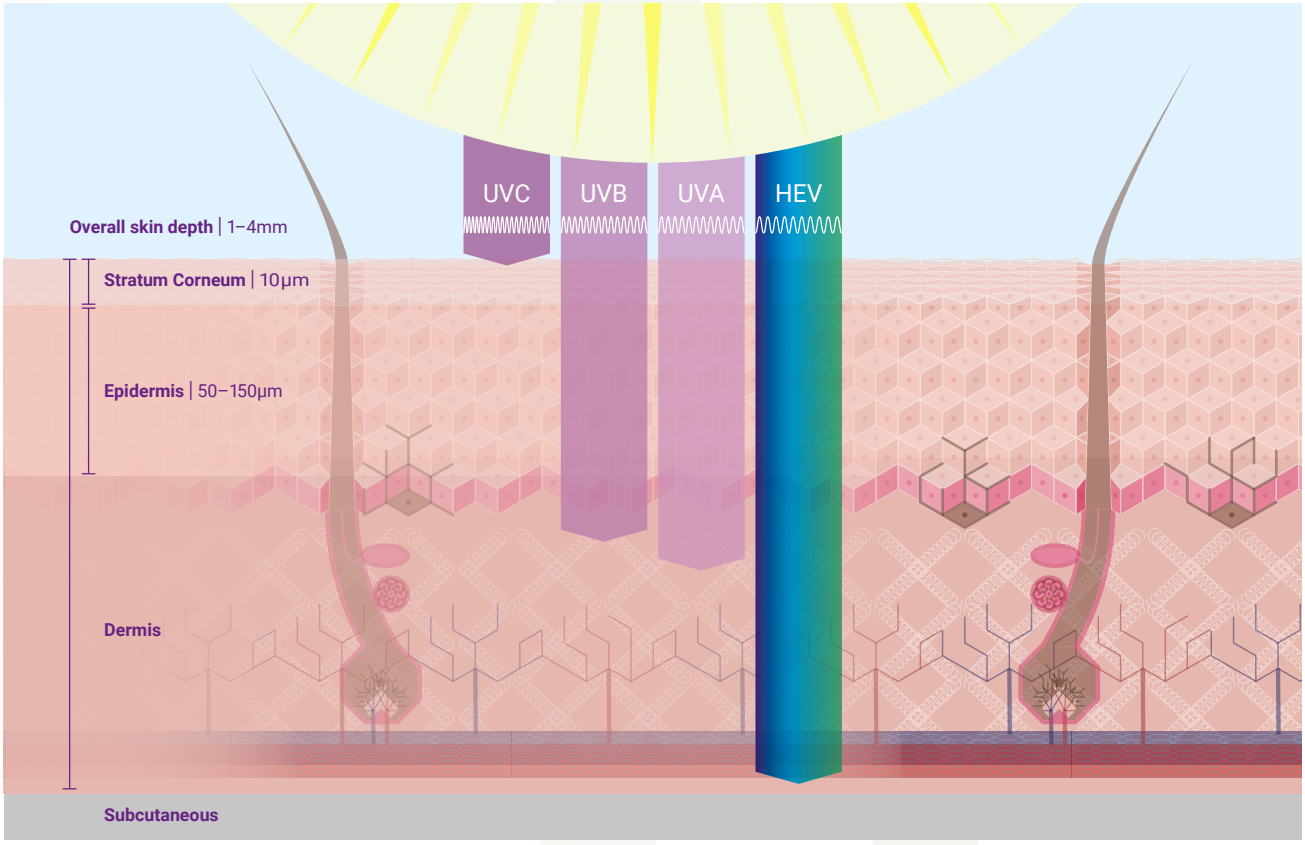
Additional Indication

We are also working towards institutional agreements to start a first study in an additional indication.

Healthcare Solutions

A beneficial relationship between our human skin and light requires balance. Chronic overexposure to light poses a direct threat to health. Yet, lack of light exposure leads to vitamin D deficiency and depressive disorders. In short, we need solutions that help maintain a healthy balance.

CLINUVEL's proven pharmaceutical technology protects skin from light (photoprotection) for patients with one of the most severely expressed genetic conditions. It has also been shown to play a key role in repairing DNA which has been damaged by light exposure. Over decades, we have developed know-how to understand what is required to achieve a balanced relationship with light. As part of CLINUVEL's expansion, we are now working to deliver solutions to targeted audiences, which help them achieve a lifelong balance.



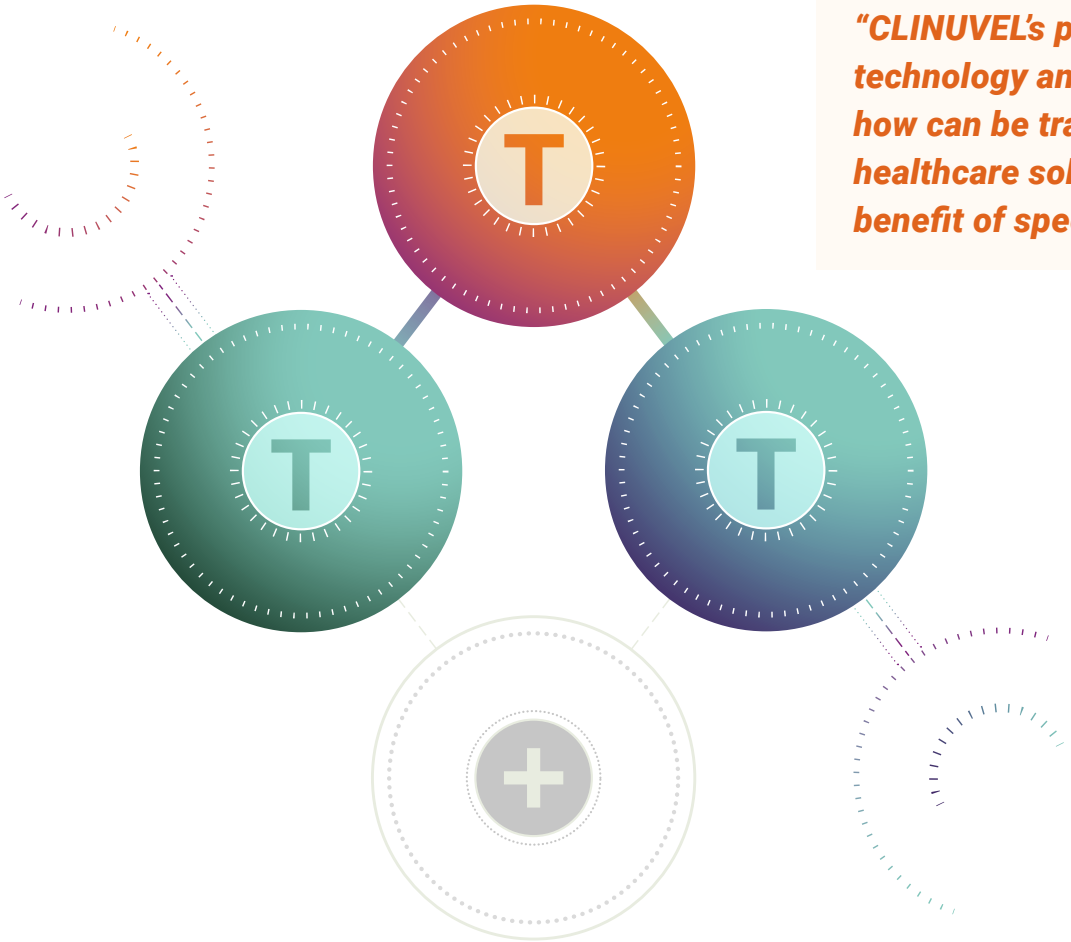
Skin cross section, demonstrating the depth of penetration attributed to UVC/UVB/UVA and HEV solar radiation.

We Are All at Risk of Skin Damage

Every hour of exposure to ultraviolet (UV) and high energy visible (HEV) light causes of thousands of DNA lesions in our skin. The first of these occurs within a picosecond of light exposure, and damage can continue to accumulate for hours after exposure.

Over time, under general conditions our bodies are expected to repair much of the light-induced DNA damage. Yet, many of these lesions actually are left unrepaired as we age and as the frequency of UV exposure increases, the damage ultimately leads to skin cancer.

In addition, some of us are much higher risk to incur skin cancers than others due to variations in our ability to repair DNA damage. Genetics, age, and specific diseases or medications can play a role in impairing our reparative functions. As a result, the potential population numbers are high: collectively, some 2 billion people are at increased skin cancer risk. Within these groups we have identified eligible populations for our future products.



"CLINUVEL's pharmaceutical technology and know-how can be translated to healthcare solutions for the benefit of specific groups"

Next Generation Skin Care: Dermatocosmetics

Due to the public's increasing awareness of the adverse impact of prolonged exposure to solar and HEV light on the skin, there is growing demand for innovative non-prescription skin care products. Dermatocosmetic products are being provided by a large range of purely cosmetic and lifestyle-focused companies to meet this demand. Dermatocosmetics are specially formulated products designed to assist skin health with a focus on anti-ageing, repair and regeneration of the skin. To achieve this, 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. The worldwide market for dermatocosmetics is large and growing rapidly. It is estimated that the market, at US$57 billion in 2020, will grow by more than 7% per annum through to 2030.[1] The wide range of products available offer different benefits and their efficacy varies markedly. This is one of the opportunities for CLINUVEL. Whilst many products promise regeneration and rejuvenation of the skin, seldom are these based on the research into a new class of molecules tested in human pathology over decades or the knowledge accumulated by teams focused on photoprotection, as has been undertaken by CLINUVEL.

1. Prescient Strategic Intelligence, Dermacosmetics Market Research Report, July 2021.

From Medicinal Use to Healthcare Solutions

CLINUVEL stands for a notion that pharmaceutical technology and know-how can be translated to healthcare solutions for the benefit of specific groups in the general population at high risk of UV and HEV light exposure. In October 2020, we announced the establishment of CLINUVEL's Healthcare Solutions Division to develop and advance a range of non-prescription dermatocosmetic products, which will use various ingredients, and in some product lines the melanocortin technology developed by CLINUVEL over the decades. We aim to prevent and assist the repair of light-induced DNA damage of the skin. The area of acute and chronic photodamage following UV and HEV exposure is an underdeveloped area of the dermatocosmetics market.

CLINUVEL's Dermatocosmetic Products

CLINUVEL has identified specific target groups who are poorly attended and with a certain unmet need to assist skin's DNA protection and repair. We are building a network of communities to understand their needs and develop solutions to help them. These groups of individuals have high sensitivity to light/UV and are prone to long-term damage and are at high risk due to:

- their 'fair' skin types;
- their work or lifestyle activities; or
- lifelong immunosuppression, having received an organ transplant.

The objective of CLINUVEL's Healthcare Solutions Division is to introduce leave-on products, topical formulations based on melanocortin molecules, to provide photoprotection and DNA-restoration for these groups of individuals.

We will take a prudent and gradual approach to the launch of the dermatocosmetics product range. The first product line offers polychromatic protection for extreme conditions; the second and third product lines aim to provide DNA protection and repair.

CLINUVEL is introducing and adding new technology and know-how originating from a long executed pharmaceutical program. This specific origin, scientific focus, target groups and pharmacology itself sets CLINUVEL apart from any of the established cosmetic houses.

CLINUVEL will provide regular updates on the progress of the Healthcare Solutions Division through to the launch of the first polychromatic product in FY2022.

"Record financial results, achieved in our fifth year of commercial operations, validate the strength of CLINUVEL's business model and the strategic direction of the Company."

Darren Keamy, Chief Financial Officer, CLINUVEL Group

CLINUVEL

ANNUAL RESULTS

Financial Year Ending 30 June 2021

Directors' Report

The Directors of the Board present their report on the Company for the financial year ended 30 June 2021 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.

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 3,175,321 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 distributed 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. 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 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 and prepare 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
Non-Executive Director, AO, 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)
Bell Financial Group (ASX: BFG, from 2012 to 2018)

Relevant Interest in Shares and Performance Rights

Shares 233,969 Performance Rights 25,000

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 and also a non-executive director of Challenger Limited (ASX: CGF). 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). 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 Board-Certified Endocrinologist in Pennsylvania, USA, currently serving as Clinical Endocrinologist at Cape Regional Physicians Associates specialising in Endocrinology, Diabetes & Metabolism. Dr Agersborg had previously worked at Easton Hospital, Steward Health, at Reading Hospital, West Reading and at Suburban Hospital, Norristown as Clinical Endocrinologist and served as Chief, Endocrinology, Diabetes, Metabolism at Chestnut Hill Hospital.

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 commercial strategy, resulting in the US FDA's approval of SCENESSE® in October 2019.

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

Non-Executive Board Chair of Women's Health (London West One) Ltd
Non-Executive Director of Elite Medicine Ltd
Trustee of the HCA International Foundation

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 practicing physicians within the UK independent healthcare sector.

Her past experience is now successfully translating into a diverse portfolio with non-executive director appointments, having been successful in completing the *Financial Times* Non-Executive Director Advanced Professional Diploma. She is Board Chair of the Evewell (Harley St) Ltd, a fully integrated centre of medical excellence dedicated to caring for, and protecting, all aspects of fertility and gynaecological health. She also sits on the Advisory Board for SweetTree Home Care Services, providing the bridge between hospital and community care. In the face of the ever-changing healthcare market Mrs Smith fosters first class relationships with a wide range of healthcare stakeholders to build first class services for patients.

JEFFREY ROSENFELD
Non-Executive Director, AC, OBE
Appointed 26 November 2019

Committee Membership

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

Current Directorships and Other Interests

Director of Vision for TBI Ltd
Former Major General, Australian Defence Force (Army Reserve)

Other Listed Company Directorships (last 3 years)

None

Relevant Interest in Shares and Performance Rights

Shares 2,363 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 blind people, 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.

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.

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	9	9	3	3			1	1
Dr. P.J. Wolgen	9	9						
Mr. W. Blijdorp	9	9	3	3	5	5	1	1
Dr. K. A. Agersborg	9	8			5	5	1	1
Mrs. S. E. Smith	9	9			5	5	1	1
Prof J. V. Rosenfeld	9	9	3	3			1	1

Column A indicates the number of meetings held during the period the Director was a member of the Board and/or Board Committee.
Column B indicates the number of meetings attended during the period the Director was a member of the Board and/or Board Committee.
The Nomination Committee intends to meet twice a year. The second meeting for the financial year was held 16 July, with at least 2 more meetings to be held in FY2022.

Principle 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 and novel products to patient groups and individuals at high risk of exposure to light.

CLINUVEL's expertise in understanding the interaction of melanocortins and human biology is focussed on developing treatments for patients with genetic and acute diseases who lack therapy. Research into afamelanotide focuses on the use of the hormone in severe light related disorders and depigmentation, and has recently expanded into diseases of the Central Nervous System and various other organs. The patient populations in these diseases range in size from 5,000 to 45 million worldwide.

CLINUVEL has developed and launched the world's first systemic photoprotective drug, SCENESSE® (afamelanotide 16mg), in Europe and the USA. During the year, the scope of CLINUVEL's research and development program was extended to the application of melanocortins to treat acute disorders and vascular anomalies.

The long-term financial objective of the Group is to maximise company value through the distribution of treatments to patients and special populations in need. 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 financial year were to:

- manage and expand the commercial distribution in Europe and the USA of its leading drug candidate SCENESSE® 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® in combination with narrowband ultraviolet B (NB-UVB) phototherapy and topical pharmaceutical formulations of melanocortin analogues for the treatment of the skin depigmentation disorder, vitiligo;
    - topical based pharmaceutical formulations for photoprotection of the skin;
    - medicinal photoprotection through DNA repair of the skin and initiating first studies in the genetic disorder, xeroderma pigmentosum (XP);
    - commencing first pilot studies to investigate the use of SCENESSE® as a medicinal therapy for acute arterial ischaemic stroke (AIS); and
    - the ongoing development of PRÉNUMBRA®, a new liquid formulation of afamelanotide for the treatment of acute disorders and vascular anomalies.
- through the Healthcare Solutions Division, progress the development of a range of non-prescription, dermatocosmetic products for individuals at high risk of exposure to ultraviolet (UV) and High Energy Visible (HEV) light.

Review of Operations and Financial Condition

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

Key Features of Business Operations

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

- The commercial operations of the Group are undertaken in Europe 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 US, in accordance with the approval of the FDA, granted in October 2019.
- 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 by all patients.
- 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 Specialty Centers in the USA.
- CLINUVEL's cash receipts 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; and DNA repair of the skin with initial clinical studies to commence in xeroderma pigmentosum (XP); in acute arterial ischaemic stoke (AIS); and in an undisclosed further indication.
- The research and development program has been extended through the development of a second formulation of afamelanotide, PRÉNUMBRA®, with a focus on its application in acute disorders and vascular anomalies.
- 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 and an over-the-counter, dermatocosmetic product range.
- The Melbourne headquarters of the Group covers the key regulatory affairs, scientific programme, finance, and investor relations functions, whilst the United Kingdom office co-ordinates global operations, communications, and marketing.

