CLINUVEL

Building a global biopharmaceutical group

BTIG Biotechnology Conference, New York

Lachlan Hay, COO, Acting CEO

30 July 2025

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 and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed and characterised by us as PhotoCosmetics; 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, the UK, Israel, China, Japan, and/or LATAM regions 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®, NEURACTHEL® or products developed as PhotoCosmetics which may lead to the Company being unable to launch, supply or serve its commercial markets, special access programs and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare, Medicaid, and U.S. Department of Veteran's Affairs) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology, cosmetic 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, cosmetic 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.

CLINUVEL

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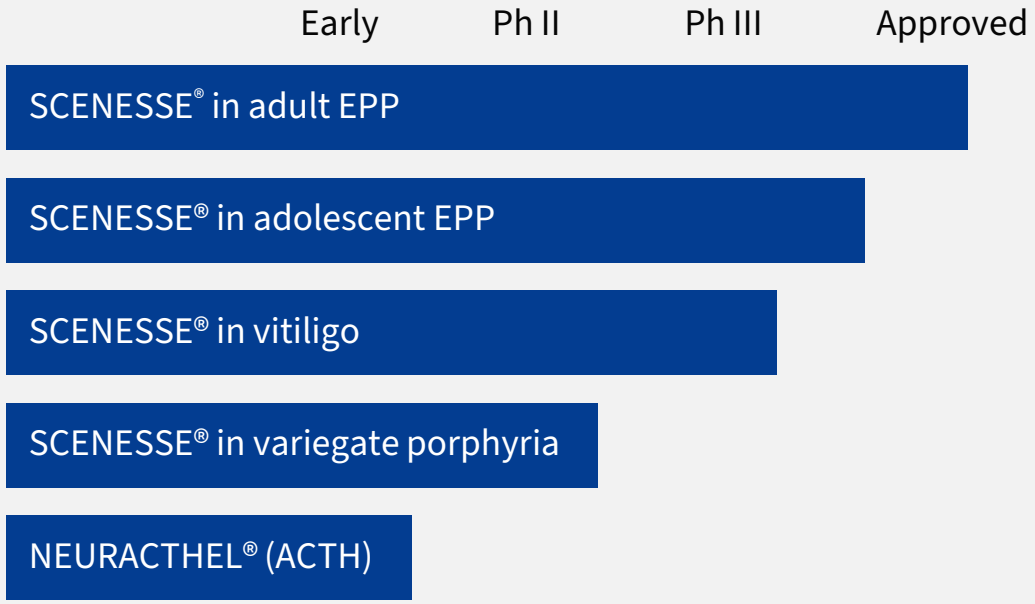
Commercial stage biopharmaceutical

- Commercialized NCE[1] SCENESSE® (afamelanotide) for rare metabolic disorder
- Profitable, A$198m in cash/equivalents (~US$130m)[2], 8 years' consecutive annual revenues growth
- Vitiligo program in Phase III
- Establishing US infrastructure to realize vitiligo opportunity, US$490-570m revenues in yrs 1-2

