



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.

Mission & Objectives

Establishing a specialty pharmaceutical group
which is

diversified,
vertically integrated,
and which serves unmet patient and
healthcare needs.

We aim to provide a safe and accountable
environment, where our staff are able to grow,
thrive and build a career. In pursuing this mission,
we provide long-term value for society and our
shareholders.

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.

Business

Specialty Pharmaceuticals
Value Chain
Healthcare Solutions

Differentiation

Risk Management
Finance
Human Capital

Value Creation

Resources

Proprietary Technology

Position

Defined Expertise

Opportunity

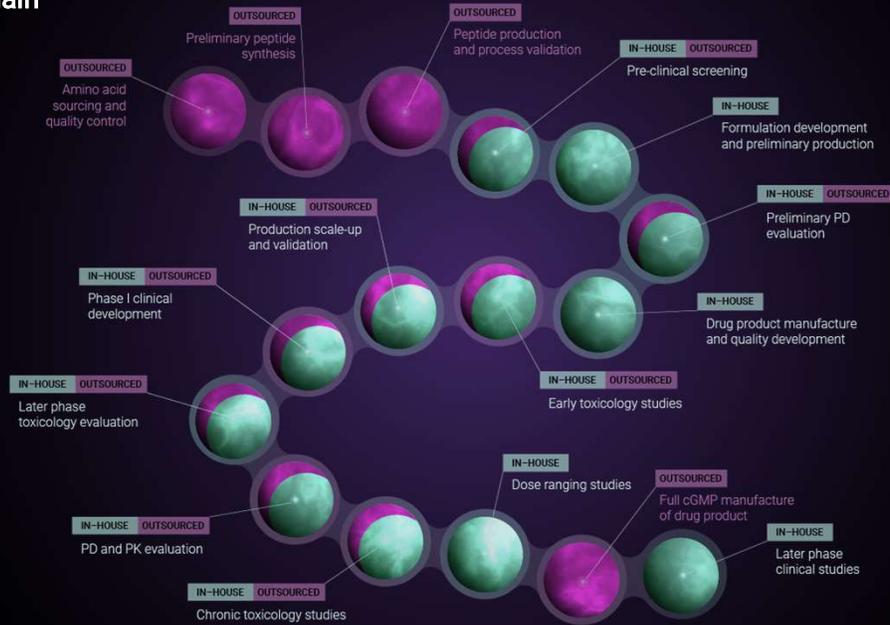
Unserved Populations

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.

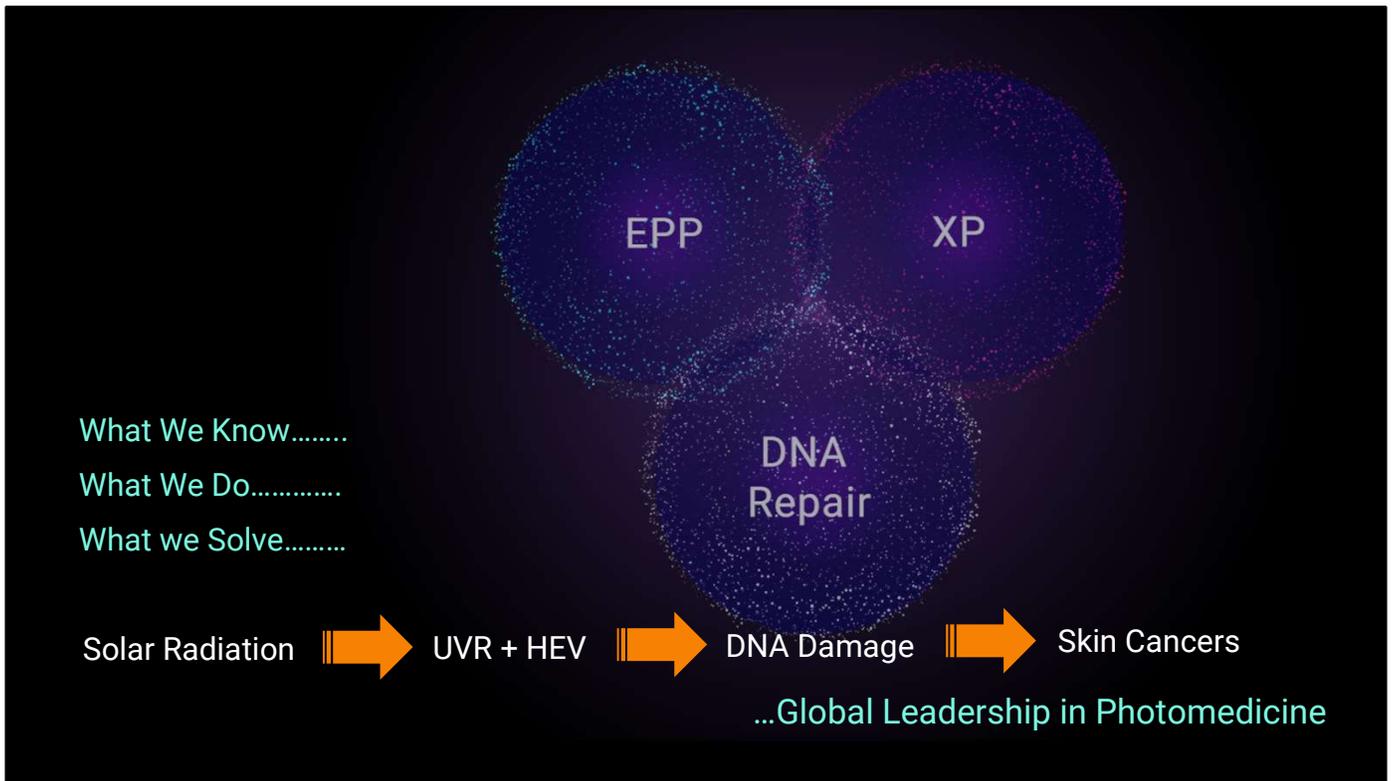
Ultimately, value creation is based on the economic use of resources, the risk assessment and ability to see through a selected project over a long period of time.