Review of Operations

The review of operations for the year ended 30 June 2021 (FY2021) focuses on:

- the distribution of SCENESSE® in Europe and the USA;
- ongoing work to obtain regulatory approval of SCENESSE® in new jurisdictions;
- 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 skin and vascular disorders; and
- the development of non-prescription, dermatocosmetic products.

Distribution of SCENESSE® in Europe

The supply of SCENESSE® to EPP Expert Centres across key European countries, including under a special access scheme to Switzerland, continued in FY2021. During the COVID-19 pandemic, the majority of EPP Expert Centres have continued to prescribe SCENESSE® due to strong patient demand. A small number of Centres either deferred orders or reduced order sizes in the initial months of the COVID-19 infections in the second half of FY2020. These few Centres were not able to provide treatment access to patients, or patients were unable to travel to Centres. Despite the uncertainty surrounding the pandemic, patient demand for SCENESSE® remained high during FY2021, with

existing patients continuing to seek treatment and new patients receiving treatment for the first time.

We continue to progress reimbursement of the cost of treatment with authorities in several European countries.

Distribution of SCENESSE® in the USA

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 codes for treatment to ensure seamless operations and reimbursement, initial insurer discussions and agreement to obtain reimbursement for the cost of treatment, and identification of the initial Specialty Centers to be accredited and trained by CLINUVEL.

In April 2021, CLINUVEL recorded its first anniversary of distributing SCENESSE® for adult EPP patients in the USA. Over 60 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 to liaise with insurance companies to obtain approvals to reimburse the cost of treatment under PA.

The initial target was to accredit up to 30 Specialty Centers across the USA over a phased period by the end of calendar year 2021. CLINUVEL has currently trained and accredited over 40 Specialty Centers which is well ahead of planning. Cash receipts for FY2021 included the first receipts from the supply of SCENESSE® in the US market. The Company's experience is that payment terms are longer in duration in the US than the 30 to 60 days average length of payment term in Europe. After initial revenues were recorded from first-adopter orders prior to 30 June 2020, revenues rose throughout FY2021, underpinned by the progress achieved in the number of Specialty Centers accredited and the approvals under PA with insurers to reimburse the cost of treatment. These activities were one factor driving the Company's record revenues and profit in FY2021.

SCENESSE® for EPP 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® has been 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 file for 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.

Expansion Singapore Laboratory

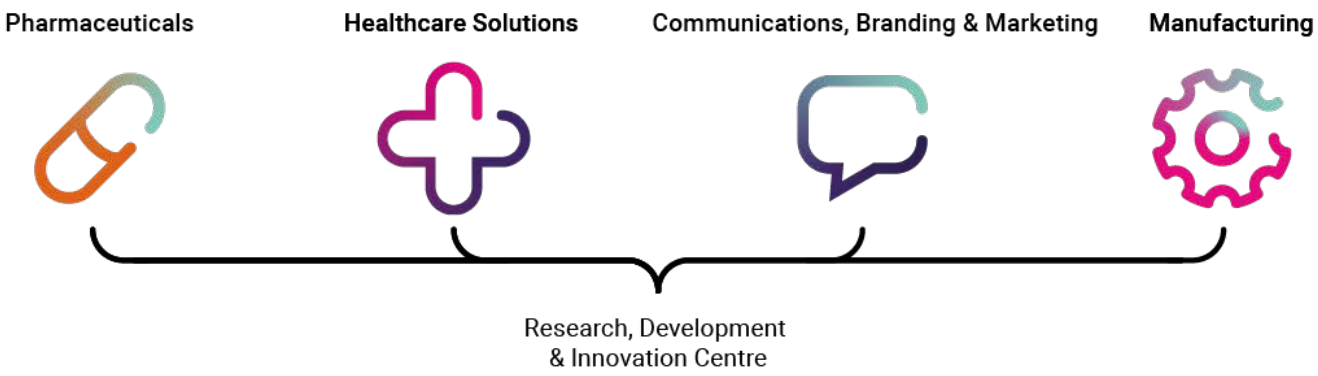
New state of the art and expanded laboratories in Singapore were commissioned in August 2020 to further progress R&D on novel melanocortins, and prescription and over-the-counter products. After minor delays due to the COVID-19 pandemic in opening the expanded Company's Research, Development & Innovation (RDI) Centre, the facility commenced operations with an expanded and skilled team and fitted with specialised technical laboratory equipment to further enhance the progress of its product pipeline and underly a new divisional structure.

The RDI Centre is operated by the Group's wholly owned subsidiary, VALLAURIX Pte Ltd. The Singapore Economic Development Board (EDB) is supporting this expansion 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.

New Organisational Structure

To support the strategic objectives and initiatives of the Group, a new organisational structure of four divisions was implemented during 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;
- the Communications, Branding and Marketing Division which prepares communications to wider differentiated audiences, positioning the Group for broader engagement; and the
- Manufacturing Division, focussed on novel formulations and products for CLINUVEL and research, development and production for other companies and research groups 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 an extensive product development pipeline that encompasses the application of SCENESSE® 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 VLRX001, currently being evaluated as an adjuvant maintenance therapy in vitiligo, with the intention of developing these analogues for medicinal purposes to be administered topically;
- a range of over-the-counter products for general photoprotective application;
- the use of melanocortins in DNA repair of the 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 trials for acute disorders and vascular anomalies.

Vitiligo Program

The Group continues to pursue a clinical program 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.

In FY2020 a Type C Guidance Meeting was held with the FDA, the purpose of which was to seek agreement on the design of a multicentre Phase IIb vitiligo clinical study (CUV104) and the data package necessary to support a supplemental New Drug Application (sNDA) filing for SCENESSE® in vitiligo. Following the meeting, CLINUVEL has been liaising with the FDA and clinical experts to finalise the documentation and clinical trial protocol (CUV104) to advance SCENESSE® as the first systemic repigmentation agent in North America.

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

Subject to agreement of the clinical protocol by the FDA and pending acceptable results on the ongoing safety and efficacy in its vitiligo program, CLINUVEL would seek to file a sNDA for SCENESSE®. A sNDA, referred to as an "efficacy supplement", 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 this effect in humans, with an initial focus on xeroderma pigmentosum (XP), acknowledging a broader application of up to 2 billion people worldwide with a deficiency in their natural DNA repair processes.

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 trials. In November 2020, a trial in healthy patients was approved and, in March 2021, the program was extended to patients with the XP-V variant.

There has been understandable caution by authorities and decision makers about the impact of conducting clinical trials on XP patients during the COVID-19 pandemic. 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. Three trials (CUV150, CUV152 and CUV153) have been designed to assess ultraviolet (UV) induced DNA damage and oxidative stress in XP patients. Dosing of the drug will occur at variable intervals for a maximum of four months. A fourth trial, CUV151, is designed to assess DNA repair in healthy

volunteers. COVID-19 has caused some delay in allowing XP patients to attend the clinics.

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 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.

Due to the COVID-19 pandemic, the start of the clinical trial in stroke patients (study CUV801) incurred a delay, but the first AIS patient was treated with afamelanotide in June 2021. In August 2021 an update was provided on the treatment of the first three AIS patients, with treatment well tolerated. Two patients showed improvement in neurological deficit while one patient showed no improvement. The CUV801 study is ongoing.

PRÉNUMBRA®

At the start of FY2021, the Group announced the development of a second formulation of afamelanotide, PRÉNUMBRA®. This non-solid controlled-release formulation 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®. Development of this formulation is progressing and is managed through our RDI centre in Singapore.

Financial Review

The financial year ended 30 June 2021 marks the completion of the Group's fifth consecutive year of achieving a net profit, a positive cash flow result and increased revenue growth.

The result for the Group for FY2021 was a $25.713 million profit before tax, compared to $11.541 million for FY2020 (restated from $13.136 million), a 123% increase. 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 prepare for future business growth. Total expenses increased by 2% year-on-year, compared to a 43% increase in Total Revenues and Other Income.

Net Cash provided by Operating Activities was a positive $19.262 million for FY2021, up from a $14.188 million positive result for FY2020. After the deployment of cash in investing and financing activities, net cash added $15.944 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 2016 without reliance on debt or equity funding, from $13.845 million at 30 June 2016 to the 30 June 2021 level of $82.691 million.

Summary Financials FY2021

Consolidated Entity	FY2021	FY2020 restated
	$	$
Revenues and Other Income	48,450,599 +43%	33,909,670 +4%
Net Profit before income tax	25,712,644 +123%	11,540,811 -36.3%
Profit after income tax expense	24,728,247 +64%	15,051,199 -17%
Basic earnings per share	0.500 +64%	0.306 -18.6%
Net tangible assets backing per share	1.911 +41%	1.351 +17%
Dividends	2.5 cents	2.5 cents

Note: CLINUVEL has one operating segment for reporting purposes.

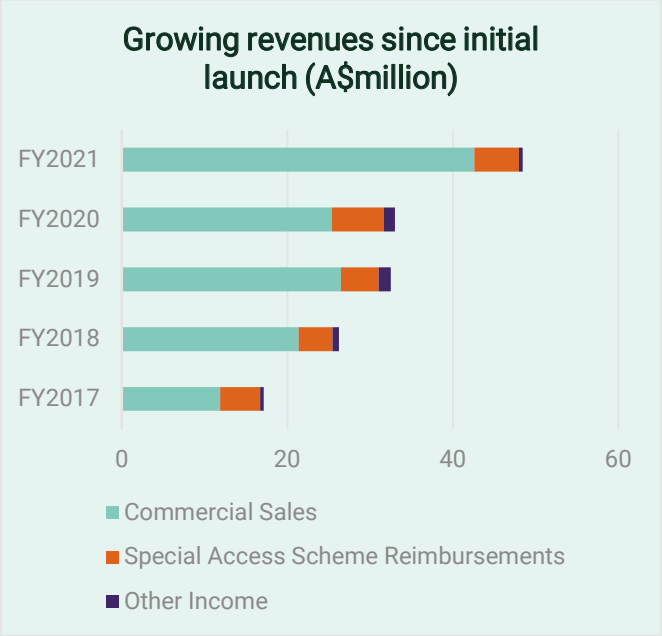
There is an increase in expenses and a corresponding decrease in Net Profit before tax of $1.596 million for FY2020. Further details are provided in Note 1 to the Financial Statements.

Revenues

The Group achieved a Total Revenue result of $47.976 million for FY2021. This strong top line result is a 47.3% increase on the prior year 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 medicinal product. The graph below depicts the growth in Total Revenues year on year since FY2017.



A comparison of the FY2021 reported and constant currency results against the FY2020 reported results for Commercial Sales and Special Access Scheme Reimbursements is shown in the table below.

Throughout FY2021, the Australian dollar currency was stronger relative to most other currencies the Group had an exposure to when compared to FY2020. As a result, movements in foreign exchange rates against the Australian dollar presentation currency resulted in a $3.888 million adverse impact to the reported Total Revenue result for the year.

	Commercial Sales	SAS Reimburse-ments – Switzerland, Other	Total
AU $ million			
FY2021 Reported	42.603	5.373	47.976
FY2021 Constant*	46.236	5.627	51.864
FY2020 Reported	26.306	6.259	32.565
% change (Constant)	75.8%	-10.1%	65.7%
% change (Reported)	62.0%	-14.2%	47.8%

* FY2021 revenues converted to A$ monthly at the average conversion rate of the same month of FY2020

Commercial Sales

Commercial sales for FY2021 were $42.603 million, a 62% increase to the commercial sales result for FY2020 ($26.306 million). On a constant currency basis, commercial sales revenues of SCENESSE® increased 75.8% for the year. The Group views its commercial sales as a single operating segment for reporting purposes but provide insights into the trends in key markets below

The increase in commercial sales was also driven by the impact of recognising commercial sales in the USA across a full financial year for the first time. At the end of FY2020, more than forty insurance companies had agreed to reimburse SCENESSE® either via Prior Authorization (PA) or through acceptance of the drug on individual formularies. This number had increased to over 60 by the end of FY2021. The number of Specialty Centers participating in the distribution program who are trained and accredited has now grown to over 40.

Unit sales by month in the US was relatively consistent from the start of the financial year through the winter months in the northern hemisphere, progressively increasing in the latter months of the year, reflecting higher patient enrolment in the time of year where the level of ambient light emission intensifies for EPP patients. This indicates a level of year-round demand for SCENESSE® in the US.

Commercial sales in Europe improved in FY2021 after some disruption was experienced by select EPP Expert Centres in the latter half of FY2020 in responding to the COVID-19 pandemic. There were some competing trends in patient demand and the experience of EPP Expert Centres during the year:

- Patients unwilling or unable to travel to seek treatment during FY2020 returned to seek and receive treatment in FY2021;
- Some EPP Expert Centres treated new patients for the first time, increasing the number of patients they were able to treat;
- A few Centres treating smaller patient numbers reduced orders of SCENESSE®; and
- Other EPP Expert Centres who have been participating under the post-authorisation safety setting for multiple years are gradually reaching a critical mass and experienced relatively steady patient numbers.

A stronger Australian dollar in FY2021 affected the year-on-year increase in commercial sales recorded in

original Euro currency, however the Group still recorded a 4% increase upon converting Euro sales into the Australian reporting currency.

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 decreased 10.0% for the year. The result was driven by a decline in the number of patients seeking treatment in Switzerland, either due to the COVID-19 pandemic, or who are now understood to be receiving treatment in other countries.

Other Income

Interest Revenue and Other Income

Interest received from funds held in bank accounts and term deposits for FY2021 was $0.342 million compared to $0.563 million for FY2020.

The positive financial performance of the Group saw an increase over the 12 months to 30 June 2021 of $15.944 million to its cash reserves. Over the course of FY2021 the Group continued the trend in prior years to transfer more funds into higher-yielding Australian dollar fixed-rate term deposits. The average amount of cash held in term deposits was 27.6% higher than for FY2020. However, the higher cash balances were offset by a lower interest rate yield earned on holding interest-bearing term deposits, averaging 96 basis points less year-on-year. The decrease in interest rate yield reflected the impact of Australian government monetary policy on term deposit rates on offer throughout the year. The Group's policy to maintain lower-yielding foreign currencies to cover working capital requirements is reflected in this result. 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 FY 2021 has remained stable, decreasing 3% on average when compared to FY2020. The average amount of Australian currency held year-on-year increased 44%.

The Group recorded other income of $0.130 million in government grants received in Australia and Singapore to assist companies respond to the economic impact of the COVID-19 pandemic.

Expenditures

Total Expenses for the Group for FY2021 were $22.738 million, up 2% from FY2020 ($22.369 million). Expenses were well contained in a period where the Group was focussed to re-invest in the business to expand its activities across the four recently announced divisions: (a) Pharmaceutical, (b) Healthcare Solutions, (c) Communications, Branding & Marketing, and (d) Manufacturing, supported by the RDI Centre. This result occurred in a challenging environment of escalating cost of goods and services across all key inputs to the business.

New expense groupings are reported for FY2021 and FY2020, to reflect the expansion and diversification of activities of the Group.

Clinical & non-Clinical Development

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

Clinical and non-clinical development fees increased 82% from $0.341 million in FY2020 to $0.548 million in FY2021. 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 FY2021 was driven by:

- Growth in product development and testing services in the VALLAURIX laboratories;
- Completion of pre-clinical studies to support the Group's strategic focus to develop solutions for population groups most at risk of skin damage and cancers; and
- Trial fees toward the stroke study CUV801.

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. These activities include pharmacovigilance, quality systems, safety reporting, PASS Registry data capture and dossier updates.

During the year new distribution centres with contracted parties and third-party service providers were established in the US to support supply to EPP Specialty Centers. Permits and licenses across participating US states were established. Regulatory dossier changes were submitted and approved. Assistance on market access initiatives in new countries and further pricing negotiation continued throughout the year.

These expenditures in FY2021 were a 1% improvement to FY2020, from $2.443 million to $2.421 million, noting:

- Increased freight, product handling, distribution and manufacturing royalty expenses from higher transportation volumes, largely offset by:
- Reduced costs in responding to regulatory audits relating to the manufacturing and quality systems

Materials Expense

Materials and related expenses primarily reflect some of the acquisition purchases to support the production of finished product by the Group's contract manufacturer, along with other materials purchases. The Group continues to prepare for future sales growth and to meet short-term and long-term inventory requirements. The Group concluded a manufacturing campaign to secure raw material peptide via a critical process change to support future scale-up. This is in final stages of validation. Multiple batch manufacturing campaigns were conducted throughout FY2021 and continue into FY2022.

Expenditures on essential materials increased 34%, from $2.350 million in FY2020 to $3.650 million in FY2021. 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 47%, from $0.589 million in FY2020 to $0.314 million in FY2021.

The Group has invested in resources to expand its visibility and to engage with new audiences. It is building 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 brand.