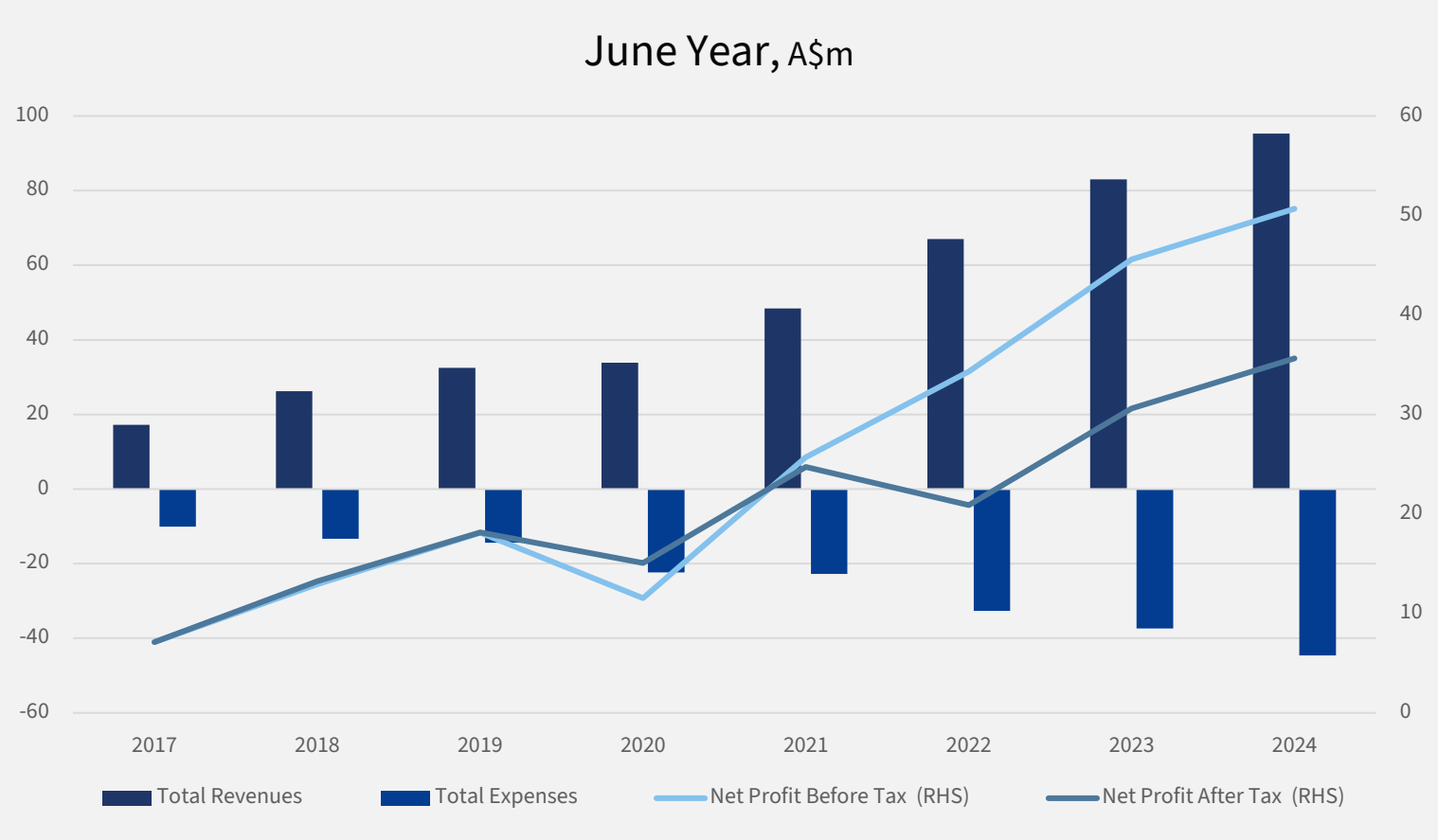
Pipeline – melanocortin peptides



[1] New Chemical Entity
[2] Cash position at 31 December 2024. CLINUVEL's financial year 2025 (year to 30 June 2025) will be released by the end of August 2025. A$1 AUD ≈ US$0.65.

Profitability

Revenue growth, profitability from distribution of SCENESSE® in EPP

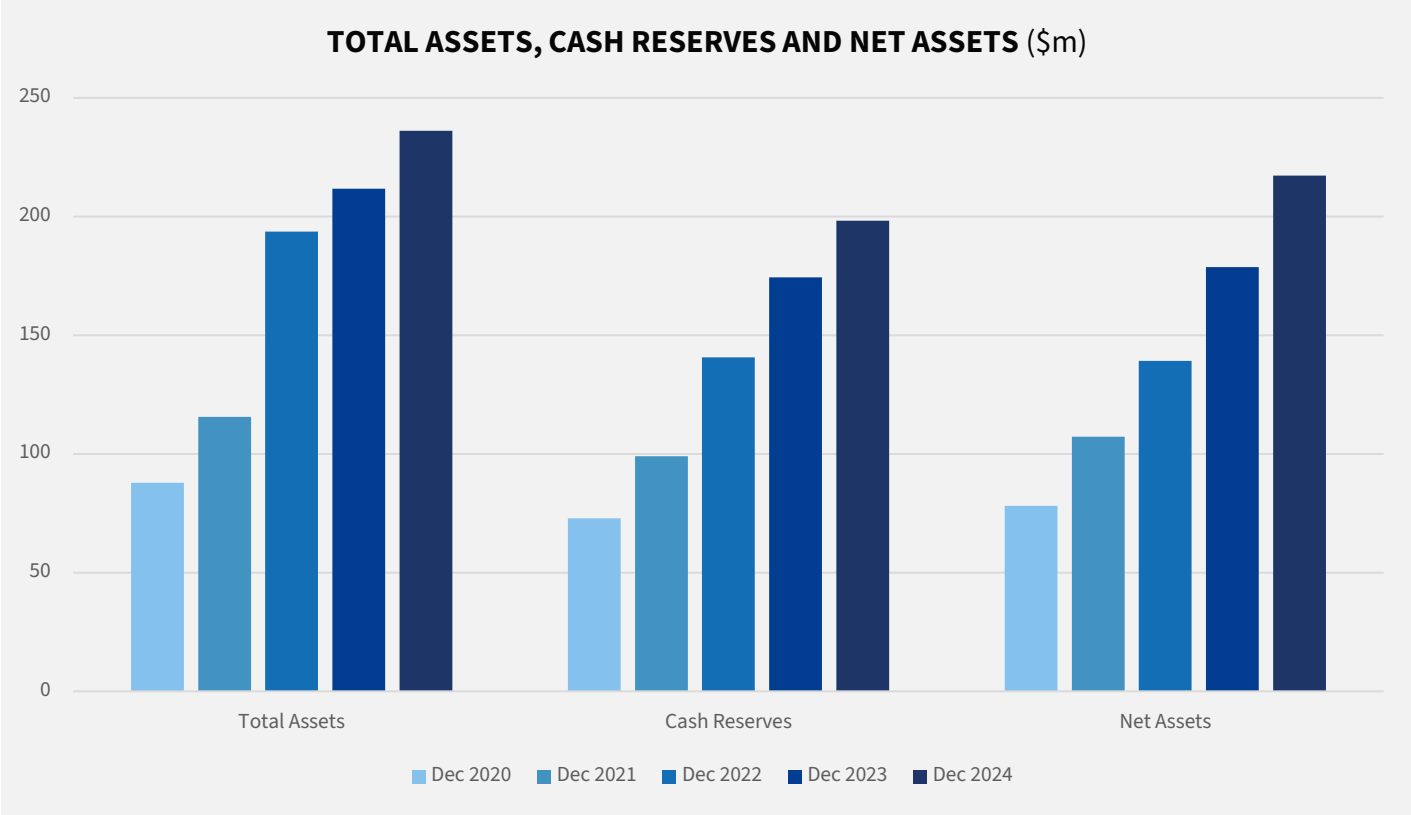


- 8 years consecutive annual revenues growth (CAGR 38%)
- Controlled fixed costs support expansion (expenses CAGR 20%)
- 8-year average EBIT Margin 48%, Profit Margin 45%
- 7 years consecutive annual dividends – FY24 A$0.05 fully franked
- FY24: Earnings per Share A$0.72, Return on Equity 18%
- H1FY25: Revenues up 10.5%, NPBT up 48.1%, NPAT up 28.7%

