CLINUVEL PHARMACEUTICALS
ANNUAL REPORT 2019

CONTENTS

CLINUVEL'S Mission

The CLINUVEL Group focuses its research and development on the interaction of skin with its environments, aiming to deliver innovative medical solutions for complex problems.

CLINUVEL'S Vision

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

We are relentless 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 values its People and Environment as central to all of the Group's working practise.

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.

CLINUVEL'S ENVIRONMENTAL AND SOCIAL GOVERNANCE FRAMEWORK

What is an Environmental and Social Governance Framework?

We live in an ever changing and dynamic world. This encompasses, but is not limited to, technological, environmental, societal, economic and political changes. Since the world is continually evolving, so should CLINUVEL. We strive to adapt to, and manage, 'change' with prudence and positivity.

One of many changes that has gathered pace over the last decade is the focus on Environmental and Social Governance (ESG) issues in capital markets. In January 2004, then United Nations Secretary General Kofi Annan, initiated a study involving CEOs of significant companies to integrate ESG into capital markets. ESG criteria have since become more important in the investment decision of a wide range of investors and for forward looking companies, a key part of their modi operandi.

As a socially responsible pharmaceutical company and part of the global community, CLINUVEL is highly conscious of its accountability for the management and governance of environmental and social issues. However, a focus on ESG is more than just doing the right thing to align with changing societal norms and expectations.

Adoption of an ESG Framework is linked to long-term business sustainability and financial performance. CLINUVEL looks to the future with an objective to build a group of companies which prove sustainable in the long-term. Embracing an ESG Framework is integral to achieving this objective.

The Components of an ESG Framework

CLINUVEL's corporate vision and values are intrinsically linked to the ESG Framework. These are well defined and summarised in this report. Our values underpin how we conduct ourselves and operate in relation to the environment, our society and governance matters.

Environmental criteria relate to how the Company operates responsibly in relation to the environment. The Kyoto Accord for example, provides a guide to the focus companies should have on reducing and managing CO2 emissions.

There are a range of social criteria in the ESG arena which cover relationships with employees, suppliers, customers and the communities in which we operate.

Governance is how the Company leads the business and its people to operate – not only within laws and regulations but more so how it meets responsible environmental and social expectations. More specifically, some of its key elements are transparency and accountability on remuneration, effective audit and internal controls, and appropriate business ethics.

Stakeholder Summary

CLINUVEL operates within the responsible ESG Framework outlined below. As part of our overall focus on continuous improvement, we will be working over the course of the ensuing year to develop aspects of our ESG Framework with more detailed policy and procedures.

Stakeholders, and particularly shareholders who have an interest in the Company, should be assured by our recognition of ESG issues and our responsible approach to ensure we operate within acceptable societal expectations and norms, as an active member of the global community.

We believe this framework forms the basis of our intention to underpin the long-term sustainability and performance of the Group of companies.

KEY FEATURES OF CLINUVEL'S ESG FRAMEWORK

Conscious of Our World

We are conscious of the environment and the need to guard its health for the future, particularly the conservation and management of the world's finite resources.

The Kyoto Accord recognised that global warming is occurring, and it is extremely likely that human made CO2 emissions have caused this. We are guided by the Accord to support the reduction of greenhouse gas emissions.

In general, we monitor the impact of our activities on the environment and seek to ensure our products have no material impact on key international environmental objectives and initiatives.

Our respect of the environment is specifically reflected in an ongoing focus on energy conservation, waste minimisation and safe materials handling. Our 'state of the art' research and development facility in Singapore aims to adhere to good laboratory practices and standards.

Fairness and Equity

Our strong belief in the equitable treatment of people is reflected in our Diversity Policy (available on our website www.clinuvel.com). We value people equally irrespective of age, gender, ethnicity, religious beliefs and disabilities. We are proud that this policy is reflected in the composition of our Board of Directors.

In addition, we:

- do not tolerate discrimination of any kind;
- support freedom of association and human rights;
- promote a reasonable balance of work and life with our employees who are committed to CLINUVEL's competitiveness and objectives; and
- support the personal development of our people with training programs and periodic feedback for guidance.

Responsibility and Compliance

Accountability for effective governance is critical to ensure we operate in accordance with our commitments on ESG. We monitor our commitments and adherence to specific policies and procedures. We ensure existing and new employees receive training to understand the ESG Framework and our commitments. Periodic compliance reviews and training updates reinforce and correct as necessary, our expected practice across the companies of the Group.

The Group adheres to a practice whereby errors and oversights can be made and are discussed and evaluated to enable corrective action plans to be formulated and promulgated throughout the Group, for all staff to learn and develop. This is a positive culture in which there is no intention, attitude or expectation to assign blame, but rather emphasise collective responsibility and accountability to enable people to grow.

Corporate Governance Policy fits within the overall ESG Framework. Our Policy complies with the corporate governance principles and recommendations issued by the Australian Securities Exchange and is accessible on our website (www.clinuvel.com). It encompasses our code of ethics and conduct in accordance with our values.

Some of the principles specifically relate to the expectations of shareholders. We uphold shareholders' right to be informed in a timely manner on material developments affecting the affairs of the Company, whereby operational matters, strategic decisions and sometimes directional changes are necessitated by new facts, data and circumstances which remain within the remit of the Board of Directors and management. In this regard, we have long provided in-depth information on CLINUVEL through the Company website and social media. CLINUVEL News Communiqués and public releases are regularly issued and provide insights on the Company in-between mandatory market announcements, with the aim for all stakeholders to gain insight on the incremental progress and operational matters of the Group.

We look beyond ourselves and expect our suppliers and third-party contractors to operate with integrity and honesty, and act ethically with an appropriate focus on environmental and social responsibility. We expect those who communicate and interact with the Company to maintain the highest standards and ethical behaviour.

We do not take a moral high ground; however, business ethics is important to us and this means operating within the laws and regulations of the countries in which we operate. CLINUVEL highly values integrity and honesty. For each decision we make, there must be a justification and rationale which takes into account expected behaviour throughout the Group of companies.

Our focus on ethics extends to research and development given we are a pharmaceutical company which develops and distributes treatments for indications with unmet medical need. We consistently apply industry best practice standards for the conduct of research and development and studies involving non-human and human subjects. When necessary to obtain regulatory approvals of treatments, we actively seek to minimise the extent of these studies.

We are committed to the OECD endorsed, Replacement, Reduction and Refinement (3R) Principles of non-human studies and ensure studies are responsibly designed and conducted by laboratories that adhere to good laboratory practice and are certified by internationally recognised and respected bodies.

Clinical studies involving humans are submitted and passed by Ethics Committees and conducted with care in accordance with Good Clinical Practice guidelines. We care about the well-being of patients and their families, particularly those with genetic metabolic disorders who are involved in clinical studies and use our treatments. This is reflected in the pharmacovigilance program we have supported since 2016 to monitor the experience of patients using SCENESSE® to treat the rare metabolic disorder, erythropoietic protoporphyria (EPP).

CLINUVEL'S ESG FRAMEWORK

		
ENVIRONMENT	**SOCIAL**	**GOVERNANCE**
CONSCIOUS OF OUR WORLD	**FAIRNESS AND EQUITY**	**RESPONSIBILITY AND COMPLIANCE**
Recognise climate change Energy management Supplier standards on environmental issues Safe and responsible materials handling No adverse impact on global objectives	Human rights Freedom of association Equal opportunity Value diversity Work-life balance Training and education	Honesty and integrity Corporate governance Compliance Ethics Supplier standards

CLINUVEL VALUES

THE IMPACT OF EPP

"I've been asked to describe the pain, and I liken it to taking your hand and putting it on top of a broiler."

"The worst of all is the mental mind game that is EPP. The constant worry, fear, and planning is exhausting... We have to think and plan every minute of our lives."

"My child has had so much pain that she has had broken bones and not even realized it."

"My twin sister gets to play outdoors, and I have to watch her from the window. I really wish I could spend time outside with her."

"The emotional pain, the anger, the sadness, the depression, isolation, wanting to tear and rip your skin off."

"The feeling of wanting to die to get rid of the pain -- every day, 24 hours a day, 7 days a week, 365 days a year."

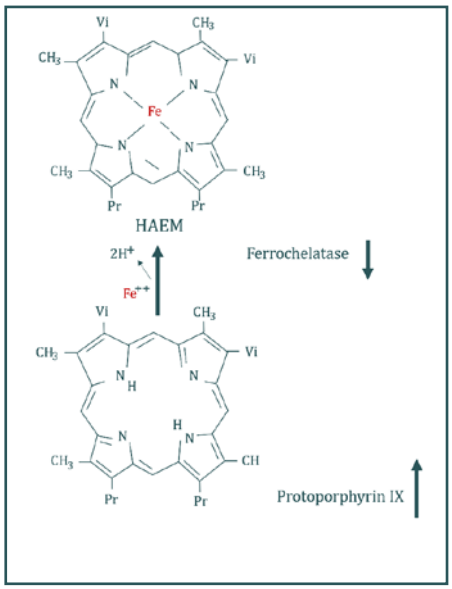
"My skin crawls to the point I want to rip it off."

"It's like a burn from the inside out."

Meeting of Scientific Workshop on Erythropoietic Protoporphyria, *Food and Drug Administration* (24 October 2016)

What is Erythropoietic Protoporphyria (EPP)?

Erythropoietic protoporphyria (EPP) is a genetic metabolic disorder of the haem biosynthesis pathway. Due to a deficiency in the enzyme ferrochelatase (FECH), EPP patients accumulate a photoreactive molecule – known as protoporphyrin IX or PPIX – in the bone marrow, the liver and in the deeper layers of the skin.



When exposed to certain wavelengths of light, PPIX absorbs photons and leads to the generation of reactive oxygen species (ROS) which then damage surrounding tissues. Most of the tissue damage takes place in the in the skin's capillaries, with ROS attacking and damaging the interior surface of the capillaries. Mast cells in the surrounding tissue are degranulated, releasing inflammatory compounds which are understood to contribute to the swelling, redness and intense pain experienced by EPP patients immediately following light exposure.

EPP belongs to a family of disorders called porphyrias that are all associated with unusually high levels of porphyrins or precursors of porphyrins which cause tissue damage. Porphyrins are products used in the making of haem which is essential to many functions in the body.

Phototoxicity in EPP

Due to the accumulation of PPIX deep within the circulation of the skin, EPP patients experience phototoxicity when they are exposed to light sources, even briefly. EPP symptoms can be acute, or delayed (subacute) and most often expressed as phototoxic anaphylactoid reactions.

Reactions vary per patient per day. Most patients will report 'intolerable pain' or 'intense burning' within the surfaces of the skin due to the damage incurred to blood vessels, caused by the ROS which are generated following light or sun exposure. Most patients will show a generalised swelling (oedema) of the body parts exposed to light and, in other cases, generalised oedema of the entire body. A phototoxic reaction occurs after exposure to sources emitting visible light, especially blue and green light, which excites PPIX molecules. The phototoxic reaction, once started, can last for several days or weeks.

The phenomena of 'priming' and 'prodromes' are unique to EPP and have not been observed in other light mediated disorders. Phototoxic reactions are onset by cumulative exposure to light, meaning patients' symptoms may be 'primed' over a series of days of minor light exposure, with only a few seconds or minutes of subsequent exposure causing the onset of a reaction. Prodromal symptoms – described as rapid onset of uncomfortable lasting sensations and subdermal heat – act as a warning sign to patients that a reaction is starting and occurring. Patients are then forced to retract from light sources to avoid any further exposure to prevent the onset of an anaphylactoid reaction.

Impact on Patients' Existence

EPP has a significant impact upon the existence of patients and causes a severe lifelong handicap which has never been fully captured in the medical literature. In addition to the psychological impact during an anaphylactoid phototoxic reaction, patients report multiple effects of the disorder including:

Anxiety towards exposure to light sources - this is often reported in response to weather changes or an upcoming social or professional situation where sun/light avoidance may be impossible. Patients will become anxious that they may inadvertently experience a reaction due to a lack of control over their circumstances or environment. Younger patients, keen to avoid social isolation, will also attempt to hide their condition, causing significant anxiety.

Frustration, anger, distress - resulting from frequent situations of disbelief or a lack of understanding towards their condition, particularly from medical professionals.

Impact on daily activities - a significant impact upon quality of life. The majority of patients have reported that EPP limits "simple everyday activities", limiting joy and optimism towards life. One cohort study showed that nearly half of all patients reported that EPP "significantly influenced" their professional career vocation, while others have reported that photo-related disorders – including EPP – lead to a significantly higher rate of unemployment.

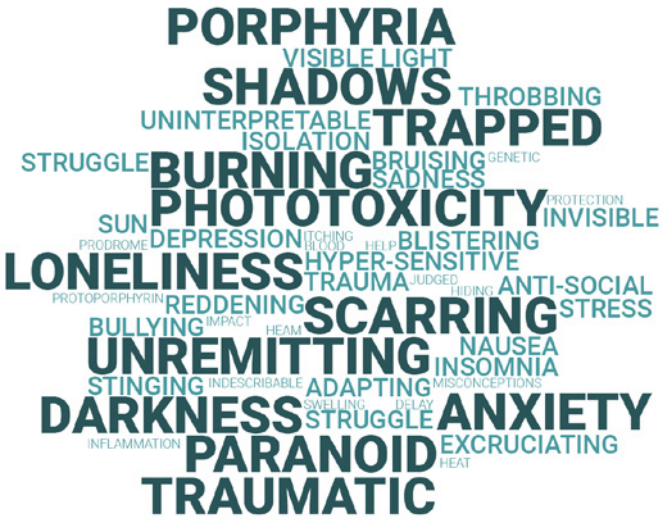
Social impact - the effect on relationships with family and friends. The lack of understanding of close family or spouses can be a source of great distress, with 58% and 40% of patients in one study reporting the disease influenced relations with their family and friends, respectively. Patients report choosing not to have children or adopting children to avoid transmitting EPP to the next generation. Patients diagnosed prior to the availability of full genetic testing were often advised of a significant transmission risk which was to be considered during family planning, adding to the burden of the disease.

Social isolation and depressive mood disorder - due to the need to avoid light sources and exposure, many patients avoid external social contact to prevent potential reactions, particularly during spring and summer months. This leads to isolation and may lead to clinical depressive tendencies.

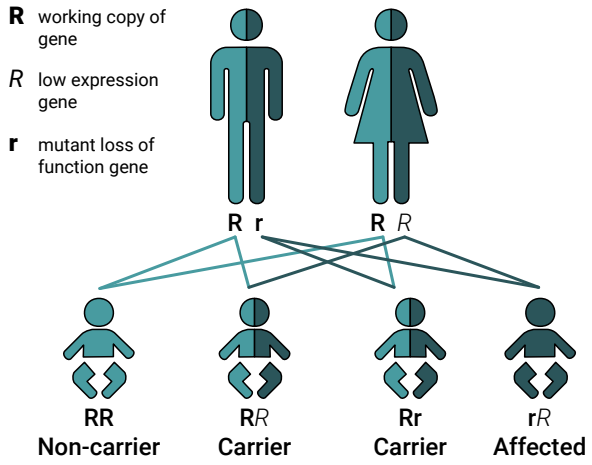
The Anaphylactoid Reaction

The anaphylactoid phototoxic reaction starts off being generally invisible, but is mostly accompanied by gradual swelling of exposed areas, reddening, blistering, crusting, bruising, petechaie (small spot-like bleeds) and fissures in the skin. Eventually this leads to skin thickening and visible scarring. Patients often remain sensitive to any further light exposure, as well as to heat, air movement (such as fans) or any pressure for several days after a reaction. During a phototoxic reaction, EPP patients are in a state of physical and mental distress. There is no effective therapy or method to relieve an EPP reaction; patients must simply bear it until it dissipates. They frequently express irritability, depression, nausea, and being unable to sleep during a reaction. During the reactions, most will seek a cool, dark refuge – such as a basement or darkened room – to avoid any further aggravation of symptoms. Young patients, often unable to vocalise their 'internal' ordeal, cry uncontrollably, causing great anxiety for parents and carers. At the height of the reaction patients can show a change in personality and, according to one literature report, "[t]he patient becomes nervous, tense, aggressive, even feeling detached from the surroundings and harbouring suicidal thoughts or has an irrational fear of death".[1]

[1] Thunell, Harper & Brun (2000). Porphyrins, porphyrin metabolism and porphyrias. IV. Pathophysiology of erythropoietic protoporphyria – diagnosis, care and monitoring of the patient. Scand J Clin Lab Invest. 60:581-604.



Genetic Inheritance of EPP

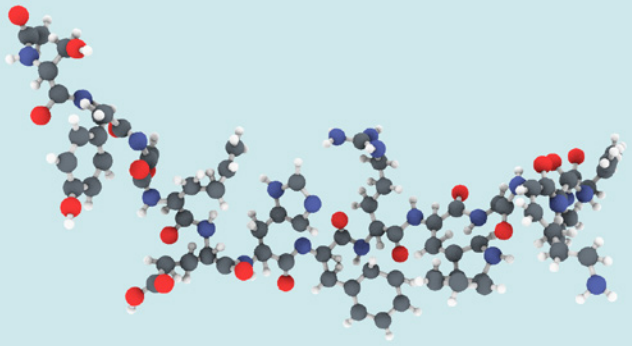


Genetic Inheritance

Most patients with EPP inherit two genetic mutations, one from each parent. In the most common form of inheritance a patient inherits a "mutant loss of function" gene from one parent and a "low expression" gene from the other parent. The combination of these two genetic mutations reduces overall ferrochelatase (FECH) activity to 35% of normal or less, causing accumulation of protoporphyrin during hemoglobin synthesis. This is known as the "pseudodominant" inheritance pattern. In rarer instances a child may inherit the "mutant loss of function" genes from both parents, reducing overall FECH activity to less than 20%. This is known as the "autosomal recessive" form.

Developing the First EPP Treatment

CLINUVEL is the first company to have completed a clinical trial program in EPP patients as part of its focus on rare and genetic skin related disorders. CLINUVEL obtained marketing authorisation for SCENESSE® (afamelanotide 16mg) to treat EPP in the European Union in 2014 and has been distributing SCENESSE® since June 2016. We are committed to ongoing research and development into EPP and its treatment.



Afamelanotide molecule

CLINUVEL IN THE MEDIA

VANCOUVER SUN

Bone-marrow transplant lets sun shine on Langley toddler for Father's Day

Three-year-old Charlie Lock's first time outside since she was diagnosed with porphyria — a severe sun allergy — was quiet, but 'very, very sweet.'

GLENDA LUYMES Updated: June 15, 2019

Voor mensen die lijden aan EPP doet de zon pijn

Als de zon schijnt, blijven deze mensen liefst binnen. Zonneschijn doet pijn voor mensen die lijden aan de lichtziekte EPP.

