



# Growth and Profitability

Daiwa Investment Conference Tokyo 2021

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CLINUVEL Group  
ASX:  
Level 1 ADR (Nasdaq Int'l Designation):  
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Presented by  
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Head of Investor Relations

I'm Malcolm Bull, Head of Investor Relations for CLINUVEL PHARMACEUTICALS. I'm pleased to brief the Daiwa Investment Conference on CLINUVEL's evolution and strategy, provide an update on the Company's financial and operational performance, and outline our plans in 2021 and beyond.

## 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.

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## CLINUVEL GROUP

### Phases of Evolution

#### Up to 2005

Formation and initial strategy

#### 2005 – 2020

Drug development and commercialisation

#### 2020 onwards

Targeted translation of technology, growth and expansion

From medicinal therapies...



To universal skin care products  
for DNA repair

CLINUVEL has entered a third distinct stage in its evolution.

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

The second phase was drug development and commercialisation: In 2005 a new management team, vision and strategy were put in place. From 2005 to 2020 we developed and commercialised a novel drug for an unmet medical need. SCENESSE® (afamelanotide 16mg) was developed as a controlled release subcutaneous injectable implant; erythropoietic protoporphyria (EPP) was selected as the lead indication; we completed clinical studies; obtained regulatory approvals; and commercialised SCENESSE® as the world's first systemic photoprotective.

The European Medicines Agency (EMA) 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 more than four years of commercial operations, we have built a viable business generating positive cashflow and profit, 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



***Healthcare Solutions***



***Pharmaceuticals***



***Branding, Marketing,  
Communications***



***Research, Development  
& Innovation Centre***  
***VALLAURIX (SG)***

The 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 a Level One American Depositary Receipt (CLVLY). We have grown to eight subsidiaries and organised the Group across three 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 which prepares communications to wider differentiated audiences, positioning the Group for broader engagement.

Underlying this divisional structure is the Research, Development & Innovation (RDI) Centre in Singapore, researching molecular science, biology, and follow-on formulations.



## CLINUVEL GROUP

### Proven Technology

- **SCENESSE® (afamelanotide 16mg)**
  - Synthetic peptide, mimics naturally occurring  $\alpha$ -MSH
  - First systemic photoprotective for erythropoietic protoporphyria (EPP)
- **SCENESSE® positive safety profile - over 10,000 doses**
- **$\alpha$ -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**



At the core of the business is SCENESSE®, the only approved treatment for EPP, a poorly characterised, rare 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.

Afamelanotide is the active ingredient in SCENESSE®. The drug:

- was developed as a controlled release subcutaneous injectable implant formulation, administered in an outpatient setting;
- has been shown to reduce the incidence and severity of phototoxic reactions and increase the time EPP patients can expose to light without phototoxicity;
- is monitored in post-authorisation use in EPP patients by an extensive pharmacovigilance program; and
- has maintained a positive safety profile from over 10,000 doses to over 1,400 individuals worldwide.

$\alpha$ -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**

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



- Four financial years of commercial operations
- Standard of care in EPP Expert Centres
- First publication on long-term post-MA use confirms safety, effectiveness (Wensik 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 June 2016 and under FDA approval in April 2020.

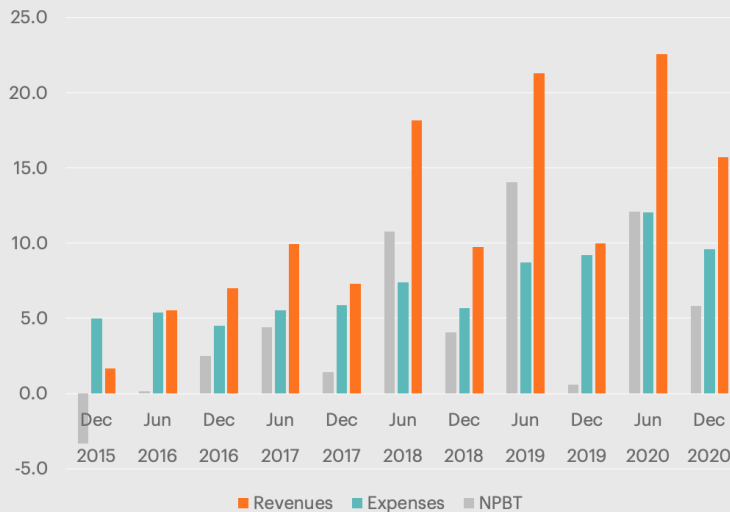
In the US, we distribute largely through certified dermatologists. We have trained and accredited 34 Specialty Centers compared to 30 planned by the end of 2021. Treatment under Prior Authorization means each patient confirms insurance coverage before treatment by their Specialty Center. Additionally, 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 two months.

