



Diversified Specialised Pharmaceutical

H.C. Wainwright 24th Annual Global Investment Conference

September 12-14, 2022

ASX: CUV
XETRA-DAX: UR9
Level 1 ADR: CLVLY

clinuvel.com
news.clinuvel.com

Presented by:

Malcolm Bull

Head of Australian Operations
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Forward-Looking Statements

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products; the COVID-19 pandemic and/or other world, regional or national events affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg), PRÉNUMBRA® or NEURACTHEL®; our ability to achieve expected safety and efficacy results in a timely manner through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe, Israel, China and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE®, PRÉNUMBRA® or NEURACTHEL® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; our ability to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2022 Annual Report. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.



Mission & Objectives

Establishing a specialised
pharmaceutical group -
diversified and vertically integrated to
serve unmet medical and healthcare needs

We provide a safe and accountable environment,
where our staff grow and build a career.

In pursuing this mission, we provide long-term
value for society and our shareholders.



CLINUVEL Group

Functional Divisions

Pharmaceutical
R&D + Commercial

Healthcare Solutions
Translational science to
OTC products

Communications, Branding & Marketing
Establishing & addressing new audiences

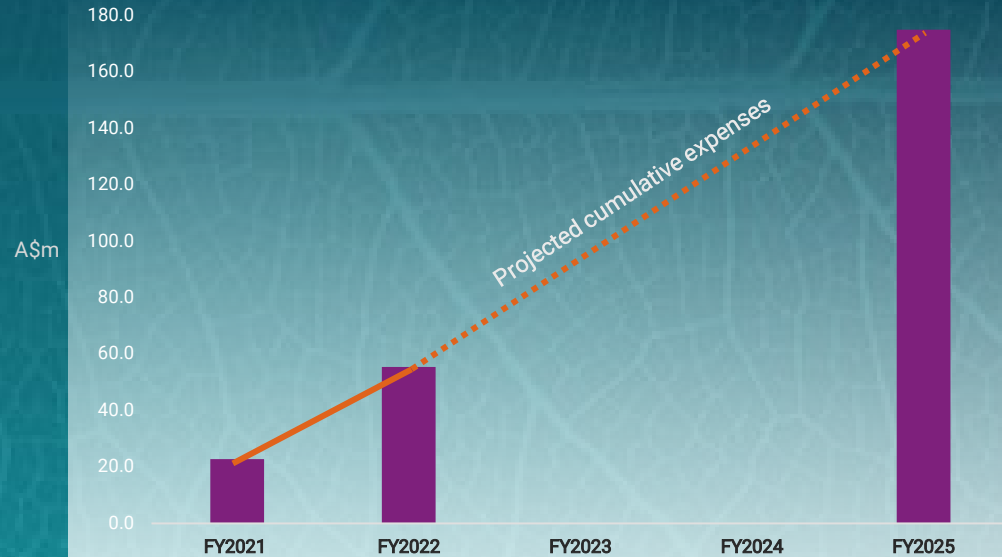
Manufacturing
Integrated supply chain

Focus:
Growth - Profitability - Innovation

Risk Management:
Financial - R&D - Commercial

Commitment to R&D:
Targeted Technology Translation

Projected Expenditures:
A\$175m FY2021-2025



Actual expenses FY2021 and FY2022, indicative path FY2023 and FY2024 to planned cumulative expenses to FY2025.



CLINUVEL Group

Proven Technology

1. SCENESSE® (afamelanotide 16mg)
 - Synthetic peptide, mimics biological α -MSH
 - First *systemic photoprotective* (Rx) for erythropoietic protoporphyria (EPP)
2. SCENESSE® positive safety profile maintained >12,000 overall doses administered
3. α -MSH - melanocortin family (MC1,4,5R)
4. Scientific acknowledgement of ubiquitous role of melanocortins



Ongoing Commercial Operations: EU, CH, IS, US

EEA launched June 2016

- Six financial years of post-authorisation
- Standard of care established
- Long-term post-authorisation use confirms safety, effectiveness (*Wensink et al 2020*)

US launched April 2020

- Exceeded number of Specialty Centers
- Exceeded number of payors
- Direct distribution to network hospitals
- Annual bimonthly treatment cycle