Céline Toering 19 juli 2019, 15:00 deVolkskrant

Porfirie, quando la luce del sole fa paura. La ricerca avanza, nuove terapie in arrivo

Domenica 25 Novembre 2018 Redazione

PHARMASTAR il Giornale on-line sui Farmaci

The little girl allergic to the sun: Five-year-old diagnosed with rare disease that makes her so sensitive to UV light she has to ride her bike in the garage and play inside at school

- Tirion 'Tiri' Griffiths, five, suffers from an extremely rare reaction to UV light
- The young New Zealand girl must be fully clothed from head to toes at all times
- Any exposure can cause immediate reddening and blistering to her delicate skin
- Due to her condition, she can't stay outdoors for more than 10 minutes at a time

By CINDY TRAN FOR DAILY MAIL AUSTRALIA
PUBLISHED: 01:00 BST, 15 July 2019

Mail Online

COMPANY NEWS

Clinuvel expands Singapore lab facilities

by Anna Napoli October 29, 2018 11:35 AM

FINANCE NEWS NETWORK

These ASX shares have more than doubled in value in 12 months

James Mickleboro | October 4, 2018 5:16pm

The Motley Fool

Covenanter Finally Able to Step into the Light

Jul 12, 2018 By Stan Friedman

COV

OMAR OSSERVATORIO MALATTIE RARE

Porfiria: l'associazione dei pazienti che combatte contro la burocrazia

Autore: Francesco Fuggetta , 15 Novembre 2018

Coming out of the shadows: A new treatment may help people who are 'allergic' to the sun

By KAREN WEINTRAUB / JANUARY 2, 2019

STAT

A rare genetic condition makes this two year-old allergic to the sun

/ JULY 30, 2018 / BY STAFF

CANTECH LETTER
The Very Best of Canadian Science and Technology

Introducing Clinuvel Pharmaceuticals (ASX:CUV), The Stock That Rocketed 1331% In The Last Five Years

Simply Wall St July 22, 2019

SIMPLY WALL ST

FINANCE NEWS NETWORK

COMPANY NEWS

CLINUVEL steps closer to making SCENESSE available in UK

by Rachael Jones October 10, 2018 11:30 AM

TIMETABLE OF KEY EVENTS

September 2018	BioCentury NewsMakers – New York, USA
October 2018	British Porphyria Association Annual Meeting – Reading, UK
	European Porphyria Network Annual Meeting – Rotterdam, Netherlands
November 2018	Second Vitiligo International Symposium – Detroit, USA
December 2018	German EPP Patient Association Annual Meeting – Hamburg, Germany
February 2019	Global Vitiligo Foundation Abstract Session – Washington DC, USA
March 2019	American Academy of Dermatology Annual Meeting – Washington DC, USA
	Women's Dermatological Society Annual Meeting – Washington DC, USA
	German EPP Expert Meeting – Berlin, Germany
April 2019	Goldman Sachs Emerging Leaders Conference – Sydney, Australia
	Italian EPP Expert Meeting – Florence, Italy
	HC Wainwright Healthcare Conference – New York, USA
	BioCentury Future Leaders – New York, USA
May 2019	UBS Global Healthcare Conference – New York, USA
June 2019	15th Sun Protection Conference – London, UK
	Jefferies 2019 Global Healthcare Conference – New York, USA
	World Photodermatology Day – Milan, Italy
	British Porphyria Association Irish Porphyria Conference – Dublin, Ireland

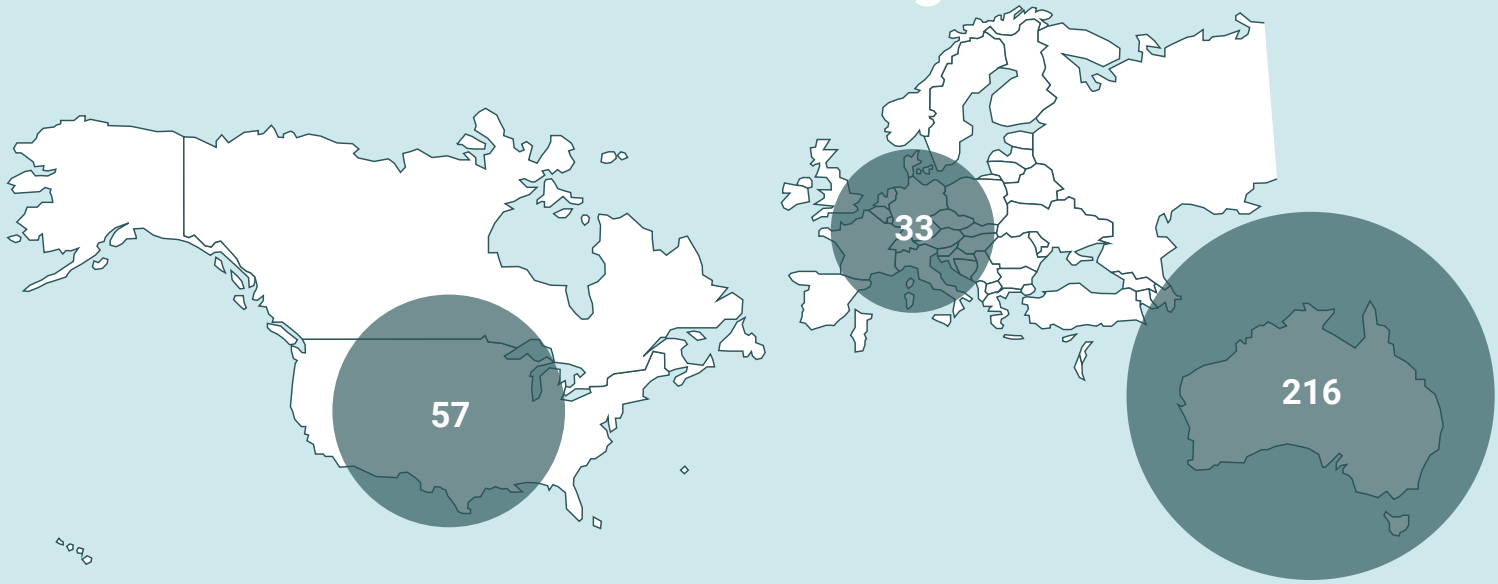
MEDIA ANALYSIS

306
Press Articles

8
Scientific and Academic Presentations

35
Peer Reviewed Journal Articles

Media Distribution - Press Coverage



CHAIR'S LETTER

My fellow shareholders,

A MOMENTOUS ACHIEVEMENT

Looking at the year in retrospect, I draw a balance between the overall resources it took to achieve the unimaginable and one of the greatest successes in Australian pharmaceutical history. At a relatively low expense of under AU$180 million, we arrived at a commercial product serving the EU and the US markets. Whilst I try to temper my euphoria, the 8 October FDA approval of a new molecular entity, a first-in-class therapy, is a rarity in the Asia Pacific region, and the world in general. It is also the most momentous achievement in CLINUVEL's history. I am delighted to have been part of this as Chairman of a brilliant team and congratulate the entire CLINUVEL staff, the patients, the carers and the long-understanding shareholders.

ORIGINS OF SUCCESS

A promising story which had started three decades ago, afamelanotide was hailed as the next wonder drug in the US. It really only got started when this management team took over the reins and executed a most ambitious and – at times – seemingly hopeless task of overturning negative US regulatory decisions issued in the nineties and at the turn of the century. When I first came across the current leadership, I now readily admit that I wasn't convinced they could succeed. In my pharmaceutical career I had come across so many teams who overpromised and failed. I assigned very poor chances to the new managers to take afamelanotide to markets in the EU and the US. I remember well the first time I met Dr Wolgen in 2005, and although I had understood the long-term vision and future plans, I had had my doubts he and his managers could see it through. In November 2005, my fellow Board members shared the same sentiment, but as US and Australian managers till then had left behind a trail of unsuccessful footprints, the Board all agreed that a fresh approach was the only way to rescue the molecule. As the operations unfolded and the development of SCENESSE® progressed we started to see the intelligence and persistence of a cohesive team willing to fight every decision along the way. We had departed from the lowest base with Epitan facing bankruptcy, having no viable strategy, program or pharmaceutical formulation. We saw the turning of a new chapter under CLINUVEL in January 2006. I must add that Hank Agersborg, who had a distinguished career in pharmaceutical research and development, provided an outstanding partnership with Philippe and his clinical and regulatory team.

PROOF OF CONCEPT AND EMA APPROVAL

One of the first objectives the Board of Directors had set management was to deliver a financial proof of concept, demonstrating to all that early reimbursement could be obtained for a novel pharmaceutical therapy. We deliberately had set a near-impossible task as the ultimate test to the management. The absence of this evidence would certainly have led to the arrest of this development program due to the relatively high costs of manufacturing and relatively small patient population. To our astonishment, the management team delivered this objective in March 2010. From that point, we set them the task to obtain regulatory approval for SCENESSE® in a major market. They delivered this by obtaining approval from the European Medicines Agency (EMA) in 2014. I personally witnessed the compelling presentation on the day of the Committee for Medicinal Products for Human Use plenary session delivered by our Managing Director in front of 28 national representatives, alternate members, medical community representatives and senior directorate of the EMA. The outcome of the vote was overwhelmingly positive with 70% in favour of marketing authorisation.

With the European marketing authorisation a feat of significance, the Company had now proven that it had been able to commercialise the product, whereas numerous attempts had failed since 1987, when the drug's effects had first been published. The decades of waste of resources and time could not be undone, but the intelligent planning of first choosing to gain European approval and collecting real-time data and then in the second instance filing the dossier in the United States was a strategy aimed to offset the past failures. I know from many biotech's and my time at CSL how many projects had been shelved as resources had been reallocated, and the factor of time had proven too costly to bring a new molecule to market. In the CLINUVEL case, many a Board meeting discussed the strategy and we decided to continue when other Boards would surely have abandoned the program. In our case, we had a strong visionary leader who kept us together and showed us a way forward despite all the setbacks, risks and resistance. The Board was always there to support the leader and management team to execute the plan, no matter how long it needed to take. Along the way, we saw step by step the evidence build and prove this team correct in its vision.

STEADFAST FOCUS ON THE PLAN

A number of retail shareholders had approached me in the past few years and questioned the pathway, the pace, the strategy and called for changes to speed the process. Long-term larger shareholders on our register remained steadfast in their belief and supported the strategy and management team. Without these majority shareholders, the Company would not have been where it is today and more likely would have strayed from its mainstream strategy, raising further capital at diluted terms. Therefore, in looking back, I am grateful that the Board followed our analyses, vision and professional intuition to stick with the execution of the plan. I express my special gratitude to the loyal Swiss, German, Austrian and Australian institutions, the high net worth individuals and family offices in California, New York and the Netherlands, and all those who recognise themselves in these profiles.

I have seen each obstacle, I have lived the CLINUVEL story along each step and have shared some tears, despair and disbelief at times, but kept faith in a team and leader who manoeuvred us through when there was really no way out. It goes beyond the realm of this evaluation to share all the resistance the CLINUVEL team has been faced with, but I summarise it by stating that the persistence and execution of the managers have surpassed what one could have asked of a pharmaceutical team. The CEO has been inspirational at all times, and particularly when required to be resourceful and find solutions when others could not. Therefore, the FDA approval without receiving a Complete Response Letter, any form of rejection, request for additional trials or further lengthy delays requires deeper reflection of how the current management team obtained the positive outcome.

A POSITIVE FUTURE

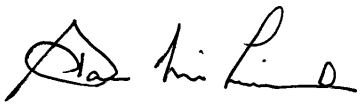
Following the long-awaited FDA approval, I am certain the Company will go from strength to strength. It is profitable, has the support of long-term shareholders, is attracting new shareholder interest across the globe, continues to operate responsibly and manages its cash prudently, serving as an example in our industry. There is no doubt in my mind, CLINUVEL will expand and build a larger group of companies to feature on the Asia-Pacific pharmaceutical landscape. At my stage in life, I do not have a crystal ball, but relying on past experiences one only needs to connect the dots since 2005 to understand how this story will continue.

PASSING THE BATON

One of my final tasks as Chairman has been to secure continuation of the Company under a competent management team. One can well imagine that following the harrowing path of the past 14 years and the pinnacle of obtaining FDA approval, this management team would want to take up new professional challenges elsewhere. As a Board, we discussed how to proceed and together with larger shareholders came to the conclusion that preservation of value was best secured by continuing with this successful and fantastic management. I am very pleased that the CEO, CFO and CSO have recently been persuaded and agreed to continue to advance the strategy of the Company.

My decision to step down from the Company after 17 years as Chairman is with mixed feelings, but a certain degree of pride in our achievements. I also have the secure knowledge that the new Chairman, Mr Willem Blijdorp, will continue and strengthen the Board with commercially savvy directors, such as Sue Smith, our most recently appointed member of the Board. Willem Blijdorp is an entrepreneur well known for his instinctive management, his ability to grow businesses and influence as a strong Chairman, a positive path for the Company. His vision to expand the Company on more than one track is refreshing and coincides with the long-held vision of our CEO. Together they will work well, and the security of the tenure of Darren Keamy and Dennis Wright bodes well for us shareholders.

I am fully aware that CLINUVEL is only at the start of further successes given the pipeline of products and projects, expansion plans, its assets and most of all, the pool of impressive professionals we have in the Company. It has been my pleasure and honour to have served as Chairman and to shareholders and staff, I thank you for your support over the past several years.



Stan McLiesh

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 2019, 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

MANAGING DIRECTOR'S LETTER

Dear Shareholders,

HIGHLIGHTS

As per protocol, one looks back on the year and draws the balance whereby the details of the approach to each event dominate our evaluation. The 2019 financial year has been marked by a number of critical moments which require time for contemplation and for appreciation of the challenges the CLINUVEL teams have faced.

First, the management of the direct distribution of CLINUVEL's novel pharmaceutical product SCENESSE® within the European Union required much of our resources and time. Amidst a changing political environment in the United Kingdom, we encountered a growing demand for SCENESSE®.

Second, the financial management of the CLINUVEL Group demanded resources in preparing the Group for new reporting standards and our desired expansion strategy. Counteracting greater financial demands in expanding our workforce, we strived to keep costs low to arrive at a third year of profitability.

Third, the intensity of the year was further compounded by the looming issue of Brexit and the necessity for CLINUVEL to retain operations in the European Union. In addition, the introduction of a new European Directive changed the conditions under which one distributes, packages and labels a pharmaceutical drug to counter potential falsification. Our main responsibility for the year was to ensure continuous supply of the drug product to all hospitals.

Since CLINUVEL's Board had opted to establish in-house quality and pharmacovigilance systems in the UK in 2014, very few of us had had the foresight of Britain opting out of the European Union. Unfortunately, at the time of the referendum a minority of politicians had imagined that the British electorate would vote for 'leave'. Immediately following the Brexit vote in June 2016, the European pharmaceutical sector came into play. One of the first activities preluding worse matters to come was the decision by the European Medicines Agency (EMA) to move its headquarters from London to Amsterdam. Subsequently, loss of capital expended, termination of the long-term lease in Canary Wharf and loss of expertise at the EMA were felt soon after. In our case, the MHRA (UK competent authority) was renouncing its role as co-rapporteur in overseeing SCENESSE®. The Brexit vote affected CLINUVEL immediately as a new country acting as co-rapporteur was appointed while a new rapporteur was assigned to oversee the pharmacovigilance of the drug. Both the co-rapporteur and new rapporteur (regulatory supervisors) will require time to gain familiarity with the product as they manage a great number of products in the market.

CLINUVEL, now forced to list its new European entity as license holder, was asked to seek creative solutions to both maintain our supply chain and ensure supply of the product for patients. The advantage of CLINUVEL distributing the product remains its tight control of the product while not becoming dependent on third parties managing supply and access.

Fourth, as the demand for CLINUVEL's business increased we executed a synchrone plan across all offices for our managers to present the Company during a number of conferences, roadshows and investor meetings exporting our story.

Finally, the most recent decision by the US Food and Drug Administration (FDA) to grant SCENESSE® (afamelanotide 16mg) marketing authorisation signifies one of the most important outcomes in modern drug development, since the US agency had to overcome various negative decisions it had issued on the drug since 1987. For the stakeholders and investors the FDA approval marked the ultimate confirmation of the strategy chosen by the CLINUVEL Board.

EUROPEAN DISTRIBUTION 2018-2019

Amidst the turmoil of Brexit in the latter half of 2018 and first quarter of 2019, we were challenged by a number of due dates. Under pressure, we had to take swift decisions with regard to distribution of SCENESSE® in the UK. Originally, we worked towards the 29 March as the announced Brexit date, a deadline by which time our scientific dossier and marketing authorisation held by CLINUVEL (UK) LTD would need to be transferred to a new European entity in order to secure continued distribution within the European Economic Area (EEA).

The Board had rightly decided to continue to invest in the UK staff, since too much energy and funding had gone into the construction of systems, databases, and operating procedures. We set off to redesign a pharmacovigilance system whereby parts of the responsibilities would remain in the UK and parts would be transferred to within the EU. We chose Dublin as our first set up. A second centre for logistics, medical support and new business activities is being established in 2020 on continental Europe. Above all the focus will remain on ensuring European supply of the product in 2020 and beyond.

Meanwhile, the British parliament and European Council agreed to postpone the Brexit date to April 16. This breathing space was a welcome gift to our teams. Despite this a new European measure was enforced in February 2019, the Falsified Medicines Directive (FMD). This piece of EU legislation would force our teams to implement anti-tampering devices and identification codes. Since, our lead product was not being distributed outside specialist centres and strict control was imposed by the PRAC (EMA's pharmacovigilance committee), it was glaringly obvious that CLINUVEL would, once again, be an exception to the rule. It was argued that the costly implementation of the FMD was unnecessary and extravagant in our case, while the product answered all legislative exemptions. Our teams sought direct dialogue with European Commission (EC), and although the EC usually does not tend to meet pharmaceutical companies directly, with persistence we succeeded in bringing our case directly in front of the EC in Brussels. On the day of the hearing, we entered the imposing offices in Brussels and as the meeting started a bomb alert was issued and we found ourselves moments later face to face with the EC Healthcare Commission in a Brussels' brasserie arguing our case.

While we had found a solution around the FMD, the Brexit negotiations came to a standstill as Westminster could not find an agreement as to the terms of leaving the EU. The EC granted Britain a

final deadline of 31 October 2019 to implement article 50 on the Treaty of European Union. Needless to say, the Brexit stalemate affected CLINUVEL's business again, since the uncertainty dictated our suppliers, contracted entities and distribution centres.

CLINUVEL is obliged to subject the pharmaceutical product to European quality testing and control to see it released by a contracted third party within the European Union. As a result, CLINUVEL's autonomy in distribution is somewhat restricted by the intervention of a number of suppliers and organisations.

Not for the first time have I witnessed that political uncertainty is used as an all-too cosy excuse by key personnel providing ancillary services to procrastinate on decisions and overturn their previous positions. In an environment where responsibilities become deferred, middle management of suppliers retreat and wait for headquarters to give the go-ahead for seemingly trivial decisions, and the chain comes to a halt. Not surprisingly, this unfolded in the wake of the Brexit uncertainty, and once again we were forced to find alternative solutions in securing distribution, release, testing and quality management.

In short, our teams performed nothing short of miracles to ensure the uninterrupted supply of SCENESSE® to EU EPP Expert Centres and therefore reaching each individual patient. Looking back, it has been a gruelling time and a tour de force by our UK team while – not short-changing any other staff member – General Manager Mr Hay, VP Commercial Affairs Mrs Colucci and Head of EU Quality Affairs and Drug Safety Dr Hamila were the leading acrobats. It is a period we all wish to embrace, but also one we wish not to experience again.

FINANCIAL MANAGEMENT OF THE CLINUVEL GROUP

The past year, we fastened a strategy to maximise financial results while expending prudently on US regulatory affairs and, in broader sense, on EU distribution. We managed to contain our operational cost at more than 10% under budgets set last year.

Overall, I welcome the quest for returns in lengthy project finance while the investment proposition remains to be dictated by the lowest possible capital outlay. In other terms, as we eye the median number spent on a new molecule to be developed to market to be north of US$600 million, we seek to provide returns in the current economic climate.

As part of our overall business plan, in anticipation of a changing political landscape scrutinising pharmaceutical expenditures on innovation, we assessed returns on A$129M of direct investments as being more realistic. The foundation of CLINUVEL's success hinged on this unique financial premise, and therefore compliments need to go to Mr Keamy, his finance team and the Board of Directors who embraced this mindset during an epic rollercoaster of more than a decade. There is no immediate need to change this corporate attitude towards financial risk, and we will continue fiscal management with prudence, aiming to build out the Group of companies.

During the financial year 2019 we recorded positive cashflows resulting in record profits booked. The increase in clinical demand has been pleasing but is really the fruit of previous years of focus and investment in ensuring that our teams developed and formulated SCENESSE® as a controlled-release implant product. Underlying our financial results is our attention to curtail our operational expenditures and minimise fixed costs to sustain the profitability of the Group. The trade-offs between accelerated expenditures on R&D yielding long-term effects, versus near-term profitability was easily made in CLINUVEL's case, since the number of profitable biotechnology and pharmaceutical peers worldwide remains low. The newly invested institutions made no secret of their desire to see CLINUVEL grow, whereby these funds unsurprisingly assessed our performance primarily against financial objectives rather than R&D output at this stage of the Company's growth. As the pendulum is swinging towards repetitive clinical demand in Europe and anticipated sales in the US, CLINUVEL will gradually increase its R&D budgets to secure a dense pipeline. In our strategy to build a robust foundation for growth, cash positivity, profitability and cash reserves remain pressing.

As the finance teams expanded, our financial management systems were updated during the year and, in conjunction with our auditors, we went through a transition to new reporting systems integrating our activities worldwide. I was most pleased to see our teams coming through the two financial audits this year, providing our finance team an unblemished record for 14 consecutive years, leaving very little commentary on our current financial position. The financial management of CLINUVEL has required intense scrutiny and discipline to arrive at where we are today.

As a result, for FYE 2019 we saw our cash balance increase by 50% and profitability increase by 40%. When it comes to financial performance, I wish to see a team which acts in modesty and with humility since – in pharmaceuticals – favourable conditions can turn quickly.

FDA REVIEW OF SCENESSE®

The year has been marked by the progress of US regulatory review of SCENESSE®, the first systemic photoprotective drug to have been approved. With the technical challenges faced by the US authority, a host of other legacy questions played a part. As mentioned in the recent News Communiqués, the historical negative opinions issued by the FDA on previous dossiers in the nineties and during the early century, the emergence of illegally distributed chemical products aiming at online consumers, and the anxiety of use of SCENESSE® as a lifestyle product in our hands have all been considerations slowing down the FDA's thinking on the product.

I have been aware of the enormity of this task since 30 November 2005, my first day in office. Where three previous management teams had exhausted the possibilities to gain market approval for SCENESSE® in the United States, it had been obvious from the rejections in 1995, 1999 and early 2005 that a yet to be formed team would need a dramatically different approach to attain the long-awaited breakthrough by the FDA.

Under the leadership of CSO Dr Wright, we pursued one strategy, one consistent approach to take on the FDA's arguments. We had a vision, strategy and execution towards that one outcome, FDA approval on the basis of effectiveness and above all, safety.

While many of the experts, medical community, financial analysts and even some of our current investors declared our strategy as flawed and unrealistic or non-profitable, I had never had a moment of doubt that this was the only and correct path to take for CLINUVEL. The nay-sayers around the Company expressing an opinion had been numerous, but always counterbalanced and dominated by those who supported our approach and believed in our teams. Those active and patient investors of the first hour deserve equal plaudit and recognition, they supported us through the hard times.

During the year, many challenging questions had been sent by the FDA, often with a three to four day turnaround. We worked incessantly to retrieve information, often residing in the hands of our suppliers, manufacturers, chemists and expert centres. At other times, we were pressed to provide more analyses, while data captured within Europe kept reinforcing the safety profile of the drug in patients on treatment longer-term. When it comes to innovative molecules and medical technology, safety is, in my view, far more important than efficacy, since regulatory doubts on safety can seldom be overcome. Once the FDA or EMA express safety concerns or start probing possible and perceived safety concerns, the outcome of a formal review is, in my professional experience, seldom positive. Armed with this experience, the CLINUVEL team set out a specific strategy to allay any anxiety on safety, while patiently awaiting the data year on year. Patience in our development has become an attitude and a corporate trait.

In the context of a submission of a novel product for an orphan disorder we "overcompensated" in safety data and presented more than 5,200 implant injections, in over 1,200 patients exposed; numbers far greater than what one could expect from innovation

in patients with a rare disorder. We witnessed a consistent pattern in side effects (adverse events), all mild in nature, an indication the drug maintained a positive safety profile. The evidence needed to convince the FDA - beyond any reasonable doubt - of the strength of our package would need to be richer in data compared to peer submissions; this was clear from the outset since there had been a considerable legacy.