Value Chain



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.



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.

Genetics

- prevalence 1:140,000
- chromosomal defects: 18q21, FECH deficiency
- defect in haem synthesis

Clinical Profile

- intolerance to UV-HEV = 320 – 450 – 650 nm
- phototoxicity – anaphylactoid reactions
- isolated life, indoors existence

Therapy

- SCENESSE® (afamelanotide 16mg)
- unmet need, no alternative therapy

Addressable Market

- 5,000- 10,000 patients globally

Real world evidence: SCENESSE® improves patients' quality of life (European PASS data)



Erythropoietic Protoporphyrria (EPP)

Absolute
Intolerance
to UV & HEV

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.

Genetics

- prevalence 1:250,000 to 1,000,000
- chromosomal defects:
 - XPC: on 3p25.1
 - XPV: on 6p21.1
- defective in DNA repair: nucleotide excision repair (NER)

Clinical Profile

- highest risk of exposure to UV-HEV: $\lambda = 320 - 450 \text{ nm}$
- highest rate of skin cancer(s)
- short life expectancy

Therapy

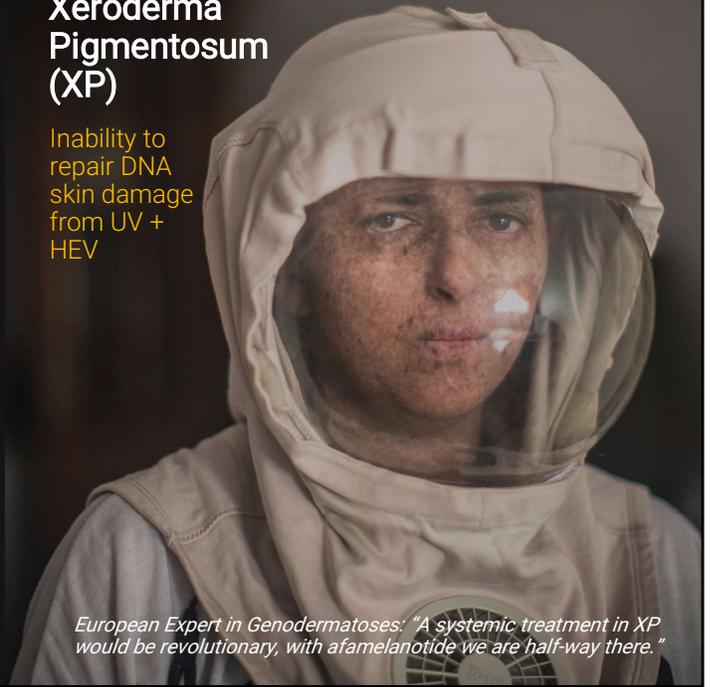
- high unmet need, no alternative treatment

Addressable Market

- 1,000 EU/US/LATAM patients

Xeroderma Pigmentosum (XP)

Inability to repair DNA skin damage from UV + HEV



European Expert in Genodermatoses: "A systemic treatment in XP would be revolutionary, with afamelanotide we are half-way there."

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.

