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While the world was dominated by the pandemic, the FY 2021 has been very positive for CLINUVEL’s patients continuing SCENESSE® (afamelanotide 16mg) treatment.

The performance of the Company outstripped expectations, while the Group continued to expand its activities.

Today’s address focuses on CLINUVEL’s expansion as a specialty pharmaceutical, based on specific know-how on melanocortins, a group of potent hormone analogues.

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.

The reader and audience is cautioned not to speculate or trade in CLINUVEL's securities following today's presentation material, speaking notes, discussion or comments made.

The pharmaceutical industry is known as a high-risk environment and various factors can influence the outcome of critical events.

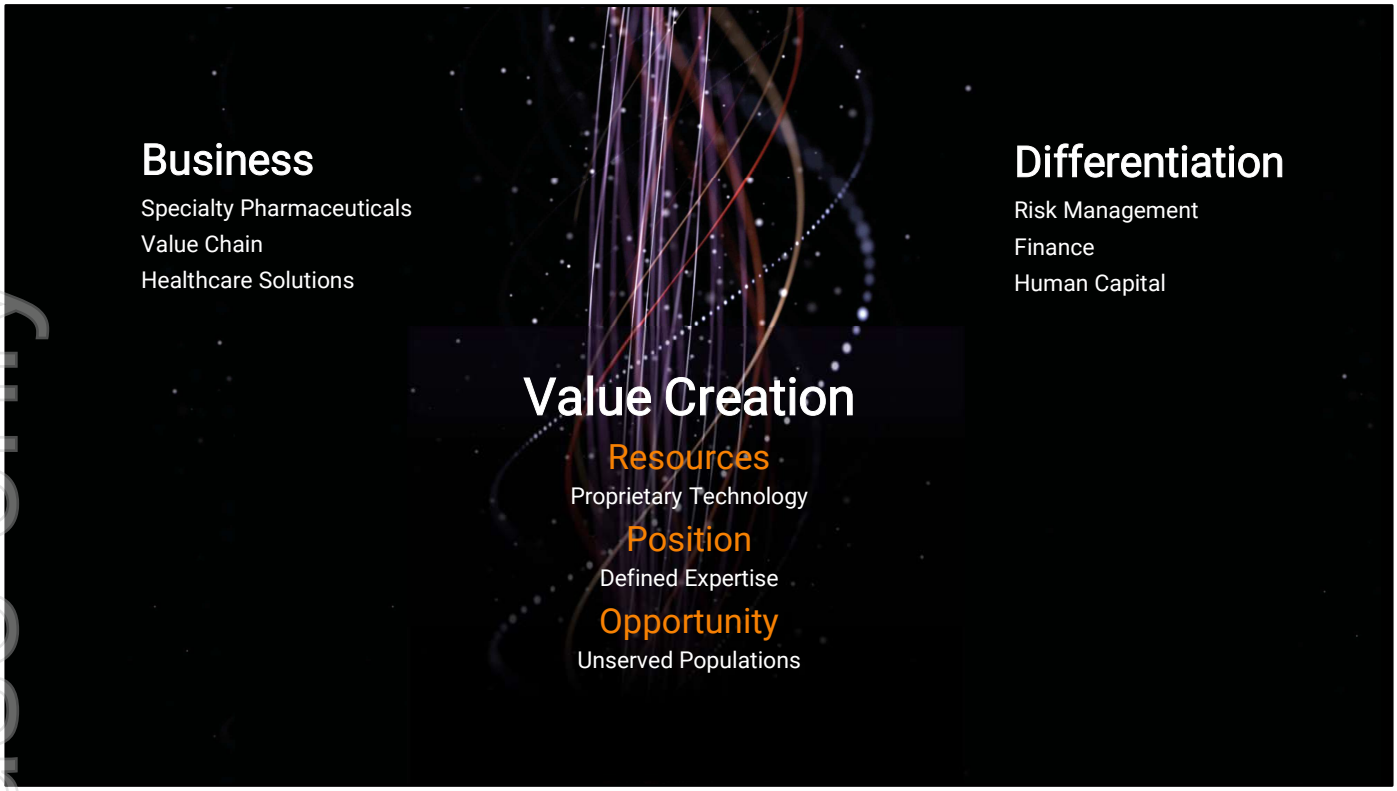
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CLINUVEL is building a specialty pharmaceutical group, based on our expertise and unparalleled knowledge and experience in the development and commercialisation of melanocortins – a family of bioactive hormones which act on human tissues.

