



CLINUVEL

Diversification and Growth

19 November 2020

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Jefferies Virtual London Healthcare Conference
17-19 November 2020

CLINUVEL Group
ASX:
Level 1 ADR (Nasdaq Int'l Designation):
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Thank-you to Jefferies for inviting CLINUVEL to tell its story to the many investors attracted to this prestigious conference.

My objective today is to help you to get to know CLINUVEL and spark your interest to follow-up with us to learn more about our dynamic company and its potential to continue to build incremental value for shareholders.

For those who already know CLINUVEL – like Jefferies and Dr David Stanton who commenced coverage of us in October 2019 – I hope this presentation provides new insights and existing investors affirm their commitment to CLINUVEL.

Legal Notice

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize pharmaceutical products, the COVID-19 pandemic affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe, China and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2020 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 the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

Your attention is drawn to our legal notice which we provide at the start of every presentation. Please keep in mind that I will make forward looking statements in this presentation and there are many risks that can materialise and impact their achievement.

CLINUVEL Group

Phases of Evolution

- Formation and strategy to 2005
- 2005-2020 - drug development and commercialisation
- 2020 onward - targeted translation of technology, growth and expansion

From medicinal therapies...



... to universal skin care products for DNA Repair

CLINUVEL's evolution can be understood across three distinct phases:

The first phase is from formation and the initial strategy to 2005: The core technology of the Company is afamelanotide, a synthetic peptide which mimics the naturally occurring alpha-melanocyte stimulating hormone (α -MSH). Afamelanotide was invented at the University of Arizona in the late 1980s and was acquired by CLINUVEL in 1999. The peptide stimulates the production of eumelanin which provides photoprotection to UV light and in doing so, tans the skin. The period to 2005 sought to apply the technology to develop a tanning preparation. This more cosmetic than medicinal strategy did not garner support from medical practitioners and regulators. The Company's strategy was unsupported and needed to change.

The second phase is drug development and commercialisation: Dr Philippe Wolgen became CEO late 2005 and formed a new management team, a new vision and new strategy. From 2005 to 2020 the focus was on the development and commercialisation of a novel drug for an unmet medical need. During this period, SCENESSE® (afamelanotide 16mg) was developed as a controlled release subcutaneous injectable implant, erythropoietic protoporphyria (EPP) was selected as the lead indication. We progressed clinical studies, regulatory applications and approvals, and commercialised SCENESSE® as the world's first systemic photoprotective.

The European Medicines Agency and US Food and Drug Administration (FDA) approved SCENESSE® for adult EPP patients in 2014 and 2019, respectively. Commercial distribution commenced in the European Union in June 2016 and the USA in April 2020. After four years of commercial operations, we have built a viable business generating positive cashflow and profitability with a strong balance sheet and cash reserves sufficient to finance planned organic growth.

The third, current and most exciting phase of CLINUVEL's evolution is to expand access to SCENESSE® in EPP and to translate the technology to new targeted indications and healthcare solutions for broader audiences. CLINUVEL is well positioned to grow and diversify, despite the challenging operating environment.

CLINUVEL Group

Functional Divisions



The CLINUVEL Group is headquartered in Australia with operations in Europe, Singapore, and the USA. Listed on the Australian Securities Exchange in 2001, we also trade, since 2004, on the Xetra-Dax in Germany (as UR9) and the OTC securities market in the USA (as CLVLY) as a Level One American Depositary Receipt. We have grown to eight subsidiaries and have recently organised the Group across three Divisions.

The Pharmaceuticals Division is CLINUVEL's core business, focussed on developing and delivering drugs for patients with an unmet medical need. The business model is geared towards seeking medical solutions for disorders for which there is no satisfactory therapy.

The Healthcare Solutions Division concentrates 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, to relay the unique product attributes and benefits.

Last, underlying the divisional structure, the Research, Development & Innovation Centre in Singapore performs fundamental research on molecular science, biology, and follow-on formulations, and actively engages with all three divisions.

The illustration shows the inter-connections between the Divisions which provides our professionals the broadest possible exposure to other disciplines, a distinctive feature of working for the CLINUVEL Group. Before providing more detail on the divisions of the Group and our forward plans, I would like to explain more about the technology developed and our story to date.