Total Revenues include interest and other income.

Balance Sheet Strength

Enables self-financing expansion



FY25 results (year to 30 Jun '25) to be reported by the end of August 2025

$m	31 Dec '24	30 Jun '24
Total Assets	236.2m (+2.2%)	231.1m
Cash Reserves	198.2m (+7.8%)	183.9m
• covers OPEX for 2-3 yrs • enables continued pipeline development • provides buffer from externalities • finances $20m 12-month share buy-back (28/03/24) • finances value-adding asset acquisition		
Total Liabilities	18.9m (-32.7%)	28.1m
• trade creditors, suppliers • debt-free		
Net Assets	217.3m (+7.0%)	203.0m

Cash Reserves equals Cash & cash equivalents plus Cash held in term deposits.

Focused Expansion strategy

Integration of key functions 'in-house'

Distribution SCENESSE®	**Melanocortin product development, clinical studies**	**Translation of technology to PhotoCosmetic products**	**M&A**
Focus on increasing patients, prescribers, treatment centres – New jurisdictions – EPP adolescents (12-17 years) – SCENESSE® dosage (EU)	PRÉNUMBRA® and NEURACTHEL® – CLINICAL STUDIES vitiligo variegate porphyria CNS	1. Polychromatic screen CYACÊLLE & CYACÊLLE Radiant – 2. DNA Repair – 3. Melanogenesis	Vertical integration – Innovative technologies

SCENESSE®
in erythropoietic protoporphyria (EPP)

"Afamelanotide has revolutionized my life. With whispers of this treatment in the pipeline for so long, I am delighted that it has been made available in my lifetime."

Adult erythropoietic protoporphyria (EPP) patient

SCENESSE® in erythropoietic protoporphyria (EPP)

CLINUVEL's novel drug for rare disease

SCENESSE® (afamelanotide)

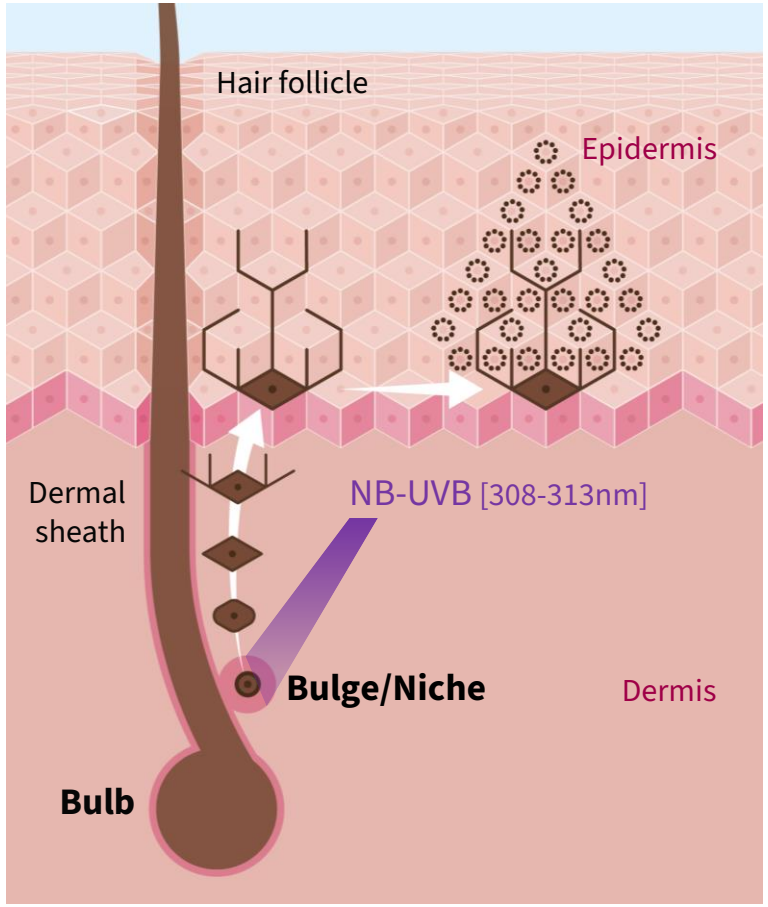
- subcutaneous, injectable, **controlled release implant**
- 60-day dosing, activates melanin, strong anti-oxidant
- world's first systemic photoprotective