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 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 patients, and some EPP patients could not travel to get treatment. Since then, notwithstanding the risk of new waves of COVID, treatment has largely normalised in 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 granted market access in Israel as a first line treatment for the prevention of phototoxicity in adult patients with EPP in February 2021. We are committed to facilitating treatment access to SCENESSE® for EPP patients worldwide.

## Ten Consecutive Half Year Profits

### A\$m



### Summary First Half December 2020

<b>Revenues</b>	+58% to A\$15.7m
<b>Expenses</b>	+5% to A\$9.6m
<b>NPBT</b>	+852% to A\$5.8m
<b>NPAT</b>	+962% to A\$6.5m
<b>EPS</b>	+956% to A\$0.133
<b>NTA</b>	+10% to A\$1.48

\* Graph in A\$m for the half years ended 31 December; change in table is on prior corresponding period

After more than a decade of research and development, CLINUVEL achieved viability posting strong revenue growth and prudently managing expenditures since the commencement of commercial operations in June 2016. The first profit 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. In addition, 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.

In more recent financial news, cash receipts in the 2020 calendar year achieved a record level of A\$33.053 million. CLINUVEL also posted a 58% increase in revenues in the half year to December 2020. Both cash and revenues reflect the normalisation of treatment activity in Europe, (after an initial COVID related impact), and the first contributions from US operations. Growth in expenses was contained to 5% in the half year. The profit before tax of A\$5.811 million was the tenth consecutive half year profit and a record for a December half year since the commencement of commercial operations. This demonstrates the resilience of the business and affirms the appropriateness of the Group's long-term strategy and the efficacy of the business model to distribute direct to the medical practitioners administering the drug to patients.

## Strengths & Character

### STRENGTHS

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

### CHARACTER

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

<sup>1</sup> A\$; financial year ending 30 June 2020

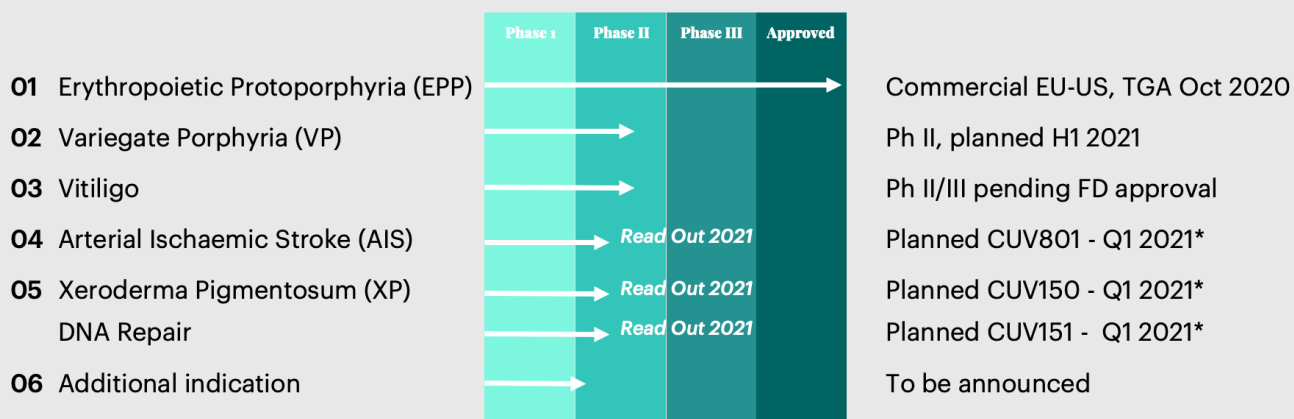
CLINUVEL's cash reserves cover more than three years of expenses and are sufficient to finance planned organic growth. We have no debt and have not raised new capital since March 2016. Unlike many biotech companies in the coronavirus pandemic environment, we have not diluted shareholders at a discount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

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 pharmaceutical firms. We have a prudent approach to risk management and are deliberate and strategic. These characteristics are reflected in:

- a long-term strategy to develop and commercialise a novel technology for an unmet medical need;
- the economic management of expenses to develop SCENESSE® for A\$154 million, far less than the US\$1-2 billion typically required to develop a new drug;
- self-management of the development of SCENESSE®, clinical studies, liaison with regulators and distribution of SCENESSE®; and
- the accumulation of cash reserves to manage adversity in all economic conditions.

