Thank you to the H.C. Wainwright team for the opportunity.

In January this year, we presented virtually at the H.C. Wainwright Bioconnect Conference, it is pleasing to be present in Miami in person to present our story at this prestigious conference.

The CLINUVEL story is one of determination and perseverance to evolve from a research and development focused company to a profitable group with growing commercial operations. Our objective is to provide a range of pharmaceutical solutions aided and flanked by healthcare products for patients and specific broader audiences with unmet needs. We base our leadership in the field of melanocortins, with a subspecialty in photomedicine.

Forward-looking Statements

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 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 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; 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 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 business or execution of CLINUVEL's plans, noting this presentation contains forward-looking statements.

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

The right talent is central to our company values and to our business, and we take a specific approach towards developing careers and encouraging our staff to seek further education in a safe, accountable environment.

e 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).

To achieve our objective to expand access to SCENESSE® in erythropoietic protoporphyria (EPP) and to translate our technology to new targeted indications and healthcare solutions for broader audiences, **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.

We are committed to develop the business with the expenditure of A$175m over 5 years to FY2025. We will achieve growth with profitability for future sustainability.

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 **acts as a strong anti-oxidative agent, serves as a hormone combatting fluid formation following tissue damage and stimulates the production of eumelanin to provide 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 3rd degree burns;
- 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 (such as ACTH, CUV9900) to address unmet medical and healthcare needs is the basis of CLINUVEL's strategy to translate the technology for broader audiences.

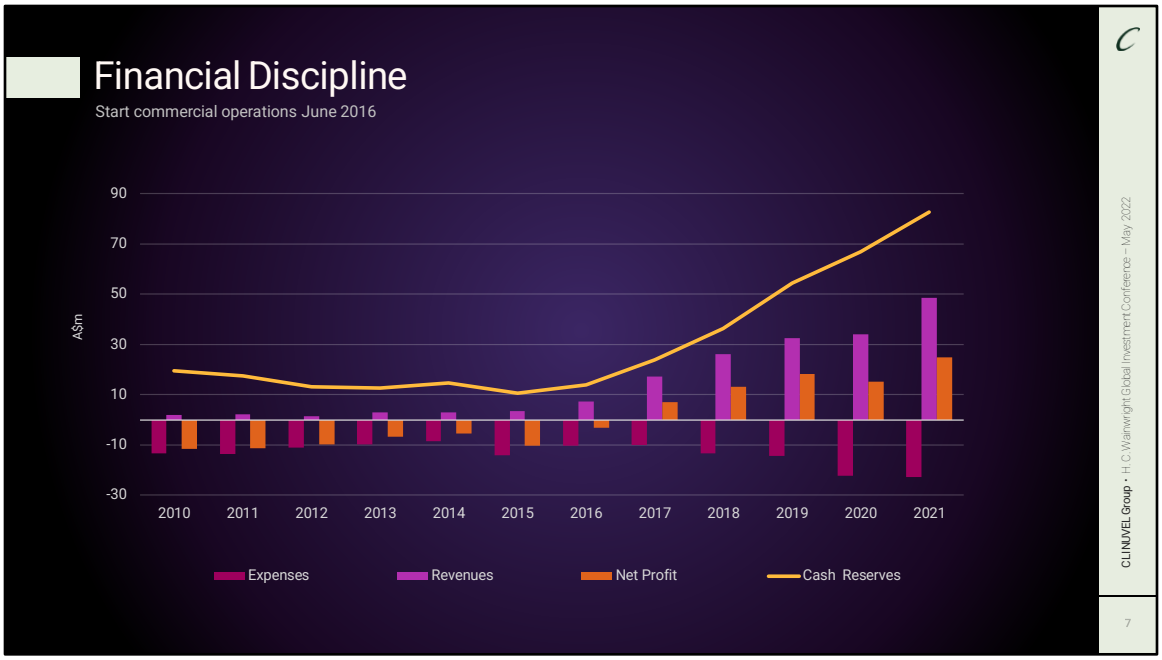
We first distributed SCENESSE® for EPP in Italy in 2010 and Switzerland in 2012 under Special Access Programs. Regulatory approval to distribute SCENESSE® in the European Union was granted by the European Medicines Agency (EMA) in 2014 and in the United States (US) by the US Food and Drug Administration (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 originally planned by the end of 2021. **Over 100 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

