This briefing provides an overview of CLINUVEL encompassing the financial results for the year ending 30 June 2021.

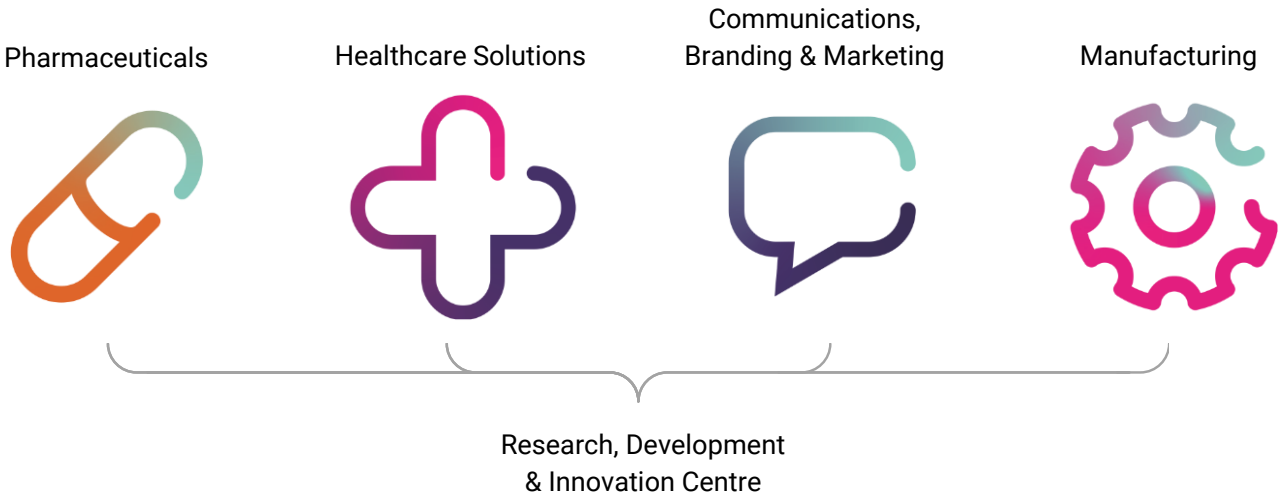
Legal Notice

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize pharmaceutical products, the COVID-19 pandemic affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe, China and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2021 Preliminary Final Report. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

Your attention is drawn to our legal notice which highlights that there are many risks that can materialise and impact the achievement of forward-looking statements contained in this briefing.

CLINUVEL GROUP

Functional divisions



The Group is headquartered in Australia with operations in Europe, Singapore, and the USA. Listed on the Australian Securities Exchange in 2001, we also trade, since 2004, on the Xetra-Dax in Germany (as UR9), and the OTC securities market in the USA as a Level One American Depositary Receipt (CLVLY).

To provide some historical perspective, **the initial phase** of the Company from formation in 1999 was marked by the acquisition of the core technology, afamelanotide, a synthetic peptide which mimics the naturally occurring alpha-melanocyte stimulating hormone (α-MSH). The peptide stimulates the production of eumelanin which provides protection from UV and visible light. The period to 2005 sought to apply the technology to develop a tanning preparation, but this more cosmetic than medicinal strategy did not garner support from medical practitioners and regulators. **The second phase** from 2005 to 2020 was focussed on drug development and commercialisation. A new management team, vision and strategy were put in place to develop and commercialise a novel drug for an unmet medical need. SCENESSE® (afamelanotide 16mg) was developed as a controlled release subcutaneous injectable implant; erythropoietic protoporphyria (EPP) was selected as the lead indication; clinical studies were completed; regulatory approvals obtained; and SCENESSE® was commercialised as the world's first systemic photoprotective. **The third, current and most exciting phase** of CLINUVEL's evolution commenced in 2021 to expand access to SCENESSE® in EPP and to translate our technology to new targeted indications and healthcare solutions for broader audiences.