On 31 May, the FDA used its discretionary tool to request a three month extension to the formal review user fee goal date, providing a new target date 6 October. We assessed the delay as a positive measure, since the Agency had had ample opportunity to reject the submission, issue a Refusal to File or even request a withdrawal. None of the events had occurred during our submission or review, and our teams kept working towards satisfying all outstanding questions from the agency. It was a period whereby many around us were tested, but the overwhelming majority of investors kept having faith in our teams. A key ingredient to CLINUVEL's success continues to be our consistency.

Consistency was exemplified by uniformity in our messages, business executions, R&D and communication with the main agencies, EMA and FDA. It was apparent from our interactions with senior regulatory staff that a submission would not only be assessed on its scientific data but also on the strength of the scientific team submitting and communicating with the regulatory bodies. At CLINUVEL we had understood that deviating from our core message first expressed in 2006 – to mitigate safety, off-label use and uncontrolled distribution of afamelanotide – would have jeopardised our approach of 14 years. Therefore, we adhered to a monotonous, uniform and consistent communication strategy to overcome 30 years of regulatory scepticism towards the use of afamelanotide. The combination of factors – part of our strategy – has resulted in obtaining marketing authorisation first in Europe and now in the US.

The late Hank Agersborg had always emphasised to pursue one's ambitions without compromising along the journey. His final words reiterated his wish for us to bring this molecule to the US market, crowning his and our work. Both Hank and Dennis Wright are an inspiration for our scientific teams, and their leadership is part of CLINUVEL's current success.

While the US news is celebrated by all who follow the Company, I do wish to thank the EPP patient community worldwide for their advocacy and words of support throughout the FDA review. Finally, it would be remiss not to recognise the efforts of Divisional head Dr Marcus and her team for the deadlock they have broken on the use of SCENESSE®; eventually the benefits observed longitudinally have been convincing.

GROWING CLINUVEL

I look back on a most successful but gruelling year, a year when new talent joined the Company and others moved on, having had the US regulatory success as part of their evolving curriculum vitae. Very few drug developers can demonstrate hands-on involvement leading to European and US regulatory success bringing a new molecule to market. We wish those seasoned managers success in their next endeavours.

The way we operate the Group of Companies is by involving each individual employee as a team member, aiming towards one common goal. The collective effort initiated in 2005 has paid off in this respect. The Board's decisions made in November 2005 were courageous and testing at times, however we never lost belief in our approach as we obtained positive feedback along the way. In my opinion, no business success comes without inevitable pain, dedication to a craft and patience. Counting from the back-office administrative duties, to financial management to the scientific execution, all functions weighed equally and formed the basis for our current status. Unlike the deliberations by the original scientists in 1987, the dream to see a melanocortin being commercialised in the US would take 32 years.

Our management team has made a commitment to the business for the coming three years, but this comes with a clear duty to build CLINUVEL for long-term success. As we grow the Group and team it is imperative that we ensure the next generation of leadership and talent is able to develop. Here we are actively working on succession planning at both Board and management level to ensure the longevity of CLINUVEL and that the business continues to grow in observing our core values.

With the FDA's approval we have now laid the foundation for further regulatory discussions for the use of SCENESSE® in other indications, such as vitiligo. The successful FDA outcome has always been the prerequisite for our teams to further develop afamelanotide in the US, a negative outcome would most certainly have led to the end of development of the product in North America. As the world's first systemic photoprotective drug had obtained approval in the largest jurisdictions, we now have taken strategic decisions leading to growth.

In the final review of the year, my words of appreciation and deep respect are directed at Stan McLiesh who was appointed a Director of the Company in 2002 and has been Chairman since 2010, I can state without doubt that CLINUVEL would not have existed without Stan's guidance, common sense and independent mind. He has been a phenomenal Chairman, calm under all circumstances and compassionate to our staff. Thousands of shareholders and patients owe Stan a wealth of gratitude for what he has achieved, first at CSL and later at CLINUVEL. Merci mon cher.

Philippe Wolgen

Managing Director, CLINUVEL Group

EUROPEAN DISTRIBUTION OF SCENESSE®

Committed to EPP

The CLINUVEL team is committed to facilitating treatment access for all EPP patients, with the European controlled distribution programme serving as a model for product supply worldwide. Individual countries assess the cost-benefit of the product and, in several countries, the SCENESSE® dossier is still under review or in negotiation.

SCENESSE® for European EPP Patients

CLINUVEL's lead product SCENESSE® (afamelanotide 16mg) was granted marketing authorisation in the European Union (EU) for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP) in 2014, under "exceptional circumstances". In granting marketing authorisation, the EMA thereby recognised that intervention with SCENESSE® provided clinical benefit to patients, as demonstrated in clinical trials and other pre-authorisation treatment programmes, but since the agency acknowledged that there was a lack of scientific methodology and instruments available to properly capture the impact of EPP on patients' lives it proceeded on the basis of clinical trial results and patients' testimonies.

European PASS Protocol

Under the terms of the marketing authorisation, CLINUVEL and the EMA agreed to implement a rigorous risk management plan for SCENESSE® in Europe, including controlling the distribution of the drug so that it is only supplied to European EPP Expert Centres trained and accredited to treat EPP patients.

CLINUVEL collects long-term data from the use of SCENESSE® in Europe. Patients are asked and encouraged to enrol in a Post Authorisation Safety Study (PASS) designed to capture long-term safety and effectiveness outcomes from the use of SCENESSE® under real-world conditions. Data is captured at EPP Expert Centres and uploaded pseudonymously to the European EPP Disease Registry (EEDR), hosted by the Erasmus Medical Center in Rotterdam. CLINUVEL conducts an annual analysis of the EEDR data and reports the results to the EMA.

The PASS annual report – submitted in January 2019 – showed that the safety profile of SCENESSE® was unchanged compared to the approved Summary of Product Characteristics (SmPC), the official product information. CLINUVEL has established a compliant pharmacovigilance system which captures and analyses adverse event reports from all centres treating EPP patients to determine patterns. CLINUVEL is responsible for monitoring and the overall safety profile of SCENESSE®.

In June 2016, the first patients were treated under the European marketing authorisation. To date, over ninety-five percent of EPP patients who commenced treatment with the product have continued to receive annual treatment. This percentage is higher than expected.

European Distribution

SCENESSE® is prescribed by physicians within EPP Expert Centres as part of their consultative relationship with their patients. There is a network of EPP Expert Centres across Europe – located within university and academic hospitals – capable of providing multidisciplinary care to patients. SCENESSE® is administered as a subcutaneous injectable implant by the physicians of EPP Expert Centres.

The controlled release of the active ingredient, afamelanotide, provides systemic photoprotection for 60 days. The SmPC recommended maximum dose is four implants per annum, with the overall duration of treatment at the treating physician's discretion.

SCENESSE® is handled by a single distributor in Europe under the guidance of CLINUVEL, with the product distributed directly to EPP Expert Centres as a cold chain product (2-8°C).


European EPP Expert Centres

CLINUVEL'S DISTRIBUTION CHAIN

Peptide manufacturer

Quality control testing and release

Finished Product Manufacture, Primary Packaging, Labelling

Finished Product Quality Control testing

Sterility sampling

EU importation & quarantine release

US manufacturer batch release

Secondary packaging design and manufacture

Secondary packaging and labelling

QA review and EU product batch release

Dedicated EU distributor

European EPP Expert Centres

SCENESSE® - MOLECULAR SIGNALLING

The Fundamentals of CLINUVEL's Research and Development

CLINUVEL's pharmaceutical research has focused on analogues of the naturally occurring alpha-Melanocyte Stimulating Hormone (α-MSH), including afamelanotide and the analogues, CUV9900 and VLRX001. In skin, natural α-MSH is one of the key paracrine and autocrine hormones released by keratinocytes as part of the stress response to ultraviolet radiation and DNA damage, with α-MSH cleaved from the longer molecule proopiomelanocortin (POMC).

Afamelanotide, an α-MSH Analogue

Afamelanotide is a MC1R agonist and structural analogue of α-MSH. SCENESSE® (afamelanotide 16 mg) is a controlled-release injectable implant formulation for subcutaneous administration. Once released in the body, afamelanotide induces the same pharmacodynamic effects as α-MSH, by binding predominantly to MC1R. Due to the stronger binding affinity and longer binding time, it demonstrates much higher potency than endogenous α-MSH. Activation of eumelanin synthesis by afamelanotide is also mediated by MC1R and its downstream pathways, and such signalling contributes to the systemic photoprotection for EPP patients through various mechanisms, such as:

- strong broadband absorption of UV and visible light, where eumelanin acts as a filter;
- antioxidant activity through scavenging of free radicals; and
- inactivation of the superoxide anion and increased availability of superoxide dismutase to reduce oxidative stress.

Signalling, a Growing Field

Our understanding of the signalling pathways within the melanocyte and other cells in the skin continues to evolve, adding to the depth of knowledge of the potential of α-MSH and its analogues in medical applications. CLINUVEL has published a series of scientific communiques on its website (www.clinuvel.com) focused on the role of proopiomelanocortins, α-MSH and skin, and exploring the relevant signalling pathways in depth. For more information, see www.clinuvel.com/photomedicine.

The role of α-MSH in the Skin

Alpha-MSH is an endogenous agonist predominantly binding to the melanocortin 1 receptor (MC1R) on the pigment producing cells, melanocytes. Alpha-MSH activates response pathways within the cell through the cAMP-dependent signalling pathway. As depicted in Figure 1 (see below), subsequent activation of protein kinase A (PKA) leads to activation of cAMP response element binding protein (CREB) which binds to the CREB in the Microphtalmia-associated Transcription Factor (MITF; a regulator of melanocyte development, differentiation and cell survival) promoter, elevating expression levels of MITF. MITF stimulates the transcriptional upregulation of tyrosinase (TYR), an enzyme which converts tyrosine into eumelanin (black-brown pigment of the skin) through a series of intermediate steps. These activities have a direct impact on the DNA damage induced by UV radiation, the survival or destruction of the cell, the generation of antioxidants and melanogenesis (pigmentation).

The cAMP pathway activates increased tyrosinase activity (regulated by p53, a human tumour suppressor protein controlling the cellular response to DNA damage, cycle progression and programmed cell death) within the melanocyte which contains melanosomes, organelles responsible for the production and transport of melanin. The melanosomes deplete their melanin content up through the melanocyte dendrites to be transferred to the keratinocytes, ultimately for melanin to provide protection to the nuclei of the keratinocyte as well as to scavenge reactive oxygen radicals which are the main cause of cellular damage following UV exposure.

Other cells in the skin also express MC1R, for instance fibroblasts and endothelial cells. Here, the binding of α-MSH is understood to activate

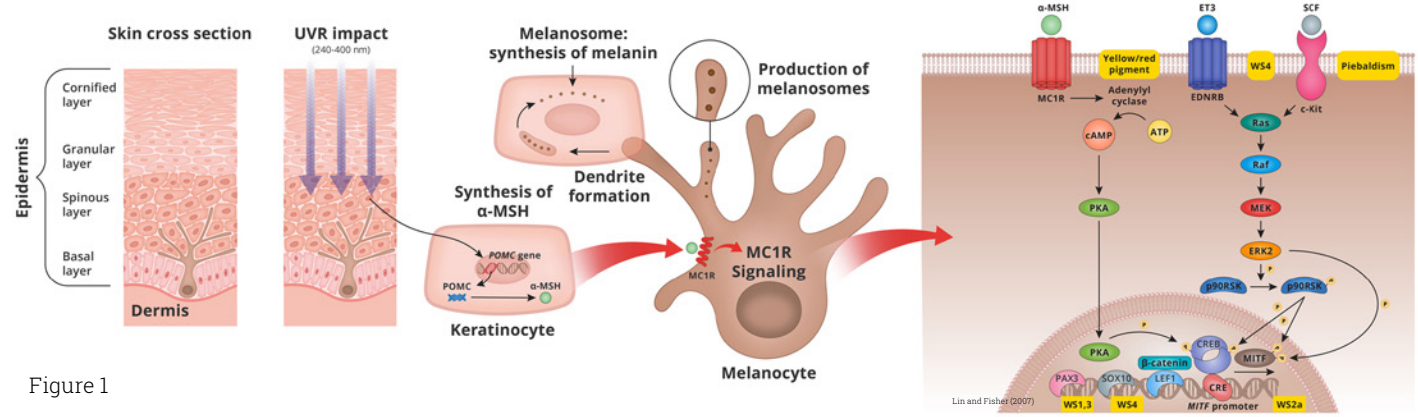


Figure 1

CLINUVEL'S R&D PROGRAMME

CLINUVEL's Active Research and Development

Having spent more than a decade focused on the understanding of light and human biology and developing the world's first photoprotective drug, CLINUVEL is committed to investing in research and development of novel products which serve patients and seek to address genuine unmet needs.

In 2014 CLINUVEL established its VALLAURIX subsidiary in Singapore to pursue R&D projects based on both α-MSH analogues and the knowledge and expertise established during the SCENESSE® (afamelanotide 16mg) development program. It is expected that the first of these products will launch in the coming years. Formulatory work, focused on the development of a dose of afamelanotide suitable for EPP patients under the age of 18, has also progressed through VALLAURIX.

In parallel, clinical development work continues with SCENESSE®, with clinical trials seeking to evaluate the safety and effectiveness of the product in the rare genetic disorder variegate porphyria (VP) – a rare genetic condition from the same family of inherited metabolic disorders as EPP – and further development work planned in the pigment loss disorder vitiligo, where SCENESSE® is being evaluated in combination with narrowband UV-B phototherapy.

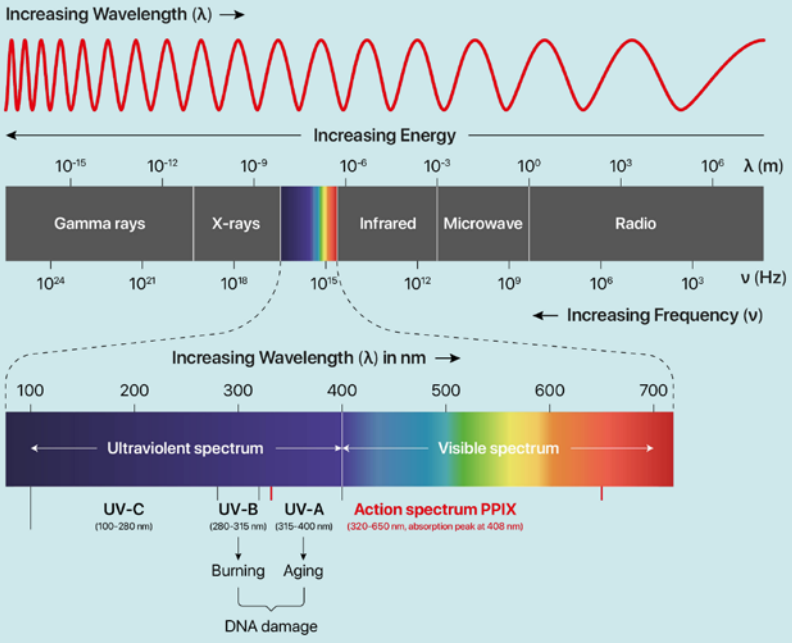
World Experts in Photomedicine

CLINUVEL has established itself as a world leader in the growing field of photomedicine – the study of the interaction of light and human biology. Humans must maintain a delicate balance with natural environmental light and the man-made artificial light with which they come into contact.

Interaction of Light and Human Biology

For many years it has been accepted that certain wavelengths of invisible light – ultraviolet radiation (UVR) along the wavelengths 280 to 400 nanometres emitted by the sun – can cause acute and chronic damage to our skin and eyes. It is well known that over-exposure to UVR causes sunburn, photoaging and cancer. At a cellular level, UVR exposure causes structural damage to DNA, so called 'photoproducts' CPD's and 6-4pp which must be repaired in order to avoid chronic lesions giving rise to skin cancers. The health impacts of exposure to other wavelengths of light – including blue light in darker skinned individuals and infrared light in all skin types as well as the causes of seasonal affective disorder – is still subject of global academic endeavours.

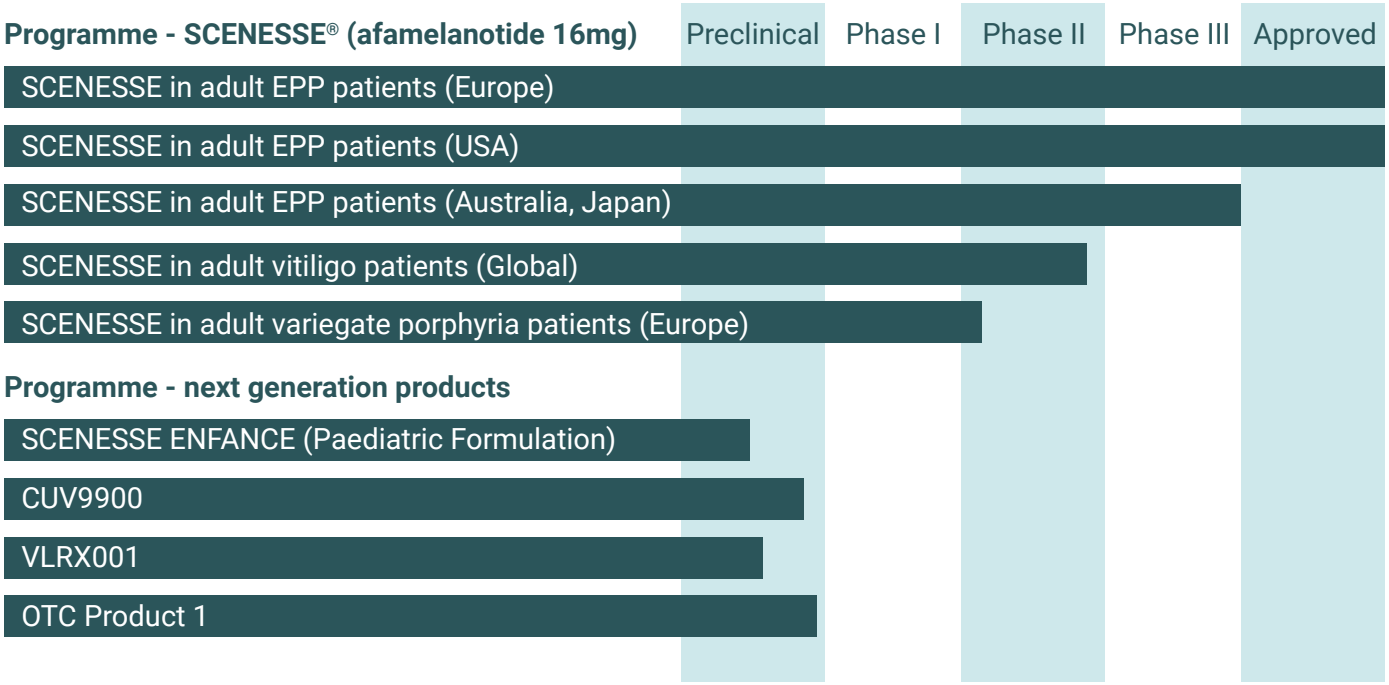
Recent research has also focused upon the benefits to our health conveyed by UVR and light exposure. Exposure to UV-B (280 to 320 nm) causes the generation of vitamin D, essential to bone health and implicated as playing a role in many other disorders. Academic attention has also turned to the generation of nitric oxide as a result of exposure to UV-A (320 to 400 nm), which is linked to reduced blood pressure and improved cardiac function. While research into these areas is at an early stage, it is clear there is much more we need to understand about the benefits of light exposure.



CLINUVEL'S R&D PIPELINE

THE PIPELINE PROVIDES GROWTH OPPORTUNITIES FOR CLINUVEL

We trust this overview of the pipeline provides detail to the range of our research and development activities and subject to time and progress, indicates the natural growth opportunities ahead of us and the benefit we can potentially provide to people with skin disorders.



DIRECTORS' REPORT

The Directors of the Board present their report on the Company and its controlled entities ('Group') for the financial year ended 30 June 2019 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.

STAN MCLIESH

Non-Executive Chair, B Ed

Appointed 12 September 2002

Background

Mr McLiesh has vast experience across pharmaceutical research and development, 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 since 2010, Mr McLiesh has been 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, pending US approval of SCENESSE®, a decision on an approval expected later in 2019.

His ability to navigate through crises and oversee clear pathways towards finding solutions makes him uniquely suitable to steer management.

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: 40,000

PHILIPPE WOLGEN

Chief Executive Officer, MBA, MD

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

Background

Under his leadership a long-term strategy for CLINUVEL was devised and the lead product SCENESSE® (afamelanotide 16mg) reformulated, its medical application identified, and European marketing authorisation ultimately obtained in 2014. Dr Wolgen has overseen the submission of the scientific dossier to the US FDA under a New Drug Application, whereby the outcome is expected in late 2019. SCENESSE® is the first melanocortin drug to have completed a clinical trial program and obtain marketing authorisation in a major market.

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 development program. His overall business execution and exact financial management is viewed as exemplary within the life sciences industry and the funding strategy he led is considered unique within the sector.

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

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

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

Committee Membership

Member of the Remuneration Committee (non-voting)

Current Directorships and other interests

None

Other listed company Directorships (last 3 years)
None
Relevant interest in Shares and performance rights
Shares: 3,296,364
Performance Rights: 208,332

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 Water Solutions Ltd. Mrs Shanahan is also a non-executive director of DMP Asset Management Ltd and SG Hiscock Ltd, a director of the Kimberly Foundation of Australia Ltd, and Chair of the Aikenhead Centre for Medical Discovery in Melbourne.

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 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 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 Water Solutions Ltd (ASX: PHK, since 2017)
Bell Financial Group (ASX: BFG, from 2012 to 2018)
Challenger Limited (ASX: CGF, until 2017)

Relevant interest in Shares and performance rights
Shares: 258,969
Performance Rights: 25,000

WILLEM BLIJDORP

Non-Executive Director, Funda
Appointed 21 January 2015

Background
Mr Blijdorp is an internationally recognised entrepreneur who has helped built 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 the wholesale and international trading of luxury and fast-moving consumer goods and pharmaceutical products. The B&S Group has global reach and is a leader in its market sector.

