Thank you to Jefferies for providing CLINUVEL this opportunity to tell our compelling investment story to this prestigious conference. Our story is one of focus and determination to evolve from a research and development focused company to a profitable group of companies with growing commercial operations and an active research and development pipeline. Our objective is to provide a range of pharmaceutical and healthcare solutions for patients and specific broader audiences with unmet needs, based on our leadership in the fields of photomedicine and melanocortins.

Legal Notice

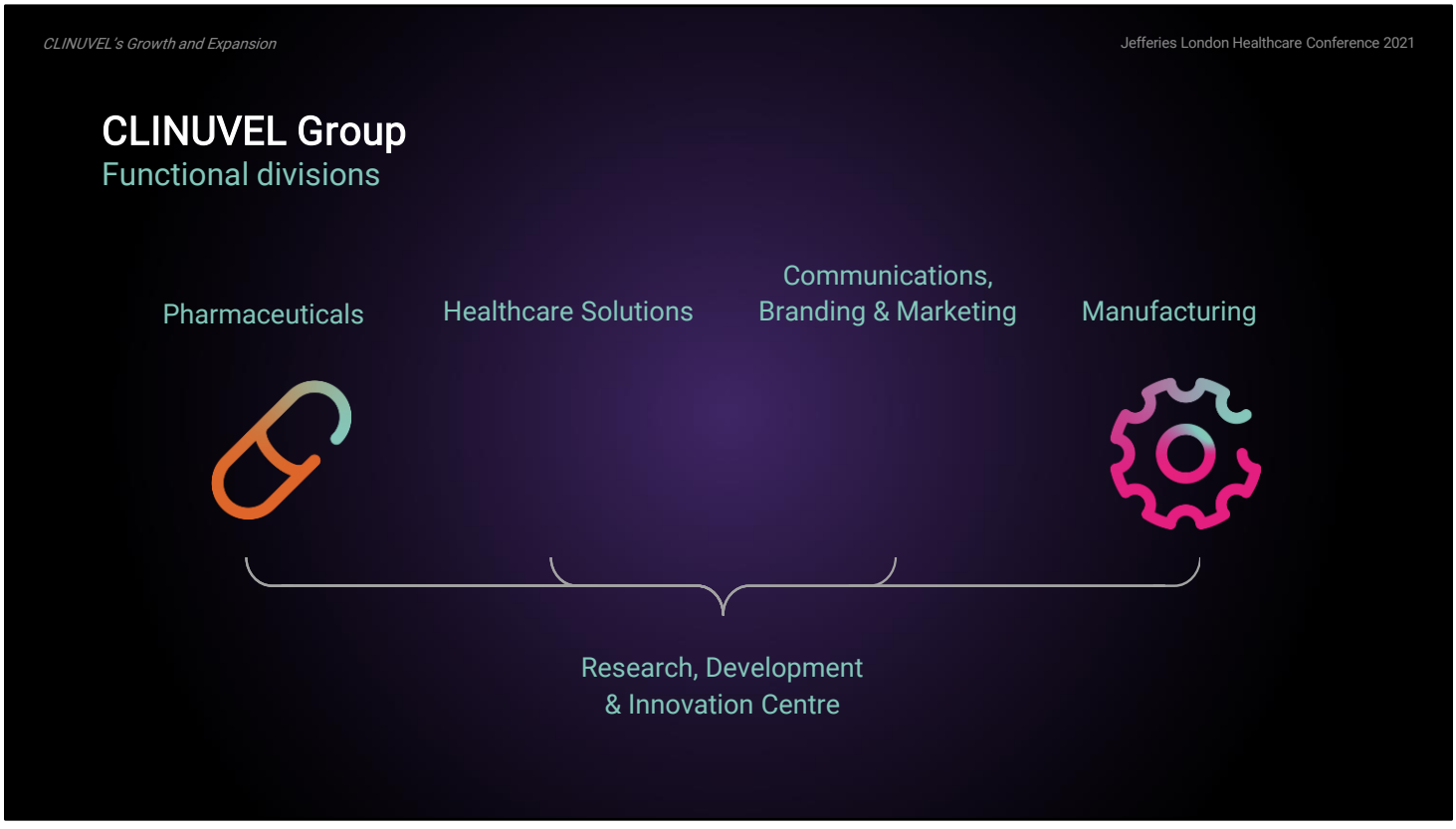
This release contains forward-looking statements, which reflect the current beliefs and intentions of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance, achievements or output to differ significantly from those expressed 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 commercialise pharmaceutical products; the COVID-19 pandemic and/or other world, regional or national events 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), PRÉNUMBRA® or NEURACTHEL®; our ability to achieve expected safety and efficacy results in a timely manner through our innovative R&D efforts; the effectiveness of our patents, trademark 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, Israel, 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®, PRÉNUMBRA® or NEURACTHEL® 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; our ability 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; risks originating from equity markets, and other factors that have been discussed in our 2021 Annual 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 material information, future events or otherwise. More information on preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that 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 is building a specialty pharmaceutical group, based on our expertise and unparalleled knowledge and experience in the development and commercialisation of melanocortins – a family of bioactive hormones which act on human tissues.