To achieve this objective, the Group is organised across four Divisions:

- The Pharmaceuticals Division – CLINUVEL's core business, focussed on developing and delivering drugs for patients with unmet medical need.
- The Healthcare Solutions Division – concentrated on non-prescription products derived from the knowhow and active ingredients used in the Pharmaceuticals Division.
- The Communications, Branding & Marketing Division – prepares communications to wider differentiated audiences, positioning the Group for broader engagement.
- The Manufacturing Division – focussed on manufacturing novel formulations and products for CLINUVEL and research, development and production for other companies and research groups in the biopharmaceutical sector.

Underlying the divisional structure is the Research, Development & Innovation (RDI) Centre in Singapore, researching molecular science, biology, and follow-on formulations.

CLINUVEL GROUP

Proven Technology

- SCENESSE® (afamelanotide 16mg)
  - Synthetic peptide, mimics naturally occurring α-MSH
  - First systemic photoprotective for erythropoietic protoporphyria (EPP)
- SCENESSE® positive safety profile - over 10,000 doses
- α-MSH part of melanocortin family of peptides that bind to melanocortin receptors throughout the body
- Growing scientific recognition of melanocortins in function of key organs of the body

The Group's lead technology is SCENESSE®, the only approved treatment for erythropoietic protoporphyria (EPP), a poorly characterised, metabolic disorder, causing lifelong light intolerance. Patients suffer acute phototoxic reactions after exposure to light. Without treatment, patients must avoid exposure to light and thus lead a life of social isolation.

Afamelanotide is the active ingredient in SCENESSE® which:

- was developed as a controlled-release subcutaneous injectable implant formulation, administered in an outpatient setting;
- has been shown to reduce the incidence and severity of phototoxic reactions and increase the time EPP patients can expose to light without phototoxicity;
- is monitored in post-authorisation use in EPP patients by an extensive pharmacovigilance program; and
- has maintained a positive safety profile from over 10,000 doses to over 1,400 individuals worldwide.

α-MSH is part of a family of peptides known as melanocortins, all of which are cleaved from the precursor polypeptide proopiomelanocortin (POMC) and bind to specific melanocortin receptors throughout the body. There is growing recognition of their role in the function of key organs of the body.

The safety and potential of SCENESSE® and other melanocortins to address other unmet medical and healthcare needs is the basis of CLINUVEL's strategy to translate the technology to new indications.

SCENESSE®

Systemic photoprotection in EPP

Commercial operations established in Europe and the USA

EEA launched June 2016

- Five financial years of post-authorisation operations
- Standard of care established in EPP Expert Centres
- Study of long-term post-authorisation use confirms safety, effectiveness (Wensink et al)

USA launched April 2020

- First full year of commercial operations FY2021
- Direct distribution to network of Specialty Centers
- Patients able to receive 'all year round' treatment

We first distributed SCENESSE® for EPP in Italy in 2010 and Switzerland in 2012 under special access programs. Regulatory approval to distribute SCENESSE® in the European Union was granted by the European Medicines Agency (EMA) in 2014 and in the United States (US) by the US Food and Drug Administration (FDA) in 2019. First supply under the EMA approval followed in June 2016 and under the FDA approval in April 2020.

Distribution in Europe is through EPP Expert Centres, trained and accredited by CLINUVEL. Demand for SCENESSE® in Europe has been strong, with patient retention of 94 to 97% in the European Economic Area. COVID-19 impacted the treatment of EPP patients in March to May 2020 when a few Centres were not able to provide treatment due to priority to COVID-19 patients, and some EPP patients could not travel to get treatment. Since then, notwithstanding new waves of COVID-19 and associated restrictions, treatment has largely normalised in Europe.

In the US, we distribute largely through certified dermatologists. We have trained and accredited over 40 Specialty Centers, compared to 30 planned by the end of 2021. Treatment is under Prior Authorization which means each patient confirms insurance coverage before treatment by their Specialty Center. Additionally, Centers require confirmation from the insurer of the treatment codes to charge for the medical consultation and drug administration. A Savings Program is operating for US EPP patients working off individual Insurance Plans. The US label allows one implant every two months.

SCENESSE® was approved by the Australian Therapeutic Goods Administration (TGA) in October 2020 for the prevention of phototoxicity in adult patients with EPP and granted market access in Israel as a first line treatment for the prevention of phototoxicity in adult patients with EPP in February 2021. We are committed to facilitating treatment access to SCENESSE® for EPP patients worldwide.