Formerly B&S'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 joining CLINUVEL in 2014, Mr Blijdorp has provided value in 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 -

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 is also integral to setting US commercial strategy, pending US approval of SCENESSE®, a decision on an approval expected later in 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 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: 4,100
Performance Rights: -

INFORMATION ON COMPANY SECRETARY

DARREN KEAMY

Company Secretary, Chief Financial Officer
Qualifications: BComm, CPA

Mr Keamy, a Certified Practicing Accountant, 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 AU$95 million in capital, and assisted the steering of the Group from a loss-making, pre-revenue position to a commercially focussed profitable enterprise.

Mr Keamy recently completed a Graduate Diploma in Applied Corporate Governance with the Governance Institute of Australia.

MEETING OF DIRECTORS

The following table summarises the number of and attendance at all meetings of Directors during the financial year:

DIRECTOR	BOARD		AUDIT & RISK COMMITTEE		REMUNERATION COMMITTEE		NOMINATION COMMITTEE*	
	A	B	A	B	A	B	A	B
Mrs. B.M. Shanahan	8	8	3	3	-	-	2	2
Mr. S.R. McLiesh	8	8	3	3	2	2	2	2
Dr. P.J. Wolgen	8	8	3	2	2	2	-	-
Mr. W. Blijdorp	8	8	-	-	2	2	2	2
Dr. K. A. Agersborg	8	8	-	-	-	-	1	1

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

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

* In addition to the 2018/19 year, The Nomination Committee met in May 2017 and in July 2019, just outside the reporting period.

PRINCIPAL ACTIVITIES

CLINUVEL has developed and launched the world's first systemic photoprotective drug. CLINUVEL's pioneering work in melanocortins aims at preventing the symptoms of skin and genetic diseases related to the exposure to light and harmful UV radiation and the repigmentation of the skin due to a range of depigmentation disorders.

In addition to providing financial and operational stability for the Group, the principal activities of the Group during the financial year were to:

- manage the commercial distribution in Europe of its leading drug candidate SCENESSE® (afamelanotide 16mg) for the treatment of a rare, genetic metabolic disorder, erythropoietic protoporphyria (EPP);
- progress its New Drug Application (NDA) to the US Food and Drug Administration (FDA) for marketing authorisation of SCENESSE® to treat patients with EPP in the USA; and
- ongoing research and development of its product pipeline for a range of severe genetic and skin disorders.

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

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 2018/19	CENTS PER SHARE	AMOUNT	DATE OF PAYMENT
Final	2.00	$957,160	8 October 2018

On 28 August 2019, the Board of Directors declared an unfranked dividend of $0.025 per ordinary share in relation to the full year ended 30 June 2019.

REVIEW OF OPERATIONS AND FINANCIAL CONDITION

COMPANY OVERVIEW

CLINUVEL PHARMACEUTICALS LTD is a global biopharmaceutical company focussed on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in understanding the interaction of light and human biology, CLINUVEL's research and development is focussed on innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient Groups range in size from 5,000 to 45 million worldwide.

CLINUVEL's headquarters is in Melbourne, Australia with operations in Europe, Singapore and the USA.

OBJECTIVES

The key focus of the Group is on research and development of products addressing the interaction of skin with its environments, aiming to deliver innovative medical solutions for complex problems. We work to translate scientific breakthroughs into commercial products to deliver lifelong care and novel products for patients and consumers.

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 profitability is:

- continuing the successful research and development of a portfolio of assets centred around its key drug candidate SCENESSE®;
- their successful commercialisation, manufacture and distribution; 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 relation to its 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.

DYNAMICS OF THE BUSINESS

Key dynamics of the business are:

- The commercial operations of the Group are currently focussed on its activities in the European Union (EU) and Switzerland. Our European subsidiaries are concentrated on working with prescribing trained and accredited EPP Expert Centres to provide SCENESSE® to patients with EPP, working within the commitments agreed with the European Medicines Agency (EMA) as a condition for continuous marketing authorisation;
- In June 2018 a NDA was submitted to the US FDA for marketing authorisation to distribute SCENESSE® in the USA for EPP. A target decision date has been set by the FDA of 6 October 2019. Should the benefit-risk assessment be deemed positive by the FDA, the Group will be positioned to significantly increase its revenue base, pending reimbursement by insurers in the US;
- 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;
- CLINUVEL has agreed with EU payors a uniform price per unit of SCENESSE®, reflecting the Group's values of fairness and equitable treatment of all prescribers;
- SCENESSE® is manufactured in the USA by a sole contract manufacturer and is distributed by the Group directly to accredited EPP Expert Centres;
- The Group has an ongoing clinical interest to further develop SCENESSE®, focussing on vitiligo in North America, a skin repigmentation disorder as well as variegate porphyria (VP), a disease indication belonging to the same family of disorders as EPP (porphyrias);
- The Group's product development program is conducted through its fully owned Singaporean subsidiary, VALLAURIX PTE LTD. The pipeline is summarised in the following Product Pipeline section;
- The Melbourne headquarters of the Group covers the regulatory affairs, scientific programme, finance and investor relations functions.

REVIEW OF OPERATIONS

European Distribution of SCENESSE®

Our efforts to supply SCENESSE® to EPP Expert Centres across key European countries, including supply under special access to Switzerland, continued in the year ended 30 June 2019.

Brexit

We changed the structure of our European business during the year, establishing a new European subsidiary in Ireland to hold the marketing authorisation and manufacturing license to supply SCENESSE® in the EU.

We also appointed an alternate manufacturing partner to fulfil EU regulations on imported implants from our primary manufacturer located outside the EU.

Steps were also put in place to meet new guidelines on pharmaceuticals entering the European supply chain.

Progress of SCENESSE® NDA to FDA

In January 2019, the US FDA confirmed acceptance of the submission of an NDA for SCENESSE® to treat EPP patients and advised a Prescription Drug User Free (PDUFA) date of 8 July 2019. Frequent dialogue between the FDA and the Company regarding the NDA submission has continued, reflecting the overall complexity of the SCENESSE® dossier and the FDA's thoroughness to assess the risk and benefit of a new molecular entity, a first-in-class pharmaceutical product. In late May 2019, the FDA advised the regulatory authority was extended the PDUFA date to 6 October 2019.

Product Pipeline

The Group's strategy is to focus on developing and commercialising SCENESSE® as a preventative therapy to photo-protect patients with EPP. These patients are severely affected by exposure to visible and UV light. Further, the Group's strategy is to develop and commercialise SCENESSE® as a combination therapy with narrowband ultraviolet B (NB-UVB) phototherapy for patients with vitiligo in order to promote repigmentation of areas of the skin affected by vitiligo, and to pursue innovation in developing new and follow-on products by leveraging the Group's knowledge in photoprotection and repigmentation.

The Group has an active product development pipeline covering existing and new treatments for a range of skin related indications.

The pipeline includes research and development into:

- a paediatric formulation of SCENESSE®;
- SCENESSE® for adult vitiligo patients;
- SCENESSE® for adult patients with VP;
- 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 and to be administered topically; and
- a range of over the counter products for general photoprotective application.

Underpinned by the regulatory approval in Europe, along with the information generated from its post-marketing commitments in Europe, the Group continues to work towards gaining regulatory approval for SCENESSE® for EPP patients in other important markets where EPP is prevalent, including North America, in order to increase its ability to provide EPP patients worldwide with access to SCENESSE®.

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 in patients with vitiligo. Data from the clinical and pre-clinical studies evaluating efficacy and/or safety of SCENESSE® in combination with NB-UVB should result in the Group moving towards later stage clinical trials. The focus on progressing the development of SCENESSE® in vitiligo in

the US is dependent upon the FDA approving the use of SCENESSE® in EPP.

RESULT OF THE CONSOLIDATED ENTITY ('GROUP')

The financial year ended 30 June 2019 marks the completion of the Group's third consecutive year of recording a profitable financial result. An increase in Total Revenues and Net Profit before Tax is a successful result and provides a sound base for the Group's future expansion.

A summary of CLINUVEL's financial result is presented in the following table:

CONSOLIDATED ENTITY	YR ENDED 30 JUNE 2019	YR ENDED 30 JUNE 2018	CHANGE
	$	$	%
Revenues and Other Income	32,498,470	26,235,963	24%
Net Profit before income tax	18,114,827	12,942,406	40%
Profit after income tax benefit	18,134,160	13,224,185	37%
Basic earnings per share	0.376	0.277	36%
Net tangible assets backing per share	1.158	0.820	42%
Dividends	2.0 cents	Nil	-

Note: CLINUVEL does not operate individual segments.

The result for the Group for the year ended 30 June 2019 was $18.115 million profit before tax, compared to $12.942 million for the prior financial year, a 39.96% increase and the highest before tax profit result in the Group's history. The result reinforces the Group's primary strategic focus during the year to maintain and progress the commercial rollout of SCENESSE® in the EU whilst the US FDA reviews the Group's NDA to make SCENESSE® available in the US for EPP patients. Total expenses increased by 8% when compared to the previous year, but total revenues and other income exceeded the prior year's result by 23.87%, resulting in the increase to before tax profit.

REVENUES

The Group achieved Total Revenues of $31,048 million in the year ended 30 June 2019, a 22% increase on the prior year to 30 June 2018.

The number of countries in which SCENESSE® is commercially distributed along with the price of SCENESSE® were unchanged in the last year. Thus, the increase in Total Revenues reflected:

- a rise in the number of units provided to patients in Europe; and
- the conversion of Total Revenues in Euros to Australian dollars, CLINUVEL's reporting currency.

EPP Expert Centres in Europe continued to prescribe SCENESSE® to existing and new patients receptive to the treatment.

Revenues are earned in Euros and converted to Australian dollars, CLINUVEL's reporting currency. This currency translation boosted Total Revenues in Australian dollars by $1.016 million, or 18% of the increase in the financial year ended 30 June 2019.

Commercial Sales

Commercial sales of SCENESSE® in Europe totalled $26.489 million for 2018/19, compared to $21.359 million for 2017/18. Unit sales increased 20% year on year, demonstrating continuous demand for the drug from the European EPP patient population. The price of SCENESSE® remained constant in 2018/19, in line with CLINUVEL's policy to charge a uniform price across all European countries. Whilst the increase in revenues was driven by volume upon a consistent and stable uniform price, 13% of the increase in revenues from commercial sales related to favourable exchange rate movements as a result of a stronger Euro relative to the Australian dollar.

Sales Reimbursements – Special Access Schemes

The distribution of SCENESSE® under Special Access Schemes continued to provide a preventative treatment for adult EPP patients in Switzerland. These reimbursement revenues increased 10% to $4.559 million for the 2018/19 year compared to $4.126 million for the 2017/18 year. Whilst the increase in revenues was driven by volume upon an underlying uniform price in Euro currency, 79% of the increase primarily related to favourable exchange rate movements as a result of a stronger Swiss Franc to the Australian dollar. 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.

OTHER INCOME

Interest Income and Other Income

Interest received from funds held in bank accounts and term deposits for the year ended 30 June 2019 was $0.565 million compared to $0.264 million for year ended 30 June 2018. The positive financial performance of the Group saw an increase to its cash reserves, and this resulted in average 101% more cash held in higher-yielding Australian dollar fixed rate term deposits compared to the prior year. The average interest rate earned on these funds was on average 14 basis points higher year-on-year, reflecting 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 in 2018/19 was on average 50% higher than the average amount held in 2017/18. This contributed to the Group reporting a gain of $0.886 million from holding non-Australian dollar currencies and in holding trade creditors in non-Australian currencies (a $0.424 million gain for the same period last year) at 30 June 2019.

EXPENDITURES

Total Expenses for the Group for the year ended 30 June 2019 were $14.384 million. This is an increase of 8% on the prior financial year ended 30 June 2018.

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 48% of the Group's total expense result for 2018/19, compared to 45% for the 2017/18 year. 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 $5.985 million in 2017/18, increasing 15% to $6.871 million in 2018/19. The increase in these overall expenditures reflects the Group's focus throughout the year to further invest in its commercial rollout to secure revenues and to respond to queries received from the FDA as part of their review of the Group's NDA regulatory submission to arrive at a positive risk-benefit of SCENESSE®.

Clinical Development

Since the granting of market authorisation by the EMA in late 2014, the Group has focussed on its commercialisation activities in the EU and on its regulatory activities in the USA ahead of advancing its clinical trial program. This is reflected in expenses towards clinical development representing 1% of total expenses. For 2018/19, clinical development expenditures increased 70%, to 0.091 million, (2017/18: $0.054 million). The increase is with respect to statistical services required to analyse data from an already-completed clinical study. This expense category also includes product development and testing in the VALLAURIX PTE LTD operations.

Drug Formulation R&D, Manufacture & Distribution

Expenses toward further research, development, manufacture and optimisation of the implant drug formulation and the freighting and distribution to the end user increased by 38%, from $1.733 million in 2017/18 to $2.388 million in 2018/19. This increase is resultant of a combination of activities to enable growth in sales volumes. Major expense items included the expensing of inventoriable costs from increased sales units under the commercial distribution program. The increase in the cost of storing, special handling, packing and

freighting SCENESSE® in the EU by contracted parties, as a result of the increase in both the number of sales units and the number of units held in inventory, also impacted this result.

Clinical, Regulatory & Commercial Overheads

As part of CLINUVEL's longer term objectives, increasing the Research, Development & Commercial (R,D&C) personnel headcount is considered an essential investment to drive the new product development program in the fully owned subsidiary, VALLAURIX PTE LTD and to support the growth in the commercial distribution program in Europe during 2018/19. An increased headcount in the UK and VALLAURIX offices of R,D&C personnel responsible for oversight and monitoring of various clinical, regulatory, manufacturing and post-marketing programs was a key driver behind the 14% increase in R,D&C overheads (from $2.576 million in 2017/18 to $2.948 million in 2018/19). This expense Group also included a 26% year-on-year increase in royalty expenses paid to the implant contract manufacturer. Royalty fees are a function of sales volume and correlate to the movement in commercial sales.

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

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 pharmacovigilance and risk minimisation commitments with the EMA and to respond to queries received from the FDA as part of their review of the NDA submission in the US. These costs decreased 11%, from $1.623 million in 2017/18 to $1.444 million in 2018/19. Costs to establish and build on the regulatory infrastructure to support EPP patient access to SCENESSE® in the EU, including audits and variations, have tapered with time. These expenditures have been partly supplanted by increased activities to support pricing dossier submissions and in responding to the pricing negotiations.

Business Marketing & Listing

The Group has maintained a focus on increasing its brand and marketing activities throughout the year as it leads into a decision by the FDA and as it progresses the product development in its VALLAURIX business. Listing and marketing expenditures increased 43% year-on-year, from $1.051 million in 2017/18 to $1.502 million in 2018/19. Additions to in-house marketing resources, US-focussed public relations, conference and exhibition participation and increases to listing and regulatory compliance costs linked to the Group's market value were the major reasons for the increase.

Patents and Trademarks

Patent fees decreased 42% from $0.522 million in 2017/18 to $0.305 million in 2018/19. In the prior year there was a significant focus on fortifying the intellectual property position on the product development of the complementary and follow-on products within the VALLAURIX business. The focus on patents for the current year was centred on maintaining and validating the position of the existing patent portfolio.

General Operations (incl Board)

The result from general operations was $5.678 million in 2018/19, broadly equivalent to the 2017/18 result of $5.713 million. General operations comprised 39% of the Group's total expense result for 2018/19 compared to 43% in 2017/18. If the prior year long-term business generation incentive paid to the Managing Director was excluded, the increase in expenses from general operations is 15%. The increase is due to further legal fees in connection to matters related to marketing authorisation and in responding to negotiations with England's National Institute for Health and Care Excellence (NICE) and various payors in the EU, in indirect taxes related to performance rights, increases in Director and Officers insurance premiums and travel costs. The expensing of the accounting valuation of share-based payments (performance rights) was $0.140 million in 2018/19, 67% lower than the 2017/18 result of $0.428 million.

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 expense of $0.019 million (2018: $0.282 million).

BALANCE SHEET

To build a robust financial position that will allow for investing in future performance, net assets increased from $39.416 million at 1 July 2018 to $57.180 million at 30 June 2019. Current liabilities increased 43% to $4.960 million whereas trade and other receivables decreased 18% to $4.156 million. The increase in net assets is due to the increase in revenues from commercial sales in the EU which saw the Group start with $36.198 million in cash and financial assets held, and finish with $54.269 million at 30 June 2019, a 50% increase. Due to the increase in cash reserves generated from operations, there was no debt or equity capital raised in 2018/19 and in 2017/18.

SHAREHOLDER RETURNS

Shareholder returns for the financial year ended 30 June 2019 are positive as summarised by:

	YEAR ENDED 30 JUNE			
	2019	2018	2017	2016
Profit attributable to owners of the parent	$18,134,160	$13,224,185	$7,180,827	$3,121,200
Basic EPS	37.6 cents	27.7 cents	14.9 cents	(7.0) cents
Dividends Paid	$957,160	-	-	-
Dividends per Share	2.0 cents	-	-	-
Change in Share Price	206%	58%	62%	52%
Return on Equity	32%	34%	28%	(18%)

Returns to shareholders increased through capital growth and dividend distribution.

INVESTMENTS FOR FUTURE PERFORMANCE

Despite investment in property plant and equipment for 2018/19 only representing approximately 2% of cash used (excluding dividends distributed to shareholders) the Group has been focussed on building for the future. It has:

- Invested in personnel providing the foundation for growth;
- Invested in laboratory expansion and progressed the development of proprietary suncare products and pharmaceutical topical formulations within its Singapore R&D operation;
- Put steps in place to move into a pilot clinical study to treat patients with VP with SCENESSE®;
- Continued to renew and maintain new and existing patents to strengthen its intellectual property position;
- Commenced preparations to move into a large-scale clinical study in vitiligo, subject to a positive outcome by the FDA in its review of SCENESSE®;
- Planned for further investment in manufacturing supply and optimisation; and
- Increased personnel to support expanded activities and supported senior management in professional development programs.

The objectives are to progress and strengthen CLINUVEL as a world leader in medicinal photoprotection and repigmentation and to support expansion into other, similar genetic and skin-related markets. Further objectives are to expand the Group through one or several acquisitions to expand the focus of the Group.

CAPITAL STRUCTURE

The Group is debt free, has a sound capital structure and a positive financial position.

CLINUVEL's outstanding shares on issue increased to 48,960,633 shares to 30 June 2019. The increase of 1,136,206 issued shares was through the exercise of performance rights under the Group's performance rights plans and as consideration to purchase the outstanding shares from the minority interest-holder in VALLAURIX PTE LTD.

TREASURY POLICY

The key operating aspects of Treasury Policy is to:

- Invest surplus cash in bank accounts and in 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 FROM OPERATIONS AND OTHER SOURCES OF CASH

Cash inflows from customer receipts increased 36% to $32.221 million compared to $23.705 million for the 2017/18 year. Payments to suppliers and employees increased by 14%, from $12.539 million to $14.241 million.

There were cash outflows of $0.258 million for the acquisition of property, plant and equipment, $0.074 million of repayment of borrowing and leasing liabilities and $0.957 million for the first-time payment of an unfranked dividend to shareholders in relation to the 30 June 2019 financial year.

LIQUIDITY AND FUNDING

The Group's liquidity is healthy, as reflected as at 30 June 2019 in:

- A current ratio of 11.9:1 (30 June 2018 12.2:1); and
- Cash and cash equivalents of $54.269 million, accounting for 88.7% of total current assets (30 June 2018: $36.198 million, 85.6% 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 – there is a risk that despite obtaining marketing authorisations, those products may ultimately prove not to be safe and/or of clinical benefit.
- Supply – there is a risk that the manufacturing process 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 – there is a risk that clinical trials will not yield the expected and desired results for the investigational medicinal product(s) to obtain further regulatory approvals.
- Drug pricing – there is a risk that third-party payors will 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 (IP) and market entry – 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.
- 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.

CHANGES IN THE STATE OF AFFAIRS

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

SIGNIFICANT EVENTS AFTER THE REPORTING DATE

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

- On 28 August 2019, 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 and has entered into pricing agreements with several European countries, and state and private insurance groups. The Group has increased its 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 bear responsibility for the manufacturing standards of the commercial drug product.

In the next financial year, it is expected that the US FDA will make a final assessment on the risk-benefit of SCENESSE®. If the regulatory evaluation is positive, subject to agreement on reimbursement of SCENESSE® with insurers, SCENESSE® will become available in the US and the Group will expand its resources and activities to support US market entry. Pending FDA approval of SCENESSE® in EPP, 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 progress its clinical program with SCENESSE®, focussing on other indications including VP.

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 REGULATION AND PERFORMANCE

The Group's operations are not regulated by any significant environmental regulation under a law of the Commonwealth, or of a State or Territory, or of any other jurisdiction.

ROUNDING OF AMOUNTS

The Company is a type of Company referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191* and therefore the amounts contained in this report and in the financial report have been rounded to the nearest $1,000, 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 Company 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 2019.

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	Full Year
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
EXECUTIVE KMP		
Dr. P.J. Wolgen	Managing Director and Chief Executive Officer	Full Year
Dr. D.J. Wright	Acting 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 2018/19

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

"This year as Chairman of the Remuneration Committee, and together with the Board, we had set a number of priorities. The first one was our desire to seek longstanding stability for the CLINUVEL group by renewing employment agreements with the two executives Mr Keamy, CFO and Dr Wolgen, CEO for a further three years. As both executives are hands-on involved in the business day to day, the discussions have taken longer than expected as Darren and Philippe both had to give priority to the financial management and regulatory progress in the United States. As I write, the Employment Agreements are being reviewed by our lawyers and remuneration consultants and an ASX announcement will be made accordingly.