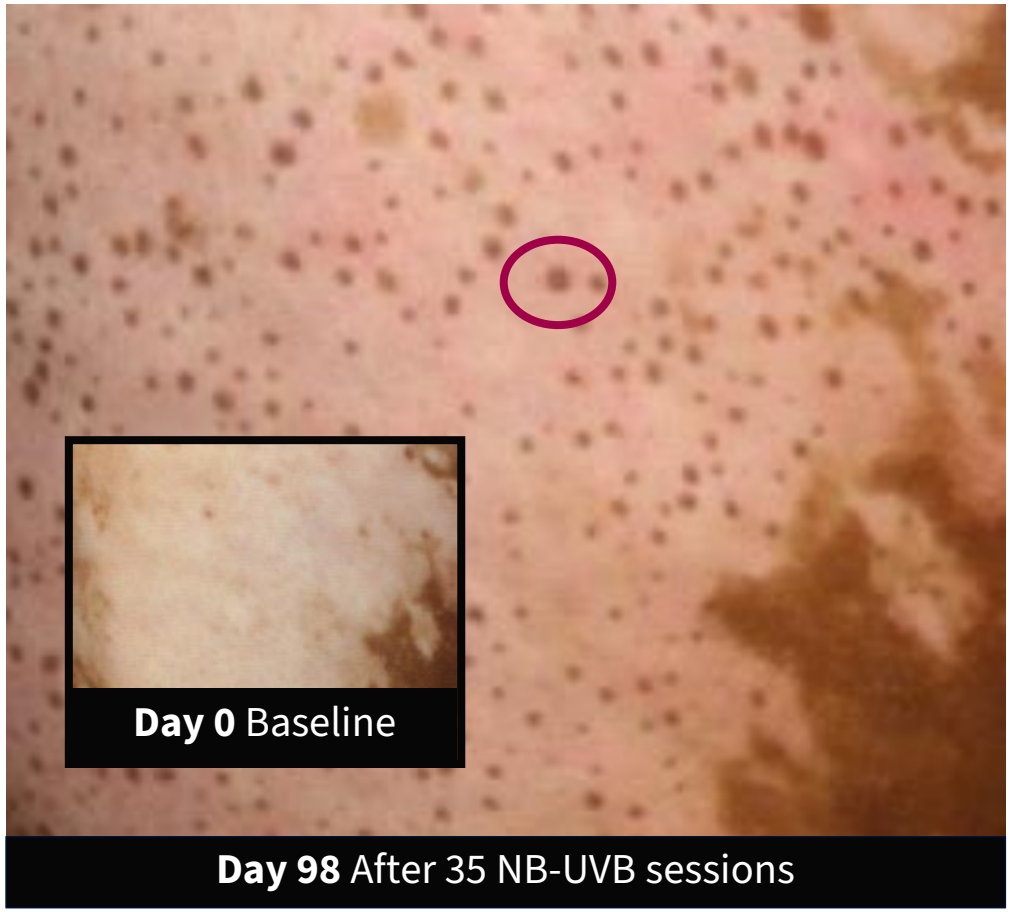
EPP

- genetic disorder, deficiency in heme pathway, debilitating phototoxicity
- ~10,000 patients worldwide
- SCENESSE® approved for EPP in Europe (2014) and USA (2019)
- CLINUVEL established commercial infrastructure, direct distribution model
- Long-term safety profile established: >18,500 SCENESSE® doses administered to EPP patients to date
- A$88m in sales FY2024


SCENESSE®
for vitiligo

NB-UVB – follicular repigmentation



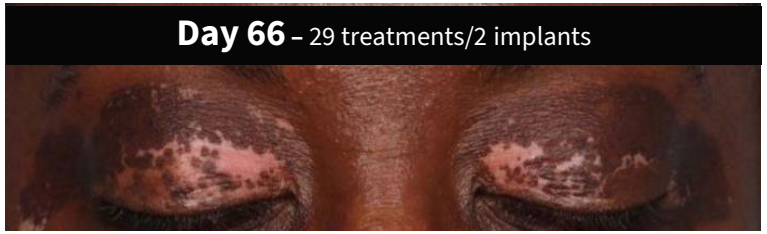


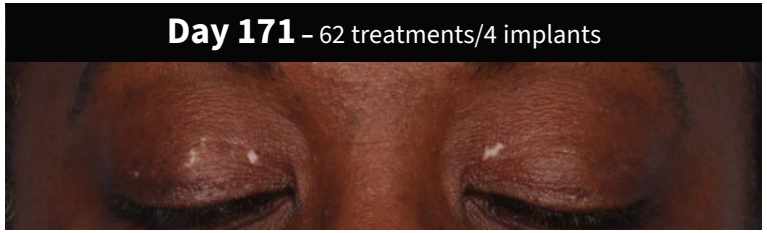
NB-UVB differentiating follicular stem cells

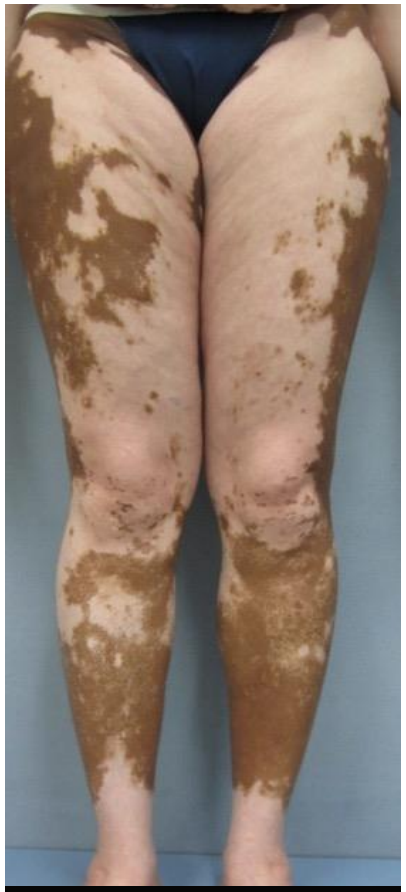
Melanoblasts migrating, become fully functioning melanocytes