These strengths and characteristics benefit shareholders by supporting the long-term value of the Company and underpin the business as it implements its forward strategy to grow the commercial operations based on SCENESSE® and diversify into new indications.

## Pharmaceutical Program 2021



\*Phase II read out expected 2021, pending COVID

Let's turn back to the Pharmaceutical Division which remain the core of our business. We are working towards a portfolio of prescription products currently targeting four identified patient populations with afamelanotide, noting we regard variegate porphyria (VP) and EPP as the same category of diseases. The Company decided that future earnings and value should come from its R&D suite, thus the focus is to expand from within, utilising our expertise of the pharmacology of melanocortins. We expect to share new activities and operations from this Division over the next 12 months.

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. These darker skin types more prominently exhibit the contrast between pigmented and depigmented skin.

The DNA Repair Program continues, following the treatment of the first xeroderma pigmentosum (XP) patient in September 2020. During 2021 we expect readouts from the XP study (Phase II CUV150) and a study in healthy subjects (CUV151). In parallel, we look to a fast outcome from the stroke study (Phase II CUV801), but note, these are all conditional on COVID restrictions being lifted.

An additional indication is also to be announced.

## Arterial Ischaemic Stroke

### SCENESSE® Targeted Technology Translation

**15 million**

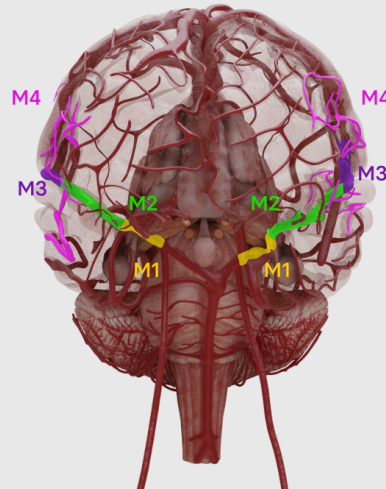
Strokes recorded annually worldwide

**85%**

Are ischaemic strokes

**Over 85%**

Not eligible for standard of care treatment<sup>1</sup>



**CUV801 Study**

Evaluating afamelanotide for stroke in the "M2" region and above, focus on safety

First readout in 2021, pending coronavirus pandemic

<sup>1</sup> cases in European hospitals not eligible for standard of care treatment (thrombectomy & thrombolysis)

In this and the next slide, I highlight in more detail two of the exciting programs we have recently initiated.

First, the role of afamelanotide in treating arterial ischaemic stroke patients. Tragically, many ischaemic stroke patients either have lasting functional impairment or do not survive the clot that has been formed and dislodged in their brain. We understand afamelanotide may well play a role in treating ischaemic stroke by rapidly exerting its effects to protect brain tissue, acting on blood vessels to optimise blood flow, and reducing the size of swelling in the brain following a stroke. Our clinical focus is on patients with ischaemic strokes in the upper regions of the brain, the so-called "M2" branches and further up in the brain. Of the 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.

## DNA Repair Program

SCENESSE® Targeted Technology Translation

**Over 2 billion individuals have inefficient DNA repair mechanisms**



**1**

Highest **unmet need** in rare disorder xeroderma pigmentosum (XP)

**Afamelanotide repairs DNA skin damage caused by UV radiation**

**2**

Afamelanotide in genetic disease XP serves as model for assisting DNA repair in all populations affected and at risk of solar damage

