



CLINUVEL PHARMACEUTICALS

ANNUAL REPORT 2020

FRONT COVER: GROWTH AND EXPANSION

CLINUVEL is well positioned to build on its established commercial and research and development operations. The Company is expanding access to its drug SCENESSE® (afamelanotide 16mg) for patients with erythropoietic protoporphyria in Europe and the USA, as well as new jurisdictions, subject to regulatory approval and agreement on reimbursement. Drawing on expertise developed in the role of melanocortin drugs – including afamelanotide – in the body, CLINUVEL has expanded its research and development program focussed on SCENESSE® and new molecules to treat multiple patient groups with severe genetic, skin, and systemic disorders. CLINUVEL is on a growth and expansion path to build a diversified and integrated biopharmaceutical business.

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FIFTEEN YEAR PERFORMANCE OVERVIEW

CLINUVEL completed its fourth full year of commercial operations in the financial year ending 30 June 2020, recording a fourth consecutive annual profit and declaring a third consecutive annual dividend.

A STORY OF STRATEGIC FOCUS

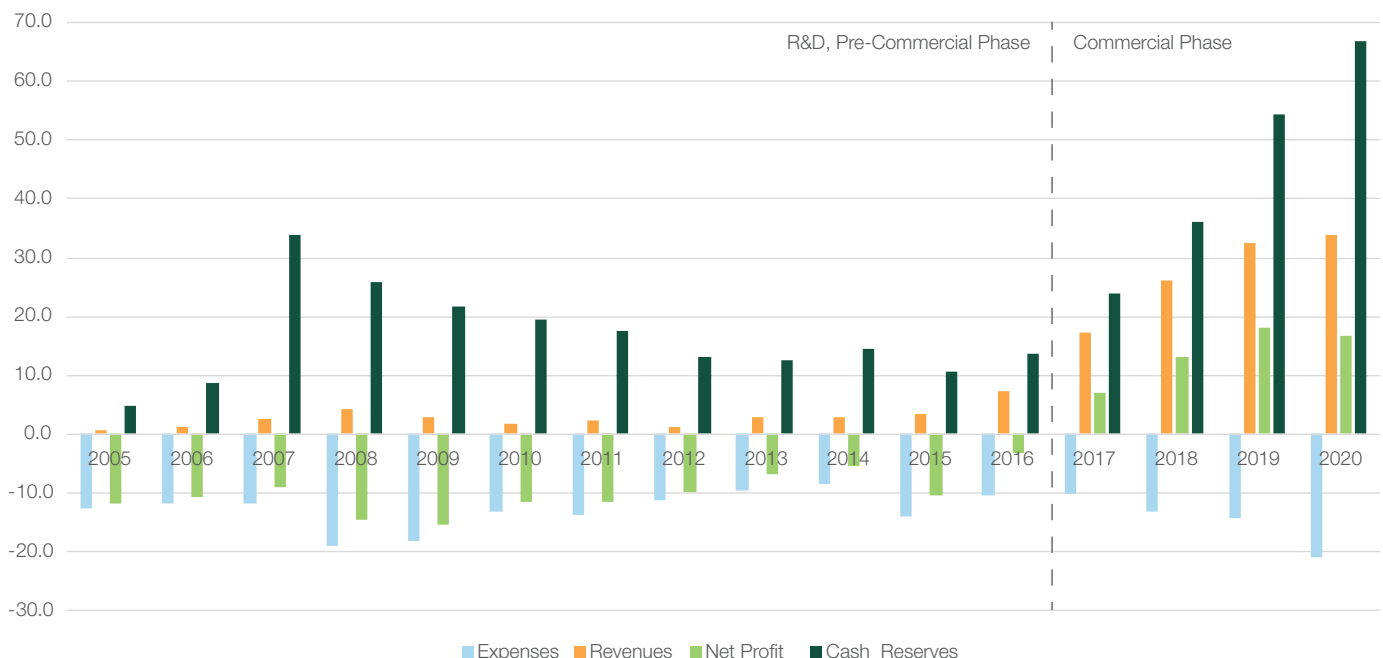
Over the last fifteen years, CLINUVEL has implemented a deliberate and focused strategy to develop and commercialise one lead drug embodying a novel technology, for an unmet need. CLINUVEL has delivered on the strategic objective set in 2005 to develop and commercialise SCENESSE® (afamelanotide 16mg), which has been approved and launched for adult patients with erythropoietic protoporphyria (EPP) in Europe and the USA.

Over the financial years 2005 to 2016, CLINUVEL's operations were research and development (R&D) focussed. During this R&D phase, expenses exceeded revenues as SCENESSE® was developed; clinical studies undertaken and completed; and regulatory approvals, sought and obtained. To finance the business during this time, over A\$94m was raised from capital markets in several installments. CLINUVEL's last capital raising was in March 2016.

COMMERCIALISATION HAS DRIVEN REVENUES, PROFITS AND CASH RESERVES

Commercial operations commenced in Europe in June 2016 following the granting of marketing authorisation by the European Commission in 2014. In the first full year of commercial operations, FY2017, the Company's first net profit after tax of A\$7.1 million was recorded. This outcome was achieved at a higher level in FY2018 (A\$13.2 million) and in FY2019 (A\$18.1 million), which was a record annual profit. Revenues from operations rose by 5% in FY2020 and there was a deliberate and controlled rise of 44% in expenditure to support the expansion of the Group's activities, including establishing commercial infrastructure in the USA following the approval of SCENESSE® by the US Food and Drug Administration (FDA). The Group delivered its fourth consecutive annual profit in FY2020 of A\$16.6 million. This is a positive outcome, achieved as the world has been adversely impacted by the coronavirus pandemic and resulting significant economic contraction in the second half of the year.

Financial Performance, 2005 to 2020, \$Am



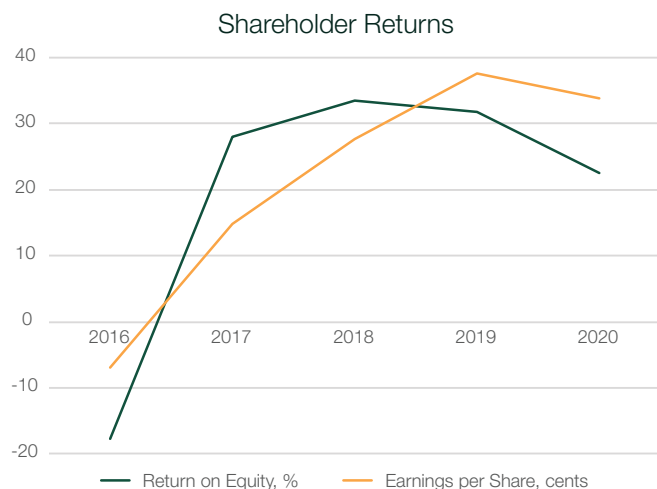
Financial years ending 30 June, revenues include all other income, cash reserves are cash & cash equivalents, net profit after tax

The Company has maintained a disciplined and conservative approach to resource management throughout its development cycle and over the last four years of commercial operations, ensuring that it is capable of withstanding global downturns, removing the need to raise capital in adverse markets and allowing

the Group to self-finance its planned expansion and growth. The rise in cash reserves to A\$66.7 million as of 30 June 2020 represents a 44% annual compound growth rate since the last capital raising in March 2016. This level of cash reserves covers more than three years of the Group's FY2020 expenses.

RETURNS TO SHAREHOLDERS

Given the level of cash reserves accumulated, the Board has been able to show its appreciation for the support of shareholders over the R&D phase of operations and into the commercial phase by declaring an unfranked dividend in each of the last three financial years – A\$0.02 following FY2018 and A\$0.025 after each of FY2019 and FY2020. As a company with positive annual net cash flow and profitability, CLINUVEL has provided shareholders with a positive return on equity and earnings per share over the last four years – 23% and 33.8 Australian cents, respectively in FY2020.



MILESTONE FDA DECISION

FY2020 is notable for the October 2019 milestone decision of the US FDA to approve SCENESSE® for the increase of 'pain-free' light exposure in adult EPP patients with a history of phototoxicity. Within six months of this approval, CLINUVEL commenced first treatment of US patients in April 2020 enabling first US revenues in FY2020. CLINUVEL is committed to providing EPP patients worldwide with access to treatment and is actively pursuing regulatory approvals in other jurisdictions.

Approvals from the world's leading regulatory bodies in the USA and Europe – validating the positive safety profile of SCENESSE® – enable the expansion and increase in pace of the Group's product development pipeline. CLINUVEL has identified other indications where afamelanotide may provide clinical benefit to patients. This is central to the evolution of the Group's strategy to become a diversified biopharmaceutical company providing treatments to multiple patient groups. The feature in this report on Innovation in DNA Repair explains a key path to this objective.

SUMMARY

CLINUVEL is a dynamic biopharmaceutical group of companies that has developed and commercialised a novel treatment from laboratory bench to patient treatment, with a track record of positive cash flow and profit since the commencement of commercial operations. This is an achievement of which stakeholders can be proud. This Annual Report provides more detail on the result for FY2020, how it was achieved and the strategies of the Group to grow and expand its activities.

FY2020 Summary

Total Revenues and Other Income



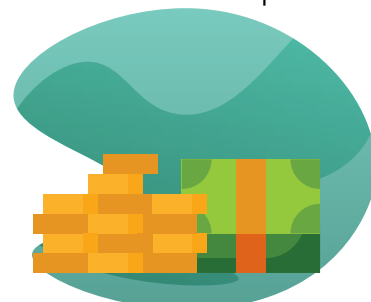
A\$33.9 Million

Net Profit After Tax



A\$16.6 Million

Cash and Cash Equivalents



A\$66.7 Million

Cash Cover and Current Ratio



3.2x and 11.3x

Return on Equity



23%

Earnings Per Share



33.8 Cents

CLINUVEL'S 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 all of the Group's working practise. CLINUVEL Group focuses its research and development on genetic metabolic and diseases not yet addressed, aiming to deliver innovative medical solutions for complex problems.

CLINUVEL'S VISION

Innovating novel solutions for unmet patient and healthcare needs.

CLINUVEL'S VALUES

PEOPLE & ENVIRONMENT

We work for physicians, consumers 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.

TECHNOLOGY

We create, develop, and advance products which are driven by medical need, consumer demand or 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 field 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.

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.

KNOWLEDGE BUILDING & SHARING

We are experts in optical physics, the interaction of light and human biology, and 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 knowhow continuously and establish a learned community. Collaboratively we seek to excel in a multifaceted field to arrive at scientific breakthroughs.

CHAIR'S LETTER



Dear Shareholders,

Which expert in business could have predicted the year 2020? The question is, were we caught by surprise and could we have managed ourselves better? The year 2020, my first complete year as Chairman of CLINUVEL, has been overshadowed by

the impact of COVID-19, and has therefore seen my main tasks change, helping navigate CLINUVEL during these uncertain times.

The financial year was one of two halves. In the first half, CLINUVEL's goal was to provide continued growth in Europe and to progress our product development pipeline. We concluded the year on a high, with a unique milestone on 8 October 2019, which was the approval by the US Food and Drug Administration (FDA) to make SCENESSE® (afamelanotide 16mg) available in the USA to adult EPP patients. We shared our celebration at the 2019 Annual General Meeting (AGM).

With much optimism, we looked forward to expanding the business into the USA, progressing our product development pipeline as we started the second half of the 2020 financial year. In January 2020, our IR Manager, Malcolm Bull, came back with considerable optimism from the JP Morgan Global Healthcare Conference in San Francisco. Then suddenly, a dramatic turn of events which turned the world upside down. In this new world, making sure that all checks and balances were crossed, my priorities became threefold: to oversee the governance and leadership, to optimise the financial management, and to make sure unique people with great knowledge would continue with this Company.

GOVERNANCE AND LEADERSHIP

I was asked how I identify executive managers to run my portfolio of companies. In my own publicly listed company BSGR, I have recently appointed a new CEO who is stress-resistant and fully understands the art of managing people to maximise their skillsets. Captains of industries are truly identified when they face changing environments and are forced to act. Therefore, this past year was particularly important to closely watch how CLINUVEL's senior managers would handle the crises and take the most suitable measures. Entrepreneurship is much more than running successful companies when all things are going well. I expect senior management to find creative solutions, come up with ideas on how to progress a company and, above all, dare to take unpopular measures to retain value. In the past year I have again seen proof of CLINUVEL's leadership, who managed the complex world of pharmaceuticals when maneuvering was really needed. At a time when the world went in lockdown and hospitals decided to put COVID first and other healthcare services second, our team managed to maintain supply and maintain SCENESSE® treatment.

With respect to governance, the Board sets clear goals. We have split the role of the CEO and Chairman. We did not just delegate all

the responsibilities to one person, helping the Managing Director get on with his daily job of running the Company and leave the supervisory matters to myself, as well as the coordination of Board matters. In many listed companies the roles are still combined, but I think it is not a wise way of running companies.

I see success in business as a simple formula which has always worked for my companies and most successful colleagues. First, always make sure you spend less than you receive. Second, formulate a clear vision and work consistently towards this goal. Third, treat the people working around you with respect and they will do the same through putting in maximum effort. With our current CEO, we see all three.

Effective leadership is not just one person, but it is a culture created where collaboration takes place across all managers on the floor and business partners without issues or friction. In this interplay, the CEO then needs to integrate a mix of long term and new employees, guarantee diversity, possess a depth of skills and experience and report progress to go through all bottlenecks. In the last 12 months, we have expanded our workforce considerably and are all working to achieve a list of our key objectives.

FINANCIAL LEADERSHIP

What is financial leadership and why does it matter? The worst business one can arrive in is a business where processes are lacking, expenditures are varying, and little financial control exists due to high commitments of forced spending. The financial books of a company are the reflection of managers' ability to make daily decisions. CLINUVEL's books are not coincidental, they follow our managers' vision.

It is clear CLINUVEL's financial management has been very successful, both our CFO and CEO protect our financial position to a maximum.

I always wish to see clean financial processes in the companies in which I am involved. In CLINUVEL, we have passed more than a decade of independent audits without remarkable findings. This helps us concentrate on our operations. The CFO Darren Keamy has built a strong team over the years and oversees the finances of all the activities in the subsidiaries and tax. His team is managing the expansion of VALLAURIX in Singapore, and the currencies across the Company. As part of the team's task this year, there was a need to avoid negative interest rates on the Euro and secure our working capital.

It is clear CLINUVEL's financial management has been very successful, both our CFO and CEO protect our financial position to a maximum. We need lean companies in this industry, and the way our management is managing this globally is the modern way to do it. We shareholders benefit long-term, since no money is leaking, and no new capital needs to be raised from the markets. I have seen many investment banks offering to raise money for CLINUVEL at high discount percentages and praise ourselves that we do not need to do it.

In CLINUVEL, we have passed more than a decade of independent audits without remarkable findings.

Cash is always king in crises and this year I have seen established companies going out of business. Many tragedies are affecting breadwinners and families. With CLINUVEL, we expand and provide people strong job security, helping our employees feel safe and motivated. The way our financial team is going about the business is the right one and as a major shareholder in the Company, I am grateful that we are rock-steady in management without unexpected or dramatic events.

For the six months to December 31 we recorded a good profit. At the end of our audited financial year, we posted a A\$16.6 million profit, whereby our cash reserves have substantially grown. As a Chairman, I cannot ask more from a team during such a global financial crisis and am very happy to be involved in such a Company.

*In our senior management team,
we have 57% women and 43%
men, a great balance based on our
CEO's aim to lead in this field.*

CONTINUATION OF SPECIAL KNOWLEDGE

CLINUVEL stands out with a special team of Directors, each of whom brings special expertise, and an exact gender balance. CLINUVEL leads many other companies in this balance, showing our different approach to business. In our senior management team, we have 57% women and 43% men, a great balance based on our CEO's aim to lead in this field.

I am a general entrepreneur without special knowledge about pharmaceutical development, but the same business principles apply to every one of my ventures. I want to see CLINUVEL keep its key people and educate new talent for the years to come. In CLINUVEL, we have become an institution whereby new graduates have started to apply for jobs since the universities have taken the CLINUVEL example of running a company in their business cases. I want to see long-term continuation in an environment where competitors are trying to emulate our approach. A strong top and talented below within our levels of hierarchy is the only way to build

a company for generations to come. Looking back at the progress this year, we are well on course.

In CLINUVEL, we need special knowledge to grow, and in Singapore we are increasing our investments each year. This year we built modern facilities which are featured in subsequent pages of this report. The Singapore government started to recognise our investments in the country and our hiring of people to lead the research of new products.

In March, I shared my vision of the Company's strategy and in October our CEO gave a detailed breakdown of how CLINUVEL will be growing. Philippe has made it clear that he has very little time to waste to perform with his team, since he wants all objectives of the Group to be met before he retires from this role. I understand his ambition is to see the name CLINUVEL strive during his time with the Company, which translates well for us shareholders. I share his frustration in a COVID-19 world, but I have confidence in him and the management team to keep surprising and impressing us, with their dedication to the Company.

I want to thank the CLINUVEL Board for the great support and guidance this year, especially during such a peculiar year, but nonetheless with great highlights.

*During these difficult and uncertain
times, we sympathise with all those
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IN CONCLUSION

During these difficult and uncertain times, we sympathise with all those affected by COVID-19 and hope all our stakeholders remain safe and well. We appreciate the loyalty of our long-term shareholders and the new shareholders who have joined CUV during the past year for the ongoing journey. Despite the current adversity, CLINUVEL's future is full of optimism and we will continue to focus without relaxing on the strategic path we have laid out. This path will lead us to adding value, pride, and satisfaction to all our stakeholders.

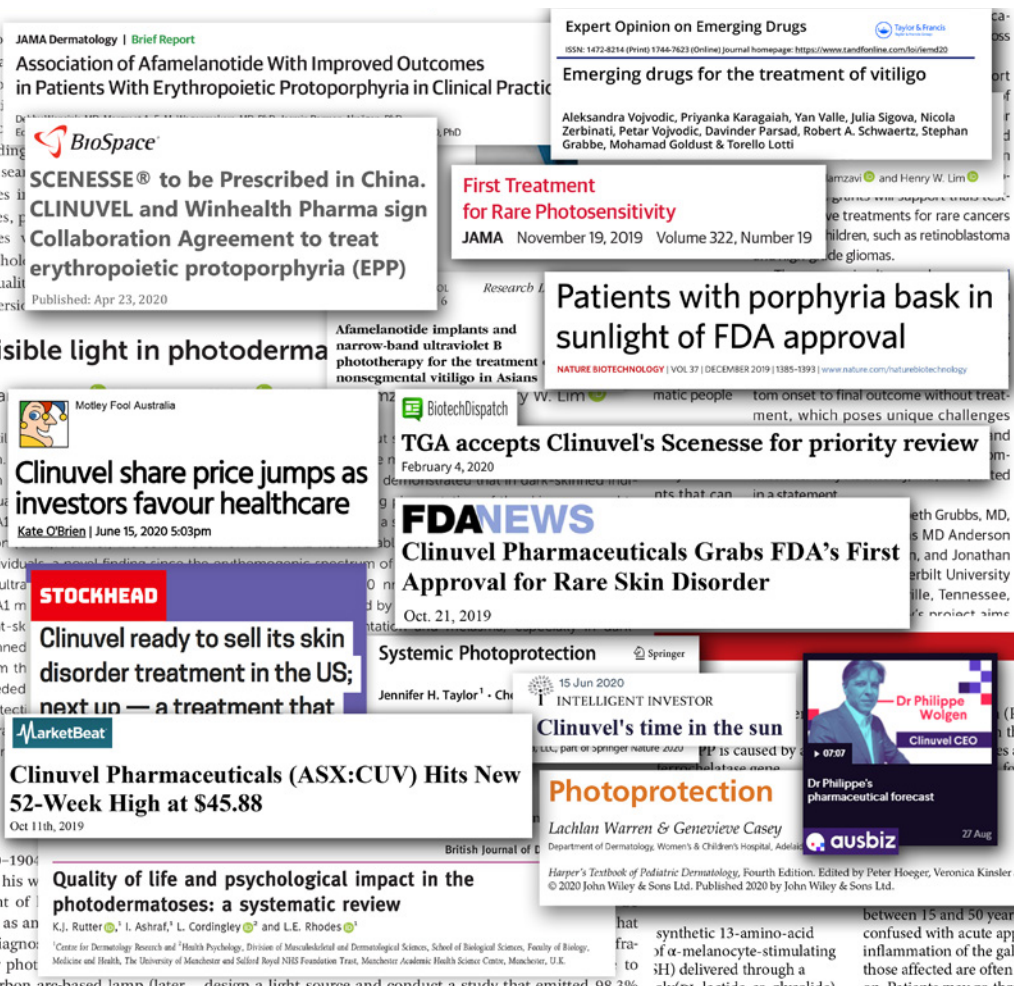


Willem Blijdorp
Chairman

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 2020, based on the Australian Securities Exchange Corporate Governance Council's (ASXCGC) Corporate Governance Principles and Recommendations, 3rd Edition, can be found on our website at <https://www.clinuvel.com/clinuvel/company-overview/corporate-governance>.

CLINUVEL IN THE MEDIA



500
Media Pieces

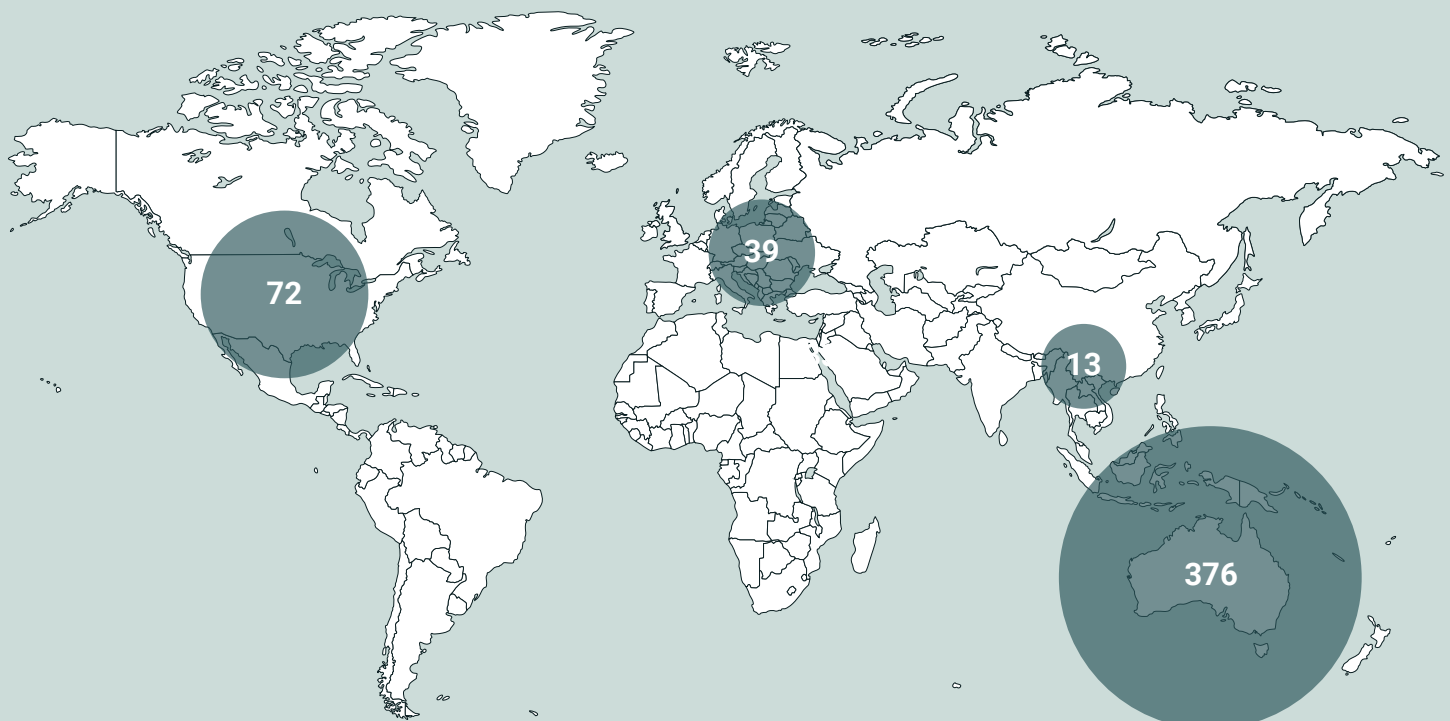


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Key Events



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Peer Reviewed Articles

Global Distribution of Media Coverage



MANAGING DIRECTOR'S LETTER



Dear Shareholders,

INTRODUCTION

I contemplate CLINUVEL's successful progress and financial results in 2020 in contrast with the unforeseen pandemic and various containment measures unfolding around the world. It has been a surrealistic

series of events in the past year, the emergence of a new epoch and existence for all of us. In the vortex of a virus working its way methodically across all borders and has already stolen 1,000,000 lives around the world, global commerce has slowed down at a rate far beyond that seen during the Great Recession and has caused millions of workers to be laid off.