I have expanded on my views during the AGM 2018 as I see the health of a company first coming from the top; strong leadership is the only remedy for a company to master difficult situations which without doubt will be encountered on our journey. Therefore, for us as a Board it had been clear the past year that continuation of the current leadership was more important than ever since major goals lie ahead.

We have had a successful year in 2019, but without visionaries the CLINUVEL story would not continue. Therefore, weighing up the options to continue current leadership or find new top management was an easy exercise, I see the CLINUVEL story as not even half way completed. In my Dutch merchant's view, it took more than a decade to realize the CEO's ambition, and with a bit of luck the FDA will give the company reward for our strong work and years of patience. Our CEO's vision to build a larger diverse company on more legs needs to come after US FDA outcome.

In making sure that CLINUVEL and the executives have an ongoing commitment, the Remuneration Committee insisted on a contract with a three years term and a 12-month notice period so that the Board is not faced with any unexpected surprises. A further goal was to minimize the short-term incentives and business generating incentives by substituting these with shares (conditional rights) in the company. I will propose this substitution in the coming Annual General Meeting.

Also, we wanted to see the remuneration of the executives in line with references to our industry, growth of the company, index in Australia and international standards. I believe that we have successfully completed these goals with both current agreements. At the same time, we have expressed our appreciation for the unusual unusually long commitment of both executives by agreeing a Loyalty Award if they see out their employment agreements in three years. I thank the legal team and remuneration consultants for their work to help CLINUVEL complete these important goals.

As part of the Committee's vision on remuneration, we look to reward executives and senior management with shares in the company, since ownership makes people work effectively and gives all shareholders the certainty that management is acting for all of us. In the current period, the Remuneration Committee will propose a Conditional Rights Plan 2019 highlighting the corporate events for the coming years and rewarding staff for their responsibility to build value when they meet certain criteria.

On many occasions, I have explained how I wish to see corporate executives as significant owners of the company since they have started the close-to-impossible mission to turn the course of a company which had no money left in the bank, no strategy, no product and lost belief from the market. Managerial ownership is the only way to expect management to fight for its company and protect us shareholders. Last year I had stated that we want to see a sizable ownership by executive management – in cases up to 20% – to make sure that their objectives are aligned with the 80% owned by other shareholders. I maintain this vision today.

In today's environment, I look for strong governance, transparency and overall responsibility from our executives. Therefore, our Board does not support the role of Chairman and Chief Executive in one person, we believe in clear division of tasks and responsibilities. In the case of our CFO, we do not see a conflict in 2020 for Darren being overall responsible for the financial execution and also the Company's secretary. Only, when we grow to a larger Group will we review the dual role.

Finally, we are very pleased that Philippe is willing to continue in the Company, it will make him one of the longest serving CEO's in Asian-Pacific lifescience businesses. This Committee knows from many larger shareholders that his straight management and integrity are the reasons they remain invested in the CLINUVEL story which has taken a long time to generate value. But as I remember our CEO saying in one of his presentations more than 10 years ago, at the end of the long focus it will have been worth staying with the CLINUVEL story. I learned this myself as a shareholder who further invested in 2018.

A second priority of the Committee has been to review the remuneration of the Board of Directors and decide whether the directors will be able in the future to participate in the Conditional Rights Plan 2019. We have come to the conclusion that the Directors, and the new ones to join, will not be able to participate in a Conditional Rights Plan but will receive the normal remuneration for their services and time involved as they do now. It is very much an international debate for directors receiving shares or not. In my modern vision, Directors supervise and oversee a public business but do not participate in shares of the business unless they buy on the market.

I am looking forward to the outcome of the FDA, an enormous milestone for this company and even bigger for our patients and shareholders. A good outcome will be the basis for further growth, a negative outcome will test our teams again to fight the decision. However, we have created a company which no longer depends on the FDA outcome and can survive and achieve success without it.

As a global successful entrepreneur, I see many opportunities on the horizon for our company and it is the wish of my Board members to explore all these chances because we are slowly in a situation where we can take more commercial risks, but with care.

To stay with my yearly comparisons in shipping, with plain sailing in calm waters and easy breeze everyone can do the job from the bridge, the true navigator is only tested in turbulent weather and choppy waters. In Philippe and Darren we have seen their ability to manoeuvre and offer us solutions when the chips were down and one normally would give up, and therefore it is the best news after 14 years for all of us that they are willing to continue for another three until 1 July 2022.

Herewith, I recommend CLINUVEL's shareholders the remuneration incentives offered to the key management personnel."

B) REMUNERATION GOVERNANCE

REMUNERATION COMMITTEE

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

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

a) Remuneration of the Company's KMP is aligned with the interests of the Company and its shareholders within an appropriate control framework, taking into account the Company's strategies and risks.

b) The level and composition of remuneration attracts, retain and motivate people of high calibre and with unique specialist industry knowledge to work towards the long-term growth and success of the Company.

c) The role that total fixed remuneration and short- and long-term incentives play is clearly defined and provides a clear relationship between performance and remuneration.

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

e) The Company gives due consideration to applicable legal requirements and appropriate standards of governance.

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

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 2019, Egan Associates Pty Ltd ("Egan") provided support and counsel to the Remuneration Committee of a nature relating to executive remuneration within international frameworks. No remuneration recommendations were received from Egan or any other specialist remuneration consultant for the purpose of section 9B to the Corporations Act 2001.

VOTING AND FEEDBACK AT THE COMPANY'S LAST ANNUAL GENERAL MEETING

In the 2018 Annual General Meeting (AGM), the Company obtained 93.46% of the proxy votes (including votes at the Board's discretion) in favour of adopting the 2017/18 remuneration report, and this resolution was carried in favour by poll with 92.81% of votes cast. The Company did not receive any further specific feedback at the AGM on its remuneration practices.

HISTORICAL VOTING AT THE COMPANY'S ANNUAL GENERAL MEETINGS SINCE 2006

Since 2006 the Company has obtained a historical average above 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.

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 non-financial performance measures have been a key link to driving share price performance and this has been reflected in the 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. The table also links to share price performance.

REGULATORY, CLINICAL & COMMERCIAL MILESTONES	YEAR ENDED 30 JUNE 2015	2016	2017	2018	2019
Ph II Vitiligo Study - Singapore					
VALLAURIX PTE LTD – formulation & melanocortin development					
Post-marketing authorisation commitments					
First commercial sales					
Application for marketing authorisation submitted with FDA					
Market capitalisation (A$ million)	127	203	333	527	1,649
Share price high ($)	5.10	5.00	9.19	13.52	39.85
Share price low ($)	1.30	2.50	4.10	5.91	9.43
Closing share price ($)	2.84	4.32	6.98	11.01	33.68
Change in share price over 1 Year (%)	67	57	62	58	206
Change in share price over 3 Years (%)	74	139	311	288	680
Dividend paid (cents)	-	-	-	-	2.0

C) EXECUTIVE REMUNERATION

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:

1. Short-term (generally cash payments in the form of performance-based incentives awarded at a fixed amount or as a percentage of base salary).

2. 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).

MANAGING DIRECTOR REMUNERATION - OVERVIEW

The inherent risk of failure within pharmaceutical development is high and this risk is magnified for the Company due to it's 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 progress 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 success, 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 Acting 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 Acting 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, it is expected that this centralised management model will also 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.

The Remuneration Committee is in the process of renewing the Managing Director's service agreement. The intention is to retain his services through to 2022. In its considerations, the Committee is evaluating:

a) the criticality of retaining all key personnel,

b) certain remuneration structures that would best align the interests of the Managing Director and key personnel with those of the Company's shareholders,

c) the remuneration standards in the international marketplace,

d) the strong demand for well-informed, highly-experienced and valued executives, scientists and professionals with specific qualifications for senior positions.

It is expected the Managing Director's service agreement will be renewed in 2019/20.

EXECUTIVE REMUNERATION STRUCTURE 2018-19

MANAGING DIRECTOR	OTHER EXECUTIVE KMP
Managing Director remuneration includes: Base salary and health insurance, accommodation, relocation, travel and statutory benefits; Cash-based short-term incentive payments through the achievement of pre-specified performance-based targets; Cash-based longer-term business generation incentive payments through the achievement of pre-specified performance-based targets; Equity-based long-term participation in CLINUVEL'S Performance Rights Plan; and Cash-based discretionary payments (only in the event of exceptional performance, innovation and/or expansion and which do not form part of short-term incentives or longer-term business generation incentives).	Remuneration packages for Other Executive KMP may include: Base pay (including statutory benefits); Short-term incentive payments that can be awarded through the achievement of pre-specified performance-based and time-based targets; Longer-term business generation incentive payments through the achievement of pre-specified performance-based targets; and Long-term equity participation in CLINUVEL'S Performance Rights Plan. The total remuneration for each executive is aimed to be market competitive in which the executive is placed, and to reflect performance and specific competencies.
A) BASE SALARY 2018/19	
MANAGING DIRECTOR	**OTHER EXECUTIVE KMP**
Fees are set by the Remuneration Committee, taking into account the Managing Director's seniority, qualifications, skill, experience, length of service, leadership, industry knowledge and strategic oversight. Base salary is generally adjusted annually for changes in CPI. Due to domicile, the Managing Director's salary is paid in Singapore dollars by the consolidated group's Singapore subsidiary company and is subject to exchange rate movements when reported in Australian dollars. For the 2018/19 year, the Managing Director's base salary was $893,660, an increase of 9.2% to the 2017/18 year ($818,348). Of the 9.2% increase, 6.8% is attributable to exchange rate movements. Base salary for the Managing Director was adjusted 2.4% on 1 July 2018.	Fees are reviewed the Managing Director who makes recommendations to the Remuneration Committee and who subsequently reviews these recommendations. Base pay is generally adjusted annually to consider changes in CPI and to ensure the executive's pay is commensurate with the responsibilities and contribution of the executive, taking into account employment market conditions. For the 2018/19 year: Acting Chief Scientific Officer — 2.9% base salary increase Chief Financial Officer — 7.5% base salary increase

B) VARIABLE – SHORT-TERM INCENTIVE (STI) 2018/19

MANAGING DIRECTOR

The Managing Director has individual STIs which have a combined potential maximum value of 100% of the 2018/19 base salary amount.

The Managing Director's performance targets are set at the start of each financial year by the Remuneration Committee and are assessed for payment in the year following the year of achievement.

The performance-based targets are unique to this particular global life sciences company at its stage of development and early commercial product distribution. The focus on growth in corporate value has been centred on achievement of regulatory, development, commercial and operational outcomes, where financial metrics are merely one part of the professional assessment of executive performance and may not be commonly expected in other market segments and industries.

The Board considers specific 2018/19 performance-based targets to be commercially sensitive. Specific targets are not disclosed. The targets are centred on:

1. Commercial distribution and clinical management of SCENESSE® in Europe;
2. Material progress in regulatory filings, with an emphasis on the US;
3. Financial management and general management of the Group; and
4. Research & development of products under development and expansion of the VALLAURIX entity.

For the 2018/19 financial year the Remuneration Committee evaluated the performance of the Managing Director and the Board approved a short-term incentive of 47.3% to base salary (2018: 56.7%).

In arriving at this assessment, the Remuneration Committee considered the following links to an increase in corporate value:

- Demonstrated growth in 2018/19 profit attributable to developing the European and Swiss market.
- Increased positive cash flows of the business.
- Followed through and oversaw the strategy to respond to the US FDA in its review of the NDA, securing a successful validation outcome to the submission and a Priority Review without a scheduled Advisory Committee meeting.
- In an uncertain political and economic environment, directed the re-structuring of the Group's European commercial operations and established new systems to minimise potential disruption resulting from the United Kingdom leaving the EU.

OTHER EXECUTIVE KMP

STIs are individually set by the Managing Director at the start of each financial year and these incentives are recommended to the Remuneration Committee for their review and approval. STIs are assessed at the end of each financial year.

STIs 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, regulatory progress, manufacturing, research and development and corporate affairs.

For 2018/19, it was determined the following percentage of base salary as the appropriate quantum for the short-term incentives for each Other Executive KMP to be evaluated against:

- Acting Chief Scientific Officer: 9%
- Chief Financial Officer: 14%

For the 2018/19 year, the Managing Director assessed overall performance against the short-term incentives and recommended to the Remuneration Committee and who approved the following assessments against the maximum short-term incentives:

- Acting Chief Scientific Officer: 80%
- Chief Financial Officer: 87%

C) VARIABLE – LONGER-TERM -BUSINESS GENERATION INCENTIVES (BGI) 2018/19

MANAGING DIRECTOR

Individual longer-term cash incentive components based on specified performance based targets which remain for the term of the Managing Director's service agreement or within six months from cessation or termination, form part of the Managing Director remuneration.

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 Board reviews BGIs each time the Company and the Managing Director enters into a new 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.

The Managing Director currently has 3 BGIs as part of executive remuneration, ranging from €150,000 to €500,000 per BGI.

These BGIs were set in 2010 and carried over into subsequent service agreements.

BGIs are met:

1. upon the Company signing license agreements in key geographical areas in relation to the marketing and distribution of SCENESSE®.
2. if the Company elects to self-distribute, when an accumulated financial benefit in excess of €10,000,000 has been received by the Company.

For the 2018/19 financial year, no BGI was achieved (2017/18: €500,000).

Beyond 2018/19, to further align the interests of the Managing Director with the interest of shareholders and to provide a retention incentive, it is intended the next service agreement will substantially revise BGIs as part of the Managing Director's remuneration framework. It is intended the next service agreement will have a greater emphasis on equity remuneration as a long term incentive in lieu of cash-based BGIs.

OTHER EXECUTIVE KMP

During 2017/18, BGIs were introduced to the remuneration package for the Chief Financial Officer. These longer-term incentives based on set performance targets must be achieved before 30 June 2019 and are linked to the Company achieving exceptional business outcomes that contribute to creating corporate value and to act as a key retention tool.

Each BGI was $60,000 cash payment, linked to:

1. successful listing of the Company on an overseas exchange; and
2. expansion of the Company through acquisition with demonstrated positive cash flows of the acquired entity post-acquisition.

For the 2018/19 financial year, no BGI was achieved by the Chief Financial Officer.

D) VARIABLE – LONGER TERM PERFORMANCE RIGHTS 2018/19

MANAGING DIRECTOR

Equity remuneration is aimed to:

- retain and incentivise the Managing Director to drive the long-term growth and success of the Company
- to align his interests with increased shareholder wealth over the longer term

Unlike other equity remuneration plans internationally, performance rights are not granted to the Managing Director annually. To date, by virtue of the nature of the Company being primarily focussed on research and development, the performance conditions have been based on non-financial strategic goals linked to shareholder value which has uncertain, longer-term anticipated milestone dates.

The Managing Director was last issued performance rights in the 2014/15 financial year.

For the financial years ended 30 June 2019 and 30 June 2018, no performance rights were granted to the Managing Director.

OTHER EXECUTIVE KMP

Equity remuneration is aimed to:

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

Performance rights are not granted to Other Executive KMP annually. To date, by virtue of the nature of the Company being primarily focussed on research and development, the performance conditions have been based on non-financial strategic goals linked to shareholder value which has uncertain, longer-term anticipated milestone dates.

The Other Executive KMP were last issued performance rights in the 2015/16 financial year.

For the financial years ended 30 June 2019 and 30 June 2018, no performance rights were granted to the Other Executive KMP.

E) VARIABLE – CASH BASED DISCRETIONARY PAYMENT 2018/19

MANAGING DIRECTOR ONLY

The Managing Director is eligible to receive cash-based discretionary payments, only in the event of exceptional performance, innovation and/or expansion and which do not form part of the STI or longer-term BGI targets.

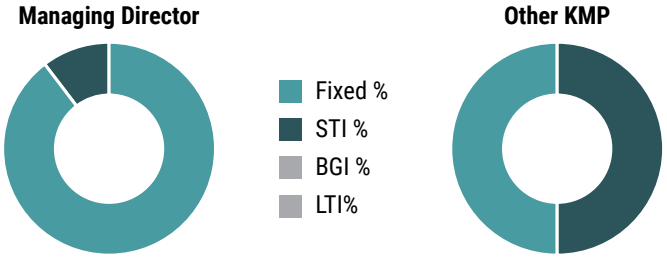
No discretionary payment was awarded to the Managing Director for the year ended 30 June 2019 or in prior years.

EXECUTIVE REMUNERATION PAY MIX & BENCHMARKING

The mix of remuneration (between fixed remuneration, maximum STI entitlement and the face value of performance rights or BGIs) granted to KMPs during the financial year is represented here.

The Board believes the remuneration mix aligns the Managing Director and Other Executive KMP to shareholder interests, bearing in mind the Managing Director has been granted performance rights in prior years and is appropriately incentivised to pursue shareholder wealth by virtue of having a 6.7% interest in the issued capital of the Company.

No BGIs or performance rights were granted to the Managing Director or to Other Executive KMP during the year.



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 nature,

b) businesses of similar scope and scale,

c) sectors requiring highly technical and specialized skills,

d) businesses of similar value, reflected in market capitalisation,

e) businesses who have demonstrated similar progress in achieving business outcomes,

f) business of similar risk profile.

CLINUVEL targets to provide competitive remuneration for the Managing Director based on comparable positions in the relevant international market(s). As CLINUVEL was included in June 2019 in the ASX-200 group of companies, a number of peers with similar enterprise value are part of the peer group analyses.

The Remuneration Committee of the Company aims to provide levels or remuneration at median levels benchmarked against peers.

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 $550,000 at the 2015 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 2019 was $335,000.

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. As referred to in the Introduction to this Remuneration Report by the Chair of the Remuneration Committee, it is no longer planned for non-executive Directors to participate in long-term equity compensation plans. Two current non-executive Directors, Mr McLiesh and Mrs Shanahan, still hold performance rights.

The Board 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 must 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 endeavours to ensure the interests of all its KMP 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 relatively significant shareholdings in the Group.

E) SERVICE AGREEMENTS 2018/19

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	DR DENNIS WRIGHT[1]	MR DARREN KEAMY[1]
Duration of contract	3 years	No fixed term	No fixed term
Notice Period (from Company)	12 months	3 months	3 months
Notice Period (from Managing Director)	12 months	-	-
Notice Period (from Executive KMP)	-	3 months	3 months
Termination Payment without Cause	12 months	3 months	3 months
Termination Payment with Cause	None	None	None

[1]It is intended for new service agreements to be entered into with all KMPs to incorporate a duration of contract of 36 months.

F) SHARE-BASED REMUNERATION

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

PERFORMANCE RIGHTS:

All performance rights that have been issued fall under two performance rights plans:

a) the CLINUVEL Conditional Performance Rights Plan (2009); and

b) the CLINUVEL Performance Rights Plan (2014).

536,540 performance rights issued under the 2009 Plan remain unvested as at 30 June 2019 and 105,873 performance rights issued under the 2014 Plan remain unvested at 30 June 2019.

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 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. 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.

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 by a Scheme Trustee on behalf of the eligible person.

The eligible person cannot trade the shares held by the Scheme Trust 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. Performance rights under this plan lapses after seven years from grant date.

Performance rights are valued for financial reporting purposes using a binomial valuation 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.

Further details of the Company's share-based remuneration are tabled below:

NUMBER OF PERFORMANCE RIGHTS THAT ARE DETERMINED	EXECUTIVE KMP 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. DIRECTORS The Remuneration Committee assesses and recommends to the Board for shareholders to approve the quantum of performance rights amounts based on: • tenure of the director at time of issue of performance rights; • weighted average share price levels at time of issue; • Chair and Committee representation; • involvement in steering management; • industry trends; • impact on share dilution; and • nature of vesting (performance) conditions attached to the issue of performance rights.
SELECTION OF PERFORMANCE CONDITIONS AFFECTING UNVESTED PERFORMANCE RIGHTS IN THE CURRENT AND FUTURE REPORTING PERIOD	The performance conditions attached to those performance rights issued and unvested at any time during 2018/19 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.
NATURE OF PERFORMANCE CONDITIONS AFFECTING UNVESTED PERFORMANCE RIGHTS IN THE CURRENT AND FUTURE REPORTING PERIOD	A. Upon submission of a dossier to the US FDA applying for market approval of SCENESSE® *(achieved in 2018/19)*; B. Granting market approval for SCENESSE® by the US FDA *(not attached to Non-Executive Directors)* C. 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)* D. Announcement of commercial partnership to distribute SCENESSE® (or derivative of) *(not attached to Managing Director)*; and E. The earlier of: (a) second molecule in new formulation, or (b) paediatric formulation for afamelanotide *(Other Executive Key Management Personnel and staff only)*
ASSESSING PERFORMANCE CONDITIONS	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.
UPON VESTING OF PERFORMANCE RIGHTS	The performance rights are exercised into new Shares and are acquired by a Plan Trustee and then, from time to time, transferred to the Non-Executive Director, but generally only when the Non-Executive ceases their 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.

No new performance rights were granted to Non-Executive Directors for the years ended 30 June 2019 and 30 June 2018.

No new performance rights were granted to the Managing Director or Other Executive KMP for the years ended 30 June 2019 and 30 June 2018.