**3**

First XP patient treated; **safety profile maintained**

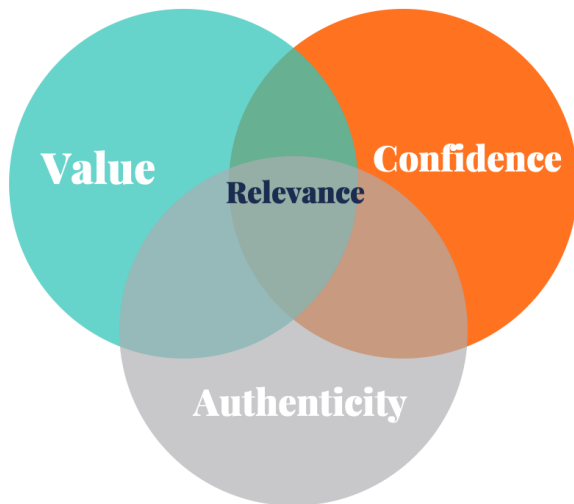
We are working to confirm the role of SCENESSE® in repairing DNA which has been damaged by exposing skin to ultraviolet light. Here the clinical focus is twofold: on both patients with the rare genetic disorder xeroderma pigmentosum (XP) and on healthy volunteers. Last year we saw the first XP patient, with the XPC complementation factor deficient, receiving treatment. This was well tolerated.

Given DNA damage and the risk of skin cancer affects almost all fair-skinned individuals on the planet, the relevance of the DNA Repair Program is clear.



## **Communications**

### **Branding & Marketing**



**Effective  
communication  
is the determinant of  
commercial success  
in dermocosmetics**

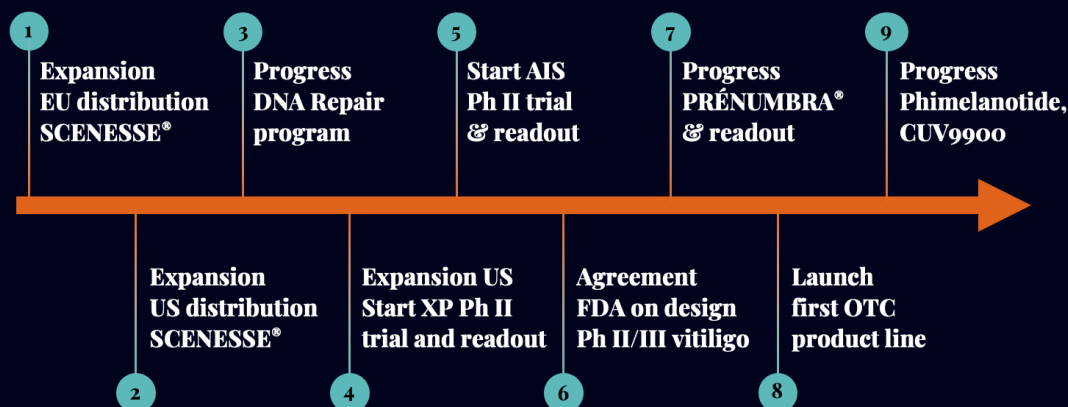
CLINUVEL's Board acknowledges the relationship between shareholder value and the visibility of a pharmaceutical program. By and large, whilst orphan drug markets excite, they do not provide wider visibility due to the relatively small size of the disease entity. However, each patient, each state of pathology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

However, in the next phase 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, hence the rationale for the Communications, Branding & Marketing Division.

CLINUVEL is embracing the opportunity to emerge as a patient and consumer focussed company. We will need to connect to diffused audiences worldwide by tailoring communications and content across platforms. A professional team – agency style – is tasked to grow audiences before it introduces its current and relevant products. Another step to a continuous dialogue with viewers and users is to concentrate on data driven engagement. CLINUVEL has chosen to be progressive and move away from the traditional pharmaceutical approach to address and connect with the current and next generation of users.