Like most businesses, CLINUVEL was forced to adapt quickly and plan its operations in a materially different way. First, Brexit caused us to relocate some of our operations to the European Economic Area while keeping other services in the UK. We made this transition successfully and kept adding new services and structures to EU distribution.

...we were proud to learn in February that CUV's Board was one of only 11 on the S&P/ASX-200 where at least half of the directors were female, reflecting the progressive and intentional approach to gender and cultural spread within the Company.

The past year taught us that limited travel required an indirect approach to CLINUVEL's operations, and the curfew and inhibited ability to enter offices forced the Board and management to rethink strategy and the future of the Company. Senior management found itself defending the healthcare needs of the targeted porphyria patients both in Europe and the US. While some erythropoietic protoporphyria (EPP) patients could not gain access to treatment due to closure of specialist hospitals, other centres needed to be immediately activated to prescribe SCENESSE®. Under extraordinary circumstances, special permissions were requested from, and granted by, national competent authorities in the European Union and the US.

Following the FDA's approval in October 2019, there has not been a second to reflect upon – let alone celebrate – the momentous occasion. Rather, it has been an accelerated path to formulate the second product PRENUMBRA®, contest Ethics Committees and regulatory authorities, and introduce SCENESSE® to US insurers, all while expanding the Company on all other fronts. We invested in new facilities in Singapore, and despite a delay of several months, were able to open our laboratories on 31 August. With newly elected Chairman, Mr Willem Blijdorp and the addition of Mrs Sue Smith and Professor Jeffrey Rosenfeld as Non-Executive Directors to the Board, new insights, new strategic discussions, and different practices were introduced. The current Board with Mrs Brenda Shanahan and Dr Karen Agersborg is well diversified in skills, and we were proud to learn in February that CUV's Board was one of

only 11 on the S&P/ASX-200 where at least half of the directors were female, reflecting the progressive and intentional approach to gender and cultural spread within the Company.

In terms of cost-efficiency, we have continued to improve with operating expenditure as a percentage of total revenues reaching 26.9%. We also saw an improvement in our overall return on invested capital to 14.2% this year (up from 13.7% in 2019). This performance demonstrates considerable momentum as we enter 2021. We built and kept our balance sheet clean to create options for the ensuing years, increased our cash reserves by 23% and expanded the Group with an eye to overall sustainability. Along a chartered course, our R&D activities gathered momentum to provide for the next generation of products. I see CLINUVEL's output the past year as one of the most memorable achievements by our dedicated team in the midst of the most severe economic recession in recent history.

As much as we could, we changed our pharmaceutical product supply and worked for weeks 24/7 to secure continued distribution. We witnessed how authorities, distribution centres and customs at various borders were tapering or shuttering operations all together. As supply chains slowed down, we were asked to find most original ways to distribute SCENESSE® under specialised transport, against the time ticking to get the hormonal therapy to hospitals on the hour. In March, northern Italy was under siege from COVID, and many porphyria patients became understandably too anxious to travel or seek treatment in designated hospitals.

It is an understatement to say 2020 has been quite a test, but not at any time have I detected a sense of panic or loss of control across our group of companies. Rather, a silent confidence underpinned our staff that they would collectively manage the uncertainty even if it meant accepting some delays. Surprisingly, during the global lockdown there was a high percentage of requests from known EPP patients for continued SCENESSE® treatment at the peak of the daily COVID hazards. As seen from our operational results, we have steadily grown the Company, despite the spread of the pandemic. In analysing the rate of continuation of SCENESSE® treatment on 30 June, we found 96.6% of patients who had started treatment in 2016 were still requesting and receiving the drug. Overall, through qualitative surveys patients have reported a positive change and or improvement in their behaviours and activities undertaken, as recorded by an inventory of daily activities. Even in 2020, the number of treatments increased year on year as well as the number of new patients.

We built and kept our balance sheet clean to create options for the ensuing years, increased our cash reserves by 23% and expanded the Group with an eye to overall sustainability.

GOVERNMENTS' ROLE

In the wake of the global pandemic we have witnessed the rise of the state's role in choosing which workers to defend, which companies to assist and where to allocate resources among the

general population. Households in G8 countries were handed free money, while relief was given to businesses for rents and additional incentives to retain workers. In a Keynesian doctrine where the state plays a central role, central banks have kept interest rates low while state debt is now predicted to rise to 15-17% of GDP as borrowed funds among western countries. The stimulus seen in Europe, the USA and Australia seems to have no boundaries with an aim to keep economies fluid.

There are many ifs and nobody, including our central banks, really knows how to forecast our economies for the next 12 months. We are in uncharted territory.

However, I continue to believe that a deflationary environment cannot be maintained, nor can prices be kept low long-term, and when inflation eventually creeps in, the concern will be how this will affect businesses and specific sectors. Without having foresight, I see it as management's task to read the markets as well as we possibly can and conceptualise how to protect the group of companies against these macro-economic waves.

Central banks are now openly intervening in public markets. In parallel, the state's financial regulators find themselves overburdened in combatting distortion of equity markets where algorithms and short selling dominate daily trades. At CLINUVEL, we have had our fair share of these practices as witnessed since April 2019. Having gone through these episodes in the past (most conspicuously in 2007), I know from experience that continued corporate performance, generating further intrinsic value will eventually wash out these short sellers. In the meantime, the pain is borne by all shareholders, including CLINUVEL's staff, ergo holding steady is the mandatory approach.

Economies are seeing the delayed effects of the pandemic, whereby the surplus nations such as Germany, Japan and China have seen a sharp decline in exports, while overall consumption has been reduced to the necessary goods and services. While the International Monetary Fund and US Federal Reserve have revised their forecast to a fall of GDP in 2021 to under 5%, the European Central Bank has been more moderate and predicts negative growth of 3% for 2021. As a footnote, the further global recovery is contingent on the fiscal and economic stimulus by the richer nations slowly waning off, central policies to remain effective, foreign demand to pick up and societal uncertainty to ebb away. There are many ifs and nobody, including our central banks, really knows how to forecast our economies for the next 12 months. We are in uncharted territory.

Reviewing 2020, chaos ruled in China first, followed by confusion on the European continent and eventually, lockdowns in the US and Australia and periods of circuit-breakers in Singapore and South-East Asia. Just when the world prepared to resume to normality in May, the second wave of the pandemic struck Europe, Australia, and parts of Asia, whereby the US had remained throughout the year in a state of nationwide restriction. At the time of going to print, there seems to be a renewed emergence of the viral spread, with an R-factor of 1.6 in the European Economic Zone and steady spread in the US. Thus, prolongation of restrictive measures seems unavoidable.

ADAPTIVE MINDSET REQUIRED

Adaptation - as in rapidly accepting a changing environment - comes to mind as the main hymn when reflecting on 2020. I have been most impressed by our teams and their interconnectedness. New professionals joining the Group were without warning asked to work from home, some of them not properly set up to work remotely and unfamiliar with the processes of the new company they had joined. Communication has become the key attribute to cross functional flow, operating procedures, and advancement of R&D, while financial discipline is maintained. Thus far, CLINUVEL's

staff have stood up to the task and the same talented pool of people will continue to rise to the challenges as the economies and markets continue to oscillate.

At the peak of the first wave of COVID, we introduced an individual monitoring system for tracking communications. The weekly reports provide us insight into the Group's activities hour by hour, since we needed a baseline number of outward and inbound emails, video conferences and connectivity between our global teams.

With a mindset to globalisation, we concluded paradoxically that crisis management needed to take place locally. While Brexit had been postponed twice and the definitive transition period is set to end on 31 December 2020, we were forced to consolidate our UK operations while establishing two new hubs within the European Economic Area. Integration of the Group is key to continued success, meaning that the same procedures, rules, and financial rigour needs to be adopted by all subsidiaries.

Talent joined the Company, and in a remote world very little time is available to young professionals to immerse themselves in our work that is heavily dictated by deadlines and due dates. I am of the belief that young people need to be endowed with responsibilities early on and I repeat this phrase in many interviews with candidates. At CLINUVEL we have laid a basis whereby staff are accountable early on in their career, errors are accepted but a thorough evaluation and avoidance of repeat is required. In these unexpected times and economic reversal of fortunes, individual responsibility is more important than ever. I have seen rays of light and real prodigies shining through our R&D, clinical, commercial, and financial management.

The new Chairman introduced advanced measures to align all staff with the corporate's objectives, while the Risk Charter and governance were reviewed in depth. The financial management of the Group remains one of our core strengths, the IR and PR efforts of our team reaped benefits and the media and communications team increased its activities by putting out more published news than previously through various social media channels, ASX announcements and translating technical news for broader audiences.

In the new economic era, I view radical changes to CLINUVEL's business plan as imperative. Less will be more: less face to face interactions, fewer meetings, and faster and more effective decisions to be taken. A relaxation of risk management implies that more errors can creep in, therefore increased controls and contingency plans are needed as part of processes. For instance, in R&D one would expect less time to repeat and reproduce experiments but more time to validate methods, a greater number of formulations, more analytics run simultaneously and increased number of planning to increase the generation of replicable data. In terms of clinical trials, it will translate to more trials sponsored by CLINUVEL, more proofs of concept studies in less centres.

For the third year in a row we have issued a dividend. With the year dominated by global turmoil we wanted to demonstrate our gratitude to the long-term shareholders staying with the CLINUVEL story.

In reviewing each single crisis I have endured with our senior staff the past decades, I can confidently say that specific to CLINUVEL at each of the troubling times, new gains were found when we put our minds to original solutions. This attitude is a repetitive trait by our people, perhaps it has even become an asset of the Company, attracting to CLINUVEL new talented professionals with the same attitude. The reality of the viral threat puts the CLINUVEL team to the test - our output, financial results and handling of suppliers

and hospitals during these sensitive times speaks volumes and I am proud of our staff's resolve and perseverance exhibited during these challenging times.

I assign the current success to the discipline bonding the Company across staff and Board. Many of the features of our team over the past months have reminded me how our key managers handled the 2007-2009 crisis. It certainly gives me courage that this assembly of professionals will be able to weather unexpected events in the future. While in 2007, the loss of CUV value was due to the managers of a hedge fund dumping their portfolio of illiquid stocks on the open market, causing a steep decline in share price, the current crisis has been triggered by global events causing externalities. The management of these seismic events is not new to our team. In effect, crisis management is part of our fire-drills across many disciplines of the Group, such as in pharmacovigilance and quality control, acted out as simulation exercises.

As Managing Director, I see it as my principal task to enable staff to excel in their performance by creating and maintaining a positive and conducive professional environment.

CLINUVEL'S EXPANSION

In a discussion first initiated by analyst Sarah Mann (of Moelis Australia Securities), other colleagues had debated the value of diversification versus focus, whereby CLINUVEL has been taken as an example with a long-term business focus. I have written about this in various News Communiqués in past years. There is no absolute answer whether this is right or wrong or whether one increases inherent business risks by focussing a company on one technology and expanding onwards. Each project, each company needs to be evaluated on its own merits, as a separate business case with specific characteristics which do not lend themselves to equal comparison. However, specialisation originating from dedication and focus often leads to domination in one area of technology, science, and operations. Naturally, success attracts others to the space, and unsurprisingly CLINUVEL will have its competitors in time to come. However, focus is difficult to replicate. Diversified companies will most likely not commit to causes like focussed entities are able to do, and whether this advantage translates to long-term sustainable value will be played out in time. Furthermore, concentration on business segments generally leads to translational use of technology and more opportunities to open-up.

Under this scenario, CLINUVEL scaled up its R&D activities in-house in Singapore (VALLAURIX PTE LTD). The Singaporean government, through the Economic Development Board, recognised our investment and decided in February to contribute up to S\$500,000 in funding allocated to equipment and the hiring of local personnel.

At the time of going to print, the state-of-the-art VALLAURIX Research & Development Centre has been delivered to our Group, albeit still working in shifts under the circuit breakers put in place by Lee Hsien Loong, Singapore's 'Chief-in-Command'. The laboratories are being equipped with modern technology, whereby both a biological and analytical laboratory are at the centre of our facilities. With this R&D hub, we have attracted a pool of talented individuals, scientists with a drive to develop Singapore's first commercial pharmaceutical products to market. As VALLAURIX is expanding, daily coordination between our Singapore and global teams take place by various channels to ensure total integration within the Company. The VALLAURIX Research & Development Centre is part of our aim to vertically integrate all facilities in-house. This will require a further diversification of disciplines across the Group in a controlled manner. I intimated before that expansion too fast carries the risk of loss of focus and eventually failure, too slow a lack of targeted progress. Two more disciplines will be added to

CLINUVEL's armamentarium before the foundations of the house can be considered complete.

The pipeline of molecules and products coming out of VALLAURIX aims to address various markets ranging from acute diseases to over-the-counter markets complementing our current treatment and providing name recognition among wider consumer communities. The first follow-on product, the liquid formulation of afamelanotide, PRÉNUMBRA® was announced in July 2020. By working on several fronts, I am certain our research teams will continue to surprise us all with further output the next year.

Diversification from within is the mantra, and expansion of pharmaceutical products originating from the knowledge and progressive insights from our professionals is the safest way to bring CLINUVEL forward. Under the authority of Chief Scientific Officer Dr Dennis Wright, VP Scientific Affairs Dr Tim Zhao, and Head of our R&D Centre Dr Uma Rai, we have ample to look forward to. Our teams have chosen the least degree of risk in diversifying yet staying within the field of melanocortins.

In planning all the Group's activities, Board and management is cautiously balancing receipts, profits versus investments. The past year we discreetly invested up to 20% of annual turnover in related technology and more in personnel but stayed well within our preferred financial parameters. Here, risk versus rate of progress is reviewed periodically to balance the company between prudent expansion and financial strength.

When entering a recession, the learnings from past downturns are multi-fold. Firstly, adverse market reactions last longer than most analysts predict, the economic reverberations run deeper. The current European plunge into recession will affect many sectors permanently: hospitality, travel, and catering, but also healthcare. A second take-away is that each company and business unit must keep its output high. Economic output is partially determined by the supply side, and of course the demand originating from the market served. Third, the ability to manage cash receipts obviates the need for capital, an invaluable protection of value. Although much jubilation exists about the records booked on US exchanges and the ASX, we remain cautious as to the possibility of major market corrections and its impact on shareholder sentiment. Our IR manager and finance team have had a plentiful year engaging actively with major institutions, and subsequently we have seen the emergence of two new and large US institutions on CLINUVEL's register, holding collectively over 6%. As CLINUVEL consolidates its financial position and expands its offerings, it will attract new international investors.

For the third year in a row we have issued a dividend. With the year dominated by global turmoil we wanted to demonstrate our gratitude to the long-term shareholders staying with the CLINUVEL story. The success of this program started with a detailed planned financial strategy and under the auspices of Darren Kearny, it has been well executed. In my last period as Managing Director, I intend to see the financial management continue for the Company to secure its longevity. With that objective, we will exert our maximum effort to diversify and generate profits within the group of companies.

As Managing Director, I see it as my principal task to enable staff to excel in their performance by creating and maintaining a positive and conducive professional environment. Remaining close to my beliefs, we demand much from our staff, but take a constructive and supportive approach when it comes to the time needed to adapt and learn new skills. With that hybrid approach to the business, we pride ourselves to attract unique talent, retain staff for the longer term and thereby increase the knowhow within the Company. In 2020, there has been a balanced mix of new professionals and seasoned managers who had reached their career objectives at CLINUVEL. Some of these managers left CLINUVEL not only as accomplished professionals, but also as shareholders with substantial experience to be used in life sciences elsewhere.

At this point in time, the Company is in the best financial position since its inception.

CONCLUSION

I see it as my duty to direct an orchestra of gifted individuals, reacting and putting measures in place to secure a future for patients, staff members and shareholders in times of desperate economic conditions. The past months, we have effectively secured the supply of product and cashflow to the Company.

At this point in time, the Company is in the best financial position since its inception. The financial strategy has been executed with accuracy and expansion has supported the growth in earnings.

An increasing percentage of patients is receiving SCENESSE® treatment in more countries, and in April 2020 the distribution of the pharmaceutical product started in the United States. Our teams have been active in Europe, the United States and China, and are awaiting the Australian regulatory outcome. R&D output is forthcoming, while the second product PRÉNUMBRA® was announced in July. While I daily observe sufficient areas for improvement within the Group, we have also arrived at a point where many of us at the start of the journey could not have predicted the current position. Of course, success is a fickle definition and can be measured by various parameters such as stock price, products in pipeline and rate of expansion: higher, bigger, and more. Realistically, the success of CLINUVEL is one to build and reflect on.

I am more optimistic than ever on the future of the Company and that all our teams are collectively working towards the same objectives, (first published in 2019) outlined below:

RATIONALE		OBJECTIVES (See the 2019 Notice of Meeting for further details)
1	To promote growth in value of the Company	Market Cap ranging from A\$1.7B to A\$7.5B (i.e. a share price +/- A\$34 to A\$151)
2	To provide financial stability and protection	A\$60 million to A\$150 million in cash for minimum of two quarters
3	To diversify the Company while maintaining profitability	Successful acquisition, profitable within 3 years
4	To increase the revenue base	US revenues, increasing 10%, >\$10 million p/a
5	To build further value from internal product development	OTC product line, topical formulation, paediatric formulation
6	To expand the use of the lead pharmaceutical product, entering new markets	Vitiligo or other indication/molecule progressing to Phase IIb and Phase III, with results published
7	New products, markets, revenue base	New regulatory approvals in EU, US, AU, JP, or CH
8	Unanticipated opportunities, which are value accretive	Extraordinary and unanticipated value accretive achievements

These self-imposed objectives are ambitious for any pharmaceutical company, and certainly for us since we opted to vertically integrate the Group. These objectives will add value to the Group and form the foundation for years of growth. Intellectual property is being secured, knowledge protected, and qualified staff groomed to become senior management. Together with my management team, I look forward to the unfolding of the CLINUVEL story over the next 22 months.

To all those who wished us well in the weeks following the announcement of the quarterly and annual financial results, I reciprocate and wish you a healthy and prosperous year ahead in holding CLINUVEL in your portfolio. To the patients and families who have long waited for SCENESSE® in the United States, we express our appreciation for your patience. On behalf of CLINUVEL's Board of Directors, we express our appreciation for your continued support.

MANAGING DIRECTOR'S MESSAGE TO GERMAN SPEAKING SHAREHOLDERS

Mein besonderer Dank gilt allen deutschsprachigen Aktionären fuer die Unterstuetzung von CLINUVEL. Wir haben von Ihnen ein gutes Feedback zu unseren deutschen Nachrichtenmitteilungen erhalten und werden diese auch weiterhin veroeffentlichen. Der diesjaehrige Geschaeftsbericht befasst sich mit Wachstum und Expansion und spiegelt den Wendepunkt in der Unternehmensgeschichte wider, der durch die Zulassung von SCENESSE® durch die US amerikanische FDA fuer die Behandlung von erwachsenen EPP-Patienten im vergangenen Oktober gekennzeichnet ist. Diese Meilensteinentscheidung ist der Katalysator, der CLINUVEL das Potenzial eroeffnet, SCENESSE® und seine Derivate auf ein breiteres Spektrum von Patientengruppen zu diversifizieren. Als langjaehrige Aktionaere wissen Sie, dass der Weg der Produktentwicklung im Pharmasektor lang sein kann. Wie in meinem Schreiben dargelegt, ist das CLINUVEL-Team entschlossen und fokussiert, diese Behandlungen fuer Patienten mit Prioritaet zum Nutzen aller voranzutreiben. Vielen Dank.



Philippe Wolgen
Managing Director, CLINUVEL Group

CLINUVEL IN THE NEW WORLD ORDER

INTRODUCTION

The coronavirus pandemic has changed the world in which we live and operate. How we engage with one another, balance work and life, produce goods and services, and manage the impact of the increase in public spending incurred to support people and economic activity has changed to varying degrees and will continue to do so. The purpose of this piece is not to analyse the changes in societal norms and structural changes in economies, as this requires more time to interpret emerging trends. Rather, it serves to highlight that CLINUVEL is entering a new world order in which the potential implications for people and economies are forever changed by the materialisation of a key risk – global pandemics and the way we will communicate and do business.

There is a multitude of known and unknown risks facing people, governments, businesses, and other operators in the economy. For businesses across the globe, as for other economic entities, the need for prudent risk management has been underscored by the coronavirus pandemic and its direct and indirect impact on their viability and future performance. This timely feature provides an overview of CLINUVEL's approach to risk management and its commitment to the prudent management of Environmental, Social and Governance (ESG) criteria which are now integrated within risk management and investment decisions, and closely linked to sustainable corporate performance.



CLINUVEL'S PRUDENT APPROACH TO RISK MANAGEMENT

The prudent management of risk is essential to the achievement of CLINUVEL's strategic initiatives and the progress of the Company towards a diverse and integrated biopharmaceutical company aimed at providing treatments to multiple patient groups. CLINUVEL has a conservative risk culture and this is reflected in its thrifty financial management over the years to develop and commercialise SCENESSE® (afamelanotide 16mg) for the treatment of adult patients with erythropoietic protoporphyria (EPP). The Board of Directors has mandated its executive management to execute a conservative strategy while growing the Group of companies. Specifically, the development cost of SCENESSE® has been well below the cost of comparable pharmaceutical company orphan drug development focused on a new molecular entity. In addition, CLINUVEL's decision to self-distribute SCENESSE® in Europe and the USA has proven cost effective and ensures value for shareholders. With careful cost control and prudent management decisions, CLINUVEL has strengthened its balance sheet after four years of commercial operations, with no debt and a cash position sufficient to finance its immediate future expansion. CLINUVEL is risk adverse and deliberate in its actions, and actively seeks to identify and proactively manage various risks.

The core of our risk approach is the maintenance of a risk register that details and ranks identified risks and their mitigation. The risk register enables the formal consideration of risk by senior management and the Board, while also highlighting potential opportunities. This in turn helps to ensure that all significant risks are suitably identified, assessed, and managed. A key part of risk management is ensuring we meet societal expectations,

regulations and laws on corporate standards and conduct. Thus, since ESG criteria cover essential aspects of our operations and adherence to these serves to minimise risk, these are very much a part of our risk management approach and are included in the risk register. There is a multitude of benefits to maintaining an active risk register, the most obvious being ensuring the Company is well-run and keeping Board and management alert to the risks which need attention.