Having commercialised our first product – SCENESSE® – CLINUVEL is now establishing a **diversified, vertically integrated group of companies** which address unmet patient and healthcare needs.

People are central to our company values and to our business, and we take a specific approach towards nurturing talent and encouraging our staff to develop their careers in a safe, accountable environment.



The CLINUVEL Group is a **global enterprise**, headquartered in Australia with operations in Europe, Singapore, and the USA. Formed in 1999 and **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).

CLINUVEL's **initial phase** from formation to late 2005 was to acquire the core technology, afamelanotide with a view to develop a tanning preparation. A new management team reset the strategy for the **second phase of evolution** from 2005 to 2020 to develop and commercialise a novel drug for an unmet medical need. SCENESSE® was developed and commercialised as the world's first systemic photoprotective for the genetic disorder erythropoietic protoporphyria (EPP). In 2021, we entered the **third, current and most exciting phase** of CLINUVEL's evolution 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 – focused 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 maintained – >10,000 doses
- α-MSH part of melanocortin family of peptides binding to melanocortin receptors
- Growing scientific recognition of role of melanocortins in key organs of the body

The Group's lead technology is SCENESSE®, the only approved treatment for 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.

The **active ingredient of SCENESSE® is 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. SCENESSE®:

- was developed as a controlled-release subcutaneous injectable implant formulation, for administration 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 administered**.

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 unmet medical and healthcare needs is the basis of CLINUVEL's strategy to translate the technology for broader audiences.

SCENESSE®

Systemic photoprotection in EPP

Commercial operations established Europe and the USA

EEA launched June 2016

- Five financial years of post-authorisation operations
- Standard of care established in EPP Expert Centers
- 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 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**.

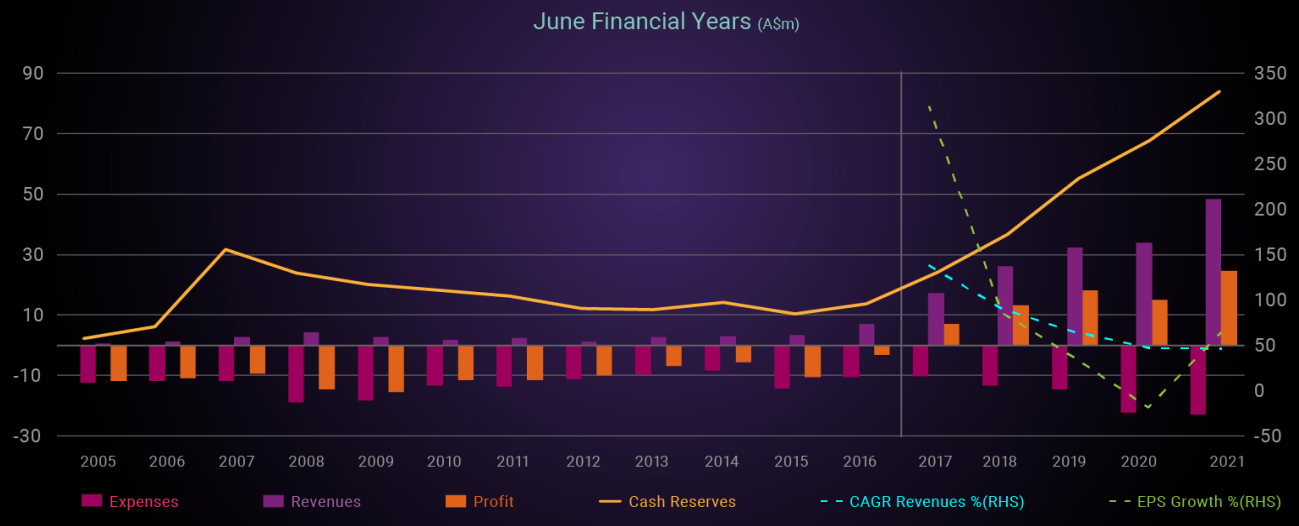
In the US, we distribute largely through certified dermatologists. We have **trained and accredited over 40 Specialty Centers**, compared to 30 planned by the end of 2021. **Over 60 national and state insurers are reimbursing the cost of treatment**, under Prior Authorization. This means each patient 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 60 days.