## Planning 2021



## Conclusion

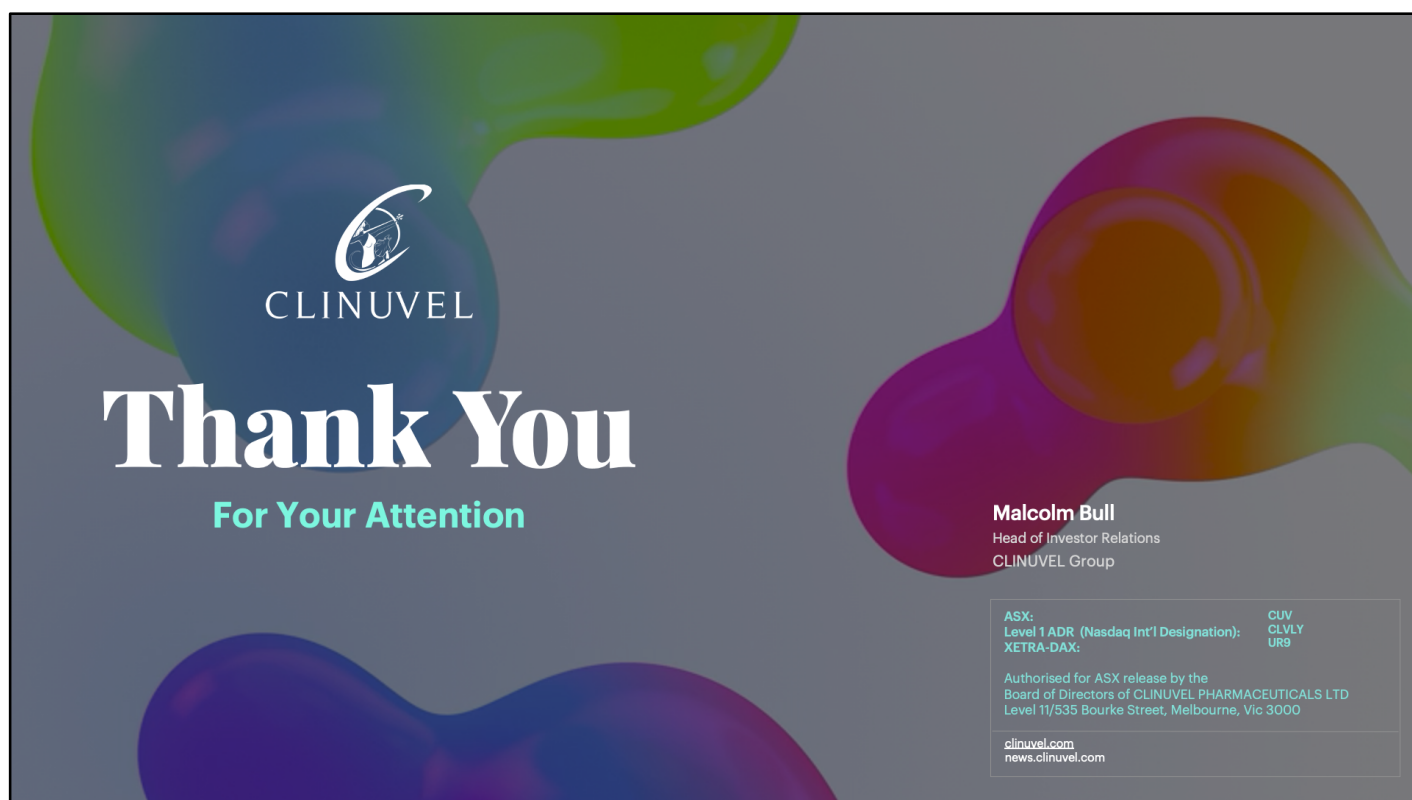
- Diversified R&D underway
- Targeted Technology Translation - DNA Repair
- Financial strength and viability established

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

The Strategic Update of October 2020 explained that our melanocortin technology lends itself uniquely to a dual strategy to serve prescription and non-prescription markets. This can be reviewed on the CLINUVEL website (at [www.clinuvel.com](http://www.clinuvel.com)). A key, but unexpected, part of the pharmaceutical legacy is that the very assurance the Company demonstrated to regulators on the safety of afamelanotide has now become one of CLINUVEL's unique propositions and the prime asset enabling us to develop derivative products for wider retail markets. Our technology originates from a highly regulated environment and can be translated to non-prescription products (pharmaceumables) with an emphasis on SAFETY and genuine care for human biology. This is a unique position which very few companies would be able to emulate and given the assessed demand for authentic dermatocosmetics, we are well positioned in this underdeveloped market segment.

Following an eventful 2020 with new milestones achieved and progressive news flow from the Company on its growth and expansion, nine key objectives listed for 2021 form the basis of ongoing news.

In conclusion, CLINUVEL's strategy is to become a diversified operation based on the dual progression of the core Pharmaceuticals Division and the new Healthcare Solutions Division. New to shareholders is our unfolding of the ischaemic stroke program and the DNA Repair Program with trials in XP and in healthy volunteers. We are diversifying our R&D and translating our technology from a position of financial strength and viability.



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, 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.clinuvvel.com>.

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