G) DETAILS OF REMUNERATION

KMP REMUNERATION OF THE COMPANY FOR THE YEARS ENDED 30 JUNE 2019 AND 30 JUNE 2018

					POST-EMPLOYMENT BENEFITS		SHARE-BASED PAYMENTS (ACCOUNTING CHARGE ONLY)[2]	
	YEAR	GROSS SALARY 4	SHORT-TERM INCENTIVE	BUSINESS GENERATION INCENTIVE	OTHER[1]	SUPER-ANNUATION/ PENSION FUND	PERFORMANCE RIGHTS	TOTAL
	$	$	$	$	$	$	$	$
Dr. P.J. Wolgen[3]	2019	893,660	422,747	-	30,373	-	68,346	**1,415,126**
	2018	818,348	464,033	762,394	36,405	-	207,097	**2,288,277**
Mr. S.R. McLiesh	2019	100,457	-	-	-	9,543	2,520	**112,520**
	2018	100,457	-	-	-	9,543	8,041	**118,041**
Mrs. B.M. Shanahan	2019	73,059	-	-	-	6,941	2,520	**82,520**
	2018	73,059	-	-	-	6,941	8,041	**88,041**
Mr. E. Ishag	2019	-	-	-	-	-	-	**-**
	2018	29,166	-	-	-	-	2,816	**31,982**
Mr. W.A. Blijdorp	2019	80,000	-	-	-	-	-	**80,000**
	2018	73,750	-	-	-	-	-	**73,750**
Dr. K.A. Agersborg	2019	65,000	-	-	-	-	-	**65,000**
	2018	27,833	-	-	-	-	-	**27,833**
OTHER KMP								
Dr. D.J. Wright	2019	252,064	18,149	-	-	20,531	5,608	**296,352**
	2018	244,959	16,535	-	-	20,049	16,664	**298,207**
Mr. D.M. Keamy	2019	265,441	32,384	-	-	20,531	18,141	**336,497**
	2018	246,922	30,124	-	-	20,049	53,086	**350,181**
TOTAL	**2019**	**1,729,681**	**473,280**	**-**	**30,373**	**57,546**	**97,135**	**2,388,015**
	2018	**1,614,494**	**510,692**	**762,394**	**36,405**	**56,582**	**295,745**	**3,276,312**

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

[2] As these values are accounting values the KMP may or may not actually receive any benefit from these amounts, either in the current or future reporting periods. 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 a binomial pricing model.

[3] Dr Wolgen's salary is paid in Singapore dollars (SGD). 6.8% of the 9.2% increase to base salary is attributable to exchange rate movements.

[4] Does not include movement in annual leave provisions.

THE RELATIVE PROPORTIONS OF REMUNERATION BETWEEN FIXED AND BASED ON PERFORMANCE FOR THE YEARS ENDED 30 JUNE 2019 & 30 JUNE 2018

	2019		2018	
	FIXED REMUNERATION	PERFORMANCE BASED	FIXED REMUNERATION	PERFORMANCE BASED
Dr. P.J. Wolgen	65%	35%	37%	63%
Dr. D.J. Wright	92%	8%	89%	11%
Mr. D.M. Keamy	85%	15%	76%	24%

REMUNERATION PERFORMANCE RIGHTS HOLDINGS OF KMP – 2019

	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	LAPSED AND EXPIRED	BALANCE AT END OF YEAR
DIRECTORS					
Mr. S.R. McLiesh	65,000	-	(25,000)	-	40,000
Mrs. B.M. Shanahan	50,000	-	(25,000)	-	25,000
Dr. P.J. Wolgen	924,974	-	(716,642)	-	208,332
Mr. W.A. Blijdorp	-	-	-	-	-
Dr. K.A. Agersborg	-		-		-
OTHER KMP					
Dr. D.J. Wright	112,125	-	(61,500)	-	50,625
Mr. D.M. Keamy	186,760	-	(88,320)	-	98,440

All performance rights held at the end of the year are unvested.

SHARES HELD BY KEY MANAGEMENT PERSONNEL

The number of ordinary shares in the Company during the 2019 reporting period held by each of the Group's Key Management Personnel, including their related parties, is set out below:

YEAR ENDING 30 JUNE 2019					
PERSONNEL	BALANCE AT START OF YEAR[1]	GRANTED AS REMUNERATION	RECEIVED ON EXERCISE	OTHER CHANGES	HELD AT THE END OF REPORTING PERIOD
Mr. S.R. McLiesh	162,774	-	25,000	-	187,774
Mrs. B.M. Shanahan	233,969	-	25,000	-	258,969
Dr. P.J. Wolgen	2,579,722	-	716,642	-	3,296,364
Mr. W.A. Blijdorp	383,145	-	-	1,359,973	1,743,118
Dr. K.A. Agersborg	2,900		-	1,200	4,100
OTHER KMP					
Dr. D.J. Wright	252,874	-	61,500	-	314,374
Mr. D.M. Keamy	218,400	-	88,320	-	306,720

[1]Includes a notifiable interest of 80,000 shares held in a charitable foundation of which Mrs Shanahan is a Trustee, disclosed 29 January 2019

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	09/01/2019	-
CLINUVEL	91,667	$1.04	Ordinary	25/11/2010	-	-
CLINUVEL	116,667	$1.04	Ordinary	25/11/2010	-	-
CLINUVEL	75,000	$1.19	Ordinary	14/01/2013	09/01/2019	-
CLINUVEL	674,975	$2.59	Ordinary	28/11/2014	09/01/2019	-
CLINUVEL	148,225	$2.16	Ordinary	17/03/2015	-	-
CLINUVEL	105,875	$2.16	Ordinary	17/03/2015	-	-
CLINUVEL	5,500	$4.20	Ordinary	05/09/2017	-	23/03/2019

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	-	-	26,691
	2014/15	2021/22	100%	-	-
Dr. P.J. Wolgen	2010/11	no limitation	-	-	312,001
	2014/15	2021/22	100%	-	-
Mrs. B.M. Shanahan	2011/12	no limitation	-	-	16,682
	2014/15	2021/22	100%	-	-
Mr. W.A. Blijdorp	-	-	-	-	-
Dr. K.A. Agersborg	-	-	-	-	-
OTHER KMP					
Dr. D.J. Wright	2011/12	no limitation	36%	-	27,281
	2012/13	no limitation	100%	-	-
	2014/15	2021/22	58%	-	21,600
Mr. D.M. Keamy	2011/12	no limitation	21%	-	46,028
	2012/13	no limitation	100%	-	-
	2014/15	2021/22	58%	-	70,200

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 2009/10 and 2014/15 was $Nil.

REMUNERATION DETAILS OF CASH INCENTIVES

CASH INCENTIVES				
NAME	MAX POTENTIAL OPPORTUNITY (%)	STI AWARDED (%)	STI FORFEITED (%)	TOTAL GRANTED ($)
Dr. P.J. Wolgen	100%	47%	53%	422,747
Dr. D.J. Wright	9%	80%	20%	18,149
Mr. D.M. Keamy	14%	87%	13%	32,384

LOANS TO DIRECTORS AND EXECUTIVES

No loans were granted to Directors or executives for the years ended 30 June 2019 and 30 June 2018.

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	1,102,647	Nil$	Ordinary

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

DETAILS OF SHARES TRANSFERRED DURING THE YEAR TO EMPLOYEES FROM THE SCHEME TRUST

ENTITY	NUMBER OF SHARES ISSUED[1]	ISSUE PRICE FOR SHARES	CLASS
CLINUVEL PHARMACEUTICALS LTD	420,511	Nil$	Ordinary

[1] These shares were issued by the Scheme Trustee 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	536,540	$Nil	Ordinary	Upon achievement of specific performance and time-based milestones or upon cessation of employment
CLINUVEL PHARMACEUTICALS LTD	105,873	$Nil	Ordinary	17 March 2022
	642,413	-	-	-

NON-AUDIT SERVICES

For the years ended 30 June 2019 and 30 June 2018, Grant Thornton Australia only provided audit services to the Company.

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 28th day of August, 2019

STATEMENT OF PROFIT AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2019

		CONSOLIDATED ENTITY	
	NOTE	2019	2018
		$	$
Total revenues[1]	2(a)	31,047,776	25,485,673
Interest income	2(b)	564,657	264,452
Other income[2]	2(c)	886,037	485,838
Total expenses	2(d)	(14,383,643)	(13,293,557)
PROFIT BEFORE INCOME TAX BENEFIT		**18,114,827**	**12,942,406**
Income tax benefit	3(a)	19,333	281,779
PROFIT AFTER INCOME TAX BENEFIT		**18,134,160**	**13,224,185**
NET PROFIT FOR THE YEAR		**18,134,160**	**13,224,185**
OTHER COMPREHENSIVE INCOME (LOSS)			
Items that may be re-classified subsequently to profit or loss			
Exchange differences of foreign exchange translation of foreign operations		(80,077)	(493,287)
Other comprehensive loss for the period		(80,077)	(493,287)
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD		**18,054,083**	**12,730,898**
PROFIT FOR THE YEAR ATTRIBUTABLE TO:			
Owners of the parent		18,134,160	13,224,185
		18,134,160	**13,224,185**
TOTAL COMPREHENSIVE INCOME/(LOSS) ATTRIBUTABLE TO:			
Owners of the parent		18,054,083	12,730,898
		18,054,083	**12,730,898**
Basic earnings per share - cents per share	16	37.6	27.7
Diluted earnings per share - cents per share	16	36.6	26.7

The accompanying notes form part of these financial statements.

1, 2 Under AASB 15 Revenue from Contracts with Customers, Interest Income previously classified under Total Income is now shown under Total Other Income. Interest Income for the year ended 30 June 2018 has also been re-classified.

STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2019

		CONSOLIDATED ENTITY	
	NOTE	2019	2018
		$	$
CURRENT ASSETS			
Cash and cash equivalents	17(a)	54,268,758	36,198,451
Trade and other receivables	4	4,156,216	5,090,271
Inventory	5	2,136,084	641,285
Other assets	6	591,516	339,062
TOTAL CURRENT ASSETS		**61,152,574**	**42,269,069**
NON-CURRENT ASSETS			
Property, plant and equipment - net	7	337,851	168,739
Right-of-use asset - net	8	368,805	-
Intangible assets - net	9	185,030	185,030
Deferred tax assets - net	3(c)	301,112	281,779
TOTAL NON-CURRENT ASSETS		**1,192,798**	**635,548**
TOTAL ASSETS		**62,345,372**	**42,904,617**
CURRENT LIABILITIES			
Trade and other payables	11	3,633,281	2,499,915
Lease liabilities	8	261,251	-
Provisions	12	1,065,510	970,906
TOTAL CURRENT LIABILITIES		**4,960,042**	**3,470,821**
NON-CURRENT LIABILITIES			
Lease liabilities	8	171,267	-
Provisions	12	34,210	17,808
TOTAL NON-CURRENT LIABILITIES		**205,477**	**17,808**
TOTAL LIABILITIES		**5,165,519**	**3,488,629**
NET ASSETS		**57,179,853**	**39,415,988**
EQUITY			
EQUITY ATTRIBUTABLE TO OWNERS OF THE PARENT:			
Contributed equity	13	151,314,175	148,614,908
Reserves	14	1,352,416	3,481,916
Accumulated losses		(95,486,738)	(112,680,836)
EQUITY ATTRIBUTABLE TO THE OWNERS OF THE PARENT		**57,179,853**	**39,415,988**
TOTAL EQUITY		**57,179,853**	**39,415,988**

STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2019

	NOTE	CONSOLIDATED ENTITY 2019 $	2018 $
CASH FLOWS FROM OPERATING ACTIVITIES			
Receipts from customers		32,221,122	23,705,378
Interest received		440,919	290,566
GST and VAT refunds		35,276	183,842
Payments to suppliers and employees[1]		(14,241,210)	(12,539,522)
Government R&D tax incentive		-	53,069
NET CASH PROVIDED BY/(USED IN) OPERATING ACTIVITIES	17(b)	**18,456,107**	**11,693,333**
CASH FLOWS FROM INVESTING ACTIVITIES			
Payments for property, plant and equipment		(257,616)	(75,123)
NET CASH USED IN INVESTING ACTIVITIES		**(257,616)**	**(75,123)**
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of borrowing and leasing liabilities[2]		(73,506)	-
Dividends paid		(957,160)	-
NET CASH USED IN FINANCING ACTIVITIES		**(1,030,666)**	**-**
NET INCREASE IN CASH HELD		**17,167,825**	**11,618,210**
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR		**36,198,451**	**23,752,312**
Effects of exchange rate changes on foreign currency held		902,482	827,929
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	17(a)	**54,268,758**	**36,198,451**

The accompanying notes form part of these financial statements.

[1,2] Under AASB 16 Leases, Repayments of borrowings and leasing liabilities previously included in payments to suppliers and employees under operating activities is now under financing activities.

STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2019

	SHARE CAPITAL	PERFORMANCE RIGHTS RESERVE	FOREIGN CURRENCY TRANSLATION RESERVE	RETAINED EARNINGS	TOTAL ATTRIBUTABLE TO OWNERS OF PARENT	NON-CONTROLLING INTEREST	TOTAL EQUITY
	$	$	$	$	$	$	$
BALANCE AT 30 JUNE 2017	148,413,095	2,695,484	124,728	(125,847,024)	25,386,283	57,742	25,444,025
Issue of Share Capital under share-based payment	201,813	(201,813)	-	-	-	-	-
Employee share-based payment options	-	370,230	-	57,405	427,635	-	427,635
Purchase of shares held in subsidiary from non-controlling interest	-	-	-	-	-	(173,144)	(173,144)
Transfer of Accumulated Loss of non-controlling interest to owner upon purchase of minority interest	-	-	-	(115,402)	(115,402)	115,402	-
TRANSACTIONS WITH OWNERS	148,614,908	2,863,901	124,728	(125,905,021)	25,698,516	-	25,698,516
PROFIT FOR THE YEAR				13,224,185	13,224,185	-	13,224,185
OTHER COMPREHENSIVE LOSS:							
Exchange differences of foreign exchange translation of foreign operations	-	-	493,287	-	493,287	-	493,287
TOTAL OTHER COMPREHENSIVE LOSS	-	-	493,287	-	493,287	-	493,287
BALANCE AT 30 JUNE 2018	148,614,908	2,863,901	618,015	(112,680,836)	39,415,988	-	39,415,988
Issue of Share Capital under share-based payment	2,332,062	(2,332,062)	-	-	-	-	-
Employee share-based payment options	-	122,485	-	17,098	139,583	-	139,583
Purchase of shares of non-controlling interest from minority owners via issue of Share Capital	367,205	-	-	-	367,205	-	367,205
Dividends paid	-	-	-	(957,160)	(957,160)		(957,160)
TRANSACTIONS WITH OWNERS	151,314,175	654,324	618,015	(113,620,898)	38,965,616	-	38,965,616
PROFIT FOR THE YEAR				18,134,160	18,134,160	-	18,134,160
OTHER COMPREHENSIVE LOSS:							
Exchange differences of foreign exchange translation of foreign operations	-	-	80,077	-	80,077	-	80,077
TOTAL OTHER COMPREHENSIVE LOSS	-	-	80,077	-	80,077	-	80,077
BALANCE AT 30 JUNE 2019	151,314,175	654,324	698,092	(95,486,738)	57,179,853	-	57,179,853

NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2019

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.

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.

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) 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 2018 based on the following management judgements:

- The consolidated entity has experienced consecutive years of profitably and revenue growth;
- Current pricing agreements with European payors not expected to change in the next financial year; and
- Internal targets continue to expect ongoing profitability in the near term.

C) 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.

D) 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.

E) INVESTMENTS AND OTHER FINANCIAL ASSETS

The Group has applied AASB 9 for the first time for the full year ended 30 June 2019.

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

As the accounting for financial liabilities remains largely unchanged from AASB 139, the Group's financial liabilities were not impacted by the adoption of AASB 9. However, for completeness, the accounting policy is disclosed below.

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.

The new Standard has been applied as at 1 July 2018 using the modified retrospective approach. The Group has assessed of the impact of AASB 9's changes and there is no impact on the financial instruments transactions and balances recognised in the financial statements.

For the year ended 30 June 2018, financial assets and liabilities were prepared under AASB 139:

Financial assets at fair value through profit or loss (FVTPL)

The consolidated entity does not hold financial assets at FVTPL at balance sheet date. FVTPL include financial assets that are either classified as held for trading or that meet certain conditions and are designated at FVTPL upon initial recognition. All derivative financial instruments fall into this category, except for those designated and effective as hedging instruments, for which the hedge accounting requirements apply. Assets in this category are measured at fair value with gains or losses recognised in profit or loss. The fair values of financial assets in this category are determined by reference to active market transactions or using a valuation technique where no active market exists.

Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. After initial recognition, these are measured at amortised cost using the effective interest method, less provision for impairment. Discounting is omitted where the effect of discounting is immaterial. The Group's trade and most other receivables fall into this category of financial instruments. Individually significant receivables are considered for impairment when they are past due or when other objective evidence is received that a specific counterparty will default. Receivables that are not considered to be individually impaired are reviewed for impairment in groups, which are determined by reference to the industry and region of a counterparty and other shared credit risk characteristics. The impairment loss estimate is then based on recent historical counterparty default rates for each identified group.

F) INVENTORY

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.

G) 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.

H) 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.

I) 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.

J) 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.

K) DIRECTORS' REMUNERATION – SHARE-BASED PAYMENTS

Under AASB 2 Share-based Payments, the consolidated entity must determine the fair value of options and conditional performance rights issued to employees as remuneration and recognise an expense in the Statement of Profit or Loss and Other Comprehensive Income. This standard is not limited to options and to conditional performance rights. It also extends to other forms of equity based remuneration. The fair value of options is measured by the use of the binominal options pricing model. The fair value of conditional performance rights is measured by either a binomial or a trinomial model. It is determined at grant date and expensed on a straight- line basis over the vesting period. The fair value of options and conditional performance rights is shown as an expense in profit or loss.

L) REVENUE AND OTHER INCOME

Revenue

Revenue arises from the sale of SCENESSE® implants.

The Group's revenue from contracts with customers arise from the commercial sales of goods and sales reimbursements. Commercial sales of goods are the commercial sales of SCENESSE® implants in Europe. 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 revenue based on at a point in time rather than over time.

The below table summarises the application of AASB 15 to the Group's revenue streams:

DESCRIPTION AND PERFORMANCE OBLIGATIONS	REVENUE RECOGNITION POLICY UNDER AASB 15
Commercial sales of goods (Commercial sale of SCENESSE® implants in Europe)	Point in time
Performance obligation: Delivery of goods to customer	
Sales reimbursements (Distribution of SCENESSE® implants under special access reimbursement schemes)	Point in time
Performance obligation: Delivery of goods to customer	

The new Standard has been applied as at 1 July 2018 using the modified retrospective approach. The Group has assessed of the impact of AASB 15's changes and there is no impact on the Revenue from Contracts with Customers transactions and balances recognised in the financial statements.

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.

In the year ended 30 June 2018, under the old AASB 118, revenue from reimbursement of implant sales from insurance companies is recognised when the consolidated entity has transferred to the buyer the significant risks and rewards of ownership of the goods.

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 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.

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 Statement of 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 Statement of Profit or Loss immediately.

Q) LEASES

The Group has early adopted AASB 16 – Leases as of 1 July 2018 using the modified retrospective approach and therefore comparative information has not been restated. This means comparative information is still reported under AASB 117.

For any new contracts entered into on or after 1 July 2018, 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 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 asset and a lease liability 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 diminishing value basis from the lease commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term which is currently between 2 – 3 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 asset for impairment when such indicators exist.

At the commencement date, the Group measures the lease liability 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 1.01%.

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.

Accounting policy applicable before 1 July 2018

Lease payments for operating leases, where substantially all the risks and benefits remain with the lessors, are charged as expenses in the periods in which they are incurred.

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 is determined using either a binomial or a trinomial options pricing model. 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 payment 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 Black-Scholes, a binomial or a trinomial model, using the assumptions detailed in Note 23.

Key judgments – tax losses

Given the Company's and each individual entities' history of losses, the Group has not recognised a deferred tax asset with regard to unused tax losses and other temporary differences until this year. For the first time, 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.

X) NEW ACCOUNTING STANDARDS AND INTERPRETATIONS

In the year ended 30 June 2019, the Group has adopted all of the new and revised Standards and Interpretations issued by the Australian Accounting Standards Board that are relevant to its operations and effective for the current annual reporting period.

The Group adopted:

AASB 15 Revenue with Contracts:

- replaced AASB 118 Revenue, AASB 111 Construction Contracts and some revenue-related Interpretations;
- establishes a new control-based revenue recognition model;
- changes the basis for deciding whether revenue is to be recognised over time or at a point in time;
- provides new and more detailed guidance on specific topics (e.g., multiple element arrangements, variable pricing, rights of return, warranties and licensing); and
- expands and improves disclosures about revenue.

AASB 9 Financial Instruments

AASB 9 introduces new requirements for the classification and measurement of financial assets and liabilities and includes a forward-looking 'expected loss' impairment model and a substantially-changed approach to hedge accounting.

These requirements improve and simplify the approach for classification and measurement of financial assets compared with the requirements of AASB 139. The main changes are:

- Financial assets that are debt instruments will be classified based on: (i) the objective of the entity's business model for managing the financial assets; and (ii) the characteristics of the contractual cash flows.
- Allows an irrevocable election on initial recognition to present gains and losses on investments in equity instruments that are not held for trading in other comprehensive income (instead of in profit or loss). Dividends in respect of these investments that are a return on investment can be recognised in profit or loss and there is no impairment or recycling on disposal of the instrument.
- Introduces a 'fair value through other comprehensive income' measurement category for particular simple debt instruments.
- Financial assets can be designated and measured at fair value through profit or loss at initial recognition if doing so eliminates or significantly reduces a measurement or recognition inconsistency that would arise from measuring assets or liabilities, or recognising the gains and losses on them, on different bases.

Where the fair value option is used for financial liabilities the change in fair value is to be accounted for as follows:

- the change attributable to changes in credit risk are presented in Other Comprehensive Income ('OCI'); and
- the remaining change is presented in profit or loss.

If this approach creates or enlarges an accounting mismatch in the profit or loss, the effect of the changes in credit risk are also presented in profit or loss. Otherwise, the following requirements have generally been carried forward unchanged from AASB 139 into AASB 9:

- classification and measurement of financial liabilities; and
- derecognition requirements for financial assets and liabilities.

AASB 9 requirements regarding hedge accounting represent a substantial overhaul of hedge accounting that enable entities to better reflect their risk management activities in the financial statements.