Record Revenues and Profit, Controlled Expenses

FY2021 - Summary of Results

Revenues	+43%	A$48.5m
Expenses	+2%	A$22.7m
NPBT	+123%	A$25.7m
NPAT	+64%	A$24.7m
EPS	+64%	A$0.50
NTA	+41%	A$1.91

After more than a decade of research and development, CLINUVEL commenced commercial operations in June 2016 and has achieved viability through strong revenue growth and prudent management of expenditures. The first profit was recorded in 2016/17, the first full year of commercial operations. Through the prevailing adversity of the COVID-19 pandemic, CLINUVEL has remained focussed on its long-term strategy and posted a fifth consecutive profit in FY2021.

Revenues rose by 43% to a record A$48.5 million due to the near normalisation of patient demand in Europe and strong demand for treatment in the USA. Despite cost pressures on inputs to the business, total expenses were well contained in FY2021 with a 2% increase to A$22.7m; this follows a deliberate and controlled increase of 56% in FY2020 to support the expansion of the Group's activities. There were increases in costs across the business, particularly materials expenses and freight and handling expenses, partly offset by savings in several areas, such as: the cost of responding to regulatory audits; bringing communication and marketing services 'in-house'; and reduced local and international staff travel due to the COVID-19 pandemic. New expense categories are presented for FY2021 with comparisons to FY2020. Personnel related expenses account for more than half of total expenses and reflects CLINUVEL's self-reliant business model in which a range of functions are completed in-house.

The Company's research and development expenses are spread across expense categories of the business. This is because many of the research and development activities are completed in-house, aligning with CLINUVEL's integrated business model. As a guide, total research and development expenses account for around 30% of total annual expenses. This can vary year to year and reflects the essential role of research and development to support the planned expansion of medicinal and dermatocosmetic solutions to new patient groups and individuals in need.

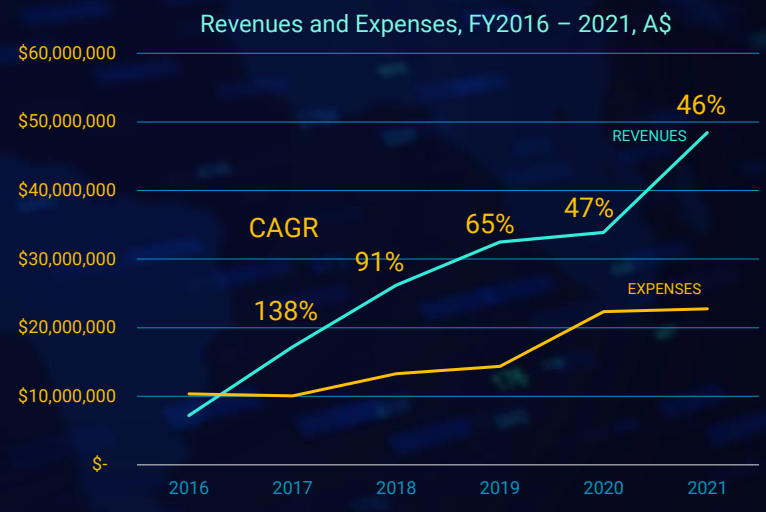
The record profit was A$25.7m before tax and A$24.7m after tax. These results reflect the disciplined implementation of CLINUVEL's long-term, focussed strategy, and the efficacy of a highly integrated business model. The resilience and sustainability of the business, particularly during the adverse global economic impact of the COVID-19 pandemic over the last 18 months, is demonstrated. The Company has a track record of positive annual cashflow and profitability, and has built cash reserves sufficient to self finance planned organic growth. This solid financial foundation, coupled with the endorsement of the safety of SCENESSE® conferred by key regulatory approvals, supports the expansion of the Company's research and development program into treatments for other indications to assist patient groups with unmet medical needs and to provide healthcare solutions to individuals who are at high risk of exposure to UV and visible light and will benefit from photoprotection and DNA repair of their skin.