The decrease in this expense result is due to:

- Services previously conducted by external parties have being brought in-house;
- Conference attendance and presentation costs in FY2020 not being repeated in FY2021 due to the COVID-19 pandemic

Legal, Insurance and IP

Legal, insurance and IP-related fees decreased 5% from $1.148 million in FY2020 to $1.095 million in FY2021.

Incurring expenditures in external legal support, in patent & trademark expenses and various insurances provides the Group with vital property protection and a competitive advantage over others. It also plays an important part in the Group's risk management plans

This expense result was driven by a tapering in overall IP fees, partly offset by increases in annual insurances reflecting the growth in scale of the business amid a general softening of the global insurance market.

Personnel

People are integral to the Group's success and are the key driver for executing the Company strategy. The Group increased its workforce in the current year, with an emphasis on distribution, clinical and non-clinical development roles, primarily to drive business growth.

The personnel expense result for FY2021 was $10.158 million, a 3% reduction from FY2020 of $10.490 million. FY2020 was restated and included first-time recognition of long-term employee retention benefits of $1.596 million (FY2021: $0.118 million).

Share Based Payment

The share-based payment charge increased 57% from $1.659 million in FY2020 to $2.602 million. This is a non-cash accounting charge for share-based payments

provided to the Managing Director and other staff. The prior year's non-cash charge was less than 12 months charge as the majority of the share-based payments were granted part way through FY2020.

Finance, Corporate and General

Expenditures from finance, corporate and general activities decreased 21% from $2.054 million in FY2020 to $1.618 million in FY2021.

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.

The improvement in this expense result year on year was due to a near absence of local and international staff travel, brought on by restrictions in movement by countries dealing with the COVID-19 pandemic.

Depreciation and Amortisation

Depreciation and amortisation increased by $0.415 million, from $0.446 million to $0.861 million. The increase is attributable to 12 months depreciation of the expanded RDI Centre in Singapore.

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 commercial sales. For FY2021, an adjustment was recorded increasing inventory levels by $1.899 million, demonstrating the Group's strategy to prepare for future near-term sales demand. For FY2020, the result was a $0.848 million charge to the expense result, reflecting reduction in inventory levels.

Unrealised loss on restating foreign currency balances and currencies held

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.

Unrealised adjustments are brought to account to restate trade debtors and creditors and foreign currencies held to Australian dollar currency as at 30 June.

As a result of the movement in the Australian dollar during FY2021, the Group recorded a $1.368 million loss as at 30 June 2021 (30 June 2020: $0.537 million gain).

Deferred Tax Asset

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.

The amount of the DTA account reflects:

- the benefit to be received from utilising unused tax losses against the temporary differences that result in a deferred tax liability for the business; and
- the expected utilisation of unused tax losses against probable near term taxable profits

Balance Sheet

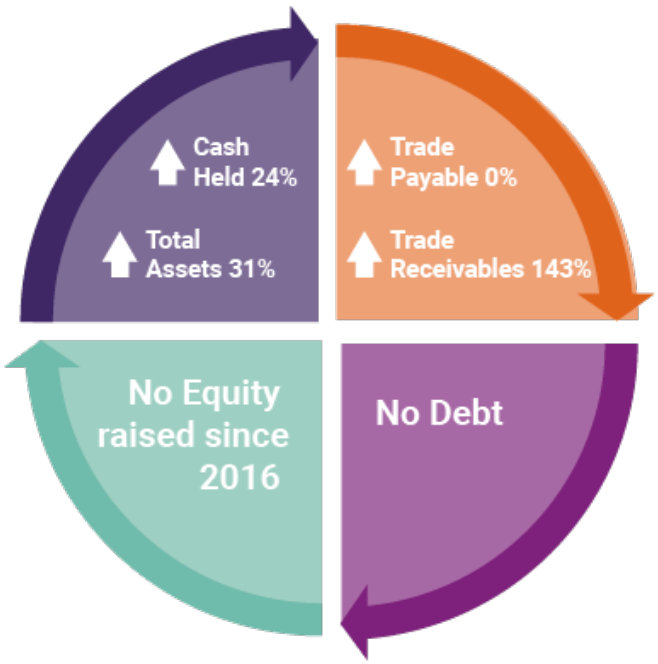
One of the key objectives of the Company is to ensure its Balance Sheet is sufficiently positioned and robust to allow investment in future performance with a financial buffer to respond to unexpected adverse events. The Company has continued to preserve cash and cash equivalents held without need to raise capital and diluting shareholder returns, nor has it raised debt capital and increasing the debt leverage of the Group. The cash position has enabled the Group to withstand anticipated increases to short term liabilities to support the growth of the business and to sudden adverse economic conditions following unexpected events such as the coronavirus pandemic. This remains a deliberate and planned strategy, reflecting CLINUVEL's prudent approach to risk management.

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 24% from $66.747 million in FY2020 to $82.691 million in FY2021.

The increase in US sales combined with longer cash receipt cycle on sales of SCENESSE® in the US when compared to Europe was the main reason for the increase of 143% in trade receivables on the balance sheet in FY2021.

Total liabilities increased 4%, from $9.475 million to $9.830 million, with no long-term debt. The ratio of the Company's overall debt to equity is 10%.



Returns on Equity

Returns for FY2021 remain strong and are summarised by:

	FY2021	FY2020 Restated	FY2019	FY2018	FY2017	FY2016
AU $ million						
Profit attributable to owners of parent	$24.728	$15.051*	$18.134	$13.224	$7.180	($3.121)
Basic EPS	50.0 cents	30.6 cents*	37.6 cents	27.7 cents	14.9 cents	(7.0) cents
Dividends Paid in Year	$1.235	$1.224	$0.957	-	-	-
Dividends per Share Declared	2.5 cents	2.5 cents	2.5 cents	2.0 cents	-	-
Change in Share Price YoY	20%	(24%)	206%	58%	62%	52%
Return on Equity	25%	21%*	32%	34%	28%	(18%)

Shareholder **returns have been generated in both the short-term and the longer-term through:**
capital appreciation (through Total Shareholder Return exceeding the Nasdaq Biotech Index and ASX200 Healthcare Index since first product launch, and dividend distribution in the past 3 financial years.

*** Restated**

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 and skin-related disorders, as well as acute disorders and 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 business functions • Created new roles across all business functions
Research & Development	• Commenced operation of larger laboratory with expanded analytical capabilities & fixed asset purchases • non-solid dosage formulation development • non-clinical development
Clinical	Activities in progress to obtain approvals to move into next phase clinical studies to pursue potential new markets for SCENESSE® in: • Vitiligo • DNA Repair, focussed on XP • Acute Stroke (AIS) • Undisclosed indication
Manufacturing	• Program to manufacture raw material peptide via a process change to support future scale-up. • Increase product inventories to meet expected commercial and clinical demand
IP	• Continued to renew and maintain new and existing patents to strengthen its 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 the Group meeting certain performance conditions.

CLINUVEL's outstanding shares on issue remained at 49,410,338 shares to 30 June 2021. 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	18 September 2020

On 25 August 2021, the Board of Directors declared an unfranked dividend of $0.025 per ordinary share in relation to the full year ended 30 June 2021.

Cash from Operations and Other Sources of Cash

Overall, the Company generated cash from its operating activities by $19.262 million in FY2021 (FY2020: $14.188 million)

Cash inflows from customer receipts increased 32% to $38.724 million in FY2021, compared to $29.288 million for FY2020.

Cash outflows for payments to suppliers and employees increased by 23%, from $16.281 million to $20.032 million.

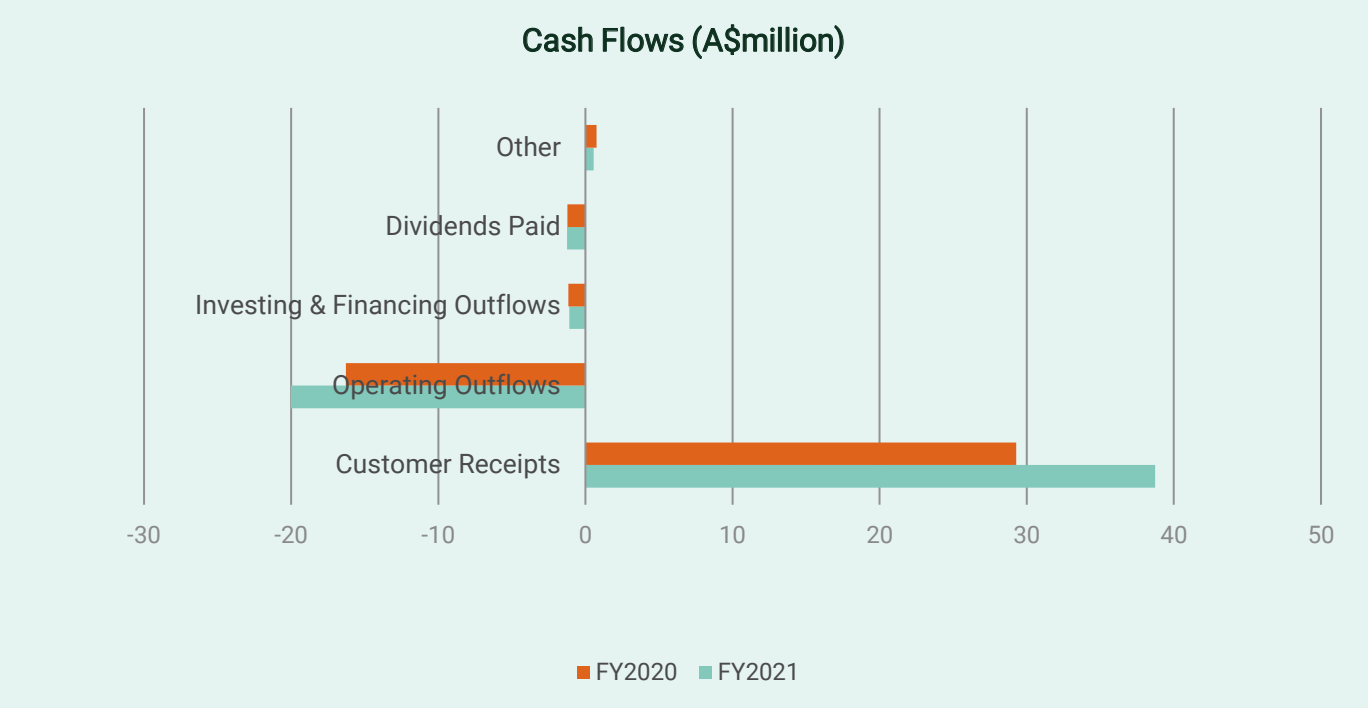
There were also cash outflows of $0.854 million for the acquisition of property, plant and equipment, $0.245 million of repayment of borrowing and leasing liabilities, and $1.235 million for the payment of an unfranked dividend to shareholders in relation to FY2020.

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 2021 is reflected in:

- A quick ratio of 11.3:1 (30 June 2020 8.9:1); and
- Cash and cash equivalents of $82.691 million, accounting for 80.4% of total current assets (FY2020: $66.747 million, 88.8% of total current assets).



Material Business Risks

The following specific business risks are reviewed continually by the Board and management, as they 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 not result in product batches meeting minimum specification levels, that raw material components could not be sourced to specification, that the manufacturing process may encounter process issues not previously identified and controlled, and of non-controllable disruptions to the operations of the products' contract manufacturers. These factors may lead to 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 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 Competiton	• New entrants could enter the same market to directly compete against CLINUVEL's products with new products proven to be safer, more effective and priced lower than CLINUVEL's.
Management	• The Group's 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 Coronavirus Pandemic on CLINUVEL's Business

The coronavirus pandemic continues to adversely impact both people's health and global economic activity. Many countries are focussed on vaccinating their populations to provide ongoing protection from the variants of the virus. 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 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, or patients were unable to travel to them. Notwithstanding the uncertainty surrounding the pandemic, patient demand for SCENESSE® in Europe remained strong, with existing patients continuing to demand treatment and new patients receiving treatment for the first time. CLINUVEL is conscious of the patients it serves and the anxiety and uncertainty they face during the coronavirus-pandemic and it has worked to continue to meet their demand for SCENESSE®.

Research and Development

CLINUVEL's research and development program continued to progress in FY2021. 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 2020.

Supply of SCENESSE®

The sourcing, manufacturing and controlled distribution of SCENESSE® continued without material disruption or delay from the coronavirus 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 the coronavirus pandemic.

CLINUVEL's People

CLINUVEL has played a responsible role to assist the global effort to manage the spread of COVID-19. CLINUVEL personnel have adapted to work remotely, attending the office only as necessary and when permitted under government regulations. Video-based communications technology has been maximised whilst local and international travel has been minimised, and in most cases, ceased. 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 25 August 2021, the Board of Directors declared an unfranked dividend of $0.025 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 as additional pricing agreements per country are established with payors, and as the required pharmacovigilance activities continue to expand.

The Group has focused on its manufacturing requirements by working with its contract manufacturer and raw material supplier 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 improvement and will form part of the Group's expenditure base moving forward. The contract manufacturer bear responsibility for the manufacturing standards of the commercial drug product. The Group announced in March 2021 it will establish a Manufacturing Division where it will manufacture own products and will be eventually set up as a contract manufacturer for other pharmaceutical companies and research groups.

SCENESSE® was launched in the US in April 2020. The Group is focussed on securing agreement on reimbursement of SCENESSE® with insurers to make SCENESSE® available to all US patients receptive to the treatment. The Group will continue to expand its resources and activities to support US market entry which includes operating a risk management plan similar to what has been instituted in Europe.

The Group will continue its North American clinical program to evaluate the effectiveness of its lead product to repigment vitiliginous lesions (depigmented skin areas) in combination with NB-UVB light therapy in patients with vitiligo and also as a standalone therapy. This program would include advancing into the next phases of clinical studies to demonstrate the efficacy and long-term safety of SCENESSE® in combination with NB-UVB in the treatment of vitiligo.

The Group also intends to further progress its clinical program with SCENESSE® in other indications, including VP, in DNA Repair with a focus on treating patients with XP, in AIS and in another yet to be disclosed acute indication. 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 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 clinical use. The Group has increased its resources and expanded its capabilities to progress these projects underway at VALLAURIX.

Ultimately, the long-term financial objective of the Group is to establish 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 2021.

Key Management Personnel ('KMP') has the meaning given in the Australian Corporations Act 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
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
B. Response To Shareholder Feedback and the first strike in FY2020
C. Remuneration Governance
D. Executive Remuneration
E. Non-Executive Remuneration
F. Service Agreements FY2021
G. Share Based Remuneration
H. Details of Remuneration

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 2021. Our FY2021 Remuneration Report details our remuneration policy for our Executive KMP and Directors and explains how FY2021 remuneration outcomes for Executive KMP align with CLINUVEL's performance, long-term objectives, and shareholder outcomes.

Our year

FY2021 was another challenging year due to the ongoing COVID-19 pandemic adversely affecting our people and the broader community, as well as impacting CLINUVEL's commercial operations, product supply, productivity, and clinical program. While CLINUVEL's business performance should be assessed in the context of this difficult operating environment, our Board is extremely proud of how our executives, the RDI Centre, finance, clinical, regulatory and the overall team have responded to these challenges and continued to execute our strategy, while ensuring the well-being of our employees and customers.

Despite these impacts, CLINUVEL delivered another year of positive financial performance. FY2021 marked our fifth consecutive year of annual profit (FY2021: PBIT of A$25.7m) and positive cashflow, which has provided shareholders with a positive return on equity (FY2021: 25%) and earnings per share (FY2021: A$0.500 cents) over this period. Shareholders have been rewarded with consistent annual dividends over the last three years, and substantial Total Shareholder Return (TSR) growth over the last 15 years as of 30 June 2021 (28% over 1 year, 147% over 3 years, 591% over 5 years, 692% over 15 years).

FY2021 has seen significant expansion in CLINUVEL's research and development (R&D) program, as part of the overall strategy to translate CLINUVEL's proven technology and expertise to a range of pharmaceutical and non-prescription products for unmet patient and consumer needs. Due to the cash reserves accumulated over the last five years, CLINUVEL is in a strong position to fund this expansion.

Remuneration Outcomes

CLINUVEL relies on a management team with the right innovative mindset and entrepreneurial spirit to execute our ambitious growth strategy, which will continue to deliver sustainable returns to shareholders. Rewarding and recognising our people fairly is a key priority for the Committee, to ensure we continue to attract, motivate and retain top talent. The Committee believes that the overall remuneration structure appropriately considers short, medium, and long-term strategic priorities across a mix of financial and non-financial measures that contribute to value creation for both the Company and shareholders.

Fixed remuneration increases of 3.5% were applied to the CFO and CSO in FY2021 to improve market positioning, with no fixed pay increases to apply to the CEO for the remainder of his service agreement (other than CPI adjustments).