XP CLINICAL TRIAL DESIGN (CUV156)

Start date: 21 October 2021

Duration: 6-9 months

- open label study of 6 adult patients: XP-C
- multiple dosing with afamelanotide
- analyses of afamelanotide treatment
 - safety (systemic/cutaneous)
 - anti-oxidative effects
 - DNA repair capacities
 - UV + HEV light tolerance
 - quality of life

XP Clinical Trials Program 2021-22

XP CLINICAL TRIAL PROGRAM 2021 - 22

CUV156
XP-C patients (n=6)

CUV151
Healthy control group (n=6)
UV-provoked skin damage

CUV152
XP-C & XP-V patients (n=6)

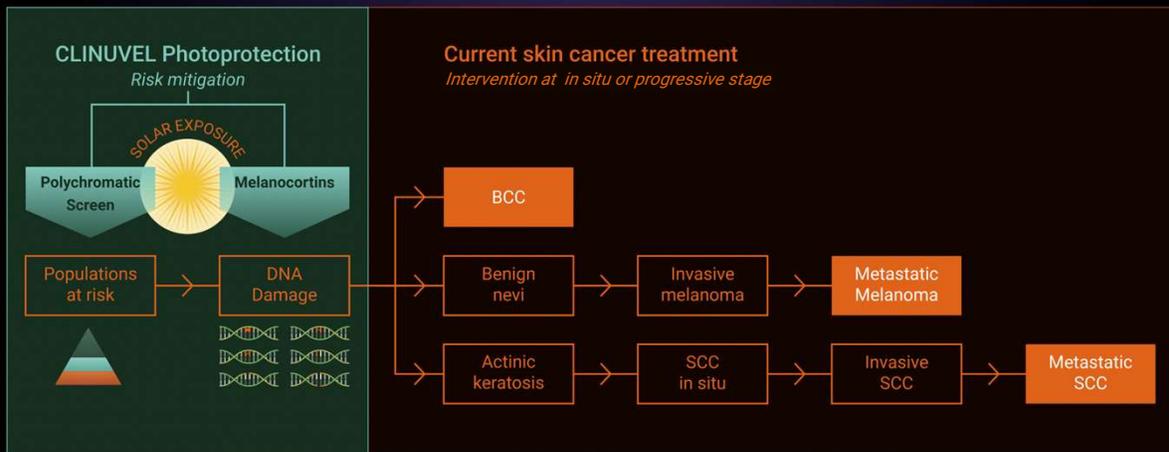
CUV153
XP-V patients (n=6)

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.

Global Leadership in Photomedicine



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.

Global Leadership in Photomedicine

DIVISION OF PHARMACEUTICALS

Rx Product Lines

Photomedicine, DNA Repair Program

- Focus on highest unmet medical need: Xeroderma Pigmentosum
- Afamelanotide evaluated: DNA skin damage caused by ultraviolet radiation
- Validation of model: assisting populations at highest risk of solar damage

Targeted Technology Translation

DIVISION OF HEALTHCARE SOLUTIONS

OTC Product Lines

Polychromatic Photoprotection, Assist DNA Repair

Focus on Highest Risk Populations, neglected by industry:

- immune-suppressed
- history of skin cancer
- extreme outdoor exposure

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

Addressable communities

In 2020, there were 120,774 deaths due to skin cancer.¹

An estimated 5.4 million non-melanoma skin cancers and >100,000 melanomas are diagnosed in the USA each year.²

By 2040, 2.7 million new skin cancer cases are predicted.¹

The mission of CLINUVEL's Healthcare Solutions Division is to:

- build communities
- provide information, education
- introduce personal care solutions



IMMUNE-SUPPRESSED

- 153,863 organ transplants were recorded globally in 2019.³
- 4.5% to 13.3% of organ transplant recipients have had at least 1 skin cancer treatment. Of those, approx. 50% will develop further skin cancers within 2 years.⁴



SKIN CANCER HISTORY

- 35-55% of people diagnosed with a basal cell carcinoma will develop another skin cancer within 5 years.⁵
- Individuals with a family history of melanoma have a markedly increased risk of being diagnosed with melanoma (74% increased), squamous cell carcinoma (22%) and basal cell carcinoma (27%), compared to those without a family history of melanoma.⁶



EXTREME OUTDOORS

- Of the 53 percent of Americans who participated in outdoors activities in 2020, 20% did so twice or more per week.⁷
- 1.2m people completed a marathon in 2018, nearly 500,000 of whom were in the USA.⁸
- The global surfing population is estimated to be between 17-35m people, >2.8m in the USA.⁹
- People who practice outdoor sports experience much higher UV exposure, exceed recommended exposure limits, and are at a higher risk of developing skin cancer.¹⁰

COMMONALITY OF THE 3 POPULATIONS

- unaddressed, neglected by the medical community (prevention = "staying indoors")
- lack of longitudinal care and communication
- fragmented, lack of strong online community

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).