CLINUVEL's success

FY2021 - growth in

- treatment centres
- patients
- prescriptions SCENESSE®

Constant rate of reinvestment



We can see the strong annual increase in revenues relative to the controlled growth in expenses over the five years of commercial operations. The CAGR of revenues is clearly strong.

In FY2021, we experienced growth in:

- treatment centres;
- patients; and
- prescriptions of SCENESSE®.

We also maintained a constant rate of reinvestment in the business.

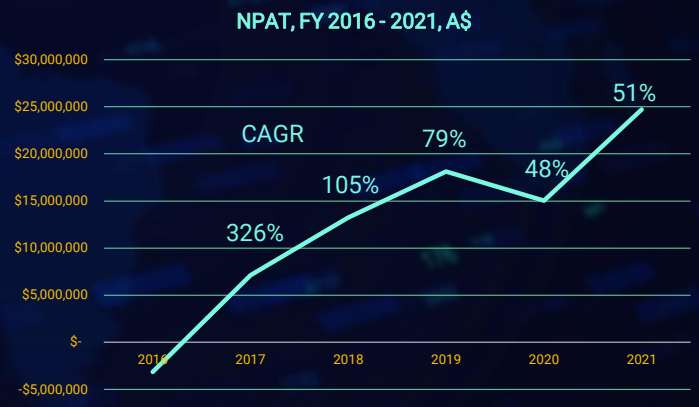
Clinical Value Translated

...to advance the trajectory... rigidity in focus, elasticity in business attitude...

1. Focus, longevity
2. Risk management
3. Cost management
4. Reinvestment
5. Preparation for cyclicality

Distinct business model:

- Equitability
- Investment in talent
- Aim for vertical integration



CLINUVEL's distinct business model has played a key role in the achievement of a strong CAGR of net profit.

Key factors in the translation of clinical value have been:

1. Focus, longevity
2. Risk management
3. Cost management
4. Reinvestment
5. Preparation for cyclicality

Clinical Value Translated

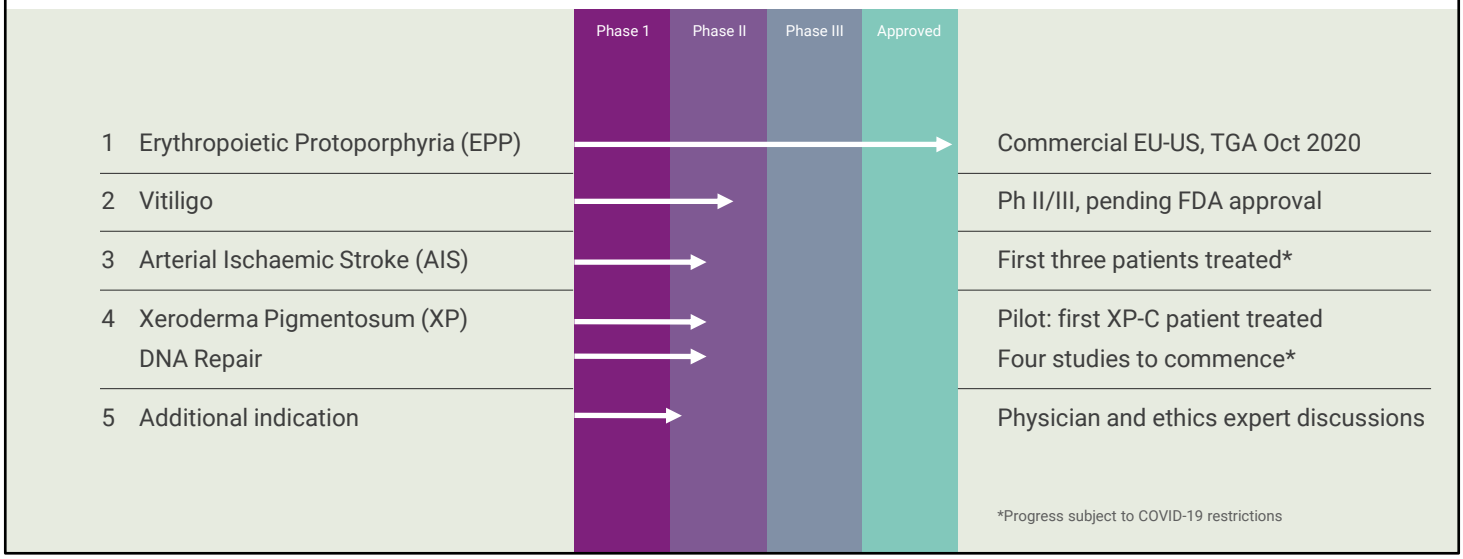
CUV Total Shareholder Return

15 Years	692 %
10 Years	1,487 %
5 Years	591 %
1 Year	28 %

Based on the median share price in the three months to 30 June in each year of comparison.

In terms of total shareholder return, the change in the share price over the past year, 5 years, 10 years and 15 years, has been commendable. This is calculated based on the change in the median three-month price to 30 June for each of the years – this provides a more meaningful series than comparison of changes on a specific date. When you consider CLINUVEL has declared a dividend in each year since FY2018, the returns to shareholders are demonstrated.

Pharmaceutical Pipeline



In the core Pharmaceuticals Division, we are working towards a portfolio of prescription products, currently targeting identified patient populations with afamelanotide. These patient groups lack therapeutic alternatives. The Company decided that future earnings and value should come from its R&D program, thus the focus is to expand from within and utilise our expertise of the pharmacology of melanocortins.

Vitiligo progression depends on agreement on final protocol with the FDA. There is consensus among our scientific team and global vitiligo experts to focus drug availability on patients with darker skin complexions. These darker skin types more prominently exhibit the contrast between pigmented and depigmented skin.

The DNA Repair Program continues, following the treatment of the first xeroderma pigmentosum (XP) patient in September 2020 with four studies set to commence.

In parallel, we recently announced the treatment of three (out of a planned six) patients in the stroke study (Phase II CUV801) and will report read outs when available.

Plans are also progressing to develop a further clinical indication.

Arterial Ischaemic Stroke

SCENESSE® Targeted Technology Translation

15 million

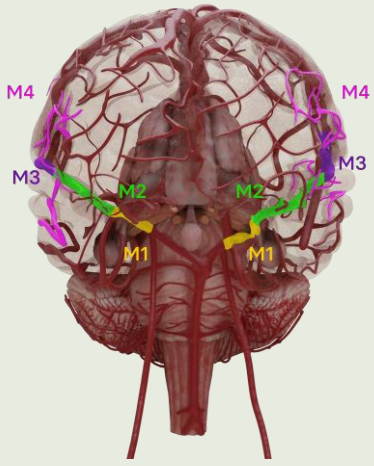
Strokes recorded annually worldwide

85%

Are ischaemic strokes

Over 80%

Not eligible for standard of care treatment[1]



CUV801 Study

Targeting afamelanotide for stroke in the higher "M2" regions of the brain with key focus on safety

[1] Cases in European hospitals not eligible for standard of care treatment (thrombectomy & thrombosis) when clots are in higher regions of the brain.

In this and the next slide, we highlight two of the clinical programs evaluating novel uses for afamelanotide.

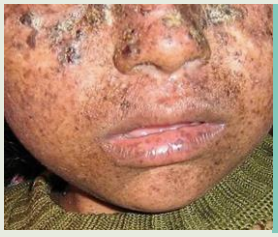
First, the potential for afamelanotide to treat arterial ischaemic stroke (AIS) patients. Tragically, many AIS patients either have lasting functional impairment or do not survive the clot that has been formed and dislodged in their brain. We understand afamelanotide may well play a role in treating ischaemic stroke by rapidly exerting its effects to protect brain tissue, acting on blood vessels to optimise blood flow, and reducing the size of swelling in the brain following a stroke. Our clinical focus is on patients with clots in the upper regions of the brain, the so-called "M2" branches and further up in the brain. Of the 15 million strokes reported each year, over 85 percent are ischaemic strokes, and a majority of these are untreatable with the current standard of care, representing a genuine unmet medical need.

The first AIS patient was treated in a world first clinical study in Melbourne in June 2021. During August 2021, we reported that three patients had tolerated afamelanotide well with no treatment related adverse events; two patients significantly improved, one showed no improvement.