THE UNITED NATIONS GLOBAL COMPACT AND ESG

The United Nations Global Compact (Global Compact) was established in 2000 by then United Nations (UN) Secretary-General Kofi Annan to implement universal principles in business that advance responsible corporate citizenship, better aligned to the UN's global development objectives. In January 2004, Annan wrote to 55 of the world's leading financial institutions to invite them to develop guidelines and recommendations to better integrate ESG criteria in the operation of financial markets. Twenty financial institutions participated and endorsed the resulting report, "Who Cares Wins", in December 2004. The report was completed under the auspices of the Global Compact and contained a "call to action" to stakeholders in the financial and business world: companies were asked to lead the implementation of ESG principles and policies by providing information and reporting on related performance and to identify and communicate the key challenges and value drivers associated with ESG issues.

Since then, ESG has gained prominence throughout the global investment community, playing a key role in the analytical assessment of companies and investment decisions. (ESG-based investment is often referred to as sustainable investing, responsible investing, impact investing or socially responsible investing.) Large and influential institutional investors have aligned prudent management of ESG criteria with sustainable long-term growth and have integrated ESG criteria into their due diligence of investments. An online search for the term "ESG and company performance" reveals a multitude of studies that support a positive correlation between responsible ESG management and enhanced financial performance, efficiency, and firm value. A review by Friede, Busch and Bassen (2015) of around 2,200 individual studies since the 1970s concluded that roughly 90% of studies found a non-negative correlation between ESG criteria and corporate financial performance, with a stable link evident over time.



The Global Compact is a call to action to companies around the world to align their strategies and operations with five defining characteristics of corporate sustainability and ten universal principles in the areas of human rights, labour, environment, and anti-corruption. The UN vision is that appropriate action in these areas will support their broader sustainable development goals. The Global Compact is the world's largest global voluntary corporate sustainability initiative with over 8,000 companies and 4,000 non-business participants in over 160 countries. The five defining features of corporate sustainability and ten universal principles promoted by the Global Compact are outlined below:

Five Defining Features of Corporate Sustainability	Ten Universal Principles
1. Principled Business Operating with integrity in alignment with ten principles in the areas of human rights, labour, the environment, and anti-corruption	Human Rights - Businesses should support and respect the protection of internationally proclaimed human rights; and - Make sure that they are not complicit in human rights abuses.
2. Strengthening Society Taking action and collaborating with others to advance global challenges	Labour - Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining; - The elimination of all forms of forced and compulsory labour; - The effective abolition of child labour; and - The elimination of discrimination in respect of employment and occupation
3. Leadership Commitment Effective long-term change begins with a company's leadership	Environment - Businesses should support a precautionary approach to environmental challenges; - Undertake initiatives to promote greater environmental responsibility; and - Encourage the development and diffusion of environmentally friendly technologies
4. Reporting Progress Transparency in business practice is crucial for sustainability	Anti-Corruption Businesses should work against corruption in all its forms, including extortion and bribery
5. Local Action Viewing sustainability through a local lense	
Source: United Nations Global Compact (2014), Guide to Corporate Sustainability, Shaping A Sustainable Future	

CLINUVEL'S ESG FRAMEWORK

The Global Compact and UN tenets on ESG and sustainability inform CLINUVEL's approach. As a responsible corporate citizen and active manager of risk, CLINUVEL embraces the ESG Framework below, as outlined in the Company's 2019 Annual Report to Shareholders.

CLINUVEL'S ESG Framework		
Environment	Social	Governance
Conscious of our World	Fairness and Equity	Responsibility and Compliance
recognise climate change	human rights	honesty and integrity
energy management	freedom of association	corporate governance
supplier standards	equal opportunity	compliance
safe and responsible materials handling	value diversity	ethics
no adverse impact on global objectives	work-life balance	supplier standards
	training and education	
	supplier standards	
CLINUVEL Values		

CLINUVEL's values are placed at the base of the framework to reflect their fundamental foundation in governing our behaviours and how we conduct our business. The key tenets of this framework are explained further below.

FOCUS ON THE ENVIRONMENT

We are conscious of the world in which we operate and importantly, have no adverse impact on the achievement of the UN's global environmental objectives. Our management of environmental risk is appropriate for a relatively small company (with less than 100 employees), striving to minimise energy and water use and exercise prudence in the management of office waste as we work towards

a paperless office. SCENESSE® and its key input, afamelanotide, are manufactured by reputable contractors in developed countries under World Health Organization Good Laboratory Practice (GLP) and manufacturing standards. Upon final regulatory inspections and certifications, our new laboratory facility in Singapore will operate to GLP under ISO 17025. CLINUVEL's product SCENESSE® is administered by subcutaneous injection and dissolves in the human body and has no adverse environmental impact. We also regularly assess the commitment of our suppliers to minimise their use of scarce resources and act in an environmentally responsible manner in accordance with ESG criteria.

SOCIAL RESPONSIBILITY

CLINUVEL is a responsible corporate citizen and reflects international community standards in our policies. The UN tenets on human rights and labour standards embedded in the UN International Covenant on Economic Social and Cultural Rights (1966) and International Covenant on Civil and Political Rights (1966) are reflected in our Employee Handbook. These covenants recognise the right to work, including the opportunity to earn a living by work that is freely chosen and accepted (Article 6); the right to enjoy just and favourable conditions of work, including minimum remuneration, safe and healthy conditions of work, equal opportunities for all, rest, leisure, initiation of working hours and holidays with pay (Article 7); and the freedom of association and collective bargaining and the right to strike (Article 8). Specifically, CLINUVEL is committed:

- on Human Rights, to
 - freedom of association; and
 - supporting a diverse and inclusive workplace, with equality of opportunity of all employees regardless of race, colour, gender, religion, ethnicity, culture, political opinion, age, and disability.
- on Labour Standards, to
 - the right to organise and collective bargaining;
 - zero tolerance of child labour, forced labour and discrimination, harassment, and abuse of any kind;

- o providing a decent workplace focused on the health and safety of employees;
- o supporting the training and education of all employees.

Opportunity is equal to all people in CLINUVEL and procedures are in place to escalate, review and address any human rights and labour standard concerns. The Group's employees span 16 nationalities and gender representation is balanced, as reflected in the following table on the composition of genders on the Board, in senior management and across all employees.

Gender Representation in CLINUVEL

Category	Date	Female	Male
Board	30 June 2020	50%	50%
	30 June 2019	40%	60%
	30 June 2018	40%	60%
Top 7 salaried employees ¹	30 June 2020	57%	43%
	30 June 2019	57%	43%
	30 June 2018	57%	43%
All Employees ²	30 June 2020	60%	40%
	30 June 2019	66%	34%
	30 June 2018	66%	34%

¹ excludes Executive Director.

² consolidated entity.

Work-life balance is supported by our Employee Handbook and a new Remote Working Policy. Necessitated by the coronavirus pandemic, CLINUVEL initiated the Remote Working Policy to ensure the ongoing health and safety of all CLINUVEL employees and provides guidelines to enable an appropriate work-life balance with overall flexibility in the conduct of employees' work, during and beyond the coronavirus pandemic. Employment security is conducted in accordance with labour laws and regulations in each of the countries in which we operate. All staff are encouraged to own an active training and development plan to support their professional fulfilment and job satisfaction.

We take a responsible approach to product development and distribution. CLINUVEL has no adverse impact on UN social objectives and makes a positive contribution through its pharmaceutical product development and distribution for unmet medical needs.

CLINUVEL's research and development program is highly ethical. We undertake the minimum studies necessary to obtain the regulatory approvals required to distribute our treatments in man. We use Ethics Committees for study approval, adhere to OECD Testing Guidelines and the principles of GLP. We are committed to the OECD Replacement Reduction and Refinement Principles for non-human studies and ensure all studies undertaken are responsibly designed and conducted by laboratories certified by internationally recognised and respected bodies. CLINUVEL disseminates its research and encourages the independent publication of the results of its clinical studies in peer-reviewed scientific journals.

A rigorous pharmacovigilance program is maintained and reported to the European Medicines Agency (EMA) in the European Union and the United States Food and Drug Administration (FDA) on the real-world experience of SCENESSE[®] for adult patients with EPP. SCENESSE[®] is carefully managed to ensure no off-label usage. Marketing and communications are aligned to the approval terms and conditions of distribution of the EMA and FDA.

CLINUVEL is responsible for ensuring that its suppliers are fit for purpose throughout the product lifecycle (from product development to commercial distribution), through risk-based quality control procedures and open communication. CLINUVEL qualifies

suppliers and reviews existing relationships according to a range of expectations and standards before commencing or continuing supply arrangements. CLINUVEL has over 15 key suppliers, most of which are domiciled in well-regulated countries that are signatories to the UN standards and objectives on sustainability and ESG criteria. CLINUVEL has a high proportion of medium- to long-term supplier relationships, enabling us to develop a good understanding of their values and commitment to ESG criteria. This diligent approach also applies to the assessment of our relationship with collaborative partners.

Should an area of concern be identified during a review of a supplier, a risk assessment is conducted to ensure the supplier is functioning within contracted capacity and standards. CLINUVEL then applies a collaborative approach with the supplier to engage in discussions with the aim of improving their qualification status and strengthening the relationship. These procedures enable CLINUVEL to maintain the qualified status of its medium to long term tenured suppliers. Furthermore, it ensures CLINUVEL's ESG principles and those of its suppliers are consistently aligned.



CORPORATE CONDUCT AND ETHICS

Corporate governance is a key to effective risk management as it provides the policy, procedures, and compliance framework for a company's operations. Our corporate conduct and ethics are guided by our key corporate values and governed by our Corporate Governance Protocol and annual Corporate Governance Statement.

CLINUVEL's Board of Directors comprises the Managing Director, Dr Philippe Wolgen, and five independent Directors. They are, individually and collectively, well credentialed, with a breadth of qualifications and depth of experience in a range of fields to provide appropriate guidance to the Company. In the last year, the number of Directors has increased by one to six. The Board operates in accordance with a Board Charter that is set out in the Corporate Governance Protocol. The election and tenure of Directors is managed in accordance with the Australian Securities Exchange (ASX) Listing Guidelines. The gender representation at Board level is uniquely balanced, reflecting the broader Company. The compensation of Directors and key executives, covering key performance indicators for the assessment of short-term and long-term performance awards, are detailed annually in the Remuneration Report in the Annual Report.

CLINUVEL is focused on the maintenance of a long-term shareholder base which includes employees and a balanced composition of private, corporate, and institutional investors. CLINUVEL seeks an active and constructive dialogue with its shareholders, in accordance with ASX Listing Guidelines. We communicate frequently with shareholders, as outlined below, by operating an active program of regulatory and discretionary disclosures of information on the Company through announcements to the ASX. This includes regular corporate updates to keep shareholders informed on the Company's performance and progress on key strategic initiatives.

CLINUVEL's Corporate Governance Protocol meets the requirements of ASX principles and recommendations and includes a Code of Conduct and Ethics and policies on Conflicts of Interest, Share Trading and Shareholder Communications. CLINUVEL has zero tolerance of corruption of any kind. We operate a training schedule to ensure compliance with laws and regulations in the countries in which we operate. CLINUVEL staff are also encouraged to report any breaches of company values, regulations and laws and are protected from harassment and abuse on any reports of non-compliance or breaches. CLINUVEL engages with the leading law firms across the continents to ensure adherence to the highest level of governance.

CLINUVEL's Corporate Governance Protocol sets out the code of conduct and ethics and other policies to ensure conflicts of interest are avoided and honesty and integrity prevails. We are law abiding and comply with anti-bribery and anti-corruption laws in the countries in which we operate.



MANAGEMENT OF STAKEHOLDER COMMUNICATIONS

The twenty-first century has heralded new and improved innovation in communication channels that enable the instantaneous worldwide dissemination of information – in itself, this constitutes a new world order. These advances are advantageous for the operation of capital markets and investment activities. A key part of CLINUVEL's approach to communicating to stakeholders is the use of multiple online channels to provide up to date information on the Company's strategy and performance. The process of dissemination starts with an announcement to the ASX, after which CLINUVEL distributes to multiple news media outlets, our 'email updates' list, and posts on various social media platforms. We also maintain a library of announcements and information on the Company on our website, www.clinuvel.com. However, the technological advances in communications and information exchange are not without significant potential risk to companies and orderly investment activities in general.

Information dissemination online has become the social norm and has outpaced the protection of privacy and copyright regulation and enforcement. Laws and regulatory instruments have been unable to keep up with these real-world practices and trading activities on equity markets. Identified and anonymous parties can copy and post information in breach of copyright and can make false and misleading statements, either intentionally or unintentionally, in many online channels near-simultaneously.

Parties involved in stock shorting activity actively seek to drive a company's share price down to make a profit from share trading – they buy shares at a lower price than the shares they have borrowed to sell. Katz and Hancock (2017) of Ropes and Gray LLP note that 'shorters' actively use online communications either directly or indirectly through antagonists, to post reports on business platforms and discussion forums to undermine the confidence of shareholders and induce them to sell their shares at lower prices. CLINUVEL has not been immune to this type of conduct with shorting activity of CUV increasing from less than 1% of issued capital in April 2019 to a peak of 9.65% of issued capital in April 2020, before lowering to around 7.7% after mid-September, at the time of finalising this article. There has been an increase in false and misleading comment on CLINUVEL in discussion groups, which Katz and Hancock (2017) normally associate with an active shorting campaign.

CLINUVEL's approach in the face of this activity is to focus on the progression of publicly stated strategic initiatives and provide regular and objective information to markets on the Company's progress. This approach enables market participants to assess an objective flow of information to appropriately inform their investment decision in CLINUVEL. In the medium- to long-term, the performance of the Company should improve the demand for CUV and curtail the activity of 'shorters'. This approach in action is reflected in the pace of the progress of the Company which has enabled more frequent material announcements to the ASX. The number of CLINUVEL announcements to the ASX increased from 44 in the year ending June 2018 to 62 and 67 in the 2019 and 2020 financial years, respectively. The Company's discretionary announcements providing updates of the business in Chair Letters and News Communiqués are more frequent than other companies or peers in the ASX / S&P 200 Index and are authored by the Chairman and Managing Director to communicate directly to shareholders. This is a peer group leading practice. We also play a role to point regulators in the countries in which our shares are actively traded – CUV on the ASX in Australia, UR9 on the Xetra-DAX in Germany and CLVLY in the US through over-the-counter

traded American Depositary Receipts administered by the Bank of New York Mellon – to inappropriate activities.

We feel a responsibility to protect key stakeholders, patients, and doctors as well as shareholders, from inappropriate online activities. This extends to us liaising with online service providers and moderators of online channels when laws and regulations are breached. There are recent indications that regulation may be starting to make up some ground in the area of online defamation with precedent setting court decisions in Australia and the United Kingdom providing clarity of what constitutes a 'publisher' under defamation law. Online service providers and owners of online discussion forums have been held liable as a 'publisher' under defamation law with the trigger of culpability being their inaction upon being made aware of defamatory posts. Interestingly, each view, like or retweet of a defamatory post is considered a new publication and individuals who anonymously post defamatory material online are at risk of being identified by online service providers and owners of online channels in response to court orders issued during pre-trial discovery. US courts have made mixed judgements depending on the circumstances of the case, but some have held online service providers liable for defamation. In the US, plaintiffs have one year to take legal action against the initial defamation and cannot claim against successive and multiple re-publications. We will not cite the sources of legal precedent here, but they can be found online. The point of these comments is to highlight that your Company is focused on reducing the risk of misinformation and breaches of the law for the sake of objective information and the protection of key stakeholders.

SUMMARY AND CONCLUSIONS

CLINUVEL has a conservative and prudent risk management culture with a firm commitment to environmental and social responsibility with appropriate corporate governance as a key accountability to underpin long-term sustainability and performance. The commitment to prudently manage risk and adhere to ESG criteria as a responsible corporate citizen is strongly held at Board level, by executive management and extends to all CLINUVEL staff. The Company's vision and values, presented in earlier pages of this report, support effective operations aligned to the achievement of ESG and sustainability criteria. We regard our journey to sustainability as an ongoing process of continuous review and improvement to enhance our ESG performance and to share our progress with stakeholders in periodic announcements and reports, such as this Annual Report. All stakeholders should be comforted by this responsible and prudent approach, particularly as we enter a new world order.

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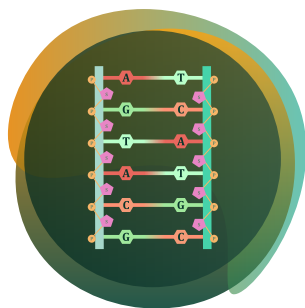
INNOVATION IN DNA REPAIR

CLINUVEL'S FOCUS ON DNA REGENERATION

The backbone of human life is created by two structures forming our genetic material: pyrimidines and purines, which in turn consist of four nucleotides adenine (A), thymine (T), guanine (G), and cytosine (C). These form the DNA-helix which carries our present and future make-up, our genetic codes. Human physiology tries to keep DNA strands intact at all costs. As we are exposed to daily oxidative stress, skin cells work hard to preserve our genetic program.

At CLINUVEL, we have focussed for two decades on the interaction of light and human biology, whereby our scientific teams have worked on replicating the deleterious effects of solar radiation through standardised conditions in our laboratories. We have used broadband ultraviolet B (UVB), narrowband UVB, ultraviolet A 1 and 2 and High Energy Visible (HEV) light to irradiate human skin and observe the instantaneous reactions and damage to the epidermis and dermis. Both in healthy and diseased individuals, skin reactions can be predicted and mapped out. In most of CLINUVEL's clinical trials, skin surfaces of various patient groups were exposed to light sources to provoke typical sun-related symptoms. In testing the lead drug afamelanotide, we collected this data and assessed its potency for systemic photoprotection.

Going a step further, CLINUVEL evaluated its drug afamelanotide in various photodermatoses and light-induced disorders such as polymorphic light eruption (PLE), solar urticaria (SU), acne, and Hailey-Hailey Disease, and in genodermatoses erythropoietic protoporphyria (EPP), congenital erythropoietic porphyria (CEP) and xeroderma pigmentosum (XP), all diseases where radiation at certain wavelengths play a part in the triggering of severe symptoms. In optics and physics precision is key, and in some disorders, one specifies action spectra and the inhibition spectra at particular wavelengths causing the start of symptoms in patients. Mapping out each monochromatic wavelength along the electromagnetic spectrum is part of the disciplines of photobiology, photodermatology and radiation biology, deriving scientific knowledge from optics and physics. This knowledge has become part of our in-house strength, expertise and starting point to transgress into the area of UV-provoked DNA damage.

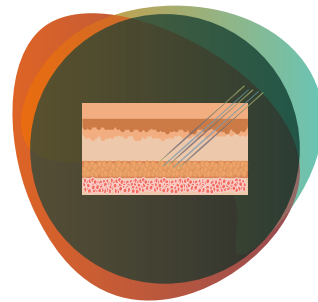


Pyrimidines and purines are the backbone of our DNA helix



SCENESSE® (afamelanotide 16mg)

As genetics and cellular biology took a flight the past decennia, the knowledge of the effects of ultraviolet radiation (UVR) on human cells (skin, eyes, and organs) has increased. Most are aware of the beneficial effects of 15-30 minutes of UVR per day to stimulate the synthesis of vitamin D in our skin. However, we are also made aware of how longer periods of exposure to UVR and HEV light may lead to sunburns, photodamage, actinic damage (elastosis) and an increased risk of skin cancers as skin damage becomes chronic and permanent.



UVR and the cell

The progression from healthy human volunteers to genetic disorders has been logical for CLINUVEL, whereby the most severe diseases have deserved treatment first, not least as these stand the greatest chance of regulatory approval in global pharmaceutical markets, such as Europe, the United States, Australia and Asia. That is not to say that other disorders would not benefit from afamelanotide or melanocortins, but the development route is best justified when regulatory support is given early on in a program.

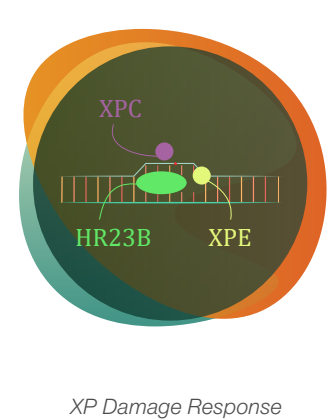
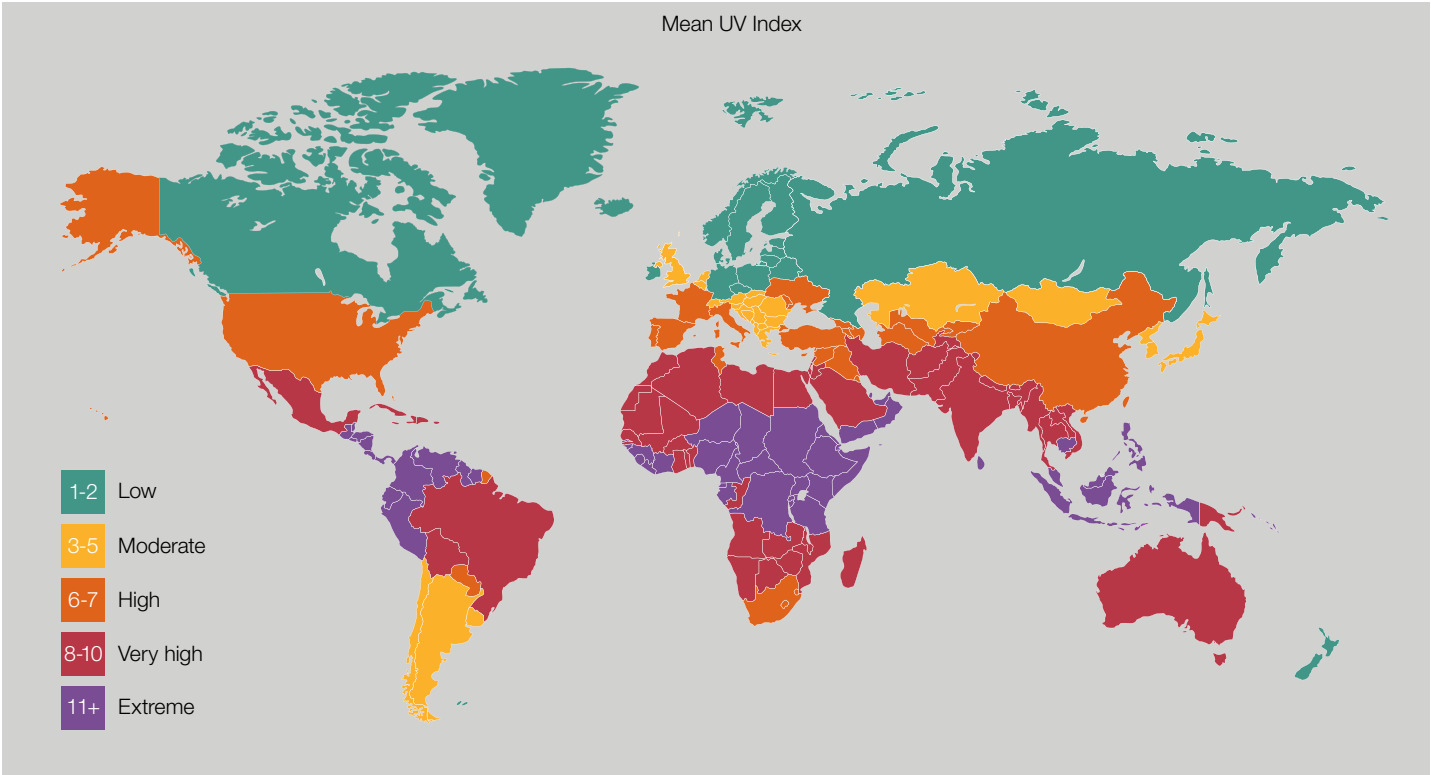
HISTORY OF DNA RESEARCH

Damage to DNA provoked by UV radiation received first attention in 1893, when Robert Bowles published an article in the British Journal of Dermatology suggesting that sunlight may be responsible for skin cancers: "If the sun's rays will produce sunburn, erythema, eczema solare, inflammation, and blistering, it is clearly capable of producing deep and intractable ulcerations of a low and chronic nature." This finding was corroborated one year later by Paul Gerson Unna, who associated the severe degenerative changes on exposed areas of sailors' skin with the development of skin cancer and rapid aging.