Reaching our addressable audience

- To connect and unite our diverse and disparate communities we must go where they go and be where they are – join their digital world with a common purpose of reducing the number of skin cancers globally.
- As far back as 2015 'A positive effect of Social Networking Sites interventions on health behaviour outcomes was found'.¹
- Today, sites such as patientslikeme.com have communities with almost a million members, looking for and giving advice.

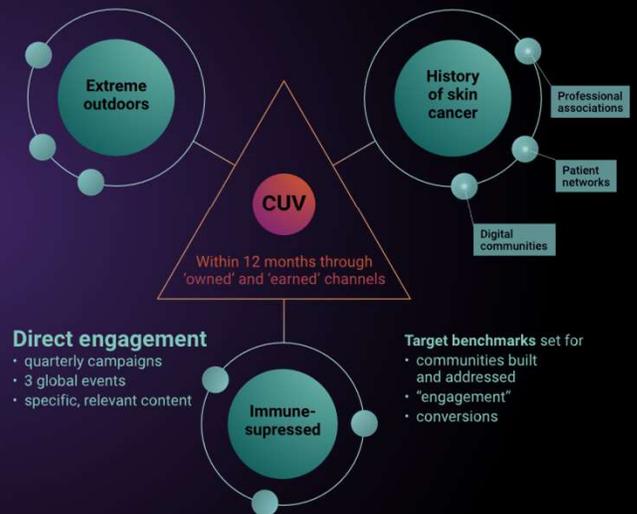
What do your groups want out of a community?

Education, resources, not feeling alone, feeling understood, sharing and hearing similar experiences

How do we deliver this for our community?

A conversation, not a broadcast. Establish our credentials in photomedicine and build trust over time

SELECTED: 60 global ambassadors (3 populations)



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

Global Leadership in Photomedicine

| MEDICAL PROBLEM | 1. EPP | 2. XP | 3. AT HIGHEST RISK |
|--------------------|---|---|---|
| | <ul style="list-style-type: none"> > isolated life > absolute light intolerance | <ul style="list-style-type: none"> > high mortality > UV intolerance | <ul style="list-style-type: none"> > immune-suppressed > family history of skin cancer > extreme outdoors |
| | UVR + HEV | DNA damage | Skin cancer(s) |
| ADDRESSABLE MARKET | 5,000–10,000 worldwide | 1,000 | 15–35 M |
| OBJECTIVES | SYSTEMIC PHOTOPROTECTION | DNA REPAIR | } Reduction of skin cancer risk |
| Endpoints | <ul style="list-style-type: none"> • decrease oxydative damage • supranuclear barrier | <ul style="list-style-type: none"> • remove photoproducts • decrease oxydative damage • assist NER | |
| PHOTOPROTECTION | SYSTEMIC | SYSTEMIC | TOPICAL |
| Progress | first systemic drug | breakthrough program | complementary products |

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.

Clinical Development



Vitiligo

CUV104 [2022]

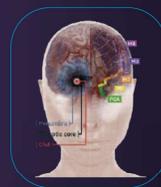
- patients of darker skin types (Fitzpatrick IV-V)
- inclusion > 10% depigmentation
- endpoints: face, head & neck
- >70% repigmentation



Variegate Porphyria

CUV040

- confirmed biochemical diagnosis
- inclusion: multiple lesions p/a
- endpoints: reduction in blister formation
- controlled photo-provocation



Arterial Ischaemic Stroke

CUV801 (n=6)

- safety confirmed, no cerebral adverse events
- first three patients completed treatment
- improvement neurological functions (n=3)
- read out 2022



New Indication

CUV901

- awaiting administrative sign-off, IP

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.