Proven Technology

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



Afamelanotide is the lead compound of the Pharmaceuticals Division and is the active component of SCENESSE®, the world's first systemic photoprotective treatment for EPP:

- EPP is a poorly characterised, rare metabolic disorder, causing lifelong light intolerance. Due to a genetic defect, patients suffer acute phototoxic reactions (anaphylactic reactions and second-degree burns) after exposure to light. Without treatment, patients must avoid exposure to light and thus lead a life of social isolation;
- SCENESSE® has been shown to reduce the incidence and severity of phototoxic reactions and increase the amount of time patients can expose to light without phototoxicity;
- SCENESSE® is administered as a controlled release subcutaneous injectable implant in an outpatient setting;
- CLINUVEL manages an extensive pharmacovigilance program to monitor the use of SCENESSE® in EPP patients;
- SCENESSE® has maintained a positive safety profile from over 10,000 doses to over 1,400 individuals worldwide.

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

The safety and potential of SCENESSE® to treat other indications is the basis of CLINUVEL's strategy to translate the technology to new indications.

SCENESSE® - systemic photoprotection in EPP



* Locations are approximate



USA: launched April 2020

- 29 Specialty Centers trained & accredited
- Treatment under Prior Authorization
- Over 55 national and local private insurers
- Savings Program for patients
- US patients starting third treatment dose

EEA: four years of post-marketing experience

- Four financial years of commercial operations
- Standard of care in EPP Expert Centres
- First publication on long-term post-MA use confirms safety, effectiveness (Wensink et al)

We first distributed SCENESSE® for EPP in Italy in 2010 and Switzerland in 2012 under special access programs. First supply under the EMA approval followed in the European Union in June 2016 and under FDA approval in the USA in April 2020.

In the US, we are distributing largely through certified dermatologists. We have trained and accredited 29 Specialty Centers out of 30 planned by July 2022. Treatment under Prior Authorization means all patients require written confirmation from their insurer before receiving the drug from their nominated Specialty Center. Additionally, US prescribers require confirmation from the insurer of the appropriate treatment codes, which allows them to charge for both the medical consultation and drug administration. A Savings Program is also underway for US EPP patients working off individual Insurance Plans. Some US patients are now requesting a second and third dose of SCENESSE®.

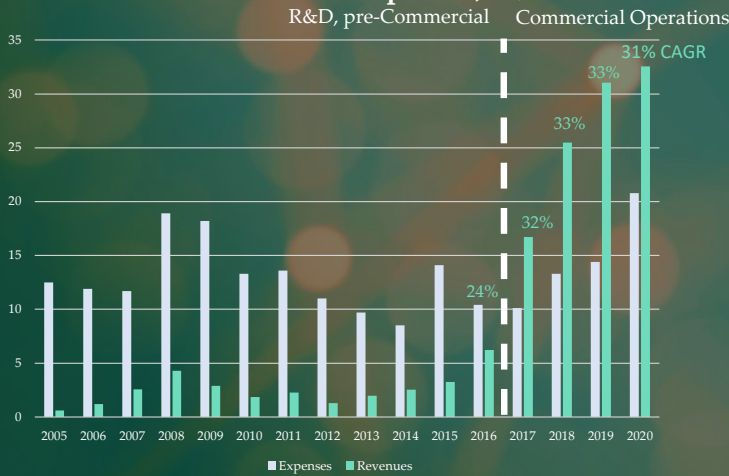
Demand for SCENESSE® in Europe has been strong with patient retention of 94 to 97% in the European Economic Area. Distribution is through EPP Expert Centres, accredited and trained by CLINUVEL. COVID impacted the treatment of EPP patients in March-April-May 2020. A few centres were not able to provide treatment due to priority given to COVID patients, while in other instances EPP patients could not travel to get treatment. Our team worked to find ways to facilitate treatment and whilst conditions subsequently improved, a second wave of COVID is now passing through Europe.

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

Reference: Wensink, D., et al., (2020). Association of Afamelanotide With Improved Outcomes in Patients With Erythropoietic Protoporphyrinemia in Clinical Practice. *JAMA Dermatology*. 156(5):570-575.