In the last three decades, various renowned research institutions have focussed on the acute and chronic damage of UV and HEV radiation to human skin. Latitudinal predispositions, localisation, skin type, family history of skin damage and skin cancers were among the variables studied. As cellular biology attracted attention the cellular signalling, expressions of genes and proteins, became a focus. As the human genome project gathered momentum at the start of the millennium, the importance of MAP kinases, endothelin, WNT, cKIT, MITF and MC1R pathways in providing skin cells with the right input, directions and stimulus became widely known.

DNA REPAIR

The double-page figure to this article explains the DNA Damage Response (DDR). Starting on the left-hand side, one sees the DDR by skin cells which leads to a human defence reaction. The activation of MC1R leads to a cascade of reactions seen within the cell. Human biology is fascinating in that many reactions take place simultaneously at the speed of nanoseconds. The signalling of a skin cell – there are many different types – occurs from top to bottom, starting with a particular receptor.



XP Damage Response

UV radiation can lead to double or single strand DNA breaks, although the scientific experts tend to focus on single strand breaks. UV causes typical mutations to DNA, known as UV-signature mutations, connotated as C→T or CC→TT substitutions of nucleotides within a DNA strand. Thus, we can detect and recognise the kind of DNA damage caused by solar exposure. UV also causes some of the protein expressions to be downgraded, suppressed, and dysfunctional, making the cell work at a suboptimal level, in turn causing an inferior output by the skin cell. Together, the cellular dysfunction and substitutions of nucleotides are a cause of great concern since human biology is forced to restore the balance immediately by repairing the cellular structures. Sun exposure makes skin cells work overtime. In the double-page figure, one sees the result of this UV cascade, the formation of Cyclobutane Pyrimidine Dimers (CPDs) and 6-4 Pyrimidine Pyrimidone Dimers (6-4PPs), or photoproducts within the nucleus caused by the sun/UVR/HEV light.

The PKA-ATM-ATR axis, or the communication between these intracellular proteins, causes multiple reactions further down the cell. Following solar (UV-HEV) exposure, human reactions are needed to protect cellular structures: organelles and proteins, but specifically the nucleus which may also require reinforcement. In many ways, all the process and activity taking place above the nucleus aim to protect the genomic information, DNA, within the core of each skin cell.

Our task after each sun exposure and sunburn is to eliminate these photoproducts by replacing a piece of DNA. Under normal circumstances, the human body is quite effective at doing so, although fair-skinned individuals (skin type I, II and III) are less efficient than darker skin types (IV, V, VI). In the first group the risk of permanent mutations is increased and in these individuals the incidence of skin cancers is much higher.

While we are interested in one pathway, the breakthrough in knowledge gained the last 15 years is that various pathways and genes within a cell communicate with each other; “horizontal discussions” occur between pathways. Therefore, the dysfunction along one pathway is sought to be compensated along another, all with the aim to restore function and UV damage.

On the right-hand side of the double-page figure one reads the properties of alpha-melanocyte stimulating hormone and its reinforced analogue – afamelanotide – in its role restoring UV damage. There are more than 30 cellular domains where the protein and DNA function are aided by alpha-melanocyte stimulating hormone, and here the 17 most important ones are listed. From CLINUVEL’s data and specific scientific work performed, one expects that afamelanotide will be a determinant in the DNA reparative processes within the cell, specifically needed for those individuals at higher risk of developing skin cancers due to genetic receptors, and their ability to respond to the UV signal.

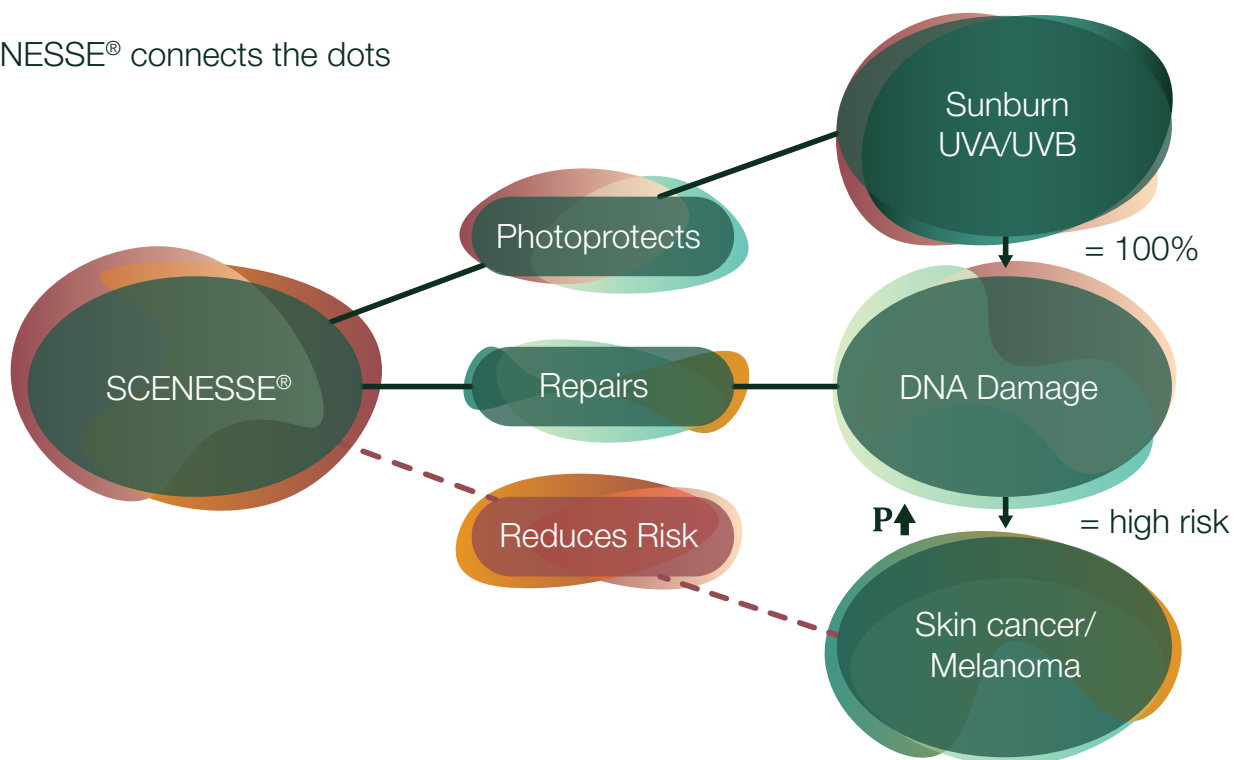
AN EXCITING FUTURE IN PROSPECT

The coming year, CLINUVEL will be furthering this field of research in human subjects (XP patients and healthy volunteers) to confirm the efficiency of afamelanotide in these cellular and DNA reparative processes.

Fitzpatrick Types I-VI

Skin Type	I	II	III	IV	V-VI
Sunburn and Tan Tendency	Always burns; Seldom tans	Usually burns; Sometimes tans	Sometimes burns; Usually tans	Seldom burns; Always Tans	Never burns; Always Tans
Skin, Hair and Eye Colour	White skin, freckles; blond or red hair; blue or green eyes	White skin; blond hair; blue or green eyes	White skin; usually dark hair; brown eyes	Darker skin; usually dark hair; brown eyes	Naturally brown to dark skin; brown or black hair; brown eyes

SCENESSE® connects the dots



CLINUVEL's DNA Repair Program aims to confirm that intervention with SCENESSE® causes elimination of DNA damage (photoproducts) and regeneration of DNA. The figure shows that SCENESSE® has been proven to protect skin from light (photoprotection) and shown to repair DNA damage. Since photoprotection and regeneration are necessary to reduce the risk of skin cancer, the role of SCENESSE® is obvious. In the figure, "P" stands for probability.

Having taken more than a decade of clinical and scientific research, it is exciting to 'close the loop' in using afamelanotide from:

- (i) assessing UV-induced skin damage in healthy volunteers, to
- (ii) systemic photoprotection in diseases patients (photodermatoses), and finally, to
- (iii) reducing the risk of cellular and DNA damage caused by sun/ UVR/HEV light in higher risk populations (both healthy and diseased individuals), and therefore reducing the risk of skin cancer(s).

Skin cancer comes in many forms, but the three most frequently seen in the clinic are basal cell carcinoma, squamous cell carcinoma and melanoma (various types). Common to all three

forms is that UV and sun exposure play a part in the development, whereby other genetic and epigenetic factors play a role. However, the ability to eliminate or reduce the UV-inducing factor in the genesis of skin cancer is a big step forward. Hormonal therapy with a melanocortin may well be the future answer, since the use of the hormone simulates the biological function of the peptide in our body, protecting us against the insult of solar radiation. Within seconds of sun exposure, alpha-melanocyte stimulating hormone is detected as being released by our skin cells as a protective measure.

A reinforced version of alpha-melanocyte stimulating hormone was developed and formulated as afamelanotide, and the vision is to use the drug as a DNA-protectant in many formulations.

The requisite is and remains the safety of afamelanotide in patients and healthy volunteers, but each day that goes by is one extra day towards the 100,000 plus patient-exposure days providing evidence of safe use.

Biomimicry is the phenomenon found in biology capturing and replicating nature's ability to provide function and protection. In afamelanotide, CLINUVEL has developed a long used potent hormone to prevent sun and light damage in those who need this most, namely, those who are at risk and those who suffer from genetic disorders affecting their ability to go outdoors. Over the next 12 months, the CLINUVEL story will unfold and the significance of our progress in DNA repair in XP and healthy individuals to the general population at risk of UV-HEV damage will become apparent.



Biomimicry [from the Latin mimesis (imitation) and bios (of life or a natural process)] involves the understanding and observation of naturally occurring processes for technological inspiration and innovation

Afamelanotide mimics the body's natural response to UVR and light to protect skin and repair damage

SCENESSE® (afamelanotide 16mg)

REPAIRS DNA DAMAGE CAUSED BY UV AND LOWERS RISKS OF SKIN CANCERS

DNA DAMAGE RESPONSE BY SKIN

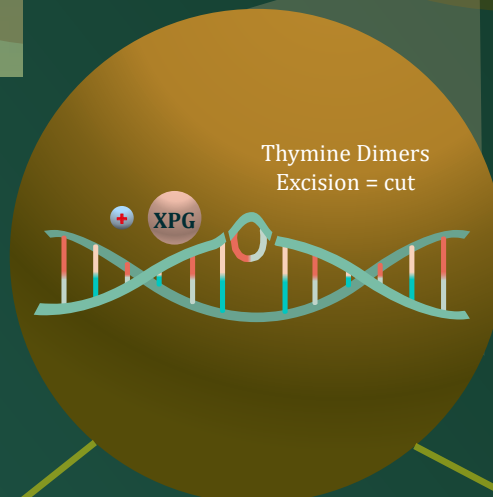
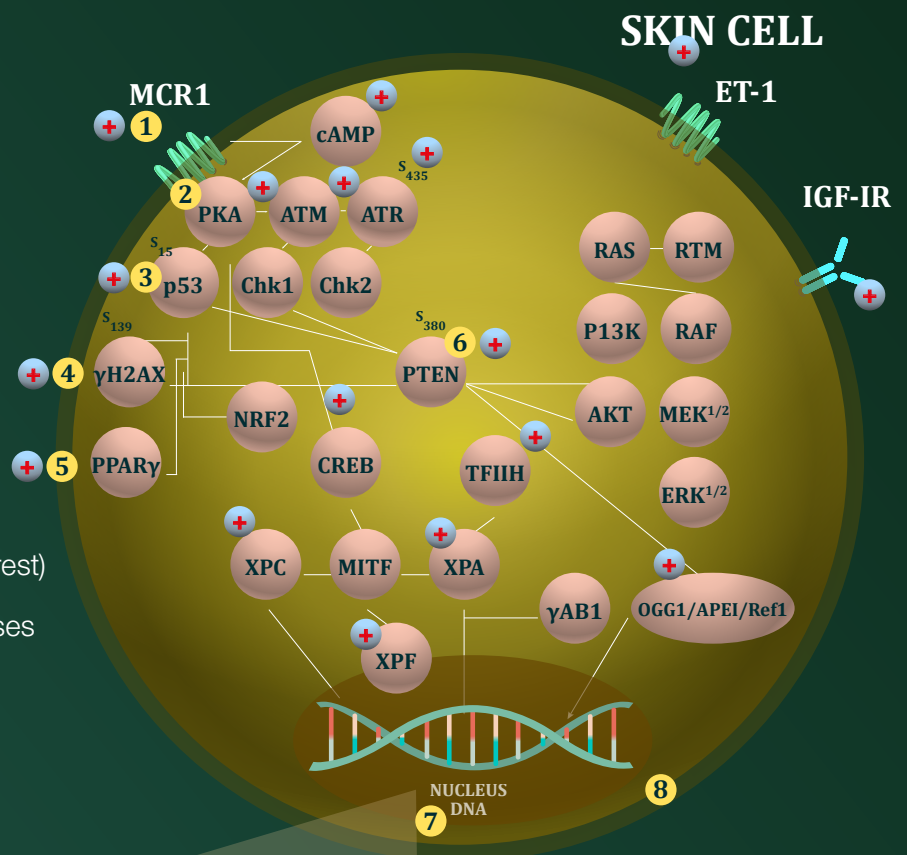
Ultraviolet radiation (UVR) leads to cellular stress and DNA damage and increases risk of skin cancers, specifically UVR leads to:

1. Activation of the MC1R receptor
2. DNA damage response by protein kinases PKA-ATM-ATR
3. High levels of p53 indicating a stress response – (less efficient in Caucasian skin)
4. Single strand and double breaks (γH2AX mainly in DSBs)
5. Activation PPARγ
6. PTEN degradation
7. Cell death (apoptosis) (Cell cycle arrest)
8. Increases in matrix metalloproteinases

UV radiation leads to skin cell damage, expression of genes, proteins and degradation of surrounding structures.

SOLAR RADIATION

UVC	UVB	UVA	HEV	IR
200-290	290-320	320-400	400-600	600-800



UV damage leads to the formation of:
Cyclobutane Pyrimidine Dimers
6-4 Pyrimidine Pyrimidone Dimers

REGENERATION

HIGH RISK SKIN CANCER

I. DNA REPAIR = CELL SURVIVAL = SENESCENCE

II. DNA DAMAGE UNREPAIRED = CELL DEATH = APOPTOSIS

DNA REPAIR

SCENESSE® (afamelanotide 16mg) beneficial effects on DNA repair [+ in diagram]

1. Stronger binding to MC1R
2. Optimises cAMP response
3. Optimises DNA sensors PKA-ATM-ATR
4. Phosphorylates p53
5. Decreases amount of UV photoproducts
6. Increases nucleotide excision repair DNA
7. Increases γ H2AX
8. Increase level of PPAR γ
9. Increase levels of XPC and XPA
10. Increase levels of XAB1
11. Increases efficiency PTEN and XPC
12. Increases efficiency MITF
13. Increases base excision repair DNA
14. Blocks UVB activated cell death
15. Suppresses oxidative stress
16. Provides genomic stability
17. Rebalances connective tissue

Reduces chances of malignant transformation following UV and sun exposure and sunburns.

6 KEY HIGHLIGHTS: SCENESSE® DNA REPAIR

1. Acts as a physical barrier to UV
2. Optimises MC1R and ET-1 signalling
3. Reduces oxidative stress [after UV]
4. Reduces photoproducts [caused by UV]
5. Increases activity key proteins XPC-XPA
6. Increases NER and BER [DNA repair mechanisms]

SIMPLIFIED EXPLANATION

SCENESSE® is proven to assist repair of DNA which has been damaged by sun and UVR (per 17 facts provided)

1. UVR causes instant DNA damage of skin cells
2. If this damage is not repaired, the chances increase in fair-skinned individuals that DNA-damaged cells are replicated, leading to skin cancer[s] including melanoma
3. SCENESSE® reduces DNA damage caused by the sun's energy by:
 - Absorbing UVB and UVA rays
 - Activating skin pigmentation
 - Reducing free radical formation
4. SCENESSE® assists and expedites DNA repair of damaged skin by:
 - Activating key repair genes and proteins
 - Assisting in cutting out damaged DNA and replacing with new DNA fragment
 - Stabilising the cell and its surrounding tissues

CONCLUSION IN SIMPLIFIED TERMS

The use of SCENESSE® in fair-skinned individuals and high risk patients results in less skin damage caused by sun and UV and therefore most likely reduces the chance of skin cancer including melanoma.

SINGAPORE RESEARCH, DEVELOPMENT & INNOVATION CENTRE

SINGAPORE – WORLD LEADING TECHNOLOGY HUB

- Sovereign island city-state
- Culturally diverse population of 5.7 million
- Excellent infrastructure and public safety
- Superior education system and access to scientific talent
- Financial centre and largest port in South-East Asia
- Technological centre of South-East Asia with a highly skilled workforce and business friendly environment
- Singapore Government supportive to attract and encourage growth of R&D capabilities and technologies with investment incentives and schemes.

THE NEW AND EXPANDED VALLAURIX FACILITY

- Opened August 2020 in Singapore Science Park
- State-of-the-art research and development centre
- Divided into analytical and biological laboratories
- Biological lab capabilities in ex vivo experiments and bioassays, and studies on fresh biological and tissue cultures
- Expanded analytical capabilities with compendial methodologies
- Capacity to accelerate the CLINUVEL Group's research program
- Upon final regulatory inspections and certification, the laboratories will operate according to Good Laboratory Practice under ISO 17025





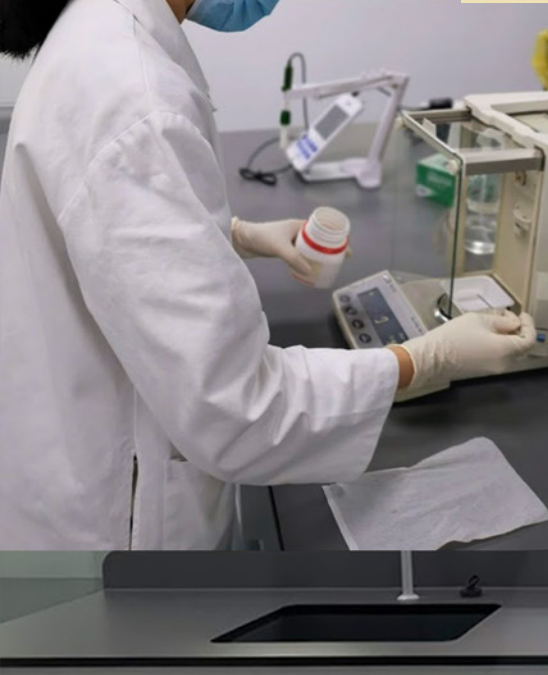
ROLE OF VALLAURIX

- CLINUVEL Group's centralised research, development and innovation centre
 - Principle objective is to commercialise innovative pharmaceuticals and new over-the-counter (OTC) product lines which complement the specialised field of medicine on which the Company has focussed
 - Operates key functions of:
 - Advanced Analytical Chemistry;
 - Materials Science;
 - Regulatory Chemistry-Manufacturing-Control;
 - Quality Assurance;
 - Good Laboratory Practice;
 - Informatics and Computational Modelling;
 - Pharmaceutical and Formulation Science;
 - Analytical Sciences;
 - Comparative Medicine; and
 - ASEAN regulatory affairs
 - Integral to support the strategy to become a diversified biopharmaceutical company
 - Part of CLINUVEL's strategy to integrate key functions 'in-house'
- 



THE PEOPLE

- Committed, well qualified professional scientists and analysts
 - Expertise across product and formulation development, analysis, and support
 - Capable and diverse to support the research program
- 



THE RESEARCH PROGRAM

- Focus on molecular profiling, peptide chemistry, and polymer and formulation sciences
 - Key projects are:
 - Pilot launch of OTC product line to target groups;
 - Establish stability dataset and commission manufacturing for PRÉNUMBRA®, a liquid formulation of afamelanotide (announced in July 2020); and
 - Formulation of second-generation melanocortins, including CUV9900, phimelanotide and parvysmelanotide
- 

DIRECTORS' REPORT

The Directors of the Board present their report on the Company for the financial year ended 30 June 2020 and the Auditor's Independence Declaration thereon.

DIRECTORS

The names of Directors in office during or since the end of the year are set out below.



WILLEM BLIJDORP

Non-Executive Director, Funda

Appointed 21 January 2015, Chair since 30 November 2019

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 merger 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 future plans to further diversify CLINUVEL.

Relevant Skills

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

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: -



PHILIPPE WOLGEN

Chief Executive Officer, MBA, MD

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

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, 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 the next generation of managers.

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

Relevant Skills

- pharmaceutical research & development, commercialisation
- clinical expertise
- commercial knowhow, entrepreneurial outlook
- executive management, corporate turnarounds
- financial management
- capital market understanding
- experienced in listed company Directorships

Current Directorships and other interests

None

Other listed company Directorships (last 3 years)

None

Relevant interest in Shares and performance rights

Shares: 3,504,696

Performance Rights: 1,513,750*

*Performance Rights were issued to Dr Wolgen on 26 August 2020, consequent to shareholder approval at the 2019 AGM

**BRENDA SHANAHAN**

Non-Executive Director, BComm, FAICD, ASIA

Appointed 6 February 2007

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 Environmental Technologies Ltd (ASX: PET). 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.

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 also has served on 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. She is the current Chair of the Audit Committee for Phoslock Environmental Technologies Ltd (ASX: PET).

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.

Relevant Skills

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

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

Director of DMP Asset Management Ltd

Director of Kimberly Foundation of Australia Ltd

Other listed company Directorships (last 3 years)

Phoslock Environmental Technologies Ltd (ASX: PET, since 2017)

Bell Financial Group (ASX: BFG, from 2012 to 2018)

Challenger Limited (ASX: CGF, from 2014 to 2017)

Relevant interest in Shares and performance rights

Shares: 258,969

Performance Rights: 25,000

**KAREN AGERSBORG****Non-Executive Director, MD**

Appointed 29 January 2018

Background

Dr Agersborg is a Board-Certified Endocrinologist in Pennsylvania, USA, currently serving as Clinical Endocrinologist at Easton Hospital, Steward Health, specialising in Endocrinology, Diabetes & Metabolism. Dr Agersborg had previously worked 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.

Relevant Skills

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

Committee Membership

Member of the Remuneration Committee

Member of the Nomination Committee

Current Directorships and other interests

Member of the American Osteopathic Association

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: -

**SUSAN (SUE) SMITH****Non-Executive Director, Dipl ClinRisk**

Appointed 23 September 2019

Background

Mrs Smith manages an established consultancy business, providing advisory services to a range of healthcare organisations, investors and boards of directors. Mrs Smith has also had 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 an 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.

Relevant Skills

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

Committee Membership

Member of the Remuneration Committee
Member of the Nomination Committee

Current Directorships and other interests

Non-Executive Board Chair of the Evewell (Harley St) 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: -
Performance Rights: -



**JEFFREY ROSENFELD
AC, OBE**

Non-Executive Director

Appointed 26 November 2019

Background

Prof Rosenfeld is an internationally recognised neurosurgeon with extensive experience in senior healthcare medical and 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 is an active volunteer in 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.

Relevant Skills

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

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: 1,693
Performance Rights: -



STAN MCLIESH

Non-Executive Chair, B Ed

Appointed 12 September 2002, Ceased
Directorship 30 November 2019

Background

Mr McLiesh has vast experience across pharmaceutical research and development, and distribution and commercialisation of pharmaceutical products. He was closely involved in the transition of CSL Limited (ASX: CSL) from government ownership through corporatisation to a highly successful listed company as General Manager. During this time, he helped CSL expand its international reach, brokering numerous in-licensing agreements, M&A transactions and partnerships with multinational firms, becoming the most successful Australian life-sciences company. Mr McLiesh has previously served in non-executive roles in the medical device field.