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

Reference: Wensink, D., Wagenmakers, M. A. E. M., Barman-Aksözen, J., Friesema, E. C. H., Wilson, J. H. P., van Rosmalen, J., & Langendonk, J. G. (2020). Association of Afamelanotide With Improved Outcomes in Patients With Erythropoietic Protoporphyria in Clinical Practice. *JAMA Dermatology*, *156*(5), 570–575. https://doi.org/10.1001/jamadermatol.2020.0352

Financial Discipline

Start commercial operations June 2016



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 FY2017, 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 annual profit in FY2021.

The profit in FY2021 was **a record A$25.7 million before tax, with a rise in revenues of 43% to A$48.5 million and a contained 2% rise in expenses to A$22.7 million,** following a deliberate and controlled increase of 56% in FY2020 to support the expansion of the Group's activities. The growth of revenues reflect the near-normalisation of sales in Europe and the growing contribution of US sales in the first full year of commercial operations.

These results reflect the disciplined implementation of CLINUVEL's long-term, focused 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, is demonstrated. The Company has a track record of positive annual cashflow and profitability. It has built cash reserves sufficient to self-finance planned organic growth and declared dividends for the last four financial years (A$0.025 in FY2021, FY2020 and FY2019 and A$0.02 in FY2018). This solid financial foundation 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 from exposure to UV and high energy visible (HEV) light.

Clinical Value Translated

…to advance the trajectory… rigidity in focus, elasticity in business …

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

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.

The translation of clinical value has been enabled by a distinct business model, particularly the equitable treatment of patients, centres, and payors, investment in the development of people, and integration of key functions of the business 'in-house', as well as:

1. Focus and longevity of management and the Board;
2. Prudent risk and cost management;
3. Constant reinvestment in the business; and
4. Preparation to manage economic cycles.

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, as this provides a more meaningful series than comparison of changes on a specific date). When you also note that CLINUVEL has declared a dividend in each of the last four years, (from FY2018 to FY2021), the returns to shareholders are demonstrated.

CLINUVEL has established strong foundations to support planned organic growth and expansion. These include:

- Ongoing commercial operations in Europe and the US which have delivered five years of positive cashflow and profits;
- A strong balance sheet with high liquidity and no debt; cash reserves are sufficient to self-finance planned organic growth;
- Proven technology and expertise; in particular, the long-term safety record of SCENESSE®;
- A motivated and committed team, with a tenacious culture;
- Strategic focus, with prudent risk and cost management; and
- A highly integrated business model.

EPP Therapeutic Landscape

SCENESSE® is the only approved treatment for EPP

- Safety profile demonstrated in EPP patients 2006 onwards
- >10,000 doses administered to EPP patients
- >25 review and research articles published, lifelong data capture
- First standard of care, multidisciplinary treatment
- Growing global network of physicians, treatment centres

Experimental treatments under evaluation

- Genetic therapies (pre-clinical, literature)
- MC1R agonists (pre-clinical and clinical stage)

"Competition whose motive is merely to compete, to drive some other fellow out, never carries very far. The competitor to be feared is one who never bothers about you at all, but goes on making his own business better all the time."

Henry Ford

Having established a viable business based on the treatment of EPP patients with SCENESSE®, we are asked about the longer-term therapeutic landscape for erythropoietic protoporphyria.