Specialty Pharmaceutical: Portfolio of melanocortins

1. Afamelanotide

| | | | | |
|-----------------------------|------------------|--------|----------------|-------------------|
| SCENESSE® | adults | solid | in production | EPP, XP, vitiligo |
| SCENESSE® Enfance | paediatric 12-17 | liquid | in development | EPP, XP, vitiligo |
| PRÉNUMBRA® Instant | all ages | liquid | in production | stroke, XP |
| PRÉNUMBRA® Modified-release | adults | liquid | in development | stroke |

2. CUV9900

| | | | | |
|---------|--------|-------------------|----------------|----------------------------|
| CUV9900 | adults | topical, leave on | in development | anti-oxidative, DNA repair |
|---------|--------|-------------------|----------------|----------------------------|

3. ACTH

| | | | | |
|------------------------------|--------|--------|---------------------|--|
| NEURACTHEL® Instant | adults | liquid | awaiting production | acute neurological, endocrinological, and degenerative disorders |
| NEURACTHEL® Modified-release | adults | liquid | awaiting production | acute neurological, endocrinological, and degenerative disorders |

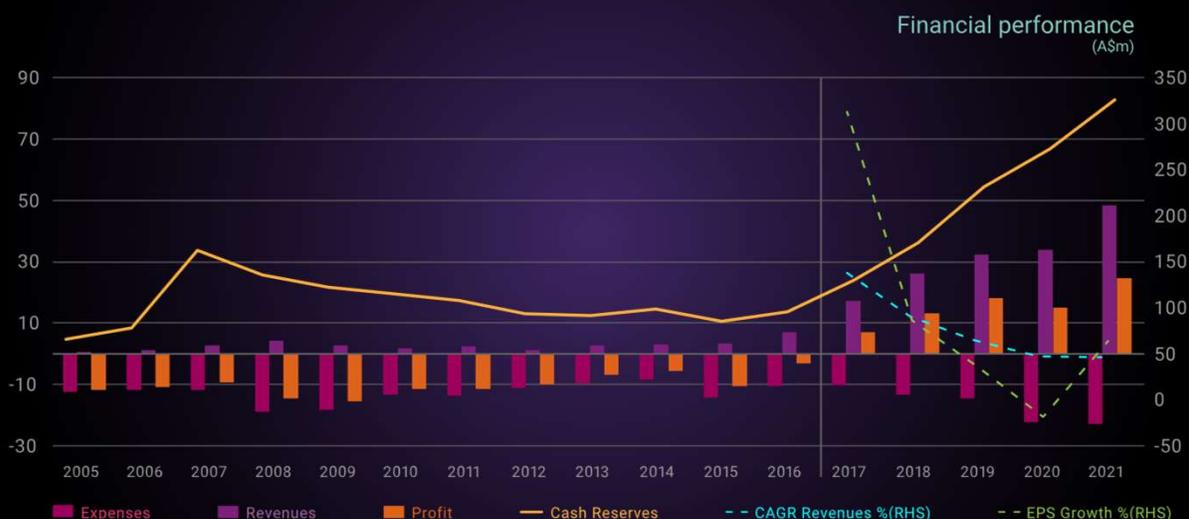
The basis of CLINUVEL's portfolio expansion has been focused on specific technological knowledge, its IP position, and new formulations. This has enabled CLINUVEL to add ACTH analogue - NEURACTHEL® - to its melanocortins stable.

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®.

Financial Discipline

Start commercial operations 2016



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.

Finance

Planned Expenditures – FY2021-2025 (A\$000)

*Expenditures – excluding CAPEX – presented may deviate from actuals depending on changing business needs and/or model
CLINUVEL does not provide financial guidance.*

Leadership photomedicine

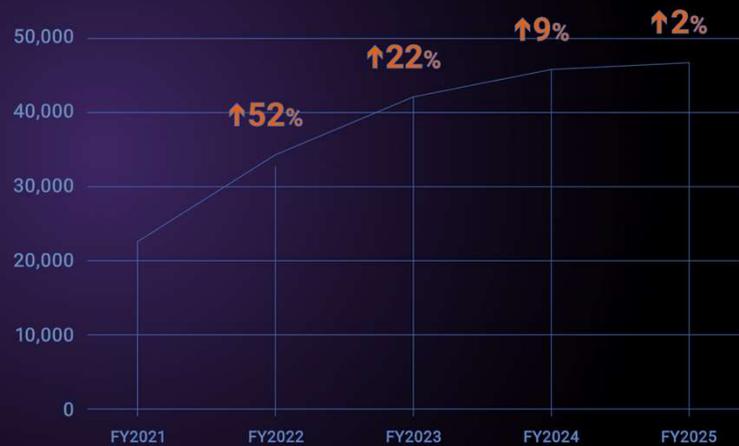
- EPP children
- XP
- 3 OTC product lines

Life-threatening diseases

- Stroke
- New indication
- ACTH

Control supply chain

- New formulations
- Manufacturing
- Inorganic expansion



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

We thank CLINUVEL's long-term supporters,
Board of Directors and most of all
our highly committed staff

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

Investor Enquiries

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