As Chair of CLINUVEL from 2010 to 2019, Mr McLiesh was involved in formulating the successful European commercial strategy for SCENESSE® (afamelanotide 16mg) and overseeing the continuity and stability of the CLINUVEL Group.

He has taken a leading role in setting US commercial strategy, culminating in US FDA's approval of SCENESSE® in October 2019.

His ability to navigate through crises and oversee clear pathways towards finding solutions made him highly capable to steer management over many years, up until his retirement in November 2019.

Relevant Skills

- pharmaceutical research & development, commercialisation
- commercial acumen
- general management
- experienced in listed company Directorships

Committee Membership

Member of the Remuneration Committee
Member of the Audit and Risk Committee
Member of the Nomination Committee
Current Directorships and other interests
Vice President of the Board of Ivanhoe Girls
Grammar School, Melbourne

Other listed company Directorships (last 3 years)

None

Relevant interest in Shares and performance rights

Shares: 187,774
Performance Rights: -

INFORMATION ON COMPANY SECRETARY

DARREN KEAMY

Company Secretary, Chief Financial Officer

Qualifications: BComm, CPA, GradDip ACG

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

regulation and control within the banking and retail pharmaceutical industries. He has overseen the financial management of the Group since 2005, played a role in raising AUD\$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	10	10	3	3	-	-	2	2
Mr. S.R. McLiesh	5	5	2	2	2	2	2	2
Dr. P.J. Wolgen *	10	10	1	1	2	2	-	-
Mr. W. A. Blijdorp	10	10	2	2	2	2	2	2
Dr. K. A. Agersborg	10	8	-	-	-	-	2	2
Mrs. S. E. Smith	7	7					1	1
Prof J. V. Rosenfeld	5	5						
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.			
During 2019/20 changes to the composition of the Audit and Risk Committee and the Remuneration Committee saw Dr Wolgen be replaced by non-executive Directors.								

PRINCIPAL OBJECTIVES AND ACTIVITIES

Objectives

CLINUVEL PHARMACEUTICALS LTD (CLINUVEL) is a global biopharmaceutical company focussed on developing and delivering treatments for patients with a range of genetic and vascular disorders. 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 patients and consumers.

CLINUVEL's expertise in understanding the interaction of light and human biology is focussed on preventing the symptoms of genetic diseases related to the exposure to the visible light spectrum and UV radiation along with addressing a range of depigmentation disorders. These patient groups range in size from 5,000 to 45 million worldwide.

CLINUVEL has developed and launched *the world's first systemic photoprotective drug* 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 in need. The key to long term sustainable performance is:

- continuing the successful research and development of a portfolio of assets centred around its key drug candidate SCENESSE® and its melanocortin derivatives;
- the successful commercialisation, manufacture and distribution of these products; and
- maintaining financial discipline and stability.

A key facilitator of these objectives is the ability to attract funding to support CLINUVEL's activities, should the need arise.

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 the commercial distribution in Europe of its leading drug product SCENESSE® (afamelanotide 16mg) for the treatment of a rare, genetic metabolic disorder, erythropoietic protoporphyria (EPP);
- establish commercial distribution of SCENESSE® in the USA following the approval of the US Food and Drug Administration (FDA) in October 2019 of SCENESSE® for the treatment of adult EPP patients;
- progress the ongoing research and development of its 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 over-the-counter formulations for photoprotection of the skin;
 - medicinal photoprotection through DNA repair of the skin; and
 - the development of PRÉNUMBRA®, a new liquid formulation of afamelanotide for the treatment of critical indications to be announced.

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

REVIEW OF OPERATIONS AND FINANCIAL CONDITION

Key Features of Business Operations

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

- The commercial operations of the Group are undertaken in Europe and the USA.

- Since June 2016 CLINUVEL has distributed SCENESSE® to EPP patients through accredited 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 treating 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.
 - Distribution costs specific to each jurisdiction determines the gross price of SCENESSE®.
 - This 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 Expert Centres in Europe and Specialty Centers in the USA.
- CLINUVEL's cash receipts are markedly higher in the northern hemisphere during spring and summer when ambient light is more intense and demand for treatment from EPP patients is higher than in autumn and winter.
- 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, in an undisclosed 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 to acute disorders and vascular anomalies in indications to be announced.
- The Group's product development program is conducted through its fully owned Singaporean subsidiary, VALLAURIX PTE LTD (VALLAURIX).
- 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 FY2020 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 laboratory facilities in Singapore, and the progression of the product pipeline to develop SCENESSE® and its analogues for the treatment of patients with a range of severe genetic, skin, and vascular disorders.

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 the year ended 30 June 2020 (FY2020). During the corona-pandemic, the majority of EPP Expert Centres continued prescription of SCENESSE® due to the ongoing clinical demand, while a small number of Centres either deferred orders or reduced order sizes in the initial months of the COVID infections. 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, 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 other European countries.

Distribution of SCENESSE® in the USA

On 8 October 2019, the 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 which had an unmet medical need for treatment. 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, identification of the correct codes for treatment to ensure smooth operations and reimbursement, initial insurer discussions and agreement to reimburse the cost of treatment, and identification of the initial Specialty Centers to be accredited and trained by CLINUVEL.

In April 2020, CLINUVEL commenced distribution of SCENESSE® for adult EPP patients with the first US insurance companies initiating reimbursement for treatment under Prior Authorization (PA). Over 40 insurance companies have now agreed to consider SCENESSE® under PA. CLINUVEL has established 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 in their applications to insurance companies for approval to reimburse the cost of treatment of SCENESSE®.

Our plan is to accredit 30 Specialty Centers over a phased period. At the time of writing, 17 Specialty Centers have been accredited, which is ahead of our planning. Cash receipts for the financial year ending 30 June 2020 did not include any receipts from the supply of SCENESSE® in the US market. The Company expects, in these early stages of US launch, that payment terms may be longer in duration than the 30 to 60 days average length of payment term in Europe. Modest revenue was recorded in the first few months of treatment to 30 June 2020 and the outlook for the US business is underpinned by the progress being achieved in the number of Specialty Centers accredited and patients treated.

SCENESSE® for EPP in New Jurisdictions

With regulatory approvals from the EMA in Europe and more recently, the FDA in the USA, and information on the patient experience in Europe generated from its post-marketing commitments, 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 2019, the Australian Therapeutic Goods Administration (TGA) granted SCENESSE® the right to be filed under its priority registration process. In December 2019, CLINUVEL applied to the TGA for SCENESSE® to be registered in the Australian Register of Therapeutic Goods (ARTG). If registered, SCENESSE® would be made available by prescription in Australia for the prevention of phototoxicity in adult patients with EPP. In January 2020, the TGA accepted the registration dossier for review. A decision is expected during the fourth quarter of calendar 2020. In parallel, interactions with the Pharmaceutical Benefit Scheme (PBS) have occurred to exchange information on risk, benefit, and budget impact in Australia. The aim is to assess whether SCENESSE® can become listed on the PBS in Australia. It is expected that the drug will be made available exclusively through outpatient departments of speciality centres since it will be administered by specialists only.

In April 2020, the Group commenced a Collaboration Agreement to launch SCENESSE® (afamelanotide 16mg) under a Named Patient Program (NPP) for the treatment of EPP patients in the People's Republic of China. The collaboration with HK Winhealth Pharma Group Co. Limited (Winhealth) focuses on facilitating early access for Chinese EPP patients while collecting data for a new drug application (NDA) to the Chinese National Medical Products Administration (NMPA). CLINUVEL and Winhealth will work with prominent hospitals in China to facilitate EPP patient treatment. 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 Winhealth will evaluate the 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.

An application was also lodged during the year for regulatory approval to distribute SCENESSE® in a non-EU country, and submissions to regulatory authorities in Japan and Latin America are planned.

Expansion Singapore Laboratory

During FY2020, CLINUVEL invested in the further expansion of its facilities in Singapore with new state of the art and expanded laboratories to further progress R&D on novel melanocortins, and prescription and over-the-counter products. In February 2020, the Group announced that the research and development capacity of its wholly owned subsidiary, VALLAURIX, will be expanded through both a new biological and analytical laboratory, which are planned to work according to both ISO17025 and Good Laboratory Practice (GLP) specifications. CLINUVEL has added new highly skilled local personnel to its existing team and specialised technical laboratory equipment to further enhance the progress of its product pipeline. VALLAURIX has received support of its expansion plan from the Singapore Economic Development Board (EDB) 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 3 years. The opening of the laboratory was planned for July 2020, but due to the introduction of prudent regulations by the Singapore Government to contain the coronavirus pandemic, it is expected the new facilities will be completed by the end of the third quarter of calendar year 2020.

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; and
- the application of a newly developed second formulation of afamelanotide, PRÉNUMBRA®, a liquid controlled-release formulation, to be evaluated in clinical trials for acute disorders and vascular anomalies.

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 February 2020, the Group requested a Type C Guidance Meeting with the FDA and they consented to a meeting held on 29 April 2020. The purpose of the meeting 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 is proceeding 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.

Subject to acceptance of the clinical protocol by the FDA, and depending on 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.

Scientific advancements and CLINUVEL's programs have shown that afamelanotide can assist in the repair of cellular DNA damage caused by exposure to ultraviolet radiation. CLINUVEL is working to evaluate this effect in humans, with protocols prepared in target patient populations currently pending approvals.

In July 2020, at the start of the new financial year, the Group announced the development of a second formulation of afamelanotide, PRÉNUMBRA®. This liquid controlled-release formulation is aimed at dosing flexibility as part of the active life-cycle management of afamelanotide to address clinical needs in acute disorders and vascular anomalies. The indications of focus are to be announced when ethics committee and regulatory approvals are held. The Group has secured the intellectual property rights for the dosage form in the identified indications, as well as the international trademarks for PRÉNUMBRA®.

Financial Review

The financial year ended 30 June 2020 marks the completion of the Group's fourth consecutive year of achieving a net profit, a positive cash flow result and increased revenue growth.

Financial Summary

Consolidated Entity	FY 2020	FY 2019
	\$	\$
Revenues and Other Income	33,909,670	32,498,470
	+4%	+24%
Net Profit before income tax	13,136,471	18,114,827
	-27%	+40%
Profit after income tax expense	16,646,859	18,134,160
	-8%	+37%
Basic earnings per share	0.338	0.376
	-10%	+36%
Net tangible assets backing per share	1.383 ¹	1.158
	19%	+42%
Dividends	2.5 cents	2.0 cents

¹ This has been adjusted to reflect the requirement of Australian Securities and Investments Commission to exclude right of use assets arising from the application of AASB 16 'Leases' from the calculation of net tangible assets.

Note: CLINUVEL has one operating segment for reporting purposes.

The result for the Group for FY2020 was a \$13.136 million profit before tax, compared to \$18.115 million for FY2019, a 27% decrease. The result reinforces the Group's primary strategic focus to grow its commercial operations of SCENESSE® in the EU and the US and to prepare for future product growth and business expansion. Total expenses increased by 44% year-on-year, complemented by a combined increase in total revenues, interest income and other income of 4% year-on-year.

Net Cash provided by Operating Activities was \$14.188 million for FY2020. After the deployment of cash in investing and financing activities, net cash added \$12.478 million to cash and cash equivalents on the balance sheet. Cash reserves have increased steadily since 2016, from \$14.170 million to the 30 June 2020 level of \$66.747 million, a 44% compound annual growth rate over the last 4 years.

Revenues

The Group achieved Total Revenues of \$32.565 million for FY2020, a 5% increase on the prior year revenue result of \$31.048 million.

A comparison of the FY2020 reported and constant currency results against the FY2019 reported results for Commercial Sales and Special Access Scheme Reimbursements is shown below:

AU \$ million	FY2020 Reported	FY2020 Constant*	FY2019 Reported	% change
Commercial Sales - Europe	25.407	24.409	26.488	(7.9)
Commercial Sales - USA	0.899	n/a	n/a	-
SAS Reimbursements - SUI + Other	6.259	5.922	4.559	+29.9
* FY2020 revenues converted to A\$ monthly at the average conversion rate of the same month used for FY2019				

Commercial Sales - Europe

On a constant currency basis commercial sales revenues of SCENESSE® in Europe decreased 7.9% for the year. The result was driven by a combination of:

- EPP Expert Centres located in regions severely affected by COVID19 either deferring or reducing orders at a time when orders typically increase in the warmer months;
- EPP Expert Centres running down inventories, offset by
- Further increases in new patients enrolled under the post-authorisation safety setting and treated by EPP Expert Centres before and during lockdown.

Despite difficult conditions from the coronavirus pandemic in Europe to access patients during the second half of FY2020 when demand for SCENESSE® generally increases, EPP Expert Centres continued to prescribe SCENESSE® to existing and to new patients receptive to the treatment.

Whilst the price of SCENESSE® remained constant in FY2020, in line with CLINUVEL's policy to charge a net uniform price across all European countries, commercial sales in Europe were positively impacted by favourable foreign exchange rate movements by \$0.998 million.

Commercial Sales - USA

First commercial sales occurred in the latter part of FY2020 to one EPP treatment centre. Reimbursement of SCENESSE® was initiated by first-mover US insurance companies for treatment under Prior Authorization ('PA') arrangements. More than forty insurers have agreed to reimburse SCENESSE® either via PA or through acceptance of the drug on individual formularies.

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 exceptionally supplied outside Switzerland under a special access arrangement whereby CLINUVEL received full cost compensation, linked to the uniform price of SCENESSE® sold in Europe under the marketing authorisation.

On a constant currency basis, sales reimbursements from special access schemes increased 29.9% for the year. The result was driven by:

- Growth in the average number of prescriptions per patient throughout the course of the year, and
- New patients receiving treatment for the first time

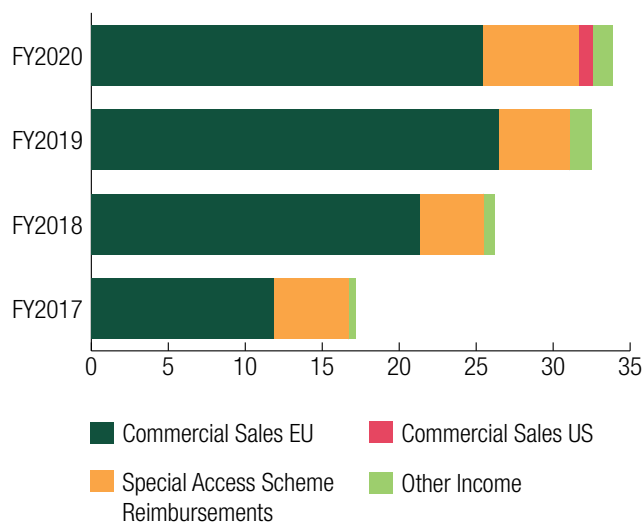
Other Income

Interest Revenue and Other Income

Interest received from funds held in bank accounts and term deposits for the year ended 30 June 2020 was \$0.563 million compared to \$0.565 million for year ended 30 June 2019.

The positive financial performance of the Group saw an increase over the 12 months to 30 June of \$12.478 million to its cash reserves. Over the course of FY2020 the Company was able to transfer more funds into higher-yielding Australian dollar fixed-rate term deposits. The average amount of cash held in term deposits was 55% higher than for FY2019. However, the higher cash balances were offset by

Growing revenues since initial launch(A\$M)



a lower interest rate yield it earned on holding interest-bearing term deposits, averaging 95 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 2020 has remained stable, decreasing 4% on average when compared to FY2019.

This exposure in holding funds in non-Australian dollar currency, combined with revaluing end date trade debtors and creditors from their original currency into Australian dollar presentation currency, contributed to the Group reporting a gain of \$0.537 million for FY2020 (FY2019: \$0.886 million gain).

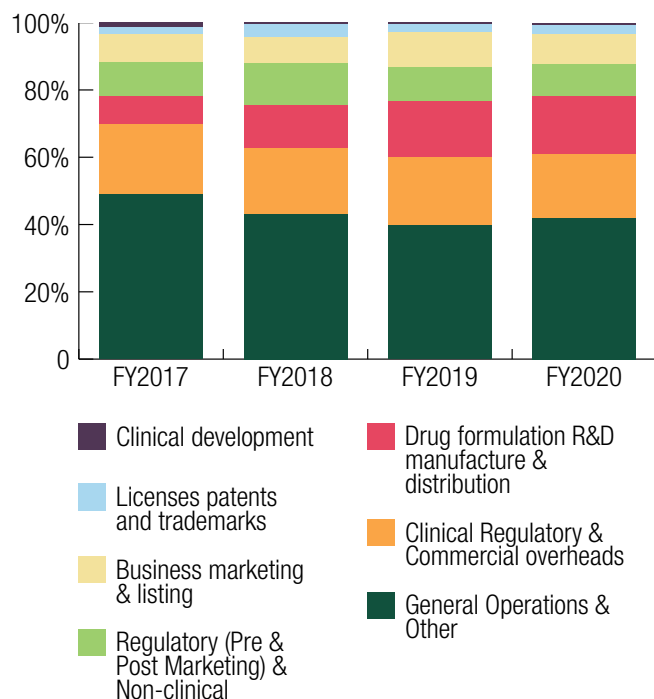
The Group recorded other income of \$0.127 million in government grants received in Australia and Singapore to assist companies responding to the economic impact of the COVID19 pandemic. The Group also benefited from realising exchange rate gains on transactions in non-Australian currency throughout the year of \$0.117 million.

Expenditures

Total Expenses for the Group for FY2020 were \$20.773 million. There was a deliberate and controlled increase in expenses of 44% during the year compared to FY2019 to support the Company's strategic initiatives, including investment in the research and development program for future organic growth.

The Group maintained its focus on its expenditure mix as it has done throughout the SCENESSE® development program. Overall, total R&D and commercialisation expenditures accounted for 46% of the Group's total expense result for FY2020, compared to 48% for FY2019. Whilst the expenditure mix showed a 2% decline, the total expenditures on R&D and commercialisation costs, comprising clinical study costs, drug formulation research, manufacture and distribution, regulatory fees and research, development and commercialisation-specific overheads such as personnel, were \$9.630 million in FY2020, increasing 40% from \$6.871 million in FY2019. The increase in these overall expenditures reflects the Group's focus throughout the year to further invest in its commercial rollout to secure revenues in the EU and for the first-time, the USA.

Expenditure Mix since EU product launch



Clinical Development

Clinical development fees increased 102% from \$0.091 million in FY2019 to \$0.185 million in FY2020.

Since the granting of market authorisation by the EMA in late 2014, the Group has prioritised its commercialisation activities in the EU and in pursuing a regulatory approval in the USA ahead of advancing its clinical trial program. This has been reflected in expenses towards clinical development representing approximately 1% of total expenses in each year since the year of European regulatory approval. Moving forward, the Group intends to invest funds in its clinical activities, both in the use of SCENESSE® in various therapeutic fields and in the clinical development and testing activities of the new products and formulations as part of the VALLAURIX operations.

This expense result for FY2020 was driven by:

- Increased clinical expert support services to advise on initiatives on the expanded use of SCENESSE®, and
- Growth in product development and testing services in the VALLAURIX operations under laboratory setting.

Drug Formulation R&D, Manufacture & Distribution

Expenses toward further research, development, manufacture and optimisation of the implant drug formulation and the freight and distribution to the end user increased 52%, from \$2.388 million in FY2019 to \$3.624 million in FY2020.

The Group continues to invest in its manufacturing supply chain to prepare for future sales growth and to meet short-term and long-term inventory requirements. During the year the Group embarked on a manufacturing program to replenish raw material peptide via a process change to support future scale-up. Validation of the process change is underway and will extend into FY2021. Continuous process improvement initiatives with the implant contract manufacturer were a part of the batch manufacturing campaigns that were conducted during FY2020. New distribution centres with contracted parties and third-party service providers were established in Europe to respond to the UK's pending departure from the EU as part of Brexit and to support supply to US EPP Expert Centres. Drug formulation R&D also includes the development work and usage of derivative peptide material within the VALLAURIX Singapore operations.

This expense result for FY2020 was driven by:

- Cost increases passed to the Group from its contract manufacturer as part of FY2020 implant manufacturing campaigns;
- Investment in process development of afamelanotide raw material peptide manufacturing which had commenced in FY2020;
- Growth in handling and freight activities to support the movement of serialised goods around Europe under the Falsified Medicines Directive and to move goods in the US; and
- Increased formulation development work in topical formulations, recognising the usage of derivative peptides.

Clinical, Regulatory & Commercial (C,R&C) Overheads

C,R&C overheads increased 32% from \$2.948 million in FY2019 to \$3.893 million in FY2020.

As part of CLINUVEL's longer term objectives, increasing the C,R&C personnel headcount is considered an essential investment to:

- drive the new product development program in its internal innovation centre, VALLAURIX PTE LTD;
- establish and grow a commercial distribution program in the USA;
- further sustain the ongoing commercial activities in Europe; and
- investigate the further use of SCENESSE® in indications other than EPP for the aim to expand its market potential.

FY2020 follows the trend since SCENESSE® was first launched in Europe in 2016 of gradually increasing C,R&C staff count in those key business areas to drive organic growth. As the Company continues to expand, C,R&C overheads will follow.

This expense result for FY2020 was driven by:

- Increased global staff headcount across its scientific affairs and commercial affairs teams.

Regulatory (Pre- & Post-Marketing) & Non-clinical

Regulatory and non-clinical fees increased 33% from \$1.444 million in FY2019 to \$1.928 million in FY2020.

Fees related to regulatory affairs for both pre- and post-marketing activities are directly related to the Group's strategic focus in the current year to meet its ongoing regulatory compliance activities to distribute SCENESSE® in Europe and in the USA. These activities include pharmacovigilance, safety reporting, PASS registry data capture and dossier updates. SCENESSE® is established as standard of care in a number of European countries. The first treatment results from the European EPP Disease Registry study were independently published during FY2020, showing ongoing longer-term maintenance of the safety profile of SCENESSE® and clinical benefit for patients receiving treatment.

Pre-marketing regulatory fees for FY2020 included finalising and submitting an application to the Australian Therapeutic Goods Administration for the use of SCENESSE® in EPP. An outcome is anticipated in late 2020.

Regulatory and non-clinical fees also include the support required for pricing dossier submissions and in responding to the pricing negotiations.

This expense result for FY2020 was driven by:

- Growth in ongoing pharmacovigilance services; and
- Fees to prepare and respond to an increased number of audits and inspections from various regulatory bodies including the UK MHRA and FDA.

Business Marketing & Listing

Business marketing and listing fees increased 26% from \$1.502 million in FY2019 to \$1.889 million in FY2020.

The Group has been further investing in its marketing and brand-building resources throughout the year. The focus to this business

function has been to build a greater online awareness of the CLINUVEL brand in consideration of the US FDA's approval of SCENESSE®. In addition, as the product development program in VALLAURIX progresses, resources and strategies are being put in place to support future product launch. Brand-awareness strategies were implemented during industry conferences at the start of FY2020 but were later impacted by the onset of COVID19.

This expense result was driven by:

- Additional in-house marketing resources through more personnel to support the building of CLINUVEL's brand exposure across multiple forums and the promotion of VALLAURIX's over the counter (OTC) products leading up to launch; and
- Increases to listing, share registry and corporate regulatory fees tied to market capitalisation growth and investor mix.