DNA Repair Program

SCENESSE® Targeted Technology Translation

Over 2 billion individuals have inefficient DNA repair mechanisms



1

Highest unmet need in most severe disorder, xeroderma pigmentosum (XP)

Afamelanotide repairs DNA skin damage caused by UV radiation

2

Afamelanotide in genetic disease XP serves as model for assisting DNA repair in all populations affected and at risk of solar damage

3

First XP patient treated; safety profile maintained

Afamelanotide is understood to assist the body to repair DNA damaged by exposure of skin to ultraviolet light. CLINUVEL is now working to prove this in clinical trials.

The clinical focus of the DNA Repair Program is twofold: firstly, patients with the rare genetic disorder xeroderma pigmentosum (XP); and, secondly, healthy volunteers. Last year the first XP patient, with the XP-C complementation factor deficient, received and tolerated the treatment well. In March 2021, we expanded the program to patients with the XP-V variant. The studies are set to commence with the objectives to evaluate afamelanotide in XP-C and XP-V patients in relation to safety, the effect on the integrity of the skin, photoproducts, DNA repair and as a photoprotective drug. They involve the administration of the drug over four months, the taking of skin biopsies to assess UV damage and the administration of ultraviolent radiation to assess erythemal exposure.

Given DNA damage and the risk of skin cancer affects almost all fair-skinned individuals on the planet, the relevance of the DNA Repair Program is clear.

Healthcare Solutions Program

Dermatocosmetics

1. Translation of Technology

From the Pharmaceuticals Division to universal healthcare solutions

2. Afamelanotide and Melanocortin Molecules

Use in non-prescription products

3. Individuals at High Risk of Exposure to UV and HEV light

Individuals of fair skin, at risk due to work and lifestyle activities and organ transplant recipients

4. Dermatocosmetic Products

First for polychromatic protection, then DNA repair of the skin

The Healthcare Solutions Program will result in the release of topical products in a presently underdeveloped segment of the dermatocosmetics market. Many products promise regeneration and rejuvenation of the skin, but seldom are they based on a new class of molecules tested in human pathology over decades.

CLINUVEL's focus is to introduce leave-on products, topical formulations based on melanocortin molecules from the Pharmaceutical Division to provide photoprotection and DNA-restoration for those at high risk of long-term solar and high energy visible (HEV) light insult. These individuals have skin types highly sensitive to light, experience extensive exposure to light due to their work or lifestyle activities, or have received organ transplants. The first product line offers polychromatic protection for extreme conditions; the second product line aims to provide DNA protection and repair.

It is important to recognise that we are not disrupting an existing market, rather introducing new technology, originating from a long executed pharmaceutical program. This specific origin, scientific focus, and pharmacology itself sets CLINUVEL apart from any of the established cosmetic houses.