Prior to CLINUVEL's work with EPP patients there was no treatment for this metabolic disorder. CLINUVEL has spent over 15 years understanding EPP and the unique impact of this disease on patients, with a small (but growing) cohort of patients receiving continuous treatment for over 10 years through clinical trials, and then compassionate use, special access and commercial supply. The safety profile of the drug has been maintained long-term and is well recognised by EPP experts, treating physicians and the lead global regulators. Research into the use of SCENESSE® in EPP, including real-world evidence captured in Europe, has been published in leading medical journals, including the *New England Journal of Medicine*, the *Journal of the American Academy of Dermatology*, and the *British Journal of Dermatology*. Further peer-review research is currently in pre-press.

CLINUVEL has established a standard of care for EPP patients, focused on lifelong care and monitoring of patient safety and effectiveness outcomes. The European EPP Disease Registry, established by CLINUVEL for its post-authorisation program in Europe, is the largest EPP registry in the world. The Company has focused on establishing a network of committed, multidisciplinary centres to facilitate EPP patient treatment and care. CLINUVEL is now focusing on expanding patient access to treatment, including treating children with EPP.

New therapies are expected for any patient population once a standard of care has been established and an innovator establishes proof of concept. Experimental therapies currently under evaluation include gene therapies (currently in pre-clinical stages) and melanocortin-1 receptor agonists (other than afamelanotide) in various formulations and doses. The most advanced of MC1R products has only completed Phase II studies, with limited data available for review (no peer-review publications), and Phase III studies ongoing.

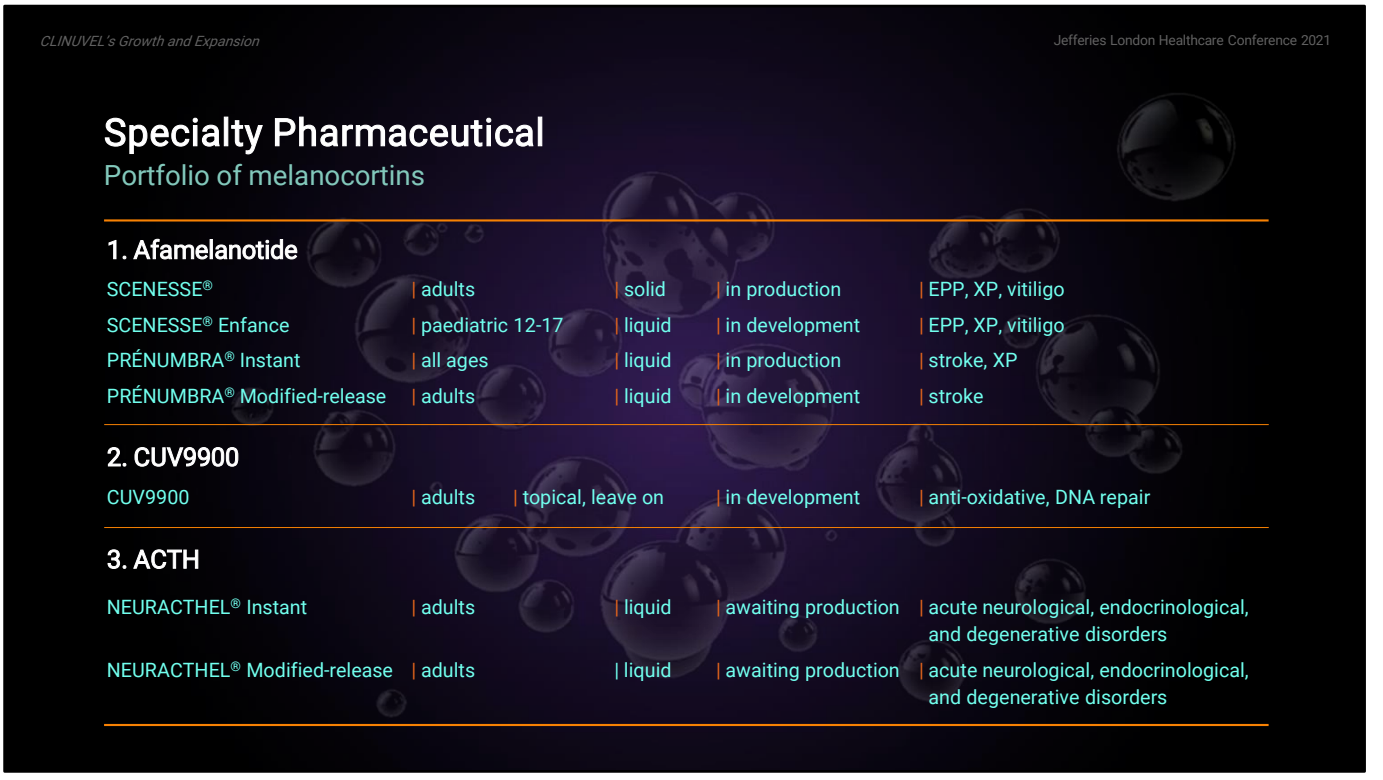
At CLINUVEL, we take the Henry Ford approach of striving to make our business better all the time. The ultimate winners from competition are the patients, who have always been our focus.