Patents and Trademarks

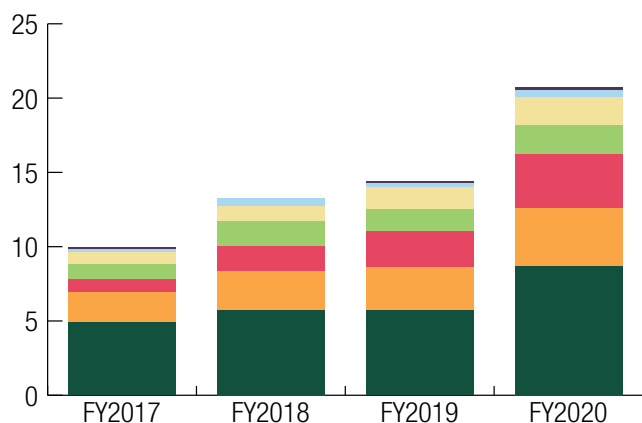
Patent fees increased 69% from \$0.305 million in FY2019 to \$0.516 million in FY2020.

Incurring expenditures in patent and trademarks provides the Group with essential protection and a competitive advantage over others.

This expense result was driven by:

- Further fortification of the intellectual property position on the new product development and complementary formulations within the VALLAURIX business;
- Further maintaining, strengthening and validating the position of the existing patent portfolio, including patent term extension requests; and
- Investments in trademarks of new product names including PRÉNUMBRA®, CLINUVEL's new non-solid (liquid) presentation of its drug afamelanotide.

Expenditure Growth since EU product launch



General Operations (incl Board)

Expenditures from general operations increased 61% from \$4.923 million in FY2019 to \$7.963 million in FY2020.

General operations are reflective of the support function necessary to ensure the execution of the Company's demanding near-term and long-term expansion strategy. Personnel costs including the remuneration of senior management is considered part of general operations along with IT, corporate support, legal, Board and various non-cash items.

This expense result for FY2020 was driven by:

- Growth in non-cash expensing of share-based payments, the accounting charge directly related to the approval by shareholders of performance rights to the Managing Director at the 2019 AGM;
- changes to the remuneration arrangements of key management personnel, impacting salary and employee benefit expenses; and
- General increases to recruitment and insurances to support business growth, offset by savings to legal-related fees, principally from FY2019 including legal fees in connection to matters related to the EMA marketing authorisation and in responding to negotiations with England's National Institute for Health and Care Excellence (NICE).

Other Expenses

Other expenses decreased less than 1% from \$0.755 million in FY2019 to \$0.750 million in FY2020.

Other expenses include travel and ad-hoc staff-related expenses. Whilst there was a steep increase in travel related costs in the first half of FY2020, staff mobility was severely restricted in the second half of FY2020.

Deferred Tax Asset

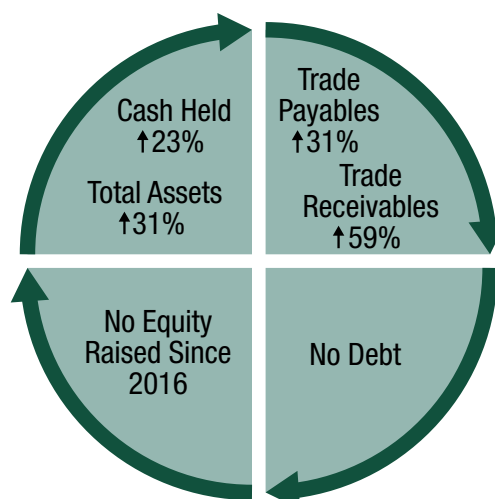
The Group has brought to account a deferred tax asset (DTA) relating to previously unrecognised prior period tax losses, resulting in a credit to income tax benefit of \$3.510 million (FY2019: \$0.019 million). The amount of the DTA brought to account reflects:

- 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 enough 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 and, in doing so, is able 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 has been a deliberate and planned strategy, reflecting CLINUVEL's conservative approach to risk management.

Key Balance Sheet highlights of the year:



The changes to the Balance Sheet was generated from positive cashflows flowing into the company from its commercial distribution program in the EU, increasing cash reserves by 23% from \$54.269 million at FY2019 to \$66.747 million at FY2020. Into FY2021, cashflows are expected to be received from the distribution of SCENESSE® in the US.

Total liabilities increased 52%, from \$5.166 million to \$7.873 million, with no long-term debt. The ratio of the Company's overall debt to equity is 12%.

Shareholder Returns

Shareholder returns for FY2020 remain strong and are summarised by:

A\$M	FY2020	FY2019	FY2018	FY2017	FY2016
Profit attributable to owners of parent	\$16.647	\$18.134	\$13.224	\$7.180	(\$3.121)
Basic EPS	33.8 cents	37.6 cents	27.7 cents	14.9 cents	(7.0) cents
Dividends Paid	\$1.224	\$0.957	-	-	-
Dividends per Share	2.5 cents	2.0 cents	-	-	-
Change in Share Price YoY	(24%)	206%	58%	62%	52%
Return on Equity	23%	32%	34%	28%	(18%)
Shareholder returns have been generated in both the short-term and the longer-term through:					
- capital appreciation (Total Shareholder Return exceeding the Nasdaq Biotech Index and ASX200 Healthcare Index since first product launch), and - dividend distribution in the past two financial years					

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 open to consider 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 - Supported senior management and key personnel in ongoing professional development
Research & Development	- Relocating its laboratory to larger premises with expanded analytical capabilities - Fixed asset purchases - Non-solid dosage formulation development
Clinical	Activities in progress to obtain approvals to move into next phase clinical studies to pursue potential new markets for SCENESSE® in : - Vitiligo - Other indications (to be disclosed)
Manufacturing	Program to manufacture raw material peptide via a process change to support future scale-up
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 sound capital structure of ordinary shares on issue plus unlisted securities in the form of conditional performance rights.

CLINUVEL's outstanding shares on issue increased to 49,410,338 shares to 30 June 2020. The increase of 449,705 issued shares was through the exercise of performance rights under the Group's performance rights plans.

Dividends Paid or Recommended

Dividends paid or declared by the Group to members since the end of the previous financial year were:

Declared & paid in 2019/20	Cents per Share	Amount	Date of Payment
Final	2.50	\$1,224,021	19 September 2019

On 26 August 2020, the Board of Directors declared an unfranked dividend of \$0.025 per ordinary share in relation to the full year ended 30 June 2020.

Cash from Operations and Other Sources of Cash

Overall, the Company generated \$14.188 million in cash from its operating activities in FY2020 (FY2019: \$18.456 million)

Cash inflows from customer receipts decreased 9% to \$29.288 million compared to \$32.221 million for FY2019.

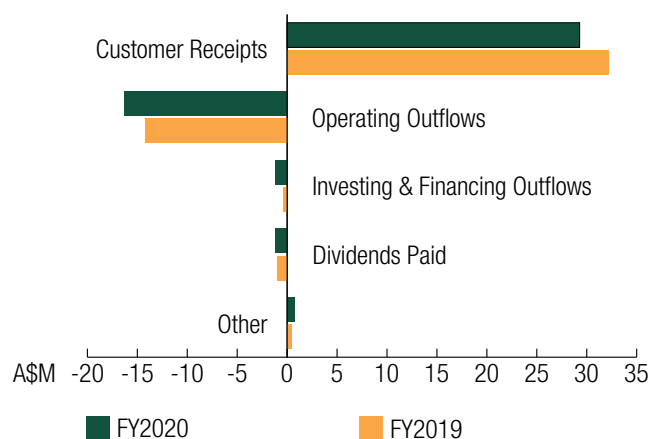
Cash outflows from operations increased by 14%, from \$14.241 million to \$16.281 million.

There were also cash outflows of \$0.889 million for the acquisition of property, plant and equipment, \$0.262 million of repayment of borrowing and leasing liabilities and \$1.224 million for the payment of an unfranked dividend to shareholders in relation to FY2019.

The Group's 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 foreign exchange forward contracts and other foreign exchange risk management products, as considered appropriate.

Cash Flows



The Group's financial liquidity as at 30 June 2020 is reflected in:

- A quick ratio of 11.0:1 (30 June 2019 11.8:1); and
- Cash and cash equivalents of \$66.747 million, accounting for 88.8% of total current assets (FY2019: \$54.269 million, 88.7% 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 Competition	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 impact of the coronavirus pandemic on the human population across the globe is significant and has caused the most severe contraction in the world economy since the 1929 Great Depression. 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. 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 to patients was affected particularly during the initial months when population lockdowns across Europe were first instituted. EPP Expert Centres either deferred orders or reduced order sizes in the initial months of the COVID infections because they were not able 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 seek 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 FY2020. The operations of the laboratory facilities in Singapore were restricted during the circuit-breaker period, with some remote working required. The circuit-breaker also resulted in minor delays to the laboratory expansion project, now set to be completed by the end of the third quarter of calendar year 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 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. Diligence under a difficult operating environment by the entire CLINUVEL team has seen productivity and focus remain largely unaffected.

Summary

CLINUVEL recorded a fourth consecutive annual positive cash flow and profit in FY2020. The impact of the corona-pandemic on the business during the second half of FY2020 has been managed and it has been able to respond to this challenge through the sound foundations established over a long period of time by management and the Board. CLINUVEL has entered FY2021 with cash reserves sufficient to respond to unforeseen negative global economic events.

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 26 August 2020, 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 more 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 bears responsibility for the manufacturing standards of the commercial drug product.

The US FDA approved SCENESSE® for the use in EPP during the financial year. 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. 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 yet to be disclosed acute and critical disorders. 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 achieve and maintain sustainable profitability. 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 Regulations 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 2020.

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		
Mr. S.R. McLiesh	Non-Executive Director	To 30 November 2019
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	From 24 September 2019
Prof. J. V. Rosenfeld	Non-Executive Director	From 26 November 2019
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. Remuneration Governance
- C. Executive Remuneration
- D. Non-Executive Remuneration
- E. Service Agreements 2019/20
- F. Share Based Remuneration
- G. Details of Remuneration
- H. Additional Information – Remuneration

A. INTRODUCTION BY THE CHAIR OF THE REMUNERATION COMMITTEE



Chairman of the Remuneration Committee: Mr Willem Blijdorp

As the Chair of the Remuneration Committee, I am pleased to present our Board' Remuneration Report for the year ended 30 June 2020.

We have kept the format of this year's Remuneration Report consistent with last year's since there have not been any significant changes in internal policies or regulations.

I oversee the Group's remuneration philosophy which aims to attract, retain and motivate talented professionals we require for the Company to meet its strategic objectives. In this process, we wish to see professionals receive appropriate acknowledgement and remuneration.

The Remuneration Committee oversees a remuneration policy of the Group to ensure it is fair, competitive with international peers and transparent. All in all, we strongly believe that a remuneration policy well implemented should help us drive growth strategy and sustainability of CLINUVEL, and thus far we have been proven right.

In 2020, CLINUVEL delivered another year of growth despite the global pandemic and lockdowns affecting all EU countries and the US. Whilst many peer companies have been posting losses and have been required to raise capital, CLINUVEL's Board and shareholders were fortunate to have a prudent executive management team who had foreseen and planned for the economic downturn and maneuvered the Company through tough times.

In the past year, we increased our revenues by 4%, our cash reserves by 23% and expanded the distribution of SCENESSE® across Europe. Standing tall and with some Dutch pride I look at how CLINUVEL posted an NPAT of A\$16.6M and PBIT of A\$13.1M in the middle of a global crisis and when many hospitals in Europe and US were not seeing out-patients in the first half of 2020. Our management skilfully came up with a plan to guarantee continuity of treatment for these patients able to travel under the national restrictions imposed by governments.

The Remuneration Committee with consensus of the full Board designed a Performance Rights Plan, which had received shareholder approval in November 2019 and which outlines step by step the Performance Conditions which need to be met for the Company to grow on all fronts within a vesting period of 4 years. This progressive but realistic business plan is being implemented and incentivizes executives and staff along the way. Assuming these Performance Conditions are met the Company should have grown significantly in value, providing commensurate returns for shareholders.

As I had stated in relation to the Committee's intentions in 2019, this year we reformed the Executive Agreements by eliminating cash-based Business Generating Incentives, and substituting these by a Performance Rights Plan vesting over 4 years. This PRP aims to incentivize and align the interests of the management team with those of shareholders, and in a dual position as Chairman of

the Remuneration Committee and also as larger investor of the Company I fully support this direction.

In building this Company, a careful financial and operational approach is taken which is receiving much recognition from the financial community I am in contact with and despite the shortselling we have seen in CLINUVEL the past year. The cost of issuing shares repetitively, the dilution caused to shareholders and the distraction to a management has been successfully avoided, and in terms of risk management we could not have asked for more.

In 2020, we also implemented the decision which forms part of the Company's policy that non executive directors will not participate in a Performance Rights Plan or Options Scheme since we wish to retain the independence of the non-executive directors.

In recent weeks, the Remuneration Committee and Board has been surprised, impressed but proud to learn that our CEO has waived and rejected his STI awarded to him for achieving 70% of the KPIs for 2020. His decision reflects an unusual and amazing leadership in the industry, awareness of the world and extraordinary sensitivities to ask the Remuneration Committee to reinvest these monies for further growth of the Company. In my long career it is rare to find executives who independently pass on their incentives and financial awards for the greater benefit of the Company, shareholders and patients: in Philippe we have long identified a professional of different calibre.

Finally, to summarize in a more personal way, I see the current performance of the Company as follows. The approach and

policies of the Remuneration Committee need to change with the times we are living in, and therefore a company and management team needs to be innovative and behave in an entrepreneurial way. For this to succeed, the Company needs to provide a working environment for them to stay on and incentivize them for their achievements.

In CLINUVEL, we have a CFO, CSO and CEO who have this mindset and are not getting out of the boat half-way down the trip: their trip is far from easy, but they have delivered and continue to perform and have built a Company to survive all challenges. As Chairman of the Remuneration Committee this is amazing, I am not sure I would have the stamina to stay on this project for 2 decades.

My vision is simple, entrepreneurship is to implement new combinations, create new business models and change when the environment asks you to do this. With this mindset, this management team is beating all challenges even in the face of economic hard times.

I recommend the Remuneration Report 2020 to all our shareholders and proxy representatives.

Willem Blijdorp, Chairman of the Remuneration Committee

Amsterdam

B. REMUNERATION GOVERNANCE

(i) Remuneration Committee

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

The objectives of the Remunerations Committee's responsibilities are to ensure that:

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

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

(ii) Remuneration Recommendations

Under the provisions of the Committee's Charter, the Committee may engage the assistance and advice from external remuneration advisors. To ensure that any recommendations made by remuneration consultants are provided without undue influence

being exerted by Executives, external remuneration consultants deliver their advice directly to members of the Committee.

In the year ended 30 June 2020, the Remuneration Committee engaged the services of remuneration advisors to assist with a review of the remuneration framework, to benchmark executive KMP salaries and to provide comparable peer company market data. No remuneration recommendations as defined by the Corporations Act was received from external consultants during the financial year.

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

In the 2019 Annual General Meeting (AGM), the Company obtained 88.96% of the proxy votes (including votes at the Board's discretion) in favour of adopting the 2018/19 Remuneration Report, and this resolution was carried in favour by poll with 87.69% of votes cast. The Company did not receive any further specific feedback at the AGM on its remuneration practices.

(iv) Historical voting at the Company's Annual General Meetings since 2006

Since 2006 the Company has obtained a historical average of 92% of proxy votes received (including votes at the proxy's discretion), either carried by a show of hands prior to and including the 2014 AGM or by a poll result after the 2014 AGM, in favour of adopting the Remuneration Reports presented.

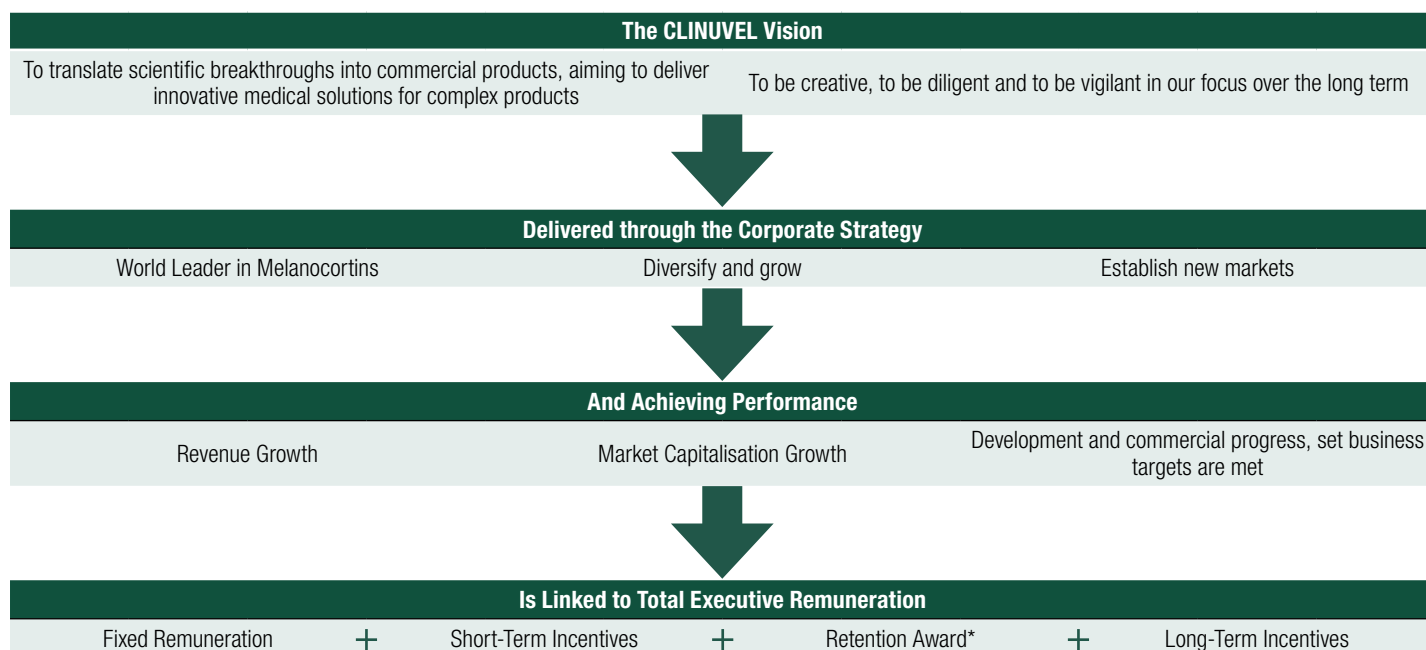
C. EXECUTIVE REMUNERATION

(i) Executive Remuneration Framework

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).

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



* Managing Director and CFO only

(ii) Executive Remuneration Structure 2019-20

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.
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b. Variable Remuneration – Cash Based

Short-Term Incentive	Short-Term Incentives are annual payments to reward executives for achieving certain regulatory, development, commercial and operational outcomes which are expected to contribute to increasing shareholder value. The Managing Director's performance targets are set at the start of each financial year by the Remuneration Committee and are assessed at the end of the financial year. The other Executive performance targets are set at the start of each financial year by the Managing Director and are recommended to the Remuneration Committee for their review and approval. Payment occurs in the year following the year of achievement. The target opportunity for the Executives for 2019/20 are: - Managing Director: \$750,000 Singapore dollars - Chief Financial Officer: 17% of Base Salary - Chief Scientific Officer: 9% of Base Salary
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Short-Term Incentive (continued)	Short-term incentive targets are a mix between 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. For the Managing Director, the weighting for 2019/20 was 30% financial targets and 70% in individual performance targets. The Board considers the specific performance-based targets to be commercially sensitive and are not provided in detail. The targets for 2019/20 were connected to: 1. Material progress in regulatory filings and in establishing price agreements with final payors, with an emphasis on the US; 2. Profitability and cash preservation; and 3. Progress in products and formulations under research & development by the VALLAURIX subsidiary entity. For the year ended 30 June 2020, the Remuneration Committee assessed the Managing Director's performance targets which form his Short-Term Incentive and awarded a 70% assessment against the targets. The Managing Director has autonomously chosen to forego this year's STI award 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. The remainder of CLINUVEL's staff and executives will receive their awards towards Key Performance Indicators for FY2020. For the Other Executives, the Short-Term Incentive targets can be a mix of individual performance-based incentives and have a component for time served to encourage staff retention. Each performance-based target is based on specific individual responsibilities and objectives typical for these roles in a global life sciences company at its stage of development and commercialisation. The performance-based incentives covered revenue generation, business expansion and optimisation, regulatory progress, manufacturing, research and development and corporate affairs. The Managing Director assessed overall performance for the 2019/20 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: 95% • Chief Financial Officer: 89%
Business Generation Incentive	Business Generation Incentives (BGI) 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 July 1 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®; • 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 2019/20 financial year, BGI1 was achieved by the Chief Financial Officer.
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 employment start. Managing Director: A\$7,500 Chief Financial Officer: A\$1,000 There is a risk of forfeiture of 100% of the longevity-based award for 12 months following the July 1 2019 Effective Date of the 2019/20 service agreement should the executives provide a notice of termination during this period. Once the forfeiture period lapses, 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.

Discretionary Payment	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 2020 or 30 June 2019.
c. Variable Remuneration – Equity Based	
Performance Rights	Performance Rights, being an option to acquire ordinary shares of CLINUVEL PHARMACEUTICALS LTD for nil exercise price, are offered to Executives from time to time to: • retain and motivate the Other Executive KMP to drive the long-term growth and success of the Company • 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 (performance) conditions attached to the issue of performance rights. Performance Rights have vesting periods either up to 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. 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 the financial years ended 30 June 2020 and 30 June 2019, 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 2019/20 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. These unvested Performance Conditions are: - Granting market approval for SCENESSE® by the US FDA (not attached to Non-Executive Directors) – achieved in 2019/20; - Securing sufficient funding to secure 5 performance conditions (including the performance condition ‘Granting market approval for SCENESSE® by the US FDA’) (not attached to Non-Executive Directors) – achieved in 2019/20; - Announcement of commercial partnership to distribute SCENESSE® (or derivative of) (One Non-Executive Director, and Other Executive KMP and staff only); and - The earlier of: (a) second molecule in new formulation, or (b) paediatric formulation for afamelanotide (Other Executive KMP and staff only) 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. 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 entirely 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. 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 below:

Description of Performance Conditions	Performance Rights
Executive management and staff succeeding in steering the Company to a: i) Market capitalisation of a minimum A\$1,600,000,000 - 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, 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	450,000
PC2 i) Upon quarterly reporting of A\$55 million in cash and cash equivalents held for 2 consecutive quarters, 15% of PC2 shall vest, ii) Upon quarterly reporting of A\$65 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\$100million 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 authorisation 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 a 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 most 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 commercial drug pricing and reimbursement negotiations. 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 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 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 on international securities exchanges for the purpose of peer group analyses. The selection criteria for these companies is 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) businesses of similar risk profile.

CLINUVEL aims to provide competitive remuneration for the Managing Director based on both local and international comparable positions in the relevant market(s). 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.

During the year the Managing Director's remuneration was benchmarked against 6 revenue-generating Australian-listed life science companies with market capitalisation between \$400 million and \$2 billion, along with 11 profit-generating US-listed pharmaceutical companies with market capitalisation between US\$200 million and US\$10 billion. The current total remuneration level of the Managing Director remains below the median level.