Afamelanotide acting as agonist to MC1R expressed

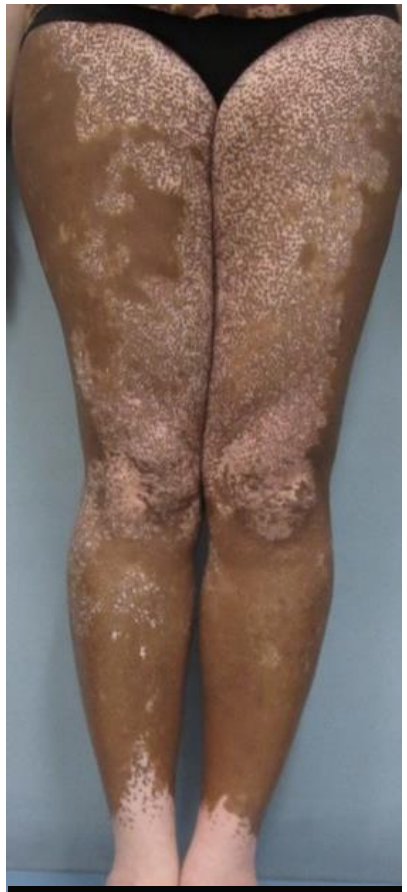
CUV102 Phase II study results



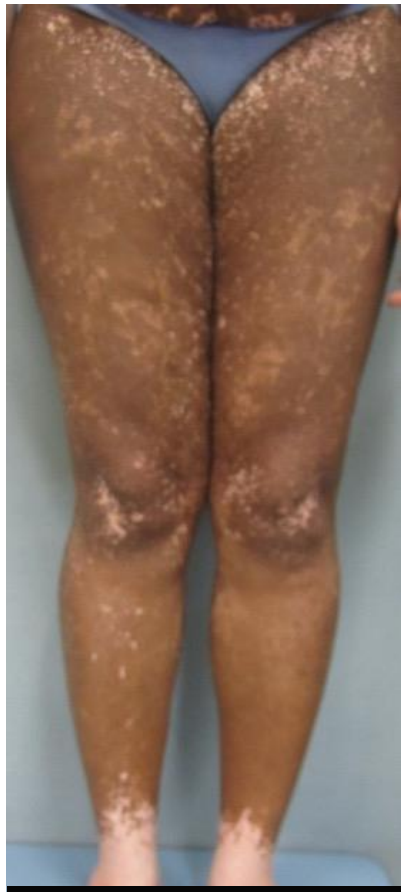




Day 0
Baseline



Day 111
27 treatments/3 implants



Day 179
40 treatments/4 implants

Images have been amended/cropped and pixelated to protect the patient's privacy but are otherwise unaltered. Images courtesy of the investigator.

CUV105 Phase III study – first clinical observations

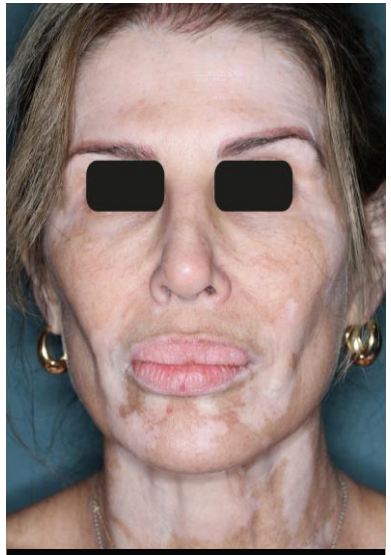
CASE REPORT 1

Female, 55 years old, Skin Type IV

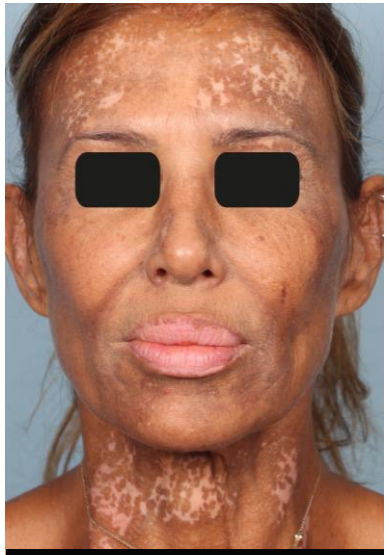
Diagnosed with vitiligo in 2006, slowly progressive disease activity, no previous episodes of repigmentation, and no family history of vitiligo. Unresponsive to previous vitiligo treatments.

PHYSICIAN'S REPORT

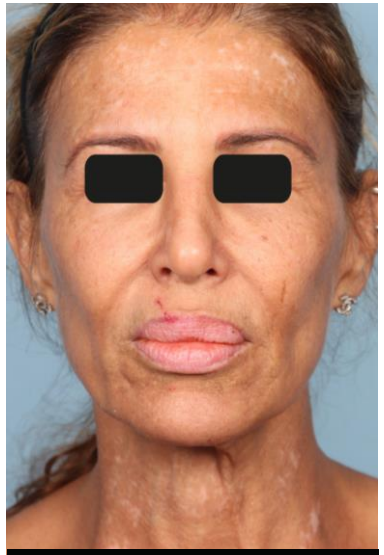
0–90% repigmentation seen after Day 140 but near total repigmentation achieved after continued NB-UVB monotherapy.