Based on these foundations, the Group is pursuing a multi-pronged strategy through the Pharmaceuticals Division and the Healthcare Solutions Division to translate its technology for targeted markets. More specifically, we aim to:

- Grow commercial operations based on the pharmaceutical drug SCENESSE® for EPP patients;
- Develop pharmaceutical products to treat a range of indications with an unmet medical need; and
- Provide non-prescription healthcare solutions to individuals in the wider population at high risk of exposure to UV and HEV light.

This strategy will build a diversified and sustainable healthcare business and serve to enhance the quality of life and well-being of many patient groups and individuals in the wider population.

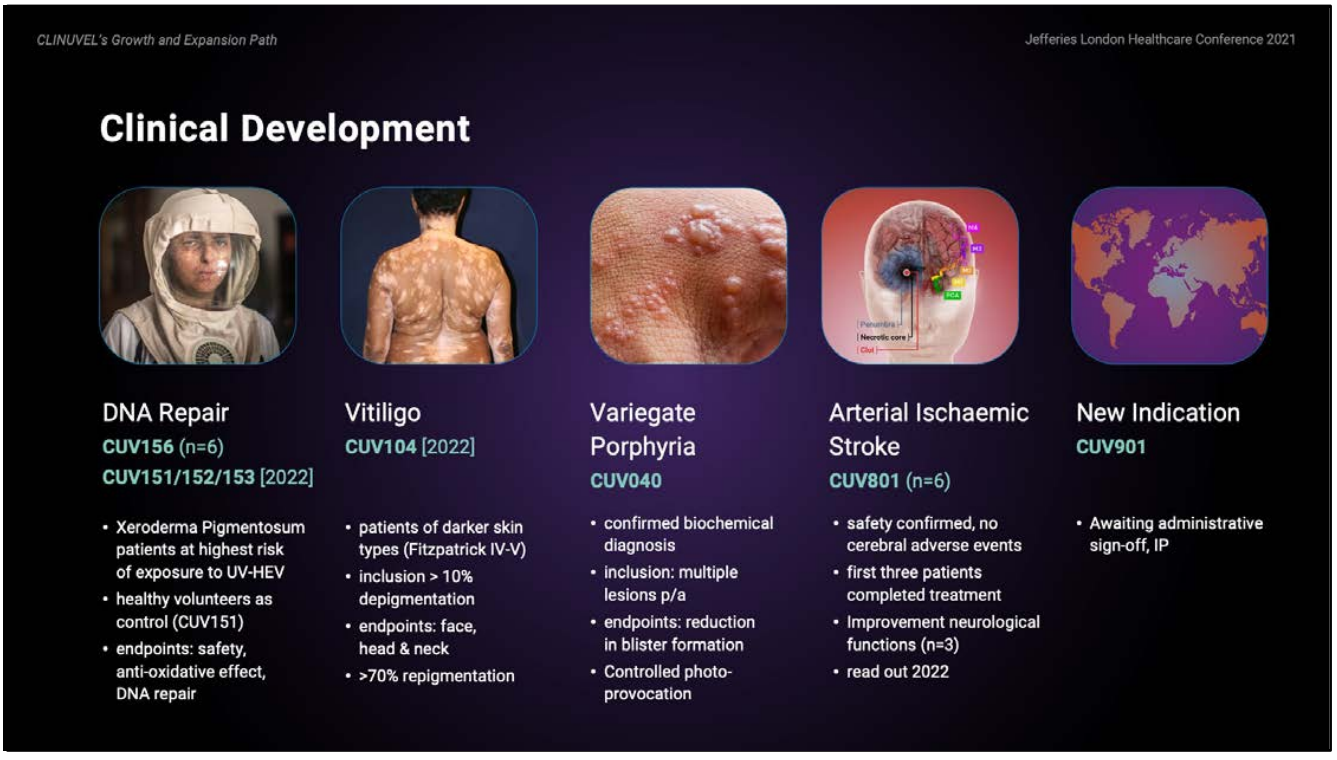
I'll now outline our pharmaceuticals and healthcare solutions programs.