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

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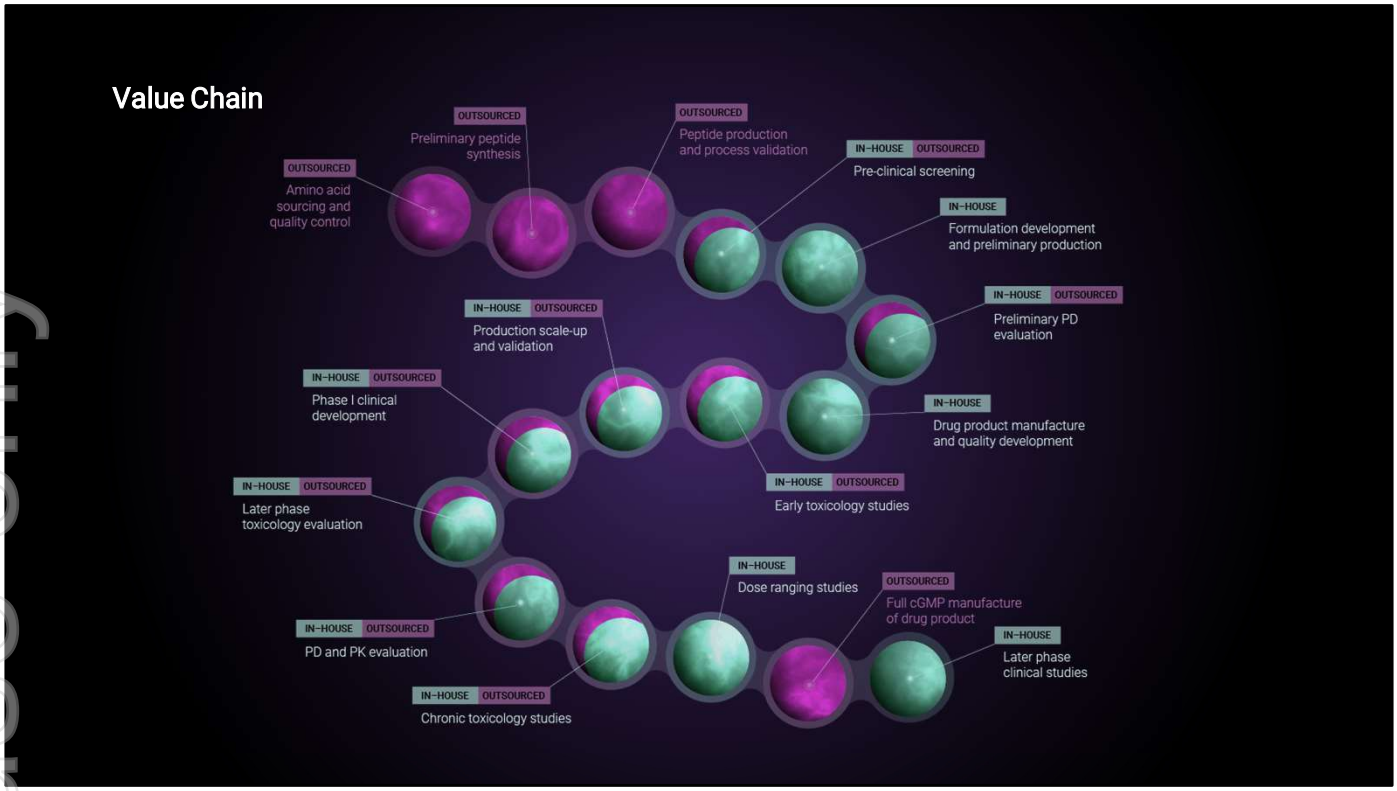


The basis of our business is found in our focused operational team, who set out to build expertise in a group of hormones and human dosage forms. The translation of knowledge and technology will eventually benefit large populations at highest risk of solar damage. In balancing its use of afamelanotide, the Company has expanded into new indications for life-threatening diseases, where need for innovation is high.

As a specialty pharmaceutical group, today we present CLINUVEL's differentiation from its peers.

Ultimately, value creation is based on the economic use of resources, the risk assessment and ability to see through a selected project over a long period of time.

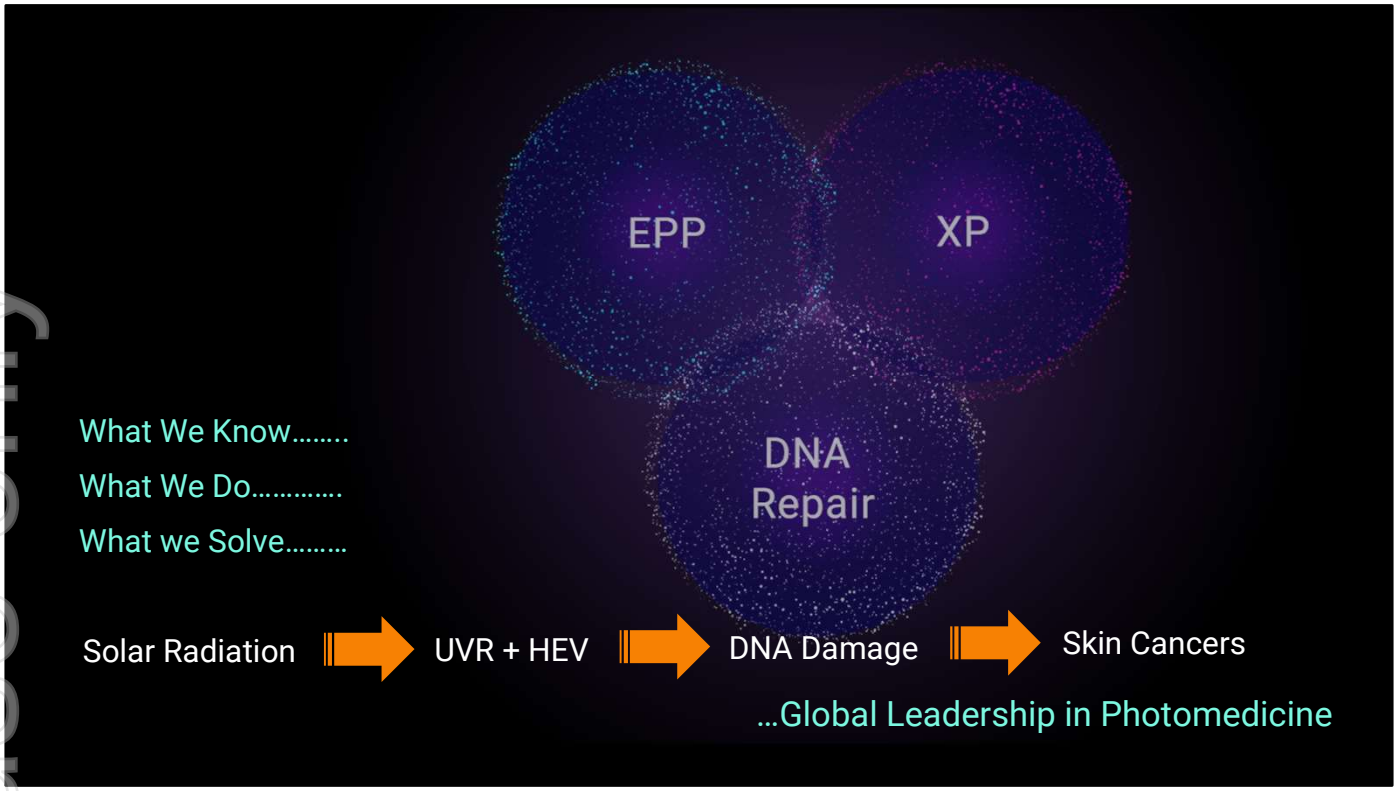
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The value chain in pharmaceuticals has become a much discussed subject. Economic conditions have urged companies to rethink the management of procurement, sourcing and supply of raw materials, all the way to product development and distribution. CLINUVEL has gradually incorporated critical parts of the value chain, starting from market access through to distribution. Management is systematically working to integrate further elements to the business.