CLINUVEL GROUP

Summary

Record revenues and profit achieved FY2021

• Crowning five years of commercial operations

Results validate long-term strategy and business model

• Generating solid returns to shareholders

Sound position to grow and expand

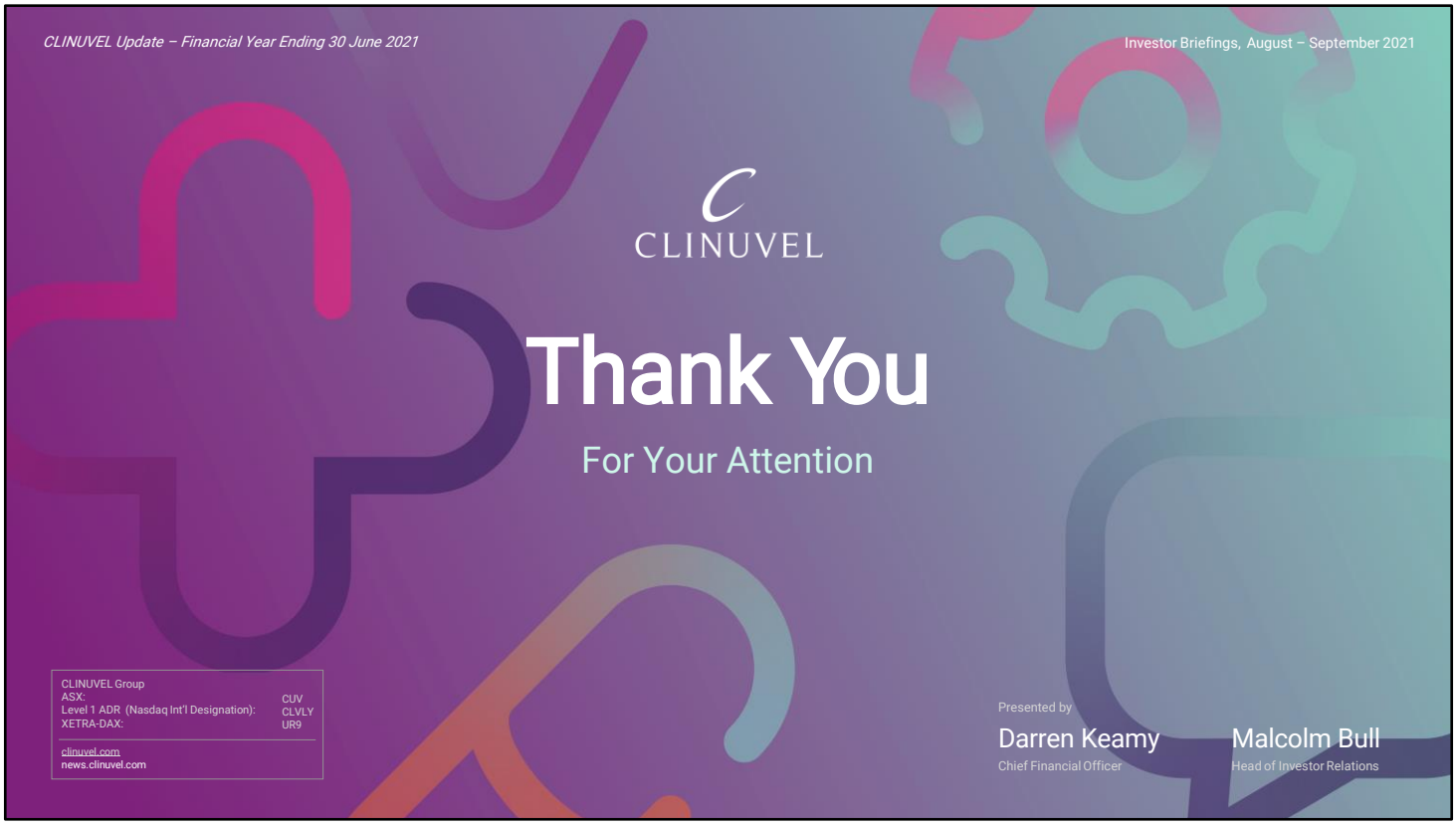
• Based on positive safety record SCENESSE®; and

• Established sustainability

EXPECT

- regular updates as we progress
- ongoing prudent management

In summary, CLINUVEL's strategy is to become a diversified healthcare business based on the dual progression of the core Pharmaceuticals Division and the new Healthcare Solutions Division. We are diversifying our R&D and translating our technology from a position of financial strength and viability, providing sound returns to shareholders. We will continue to provide ongoing news and updates on the Company's progress.



Thank you.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global and diversified healthcare company focused on delivering innovative solutions for patients with genetic, metabolic, and life-threatening disorders, as well as lifelong care products for the general population. As pioneers in photomedicine, understanding the interaction of light and human biology, and melanocortin drug development, CLINUVEL's work has delivered a world-first innovative treatment for patient populations with a clinical need for systemic photoprotection. CLINUVEL's pharmaceutical R&D programs are focused on melanocortins for use in genetic and metabolic disorders, DNA repair, and acute and life-threatening conditions. These patient groups lack therapeutic alternatives. CLINUVEL's Healthcare Solutions Division is dedicated to translating the Company's technology to deliver lifelong care products that protect and repair the skin of those at greatest risk of environmental damage. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA. For more information, please go to www.clinuvel.com.