In formulating its strategy to grow and expand, the Company determined that future earnings and value should come from its R&D program. Thus, our focus is to expand from within and utilise our expertise on the pharmacology of melanocortins. This specific technological knowledge and accumulated IP position form the basis of the expansion of CLINUVEL's portfolio of melanocortin formulations.

You can see in the chart the formulations of afamelanotide that have application in systemic photoprotection, repigmentation and DNA repair of the skin, and the treatment of stroke. The melanocortin formulations also extend to topical applications for the skin in photoprotection and DNA repair.

The Company's focus has enabled the addition of the ACTH analogue – to be commercialised as NEURACTHEL® - to its melanocortins stable earlier this month, with application to neurological, endocrinological and degenerative disorders. Years of preparation and decision making were needed to arrive at this stage. We will be building our 'in-house' capabilities to access new markets for the NEURACTHEL® Instant and NEURACTHEL® Modified-release formulations.



The portfolio of prescription products of the core Pharmaceuticals Division is **targeting several identified patient populations with afamelanotide**. **These patient groups lack therapeutic alternatives**.

CLINUVEL's **DNA Repair Program** is significant to **over 2 billion individuals have inefficient DNA repair mechanisms**, making them susceptible to skin cancer. Afamelanotide is understood to assist the body repair DNA damaged by exposure of the skin to UV and high energy visible (HEV) light. CLINUVEL's initial focus is on patients with the **rare genetic disorder xeroderma pigmentosum (XP) and healthy volunteers**. **The first of four studies commenced patient treatment in October 2021**, 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.

Vitiligo is a skin disorder causing lighter depigmented patches of skin in different parts of the body due to dysfunction of pigment producing cells (melanocytes). CUV has completed two Phase 2 studies – in the USA (CUV102) and Singapore (CUV103) – where pronounced clinically meaningful recurrence of pigmentation were observed following treatment with SCENESSE® in conjunction with narrowband UVB phototherapy. Supported by global vitiligo experts, CLINUVEL's focus is on people with darker skin types (Fitzpatrick scale IV-VI) because their need for repigmentation is greatest. **We are liaising with the US FDA on the design of a new study (CUV104)**. Following agreement, the drug development path follows stages of study recruitment, commencement, post study analysis, submission of a drug application, regulatory review and approval, to commercialisation.

Afamelanotide is also being assessed for treatment of **arterial ischaemic stroke** (AIS). Tragically, many AIS patients either have lasting functional impairment or do not survive the clot formed and dislodged in their brain. Of 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**. Afamelanotide's potential is to rapidly protect brain tissue, act on blood vessels to optimise blood flow, and reduce the size of swelling in the brain following a stroke. The first AIS patient was treated in a world first clinical study in Australia in June 2021. **During August 2021, we reported three patients had tolerated afamelanotide well with no treatment related adverse events**; all patients have been released from critical care.

We are also planning a study on **variegate porphyria** (VP), a related indication to EPP, and developing a new clinical indication, yet to be announced.

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 immune suppressed (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 Pharmaceuticals Division to provide photoprotection and DNA-restoration for those at high risk of long-term solar and HEV light insult. These individuals have skin types highly sensitive to light/UV; 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