Viability Established

Revenues & Expenses, A\$m



Summary Financial Year 2020

- Revenues +4.9%
- NPAT A\$16.6 M
- Cash reserves +23%
- Expenditures +44%

- Financial years ending 30 June
- CLINUVEL does not provide financial guidance for 2021

CLINUVEL has achieved strong revenue growth and prudently managed expenditures since June 2016. The first profit of the Group was recorded in 2016/17, the first full year of commercial operations. Despite the human impact of the coronavirus pandemic and the world's most significant economic contraction since the Great Depression, CLINUVEL recorded a fourth profit in 2019/20, after a deliberate and controlled increase of 44% in expenditures to support the Group's growth initiatives.

Cash receipts for the first quarter of the 2021 financial year from the distribution of SCENESSE® in Europe and the USA, were A\$12.015 million. Net operating cashflow was A\$7.881 million, taking cash reserves to A\$72.759 million. This was after the payment of an annual dividend (of A\$1.235 million) to shareholders. The CLINUVEL Board has declared three consecutive annual dividends to shareholders, the first in 2017/18 of A\$0.02 and in 2018/19 and 2019/20 of A\$0.025.

These financial results have been achieved by a focussed and committed team of professionals. CEO Dr Wolgen stated at the recent 2020 Annual General Meeting of Shareholders, "we have created at CLINUVEL an animated team who knows to perform in the most dire economic climate, working all hours, answering calls weekends and holidays – a culture of give without reservation. No business activity seems off-limits to this eager and hungry team".

Strength and Character

Strengths

- Cash reserves to self-finance growth and expansion and no debt
- Peer leading performance
 - ROE 23%
 - EPS 33.8 cents ¹
- Stable and skilled Board
- Proven long-term management team

Character

- Patient focused
- Values based
 - Uniform net price maintained
- Resourceful, integrating many functions 'in-house'
- Prudent risk management

¹ A\$; financial year ending 30 June 2020

CLINUVEL's cash reserves cover more than three years of operating expenses and is sufficient to finance growth and expansion. We have no debt and have not raised new capital since March 2016. Thus, unlike many biotech companies, we have not diluted shareholders at a discount to support business operations. Our performance is peer leading, achieving return on equity of 23% and earnings per share of A\$0.338 in 2019/20.

To invest in a company, you need to assess its character. CLINUVEL is patient focused and values based, with a tenacious culture. We are resourceful, undertaking many functions 'in-house' that are typically outsourced by other pharmaceuticals. We have a prudent approach to risk management and are deliberate and strategic. These characteristics are reflected in:

- the long-term strategy to develop and commercialise a novel technology for an unmet medical need;
- the frugality of expense management to develop SCENESSE[®] (for A\$154 million), a cost far less than the typical billion-dollars incurred to develop a new drug;
- self-management of the development of SCENESSE[®], clinical studies, liaison with regulators and distribution of SCENESSE[®]; and
- a prudent risk management ethos to accumulate cash reserves to manage adversity in all economic conditions.

These characteristics benefit shareholders by supporting the long-term value of the Company.

The strengths and characteristics outlined underpin the business as it implements its forward strategy focused on the ongoing growth of commercial operations based on SCENESSE[®] and diversifying the business into three distinct Divisions, underpinned by our Singaporean Research, Development & Innovation Centre.

Pharmaceuticals Core Business

- I SCENESSE®
- II SCENESSE® ENFANCE
- III PRÉNUMBRA®
- IV Phimelanotide
- V CUV9900

CLINUVEL works towards a portfolio of minimum five prescription products currently targeting four patient populations.

Pharmaceuticals remains our core business as we diversify. We are working towards a portfolio of five prescription products as listed on screen. The intention is to target four identified patient populations.

The Company decided that future earnings and value should come from our own R&D suite and thus we are focusing on expanding from within, to utilise our expertise of the pharmacology of melanocortins. CLINUVEL actively evaluates outside assets, the criterium is that these need to be short-to-mid-term accretive to value per share.

We expect to share a number of new activities and operations in this Division over the next 12 months.

Pharmaceutical Program 2021



* Phase II read out expected 2021, pending COVID

The chart demonstrates five targeted indications, although we interpret variegate porphyria (VP) and EPP as belonging to the same category of diseases.