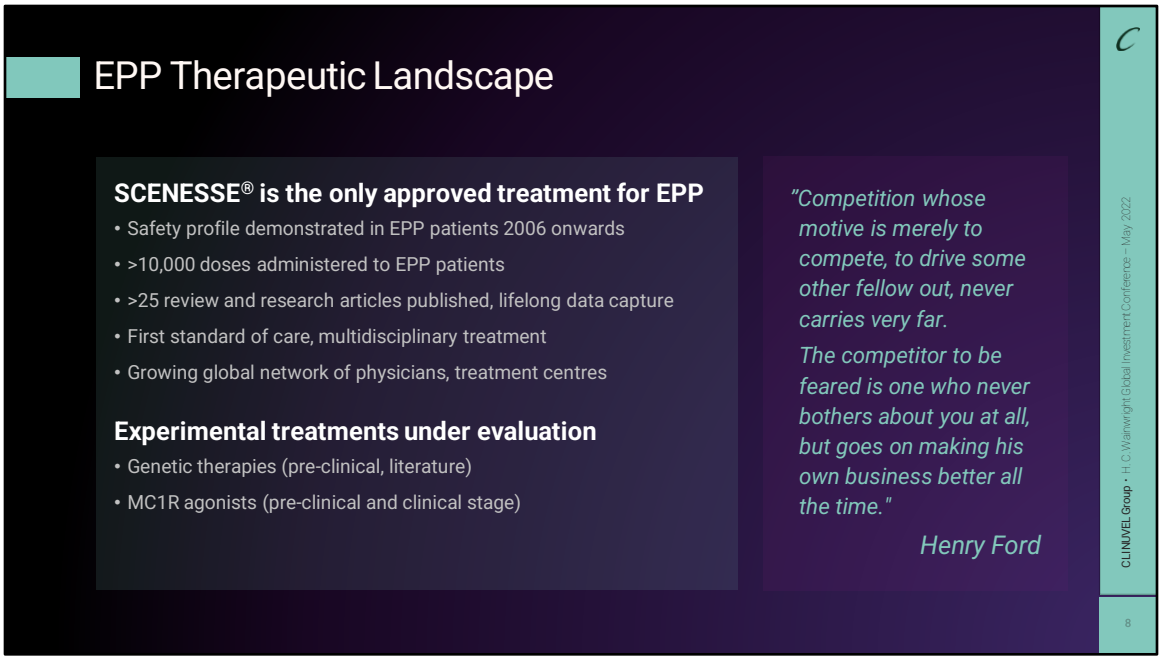


After more than a decade of research and development, CLINUVEL commenced commercial operations in June 2016 and has achieved viability through strong revenue growth and prudent management of expenditures. The Company's first profit was recorded in FY2017, the first full year of commercial operations. 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.** The growth of revenues reflect the normalisation of sales in Europe and the growing contribution of US sales in the first full year of commercial operations.

More recently, we achieved growth in revenues of 56% and growth in profit before tax of 50% in the six months to December 2021, a record for the first half of a financial year. Expenses growth was 67% compared to the first half of 2020 to support the growth and expansion of the Group. The most recent quarterly cash receipts have been similarly positive. The first three quarters of FY2022 each delivered a record level for a September, December and March quarter. The annual growth of cash receipts to the end of March 2022 was 67%.

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.



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

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*.

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 (in pre-clinical stages) and melanocortin-1 receptor (MC1R) 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.

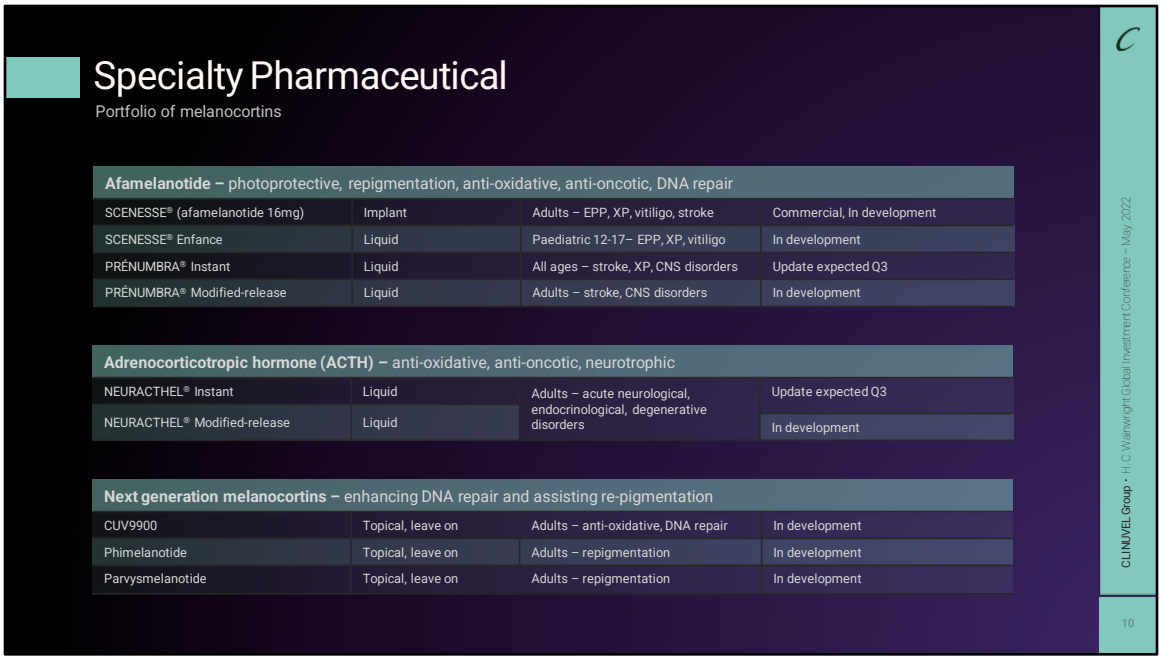
At CLINUVEL, we take the Henry Ford approach of striving to make our business better all the time. The ultimate winners from competition are the patients, who have always been our focus.