DAY 0
Baseline



DAY 134
7 afamelanotide implants
39 NB-UVB treatments



DAY 222
82 days after completing study
53 NB-UVB treatments

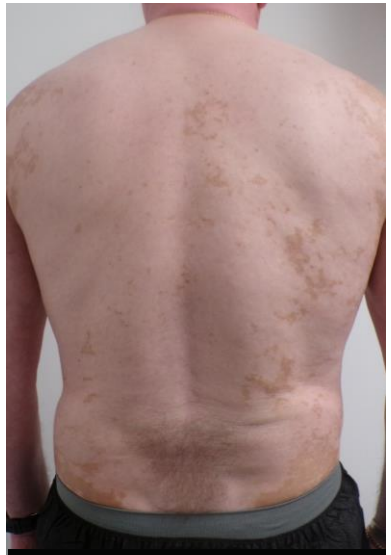
CASE REPORT 3

Male, 56 years old, Skin Type IV

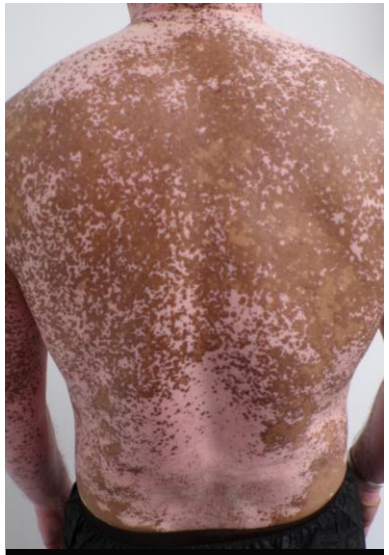
Diagnosed with vitiligo in 1999

PHYSICIAN'S REPORT

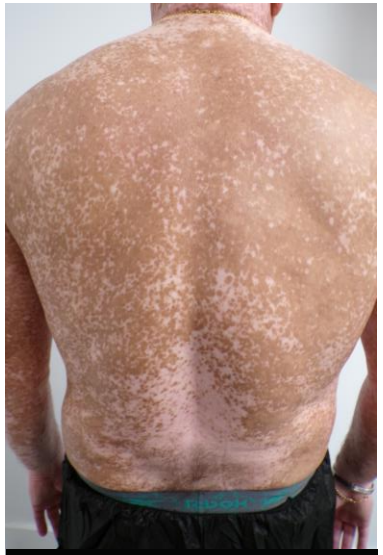
First repigmentation seen around day 42, considerable repigmentation seen by day 106. Patient continued to repigment after conclusion of treatment protocol with no further therapy.