The visual illustrates various elements which are outsourced versus those operated in-house.

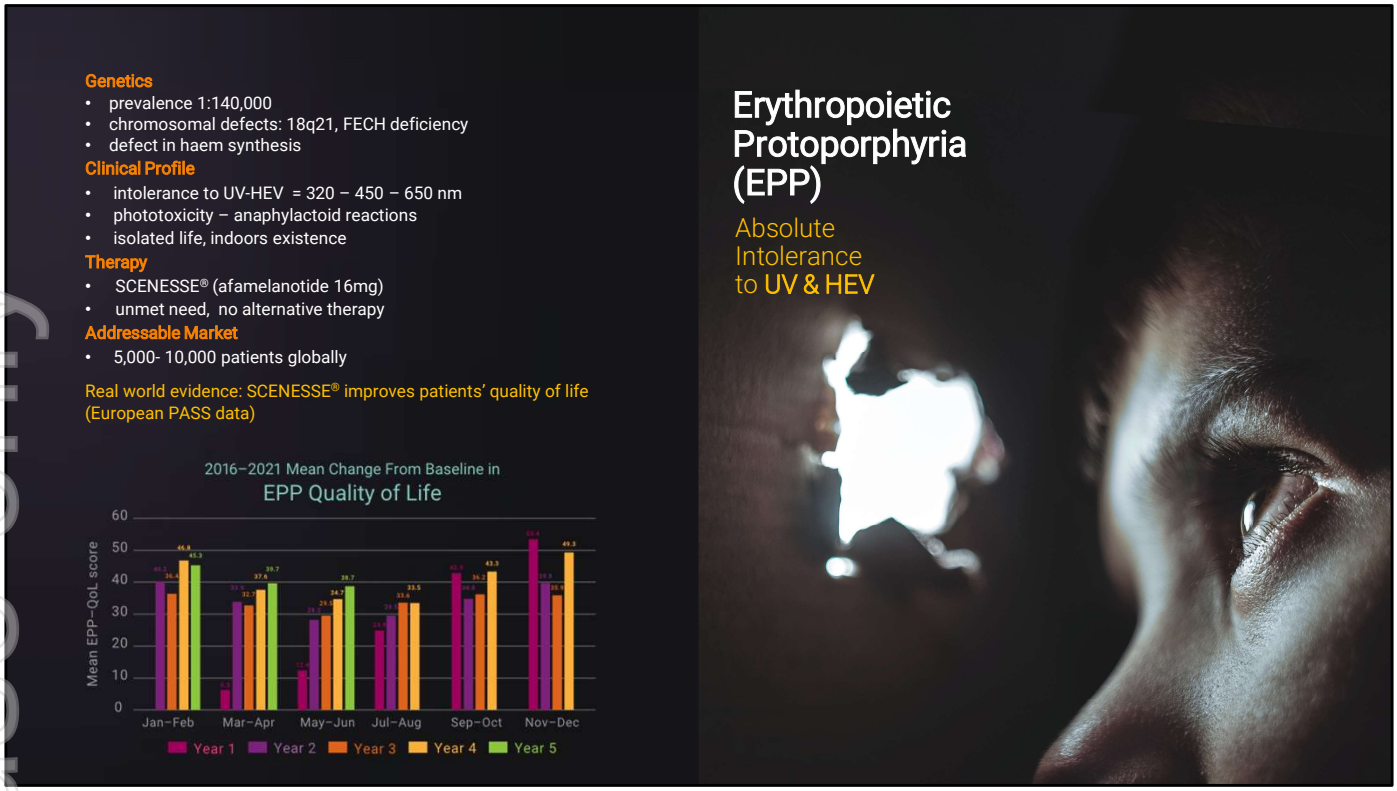
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As a specialty pharmaceutical group we develop, we learn, and we progress, all with one objective: to solve critical problems for larger populations.

In the domain of photomedicine, we solve issues at the origin of the medical problem: attenuation of UV and HEV emitted light to reduce the long-term effect of photodamage to the skin, leading (in percentages of the population) to skin cancer.

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The first part of our foray and expertise of photomedicine has been completed with the launch of SCENESSE® as the world's first systemic photoprotective drug in EPP.