Based on the solid foundations outlined, 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 pharmaceutical 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 in November 2021, 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 because **over 2 billion individuals have some kind of photodamage following UV exposure. Global annual skin cancer incidence continues to rise**. Afamelanotide is understood to assist the repair of cellular DNA, damaged by UV/HEV exposure. CLINUVEL's initial focus is on patients with the rare genetic disorder **xeroderma pigmentosum (XP**) and disease-free volunteers. We have commenced three out of four planned studies with the objective to evaluate afamelanotide 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. In December 2021, the US FDA agreed on the design of a new study (CUV104) to assess afamelanotide as a monotherapy. The drug development path will now proceed through study recruitment, commencement, post study analysis, submission of a drug application, regulatory review and approval, through to commercialisation. CUV104 will commence shortly, during the northern hemisphere summer.

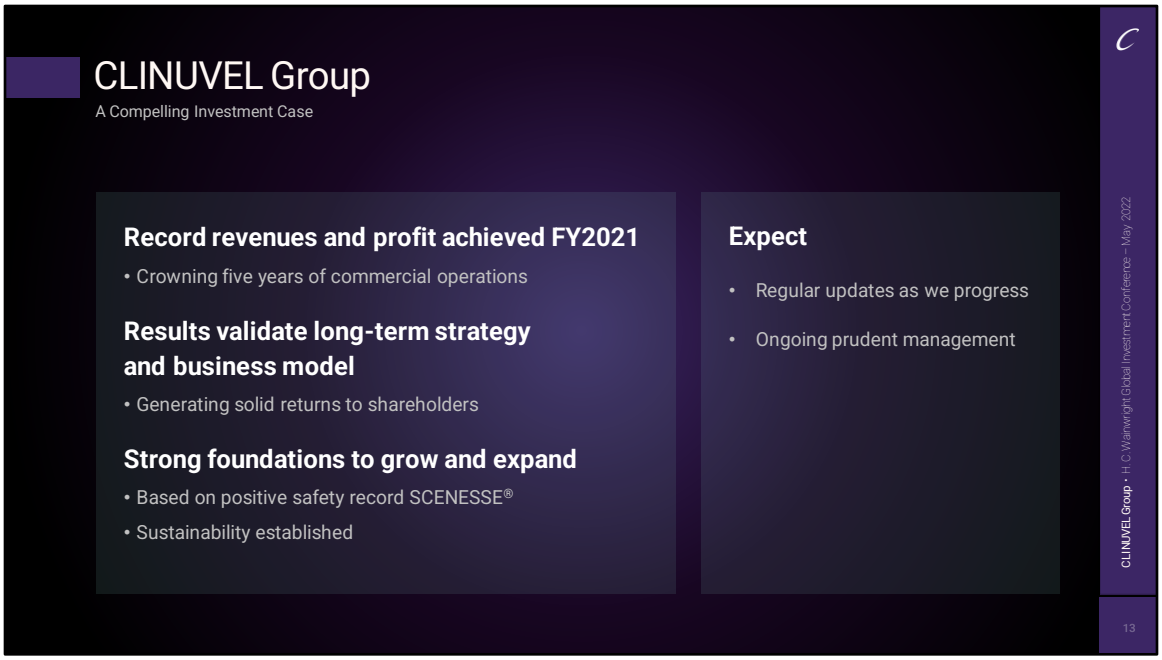
Afamelanotide is also being assessed for treatment of **arterial ischaemic stroke (AIS)**. Tragically, many AIS patients either have lasting functional impairment or do not survive the clot formed and dislodged in their brain. Of 15 million strokes reported each year, over 85 percent are ischaemic strokes, 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 (CUV801) in Australia in June 2021. This month, we reported the final results of the study whereby the safety of the drug was demonstrated with positive efficacy reflected in improved neurological functions of five of the six patients. We have also announced a second study, CUV803, will commence in the second half of 2022.

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.

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. It is also 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'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.



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. The Company has been able to navigate various financial crises without funding need, due to its risk management. Risks always remain in the sector, but our long-standing focus on business risks has led to the current strength of CUV's balance sheet.

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 (ASX: CUV; ADR LEVEL 1: CLVLY; XETRA-DAX: UR9) is a global specialty pharmaceutical group 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 the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.
CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to https://www.clinuvel.com.

SCENESSE®, PRÉNUMBRA®, and NEURACTHEL® are registered trademarks of CLINUVEL.

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