As outlined above, despite the challenging external environment, several key milestones were achieved in FY2021 across CLINUVEL's commercial operations, financial performance, R&D program, communications and analyst coverage, and strategy development. Reflecting these achievements, and the effort required to navigate the issues and challenges from the COVID-19 pandemic, the Board determined to award the CEO a FY2021 short-term incentive (STI) award of 70% of maximum opportunity but capped at 53%. The CFO and CSO received STI awards of 82% and 65% of maximum, respectively.

Some of the progress resulted in 6% of the CEO's FY2020 grant of LTI performance rights to vest up to the end of FY2021 (with a final vesting date of 20 November 2023 for this grant).

Our response to the strike against the FY2020 Remuneration Report

Following the strike against our FY2020 Remuneration Report, the Committee engaged extensively with major shareholders and proxy advisors to understand any concerns with our remuneration framework, and to keep apace of both Australian and global market practice. In addition, a robust review of CLINUVEL's remuneration practices and disclosures were completed in FY2021 with support from independent external advisors.

We appreciate and respect all the feedback from our key stakeholders, and we strive to consider a balanced view of all perspectives. However, achieving this balance is no easy feat, given our diverse Australian and international shareholder base. The table in section B details the Committee's response to the main concerns raised by stakeholders, which include enhanced disclosure and transparency of STI outcomes and how our remuneration approach reflects our significant global presence.

The Committee recognises that improving our remuneration practices will be an iterative process that will consider your ongoing feedback, whilst ensuring we continue to appropriately reward and motivate the best talent for CLINUVEL. The Committee is confident that CLINUVEL's remuneration framework remains strongly aligned to our vision and strategy, and focuses our executive team on delivering sustainable, long-term value for shareholders.

We thank you all for your thoughtful feedback and look forward to continuing to engage with our stakeholders.

Yours sincerely.

Willem Blijdorp, Chairman of the Remuneration Committee
Amsterdam

B RESPONSE TO SHAREHOLDER FEEDBACK AND THE FIRST STRIKE IN FY2020

In FY2020, the company received a first strike against the Remuneration Report, and has responded to key items of concern that were raised as follows:

Remuneration Component	Issue Raised FY2020	CLINUVEL's Response
Total Fixed Remuneration (TFR)	Significant increase in the CEO's fixed remuneration in FY2020 relative to ASX-listed peers	The Committee acknowledges the feedback received regarding the increase in the CEO's remuneration in FY2020, as part of his new service agreement. In determining the CEO's new remuneration last year, the Board considered that CLINUVEL is a truly global company, with most of its commercial operations and revenues generated in Europe and the US, a RDI Centre located in Singapore, and its CEO based in Europe. As such, CLINUVEL faces the challenge of attracting and retaining high-calibre executives in an increasingly competitive global talent market in the pharmaceutical/biotech industry – particularly given the strong focus on healthcare across the world. The Board is strongly of the view that the CEO's remuneration should reflect this global context, and more importantly, acknowledge Dr Wolgen's proven track record in delivering outstanding business performance and TSR* growth since he became CEO in late 2005 (28% over 1 year, 147% over 3 years, 591% over 5 years, 1,487% over 10 years).* The Board also waited until CLINUVEL's R&D phase was completed and sustained profitability was achieved, before adjusting Dr Wolgen's remuneration in FY2020 to better align with global peers. FY2020 marked the fourth consecutive year of annual profit for the Company (NPAT of A$15.1 million, EBIT of A$11.5 million), and the CEO and his team have delivered again in FY2021, with CLINUVEL achieving NPAT of A$24.7 million and PBIT of A$25.7 million this year. The CEO will not receive further fixed pay increase for the remainder of his service agreement (other than for CPI adjustments). To provide stakeholders with confidence around how CLINUVEL reviews and sets executive remuneration levels, we have provided enhanced disclosure and transparency in section D. This includes details of benchmarking completed by independent external consultants in March 2021.
STI Plan	Lack of disclosure of STI performance targets.	The Committee continues to consider ways to enhance the levels of disclosure of STI measures and targets, where commercial sensitivity does not prohibit this given the stage of CLINUVEL's development and competitive environment. STI performance measures are carefully selected by the Board, ensuring an appropriate balance between measures that management can influence, and which drive long-term decision making and ultimately shareholder value accretion. A rigorous process is also followed to ensure robust targets are established for all measures to drive high levels of business and individual performance. In FY2021, the Committee has provided greater transparency and granularity to shareholders of STI performance measures and outcomes, without compromising the confidential nature of some of the operational data and information used in compiling these performance measures. Refer to section D for detail.
LTI Plan	Prior LTI grants to the Executive KMP (excluding the CEO) are not linked to profitability or other financial measures.	No LTI performance rights were granted to the other Executive KMP in FY2021, with LTIs last granted in FY2016. LTI performance rights will be granted to the other Executive KMP in FY2022, under a similar structure to the CEO's FY2020 LTI grant to ensure consistency of measures linked to CLINUVEL's long-term strategy. As disclosed on pages 38 to 40 of this report, the CEO's FY2020 LTI grant includes

		several KPIs critical to the commercial growth of CLINUVEL, which are designed around the unique risks and complexities of our business. These KPIs include various financial measures linked to milestones for market capitalisation, cash reserves and sales revenues; all with significantly stretching targets that will likely increase shareholder value, if achieved.
	Significant quantum of LTI granted to the CEO in FY2020, despite a significant number of votes against the allocation at the 2019 AGM (approx. 40%).	The Committee acknowledges that at face value, the LTI grant would attract commentary from stakeholders. However, the CEO's reported LTI quantum of A$1.65 million for FY2020 (based on a total grant valuation of A$8.2 million to be realised over the 4-year vesting period) is well below (55%) the median of US-listed peer companies and within range of Australian-listed peers, based on benchmarking completed by an independent external consultant. More importantly, as described above, the Committee is confident that the LTI KPIs represent significantly stretching targets for the CEO, with strong alignment to shareholders returns. As of 30 June 2021, only 6% of the rights have vested, with only 29 months left for Dr Wolgen to achieve vesting of any further awards. If the CEO delivers minimal hurdles over the remainder of the 4-year vesting period, he will earn significantly less given the grant covers a multi-year period.
One-off retention awards	The CEO and CFO are entitled to additional cash-based loyalty/retention awards for each month of service.	The Committee acknowledges that loyalty/retention awards are a variation from Australian market practice. However, as broader economic conditions continue to improve and competition for global talent increases, the Committee believes that attracting, motivating, and retaining high-performing executive KMP is key to maintaining CLINUVEL's outperformance and management stability during this critical stage of our development and commercialisation. The loyalty award is only intended to form part of the remuneration packages of the CEO and CFO for the foreseeable future, with no awards to be granted to any other Executive KMP.

*** TSR is calculated using a median share price for the three months to June 30 for each relevant year. Dividends were ignored due to immateriality.**

C 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:

a) 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.

b) 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.

c) 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.

d) The levels and structure of remuneration are benchmarked against relevant international peers and considered against global employment market conditions.

e) 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 2021, 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.

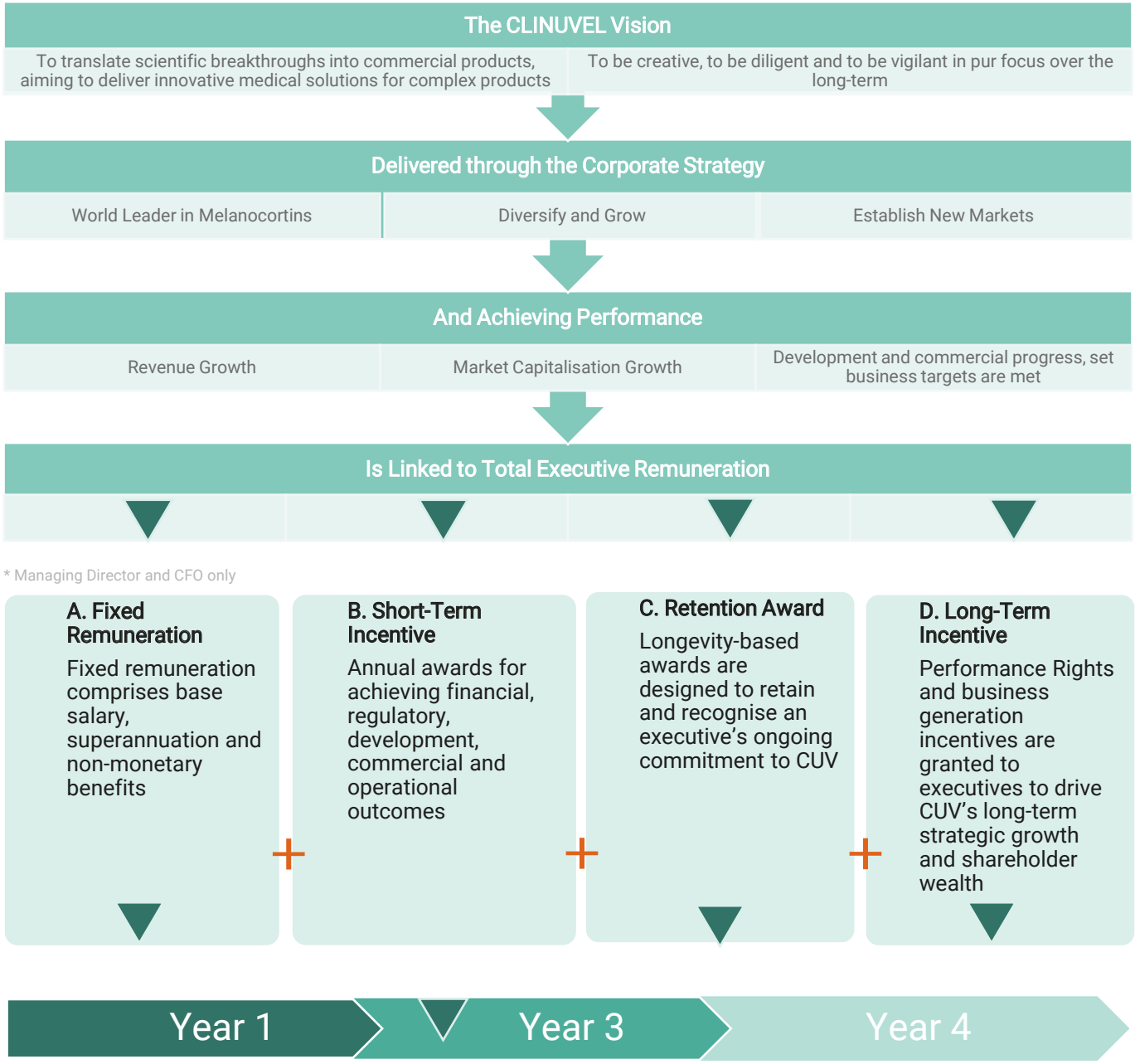
(iii) Voting and feedback at the Company's last Annual General Meeting

In the 2020 Annual General Meeting (AGM), the Company obtained 67.50% of the proxy votes (including votes at the Board's discretion) in favour of adopting the 2019/20 remuneration report, and this resolution was carried in favour by poll with 64.65% of votes cast. As more than 25% of the number of votes cast was against this resolution, this constituted a first strike for purposes of the Corporations Act 2001 (Cth). The Company did not receive any further specific feedback at the AGM on its remuneration practices.

D EXECUTIVE REMUNERATION

(i) 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 cash 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, other fixed amount cash incentives, including retention awards to recognise ongoing commitment to the Company).

(ii) Executive Remuneration Structure 2020-21

A. Fixed Remuneration Base Salary and Non-Monetary Benefits

Fixed remuneration comprises base salary, superannuation and non-monetary benefits including health insurance, accommodation, relocation, travel and statutory benefits

Base salary is set at a level to attract and retain talent with the requisite capabilities to deliver on CLINUVEL's objectives, taking into account seniority, qualifications, skill, experience, length of service, leadership, industry knowledge and level of strategic oversight.

Base salary is regularly tested for market competitiveness by reference to appropriate benchmarks sourced externally and comparing to industry-relevant local and international peer companies.

Base salary 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.

B. 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 Base Salary, payment capped at 465,000 Euros.	Chief Financial Officer: 17% of Base Salary Chief Scientific Officer: 9% of Base Salary
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 43 and 44.	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 43 & 44.

* For 2021/22 the target opportunity for the Managing Director shall be 100% of Base Salary

*For the year ended 30 June 2021, the Remuneration Committee assessed the **Managing Director**'s performance targets which form his Short-Term Incentive and awarded a 70% assessment against the targets.*

For the year ended 30 June 2020, the Managing Director had autonomously chosen to forego the STI awarded for the year and for it to be waived in solidarity with the millions of people who have been impacted and the lives lost

due to the coronavirus pandemic and for the monies to be re-invested in the Company's further research and development

*For the **Other KMP**, For the year ended 30 June 2021 the Managing Director assessed overall performance for the 2020/21 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: 65%	***Chief Financial Officer: 82%***

C. Retention Award

Longevity-based awards are remuneration payments to encourage key management retention 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
Chief Financial Officer	A$1,000

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 Effective Date of the service agreement unless the service agreement is terminated sooner.

D. 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 Other 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, seven years or undated in duration whereby if 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 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 are 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

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.

For the financial years ended 30 June 2021 and 30 June 2020, no Performance Rights were granted to the **Other Executive** KMP. The Other Executive KMP were last issued performance rights in the 2015/16 financial year.

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 2020/21 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.

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 5 years previous, in the 2014/15 financial year.

By shareholders approving the issue of Performance Rights, the cash-based Business Generation Incentives included in the Managing Director's 2019 service agreement were replaced in its entirety by equity based remuneration to vest upon the Company meeting specific performance conditions.

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. This is currently demonstrated in the number of Performance Rights that have vested since date of grant at the 2019 AGM. As at 30 June 2021, of the 1,513,750 granted to the Managing Director at the 2019 AGM, 95,375 performance rights, or 6%, have achieved their vesting conditions.

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 the following pages 38 to 40:

The rationale behind the issue of the performance rights issued to the Managing Director and 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

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 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: Consequent to shareholder approval to grant performance rights to the Managing Director at the 2019 Annual General Meeting, Business Generation Incentives were removed from the Managing Director's 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 BGIs for the Chief Financial Officer vary between $30,000 and $60,000 per BGI, linked to: • BGI1: successful regulatory outcome resulting in the first US approval for the use of SCENESSE® (achieved in 2019/20); • BGI2: 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 • BGI3: participation in an equity or debt funding event if deemed necessary to meet the business needs of the Company For the 2020/21 financial year, no BGIs were achieved by the Chief Financial Officer. **Managing Director Only**: 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 year ended 30 June 2021 or 30 June 2020.

	Description of Performance Conditions	Performance Rights granted to Managing Director
PC1	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. To achieve these targets within the vesting period, the Company must generate returns well above the performance of global biotech indices over a similar period, such as the Nasdaq Biotech Index which performed 30.32% over 5 years (ending June 2019) and 5.54% on an annualised basis over the same period. 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,	450,000

	(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	
PC2	(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.	105,000
PC3	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.	105,000
PC4	(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.	87,500
PC5	(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	175,000
PC6	(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.	262,500
PC7	(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.	212,500

PC8	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 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.	116,250

(iii) Managing Director Remuneration – Further Information

The inherent risk of failure within pharmaceutical development is high and this risk is magnified 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 which had posed 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 (acting in a dual capacity as Chief Executive Officer and Chief Medical Officer) and the Chief Scientific Officer. The Managing Director has the responsibility of guiding and overseeing the execution of the overall corporate strategy, has global responsibility for the safety aspects of the drug (including pharmacovigilance and quality management) and is responsible for market access. 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 will be 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 within the business model; and
- It is competitive in international markets, industry and related fields of expertise and providing for specific skillsets.

In the 2019/20 year the Managing Director's service agreement was renewed for a further three years, from 1 July 2019 to 30 June 2022. In determining the level and structure of the remuneration agreed with the Managing Director, the Remuneration Committee considered the following criteria:

- longevity of his 15 years of service as CEO compared against local and international peers;
- track record, integrity and professional qualifications for the position;
- the enterprise value created over the past decade and since first employment;
- the shareholder value created in the past three years leading up to the renewal to the service agreement (from 1 July 2016 to 30 June 2019);
- capability to sustain the Company's focus to maximise profitability following market access; and
- a demonstrated result to attain stability of the business and management team over the long term.

(iv) 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, importantly, on international securities exchanges for the purpose of peer group analyses. CLINUVEL is a company operating globally with the bulk of its operations and financial exposure falling outside Australia. Its remuneration structure requires to be competitive to international benchmarks in order 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.

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

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.