CLINUVEL continues to collect real-world evidence from the use of SCENESSE® in EPP patients through post-authorisation risk management programs. Annual analyses from the European post-authorisation safety study (PASS) – which commenced in 2016 – show a consistent, positive impact of treatment intervention on patient quality of life (QoL). The chart shows patient improvement in QoL, as measured with the disease-specific EPP-QoL tool, where 0 is the worst possible QoL and 100 is the best possible QoL. Data are captured during two monthly windows and compared annually, with an improved QoL maintained across the patient cohort to date.

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The XP program is a "first" for the medical community, patient population and CLINUVEL, in attempting to reduce photodamage in XP-C and XP-V, and to assist in DNA skin repair.

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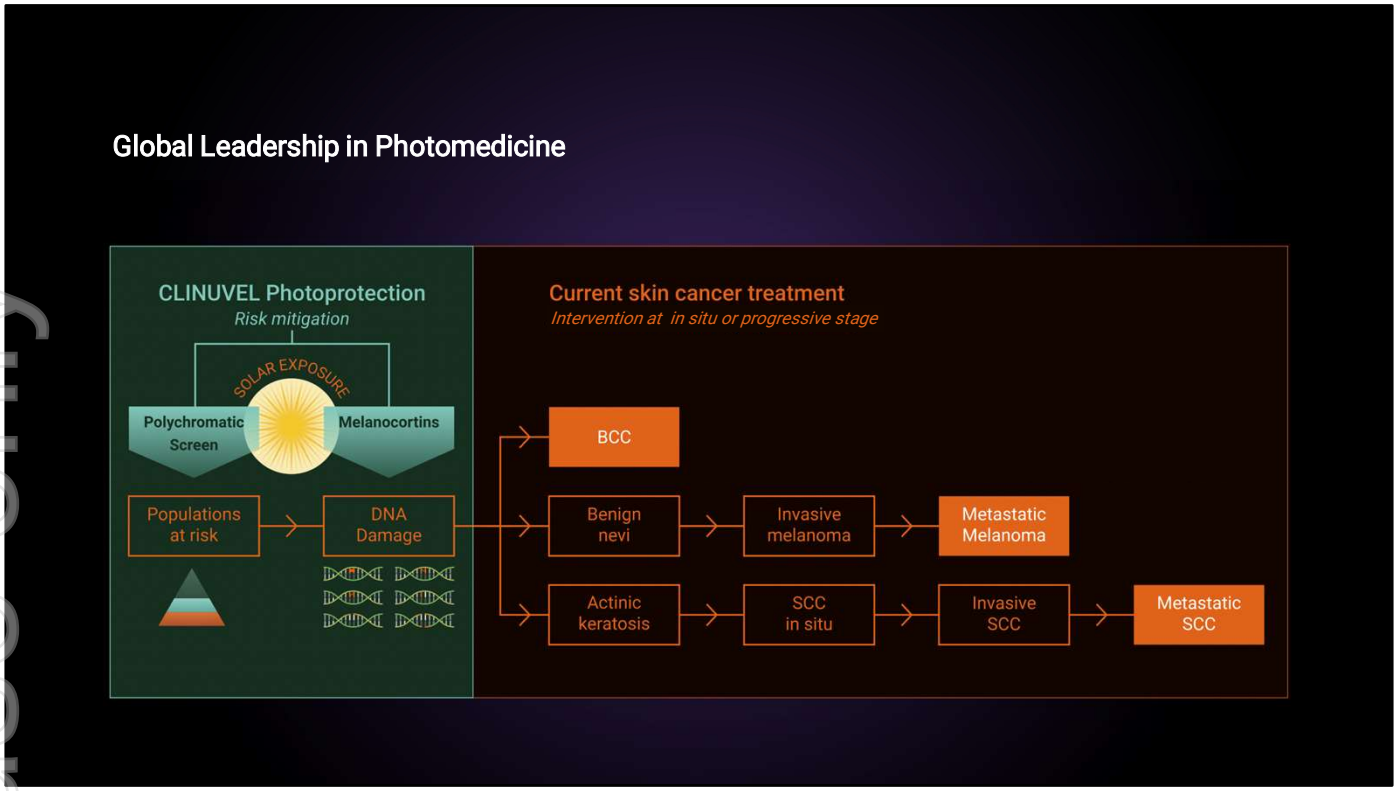


Some parts of the clinical program in XP will be conducted in parallel, and regulatory interactions will follow at each stage.

Recently, we started with the CUV156 trial, a novelty in the world, with authorities allowing – for the first time – to test XP-C patients receiving afamelanotide.

In total six patients will be evaluated as they are administered afamelanotide on safety and the drug's ability to reduce the effects of UV radiation on their fragile skin.