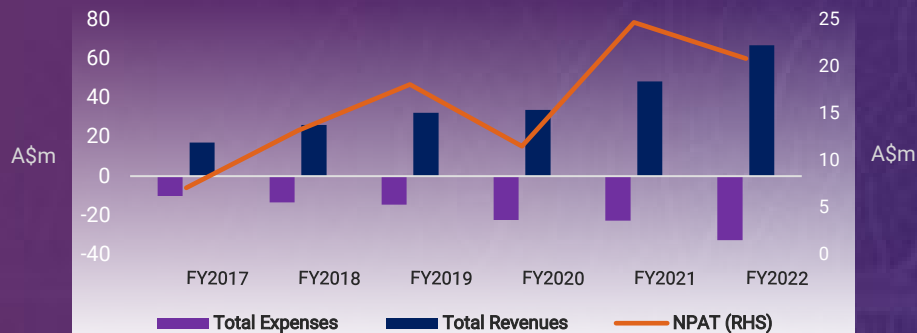
Financial Discipline

From R&D to Commercial (since June 2016)

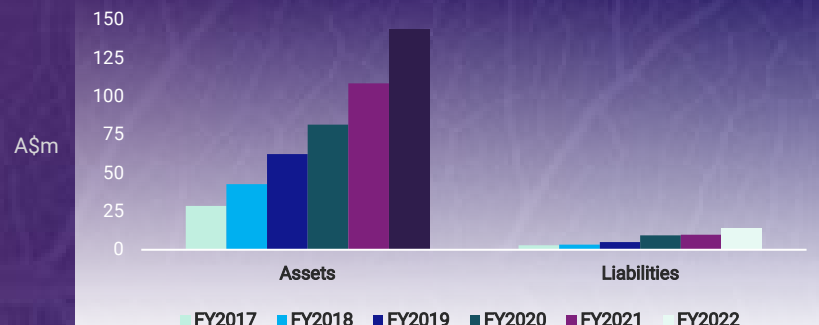


Six Year Performance

Growth in revenues, and by controlling expenses, one has arrived at....



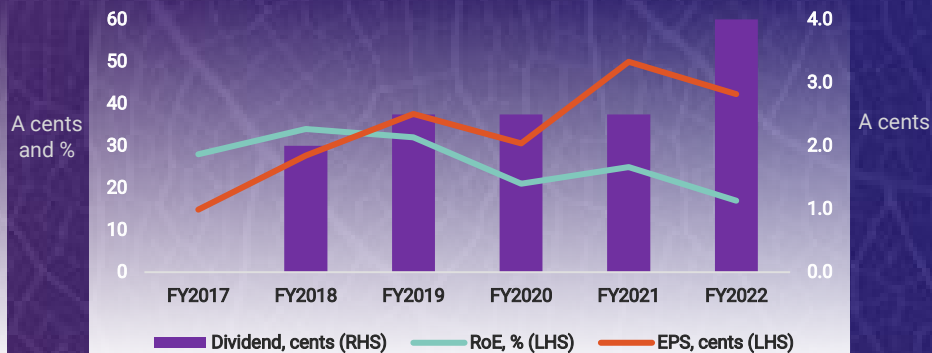
... a strong balance sheet and.....



... with growing cash reserves to self-finance organic growth.....



... delivering positive performance metrics and dividends to shareholders.



EPP Therapeutic Landscape

SCENESSE® - The Standard of Care in EPP

- Safety profile accumulated since 2006 in EPP patients
- Approx. 12,000 doses administered
- >25 peer review publications
- Lifelong data collection
- Growing global network of physicians
- EMA reviewing label extension to adolescents 12+ years

Experimental Treatments Under Evaluation

- Genetic therapies (pre-clinical, literature)
- MC1R agonists (pre-clinical and clinical stage)

"Competition whose motive is merely to compete, to drive some other fellow out, never carries very far.

The competitor to be feared is one who never bothers about you at all, but goes on making his own business better all the time."