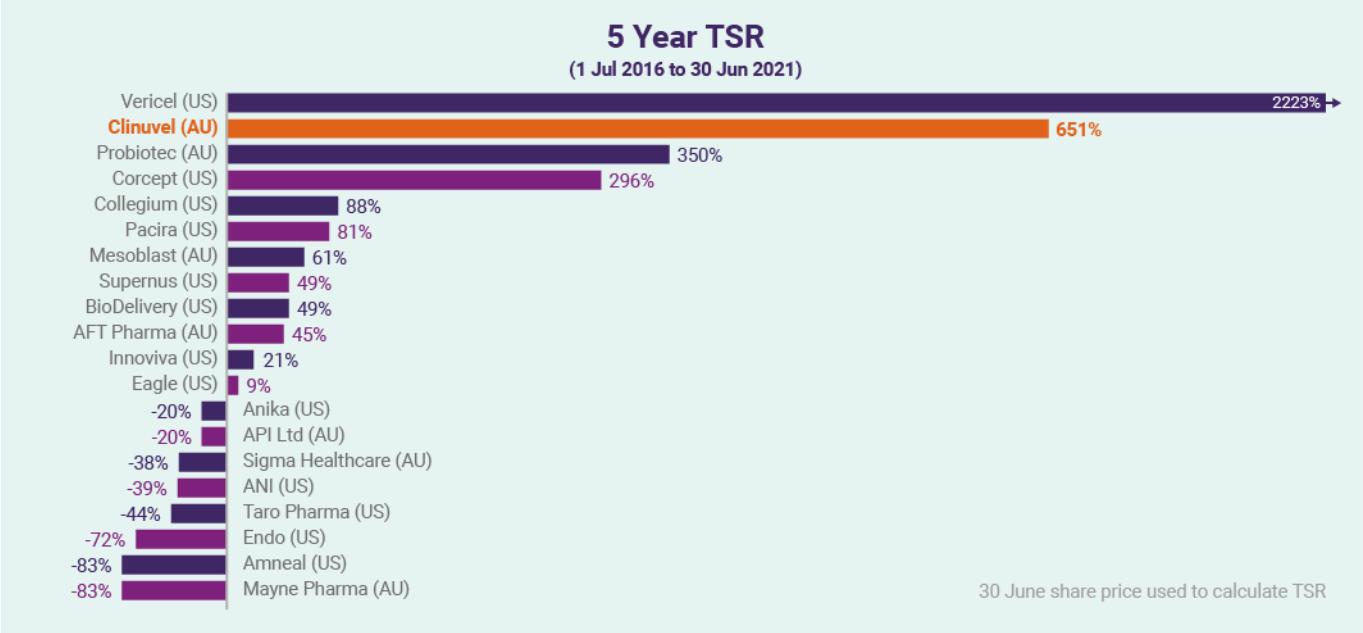
During the year the Managing Director's remuneration was benchmarked against relevant local and international (US) companies using the following quantitative criteria, consistent to the selection criteria listed above:

Benchmarking Criteria	Australian Companies	US Companies
Market Capitalisation:	Between A$100 million and A$3 billion	Between US$500 million and US$5 billion
Generating Product Revenues:	Yes	Yes
Financial Status:	Positive EBITDA	Positive EBITDA

Six Australian and 13 US life science peer companies (being a mix of medical device, pharmaceutical product and diagnostic focussed companies) were identified. The results of the peer analyses concluded that in the past 5 years, CLINUVEL:

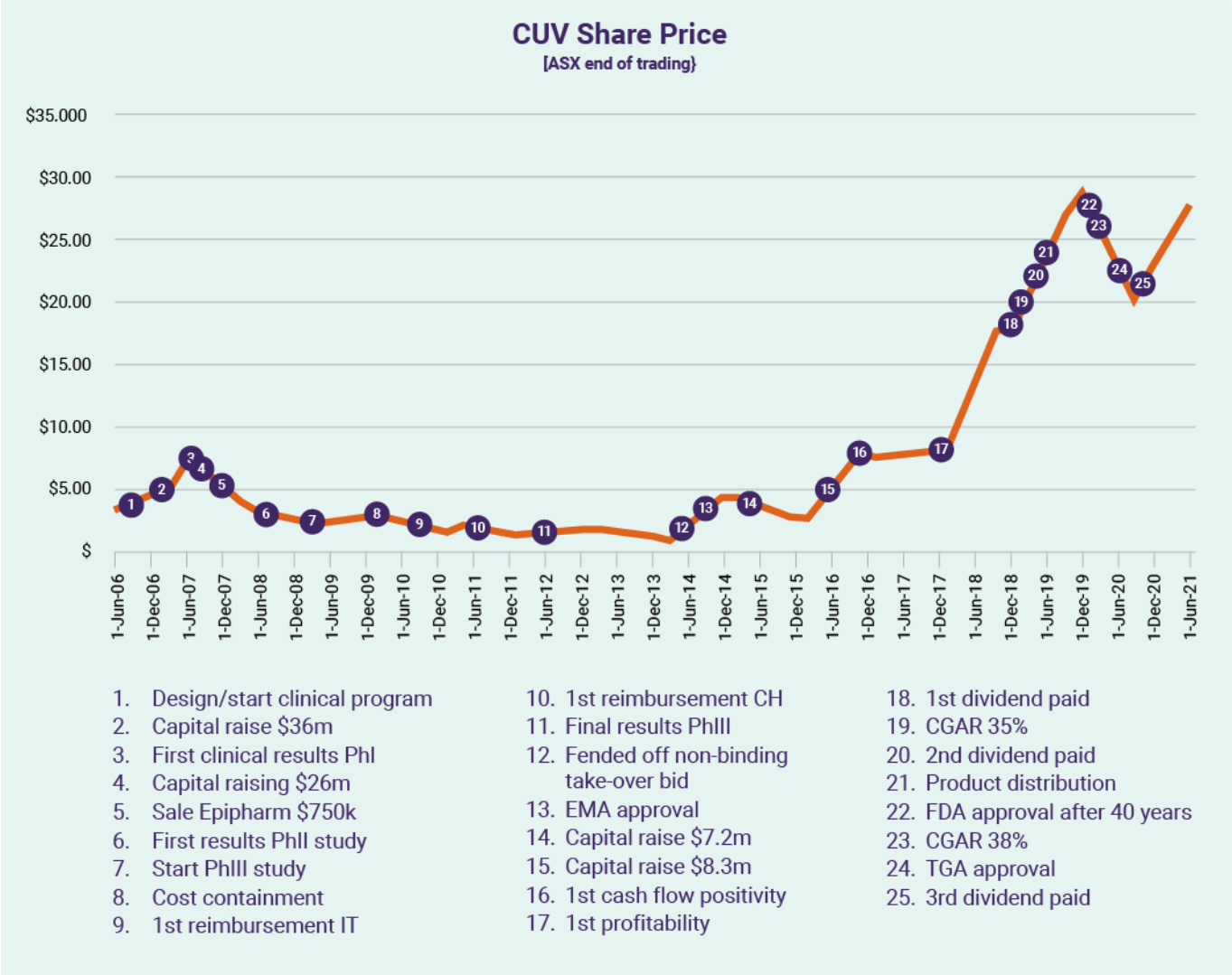
1. had raised far less capital;
2. had incurred significantly less shareholder dilution;
3. had accelerated its revenue growth,
4. had outstripped reported profit and earnings per share, and
5. had delivered a higher total shareholder return than most peers included in the analysis.

The table below compares the Total Shareholder Return between CLINUVEL and the peer companies over the past 5 years:



Throughout FY2021 CLINUVEL was trading at significantly higher P/E multiples than nearly all its Australian and 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.

In comparing Managing Director remuneration to the peer group, the fixed base remuneration was positioned above the median level, whereas the total remuneration level was positioned 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 Company since 2005, building a profitable and sustainable business whilst delivering higher than normal shareholder return. To further demonstrate this outperformance throughout the Managing Director's tenure, the following graph discloses the relationship between performance and shareholder value since 2005:



(v) Relationship Between Remuneration And Performance

The Group has been solely dedicated 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 focussed on both maximising short-term operating performance and long-term strategic growth to promote 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 this has been reflected in various performance conditions attached to the long-term equity incentives. The following performance outcomes tabled in the following page, as aligned with the CLINUVEL strategy, were achieved resulting in a performance based STI

incentive rating of 70% of the maximum potential opportunity for the Managing Director. In assessing the KPIs, the Board considered the significant achievements made during the reporting period and the effort required to navigate the issues and challenges facing the company from the COVID-19 pandemic. This included supplying 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, these are considered commercially sensitive.

STI Outcomes	Year Ended 30 June 2021		
	Managing Director		
STIs summarised into Strategic Grouping	Weighting	Rating	Outcome
Growth and Technology Translation	20%	Partially Met	• Progress made in the development of the PRÉNUMBRA® second afamelanotide formulation • Formulations developed for non-pharmaceutical topicals, preparing for commercial scale manufacture • Constructing and opening of new VALLAURIX Research, Development & Innovation (RDI) Centre in Singapore • Identifying potential acquisition targets to support inorganic expansion of the Group
Manufacturing	25%	Partially Met	• Inventory management of SCENESSE® to support future commercial and clinical supply • Raw material supply secured • Targeted alternative manufacturing solutions to allow eventual vertical integration of supply chain within the Group
Financial	35%	Partially Met	• Fourth Consecutive Annual Profit Announced, 123% increase in PBIT • Increase in Cash Reserves, Receipts and Revenues • Third Consecutive Annual Dividend Paid • Recognised as one of the Financial Times High-Growth Companies of the Asia-Pacific Region for 2020 • Maintained uniform pricing in EU, set US price
People and Culture	10%	Met	• Communications, Branding & Marketing Division established, new team of staff appointed • Increased personnel upon expanded RDI Centre in Singapore • Key leadership appointments following internal management re-structure

New Initiatives	10%	Partially Met	• DNA Repair Program announced in XP Patients:
			  ◦ Initially XP-C patients, extended to XP-V patients
			  ◦ Local approvals granted
			  ◦ First patient dosed
			  ◦ Positive safety assessment of first patient
			  ◦ Supporting non-clinical project for assay development completed
			• Stroke Program Announced, with commencement of Phase II pilot study and first patients recruited and dosed
			• DNA Repair Program Announced for Healthy Volunteers
			  ◦ Local approvals granted

Total	**100%**	**70%**	

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.

Regulatory, Clinical & Commercial Milestones	Year Ended 30 June				
	2017	2018	2019	2020	2021
Ph II Vitiligo Study - Singapore	←	—	→		
VALLAURIX PTE LTD – formulation & melanocortin development	←	—	—	—	→
First commercial sales in EU	←	—	—	—	→
Submission and subsequent approval for marketing authorisation by the US FDA				←	→
Submission and subsequent approval for marketing authorisation by the Australian TGA					↔
First commercial sales in US					↔
Ph II Arterial Ischaemic Stroke Study - Melbourne					↔
Market capitalisation (A$ million)	333	527	1,649	1,267	1,517
Share Price High ($)	9.19	13.52	39.85	45.88	31.23
Share Price Low ($)	4.10	5.91	9.43	12.92	19.53
Closing Share Price ($)	6.98	11.01	33.68	25.65	30.70
Change in Share Price over 1 Year (%)	62	58	206	(24)	20
Change in Share Price over 3 Years (%)	311	288	680	268	179
Change in Share Price over 5 Years (%)	328	508	1881	803	611%
Dividend Paid (cents)	-	-	2.0	2.5	2.5

(vi) 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 2020/21 is demonstrated as follows:

Position	Fixed Remuneration	STI Cash	LTI Cash[1]	LTI Equity[2]
Managing Director	100%	48% of Base Salary	6.9% of Base Salary	134% of Base Salary
Other Executive KMP	100%	Between 9% and 17% of Base Salary	4.6% of Base Salary	-

1. Retention Award earned during 2020/21. For Other Executive KMP, relates to CFO only
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, and includes accelerated expensing of those performance rights which vest during the year

E 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
	Prior to January 1 2021	After January 1 2021			
Chair	110,000	115,000	-	-	-
Non-Executive Director	65,000	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.

From 1 January 2021, the Board agreed to increase the Non-Executive Director fees by $5,000 per annum. The increase was to ensure the level of Non-Executive Director fees remain competitive to attract and retain high-calibre Directors. It was the first increase to Non-Executive Director fees since 2015/16.

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 2021 was $412,500.

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.

The Board had previously considered the relatively small management team comparative to peer companies when setting Non-Executive Director remuneration policy. The Board considered that from time to time its Non-Executive Directors would become involved in steering management and engage in certain operational matters that would not commonly be expected of those in a non-executive capacity. Furthermore, the Company ensured the interests of all its KMP, including those in a non-executive capacity, were aligned with the interests of the Company and its shareholders within an appropriate control framework, addressing the preference of some shareholders to see Non-Executive Directors have shareholdings in the Group.

It is no longer planned for Non-Executive Directors to participate in long-term equity compensation plans. Only one current Non-Executive Director in Mrs Shanahan still holds Performance Rights, the last date of issue being November 2014.

F SERVICE AGREEMENTS **FY2021**

Remuneration and other terms of employment for the Managing Director are formalised by a service agreement determined by the Remuneration Committee. The agreement provides for base salary, 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 Conditional 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. The details of the service agreements to the Managing Director and Executive KMP are:

Name	Dr Philippe Wolgen[1]	Dr Dennis Wright	Mr Darren Keamy[2]
Duration of contract	3 years	No fixed term	3 years
Notice Period (from Company)	12 months	3 months	12 months
Notice Period (from Managing Director)	12 months	-	-
Notice Period (from Executive KMP)	-	3 months	12 months
Termination Payment without Cause	12 months	3 months	12 months
Termination Payment with Cause	None	None	None

1. Expiry Date 30 June 2022
2. Expiry Date 30 June 2022

G 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 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.

138,335 Performance Rights issued under the 2009 Scheme remain unvested as at 30 June 2021

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. 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 lapses 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.

1,646,250 Performance Rights have been issued and 1,550,875 remain unvested under the 2014 Plan. 95,375 Performance Rights have vested but are not yet exercised.

FY2022 Planned Issue of Performance Rights to Staff

The Performance Rights Plan is an important component of the Company's remuneration reward framework which, amongst other things, strives to retain, motivate and incentivise employees to build company value and to align their interests with those of the shareholders of CLINUVEL. The Board wishes to continue incentivising those employees ('participants') who are considered by the Board to be integral to CLINUVEL achieving its future goals of successfully commercialising the Company and executing the expansion of its various R&D and commercial and programs.

In FY2022 the Board intends to issue Performance Rights to select staff. The conditions attached to these Performance Rights will be consistent to the performance conditions and the timelines to those granted to the Managing Director and approved by shareholders at the 2019 AGM. They will also consist of individual-based performance conditions tailored to each participant designed to add to company value should these conditions be met within the vesting period.

The last time employees of the Company were issued with Performance Rights was FY2015.

H DETAILS OF REMUNERATION

KMP remuneration of the company for the years ended 30 June 2021 and 30 June 2020 – Cash Based Benefits

	Year	Gross Salary [3]	Short Term Incentive	Business Generation Incentive	Retention Award	Other[1]	Superannuation/ Pension Fund	Total (Excluding Share-Based Payments)
		$	$	$	$	$	$	$
Dr. P.J. Wolgen[2]	**2021**	1,532,499	732,976	-	105,152	296,911	-	**2,667,538**
	2020 restated	1,577,235	-	-	1,422,022	152,299	-	**3,151,556**
Mrs. B.M. Shanahan	**2021**	75,343	-	-	-	-	7,157	**82,500**
	2020	73,059	-	-	-	-	6,941	**80,000**
Mr. W.A. Blijdorp	**2021**	112,500	-	-	-	-	-	**112,500**
	2020	99,167	-	-	-	-	-	**99,167**
Dr. K.A. Agersborg	**2021**	72,500	-	-	-	-	-	**72,500**
	2020	67,917	-	-	-	-	-	**67,917**
Mrs. S. E. Smith	**2021**	72,500	-	-	-	-	-	**72,500**
	2020	52,667	-	-	-	-	-	**52,667**
Prof. J. V. Rosenfeld	**2021**	66,210	-	-	-	-	6,290	**72,500**
	2020	38,204	-	-	-	-	3,629	**41,833**
Mr. S.R. McLiesh Ceased directorship 30 November 2019	**2021**	-	-	-	-	-	-	**-**
	2020	41,857	-	-	-	-	3,976	**45,833**
Dr. D.J. Wright	**2021**	264,818	15,492	-	-	-	21,694	**302,004**
	2020	257,105	17,355	-	-	-	21,003	**295,463**
Mr. D.M. Keamy	**2021**	288,468	40,385	-	13,331		21,694	**363,878**
	2020 restated	278,713	42,364	30,000	173,636	-	21,003	**545,716**
Total	**2021**	**2,484,838**	**788,853**	**-**	**118,483**	**296,911**	**56,835**	**3,745,920**
	2020 restated	**2,485,924**	**59,719**	**30,000**	**1,595,658**	**152,299**	**56,552**	**4,380,152**

1 'Other' includes health insurance, housing and other allowances that may be subject to fringe benefits tax.
3 In 2019/20 Dr Wolgen's salary is paid in Singapore dollars (SGD) and in Euro currency. In 2020/21 the salary was paid in Euro currency
3 Does not include movement in annual leave and long service leave provisions.
The natural accretion to Dr Wolgen's annual leave and long service leave entitlements for 2020/21 was $231,314 (year ending 30 June 2020: $172,950). For Mr Keamy and Dr Wright, the accretive movement to their annual leave and long service leave entitlements was $11,172 and $20,223 respectively (year ending 30 June 2020: $24,000 and $3,277 increase respectively)
In 2019/20, upon the renewal of Dr Wolgen's service agreement and the increase to his base salary, the value of his unused annual leave and long service leave entitlements were reset, resulting in a $365,923 increase to annual leave and long service leave entitlements available to Dr Wolgen.
[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 36 for further information.