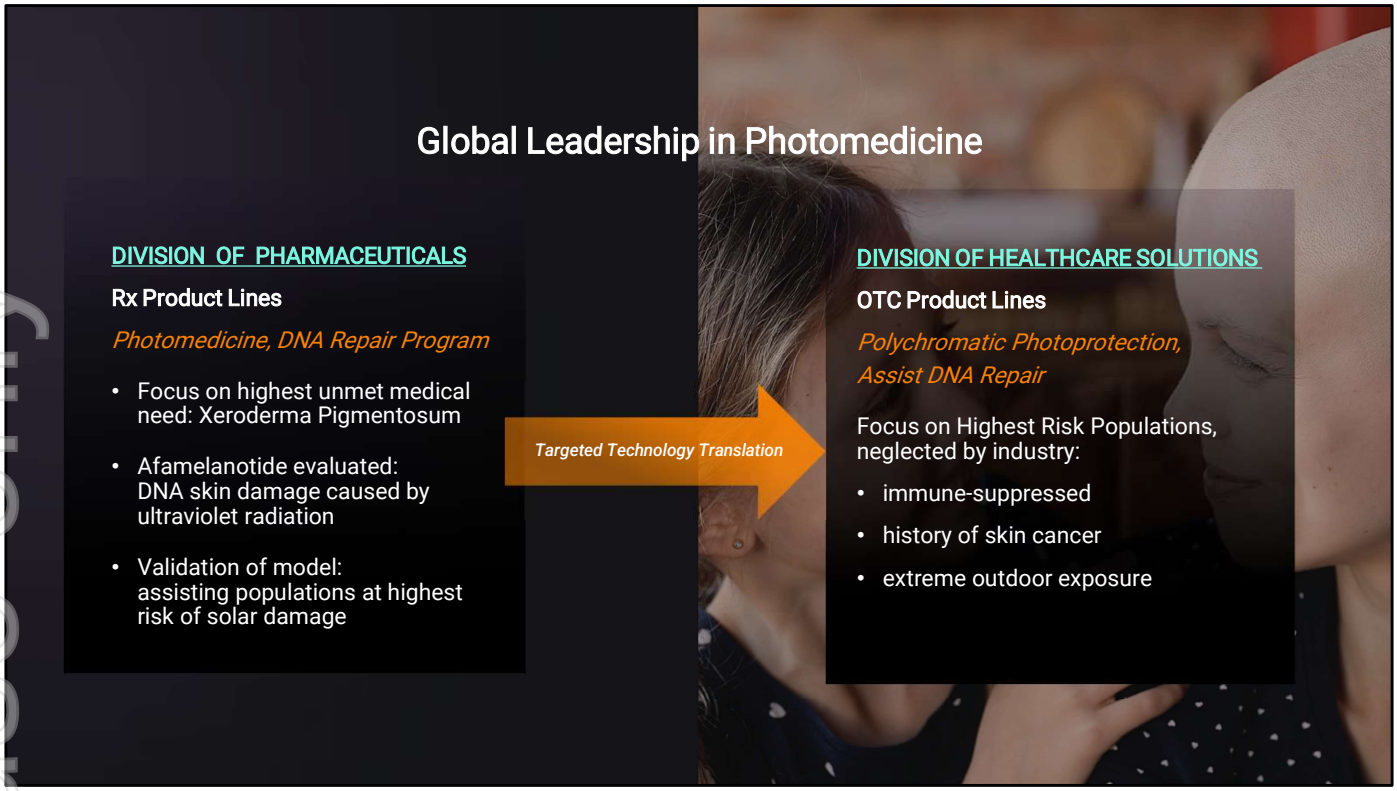
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CLINUVEL's choice is to address the risk factors before skin cells convert to a precancerous state and/or proliferate to skin cancers.

The reduction of UV and HEV damage, plus the ability to assist DNA repair, are the objectives of CLINUVEL's scientific programs.

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This illustration shows how we translate our knowledge and technology to products for wider audiences (3).

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Consistent with CLINUVEL's pioneering work in EPP and XP, we will continue to focus on unaddressed communities – the three Highest Risk Populations – with over-the-counter (OTC) product lines. The Company will be the first to establish global communities and provide up-to-date information and new products.

Sources:

[1] Global Cancer Statistics 2020: GLOBOCAN

[2] American Cancer Society (2021). Key Statistics for Basal and Squamous Cell Skin Cancers. https://www.cancer.org/cancer/basal-and-squamous-cell-skin-cancer/about/key-statistics.html. Key Statistics for Melanoma Skin Cancer. https://www.cancer.org/cancer/melanoma-skin-cancer/about/key-statistics.html

[3] 2019 Statistics: Global Observatory on Donation and Transplantation.

[4] Wehner et al (2021). Risks of Multiple Skin Cancers in Organ Transplant Recipients: A Cohort Study in 2 Administrative Data Sets. *JAMA Dermatol*. Published online 20 October 2021.

[5] American Society of Clinical Oncology (2020). Skin Cancer (Non-Melanoma): Risk Factors and Prevention. https://www.cancer.net/cancer-types/skin-cancer-non-melanoma/risk-factors-and-prevention.

[6] Wei, Li & Nan (2019). Having a first-degree relative with melanoma increases lifetime risk of melanoma, squamous cell carcinoma, and basal cell carcinoma. JAAD. 81(2): 489-99.