Furthermore, AASB 9 introduces a new impairment model based on expected credit losses. This model makes use of more forward-looking information and applies to all financial instruments that are subject to impairment accounting.

The adoption of the new and revised standards had minimum or no impact to the Group's financial statements.

Y) EARLY ADOPTION OF NEW ACCOUNTING STANDARDS

AASB 16 - Leases

The Group has adopted AASB 16 Leases as of 1 July 2018, but has not restated comparatives for the 2018 reporting period as permitted under the specific transition provisions in the standard.

AASB 16:

- replaces AASB 117 Leases and some lease-related Interpretations;
- requires all leases to be accounted for 'on-balance sheet' by lessees, other than short-term and low value asset leases;
- provides new guidance on the application of the definition of lease and on sale and lease back accounting;
- largely retains the existing lessor accounting requirements in AASB 117; and
- requires new and different disclosures about leases.

The adoption of this new Standard has resulted in the Group recognising a right-of-use asset of $491,477 and related lease liability of $432,518 in connection with all former operating leases except for those identified as low-value or having a remaining lease term of less than 12 months from the date of initial application.

The new Standard has been applied using the modified retrospective approach. For contracts in place prior to the date of initial application, the Group has elected to apply the definition of a lease from AASB 117 and has not applied AASB 16 to arrangements that were previously not identified as a lease under AASB 117. The Group evaluated the impact the adoption of this standard will have on its prior year consolidated financial statements. Where the Group is a lessee, AASB 16 will result in on-balance sheet recognition of its leases that are considered operating leases under AASB 117. The Group does not expect a significant impact of the adoption of AASB 16 for the prior year. The prior period has not been restated.

On transition, for leases previously accounted for as operating leases with a remaining lease term of less than 12 months and for leases of low-value assets, the Group has applied the optional exemptions to not recognise right-of-use assets but to account for the lease expense on a straight-line basis over the remaining lease term.

Z) NEW AUSTRALIAN ACCOUNTING STANDARDS ISSUED BUT NOT YET EFFECTIVE

AASB Interpretation 23 Uncertainty Over Income Tax Treatments

AASB Interpretation 23 clarifies how the recognition and measurement requirements of IAS 12 Income Taxes are applied where there is uncertainty over income tax treatments.

The entity is yet to undertake a detailed assessment of the impact of AASB Interpretation 23. However, based on the entity's preliminary assessment, the Interpretation is not expected to have a material impact on the transactions and balances recognised in the financial statements when it is first adopted for the year ended 30 June 2020.

AA) SEGMENT REPORTING

A segment is a component of the consolidated entity that earns revenues or incurs expenses whose results are regularly reviewed by the chief operating decision makers and for which discrete financial information is prepared. The consolidated entity has no operating segments within the definition of AASB 8 Operating Segments.

It has established entities in more than one geographical area. Revenues from reimbursement revenue and commercial sales are 100% earned from entities within Europe and Switzerland, which is consistent with the comparative period. The non-current assets that are not held within Australia are immaterial to the Group.

In the current financial year, 100% of the revenue from sales reimbursements under special access schemes was generated from three end users (2018: three end users). 100% of the revenue from commercial sales is from eighteen end users (2018: nineteen end users).

2. PROFIT/(LOSS) FROM CONTINUING OPERATIONS

		CONSOLIDATED ENTITY	
		2019	2018
		$	$
(A)	**REVENUES**		
	Commercial sales of goods	26,488,768	21,359,260
	Sales reimbursements	4,559,008	4,126,413
TOTAL REVENUES[1]		**31,047,776**	**25,485,673**
(B)	INTEREST INCOME		
	Interest income[2]	564,657	264,452
TOTAL INTEREST INCOME		**564,657**	**264,452**
(C)	**OTHER INCOME**		
	Gain/(loss) on restating foreign currency creditors and currencies held	886,037	423,562
	Government R&D tax incentive	-	147
	Realised net currency loss on transactions	-	62,129
TOTAL OTHER INCOME		**886,037**	**485,838**
(D)	**EXPENSES**		
	Clinical, Regulatory & Commercial overheads	2,947,764	2,575,752
	Drug formulation R&D, manufacture & distribution	2,387,770	1,733,082
	Business marketing & listing	1,501,946	1,051,125
	Regulatory (Pre & Post Marketing) & Non-clinical	1,444,358	1,622,829
	Licenses, patents and trademarks	305,419	522,135
	Clinical development	91,453	53,642
	General operations (incl Board)	5,678,257	5,712,729
	Finance cost	21,114	22,263
	Realised net currency gain on transactions	5,562	-
	Foreign currency translation losses	-	-
TOTAL EXPENSES		**14,383,643**	**13,293,557**
(E)	**PROFIT/(LOSS) BEFORE INCOME TAX INCLUDES THE FOLLOWING SPECIFIC EXPENSES**		
	Employee benefits expense	6,045,503	5,947,097
	Operating lease expense – minimum lease payments	329,955	310,667
	Share-based payments	139,936	427,635
	Amortisation of right-of-use asset	122,672	-
	Depreciation on property, plant & equipment	82,893	43,898
	Depreciation - make-good	8,599	645
	Loss on sale of property, plant and equipment	290	-

1, 2 Under AASB 15 Revenue from Contracts with Customers, Interest income previously classified under Total Revenues is now shown under Total Interest Income. Interest income for the year ended 30 June 2018 has also been re-classified.

3. INCOME TAX EXPENSE

		CONSOLIDATED ENTITY	
		2019	2018
		$	$
(A)	**INCOME TAX BENEFIT**		
	Current	4,981,578	3,882,722
	Deferred	(5,000,911)	(4,164,501)
	INCOME TAX BENEFIT	**(19,333)**	**(281,779)**
	DEFERRED TAX INCLUDED IN INCOME TAX BENEFIT COMPRISES:		
	Increase in deferred tax assets	(498,852)	(3,124,408)
	Increase in deferred tax liabilities	479,519	2,842,629
		(19,333)	**(281,779)**
(B)	**NUMERICAL**		
	PROFIT BEFORE INCOME TAX BENEFIT	**18,114,827**	**12,942,406**
	Tax at the statutory tax rates of 27.5% in 2019 and 30% in 2018	4,981,578	3,882,722
	Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
	Under provision of carried forward tax losses in previous years	1,470,102	228,836
	Share-based payments	38,482	128,291
	Non deductible entertainment	2,200	774
	Fines and Penalties	-	96
	Refundable tax offset	-	(44)
		6,492,362	**4,240,675**
	Recognition of temporary differences	57,712	1,747,139
	Adjustment for overseas subsidiary losses not brought into account	(800,599)	459,300
	Previously unrecognised tax losses now recognised	(5,768,808)	(6,728,893)
	INCOME TAX BENEFIT	**(19,333)**	**(281,779)**
	TAX LOSSES NOT RECOGNISED		
	Unused tax losses for which no deferred tax asset has been recognised	85,304,455	106,945,662
	POTENTIAL TAX BENEFIT AT 27.5% IN 2019 AND 30% IN 2018	**23,458,725**	**32,083,699**

3. INCOME TAX EXPENSE - CONTINUED

		CONSOLIDATED ENTITY	
		2019	2018
		$	$
(C)	**DEFERRED TAX ASSETS**		
	Deferred tax asset comprises temporary differences attributable to:		
	Carry forward tax losses	3,038,750	2,572,499
	Intangibles	391,263	441,212
	Provisions	121,842	152,491
	Lease liability	51,469	-
	Accrued Expenses	19,936	3,116
	Other	-	(44,910)
		3,623,260	**3,124,408**
	MOVEMENTS		
	Opening balance	3,124,408	-
	Carry forward tax losses	5,768,808	2,572,500
	Lease liability	51,469	-
	Accrued expenses	16,820	96
	Intangibles	(5,039)	81,476
	Provisions	(30,648)	(116,880)
	Deferred tax assets utilised	(5,302,558)	(4,156,394)
	Recognition of opening deferred tax assets	-	4,788,520
	Other	-	(44,910)
		3,623,260	**3,124,408**
(C)	**DEFERRED TAX LIABILITIES**		
	Deferred tax liability comprises temporary differences attributable to:		
	Intangibles	2,428	32,412
	Right-of-use asset-net	(52,125)	-
	Accrued income	(52,705)	(20,375)
	Unrealised gains/loss on loans to subsidiaries	(3,219,746)	(2,854,666)
		(3,322,148)	**(2,842,629)**
	MOVEMENTS		
	Opening balance	(2,842,629)	-
	Intangibles	(29,983)	(33,642)
	Adjustment to opening balance of unrealised gains/loss on loans to subsidiaries	(30,454)	-
	Accrued income	(32,330)	7,839
	Right-of-use asset-net	(52,125)	-
	Unrealised gains/loss on loans to subsidiaries	(334,627)	(437,561)
	Recognition of opening deferred tax liability	-	(2,379,265)
		(3,322,148)	**(2,842,629)**
NET DEFERRED TAX ASSETS		**301,112**	**281,779**

The tax rates used in this report are the corporate tax rates of 27.5% in 2019 and 30% in 2018.

4. TRADE AND OTHER RECEIVABLES

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
CURRENT		
Trade debtors	3,758,697	4,937,083
Accrued income	191,654	67,916
Sundry debtors	205,865	85,272
TOTAL	**4,156,216**	**5,090,271**

The carrying amount of receivables is a reasonable approximation of fair value.

5. INVENTORY

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
CURRENT		
Raw materials – at cost	311,839	454,257
Provision for obsolescence – raw materials	(75,106)	(147,888)
Work in progress – at cost	1,186,686	-
Finished goods – at cost	712,665	334,916
TOTAL	**2,136,084**	**641,285**

6. OTHER ASSETS

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
CURRENT		
Prepaid peptide	170,458	145,190
Other prepayments	421,058	193,872
TOTAL	**591,516**	**339,062**

7. PROPERTY, PLANT AND EQUIPMENT

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
PLANT AND EQUIPMENT		
At cost	297,589	187,032
Less: accumulated depreciation	(118,585)	(81,323)
SUB-TOTAL	**179,004**	**105,709**
FURNITURE AND FITTINGS		
At cost	131,348	125,189
Less: accumulated depreciation	(71,645)	(62,159)
SUB-TOTAL	**59,703**	**63,030**
LEASEHOLD IMPROVEMENTS		
At cost	128,282	-
Less: accumulated amortisation	(29,138)	-
SUB-TOTAL	**99,144**	**-**
TOTAL PROPERTY, PLANT AND EQUIPMENT	**337,851**	**168,739**

MOVEMENTS IN CARRYING AMOUNTS - PROPERTY, PLANT AND EQUIPMENT

Movements in the carrying amounts for each class of property, plant and equipment between the beginning and the end of the financial year.

	CONSOLIDATED ENTITY			
	PLANT AND EQUIPMENT	FURNITURE AND FITTINGS	LEASEHOLD IMPROVEMENTS	TOTAL
	$	$	$	$
CARRYING AMOUNT AT 30 JUNE 2017	**56,920**	**80,421**	**-**	**137,341**
Additions	76,606	1,066	-	77,672
Disposals	(2,750)	-	-	(2,750)
Depreciation written back on disposal	626	-	-	626
Depreciations expense	(25,693)	(18,457)	-	(44,150)
CARRYING AMOUNT AT 30 JUNE 2018	**105,709**	**63,030**	**-**	**168,739**
Additions	118,439	-	128,282	246,721
Disposals	(7,883)	-	-	(7,883)
Depreciation written back on disposal	1,260	-	-	1,260
Depreciations expense	(38,521)	(9,483)	(29,138)	(77,142)
Make-good	-	15,095	-	15,095
Exchange differences	-	(8,939)	-	(8,939)
CARRYING AMOUNT AT 30 JUNE 2019	**179,004**	**59,703**	**99,144**	**337,851**

8. RIGHT-OF-USE ASSET AND LEASE LIABILITIES

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
RIGHT-OF-USE ASSET		
At cost	491,477	-
Less: accumulated depreciation	(122,672)	-
TOTAL RIGHT-OF-USE ASSET	**368,805**	**-**
LEASE LIABILITIES		
Lease liabilities – Current	261,251	-
Lease liabilities – Non-current	171,267	-

The following is a reconciliation of the financial statement line items from AASB 117 to AASB 16 at 1 July 2018:

	CONSOLIDATED ENTITY		
	CARRYING AMOUNT AT 30 JUNE 2018	REMEASUREMENT	AASB 16 CARRYING AMOUNT AT 1 JULY 2018
	$	$	$
Right-of-use asset	-	491,477	491,477
Lease liabilities	-	(491,477)	(491,477)
Total	-	-	-

The adoption of AASB 16 has resulted in the Group recognising a right-of-use asset and related lease liability.

9. GOODWILL

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
GOODWILL		
At cost	185,030	185,030
Less: impairment	-	-
SUB-TOTAL	**185,030**	**185,030**

10. INTERESTS IN SUBSIDIARIES

NAME OF ENTITY	COUNTRY OF INCORPORATION	OWNERSHIP INTEREST	
		2019	2018
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%	82%
CLINUVEL EUROPE LIMITED1	Ireland	100%	-

[1] On 23 November 2018, Clinuvel Europe was incorporated.

11. TRADE AND OTHER PAYABLES

		CONSOLIDATED ENTITY	
		2019	2018
		$	$
CURRENT			
	Unsecured trade creditors	1,500,214	428,562
	Sundry creditors and accrued expenses	2,133,067	2,071,353
TOTAL		**3,633,281**	**2,499,915**
(A)	**AGGREGATE AMOUNTS PAYABLE TO:**		
	Directors and Director-related entities	420,968	464,770
(B)	**AUSTRALIAN DOLLAR EQUIVALENTS OF AMOUNTS PAYABLE IN FOREIGN CURRENCIES NOT EFFECTIVELY HEDGED AND INCLUDED IN TRADE AND SUNDRY CREDITORS:**		
	US dollars	-	-
	Euro	-	-
	British Pounds	-	-
	Swiss Francs	-	-
	Swedish Krone	-	-
	Singapore dollars	170,617	490,277
	Other	-	-
TOTAL		**170,617**	**490,277**

For an analysis of the sensitivity of trade and other payables to foreign currency risk refer to Note 21.

(C)	**TERMS AND CONDITIONS:**	
	Trade and sundry creditors are non-interest bearing and normally settled on 30 day terms.	

12. PROVISIONS

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
CURRENT		
Employee benefits	1,065,510	970,906
TOTAL	**1,065,510**	**970,906**
NON-CURRENT		
Employee benefits	2,030	3,197
Other provisions	32,180	14,611
TOTAL	**34,210**	**17,808**

MOVEMENTS IN CARRYING AMOUNTS - PROVISIONS

The carrying amounts and movements in other provisions account are as follows:

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
CARRYING AMOUNT AT 30 JUNE	**14,611**	**14,168**
Provisions made during the year	-	-
Unwind of discount	17,569	443
CARRYING AMOUNT AT 30 JUNE	**32,180**	**14,611**

13. CONTRIBUTED EQUITY

(A) ISSUED AND PAID UP CAPITAL

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
48,960,633 fully paid ordinary shares (2018: 47,824,427)	151,314,175	148,614,908

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			
	2019		2018	
	NO.	$	NO.	$
AT THE BEGINNING OF THE FINANCIAL YEAR	**47,824,427**	**148,614,908**	**47,735,227**	**148,413,095**
Issued during the year	33,559	367,205	-	-
Conditional rights issued and transferred from conditional rights reserve	1,102,647	2,332,062	89,200	201,813
Less: transaction costs	-	-	-	-
BALANCE AT THE END OF THE FINANCIAL YEAR	**48,960,633**	**151,314,175**	**47,824,427**	**148,614,908**

(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 CONDITIONAL RIGHTS**
Upon achievement of various performance milestones	Nil$	1,102,647
As at 30 June 2019 the following conditional performance rights existed which if exercised, would result in the issue of fully paid ordinary shares:		
EXPIRY DATE	**EXERCISE PRICE**	**NUMBER OF CONDITIONAL RIGHTS**
Upon achievement of various performance milestones	Nil$	642,413

14. RESERVES

	CONSOLIDATED ENTITY	
	2018	2017
	$	$
CONDITIONAL PERFORMANCE RIGHTS RESERVE:		
BALANCE AT THE BEGINNING OF PERIOD	2,863,901	2,695,484
Share-based payment	139,583	427,635
Transfer to share capital	(2,332,062)	(201,813)
Lapsed, forfeited rights	(17,098)	(57,405)
BALANCE AT THE END OF PERIOD	654,324	2,863,901
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	618,015	124,728
Translating foreign subsidiary to current rate at reporting date	80,077	493,287
BALANCE AT THE END OF PERIOD	698,092	618,015
TOTAL RESERVES	1,352,416	3,481,916

15. LEASE COMMITMENTS

	CONSOLIDATED ENTITY
	2019
	$
OPERATING LEASE COMMITMENTS	
Non-cancellable operating leases contracted for but not capitalised under AASB 16	
(payable within one year)	128,128
TOTAL	128,128
Operating leases comprises commitments for office premises and miscellaneous equipment.	
The Group has elected not to recognise a lease liability for short term leases (leases with an expected term of 12 months or less) or for leases of low value assets. Payments made under such leases are expensed on a straight-line basis. The total short-term leases expense relating to payments not included in the measurement of the lease liability amounted to $340,130 for the year ended 30 June 2019.	

The following is a reconciliation of total operating lease commitments at 30 June 2018 (as disclosed in the financial statements to 30 June 2018) to the lease liabilities recognised at 1 July 2018:

	CONSOLIDATED ENTITY
	TOTAL
	$
TOTAL OPERATING LEASE COMMITMENTS DISCLOSED AT 30 JUNE 2018	**526,190**
Recognition exemption:	
Leases with remaining lease term of less than 12 months	(227,722)
New operating lease	202,272
Operating lease liabilities before discounting	500,740
Discounted using incremental borrowing rate	(9,263)
TOTAL LEASE LIABILITIES RECOGNISED UNDER IFRS 16 AT 1 JULY 2018	**491,477**

16. EARNINGS PER SHARE (EPS)

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
(a) Basic earnings per share (cents per share)	37.6	27.7
(a) Diluted earnings per share (cents per share)	36.6	26.7
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share	48,190,080	47,742,803
(b) Weighted average number of performance rights on issue in respect of share based payments during the year	1,410,705	1,847,841
(b) The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of diluted earnings per share	49,600,786	49,590,644
(c) The numerator used in the calculation of basic earnings per share ($)	18,134,160	13,224,185

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	
	2019	2018
	$	$
(A) RECONCILIATION OF CASH		
Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled to the related items in the balance sheet as follows:		
Cash at bank	24,438,095	16,628,038
Cash on hand	622	1,411
Deposits on call	1,160,062	5,511,118
Term deposits	28,525,000	13,975,000
Security bonds	144,979	82,884
TOTAL CASH	**54,268,758**	**36,198,451**
(B) RECONCILIATION OF CASH FLOWS FROM OPERATING ACTIVITIES WITH OPERATING PROFIT (LOSS)		
OPERATING PROFIT (LOSS) AFTER INCOME TAX	**18,134,160**	**13,224,185**
Non cash flows in operating (loss):		
Depreciation expense on property, plant & equipment	91,492	44,542
Depreciation expense on right-of-use asset	122,672	-
Exchange rate effect on foreign currencies held	(902,482)	(827,929)
Executive share option expense	139,583	427,635
Loss on sale of non-current assets	290	-
Unrealised loss on foreign exchange translation	80,077	493,287
Changes in assets and liabilities:		
(Increase)/decrease in receivables	934,055	(1,851,144)
(Increase)/decrease in inventories	(1,494,799)	600,323
(Increase)/decrease in other assets	(252,454)	(102,486)
Increase/(decrease) in payables	1,511,840	(153,304)
(Increase)/decrease in deferred tax assets	(19,333)	(281,779)
Increase/(decrease) in provisions	111,006	120,003
NET CASH USED IN OPERATING ACTIVITIES	**18,456,107**	**11,693,333**

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 2.50% (2018: 2.45%). These deposits have an average maturity date of 199 days (2018: 216 days).

18. KEY MANAGEMENT PERSONNEL

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
Short-term employee benefits	2,233,334	2,923,985
Post-employment benefits	57,546	56,582
LONG-TERM BENEFITS:		
Termination benefits		
Share-based payments	97,135	295,745
TOTAL	**2,388,015**	**3,276,312**

No loans or other transactions existed with Key Management Personnel.

19. AUDITOR'S REMUNERATION

	CONSOLIDATED ENTITY	
	2018	2017
	$	$
Amounts received or due and receivable by Grant Thornton for:		
audit services and review	2019	2018
other services	-	-
TOTAL	**97,000**	**94,500**

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 2019 is $4,370,640 (2018: $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 2019 is $11,543,280 (2018: $10,885,890).

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 2019 is $13,545,135 (2018 $12,543,948).

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 2019 is $167,417 (2018: $183,473).

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 2019 is $13,670,818 (2018: $10,036,005).

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 2019 is $1,322,247 (2018: $194,110).

Director related and Key Management Personnel transactions and entities:

There are no transactions and relationships in existence as at 30 June 2019 between Directors and the Company and its related entities.

21. SEGMENT INFORMATION

A segment is a component of the consolidated entity that earns revenues or incurs expenses whose results are regularly reviewed by the chief operating decision makers and for which discrete financial information is prepared. The consolidated entity has no operating segments within the definition of AASB 8 Operating Segments.

It has established entities in more than one geographical area. Revenues from reimbursement revenue and commercial sales are 100% earned from entities within Europe, and Switzerland which is consistent with the comparative period. The non-current assets that are not held within Australia are immaterial to the Group.

100% of the revenue from sales reimbursements under special access schemes is generated from three end users (2018: three end users). 100% of the revenue from commercial sales is from eighteen end users (2018: nineteen end users).