KMP remuneration of the company for the years ended 30 June 2021 and 30 June 2020

– 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[3]	2021	2,667,538	2,312,308	4,979,846	61%
	2020 restated	3,151,556	1,645,205	4,796,761	34%
Mrs. B.M. Shanahan	2021	82,500	-	82,500	
	2020	80,000	-	80,000	
Mr. W.A. Blijdorp	2021	112,500	-	112,500	
	2020	99,167	-	99,167	
Dr. K.A. Agersborg	2021	72,500	-	72,500	
	2020	67,917	-	67,917	
Mrs. S. E. Smith	2021	72,500	-	72,500	
	2020	52,667	-	52,667	
Prof. J. V. Rosenfeld	2021	72,500	-	72,500	
	2020	41,833	-	41,833	
Mr. S.R. McLiesh Ceased directorship 30 November 2019	2021	-	-	-	
	2020	45,833	-	45,833	
Dr. D.J. Wright	2021	302,004	-	302,004	5%
	2020	295,463	1,284	296,747	6%
Mr. D.M. Keamy	2021	363,878	-	363,878	11%
	2020 restated	545,716	4,174	549,890	14%
Total	2021	3,745,920	2,312,308	6,058,228	
	2020 restated	4,380,152	1,650,663	6,030,815	

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. 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 – 2021

	Balance at Start of Year	Issued as Compensation*	Exercised	Lapsed and Expired	Balance at End of Year	Vested and Exercisable
Directors						
Mrs. B.M. Shanahan	25,000	-	-	-	25,000	-
Dr. P.J. Wolgen	-	1,513,750	-	-	1,513,750	95,375
Mr. W.A. Blijdorp	-	-	-	-	-	-
Dr. K.A. Agersborg	-	-	-	-	-	-
Mrs. S. E. Smith	-	-	-	-	-	-
Prof. J. V. Rosenfeld	-	-	-	-	-	-
Other KMP						
Dr. D.J. Wright	18,125	-	-	-	18,125	-
Mr. D.M. Keamy	32,360	-	-	-	32,360	-

All Performance Rights held at the end of the year are unvested.
* Relates to the approval by shareholders to grant performance rights to the Managing Director at the 2019 AGM.

Shares held by KMP

The number of ordinary shares in the Company during the 2020/21 reporting period held by each of the Group's KMP, including their related parties, is set out below:

Year Ended 30 June 2021					
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	258,969	-	-	(25,000)	233,969
Dr. P.J. Wolgen	3,504,696	-	-	(329,375)	3,175,321
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	1,693	-	-	670	2,363
Other KMP					
Dr. D.J. Wright	301,874	-	-	(45,000)	256,874
Mr. D.M. Keamy	331,343	-	-	(17,755)	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	Number of Rights Vested	Exercisable Date
CLINUVEL	450,000	$10.86	Ordinary	20/11/2019	26/08/2020	20/11/2023	0	-
CLINUVEL	1,063,750	$26.87	Ordinary	20/11/2019	26/08/2020	20/11/2023	45,500	26/08/2020
							21,000	29/01/2021
							28,875	20/05/2021
CLINUVEL	37,976	$8.97	Ordinary	24/12/2020	24/12/2020	20/11/2023	0	-
CLINUVEL	94,524	$20.73	Ordinary	24/12/2020	24/12/2020	20/11/2023	0	-

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	Forfeited in Year	Max Value of Right at Grant Date Yet to Vest
Dr. P.J. Wolgen	2019/20 *	2023/24	6%	0%	7,542,604
Mrs. B.M. Shanahan	2011/12	no limitation	-	-	16,682
Mr. W.A. Blijdorp	-	-	-	-	-
Dr. K.A. Agersborg	-	-	-	-	-
Mrs. S. E. Smith	-	-	-	-	-
Prof. J. V. Rosenfeld	-	-	-	-	-
Other KMP					
Dr. D.J. Wright	2011/12	no limitation	-	-	12,853
Mr. D.M. Keamy	2011/12	no limitation	-	-	23,126

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 2014/15 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	53%	70%	30%	732,976
Dr. D.J. Wright	9%	65%	35%	15,492
Mr. D.M. Keamy	17%	82%	18%	40,385

Loans to Directors and Executives

No loans were granted to Directors or executives for the years ended 30 June 2021 and 30 June 2020.

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[1]	Issue Price for Shares	Class
CLINUVEL PHARMACEUTICALS LTD	Nil	Nil$	Ordinary

[1]These shares were issued by the Group during the year after performance conditions attached to the rights were considered met. Those shares issued by the Group to Directors and Employees are held for retention by the Trustee for the 2009 Scheme and the 2014 Plan Trust. Shares issued by the Group to eligible participants were issued directly to the Trustee.

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	1,750,528	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	1,784,583	$Nil	Ordinary	Upon achievement of specific performance and time-based milestones or upon cessation of employment
Total as at 30 June 2021	1,784,583	-	-	-

Non-Audit Services

For the year ended 30 June 2021, Grant Thornton Australia provided audit services to the Company. Grant Thornton Australia also provided non-audit services, specifically tax related services. Details of amounts paid or payable to the auditor for non-audit services provided during the year by the auditor are outlined in Note 19 to the financial statements.

The Directors are satisfied that the provision of non-audit services, during the year, by the auditor is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001. The Directors are of the opinion that the services as disclosed in Note 19 to the financial statements do not compromise the external auditor's independence, based on advice received from the Audit Committee, for the following reasons:

- all non-audit services have been reviewed and approved to ensure that they do not impact the integrity and objectivity of the auditor; and
- none of the services undermine the general principles relating to auditor independence as set out in APES 110 'Code of Ethics for Professional Accountants' issued by the Accounting Professional & Ethical Standards Board, including reviewing or auditing the auditor's own work, acting in a management or decision-making capacity for the Company, acting as advocate for the Company or jointly sharing economic risks and rewards.

Auditor's Independence Declaration

The auditor's independence declaration as required by s.307C of the Corporations Act 2001 is included 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 25th day of August, 2021

Statement of Profit and Other Comprehensive Income for the Year Ended 30 June 2021

		Consolidated Entity	
	Note	2021	2020 Restated
		$	$
Total revenues	2(a)	47,975,583	32,565,423
Interest income	2(b)	342,203	562,928
Other income	2(c)	132,813	781,319
Total expenses	2(d)	(22,737,955)	(22,368,859)
Profit before income tax expense (benefit)		**25,712,644**	**11,540,811**
Income tax expense (benefit)	**3(a)**	**984,397**	**(3,510,388)**
Profit after income tax expense (benefit)		**24,728,247**	**15,051,199**
Net profit for the year		**24,728,247**	**15,051,199**
Other comprehensive income			
Items that may be re-classified subsequently to profit or loss			
Exchange differences of foreign exchange translation of foreign operations		(575,253)	592,857
Other comprehensive income/(loss) for the period, net of income tax		(575,253)	592,857
Total comprehensive income for the period		**24,152,994**	**15,644,056**
Basic earnings per share - cents per share	16	50.0	30.6
Diluted earnings per share - cents per share	16	48.4	29.8

The accompanying notes form part of these financial statements.

Statement of Financial Position as at 30 June 2021

		Consolidated Entity	
	Note	2021	2020 Restated
		$	$
Current assets			
Cash and cash equivalents	17(a)	82,690,982	66,746,521
Trade and other receivables	4	16,088,527	6,612,684
Inventories	5	3,186,670	1,287,914
Other assets	6	882,034	508,818
Total current assets		**102,848,213**	**75,155,937**
Non-current assets			
Property, plant and equipment - net	7	1,384,422	1,075,441
Right-Of-Use assets - net	8	1,218,721	1,313,937
Intangible asset - net	9	185,030	185,030
Deferred tax assets - net	3(c)	2,931,188	3,811,500
Total non-current assets		**5,719,361**	**6,385,908**
Total assets		**108,567,574**	**81,541,845**
Current liabilities			
Trade and other payables	11	4,751,138	4,771,581
Lease liabilities	8	258,236	212,331
Provisions	12	3,697,579	3,278,175
Total current liabilities		**8,706,953**	**8,262,087**
Non-current liabilities			
Lease liabilities	8	1,045,236	1,107,224
Provisions	12	77,951	105,727
Total non-current liabilities		**1,123,187**	**1,212,951**
Total liabilities		**9,830,140**	**9,475,038**
Net assets		**98,737,434**	**72,066,807**
Equity			
Contributed equity	13	151,849,375	151,849,375
Reserves	14	5,017,827	1,850,375
Accumulated losses		(58,129,768)	(81,632,943)
Total equity		**98,737,434**	**72,066,807**

The accompanying notes form part of these financial statements.

Statement of Cash Flows for the Year Ended 30 June 2021

		Consolidated Entity	
	Note	2021	2020
		$	$
Cash flows from operating activities			
Receipts from customers		38,723,858	29,287,833
Payments to suppliers and employees		(20,031,810)	(16,281,001)
Interest received		390,970	636,631
GST and VAT refunds		79,684	423,370
Government grants		99,359	121,535
Net cash provided by operating activities	17(b)	**19,262,061**	**14,188,368**
Cash flows from investing activities			
Payments for property, plant and equipment		(854,325)	(888,826)
Net cash used in investing activities		**(854,325)**	**(888,826)**
Cash flows from financing activities			
Dividends paid		(1,235,266)	(1,224,021)
Payment of lease liabilities		(200,280)	(243,341)
Payment of interest		(44,405)	(18,501)
Net cash used in financing activities		**(1,479,951)**	**(1,485,863)**
Net increase in cash held		**16,927,785**	**11,813,679**
Cash and cash equivalents at beginning of the year		**66,746,521**	**54,268,758**
Effects of exchange rate changes on foreign currency held		(983,324)	664,084
Cash and cash equivalents at end of the year	17(a)	**82,690,982**	**66,746,521**

The accompanying notes form part of these financial statements.

Statement of Changes in Equity for the Year Ended 30 June 2021

	Share Capital	Performance Rights Reserve
	$	$
Balance at 30 June 2019	**151,314,175**	**654,324**
Exercise of Performance Rights under share-based payment	535,200	(535,200)
Employee share-based payment options	-	1,632,099
Dividends Paid	-	-
Transactions with owners	**151,849,375**	**1,751,223**
Profit for the year	-	-
Prior Year Restatement (Note 1(y))	-	-
Profit for the year restated	**-**	**-**
Other comprehensive income:		
Exchange differences of foreign exchange translation of foreign operations	-	-
Total other comprehensive income	-	-
Balance at 30 June 2020 restated	**151,849,375**	**1,751,223**
Exercise of Performance Rights under share-based payment	-	-
Employee share-based payment options	-	2,592,199
Dividends Paid		
Transactions with owners	**151,849,375**	**4,343,422**
Profit for the year		
Other comprehensive income:		
Exchange differences of foreign exchange translation of foreign operations	-	-
Total other comprehensive income	-	-
Balance at 30 June 2021	**151,849,375**	**4,343,422**

Foreign Currency Translation Reserve	Retained Earnings	Total Equity
$	$	$
698,092	**(95,486,738)**	**57,179,853**
-	-	-
-	26,614	1,658,713
-	(1,224,021)	(1,224,021)
698,092	**(96,684,145)**	**57,614,545**
-	16,646,859	16,646,859
(6,083)	(1,595,657)	(1,601,740)
(6,083)	**15,051,202**	**15,045,119**
(592,857)	-	(592,857)
(592,857)	-	(592,857)
99,152	**(81,632,943)**	**72,066,807**
-	-	-
-	10,194	2,602,393
	(1,235,266)	(1,235,266)
99,152	**(82,858,015)**	**73,433,934**
	24,728,247	24,728,247
575,253	-	575,253
573,253	-	573,253
674,405	**(58,129,768)**	**98,737,434**

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Notes To And Forming Part Of The Financial Statements For The Year Ended 30 June 2021

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.

Non-controlling interests, presented as part of equity, represent the portion of a subsidiary's profit or loss and net assets that is not held by the Group. The Group attributes total comprehensive income or loss of subsidiaries between the owners of the parent and the non-controlling interests based on their respective ownership interests.

All the Group's subsidiaries are wholly-owned and 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 major risks due primarily to the nature of research, development and the commercialisation to be undertaken. The risk factors set out may 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 financial statements take no account of the consequences, if any, of the inability of the consolidated entity to obtain adequate funding or of the

effects of unsuccessful research, development and commercialisation of the consolidated entity projects. 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.

In March 2020, the World Health Organisation declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continues to spread worldwide. The spread of COVID-19 has caused significant volatility in Australian and international markets. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the Australian and international economies. The length or severity of this pandemic cannot be reasonably estimated. 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 2021.

The Company has sufficient amounts of cash to be able to continue as a going concern and therefore will be able to realise its assets and extinguish its liabilities in the normal course of business and at the amounts stated in the financial statements.

c) Income Tax

Current Tax

Current tax is calculated by reference to the amount of income tax payable or recoverable in respect of the taxable profit or loss for the period. It is calculated using tax rates and tax laws that have been enacted or substantially enacted by reporting date. Current tax for current and prior periods is recognised as a liability (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 2021 and 30 June 2020 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 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.

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 using a provision matrix.

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 as commissioned by the Group of 100 and published by Milliman Australia at reporting date.

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.

Seasonal nature of revenue from contracts with suppliers

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 "Revenue" provides additional disclosures disaggregating revenue by geographical market and the timing of revenue recognition.

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

Other income from the Australian government R&D tax incentive program is 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. The Group's R&D tax incentive program is currently derived from expenditure only. There was no other income from the government R&D tax incentive for the year ended 30 June 2021.

Government Grant

Government grants represents the Job Support Scheme, Property Tax Rebate and the Boosting Cash Flow for Employer schemes from Australian and Singaporean governments in response to ongoing novel coronavirus (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 2 – 6 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 binomial or a trinomial model, 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 – 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 has adopted Interpretation 23 from 1 July 2019, based on an assessment of 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). There has been no significant impact from the adoption of Interpretation 23 in this reporting period.

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 Group operates in a single operating segment, being the biopharmaceutical sector, and the majority of its activities are concentrated on researching, developing and commercialising a sole asset, being its leading drug candidate. Accordingly, the Group's consolidated total assets are the total reportable assets of the operating segment.

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

y) Restatement of Comparative Amounts

The Group has restated its comparatives for the year ended 30 June 2020 in these consolidated statements after re-assessing the accounting treatment of the Loyalty Payment employee benefits granted to the Managing Director and Chief Financial Officer upon the renewal of their employment contracts, the benefits disclosed in the Remuneration Report to the 2020 Annual Report. The re-assessment of the treatment of the benefits determined the amount to be recognised over its service period commencing at the time of renewal of employment agreement to its vesting date.

The impact of this treatment on the 30 June 2020 profit and loss is an overstatement of profit of $1.596 million.

There is no impact on the cash flow position of the Group reported as at 1 July 2019 and 30 June 2020 as the adjustment represents a non-cash entry.