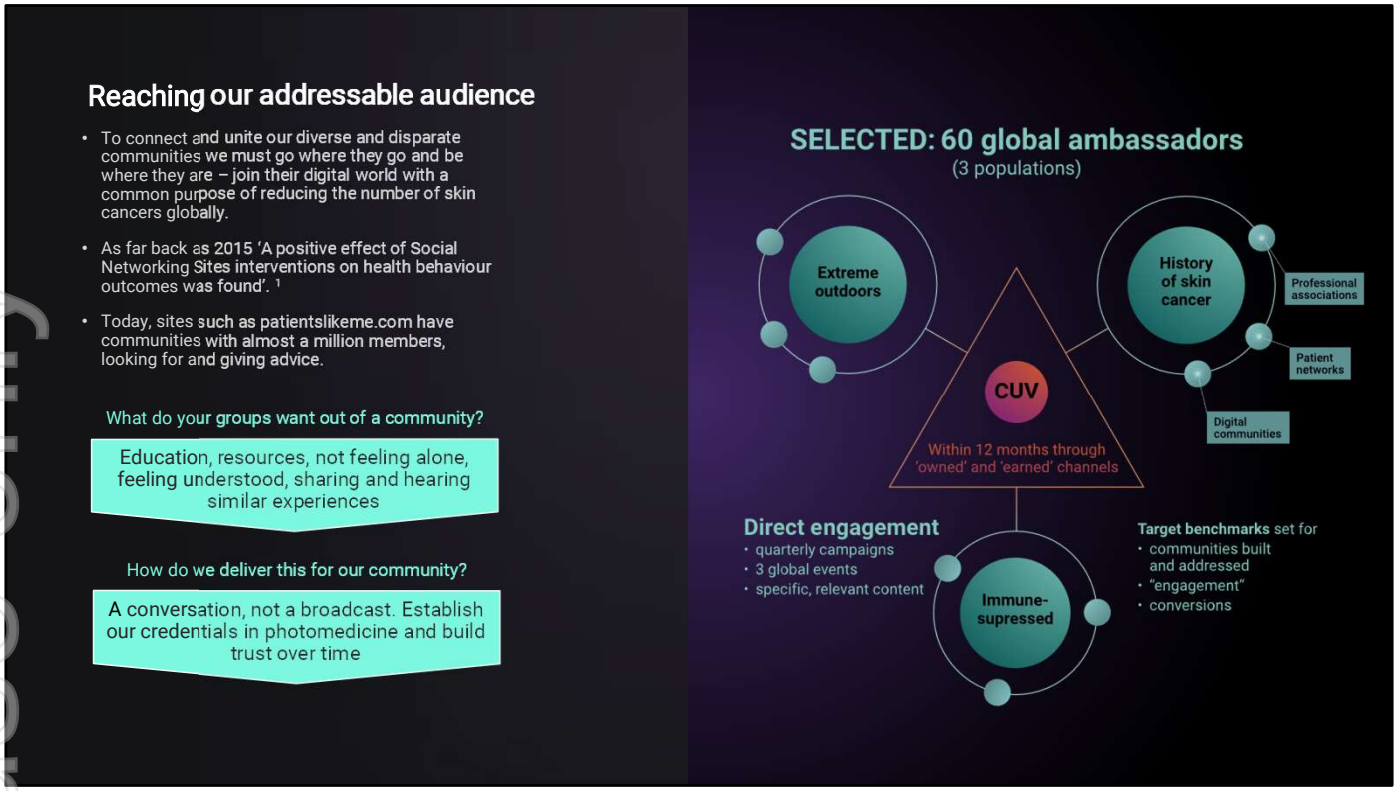
[7] Outdoor Foundation. 2021 Outdoor Participation Trends Report.

[8] RunRepeat. Marathon Statistics 2019 Worldwide. https://runrepeat.com/research-marathon-performance-across-nations.

[9] SurferToday. How many surfers are there in the world? https://www.surfertoday.com/surfing/how-many-surfers-are-there-in-the-world. Sports & Fitness Industry Association – Surfing Participation Report 2019 .

[10] Snyder et al (2020). Solar UV Exposure in Individuals Who Perform Outdoor Sport Activities. Sports Med – Open. 6(42).

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The discussion will centre around the "WHY" and "HOW" CLINUVEL will engage the three High Risk communities, whereby resources are being made available for building online platforms.

Source:

[1] Laranjo et al (2015). The influence of social networking sites on health behavior change: a systematic review and meta-analysis. *JAMIA.* 22(1):243-56

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It is illustrated how the triptych EPP – XP – Highest Risk Populations (HRP) form the basis of CLINUVEL's leadership in photomedicine.

From pharmaceuticals to wider audiences at highest need of photoprotection: a logical progression based on science and knowledge.

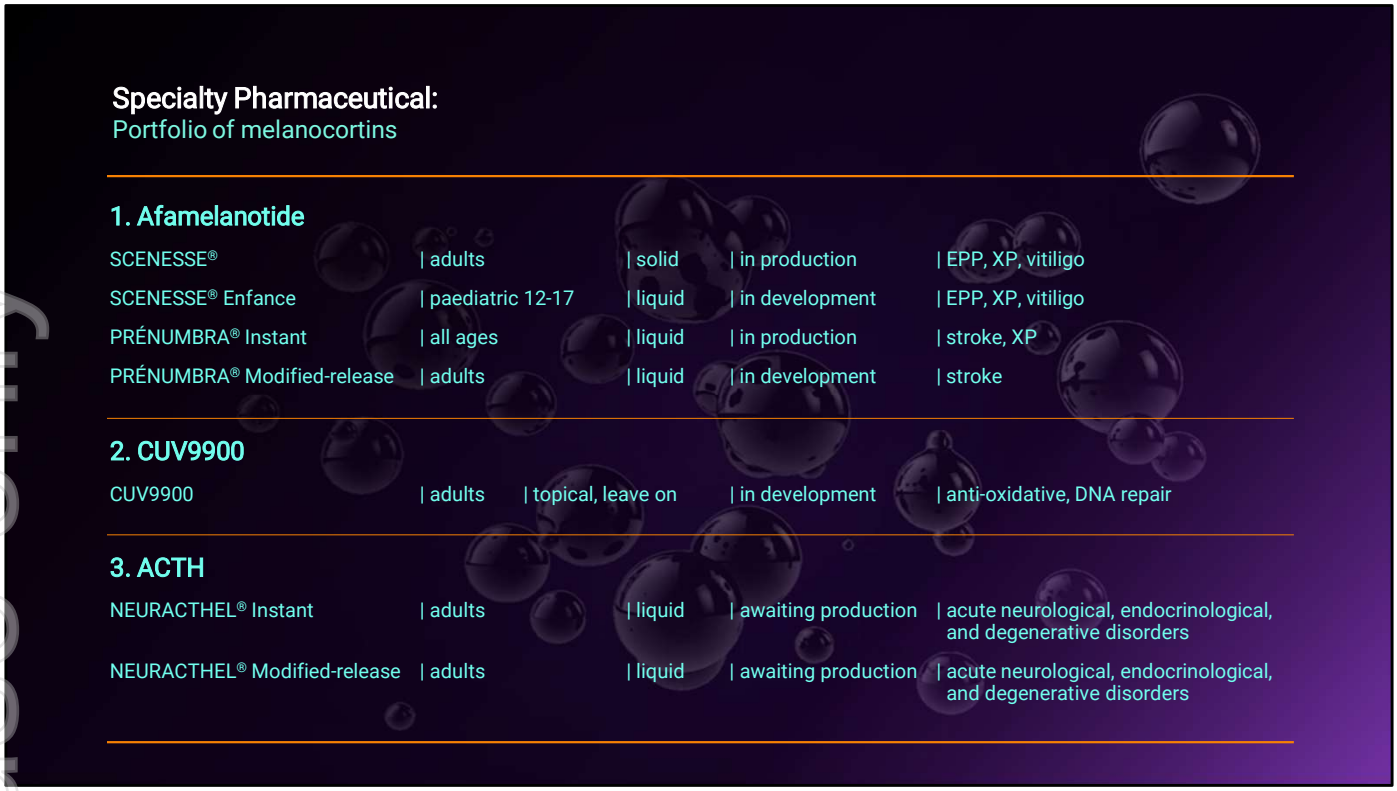
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The further expansion of clinical program of afamelanotide is illustrated and has been widely presented:

- Vitiligo in darker skin complexions;
- Variegate Porphyria, a disease characterised by intolerance to UV + HEV causing blistering and inability to function adequately;
- Arterial ischaemic stroke, awaiting the final results of the first 3 patients and further treatment of the last 3 patients with vessel occlusion at higher parts of the brain; and finally
- The announcement of CLINUVEL's last indication for afamelanotide.

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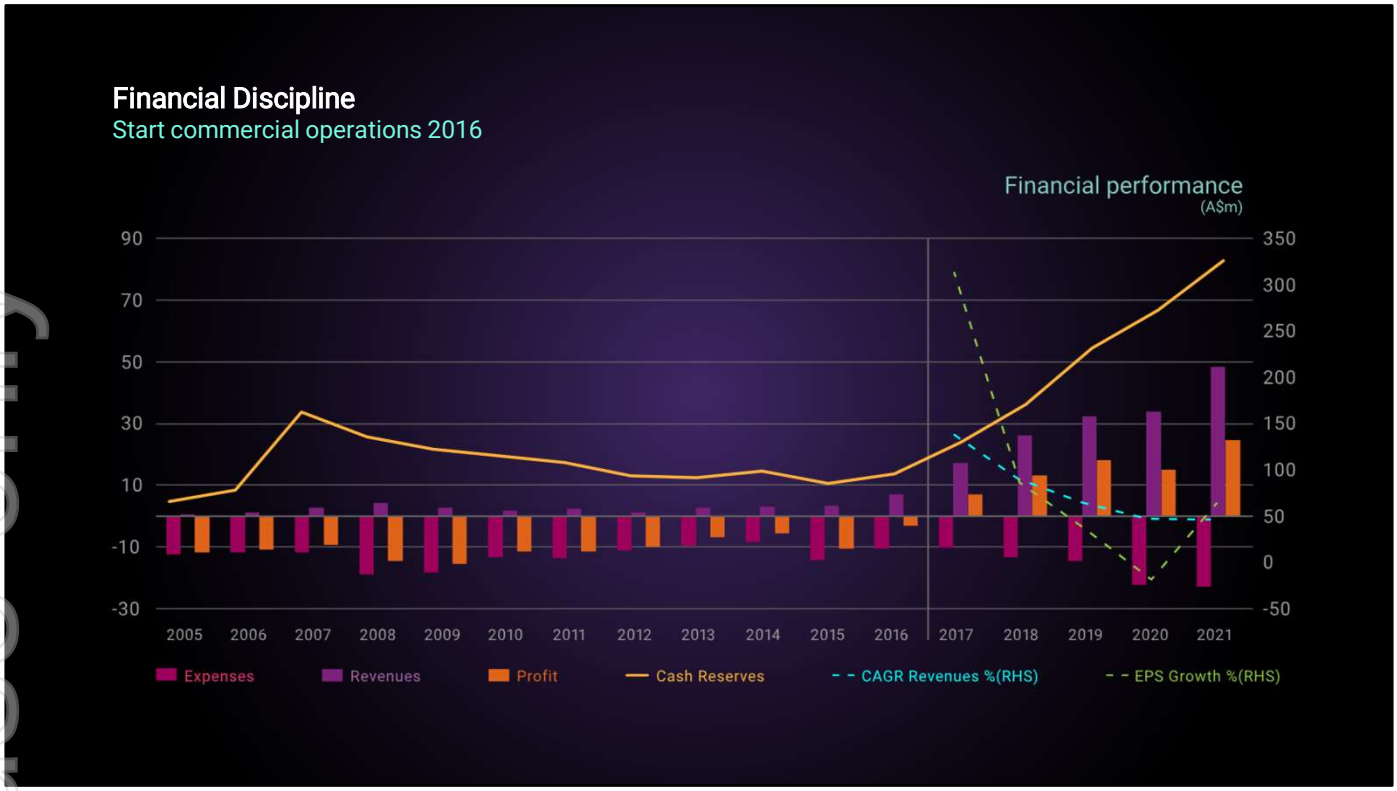


The basis of CLINUVEL's portfolio expansion has been focused on specific technological knowledge, its IP position, and new formulations. This has enabled CLINUVEL to add ACTH analogue - NEURACTHEL® - to its melanocortins stable.