The DNA Repair Program will get under way in Q1 2021. During 2021 we expect readouts from the XP study (Phase II CUV150 study) and healthy subjects (CUV151 study). In parallel, we look forward to a fast outcome from the stroke study, but note, these are all conditional on COVID restrictions being lifted.

Vitiligo progression depends on agreement on final protocol with the FDA. There is consensus among our scientific team and global vitiligo experts to focus drug availability on patients with darker skin complexions and 40% or greater loss of pigmentation. These darker skin types exhibit more prominently the contrast between pigmented and depigmented skin.

The sixth listed indication has been prepared for considerable time and depending on a regulatory meeting in December with the EMA, we hope to be granted the green light to proceed in a chronic severe condition and for which there is no effective treatment.

Healthcare Solutions

Validation of non-prescription products
originates
from active pharmaceutical ingredients



Long-term use
provided confidence in
SAFETY



Pathway to DNA Repair products

CLINUVEL's melanocortins



universal care benefiting all

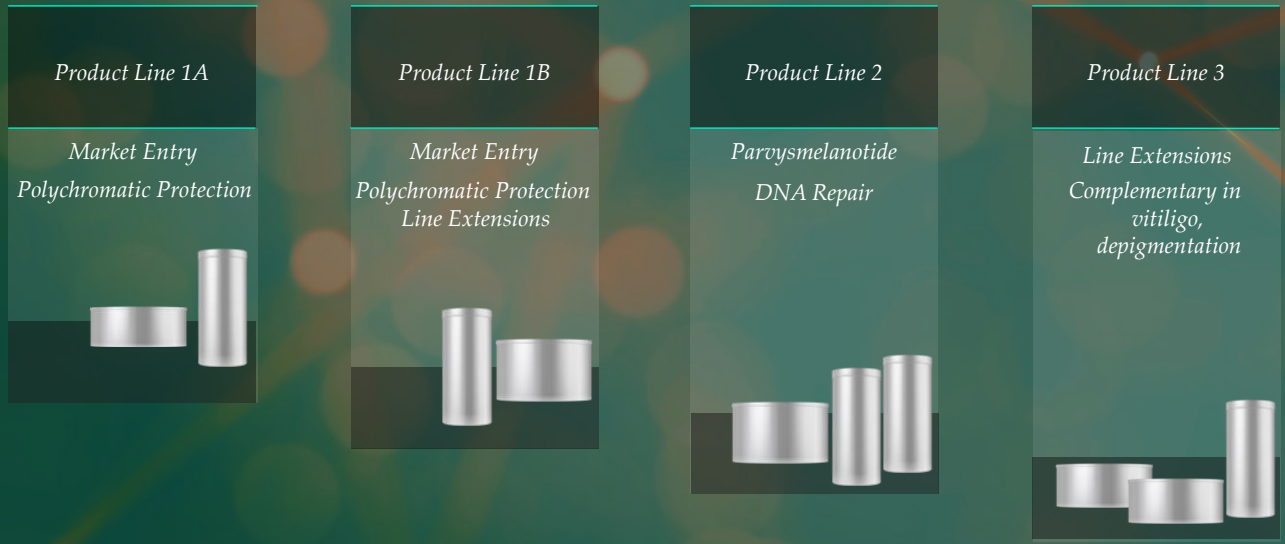
Our recently announced Healthcare Solutions Division draws upon expertise established in the core business to develop products for universal care. As explained in the CEO's Strategic Update of 29 October, we had known since 2006 that in afamelanotide and melanocortins, we had a suite of potent molecules which positively affected damage of the skin caused by UV radiation. These molecules had shown to be capable of decreasing *photoproducts* – chemical bonds formed within single strands of DNA following UV exposure, known as cyclobutane pyrimidine dimers.

However, the pathway to the DNA-repair Program was far from linear. We first had to prove to the regulatory authorities that afamelanotide, or SCENESSE® in its approved dosage form, was safe in a larger set of patients treated for sufficient years under commercial conditions. As scientific data accumulated, and analyses became repetitive and predictable, authorities gained confidence in the consistent pharmacology, and the SAFETY of afamelanotide was affirmed. As time lapsed, our pathway to a human DNA program evolved to allow several melanocortin formulations to be developed for 1) prescription products for medical use and 2) non-prescription dermocosmetic products for wider markets.