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

Balance Sheet (extract)	30 June 2020	Increase/(Decrease)	30 June 2020 (Restated)
Provisions-current	1,676,435	1,601,740	3,278,175
Liabilities – current	6,660,347	1,601,740	8,262,087
Liabilities - total	7,873,298	1,601,740	9,475,038
Net Assets	73,668,547	(1,601,740)	72,066,807
Reserves	1,856,458	(6,083)	1,850,375
Accumulated losses	(80,037,286)	(1,595,657)	(81,632,943)
Total Equity	**73,668,547**	(1,601,740)	**72,066,807**
Statement of profit or loss and other comprehensive income (extract)	30 June 2020	Increase/(Decrease)	30 June 2020 (Restated)
Total expenses	(20,773,199)	(1,595,660)	(22,368,859)
Profit before income tax expense (benefit)	13,136,471	(1,595,660)	11,540,811
Net Profit for the year	16,646,859	(1,595,660)	15,051,199
Other comprehensive income/(loss) for the period, net of income tax	592,857	0	592,857
Total comprehensive income for the period	**17,239,716**	**(1,595,660)**	**15,644,056**
Parent Company Information (extract)	30 June 2020	Increase/(Decrease)	30 June 2020 (Restated)
Liabilities – current	2,460,733	173,636	2,634,369
Liabilities - total	2,466,023	173,636	2,639,659
Accumulated losses	(76,805,002)	(173,636)	(76,978,638)
Total Equity	76,795,596	(173,636)	76,621,960
Net Profit for the year	16,769,727	(173,636))	16,596,091
Total comprehensive income for the period	**16,769,727**	**(173,636)**	**16,596,091**

2. Profit/(Loss) From Continuing Operations

	Consolidated Entity	
	2021 $	2020 Restated $
(a) Revenues*		
Commercial sales of goods	42,602,594	26,306,148
Sales reimbursements	5,372,989	6,259,275
Total revenues	**47,975,583**	**32,565,423**
(b) Interest income		
Interest income	342,203	562,928
Total interest income	**342,203**	**562,928**
(c) Other income		
Unrealised gain on restating foreign currency balances and currencies held	-	537,460
Government grants	129,734	126,611
Realised foreign currency gain on transactions	3,079	116,584
Miscellaneous	-	664
Total other income	**132,813**	**781,319**
(d) Expenses		
Clinical and non-clinical development	547,553	341,304
Commercial distribution	2,421,204	2,443,435
Changes in inventories of raw materials, work in progress and finished goods	(1,898,756)	848,170
Communication, branding and marketing	313,986	589,458
Depreciation and amortisation	861,432	446,129
Finance, corporate and general	1,618,430	2,053,990
Legal, insurance and IP	1,095,415	1,147,508
Personnel-related	10,157,625	10,489,716
Materials and related expenses	3,650,304	2,350,347
Share-based payments	2,602,393	1,658,802
Unrealised loss on restating foreign currency balances and currencies held	1,368,369	-
Total expenses	**22,737,955**	**22,368,859**
(e) Profit/(loss) before income tax includes the following specific expenses		
Employee benefits expense	9,630,783	9,588,568
Share-based payments	2,602,393	1,658,713
Expense relating to short-term leases	241,385	296,481
Depreciation of right-of-use assets	319,962	263,154
Depreciation on property, plant & equipment	499,625	164,474
Loss on sale of property, plant and equipment	90,136	-

*Revenues have been disaggregated by pattern of revenue at a point in time.

3. Income Tax Expense

	Consolidated Entity	
	2021	2020 Restated
	$	$
(a) Income tax expense (benefit)		
Current	104,085	-
Deferred	880,312	(3,510,388)
Income tax expense (benefit)	**984,397**	**(3,510,388)**
Deferred tax included in income tax expense (benefit) comprises:		
(Increase) decrease in deferred tax assets	1,612,242	(3,751,243)
Increase (decrease) in deferred tax liabilities	(731,930)	240,855
	880,312	**(3,510,388)**
(b) Numerical reconciliation of income tax expense (benefit) and tax at the statutory rate		
Profit before income tax benefit	25,712,644	11,540,811
Tax at the statutory tax rates of 26.0% in 2021 and 27.5% in 2020	6,685,287	3,173,723
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Permanent differences - Australia	417,537	1,182,470
	7,102,824	**4,356,193**
Recognition of DTA on additional losses utilised in year	(1,075,497)	(1,389,312)
Recognition of DTA on losses at year end	(5,042,930)	(6,742,994)
Recognition of temporary differences - Australia	-	265,725
Income tax expense (benefit)	**984,397**	**(3,510,388)**
Tax losses not recognised		
Unused tax losses for which no deferred tax asset has been recognised	25,737,879	46,780,392
Potential tax benefit at 26.0% in 2021 and 27.5% in 2020	6,691,849	12,864,608
(c) Deferred tax assets		
Deferred tax asset comprises temporary differences attributable to:		
Carry forward tax losses	5,042,930	6,742,993
Intangibles	433,722	449,065
Provisions	210,094	126,932
Accrued Expenses	26,797	39,617

Lease liabilities	48,719	15,897
	5,762,262	**7,374,504**
Movements		
Opening balance	7,374,504	3,623,260
Carry forward tax losses	6,118,426	8,571,113
Deferred tax assets utilised	(7,818,490)	(4,866,870)
Intangibles	(15,343)	57,803
Lease liabilities	32,823	(35,573)
Accrued Expenses	(12,821)	19,681
Provisions	83,163	5,090
	5,762,262	**7,374,504**

(c) Deferred tax liabilities

Deferred tax liability comprises temporary differences attributable to:

Unrealised gains/loss on loans to subsidiaries	(2,774,312)	(3,525,637)
Accrued income	(16,787)	(32,429)
Right-of-use assets	(49,195)	(15,142)
Intangibles	9,220	10,204
	(2,831,074)	**(3,563,004)**
Movements		
Opening balance	(3,563,004)	(3,322,148)
Unrealised gains/loss on loans to subsidiaries	751,326	(305,891)
Right-of-use assets	(34,053)	36,983
Accrued income	15,642	20,276
Intangibles	(985)	7,776
	(2,831,074)	**(3,563,004)**
Total	**2,931,188**	**3,811,500**

The tax rates used in this report are the corporate tax rate of 26% in 2021 and 27.5% in 2020.

4. Trade and Other Receivables

	Consolidated Entity	
	2021 $	2020 $
Current		
Trade debtors	15,811,629	6,349,664
Interest receivables	64,565	117,923
Sundry debtors	212,333	145,097
Total	**16,088,527**	**6,612,684**

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. Trade debtors are generally due for settlement within 30 to 90 days from date of invoice. Collectability is regularly reviewed at an operating unit level. The Group does not have a history of bad debts and the review of trade debtors outside the normal terms indicate full recoverability.

5. Inventories

	Consolidated Entity	
	2021 $	2020 $
Current		
Raw materials – at cost	504,565	255,037
Provision for obsolescence – raw materials	(159,712)	(51,655)
Work in progress – at cost	2,637,386	380,882
Finished goods – at cost	204,431	703,650
Total	**3,186,670**	**1,287,914**

6. Other Assets

	Consolidated Entity	
	2021 $	2020 $
Current		
Prepaid peptide	472,184	105,139
Other prepayments	409,850	403,679
Total	**882,034**	**508,818**

7. Property, Plant And Equipment

	Consolidated Entity	
	2021 $	2020 $
Plant and equipment		
At cost	775,324	560,483
Less: accumulated depreciation	(292,057)	(216,643)
Sub-total	**483,267**	**343,840**
Furniture and fittings		
At cost	40,629	122,555
Less: accumulated depreciation	(18,181)	(82,916)
Sub-total	**22,448**	**39,639**
Leasehold improvements		
At cost	1,253,373	758,299
Less: accumulated amortisation	(374,666)	(66,337)
Sub-total	**878,707**	**691,962**
Total property, plant and equipment	**1,384,422**	**1,075,441**

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.

	Plant and Equipment $	Furniture and Fittings $	Leasehold Improvements $	Total $
Carrying amount at 30 June 2019	179,004	59,703	99,144	337,851
Additions	264,686	7,639	630,017	902,342
Disposals	(1,792)	(16,432)	-	(18,224)
Depreciation written back on disposals	1,513	16,432	-	17,945
Depreciation expense	(99,571)	(27,703)	(37,199)	(164,473)
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
Depreciation expense	(112,693)	(5,944)	(377,881)	(496,518)
Carrying amount at 30 June 2021	**483,267**	**22,448**	**878,707**	**1,384,422**

8. Right-of-Use Assets and Lease Liabilities

	Consolidated Entity	
	2021 $	2020 $
Right-of-use assets		
At cost	1,538,929	1,693,596
Less: accumulated depreciation	(320,208)	(379,659)
Total right-of-use assets	**1,218,721**	**1,313,937**

	Consolidated Entity	
	2021 $	2020 $
Lease liabilities		
Lease liabilities - Current	258,236	212,331
Lease liabilities - Non-current	1,045,236	1,107,224
Total lease liabilities	**1,303,472**	**1,319,555**

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 borrowing rate of 3.5% in 2021 and 2020.

9. Intangible asset

	Consolidated Entity	
	2020 $	2019 $
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 method used to determine the recoverable amount is price analysis of peer companies. The results of the impairment test show that the 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 2021.

10. Interests in Subsidiaries

Name Of Entity	Country Of Incorporation s	Ownership Interest	
		2021	2020
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	
	2021 $	2020 $
Current		
Unsecured trade creditors	2,323,560	1,429,855
Sundry creditors and accrued expenses	2,427,578	3,341,726
Total	**4,751,138**	**4,771,581**
(a) Aggregate amounts payable to:		
Directors and Director-related entities*	735,701	865,192
(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade and Sundry creditors:		
Danish Krone	271	-
Israeli Shekel	105	10,875
Other	-	-
	376	**10,875**

For an analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 22.
*Accrued short-term employee benefits

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

12. Provisions

	Consolidated Entity	
	2021 $	2020 Restated $
Current		
Employee benefits	3,697,579	3,278,175
Total	**3,697,579**	**3,278,175**
Non-current		
Employee benefits	13,166	5,290
Provision for make good	64,785	100,437
Total	**77,951**	**105,727**

13. Contributed Equity

(a) Issued and Paid-Up Capital

	Consolidated Entity	
	2021 $	2020 $
49,410,338 fully paid ordinary shares (2020: 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			
	2021		2020	
	No.	$	No.	$
At the beginning of the financial year	**49,410,338**	**151,849,375**	**48,960,633**	**151,314,175**
Issued during the year	-	-	-	-
Conditional rights issues and transferred from conditional rights reserve	-	-	449,705	535,200
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 to 30 June 2021, no 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$	0

As at 30 June 2020, the year the following conditional performance rights were exercised, resulting in the issue of fully paid ordinary shares:

Expiry date	Exercise Price	Number of Conditional Rights
Upon achievement of various performance milestones	Nil$	449,705

14. Reserves

	Consolidated Entity	
	2021 $	2020 Restated $
Conditional Performance Rights reserve:		
Balance at the beginning of period	**1,751,223**	**654,324**
Share-based payment	2,602,393	1,658,713
Transfer to share capital	-	(535,200)
Lapsed, forfeited rights	(10,194)	(26,614)
Balance at the end of period	**4,343,422**	**1,751,223**

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	**99,152**	**698,092**
Translating foreign subsidiary to current rate at reporting date	575,253	(592,857)
Balance at the end of period	**674,405**	**105,235**
Prior Year Restatement	-	(6,083)
Balance at the end of period restated	**674,405**	**99,152**
Total reserves	**5,017,827**	**1,850,375**

15. Short-Term Lease Commitments

	Consolidated Entity	
	2021 $	2020 $
Short-term 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	111,817	104,983
later than 1 year but not later than 5 years	17,177	7,873
Total	**128,994**	**112,856**

Short-term leases comprise commitments for limited license agreement of furnished office accommodation. The limited license agreement has no contingent rental clauses and contains renewal options.

16. Earnings Per Share (EPS)

	Consolidated Entity	
	2021 $	2020 Restated $
(a) Basic earnings per share (cents per share)	50.0	30.6
(a) Diluted earnings per share (cents per share)	48.4	29.8
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	49,410,338	49,260,026
(b) Weighted average number of performance rights on issue in respect of share based payments during the year	1,720,732	1,198,897
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	51,131,070	50,458,922
(c) The numerator used in the calculation of basic earnings per share ($)	24,728,247	15,051,199

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	
	2021 $	2020 Restated $
(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	34,572,626	23,872,909
Cash on hand	1,317	574
Deposits on call	2,241,903	1,480,550
Term deposits	45,550,000	41,094,576
Security bonds	325,136	297,912
Total cash and cash equivalents	**82,690,982**	**66,746,521**
(b) Reconciliation of cash flows from operating activities with operating profit (loss)		
Operating profit after income tax	**24,728,247**	**16,646,859**
Prior year restatement	-	(1,595,660)
Operating profit after income tax restated	**24,728,247**	**15,051,199**
Non cash flows in operating profit after income tax:		
Depreciation expense on property, plant & equipment	499,625	164,474
Amortisation expense on right-of-use assets	319,962	263,154
Exchange rate effect on foreign currencies held	983,325	(664,084)
Executive share option expense	2,602,393	1,658,713
Unrealised loss (gain) on foreign exchange translation	575,253	(592,857)
Loss on sale of non-current assets	90,136	-
Changes in assets and liabilities:		
(Increase)/decrease in receivables	(9,475,843)	(2,456,468)
(Increase)/decrease in inventories	(1,898,756)	848,170
(Increase)/decrease in other assets	(413,782)	82,698
Increase/(decrease) in payables	(20,443)	2,661,315
(Increase)/decrease in deferred tax assets	880,312	(3,510,388)
Increase/(decrease) in provisions	391,632	682,442
Net cash used in operating activities	**19,262,061**	**14,188,368**

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 and subject to an insignificant risk of changes in value. The effective interest rate on short-term deposits was 0.70% (2020: 1.55%). These deposits have an average maturity date of 233 days (2020: 199 days).

18. Key Management Personnel

	Consolidated Entity	
	2021 $	2020 Restated $
Short-term employee benefits	3,570,602	2,697,942
Post-employment benefits	56,835	56,552
Long-term benefits	118,483	1,625,658
Share-based payments	2,312,308	1,650,663
Total	**6,058,228**	**6,030,815**

No loans existed with key management personnel, except accrued short-term employee benefits.

19. Auditors' Remuneration

	Consolidated Entity	
	2021 $	2020 $
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	113,000	97,000
tax and advisory services	10,000	43,000
Total	**123,000**	**140,000**

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 2021 is $4,370,640 (2020: $4,370,640).

The loan receivable by CLINUVEL PHARMACEUTICALS LTD from CLINUVEL, INC. 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, INC. The loan to CLINUVEL, INC. as at 30 June 2021 is $21,780,429 (2020: $12,840,377).

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 2021 is $13,972,152 (2020: $13,945,079).

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 2021 is $642,292 (2020: $604,342).

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 2021 is $13,900,471 (2020: $15,661,324).

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 2021 is $5,752,040 (2020: $3,615,257).

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 2021 is -$3,973,021 (2020: -$1,949,434). VALLAURIX MC SARL was incorporated as a wholly- owned entity of the consolidated group during 2019-20.

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 2021 is $5,039,479 (2020: $0). CLINUVEL EUROPE LIMITED was incorporated as a wholly- owned entity of the consolidated group during 2018-19.

Director related and Key Management Personnel transactions and entities:

There are no loan transactions and relationships in existence as at 30 June 2021 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 above. 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:

	30 June 2021			30 June 2020		
	Commercial sales of goods	Sales reimbursements	Total	Commercial sales of goods	Sales reimbursements	Total
	$'000	$'000	$'000	$'000	$'000	$'000
European Economic Area & USA	42,603	139	42,742	26,306	137	26,443
Switzerland, Others	-	5,234	5,234	-	6,122	6,122
Total	**42,603**	**5,373**	**47,976**	**26,306**	**6,259**	**32,565**

The Group's revenue disaggregated by pattern of revenue recognition and the Group recognises all revenue based on a point in time.

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 2021 and as at 30 June 2020.

The consolidated entities exposure to foreign currency risk at 30 June 2021

	Consolidated Entity							
	2021 $				2020 $			
	Cash and Cash Equivalents	Trade Debtors and Other Assets	Trade, Other Payables and Provision	TOTAL	Cash and Cash Equivalents	Trade Debtors and Other Assets	Trade, Other Payables and Provision	TOTAL
USD	5,089,237	6,829,485	(1,888,178)	**10,030,544**	2,026,377	1,325	(513,704)	**1,513,998**
EUR	9,330,841	3,709,227	(2,956,578)	**10,083,490**	9,405,452	2,472,442	(1,720,287)	**10,157,607**
CHF	1,623,549	664,643	(137,695)	**2,150,497**	2,118,158	1,057,956	(322,229)	**2,853,885**
GBP	420,266	100,453	(205,788)	**314,931**	456,886	32,982	(336,497)	**153,371**
SGD	521,309	233,263	(283,017)	**471,555**	1,559,596	150,072	(171,080)	**1,538,588**
ILS	-	214,500	(255)	**214,245**	-	-	(25,771)	**(25,771)**
DKK	-	-	(1,272)	**(1,272)**	-	-	--	**-**

Sensitivity Analysis

During the financial year the Company had a principal foreign currency transaction risk exposure to the US dollar. 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 10% appreciation of the Australian dollar against the US currency would have decreased profit and loss and equity by $1,447,684 for the year ended 30 June 2021 (2020: $50,077 increase), on the basis that all other variables remain constant. 10% is considered representative of the market volatility in the Australian dollar/US dollar rate for the period.

For the consolidated entity, an appreciation of the Australian dollar against the US 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 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 2021, if interest rates had changed by +/- 15 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 $106,400 higher/lower (2020: $89,952 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. The consolidated entity no longer holds income securities. 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 nearly thirty 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 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.

