CLINUVEL

A STORY OF INNOVATION & LONGEVITY, RESISTANCE & RESILIENCE

23–24 June 2025 | Frankfurt, Düsseldorf

Philippe Wolgen, Managing Director

ASX: CUV | **Börse Frankfurt**: UR9 | **ADR Level 1**: CLVLY

FORWARD-LOOKING STATEMENT CLINUVEL GROUP

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), CYACÊLLE, 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®, CYACÊLLE, 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 2024 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.

EVALUATION

20 years going concern, 39 unremarkable financial audits

"a company with no hope"

2005 Goldman Sachs (AUS)

"vitiligo is a cosmetic disease"

2012 US payor

"an attempt in vain of putting funds to a molecule that will never come to market"

2006 Prof Sir Gus Nossal

"a team pursuing an illusion which our own teams would never devote time on"

2006 CEO large pharma

"we only recognise disability as a visible handicap, not an invisible one as EPP"

2019 Head of NICE (UK) advising NHS

INNOVATION & LONGEVITY | RESISTANCE & RESILIENCE

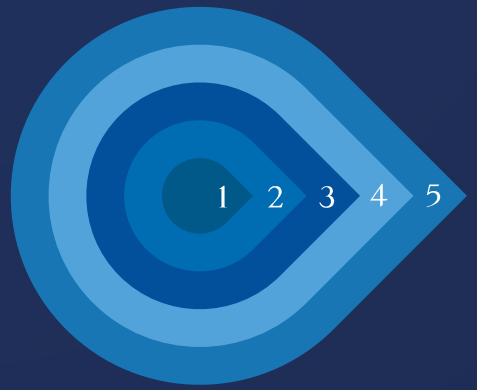
SCENESSE® – *world's first systemic photoprotective drug*

2010	2014	2016	2017	2019	2021	2023	2026
first financial proof of concept	EMA approval	first European reimbursement	first profitability	FDA approval	diversification to ACTH, PhotoCosmetics	start late-stage vitiligo program	first read out CUV105

ACTH: adrenocorticotropic hormone, EMA: European Medicines Agency, FDA: US Food and Drug Administration, NHS: (English) National Health Service, NICE: (English) National Institute for Health and Care Excellence

FOCUS ON MELANOCORTIN INNOVATION

a concentric strategy diversifying & mitigating risks – peptides + delivery technologies



1	afamelanotide	EPP, vitiligo
2	small melanocortin peptides	safety for wider use
3	ACTH – generic	relapsing MS, infantile spasms
4	next-gen delivery formulations	controlled-release liquids
5	PhotoCosmetics with melanocortins	properties & knowledge melanocortins

WHERE IS CLINUVEL ON THIS TRAJECTORY?

1. SCENESSE® commercial in EPP, in trials in vitiligo
2. small molecule(s) passed 2 safety tests, in formulation
3. ACTH in manufacturing process, dossier to be submitted as generic
4. next-gen formulation in development, confirmation of stability
5. PhotoCosmetics in final development, preparation of marketing & distribution

CLINUVEL IS ABLE TO SELF-FINANCE STRATEGY 1 TO 5

MS: multiple sclerosis

BIO-PHARMACEUTICAL CASES

Great companies which faced adversity...

Opthea – suspended
Suspended - March 2025
MCAP: from A$1.4b to zero
Lead program failed in Phase III trial, in restructuring

Mesoblast – A$2.1b
2 failed FDA submissions, succeeded at 3rd attempt in 2025, debt US$119m

Imugene – A$99m
Debt $35.4m

Metabolic – failed trial
MCAP: from >A$240m to zero
Asset abandoned after failed Phase IIb trial

Pharming – €618m
Q2 2025 Revs US$79.1m, Net loss US$14.9m
acquisition not accretive

Palatin Tech. – US$7.4m
Debt, delisted NYSE, MCAP decline

Biofrontera AG – €14.4m
Ongoing licensing and supply agreement issues with US counterpart

Amryt – trade sale US$1.25b
107% MCAP premium acquisition by Chiesi, January 2023

Viralytics – trade sale A$502m
160% MCAP premium acquisition by MSD, February 2018

MCAP figures from S&P Global Market Intelligence
All financial filings from latest/last reports unless stated otherwise

BIO-PHARMACEUTICAL CASES

What's the upshot?

- adversities: technological failure, lack of funding
- US deepest capital market for biotechnology
- Nasdaq >70 trading below cash levels, 5 ASX life sciences trading below cash
- 4 melanocortin companies left: CUV, RYTM, ANIP, LG Chem
- cash is key to execute developments, overcome setbacks, protect shareholders

- **CUV**: 10-year price range ~1,100%, catalyst driven price reactions A$1.50 to A$44.74

FINANCE

Anticipation of downcycles & capital needs

debt free	
cost of equity	5.3%
OPEX, 2005–2014	A$129.5m
OPEX, 2015–2024	A$222.1m
CAGR [1]	
revenues	38.0%
expenses	20.0%
profit	25.7%
cash reserves [2]	A$198.2m

1. Revenues and Expenses, 8 years (2017-2024); Net Profit After Tax, 7 years, (2018-2024).
2. Cash reserves as of 31 December 2024.