(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 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				
	2016	2017	2018	2019	2020
Ph II Vitiligo Study - Singapore	←→				
VALLAURIX PTE LTD – formulation & melanocortin development	←→				
Post-marketing authorisation commitments	←→				
First commercial sales in EU	←→				
Submission and subsequent approval for marketing authorisation by the US FDA				←→	
Application for marketing authorisation submitted with TGA					↔
First commercial sales in US					↔
Market capitalisation (A\$ million)	203	333	527	1,649	1,267
Share Price High (\$)	5.00	9.19	13.52	39.85	45.88
Share Price Low (\$)	2.50	4.10	5.91	9.43	12.92
Closing Share Price (\$)	4.32	6.98	11.01	33.68	25.65
Change in Share Price over 1 Year (%)	57	62	58	206	(24)
Change in Share Price over 3 Years (%)	139	311	288	680	268
Change in Share Price over 5 Years (%)	162	328	508	1881	803
Dividend Paid (cents)	-	-	-	2.0	2.5

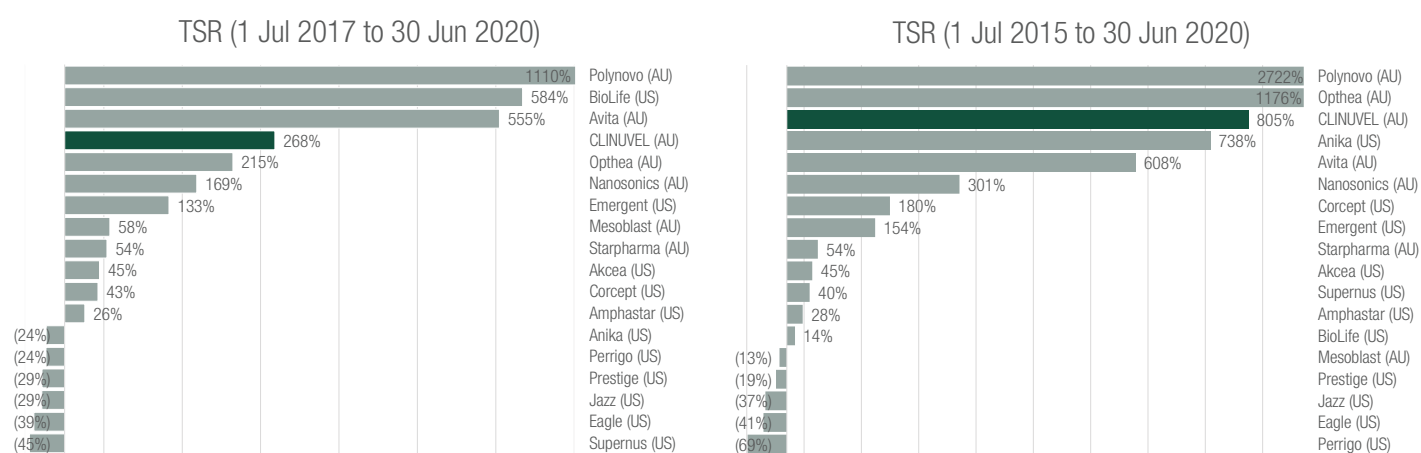
(vi) Executive Remuneration Pay Mix

The Board believes the remuneration mix aligns the Managing Director and Other Executive KMP to shareholder interest. The remuneration mix for 2019/20 is demonstrated as follows:

Position	Fixed Remuneration	STI Cash	LTI Cash ¹	LTI Equity ²
Managing Director	100%	56% of Base Salary	-	138% of Base Salary
Other Executives	100%	Between 9% and 17% of Base Salary	Up to 43% of Base Salary (CFO Only)	-

¹ Does not include Retention Award unearned as at 30 June 2020

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



A comparison of the 3-Year and 5-Year Total Shareholder Return (TSR) of life science peer companies (being a mix of medical device, pharmaceutical product and diagnostic focussed companies) referred above in section (iv) with CLINUVEL's TSR for the same period shows CLINUVEL is ranked fourth and third respectively.

D. NON-EXECUTIVE REMUNERATION

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

Non-Executive Director Fees

Non-Executive Director fees consist of base fees and committee fees and are inclusive of superannuation and all other contributions. There are no further retirement benefits. The fees are outlined in the table below:

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

	Board Fees	Audit & Risk Committee	Remuneration Committee	Nomination Committee
Chair	110,000	-	-	-
Non-Executive Director	65,000	-	-	-
Committee Chair	-	15,000	15,000	-
Committee Member	-	5,000	5,000	-

* The Chair of the Board is a member of all Committees but does not receive any additional Committee fees in addition to the base fee.

Under the Company's Constitution, the maximum aggregate remuneration available for division among the Non-Executive Directors is to be determined by the shareholders in a General Meeting and was set at \$700,000 at the 2019 AGM. This amount (or some part of it) is to be divided among the Non-Executive Directors as determined by the Board. The aggregate amount paid to Non-Executive Directors for the year ended 30 June 2020 was \$387,417.

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.

E. SERVICE AGREEMENTS 2019/20

Remuneration and other terms of employment for the Managing Director is 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 ²	Dr Dennis Wright	Mr Darren Keamy ³
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

^{2,3} Expiry Date 30 June 2022

F. SHARE-BASED REMUNERATION

The Group has an ownership based scheme for Directors⁴, 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:

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

152,710 Performance Rights issued under the 2009 Scheme remain unvested as at 30 June 2020 and there are no further performance rights issued under the 2014 Plan remaining unvested at 30 June 2020. 1,513,750 Performance rights were approved by shareholders to grant to the Managing Director at the 2019 AGM under the 2014 Plan. It is no longer intended to issue performance rights under the 2009 Plan.

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.

⁴ It is no longer planned for Non-Executive Directors to participate in long-term equity compensation plans. Please refer to 'Non-Executive Director Long-Term Incentive - Equity Compensation' in section D to this Remuneration Report

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.

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 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.

G. DETAILS OF REMUNERATION

KMP REMUNERATION OF THE COMPANY FOR THE YEARS ENDED 30 JUNE 2020 AND 30 JUNE 2019

	Year	Gross Salary ⁴	Short-Term Incentive	Business Generation Incentive	Other ¹	Super-annuation/ Pension Fund	Total (Excluding Share-Based Payments)	Post-employment benefits	Share-based payments (accounting charge only) ²
								Performance Rights	Total (Including Share-Based Payments)
		\$	\$	\$	\$	\$	\$	\$	\$
Dr. P.J. Wolgen ³	2020	1,577,235	-	-	152,299	-	1,729,534	1,645,205	3,374,739
	2019	893,660	422,747	-	30,373	-	1,346,780	68,346	1,415,126
Mr. S.R. McLiesh	2020	41,857	-	-	-	3,976	45,833	-	45,833
	2019	100,457	-	-	-	9,543	110,000	2,520	112,520
Mrs. B.M. Shanahan	2020	73,059	-	-	-	6,941	80,000	-	80,000
	2019	73,059	-	-	-	6,941	80,000	2,520	82,520
Mr. W.A. Blijdorp	2020	99,167	-	-	-	-	99,167	-	99,167
	2019	80,000	-	-	-	-	80,000	-	80,000
Dr. K.A. Agersborg	2020	67,917	-	-	-	-	67,917	-	67,917
	2019	65,000	-	-	-	-	65,000	-	65,000
Mrs. S. E. Smith	2020	52,667	-	-	-	-	52,667	-	52,667
	2019	-	-	-	-	-	-	-	-
Prof. J. V. Rosenfeld	2020	38,204	-	-	-	3,629	41,833	-	41,833
	2019	-	-	-	-	-	-	-	-
Other KMP									
Dr. D.J. Wright	2020	257,105	17,355	-	-	21,003	295,463	1,284	296,747
	2019	252,064	18,149	-	-	20,531	290,744	5,608	296,352
Mr. D.M. Keamy	2020	278,713	42,364	30,000	-	21,003	372,080	4,174	376,254
	2019	265,441	32,384	-	-	20,531	318,356	18,141	336,497
Total	2020	2,485,924	59,719	30,000	152,299	56,552	2,784,494	1,650,663	4,435,157
	2019	1,729,681	473,280	-	30,373	57,546	2,290,880	97,135	2,388,015

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

² 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.

³ In 2019/20 Dr Wolgen's salary is paid in Singapore dollars (SGD) and in Euro currency.

⁴ Does not include movement in annual leave and long service leave provisions. Upon the renewal of Dr Wolgen's service agreement in 2019/20 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. The natural accretion to his annual leave and long service leave entitlements for 2019/20 was \$172,950 (year ending 30 June 2019: \$64,483). For Mr Keamy and Dr Wright, the accretive movement to their annual leave and long service leave entitlements was \$24,000 and \$3,277 respectively (year ending 30 June 2019: \$7,429 increase for Mr Keamy and \$11,603 decrease for Dr Wright)

THE RELATIVE PROPORTIONS OF REMUNERATION BETWEEN FIXED AND BASED ON PERFORMANCE FOR THE YEARS ENDED 30 JUNE 2020 & 30 JUNE 2019

	2020		2019	
	Fixed Remuneration	Performance Based	Fixed Remuneration	Performance Based
Dr. P.J. Wolgen	51%	49%	65%	35%
Dr. D.J. Wright	94%	6%	92%	8%
Mr. D.M. Keamy	80%	20%	85%	15%

REMUNERATION PERFORMANCE RIGHTS HOLDINGS OF KMP – 2020

	Balance at Start of Year	Issued as Compensation	Exercised	Lapsed and Expired	Balance at End of Year	Issued as Compensation after 30 June 2020*
Directors						
Mr. S.R. McLiesh	40,000	-	-	(40,000)	-	-
Mrs. B.M. Shanahan	25,000	-	-	-	25,000	-
Dr. P.J. Wolgen	208,332	-	(208,332)	-	-	1,513,750
Mr. W.A. Blijdorp	-	-	-	-	-	-
Dr. K.A. Agersborg	-	-	-	-	-	-
Mrs. S. E. Smith	-	-	-	-	-	-
Prof. J. V. Rosenfeld	-	-	-	-	-	-
Other KMP						
Dr. D.J. Wright	50,625	-	(32,500)	-	18,125	-
Mr. D.M. Keamy	98,440	-	(66,080)	-	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 2019/20 reporting period held by each of the Group's KMP, including their related parties, is set out below:

Year Ended 30 June 2020					
Personnel	Balance at Start of Year	Granted as Remuneration	Received on Exercise	Other Changes	Held at the End of Reporting Period
Mr. S.R. McLiesh	187,774	-	-	-	187,774
Mrs. B.M. Shanahan	258,969	-	-	-	258,969
Dr. P.J. Wolgen	3,296,364	-	208,332	-	3,504,696
Mr. W.A. Blijdorp	1,743,118	-	-	-	1,743,118
Dr. K.A. Agersborg	4,100	-	-	1,400	5,500
Mrs. S. E. Smith	-	-	-	-	-
Prof. J. V. Rosenfeld	-	-	--	1,693	1,693
Other KMP					
Dr. D.J. Wright	314,374	-	32,500	(45,000)	301,874
Mr. D.M. Keamy	306,720	-	66,080	(41,457)	331,343

TERMS AND CONDITIONS OF EACH GRANT OF RIGHTS AFFECTING REMUNERATION IN THE CURRENT OR FUTURE REPORTING PERIODS

Entity	Number of Rights	Value per Right on Grant Date	Class	Grant Date	Vesting Date for Retention in Scheme Trust	Lapsing Date
CLINUVEL	91,667	\$1.04	Ordinary	25/11/2010	09/10/2019	-
CLINUVEL	116,667	\$1.04	Ordinary	25/11/2010	09/10/2019	-
CLINUVEL	105,875	\$2.16	Ordinary	17/03/2015	09/10/2019	-

H. ADDITIONAL INFORMATION – REMUNERATION

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
Mr. S.R. McLiesh	2011/12	no limitation	-	100%	-
Dr. P.J. Wolgen	2010/11	no limitation	100%	-	-
	2019/20*	2023/24	0%	0%	8,226,311
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	55%	-	12,853
	2014/15	2021/22	100%	-	-
Mr. D.M. Keamy	2011/12	no limitation	51%	-	23,126
	2014/15	2021/22	100%	-	-

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

Name	Max Potential Opportunity (%)	STI Awarded (%)	STI Forfeited (%)	Total Granted (\$)
Dr. P.J. Wolgen	100%	0%	100%	-
Dr. D.J. Wright	9%	95%	5%	21,982
Mr. D.M. Keamy	17%	89%	11%	42,634

LOANS TO DIRECTORS AND EXECUTIVES

No loans were granted to Directors or executives for the years ended 30 June 2020 and 30 June 2019.

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	449,705	Nil\$	Ordinary

¹These 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	359,938	Nil\$	Ordinary

¹These 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	152,710	\$Nil	Ordinary	Upon achievement of specific performance and time-based milestones or upon cessation of employment
	152,710	-	-	-

Issued after the reporting date, but granted during the year

CLINUVEL PHARMACEUTICALS LTD	1,513,750	\$Nil	Ordinary	20 November 2023
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NON-AUDIT SERVICES

For the year ended 30 June 2020, 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 26th day of August, 2020

STATEMENT OF PROFIT AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2020

Consolidated Entity			
	Note	2020	2019
		\$	\$
Total revenues	2(a)	32,565,423	31,047,776
Interest income	2(b)	562,928	564,657
Other income	2(c)	781,319	886,037
Total expenses	2(d)	(20,773,199)	(14,383,643)
Profit before income tax benefit		13,136,471	18,114,827
Income tax benefit	3(a)	3,510,388	19,333
Profit after income tax benefit		16,646,859	18,134,160
Net profit for the year		16,646,859	18,134,160
Other comprehensive income			
Items that may be re-classified subsequently to profit or loss			
Exchange differences of foreign exchange translation of foreign operations		592,857	(80,077)
Other comprehensive income/(loss) for the period, net of income tax		592,857	(80,077)
Total comprehensive income/(loss) for the period		17,239,716	18,054,083
Basic earnings per share - cents per share	16	33.8	37.6
Diluted earnings per share - cents per share	16	33.0	36.6
The accompanying notes form part of these financial statements.			

STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2020

			Consolidated Entity
	Note	2020	2019
		\$	\$
Current assets			
Cash and cash equivalents	17(a)	66,746,521	54,268,758
Trade and other receivables	4	6,612,684	4,156,216
Inventories	5	1,287,914	2,136,084
Other assets	6	508,818	591,516
Total current assets		75,155,937	61,152,574
Non-current assets			
Property, plant and equipment - net	7	1,075,441	337,851
Right-Of-Use assets - net	8	1,313,937	368,805
Intangible assets - net	9	185,030	185,030
Deferred tax assets - net	3(c)	3,811,500	301,112
Total non-current assets		6,385,908	1,192,798
Total assets		81,541,845	62,345,372
Current liabilities			
Trade and other payables	11	4,771,581	3,633,281
Lease liabilities	8	212,331	261,251
Provisions	12	1,676,435	1,065,510
Total current liabilities		6,660,347	4,960,042
Non-current liabilities			
Lease liabilities	8	1,107,224	171,267
Provisions	12	105,727	34,210
Total non-current liabilities		1,212,951	205,477
Total liabilities		7,873,298	5,165,519
Net assets		73,668,547	57,179,853
Equity			
Contributed equity	13	151,849,375	151,314,175
Reserves	14	1,856,458	1,352,416
Accumulated losses		(80,037,286)	(95,486,738)
Total equity		73,668,547	57,179,853
The accompanying notes form part of these financial statements.			

STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2020

		Consolidated Entity	
	Note	2020	2019
		\$	\$
Cash flows from operating activities			
Receipts from customers		29,287,833	32,221,122
Payments to suppliers and employees		(16,281,001)	(14,241,210)
Interest received		636,631	440,919
GST and VAT refunds		423,370	35,276
Government grant		121,535	-
Net cash provided by operating activities	17(b)	14,188,368	18,456,107
Cash flows from investing activities			
Payments for property, plant and equipment		(888,826)	(257,616)
Net cash used in investing activities		(888,826)	(257,616)
Cash flows from financing activities			
Dividends paid		(1,224,021)	(957,160)
Repayments of lease liabilities		(243,341)	(69,627)
Repayments of interest		(18,501)	(3,879)
Net cash used in financing activities		(1,485,863)	(1,030,666)
Net increase in cash held		11,813,679	17,167,825
Cash and cash equivalents at beginning of the year		54,268,758	36,198,451
Effects of exchange rate changes on foreign currency held		664,084	902,482
Cash and cash equivalents at end of the year	17(a)	66,746,521	54,268,758
The accompanying notes form part of these financial statements.			

STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2020

	Share Capital	Performance Rights Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total Equity
	\$	\$	\$	\$	\$
Balance at 30 June 2018	148,614,908	2,863,901	618,015	(112,680,836)	39,415,988
Exercise of performance rights under share-based payment	2,332,062	(2,332,062)	-	-	-
Employee share-based payment options	-	122,485	-	17,098	139,583
Purchase of shares held in subsidiary from non-controlling interest	367,205	-	-	-	367,205
Dividends paid				(957,160)	(957,160)
Transactions with owners	151,314,175	654,324	618,015	(113,620,898)	38,965,616
Profit for the year				18,134,160	18,134,160
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	80,077		80,077
Total other comprehensive income	-	-	80,077	-	80,077
Balance at 30 June 2019	151,314,175	654,324	698,092	(95,486,738)	57,179,853
Exercise of performance rights under share-based payment	535,200	(535,200)	-	-	-
Employee share-based payment options	-	1,632,099	-	26,614	1,658,713
Issue Share Capital Purchase of shares of non-controlling interest from minority owners via issue of Share Capital	-	-	-	-	-
Dividends paid				(1,224,021)	(1,224,021)
Transactions with owners	151,849,375	1,751,223	698,092	(96,684,145)	57,614,545
Profit for the year				16,646,859	16,646,859
Other comprehensive income:					
Exchange differences of foreign exchange translation of foreign operations	-	-	(592,857)		(592,857)
Total other comprehensive income	-	-	(592,857)	-	(592,857)
Balance at 30 June 2020	151,849,375	1,751,223	105,235	(80,037,286)	73,668,547

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2020

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 2020.

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 2020 and 30 June 2019 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 assets 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 expires.

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 asset; 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 regulatory approval and launched a European 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, 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 arises from the commercial sales of goods and sales reimbursements. Commercial sales of goods are the commercial sales of SCENESSE® implants in Europe and the USA. Sales reimbursements are the distribution of SCENESSE® under special access reimbursement schemes.

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
- 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 2020.

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 shares 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 a 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 IFRS 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.

It has established entities in more than one geographical area. The non-current assets that are not held within Australia are immaterial to the Group. Until April 2020, revenues from reimbursement

revenue and commercial sales were 100% earned from entities within Europe, and Switzerland. The revenues in the prior year was also 100% earned from entities within Europe, and Switzerland. In April 2020, the consolidated entity launched SCENESSE®, its sole commercial product in a second geographical market. The revenues earned from this second geographic segment is not material when compared to the revenues earned for the consolidated entity and is below the quantitative threshold for

segment reporting. The consolidated entity has one operating segment within the definition of AASB 8 Operating Segments.

100% of the revenue from sales reimbursements under special access schemes is generated from three end users (2019: three end users). 100% of the revenue from commercial sales is from sixteen end users in Europe and one end user in the USA (2019: eighteen end users).

2. PROFIT/(LOSS) FROM CONTINUING OPERATIONS

	Consolidated Entity	
	\$	\$
(a) Revenues		
Commercial sales of goods	26,306,148	26,488,768
Sales reimbursements	6,259,275	4,559,008
Total revenues	32,565,423	31,047,776
(b) Interest income		
Interest income	562,928	564,657
Total interest income	562,928	564,657
(c) Other income		
Unrealised gain on restating foreign currency creditors and currencies held	537,460	886,037
Government grants	126,611	-
Realised foreign currency gain on transactions	116,584	-
Miscellaneous	664	-
Total other income	781,319	886,037
(d) Expenses		
Clinical, regulatory & commercial overheads	3,893,059	2,947,764
Drug formulation R&D, manufacture & distribution	3,624,043	2,387,770
Regulatory (pre & post marketing) & non-clinical	1,928,085	1,444,358
Business marketing & listing	1,888,675	1,501,946
General operations (incl Board)	7,962,693	4,923,055
Licenses, patents and trademarks	515,981	305,419
Clinical development	184,656	91,453
Finance cost	25,886	21,114
Others	750,121	755,202
Realised foreign currency loss on transactions	-	5,562
Total expenses	20,773,199	14,383,643
(e) Profit/(loss) before income tax includes the following specific expenses		
Employee benefits expense	8,417,497	6,045,503
Share-based payments	1,658,713	139,936
Operating lease expense – minimum lease payments	296,481	329,955
Amortisation of right-of-use assets	263,154	122,672
Depreciation on property, plant & equipment	164,474	91,492
Loss on sale of property, plant and equipment	-	290

3. INCOME TAX BENEFIT

	Consolidated Entity	
	2020	2019
	\$	\$
(a) Income tax benefit comprises of:		
Deferred income tax benefit	(3,510,388)	(19,333)
Deferred tax included in income tax benefit comprises:		
Increase in deferred tax assets	(3,751,243)	(498,852)
Increase in deferred tax liabilities	240,855	479,519
	(3,510,388)	(19,333)

Consolidated Entity		
	2020	2019
(b) Numerical reconciliation of income tax benefit and tax at the statutory rate		
Profit before income tax benefit	13,136,471	18,114,827
Tax at the statutory tax rates of 27.5%	3,612,530	4,981,578
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Permanent differences - Australia	1,182,470	257,855
	4,795,000	5,239,433
Recognition of DTA on losses at year end	(8,571,113)	(5,768,808)
Recognition of temporary differences - Australia	265,725	510,042
Income tax benefit	(3,510,388)	(19,333)
Tax losses not recognised		
Unused tax losses for which no deferred tax asset has been recognised	46,780,392	85,304,455
Potential tax benefit at 27.5%	12,864,608	23,458,725
(c) Deferred tax assets		
Deferred tax asset comprises temporary differences attributable to:		
Carry forward tax losses	6,742,993	3,038,750
Intangibles	449,065	391,263
Provisions	126,932	121,842
Accrued Expenses	39,617	19,936
Lease liabilities	15,897	51,469
	7,374,504	3,623,260
Movements		
Opening balance	3,623,260	3,124,408
Carry forward tax losses	8,571,113	5,768,808
Deferred tax assets utilised	(4,866,870)	(5,302,558)
Intangibles	57,803	(5,039)
Lease liabilities	(35,573)	51,469
Accrued Expenses	19,681	16,820
Provisions	5,090	(30,648)
	7,374,504	3,623,260
(c) Deferred tax liabilities		
Deferred tax liability comprises temporary differences attributable to:		
Unrealised gains/loss on loans to subsidiaries	(3,525,637)	(3,219,746)
Accrued income	(32,429)	(52,705)
Right-of-use assets	(15,142)	(52,125)
Intangibles	10,204	2,428
	(3,563,004)	(3,322,148)
Movements		
Opening balance	(3,322,148)	(2,842,629)
Unrealised gains/loss on loans to subsidiaries	(305,891)	(334,627)
Right-of-use assets	36,983	(52,125)
Accrued income	20,276	(32,330)
Intangibles	7,776	(29,983)
Adjustment to opening balance of unrealised gains/loss on loans to subsidiaries	-	(30,454)
	(3,563,004)	(3,322,148)
Total	3,811,500	301,112
The tax rate used in this report is the corporate tax rate of 27.5%		

4. TRADE AND OTHER RECEIVABLES

	Consolidated Entity	
	2020	2019
	\$	\$
Current		
Trade debtors	6,349,664	3,758,697
Interest receivables	117,923	191,654
Sundry debtors	145,097	205,865
Total	6,612,684	4,156,216
Trade debtors are recognised initially at the amount of consideration that is unconditional, when they are recognised at fair value. They are subsequently measured at amortised cost using the effective interest method and due to their short-term nature, their carrying amount is considered to be the same as their fair value..		