To address a global market of users at high risk of photo-induced DNA skin damage, CLINUVEL requires a new infrastructure based on a specialised scientific team, regulatory professionals, and personnel focusing on future distribution, hence the creation of the Healthcare Solutions Division. It is essential to realise that the 'core' pharmaceuticals business, provides CLINUVEL with a competitive advantage to expand into dermocosmetics, since scientific validation of the technology originates from the pharmaceutical R&D expertise built over decades. Both the output and synergy between the Pharmaceuticals and Healthcare Solutions divisions naturally calls for greater efforts to provide global visibility to CLINUVEL's unique cause.

Healthcare Solutions Program

Dermocosmetics



To explain the Healthcare Solutions Program we can refer to the diagram showing three product lines and line extensions in development.

From this Division, we will see output of topical products where market dominance is possible in the segment of dermocosmetics which is presently underdeveloped. Many products promise regeneration and rejuvenation of the skin; however, they are seldom based on a new class of molecules tested in human pathology over decades.

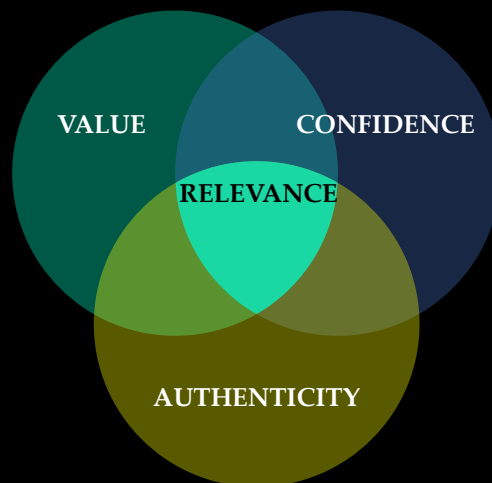
On the other hand, CLINUVEL has a different focus and will be introducing leave-on products, topical formulations, providing DNA-restoration for those at high risk of long-term solar radiation. We will be releasing our first line of non-prescription leave-on products in 2021.

Naturally, one may ask, can CLINUVEL play a role of significance at all in such a competitive market dominated by large cosmetic players? At face value, one could question whether venturing into a retail segment would generate additional enterprise value, however, 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.

That then begs the question, *how* is CLINUVEL going to compete, assuming the technology is promising? The answer takes us to the most important component – and perhaps a determinant of commercial success in this segment.

Communications, Branding & Marketing

Effective communication is
the determinant
of commercial success in dermocosmetics



CLINUVEL's Board acknowledges the relationship between shareholder value and the visibility of a pharmaceutical program. By and large, whilst orphan drug markets excite, they do not provide wider visibility due to the relatively small size of the disease entity. However, each patient, each state of pathology matters to us. From a medical viewpoint, CLINUVEL has reached maximum visibility among targeted patient populations.

However, at this next stage of growth, we seek not only to serve larger markets, but also to communicate the high relevance of our causes and objectives to wider audiences.

The DNA Repair Program answers all quests for relevance, visibility, and market size, since photodamage and the relationship between solar radiation, DNA damage and risk of skin cancer affects almost all fair-skinned individuals on the planet. This program compelled us to establish a Communications, Branding and Marketing Division.

In changing demographics, we see a partition between those who stay behind and those who seek new platforms, new content and relevance of offerings. As media consumption habits evolve constantly, CLINUVEL needed to embrace the opportunity to emerge as a patient and consumer focussed company. With that focus, connecting to diffused audiences worldwide requires CLINUVEL to tailor messages and content across platforms. A professional team – agency style – is asked to grow audiences before it introduces its current and relevant products. A next step further in arriving at a continuous dialogue with viewers and users is by concentrating on data driven engagement.

Stepping away from the traditional pharmaceutical approach, CLINUVEL chose to be progressive, addressing and connecting to the current and next generation of users.

Technology Translation DNA Repair

.....*secure tomorrow today*.....