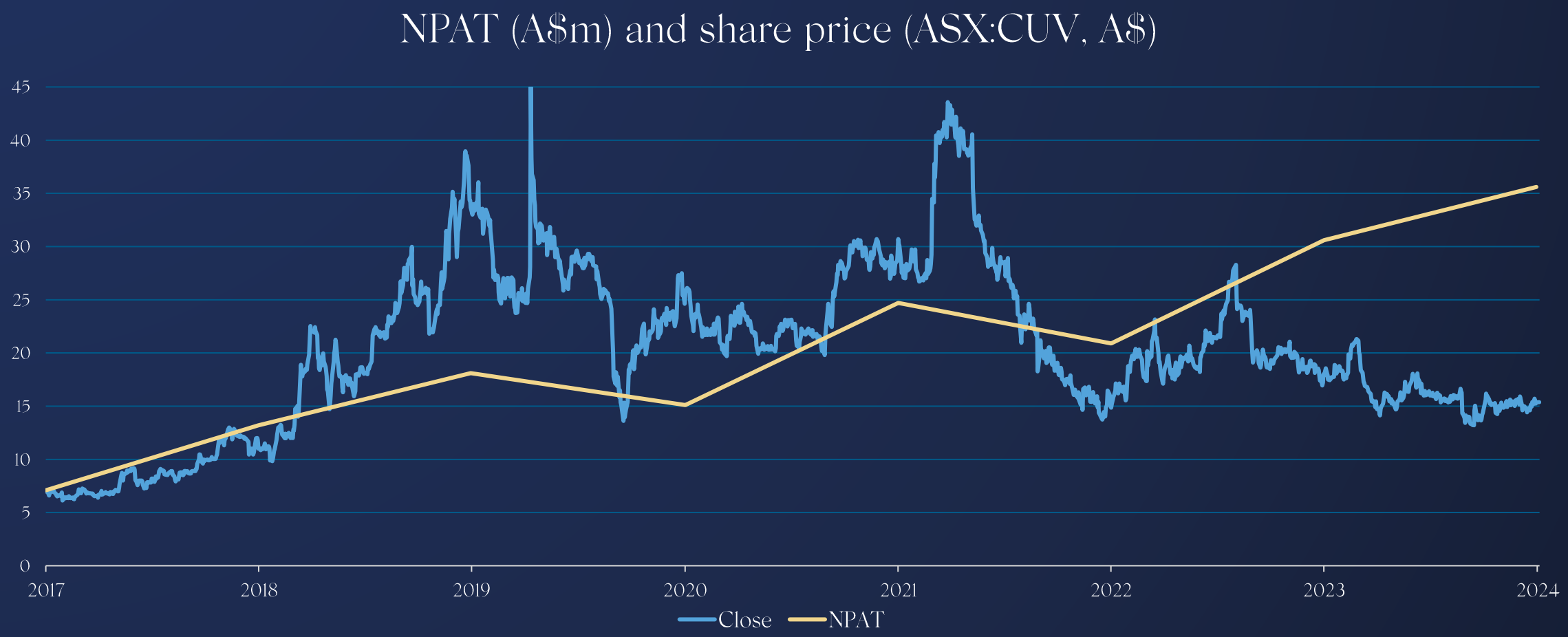
CLINUVEL'S FUTURE

What are the investments leading to?

1. SCENESSE® expansion in EPP	H2 2025/H1 2026
2. SCENESSE® in vitiligo	2027/8 depending on regulatory discussions
3. NEURACTHEL® (ACTH) to enter US generic market	FDA filing ANDA 2026
4. Expansion to next-gen formulations	clinical results 2026/7
5. Integrate manufacturing in-house	2026
6. Complementary technologies to be acquired/in-licensed	2026/7
7. Expanded with PhotoCosmetics	2026/7

A PARADOX

NPAT CAGR >25% (7yrs) versus share price decline



CATALYSTS & CALENDAR I

2025 – 2026

Commercial growth SCENESSE®	Financial year end results FY25	4th week August
	EMA decision dosage expansion adults	Q4 2025
	EMA re-file adolescents SCENESSE®	Q4 2025
	Health Canada decision marketing authorisation: SCENESSE® in EPP	Q4 2025
	Distribution expansion to 120 Specialist Centers USA–CA	Q4 2025
Clinical, regulatory	NEURACTHEL® (ACTH) manufacturing update	Q4 2025
	Regulatory update vitiligo	Q4 2025
	First patient first visit CUV107 – vitiligo	Q4 2025/Q1 2026

CATALYSTS & CALENDAR II

2025 – 2026

Clinical, regulatory	CUV105 vitiligo – primary protocol complete	H1 2026
	CUV105 first results	H2 2026
	Start CUV053, variegate porphyria study	H1 2026
Communications, IR, PR	Non-deal roadshows DE, USA, AUS	H1/2 2025
	Premarketing activities PhotoCosmetics	Q3/4 2025
	American Academy of Dermatology Meeting 2026	Q1 2026

SUMMARY
2005 – 2026

1. From high-risk novel technology to profitability

2. Expertise retained, & expanded

3. Cash reserves of >A$200 million to execute
    i. expanded access SCENESSE® - Europe, USA, RoW
    ii. new product development – pharmaceutical & PhotoCosmetic
    iii. vertical integration
    iv. M&A

4. Near-term catalysts across commercial, clinical and regulatory

Shareholder address

Globally scanning publicly listed biotechnology companies there are very few peer comparisons to CLINUVEL. Against all odds our team has achieved commercial success once, and there is no doubt we will prolong its economic performance. The firm's cash reserve has served shareholders.

Frustration from shareholders holding public stock is clearly found in price and timelines. CLINUVEL's unique dilemma or challenge is its position to advance cogent technology while not being able to publicly disclose data and progress. Patience will need to be borne in this investment to understand the full extent of product development, aiming to make a verum difference and impact to patients, industry and shareholders.

Philippe Wolgen

CLINUVEL

THANK YOU FOR YOUR INTEREST

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