Henry Ford



CLINUVEL's Strategic Path

Multi-pronged Strategy

Expansion strategy

1. Portfolio of Melanocortins (Rx):
 - Translation of a melanocortin to multiple indications
 - ACTH in development
 - Small molecules
2. Targeted Technology Translation
 - Non-Rx consumer health products
3. Vertical Integration
 - All functions inhouse
 - Manufacturing
4. Acquisitions



Specialised Pharmaceutical

Portfolio of Melanocortins

Afamelanotide – Photoprotective, Repigmentation, Anti-Oxidative, Anti-Oncotic, DNA Repair

| | | | |
|--------------------------------|---------|--------------------------------------|--------------------------------------|
| SCENESSE® (afamelanotide 16mg) | Implant | Adults – EPP, XP, vitiligo, stroke | Commercial, In development |
| SCENESSE® Enfance | Liquid | Paediatric 12-17– EPP, XP, vitiligo | In development |
| PRÉNUMBRA® Instant | Liquid | All ages – stroke, XP, CNS disorders | Developed for clinical use in stroke |
| PRÉNUMBRA® Modified-release | Liquid | Adults – stroke, CNS disorders | In development |

Adrenocorticotrophic hormone (ACTH) – Anti-Oxidative, Anti-Oncotic, Neurotrophic

| | | | |
|------------------------------|--------|---|--------------------|
| NEURACTHEL® Instant | Liquid | Adults – acute neurological, endocrinological, degenerative disorders | Update expected Q3 |
| NEURACTHEL® Modified-release | Liquid | | In development |

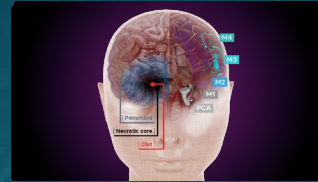
Next generation melanocortins – Enhancing DNA Repair and Assisting Re-Pigmentation

| | | | |
|------------------|-------------------|-------------------------------------|----------------|
| CUV9900 | Topical, leave on | Adults – anti-oxidative, DNA repair | In development |
| Phimelanotide | Topical, leave on | Adults – repigmentation | In development |
| Parvysmelanotide | Topical, leave on | Adults – repigmentation | In development |



Clinical Development

Targeting Several Identified Patient Populations with Afamelanotide



DNA Repair

CUV156

CUV151/152/153

- Xeroderma Pigmentosum patients – C and V variants – at highest risk of exposure to UV-HEV
- Disease-free individuals as control (CUV151)
- **Endpoints:** safety, anti-oxidative effect, DNA repair

Vitiligo

CUV104

- Patients of darker skin types (Fitzpatrick IV-VI)
- Inclusion > 10% depigmentation
- Endpoints: face, head & neck
- >70% repigmentation
- CUV104 to commence in Northern Hemisphere Q3 2022, afamelanotide as monotherapy

Arterial Ischaemic Stroke

CUV801

- First study (n=6) completed
- Results confirmed safety with no cerebral adverse events and improved neurological functions in 5 patients
- CUV803 study planned 2023

Variegate Porphyria

CUV040

- Confirmed biochemical diagnosis
- Inclusion: multiple lesions p/a
- Endpoints: reduction in blister formation
- Controlled photo-provocation

New Indication

CUV901

- Awaiting administrative sign-off, IP



Healthcare Solutions Program

Dermatocosmetics



1. Translation of Technology

Establishment of Division of
Healthcare Solutions

2. Melanocortin Molecules

Use in non-prescription products

3. Individuals at Highest Risk of UV and HEV

- History of skin cancer(s)
- Immune suppressed
- Extreme outdoors

4. Dermatocosmetic Products

3 x OTC product lines

- Polychromatic care
- Stabilisation melanogenesis
- Assisted DNA-repair



CLINUVEL Group

Summary

Six Consecutive Annual Profits to FY2022

- First in class treatment SCENESSE®
- Strong annual demand

Validated Long-Term Strategy

- Solid returns to shareholders

Strong Foundations to Grow

- Positive safety record SCENESSE®
- Robust balance sheet, debt-free, high cash reserves
- Diversification in process

Expect

- Read-outs on Xeroderma Pigmentosum (DNA-repair)
- Start vitiligo trial CUV104
- Launch 1st OTC product line
- PK study NEURACTHEL® (ACTH, generic)
- Ongoing risk management





Thank you
for your invitation

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Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTIALS LTD