Pharmaceutical
[PRESCRIPTION ONLY]

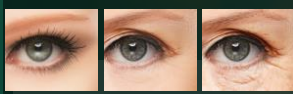


SCENESSE®
SCENESSE® ENFANCE
PRÉNUMBRA®
Phimelanotide
CUV9900

Systemic repigmentation
Systemic photoprotection
Neurotrophic – anti-oncotic
DNA Repair



Awareness among **medical community**
- innovation and medical need



Healthcare Solutions

ProdLine: Parvysmelanotide
ProdLine: DNA Repair

Polychromatic protection
DNA Repair



Awareness to be raised among **broad audience**

CLINUVEL's strategy has come together based on the proven SAFETY of the technology. The approach to deploy our first molecule afamelanotide, has led to market access in three continents, and longevity to value generation for patients and shareholders.

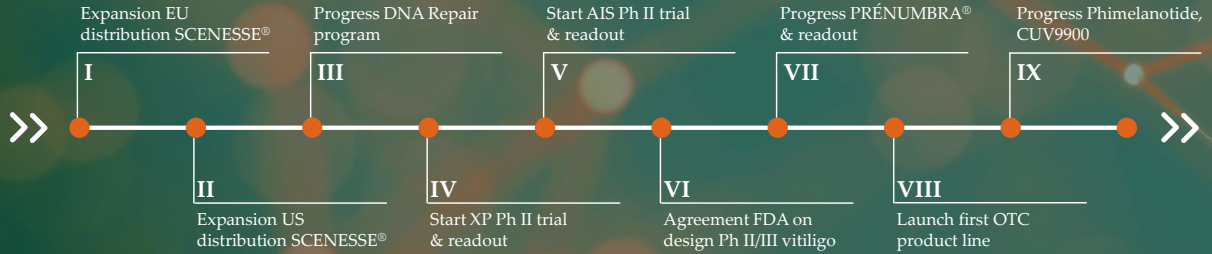
Our technology of melanocortins lends itself uniquely to a **dual strategy**: prescription and non-prescription markets. A key but unexpected part of the pharmaceutical legacy is that the very assurance the Company had to give to regulators on the safety of afamelanotide has now, after decades of review of data, become one of CLINUVEL's unique propositions and the prime asset allowing us to now commoditise derivative products downstream for wider retail markets.

Therefore taking a distant view and looking at CLINUVEL, we would argue that CLINUVEL is in a unique position which very few companies would be able to emulate, since its technology originates from a highly regulated environment translating its products to non-prescription retail markets with an emphasis on SAFETY and genuine care for human biology. As the tide is turning, and the demand for authentic dermocosmetics follows in due time, all involved at and around CLINUVEL believe it will be well positioned in an underdeveloped market segment.

In working from the attributes of melanocortins as chemical entities, it is easy to follow the product strategy. Targeted Technology Translation becomes synonymous with the use of specific knowledge from *prescription to non-prescription products* (pharmaceutables).

The first product line to be released offers polychromatic protection for extreme conditions and targeting populations at risk of solar and high energy visible (HEV) light insult. The second product line aims to provide DNA-protection and repair in individuals at risk of solar damage and specific high-risk populations. Awareness of the healthcare risk is relatively high among these users, and the communications strategy will need to result in engaging the broadest interested audience.

Planning 2021



Conclusion

- Diversified R&D under way
- Targeted Technology Translation – DNA Repair
- Financial strength and viability established

The past year has been eventful with new milestones achieved and progressive news flow from the Company on its growth and expansion.

Whilst planning can change due to unforeseen circumstances, this chart summarises nine key objectives of our team which forms the basis of news that will come to you.

In conclusion, CLINUVEL's Strategic Update of 29 October provided the rationale and implementation of a strategy discussed today to make the Group a diversified operation. This will be based on the dual progression of the core pharmaceuticals division and the new healthcare solutions division. New to shareholders is our unfolding of the stroke program, but specifically the DNA Repair trials in XP and in Caucasian individuals, which we are finally able to progress. We are diversifying our R&D and translating our technology from a position of financial strength and viability.



CLINUVEL

Thank you for your
attention

Malcolm Bull
Head of Investor Relations
CLINUVEL Group

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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, and life-threatening 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 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at <http://www.epp.care>. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA. For more information please go to <http://www.clinuvel.com>.

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