	Consolidated Entity	
	2021 $	2020 $
Trade and other payables		
Carrying amount	4,751,138	4,771,581
6 months or less	4,737,110	4,659,117
Greater than 6 months	14,028	112,464
Total	**4,751,138**	**4,771,581**
Lease liabilities		
Carrying amount	1,303,472	1,319,555
6 months or less	147,447	144,170
Greater than 6 months	1,156,025	1,175,385
Total	**1,303,472**	**1,319,555**

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 and from commercial sales currently in the European Economic Area, USA and Switzerland. 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 2021

	Consolidated Entity	
	2021 $	2020 $
Cash and cash equivalents		
Carrying amount	82,690,982	66,746,521
6 months or less	69,053,415	52,406,687
Greater than 6 months	13,637,567	14,339,834
Total	**82,690,982**	**66,746,521**
Other financial assets (includes trade and other receivables)		
Carrying amount	16,088,527	6,612,684
6 months or less	15,619,400	6,597,634
Greater than 6 months	469,127	15,050
Total	**16,088,527**	**6,612,684**

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 milestones set by the Directors of the consolidated entity.

Conditional Performance Rights Plan (2009)

The Conditional Performance Rights Plan (2009) is 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. It is no longer intended to issue 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, at the discretion of the Board, they will 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 2021, 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 2,780,840 shares (2020: 4,530,568 shares).

The following share-based payment arrangements were in existence at 30 June 2021

Performance Rights Series	Number	Grant Date	Expiry Date	Exercise Price	Fair Value at Grant Date
Issued 16/09/2011	113,335	16/09/2011	The earlier of achievement of specific performance milestones and cessation of employment/ directorship	$ Nil	between $0.55 and $0.72
Issued 16/11/2011	25,000	16/11/2011	The earlier of achievement of specific performance milestones and cessation of employment/directorship	$ Nil	$0.67
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 *

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	Vested and Exercisable	Unvested
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.

Holdings of All Issued Conditional Performance Rights – 2020

Performance Rights Series	Balance at Start of Year	Granted as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Vested and Exercisable	Unvested
Issued 25/11/2010	208,332	-	(208,332)	-	-	-	-
Issued 16/09/2011	263,206	-	(135,496)	-	127,710	-	127,710
Issued 16/11/2011	65,000	-	-	(40,000)	25,000	-	25,000
Issued 17/03/2015	105,875	-	(105,875)	-	-	-	-
Issued 05/09/2017	Market	-	-	-	-	-	-
Total	**642,413**	**-**	**(449,703)**	**(40,000)**	**152,710**	**-**	**152,710**
Weighted average exercise price	$Nil	$Nil	$Nil	$Nil	$Nil	$Nil	$Nil

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.

On 26 August 2020 1,513,750 conditional performance rights were issued to the Managing Director, consequent to shareholder approval at the 2019 Annual General Meeting. These performance rights were priced using Monte Carlo simulation pricing model for those performance rights with market capitalisation hurdles and a binomial model for those performance rights linked to non-market vesting conditions. The vesting period is up to 4 years from date of shareholder approval. 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.

24. CLINUVEL PHARMACEUTICALS LTD Parent Company Information

	CLINUVEL PHARMACEUTICALS LTD	
	2021 $	2020 Restated $
Assets		
Current assets	73,061,479	58,556,682
Non-current assets	34,530,668	20,704,937
Total assets	**107,592,147**	**79,261,619**
Liabilities		
Current liabilities	3,284,678	2,634,369
Non-current liabilities	126,355	5,290
Total liabilities	**3,411,033**	**2,639,659**
Equity		
Issued equity	151,849,375	151,849,375
Share–based payments reserve	4,343,422	1,751,223
Accumulated losses	(52,011,683)	(76,978,638)
Total equity	**104,181,114**	**76,621,960**
Financial performance		
Net profit for the year	23,741,882	16,596,091
Total comprehensive income	**23,741,882**	**16,596,091**

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 25th August 2021, the Board of Directors declared an unfranked dividend of $0.025 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 2021 and of its performance for the year ended on that date; and
   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 42 to 90 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 25th day of August, 2021

Grant Thornton

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Independent Auditor's Report

To the Members of Clinuvel Pharmaceuticals Limited

Report on the audit of the financial report

Opinion

We have audited the financial report of Clinuvel Pharmaceuticals Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 30 June 2021, 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 2021 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.

Grant Thornton

Key audit matter	How our audit addressed the key audit matter

Deferred tax asset – Note 3

The Group has recognised deferred tax assets of $2.93m (2020: $3.81m) in accordance with AASB 112 *Income Taxes*. These are primarily attributable to historic losses generated by the income tax consolidated group.

There are also $25.74m (2020: $46.78m) of unused carry-forward tax losses from its foreign subsidiaries not currently sitting on the balance sheet.

An assessment is required as to whether sufficient future taxable profits are likely to be generated to enable the assets to be realised.

This is a key audit area due to the following:

- 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 judgements about the interpretation of tax legislation and the application of accounting standard; 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 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 and objectivity of managements tax expert used, to assist in the preparation of the valuation of the deferred tax asset;
- 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

In December 2020, the Group issued 132,500 rights to the Group's Director of International Operations. The performance rights issued were allocated in two tranches:

1. Tranche A is conditional on market capitalisation over a three-year period from the Grant date.

2. Tranche B is conditional on achieving non-market based performance conditions over a three year period from the Grant date.

Performance rights were valued at $1.1m for accounting and reporting purposes using the Monte Carlo simulation and Binomial Options Valuation method. The value will be expensed over the vesting period (up to 3 years).

The share-based payments expense for FY21 is $2.60m (2020: $1.66m), which is inclusive of the 1,513,750 performance rights issued to the Group's CEO in December 2019. Under AASB 2 *Share-Based Payments*, management are required to value the performance rights and assess the expected vesting date for achievements of the milestones.

This area is a key audit matter due to the degree of judgement required in valuing the performance rights as well as determining estimates of the vesting dates.

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 review 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;
- Reviewing management's determination of fair value of the share-based payments issued, considering the appropriateness of the valuation model used and assessing the valuation inputs;
- Assessing the allocation of the share-based payment expense over the relevant vesting period (assessing appropriateness of the vesting period);
- Evaluating management's forecasts to validate 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 2021, 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: https://www.auasb.gov.au/auditors_responsibilites/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 28 to 53 of the Directors' report for the year ended 30 June 2021.

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Limited, for the year ended 30 June 2021 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, 25 August 2021

Grant Thornton

Collins Square, Tower 5
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Melbourne VIC 3008

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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 2021, 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, 25 August 2021

Shareholder Information

Additional information as at 17 September 2021 required by the ASX and not shown elsewhere in this report is as follows:

1. Shareholding

a. Distribution Of Shareholder Numbers

Ordinary Fully Paid Shares			
Category (Size Of Holding)	Total Holders	Units	% Of Issued Capital
1–1,000	3,715	1,110,040	2.25
1,001–5,000	836	1,901,207	3.85
5,001–10,000	135	985,723	1.99
10,001–100,000	176	4,776,758	9.67
100,001 & Over	27	40,636,610	82.24
TOTAL	**4,889**	**49,410,338**	**100.00**

b. Shareholdings Held In Less Than Marketable Parcels

Total	Minimum Parcel Size	Holders	Units
Minimum $500.00 parcel at $41.71 per unit	3,715	231	451

c. Substantial Shareholdings

Name	No. Ordinary Shares & American Depository Receipts
The Bank of New York Mellon Corporation[1]	4,807,380
A.C.N. 108 768 896 Pty Ltd[2]	2,927,928
Ender 1 LLC[3]	2,340,824

1. As disclosed in substantial holder notice dated 6 December 2019.
2. As disclosed in substantial holder notice dated 22 December 2020. This is inclusive of the relevant interest of shareholder Dr Philippe Jacques Wolgen, for 2,199,810 quoted ordinary shares, as disclosed in substantial holder notice dated 05 July 2021. Actual registered shareholding as at 17 September 2021 is 2,780,040.
3. As disclosed in substantial holder notice dated 16 September 2013. Actual registered shvareholding as at 17 September 2021 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	% held of issued ordinary capital
1.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	11,368,759	23.01
2.	BNP PARIBAS NOMINEES PTY LTD ACF CLEARSTREAM	5,942,326	12.03
3.	BNP PARIBAS NOMINEES PTY LTD SIX SIS LTD <DRP A/C>	5,130,894	10.38
4.	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	3,819,117	7.73
5.	ACN 108 768 896 PTY LTD	2,780,040	5.63
6.	ENDER 1 LLC	2,590,824	5.24
7.	CITICORP NOMINEES PTY LIMITED	2,385,285	4.83
8.	DR PHILIPPE JACQUES WOLGEN	975,511	1.97
9.	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAIL CLIENT DRP>	856,796	1.73
10.	M BADCOCK AND P CHU SUPERANNUATION FUND PTY LTD	632,947	1.28
11.	NATIONAL NOMINEES LIMITED <DB A/C>	603,990	1.22
12.	DR MARK EDWIN BADCOCK	547,563	1.11
13.	BNP PARIBAS NOMS PTY LTD <DRP>	452,391	0.92
14.	BNP PARIBAS NOMINEES PTY LTD <AGENCY LENDING DRP A/C>	271,419	0.55
15.	BNP PARIBAS NOMS (NZ) LTD <DRP>	241,539	0.49
16.	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	238,237	0.48
17.	MR DAVID WILLIAM TREVORROW	222,222	0.45
18.	TRUEBELL CAPITAL PTY LTD <TRUBELL INVESTMENT FUND>	200,000	0.40
19.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	192,758	0.39
20.	MR DAVID JOHN LEWIS	187,000	0.38
Totals: Top 20 Holders Of Ordinary Fully Paid Shares (Total)		**39,639,618**	**80.23**
Total Remaining Holders Balance		**9,770,720**	**19.77**

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, Prof Jeffrey Rosenfeld

MANAGING DIRECTOR AND CHIEF EXECUTIVE OFFICER
Dr Philippe Wolgen

ACTING 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

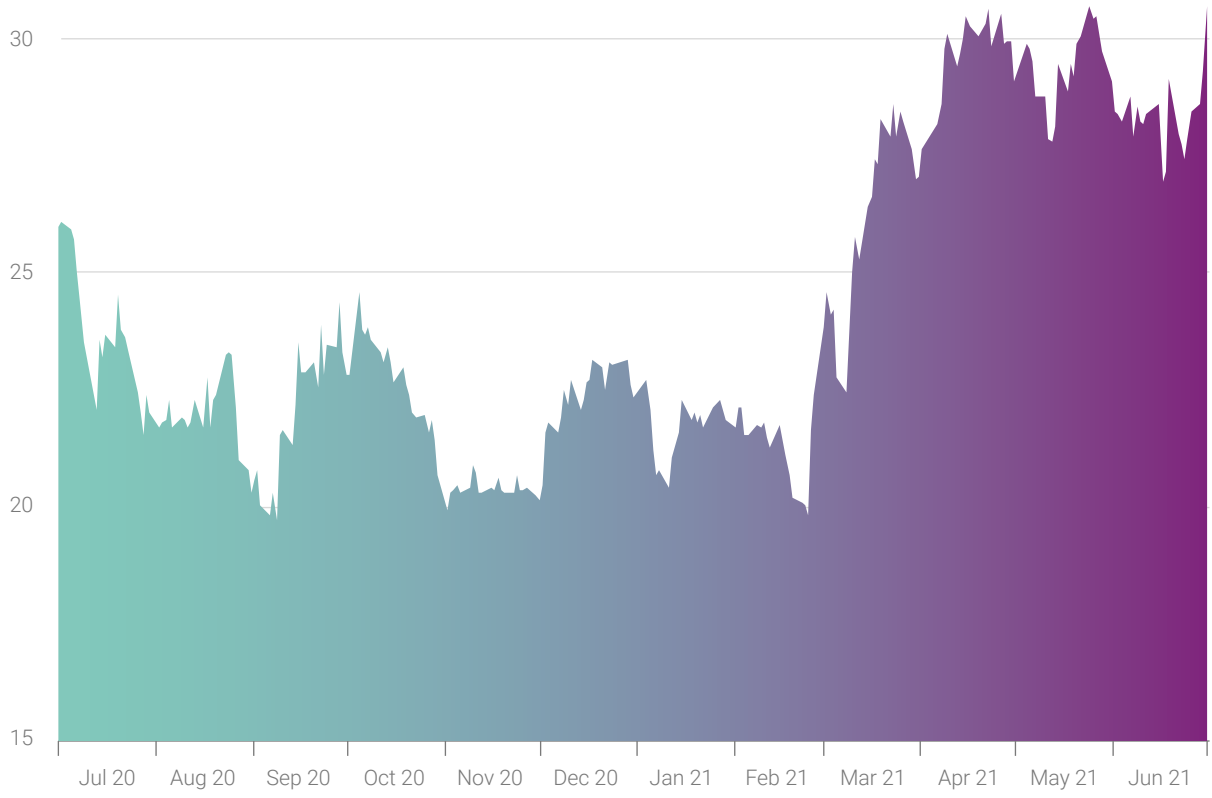
Arnold Bloch Leibler
Level 21, 333 Collins St, Melbourne, VIC 3000, Australia

Sidley Austin LLP
Woolgate Exchange, 25 Basinghall Street, London, EC2V 5HA, United Kingdom

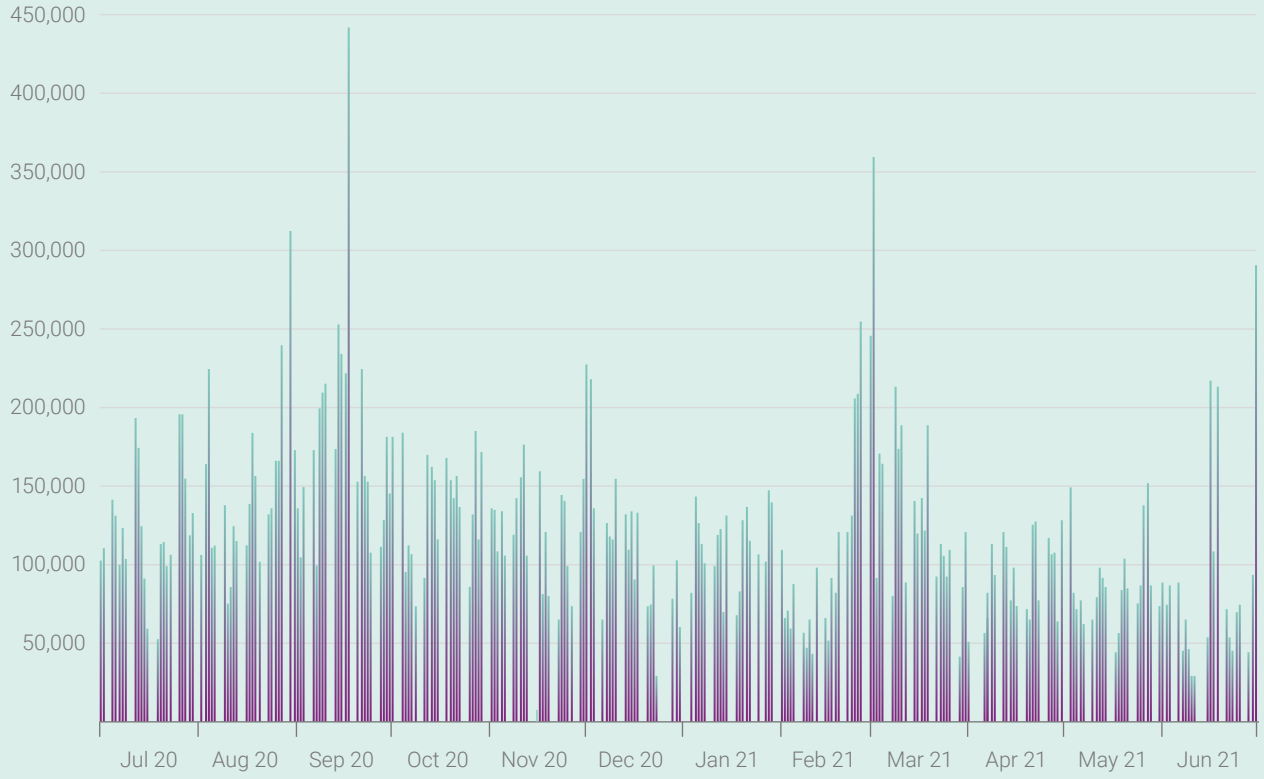
IP LAWYER
Dipl.-Ing Peter Farago
Baadestr 3, Munich 80, Germany

Market Performance

ASX:CUV – Share Price (A$)



ASX:CUV Daily Trading Volume (No)



GLOSSARY

ALPHA-MELANOCYTE STIMULATING HORMONE (α-MSH)
A peptide hormone which activates or stimulates the production and release of (eu)melanin in the skin (melanogenesis).

DERMATOCOSMETICS
Dermatocosmetics are 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.

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) and 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

www.clinuvel.com