22. FINANCIAL INSTRUMENTS

CLINUVEL PHARMACEUTICALS LTD and consolidated entities have exposure to the following risks from its use in financial instruments:

a) Market Risk

b) Credit Risk

c) 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 2019 and as at 30 June 2018.

THE CONSOLIDATED ENTITY'S EXPOSURE TO FOREIGN CURRENCY RISK AT 30 JUNE 2018

	CONSOLIDATED ENTITY							
	2019				2018			
	CASH & CASH EQUIVALENTS	TRADE DEBTORS & OTHER ASSETS	TRADE, OTHER PAYABLES & PROVISIONS	TOTAL	CASH & CASH EQUIVALENTS	TRADE DEBTORS & OTHER ASSETS	TRADE, OTHER PAYABLES & PROVISIONS	TOTAL
USD	1,302,907	1,559	(750,678)	**553,788**	1,338,322	128	(284,361)	**1,054,089**
EUR	9,067,811	1,836,455	(395,322)	**10,508,944**	6,187,830	2,567,725	(338,398)	**8,417,157**
CHF	3,092,473	429,935	(261,878)	**3,260,530**	2,001,399	418,766	(98,142)	**2,322,023**
GBP	1,186,256	136,686	(256,041)	**1,066,901**	778,795	31,119	(227,841)	**582,073**
SGD	1,016,677	35,149	(1,211,972)	**(160,146)**	883,859	12,048	(1,323,892)	**(427,985)**

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 $1,303,471 for the year ended 30 June 2019 (2018: $983,765), 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 2019, if interest rates had changed by +/- 50 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 $235,310 higher/ lower (2018: $130,246 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 approximately twenty-two counterparties across German, Italian, Swiss, Dutch and other medical institutions who are reimbursed by government or private insurance payors.

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

C) LIQUIDITY RISK

Liquidity risk is the risk the consolidated entity will not be able to meets its financial obligations when they fall due. It is the policy of the consolidated entity to ensure there is sufficient liquidity to meet 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 2019

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
CASH AND CASH EQUIVALENTS		
Carrying amount	54,268,758	36,198,451
6 months or less	52,220,997	29,748,451
Greater than 6 months	2,047,761	6,450,000
TOTAL	**54,268,758**	**36,198,451**
OTHER FINANCIAL ASSETS (INCLUDES TRADE AND OTHER RECEIVABLES)		
Carrying amount	4,156,216	5,090,271
6 months or less	4,058,659	5,040,409
Greater than 6 months	97,557	49,862
TOTAL	**4,156,216**	**5,090,271**

CONTRACTUAL MATURITIES OF FINANCIAL LIABILITIES AS AT 30 JUNE 2019

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
TRADE AND OTHER PAYABLES		
Carrying amount	3,633,281	2,499,915
6 months or less	3,541,897	2,479,749
Greater than 6 months	91,384	20,166
TOTAL	**3,633,281**	**2,499,915**

23. EMPLOYEE BENEFITS

	CONSOLIDATED ENTITY	
	2019	2018
	$	$
THE AGGREGATE EMPLOYEE BENEFIT LIABILITY IS COMPRISED OF :		
Provision for annual leave	628,397	591,833
Provision for long service leave	439,143	382,270
Accrued FBT, payroll, superannuation, pension funds, employee insurances	1,116,203	686,256
TOTAL	2,183,743	1,660,359

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.

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.

THE FOLLOWING SHARE-BASED PAYMENT ARRANGEMENTS WERE IN EXISTENCE AT 30 JUNE 2019

PERFORMANCE RIGHTS SERIES	NUMBER	GRANT DATE	EXPIRY DATE	EXERCISE PRICE	FAIR VALUE AT GRANT DATE
Issued 25/11/2010	208,332	25/11/2010	The earlier of achievement of specific performance milestones and cessation of employment/directorship	$ Nil	$1.04
Issued 16/09/2011	263,206	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	65,000	16/11/2011	The earlier of achievement of specific performance milestones and cessation of employment/directorship	$ Nil	$0.67
Issued 17/03/2015	105,875	17/03/2015	7 years from Grant Date	$ Nil	$2.16

HOLDINGS OF ALL ISSUED CONDITIONAL PERFORMANCE RIGHTS – 2019

PERFORMANCE RIGHTS SERIES	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	EXPIRED & LAPSED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
Issued 25/11/2010	299,999	-	(91,667)	-	208,332	-	208,332
Issued 16/09/2011	375,986	-	(112,780)	-	263,206	-	263,206
Issued 16/11/2011	65,000	-	-	-	65,000	-	65,000
Issued 14/01/2013	75,000	-	(75,000)	-	-	-	-
Issued 04/12/2014	674,975	-	(674,975)	-	-	-	-
Issued 17/03/2015	254,100	-	(148,225)	-	105,875	-	105,875
Issued 05/09/2017	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.

HOLDINGS OF ALL ISSUED CONDITIONAL PERFORMANCE RIGHTS – 2018

PERFORMANCE RIGHTS SERIES	BALANCE AT START OF YEAR	GRANTED AS COMPENSATION	EXERCISED	EXPIRED & LAPSED	BALANCE AT END OF YEAR	VESTED AND EXERCISABLE	UNVESTED
Issued 25/11/2010	299,999	-	-	-	299,999	-	299,999
Issued 16/09/2011	375,986	-	-	-	375,986	-	375,986
Issued 16/11/2011	90,000	-	-	(25,000)	65,000	-	65,000
Issued 14/01/2013	75,000	-	-	-	75,000	-	75,000
Issued 04/12/2014	692,475	-	-	(17,500)	674,975	-	674,975
Issued 17/03/2015	338,800	-	(84,700)	-	254,100	-	254,100
Issued 05/09/2017	-	10,000	(4,500)	-	5,500	-	5,500
TOTAL	**1,872,260**	**10,000**	**(89,200)**	**(42,500)**	**1,750,560**	**-**	**1,750,560**
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

	CLINUVEL PHARMACEUTICALS LTD	
	2019	2018
	$	$
ASSETS		
Current assets	45,924,710	31,460,940
Non-current assets	15,200,229	11,152,447
TOTAL ASSETS	**61,124,939**	**42,613,387**
LIABILITIES		
Current liabilities	2,702,525	1,664,993
Non-current liabilities	2,030	3,197
TOTAL LIABILITIES	**2,704,555**	**1,668,190**
EQUITY		
Issued equity	151,314,175	148,614,908
Share–based payments reserve	654,324	2,863,901
Accumulated losses	(93,548,115)	(110,533,612)
TOTAL EQUITY	**58,420,384**	**40,945,197**
FINANCIAL PERFORMANCE		
Net profit (loss) for the year	17,002,595	13,972,344
Other comprehensive income	-	-
TOTAL COMPREHENSIVE INCOME	**17,002,595**	**13,972,344**

CONTINGENCIES, COMMITMENTS AND GUARANTEES

The parent entity did not have any guarantees, commitments and contingent liabilities other than already mentioned in Note 15 Lease Commitments and Note 20 Related Party Disclosures as at 30 June 2019 or 30 June 2018.

25. SUBSEQUENT EVENTS

There have not been any matters financial in nature, other than reference to the financial statements that has arisen since the end of the financial year that has affected or could significantly affect the operations of the consolidated entity, other than:

- On 28th August 2019, 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 2019 and of their 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 30 to 42 of the Directors Report comply with Section 300A of the Corporations Act 2001.

This declaration is made in accordance with a resolution of the Board of Directors. The Directors have been given the declarations by the Chief Executive Officer and Chief Financial Officer required by Section 295A of the Corporations Act 2001.

Dr. Philippe Wolgen, MBA MD

Director

Dated this 29th day of August, 2019

Collins Square, Tower 5
727 Collins Street
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Melbourne Victoria 3001

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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 2019, the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and notes to the 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 2019 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.

Grant Thornton

Key audit matters

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

Key audit matter	How our audit addressed the key audit matter
Deferred tax asset – Note 3	
Clinuvel has recognised deferred tax assets of $301,112 (2018: $281,779) 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 management's forecast of future taxable income by assessing the key underlying assumptions such as future taxable income against historic performance and market trends; • Assessing the competence and objectivity of managements tax expert used, to assist in the preparation of the valuation of the deferred tax asset; • Checking the accuracy of input data and evaluating formulas and assumptions applied in the computation of the deferred tax asset; • Utilising our 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 to the carrying value of deferred tax assets.

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 2019, 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 Group 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.

Grant Thornton

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.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 12 to 26 of the Directors' report for the year ended 30 June 2019.

In our opinion, the Remuneration Report of Clinuvel Pharmaceuticals Limited, for the year ended 30 June 2019 complies with section 300A of the *Corporations Act 2001*.

Responsibilities

The Directors of the Company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

Grant Thornton Audit Pty Ltd
Chartered Accountants

B A Mackenzie
Partner – Audit & Assurance

Melbourne, 28 August 2019

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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 (Client name) for the year ended 30 June 2019, I declare that, to the best of my knowledge and belief, there have been:

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

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

Grant Thornton Audit Pty Ltd
Chartered Accountants

B A Mackenzie
Partner – Audit & Assurance

Melbourne, 28 August 2019

SHAREHOLDER INFORMATION AS AT 30 SEPTEMBER 2019

Additional information as at 30 September 2019 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	2,913	954,432	1.95
1,001-5,000	711	1,578,944	3.22
5,001-10,000	138	1,019,312	2.08
10,001-100,000	176	4,873,525	9.95
100,001 & Over	23	40,534,420	82.79
TOTAL	**3,961**	**48,960,633**	**100.00**

B) SHAREHOLDINGS HELD IN LESS THAN MARKETABLE PARCELS

TOTAL	MINIMUM PARCEL SIZE	HOLDERS	UNITS
Minimum $ 500.00 parcel at $ 24.70 per unit	21	256	1,461

C) SUBSTANTIAL SHAREHOLDINGS

NAME	NO. ORDINARY SHARES & AMERICAN DEPOSITORY RECEIPTS
The Bank of New York Mellon Corporation[1]	5,258,643
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 7 May 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 3,191,478 quoted ordinary shares, as disclosed in a further substantial holder disclosure notice dated 13 March 2019.

[3] As disclosed in substantial holder notice dated 16 September 2013.

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 LIMITED	14,872,515	30.38
2.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	10,752,933	21.96
3.	ACN 108 768 896 PTY LTD	4,440,801	9.07
4.	ENDER 1 LLC	2,590,824	5.29
5.	CITICORP NOMINEES PTY LIMITED	1,938,171	3.96
6.	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT DRP>	856,039	1.75
7.	M BADCOCK AND P CHU SUPERANNUATION FUND PTY LTD	627,447	1.28
8.	DR MARK EDWIN BADCOCK	617,023	1.26
9.	NATIONAL NOMINEES LIMITED	472,681	0.97
10.	NATIONAL NOMINEES LIMITED <DB A/C>	471,162	0.96
11.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <EUROCLEAR BANK SA NV A/C>	470,424	0.96
12.	BNP PARIBAS NOMS PTY LTD <DRP>	461,429	0.94
13.	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	383,302	0.78
14.	MR DAVID WILLIAM TREVORROW	216,242	0.44
15.	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	200,526	0.41
16.	BNP PARIBAS NOMINEES PTY LTD <AGENCY LENDING DRP A/C>	191,992	0.39
17.	MR DAVID JOHN LEWIS	187,000	0.38
18.	RUSTY HAMMER PTY LTD <ARCHIPELAGO HOLDINGS SF A/C>	166,030	0.34
19.	MORGAN STANLEY AUSTRALIA SECURITIES (NOMINEE) PTY LIMITED <NO 1 ACCOUNT>	141,862	0.29
20.	MR SIMON JOHN BOWN	139,000	0.28
TOTALS: TOP 20 HOLDERS OF ORDINARY FULLY PAID SHARES (TOTAL)		40,197,403	82.10
TOTAL REMAINING HOLDERS BALANCE		8,763,230	17.90

2. COMPANY SECRETARY

The name of the Company Secretary is:
Darren Keamy

3. REGISTERED OFFICE

The principle registered office in Australia is:

Level 11, 535 Bourke Street
Melbourne, VIC 3000, Australia
Telephone: +61 3 9660 4900
Fax: +61 3 9660 4999
Email: mail@clinuvel.com
Website: http://www.clinuvel.com

4. REGISTER OF SECURITIES

Computershare Investor Services Pty Ltd
Yarra Falls, 453 Johnston St, Abbotsford, VIC 3067, Australia
Telephone: +61 3 9415 4000

5. AUSTRALIAN SECURITIES EXCHANGE LIMITED

Quotation has been granted for all the ordinary shares on all Member Exchanges of the Australian Securities Exchange Limited (ASX):

(ASX: CUV).

The Company's shares are also traded on XETRA, an electronic trading system, based in Frankfurt, Germany, under the code UR9.

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

6. RESTRICTED SECURITIES

Restricted securities on issue at June 30 2019: Nil.

7. DIRECTORY

NON-EXECUTIVE CHAIR

Stan McLiesh

NON-EXECUTIVE DIRECTORS

Brenda Shanahan, Willem Blijdorp, Dr Karen Agersborg , Susan Smith.

MANAGING DIRECTOR AND CHIEF EXECUTIVE OFFICER

Dr Philippe Wolgen

ACTING CHIEF SCIENTIFIC OFFICER

Dr Dennis Wright

CHIEF FINANCIAL OFFICER AND COMPANY SECRETARY

Darren Keamy

AUDITOR

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BANKER

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LEGAL COUNSEL

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Sidley Austin LLP
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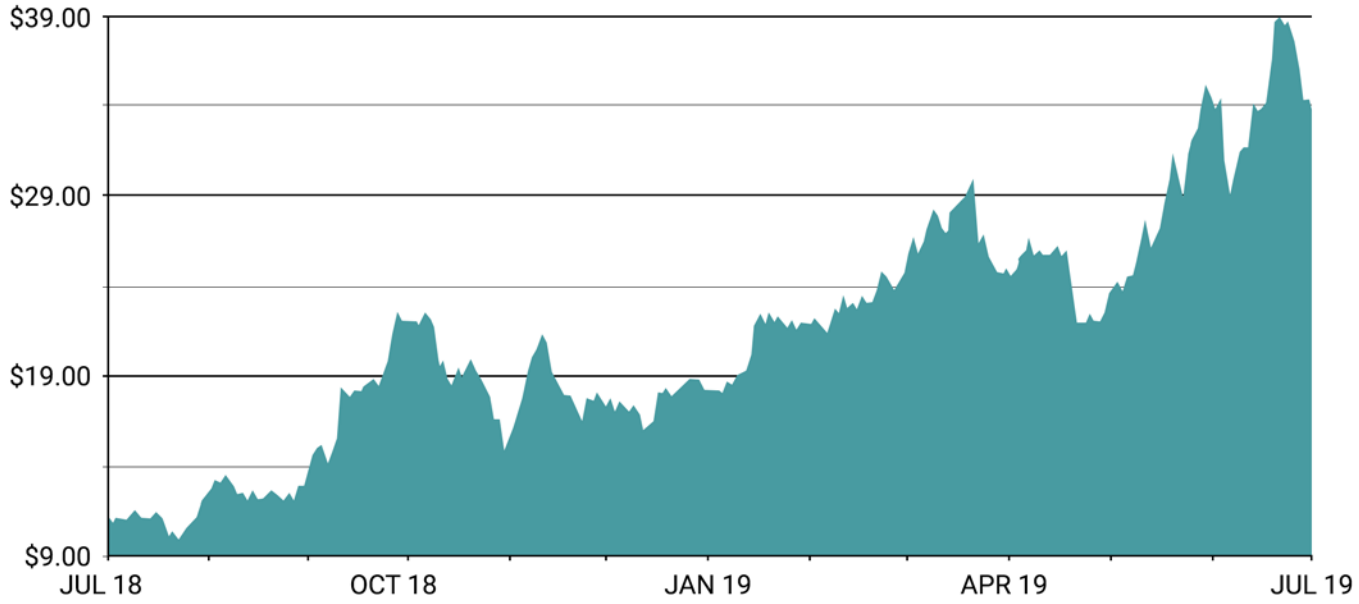
IP LAWYER

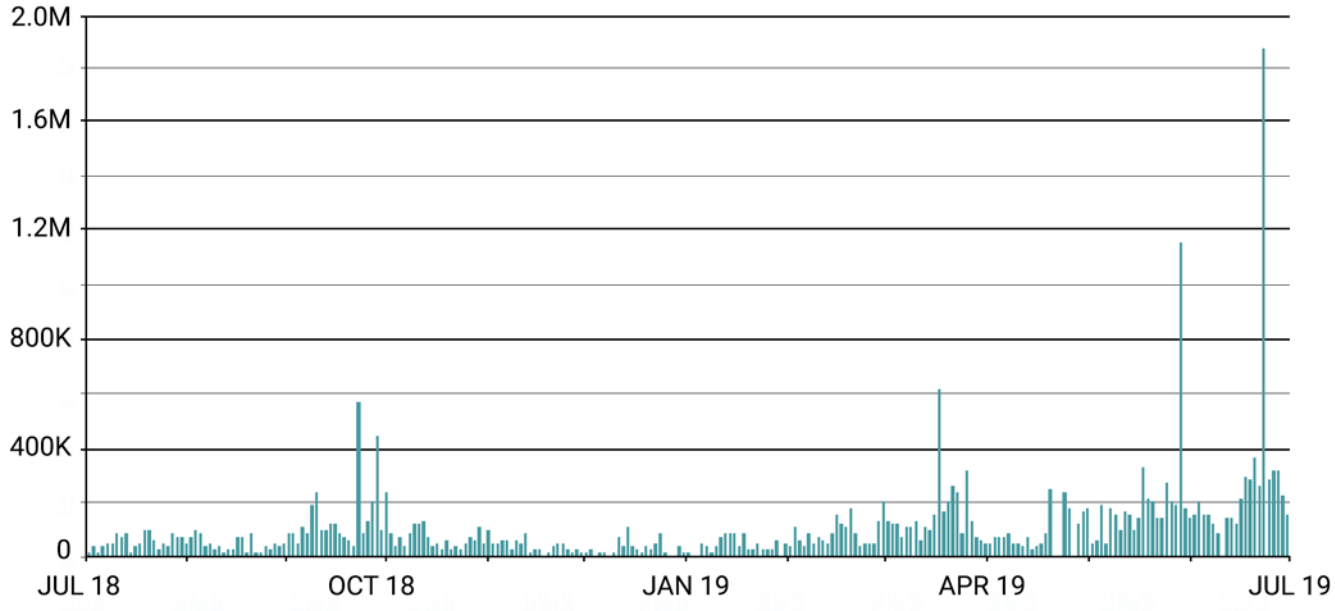
Dipl.-Ing Peter Farago
Baadestr 3, Munich 80, Germany

MARKET PERFORMANCE

SHARE PRICE - ASX:CUV



DAILY TRADING VOLUME - ASX:CUV



GLOSSARY

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

DIRECT SOLAR RADIATION
The part of extraterrestrial solar radiation which, as a collimated beam, reaches the Earth's surface after selective attenuation by the atmosphere.

EUROPEAN MEDICINES AGENCY (EMA)
The decentralised body of the European Union regulating medical drugs and devices.

ERYTHEMA (ACTINIC-SOLAR)
Reddening of the dermis (the top layer of skin), with or without inflammatory component, caused by the actinic effect of solar radiation or wavelengths of light by artificial optical radiation (source).

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.

FITZPATRICK SCALE
A numerical classification schema that classifies the response of different types of skin to UV light.

- Fitzpatrick type I - white unpigmented skin, always burns;
- Fitzpatrick type II - white unpigmented skin, usually burns;
- Fitzpatrick type III - olive pigmented skin, sometimes mild burns;
- Fitzpatrick type IV - brown pigmented skin, rarely burns;
- Fitzpatrick type V - dark brown pigmented skin, seldom burns;
- Fitzpatrick type VI - black pigmented skin, never burns.

IMMUNOCOMPROMISED
Having an immune system that has been impaired by disease or treatment, such as immunosuppressive drugs used to prevent organ rejection in transplant patients.

IMMUNOMODULATORY
Changes to the level of a person's immunity.

MARKETING AUTHORISATION APPLICATION (MAA)
A formal application to the EMA to approve a drug product or medical device for sale.

MAST CELL
A cell filled with basophil granules, found in numbers in connective tissue and releasing histamine and other substances during inflammatory and allergic reactions.

MELANIN
The dark pigment synthesised by melanocytes; responsible for skin pigmentation.

MELANOCYTES
The cells in the skin that produce melanin.

MELANOGENESIS
The process whereby melanin is produced in the body.

MINIMUM ERYTHEMA DOSE (MED)
The actinic dose that produces a just noticeable erythema on normal, non-exposed, "fair" skin. The quantity usually corresponds to a radiant exposure of monochromatic (=1 wavelength) radiation at the maximum spectral efficiency (α=295 nm) of approximately 100 J/m2.

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

NEW DRUG APPLICATION (NDA)
A formal application to the FDA to approve a drug product for sale.

OECD
The Organisation for Economic Co-operation and Development. A group of 34 member countries that discuss and develop economic and social policy. OECD members are democratic countries that support free market economies.

PHEOMELANIN
A reddish pigment, a very weak absorptive of UV radiation. It also acts as a photosensitiser (makes your skin sensitive to light), where it increases sun sensitivity and skin ageing.

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
Skin diseases onset by exposure of skin to sunlight and UV.

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.

THYMINE DIMERS
DNA changes which are characteristic of UV damage.

THERAPEUTIC GOODS ADMINISTRATION (TGA)
Australia's regulatory agency for medicinal products and devices.

ULTRAVIOLET (UV) RADIATION
Part of the electromagnetic spectrum at wavelengths below 400 nanometers, also called the invisible portion of light. There are three sub-types of UV: UVC <280 nm; UVB 280 – 320 nm; UVA 320 – 400 nm.

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

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