5. INVENTORIES

	Consolidated Entity	
	2020	2019
	\$	\$
Current		
Raw materials – at cost	255,037	311,839
Provision for obsolescence – raw materials	(51,655)	(75,106)
Work in progress – at cost	380,882	1,186,686
Finished goods – at cost	703,650	712,665
Total	1,287,914	2,136,084

6. OTHER ASSETS

	Consolidated Entity	
	2020	2019
	\$	\$
Current		
Prepaid peptide	105,139	170,458
Other prepayments	403,679	421,058
Total	508,818	591,516

7. PROPERTY, PLANT AND EQUIPMENT

	Consolidated Entity	
	2020	2019
	\$	\$
Plant and equipment		
At cost	560,483	297,589
Less: accumulated depreciation	(216,643)	(118,585)
Sub-total	343,840	179,004
Furniture and fittings		
At cost	122,555	131,348
Less: accumulated depreciation	(82,916)	(71,645)
Sub-total	39,639	59,703
Leasehold improvements		
At cost	758,299	128,282
Less: accumulated amortisation	(66,337)	(29,138)
Sub-total	691,962	99,144
Total property, plant and equipment	1,075,441	337,851

	Consolidated Entity			
	Plant And Equipment	Furniture And Fittings	Leasehold Improvements	Total
	\$	\$	\$	\$
Carrying amount at 30 June 2018	105,709	63,030	-	168,739
Additions	118,439	6,156	128,282	252,877
Disposals	(7,883)	-	-	(7,883)
Depreciation written back on disposal	1,260	-	-	1,260
Depreciations expense	(38,521)	(9,483)	(29,138)	(77,142)
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 disposal	1,513	16,432	-	17,945
Depreciations expense	(99,571)	(27,703)	(37,199)	(164,473)
Carrying amount at 30 June 2020	343,840	39,639	691,962	1,075,441

8. RIGHT-OF-USE ASSETS AND LEASE LIABILITIES

	Consolidated Entity	
	2020	2019
	\$	\$
Right-of-use assets		
At cost	1,693,596	491,477
Less: accumulated amortisation	(379,659)	(122,672)
Total right-of-use assets	1,313,937	368,805

	Consolidated Entity	
	2020	2019
	\$	\$
Lease liabilities		
Lease liabilities - Current	212,331	261,251
Lease liabilities - Non-current	1,107,224	171,267
Total lease liabilities	1,319,555	432,518

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 2020 and 1.1% in 2019.

	Consolidated Entity	
	Right-Of-Use Assets	
	\$	
Carrying amount at 30 June 2018	-	
Remeasurement	491,477	
Amortisation	(122,672)	
Carrying amount at 30 June 2019	368,805	
Additions	1,304,049	
Remeasurement	(95,763)	
Amortisation	(263,154)	
Carrying amount at 30 June 2020	1,313,937	

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 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 2020.		

10. INTERESTS IN SUBSIDIARIES

Name Of Entity	Country Of Incorporation	Ownership Interest	
		2020	2019
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%	-

11. TRADE AND OTHER PAYABLES

Consolidated Entity		
	2020	2019
	\$	\$
Current		
Unsecured trade creditors	1,429,855	1,500,214
Sundry creditors and accrued expenses	3,341,726	2,133,067
Total	4,771,581	3,633,281
(a) Aggregate amounts payable to:		
Directors and Director-related entities	865,192	420,968
(b) Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged and included in Trade and Sundry creditors:		
Israeli Shekel	10,875	-
Singapore dollars	-	170,617
Total	10,875	170,617
For an analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 22.		
(c) Terms and conditions:		
Trade and sundry creditors are non-interest bearing and normally settled on 30 day terms.		

12. PROVISIONS

Consolidated Entity		
	2020	2019
	\$	\$
Current		
Employee benefits	1,676,435	1,065,510
Total	1,676,435	1,065,510
Non-current		
Employee benefits	5,290	2,030
Other provision	100,437	32,180
Total	105,727	34,210

13. CONTRIBUTED EQUITY**(a) Issued and Paid Up Capital**

Consolidated Entity		
	2020	2019
	\$	\$
49,410,338 fully paid ordinary shares (2019: 48,960,633)	151,849,375	151,314,175
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				
	2020		2019	
	No.	\$	No.	\$
Balance at the beginning of the financial year	48,960,633	151,314,175	47,824,427	148,614,908
Issued during the year	-	-	33,559	367,205
Conditional rights issues and transferred from conditional rights reserve	449,705	535,200	1,102,647	2,332,062
Less: transaction costs	-	-	-	-
Balance at the end of the financial year	49,410,338	151,849,375	48,960,633	151,314,175

(c) Conditional Performance Rights

During the year the following Conditional Performance Rights were exercised, resulting in the issue of fully paid ordinary shares:

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

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\$	1,102,647

14. RESERVES

Consolidated Entity		
	2020	2019
	\$	\$
Conditional Performance Rights reserve:		
Balance at the beginning of period	654,324	2,863,901
Share-based payment	1,658,713	139,583
Transfer to share capital	(535,200)	(2,332,062)
Lapsed, forfeited rights	(26,614)	(17,098)
Balance at the end of period	1,751,223	654,324
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	698,092	618,015
Translating foreign subsidiary to current rate at reporting date	(592,857)	80,077
Balance at the end of period	105,235	698,092
Total reserves	1,856,458	1,352,416

15. LEASE COMMITMENTS

Consolidated Entity		
	2020	2019
	\$	\$
Operating lease commitments		
Non-cancellable operating leases contracted for but not capitalised under AASB 16 as it is short-term and are payable as follows:		
not later than 1 year	104,983	128,128
later than 1 year but not later than 5 years	7,873	-
Total	112,856	128,128
Operating leases comprises 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		
	2020	2019
	\$	\$
(a) Basic earnings per share (cents per share)	33.8	37.6
(a) Diluted earnings per share (cents per share)	33.0	36.6
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	49,260,026	48,190,080
(b) Weighted average number of performance rights on issue in respect of share based payments during the year	1,198,897	1,410,705
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	50,458,922	49,600,786
(c) The numerator used in the calculation of basic earnings per share (\$)	16,646,859	18,134,160
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		
	2020	2019
	\$	\$
(a) Reconciliation of cash and cash equivalents		
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	23,872,909	24,438,095
Cash on hand	574	622
Deposits on call	1,480,550	1,160,062
Term deposits	41,094,576	28,525,000
Security bonds	297,912	144,979
Total cash and cash equivalents	66,746,521	54,268,758
(b) Reconciliation of cash flows from operating activities with operating profit (loss)		
Operating profit after income tax	16,646,859	18,134,160
Non cash flows in operating (loss):		
Depreciation expense on property, plant & equipment	164,474	91,492
Amortisation expense on right-of-use assets	263,154	122,672
Exchange rate effect on foreign currencies held	(664,084)	(902,482)
Executive share option expense	1,658,713	139,583
Unrealised loss (gain) on foreign exchange translation	(592,857)	80,077
Loss on sale of non-current assets	-	290
Changes in assets and liabilities:		
(Increase)/decrease in receivables	(2,456,468)	934,055
(Increase)/decrease in inventories	848,170	(1,494,799)
(Increase)/decrease in other assets	82,698	(252,454)
Increase/(decrease) in payables	1,065,655	1,511,840
(Increase)/decrease in deferred tax assets	(3,510,388)	(19,333)
Increase/(decrease) in provisions	682,442	111,006
Net cash provided by operating activities	14,188,368	18,456,107
Cash at bank earns floating rates based on daily bank deposit rates. The carrying amounts of cash and cash equivalents represent fair value.		
The effective interest rate on short-term deposits was 1.55% (2019: 2.50%). These deposits have an average maturity date of 210 days (2019: 199 days).		

18. KEY MANAGEMENT PERSONNEL

Consolidated Entity		
	2020	2019
	\$	\$
Short-term employee benefits	2,697,942	2,233,334
Post-employment benefits	56,552	57,546
Long-term benefits	30,000	-
Share-based payments	1,650,663	97,135
Total	4,435,157	2,388,015
No loans or other transactions existed with key management personnel.		

19. AUDITORS' REMUNERATION

	Consolidated Entity	
	2020	2019
	\$	\$
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	97,000	97,000
tax and advisory services	43,000	-
Total	140,000	97,000

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 2020 is \$4,370,640 (2019: \$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 2020 is \$12,840,377 (2019: \$11,543,280).

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 2020 is \$13,945,079 (2019: \$13,545,135).

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 2020 is \$604,342 (2019: \$167,417).

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 2020 is \$15,661,324 (2019: \$13,670,818).

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 2020 is \$3,615,257 (2019: \$1,322,247).

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 2020 is -\$1,949,434 (2019: \$0). VALLAURIX MC SARL was incorporated as a wholly-owned entity of the consolidated group during 2019-20.

Director related and Key Management Personnel transactions and entities:

There are no transactions and relationships in existence as at 30 June 2020 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.

It has established entities in more than one geographical area. The non-current assets that are not held within Australia are immaterial to the Group. Until April 2020, revenues from reimbursement revenue and commercial sales were 100% earned from entities within Europe, and Switzerland. The revenues in the prior year was also 100% earned from entities within Europe, and Switzerland. In April 2020, the consolidated entity launched SCENESSE®, its sole commercial product in a second geographical market. The revenues earned from this second geographic segment is not material when compared to the revenues earned for the consolidated entity and is below the quantitative threshold for segment reporting. The consolidated entity has one operating segment within the definition of AASB 8 Operating Segments.

100% of the revenue from sales reimbursements under special access schemes is generated from three end users (2019: three end users). 100% of the revenue from commercial sales is from sixteen end users in Europe and one end user in the USA (2019: eighteen end users).

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 2020 and as at 30 June 2019.

The consolidated entities exposure to foreign currency risk at 30 June 2020

				Consolidated Entity				
				2020				2019
	Cash and Cash Equivalents	Trade Debtors and Other Assets	Trade, Other Payables and Provisions	TOTAL	Cash and Cash Equivalents	Trade Debtors and Other Assets	Trade, Other Payables and Provisions	TOTAL
USD	2,026,377	1,325	(513,704)	1,513,998	1,302,907	1,559	(750,678)	553,788
EUR	9,405,452	2,472,442	(1,720,287)	10,157,607	9,067,811	1,836,455	(395,322)	10,508,944
CHF	2,118,158	1,057,956	(322,229)	2,853,885	3,092,473	429,935	(261,878)	3,260,530
GBP	456,886	32,982	(336,497)	153,371	1,186,256	136,686	(256,041)	1,066,901
SGD	1,559,596	150,072	(171,080)	1,538,588	1,016,677	35,149	(1,211,972)	(160,146)
ILS	-	-	(25,771)	(25,771)	-	-	-	-

Sensitivity Analysis Of Foreign Currency Risk

During the financial year the Company had a principal foreign currency transaction risk exposure to the Euro. 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 5% appreciation of the Australian dollar against the Euro currency would have decreased profit and loss and equity by \$939,741 for the year ended 30 June 2020 (2019: \$1,303,471), on the basis that all other variables remain constant. 5% is considered representative of the market volatility in the Australian dollar/Euro rate for the period.

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

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

Interest Rate Risk

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

The consolidated entity currently finances its operations through reserves of cash and liquid resources and does not have a borrowing requirement. In order to be protected from, and to take advantage of, interest rate movements it is the consolidated entity's policy to place cash into 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 of Interest Rate Risk

For the consolidated entity, at 30 June 2020, if interest rates had changed by +/- 75 basis points from the year-end rates (a movement considered reflective of the level of interest rate movements throughout the course of the financial year), with effect from the beginning of the year, profit and equity would be \$449,761 higher/lower (2019: \$352,965 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 over twenty counterparties across German, Italian, Swiss, Dutch, US and other medical institutions who are reimbursed by government or private insurance payors.

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

c) Liquidity Risk

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

Fair Value Estimation

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

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

The 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.

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 Europe 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 expenditures.

Contractual maturities of financial assets as at 30 June 2020

	Consolidated Entity	
	2020	2019
	\$	\$
Cash and cash equivalents		
Carrying amount	66,746,521	54,268,758
6 months or less	52,406,687	52,220,997
Greater than 6 months	14,339,834	2,047,761
Total	66,746,521	54,268,758
Other financial assets (includes trade and other receivables)		
Carrying amount	6,612,684	4,156,216
6 months or less	6,597,634	4,058,659
Greater than 6 months	15,050	97,557
Total	6,612,684	4,156,216

Contractual maturities of financial liabilities as at 30 June 2020

	Consolidated Entity	
	2020	2019
	\$	\$
Trade and other payables		
Carrying amount	4,771,581	3,633,281
6 months or less	4,659,117	3,541,897
Greater than 6 months	112,464	91,384
Total	4,771,581	3,633,281
Lease liabilities		
Carrying amount	1,319,555	432,518
6 months or less	144,170	119,918
Greater than 6 months	1,175,385	312,600
Total	1,319,555	432,518

22. EMPLOYEE BENEFITS

	Consolidated Entity	
	2020	2019
	\$	\$
The aggregate employee benefit liability is comprised of:		
Provision for annual leave	1,062,232	628,397
Provision for long service leave	619,492	439,143
Accrued FBT, payroll, superannuation, pension funds, employee insurances	2,016,415	1,116,203
Total	3,698,139	2,183,743

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.

a) 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.

b) 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 2020, 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 4,530,568 shares (2019: 4,440,801 shares).

The following share-based payment arrangements were in existence at 30 June 2020

Performance Rights Series	Number	Grant date	Expiry Date	Exercise Price	Fair Value at Grant Date
Issued 16/09/2011	127,710	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

Holdings of All Issued Conditional Performance Rights – 2020

Performance Rights Series	Balance at Start of Year	Issued as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Vested and Exercisable	Unvested
Issued	208,332	-	(208,332)	-	-	-	-
Issued	263,206	-	(135,496)	-	127,710	-	127,710
Issued	65,000	-	-	(40,000)	25,000	-	25,000
Issued	105,875	-	(105,875)	-	-	-	-
Issued	-	-	-	-	-	-	-
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.

Holdings of All Issued Conditional Performance Rights – 2019

Performance Rights Series	Balance at Start of Year	Issued as Compensation	Exercised	Expired & Lapsed	Balance at End of Year	Vested and Exercisable	Unvested
Issued	299,999	-	(91,667)	-	208,332	-	208,332
Issued	375,986	-	(112,780)	-	263,206	-	263,206
Issued	65,000	-	-	-	65,000	-	65,000
Issued	75,000	-	(75,000)	-	-	-	-
Issued	674,975	-	(674,975)	-	-	-	-
Issued	254,100	-	(148,225)	-	105,875	-	105,875
Issued	5,500	-	-	(5,500)	-	-	-
Total	1,750,560	-	(1,102,647)	(5,500)	642,413	-	642,413
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.

24. CLINUVEL PHARMACEUTICALS LTD PARENT COMPANY INFORMATION

	Consolidated Entity	
	2020	2019
	\$	\$
Assets		
Current assets	58,556,682	45,924,710
Non-current assets	20,704,937	15,200,229
Total assets	79,261,619	61,124,939
Liabilities		
Current liabilities	2,460,733	2,702,525
Non-current liabilities	5,290	2,030
Total liabilities	2,466,023	2,704,555
Equity		
Issued equity	151,849,375	151,314,175
Share-based payments reserve	1,751,223	654,324
Accumulated losses	(76,805,002)	(93,548,115)
Total equity	76,795,596	58,420,384
Financial performance		
Net profit for the year	16,769,727	17,002,595
Total comprehensive income	16,769,727	17,002,595

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 26th August 2020, 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 2020 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 36 to 47 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 26th day of August, 2020



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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 2020, 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 2020 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* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

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

Key audit matters

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

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Key audit matter
How our audit addressed the key audit matter
Deferred tax asset – Note 3

Clinuvel has recognised tax assets of \$3,811,500 (2019: \$301,112) in accordance with AASB 112 *Income Taxes*. These are primarily attributable to historic losses generated by the income tax consolidated group. An assessment is required as to whether sufficient future taxable profits are likely to be generated to enable the assets to be realised.

This area is a key audit matter due to the degree of judgement required in assessing management's estimates of future taxable profits to enable the assets to be realised.

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 managements forecast of future taxable income by assessing the key underlying assumptions such as future taxable income against historic performance and market trends;
- Assessing the competence and objectivity of managements tax expert used, to assist in the preparation of the valuation of the deferred tax asset;
- Checking the accuracy of the input data and evaluating formulas and assumptions applied in the computation of the deferred tax asset;
- Utilising our internal taxation specialists to assist in this assessment of the determination of the tax bases; and
- Assessing the adequacy of the group's disclosure in relation the carrying value of deferred tax assets.

Share based payments – Note 23

In November 2019, the Group granted 1,513,750 rights to the Group's CEO. The performance rights granted were allocated in two tranches: Tranche A is conditional on market capitalisation over a four year period from the Grant date and Tranche B is conditional on achieving non-market based performance conditions over a four year period from the Grant date. 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. Performance rights were valued at \$8.2m 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 4 years) and the share based payment expense for the financial year was \$1.66m

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 corporate finance 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 2020, but does not include the financial report and our auditor's report thereon.

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

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

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

Responsibilities of the Directors for the financial report

The Directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the Directors are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: http://www.auasb.gov.au/auditors_responsibilities/ar1_2020.pdf. This description forms part of our auditor's report.

Report on the remuneration report

Opinion on the remuneration report

We have audited the Remuneration Report included in pages 36 to 47 of the Directors' report for the year ended 30 June 2020.

In our opinion, the Remuneration Report of Clinuvell Pharmaceuticals Limited, for the year ended 30 June 2020 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.

A handwritten signature in purple ink, appearing to read "Grant Thornton".

Grant Thornton Audit Pty Ltd
Chartered Accountants

A handwritten signature in purple ink, appearing to read "B A Mackenzie".

B A Mackenzie
Partner – Audit & Assurance
Melbourne, 26 August 2020



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 2020, I declare that, to the best of my knowledge and belief, there have been:

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

A handwritten signature in blue ink, appearing to read "Grant Thornton".

Grant Thornton Audit Pty Ltd
Chartered Accountants

A handwritten signature in blue ink, appearing to read "B A Mackenzie".

B A Mackenzie
Partner – Audit & Assurance

Melbourne, 26 August 2020

Grant Thornton Audit Pty Ltd ACN 130 913 594
a subsidiary or related entity of Grant Thornton Australia Ltd ABN 41 127 556 389

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SHAREHOLDER INFORMATION AS AT 18 SEPTEMBER 2020

Additional information as at 18 September 2020 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	4,206	1,274,323	2.58
1,001-5,000	880	1,978,656	4.00
5,001-10,000	148	1,100,237	2.23
10,001-100,000	179	5,245,205	10.62
100,001 & Over	25	39,811,917	80.57
TOTAL	5,438	49,410,338	100.00

B) SHAREHOLDINGS HELD IN LESS THAN MARKETABLE PARCELS

TOTAL	MINIMUM PARCEL SIZE	HOLDERS	UNITS
Minimum \$500.00 parcel at \$22.88 per unit	22	318	2,224

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	4,526,214
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 13 March 2019. This is inclusive of the relevant interest of shareholder Dr Philippe Jacques Wolgen, for 3,399,810 quoted ordinary shares, as disclosed in a further substantial holder disclosure notice dated 26 August 2020. Actual registered shareholding as at 18 September is 4,324,693.

³ As disclosed in substantial holder notice dated 16 September 2013. Actual registered shareholding as at 18 September 2020 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.	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	14,860,373	30.08
2.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	9,877,178	19.99
3.	ACN 108 768 896 PTY LTD	4,324,693	8.75
4.	ENDER 1 LLC	2,590,824	5.24
5.	CITICORP NOMINEES PTY LIMITED	1,540,396	3.12
6.	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAIL CLIENT DRP>	1,002,756	2.03
7.	NATIONAL NOMINEES LIMITED	636,062	1.29
8.	M BADCOCK AND P CHU SUPERANNUATION FUND PTY LTD	628,447	1.27
9.	DR MARK EDWIN BADCOCK	567,890	1.15
10.	BNP PARIBAS NOMS PTY LTD <DRP>	557,672	1.13
11.	NATIONAL NOMINEES LIMITED <DB A/C>	481,667	0.97
12.	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	323,059	0.65
13.	BNP PARIBAS NOMS (NZ) LTD <DRP>	261,411	0.53
14.	MR DAVID WILLIAM TREVORROW	222,222	0.45
15.	BNP PARIBAS NOMINEES PTY LTD <AGENCY LENDING DRP A/ C>	220,669	0.45
16.	BNP PARIBAS NOMINEES PTY LTD <LGT BANK AG DRP>	213,770	0.43
17.	VULCANCREST PTY LTD <THE VULANCRES A/C>	200,000	0.40
18.	MS NICOLETTA MUNER	187,625	0.38
19.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	187,000	0.38
20.	MR DAVID JOHN LEWIS	183,165	0.37
TOP 20 HOLDERS OF ORDINARY FULLY PAID SHARES (TOTAL)		39,066,879	79.07
TOTAL REMAINING HOLDERS BALANCE		10,343,459	20.93

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@clinovel.com
Website: <http://www.clinovel.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, 2020: 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

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

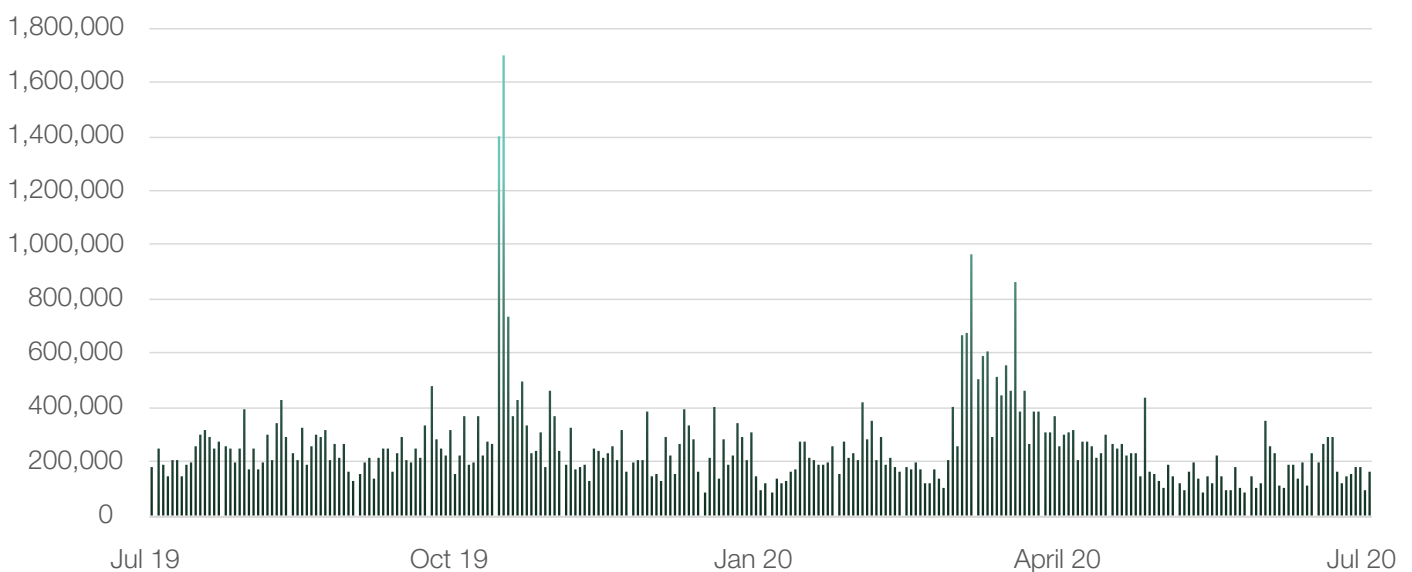
Dipl.-Ing Peter Farago
Baadestr 3, Munich 80, Germany

MARKET PERFORMANCE

ASX:CUV – SHARE PRICE, A\$



ASX:CUV – DAILY TRADING VOLUME



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).

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.

OECD

The Organisation for Economic Co-operation and Development. A group of 34 member countries that discuss and develop economic and social policy.

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



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