Years of preparation and decision making were needed to arrive at this stage, when new markets for NEURACTHEL® INSTANT and NEURACTHEL® MODIFIED-RELEASE will be accessed.

One may expect that CLINUVEL is building its own in-house team around NEURACTHEL®.

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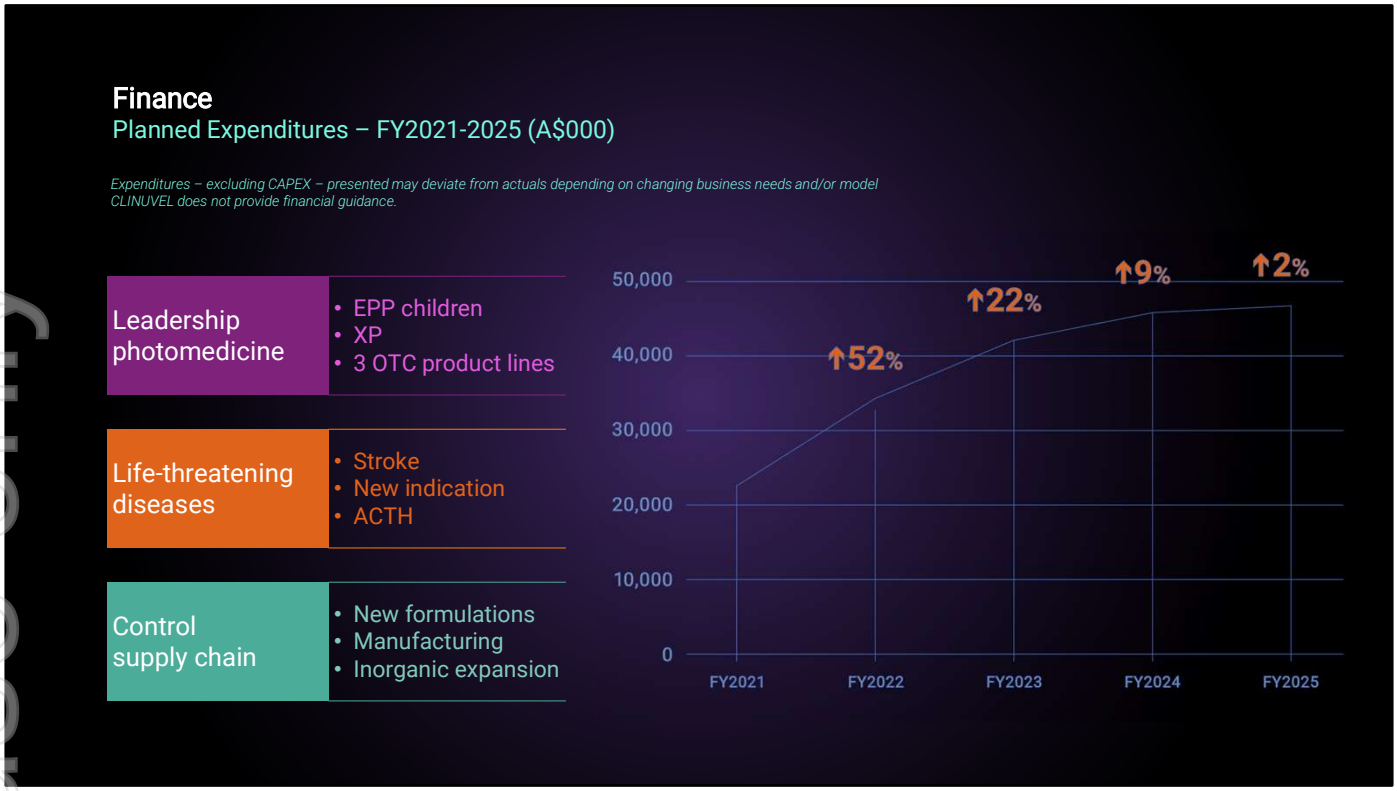
As the Company progressed, the rate of reinvestment has consistently increased. More than 40% of CLINUVEL's revenues were put towards innovation, research and development in 2020 to 2021.

The rate of reinvestment is only possible due to the high level of financial discipline across the Group, managed by our finance team. The ability to retain much of the services within the Group enabled CLINUVEL to contain its cost base and gradually increase its experimental output.

The illustration shows the cautious approach to managing available funds over the years, as well as the revenues versus expenditures. Ten years after starting the program, and three years after EMA approval of SCENESSE®, the Company became profitable. CLINUVEL's entrenched ways of approaching its operational and capital expenditures, make returns on deployed capital (ROCE) more likely and plays a part in the perception of the Company's conduct by state and private insurers. Our shareholders have reaped the long-term benefits of our fiscal discipline.

The CAGR over the years has reached double digits, while the earnings per share were A$0.50 in FY2021.
As the Company increases its operations, the operating and capital expenditures will increase to ensure further growth, but most of all will enable us to achieve a sustainable integrated group of companies.

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The growth of CLINUVEL is expected from three categories (left). Reinvestment will be increasing, reaching a ceiling by 2024-2025.

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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.

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Investor Enquiries

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