DAY 0
Baseline



DAY 134
7 afamelanotide implants
39 NB-UVB treatments

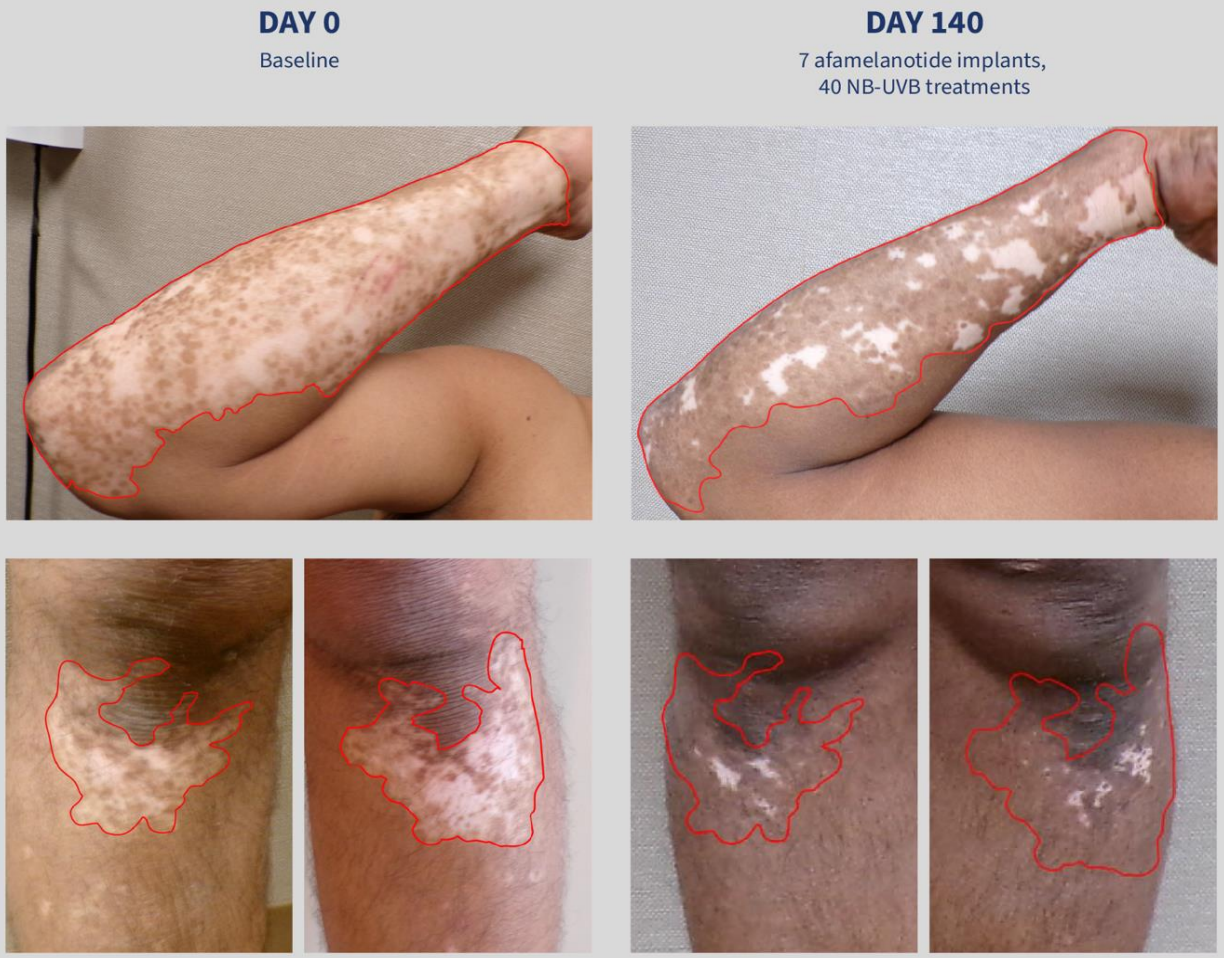


DAY 308
168 days after completing study – no further therapy

CUV105 Phase III study – first clinical observations

CASE REPORT 5

- Male, 46 years old, Skin Type V, diagnosed with vitiligo in 2004
- Images demonstrate repigmentation of vitiliginous lesions on right forearm (top) and lower legs (bottom). The red outlines demonstrates the extent of the initially affected skin.



Overview of Key Milestones

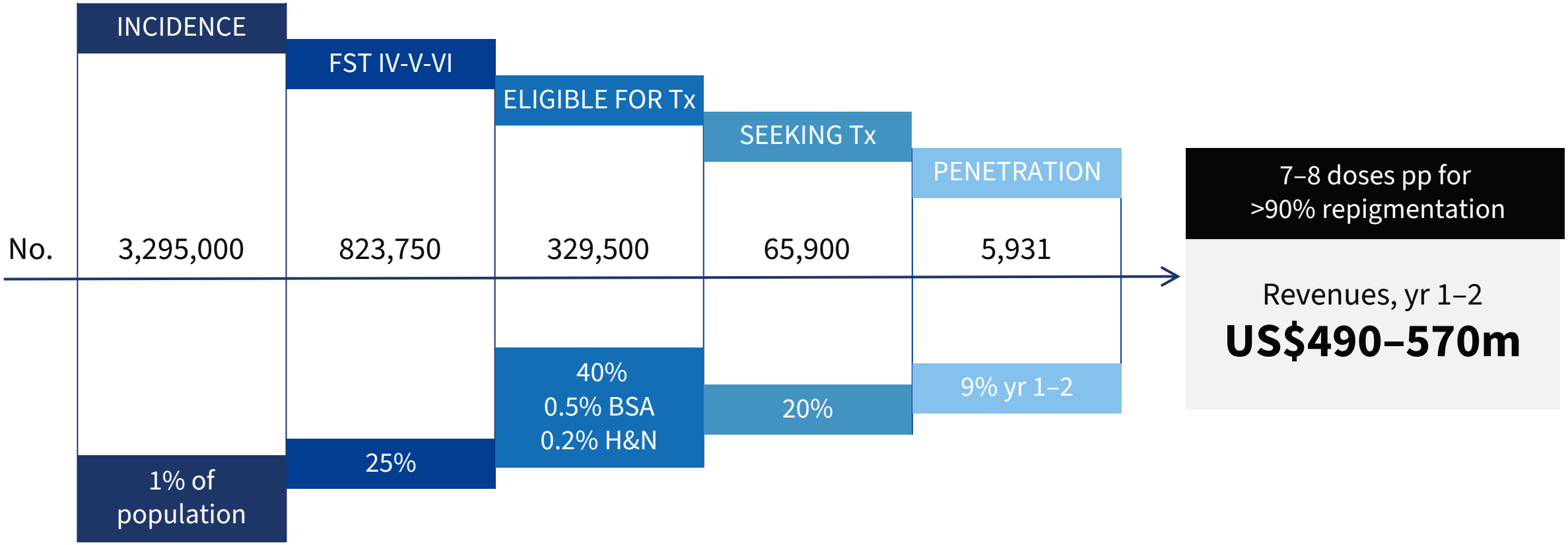
Phase II complete
Results published in *JAMA Dermatology*

Phase III CUV105 (n=210)
- Recruitment completed May 2025
- Treatment period 5 months
- Follow-up 6 months
- First Results 2H 2026

Phase III CUV107
- To commence, Q4 2025/Q1 2026

Vitiligo

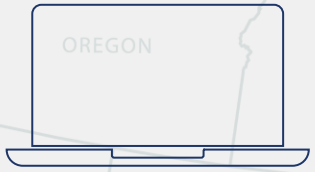
Addressable Market USA – afamelanotide for FST IV-V-VI



*Abbreviations. FST = Fitzpatrick Skin Type; Tx = treatment; BSA = body surface area; H&N = head and neck.