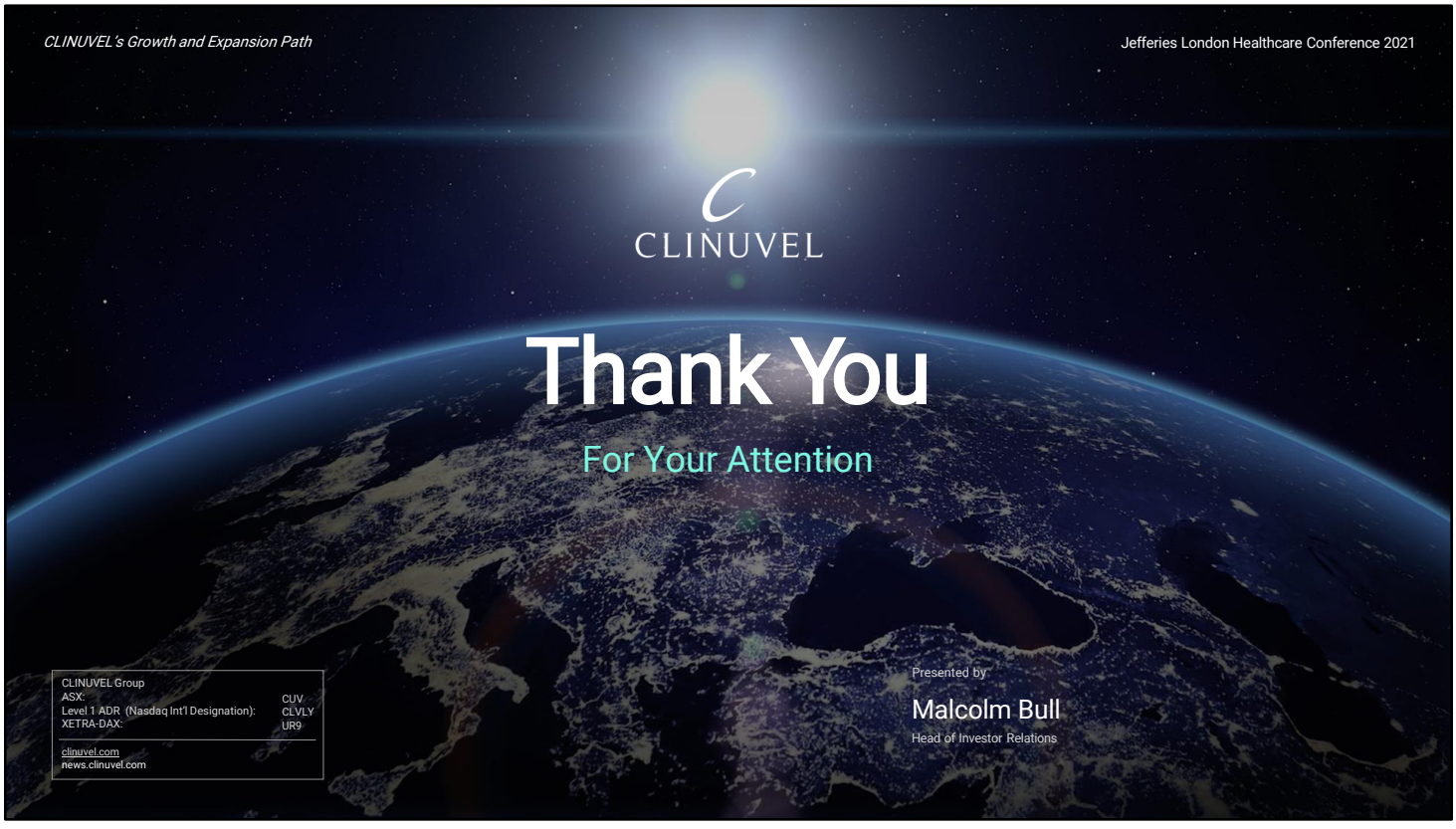
Record revenues and profit achieved FY2021
- Crowning five years of commercial operations

Results validate long-term strategy and business model
- Generating solid returns to shareholders

Strong foundations to grow and expand
- Based on positive safety record SCENESSE®
- Established sustainability

Expect
- regular updates as we progress
- ongoing prudent management

In summary, **CLINUVEL's strategy is to become a diversified and sustainable specialty pharmaceutical group** based on the progression of the core Pharmaceuticals Division and the 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 regular news and updates on the Company's progress. You can also expect our ongoing focus and prudence in the execution of our initiatives.



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 biopharmaceutical company focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair and acute or life-threatening conditions. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014, the US Food and Drug Administration in 2019 and the Australian Therapeutic Goods Administration in 2020 as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at https://www.epp.care. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to https://www.clinuvel.com.

Investor Enquiries

https://www.clinuvel.com/investors/contact-us