US Commercial Infrastructure

Direct Distribution 2019–2025



In-house commercial team

Director, Nth American Operations
Financial specialists
VA-Medicare-Medicaid
Patient liaison
Executive support
Finance support
Pharmacovigilance
Quality Assurance / distribution

Logistics

DC – cold storage
labelling / packaging
QA
product release

Shipping

cold transportation
direct supply
US medical centers

Medical centers

orders
pharmacy storage
Rx filled
direct contact
104 Specialty Centers US-CAN

<US$5m p/a

Catalysts and calendar

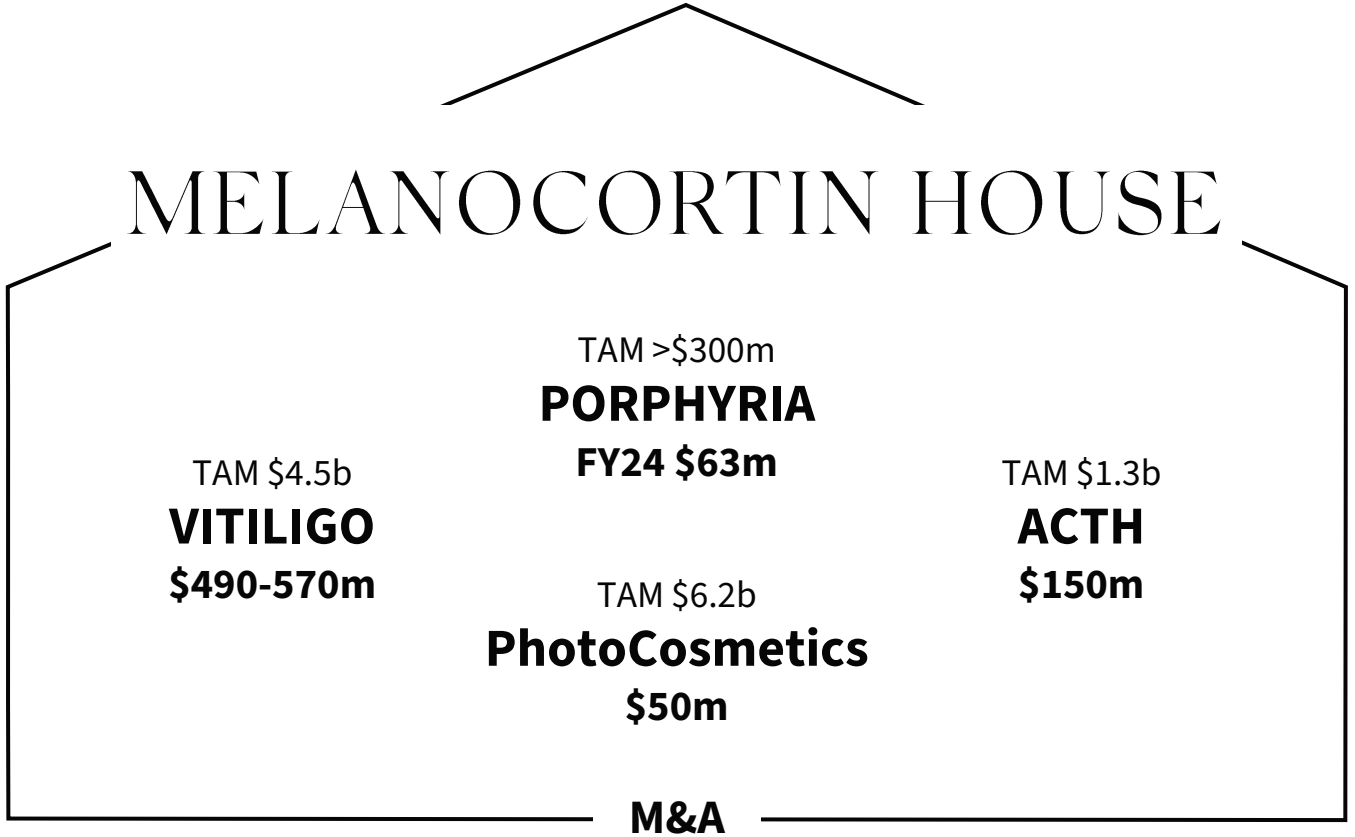
2025-2026

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
	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 & conferences DE, USA, AUS	H2 2025
	Premarketing activities PhotoCosmetics	Q3/4 2025
	American Academy of Dermatology Meeting 2026	Q1 2026

Milestones subject to ongoing regulatory discussions

Vision of the Future

A house of melanocortins



A pharmaceutical group, diversified and integrated to sustain long-term performance

Products, indications & healthcare solutions

- 3 pharmaceutical products
- 5 conditions treated
- 3 PhotoCosmetic product lines

CLINUVEL will

- develop new formulations & products
- treat new indications
- integrate in-house manufacturing
- maintain financial performance
- exercise disciplined deployment of capital
- become a household name

TAM and penetration figures are in US dollars.

CLINUVEL

Thank you for your interest

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

Head of Investor Relations: Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

Investor Enquiries: https://www.clinuvel.com/investors/contact-us

Level 22, 535 Bourke Street, Melbourne – Victoria, Australia, 3000 | T +61 3 9660 4900 | F +61 3 9660 4909

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