CLINUVEL

A distinct business model

Success through discipline

Stifel Healthcare Conference : 11–13 November 2025
Philippe Wolgen | CEO

ASX: CUV | Börse Frankfurt: UR9 | ADR Level 1: CLVLY (uplist to Level 2 in progress)

FORWARD-LOOKING STATEMENT

CLINUVEL GROUP

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. All statements other than statements of historical or current facts made in this document are forward-looking. We identify forward-looking statements in this document by using words or phrases such as "anticipate," "believe," "consider," "continue," "could," "estimate," "expect," "foresee," "intend," "likely," "may," "objective," "potential," "plan," "predict," "project," "seek," "should," "will" and similar words or phrases and their negatives. Forward-looking statements reflect our current expectations and are inherently uncertain. Actual outcomes or results could differ materially for a variety of reasons. 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 2025 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.

Expanding a U.S.A. presence

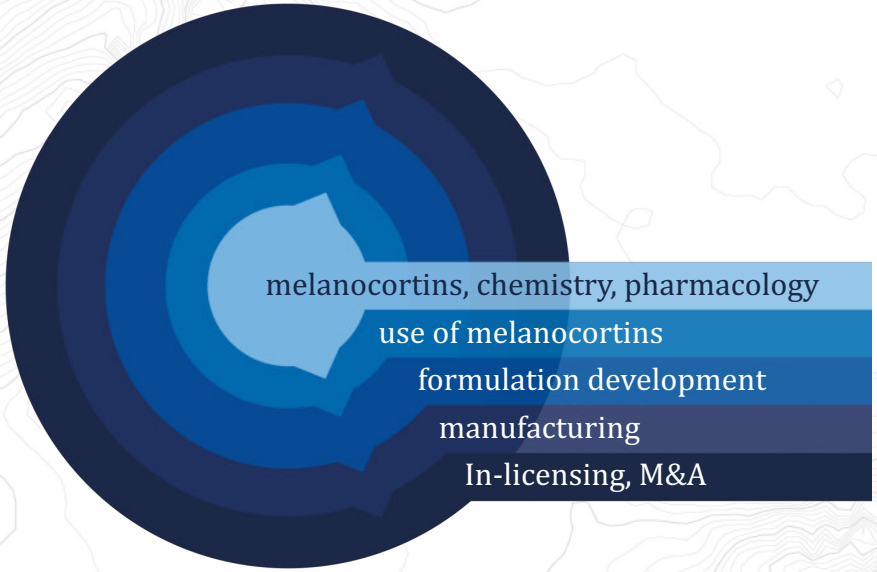
Increased American investor interest

- Phase III vitiligo – 1st systemic Rx [not immune suppressive]
- SCENESSE® in EPP - direct distribution >100 US centers
- American revenues >50%
- Nasdaq uplisting ADRs (Level 2) – SEC filing Q4
- American management – Q2/3 2026

Focused, scalable, disciplined,

HQ – Melbourne
Principle operations – U.S.A, Europe, UK, Ireland, Singapore

Building a sustainable, integrated biopharmaceutical company



Milestones

1999
Incorporated in Australia upon acquisition of afamelanotide technology

2001
Listed on Australian Securities Exchange; trades as CUV

2004
Established American Depositary Receipt, Level 1 program; trades as CLVLY

2004
Commenced trading on Börse Frankfurt; trades as UR9

2006
Strategic refocus – "one drug for one indication"

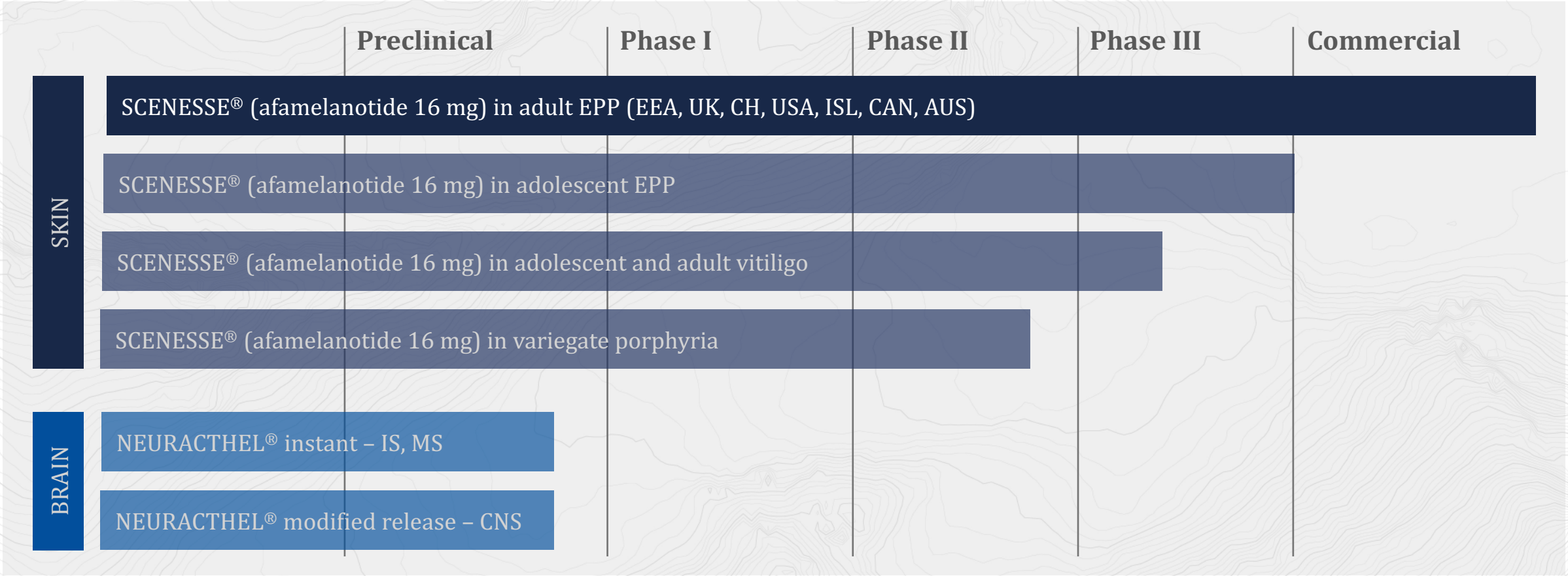
2016
SCENESSE® distribution EU

2020
SCENESSE® distribution USA

2021/22
Expansion of Product Range & Clinical Program; First adolescent EPP patient treated

2025
First phase III vitiligo trial fully recruited; EU maximum recommended dose removed

Pipeline focus: melanocortins (Skin, CNS)



IS= infantile spasms | MS = multiple sclerosis | CNS = central nervous system.

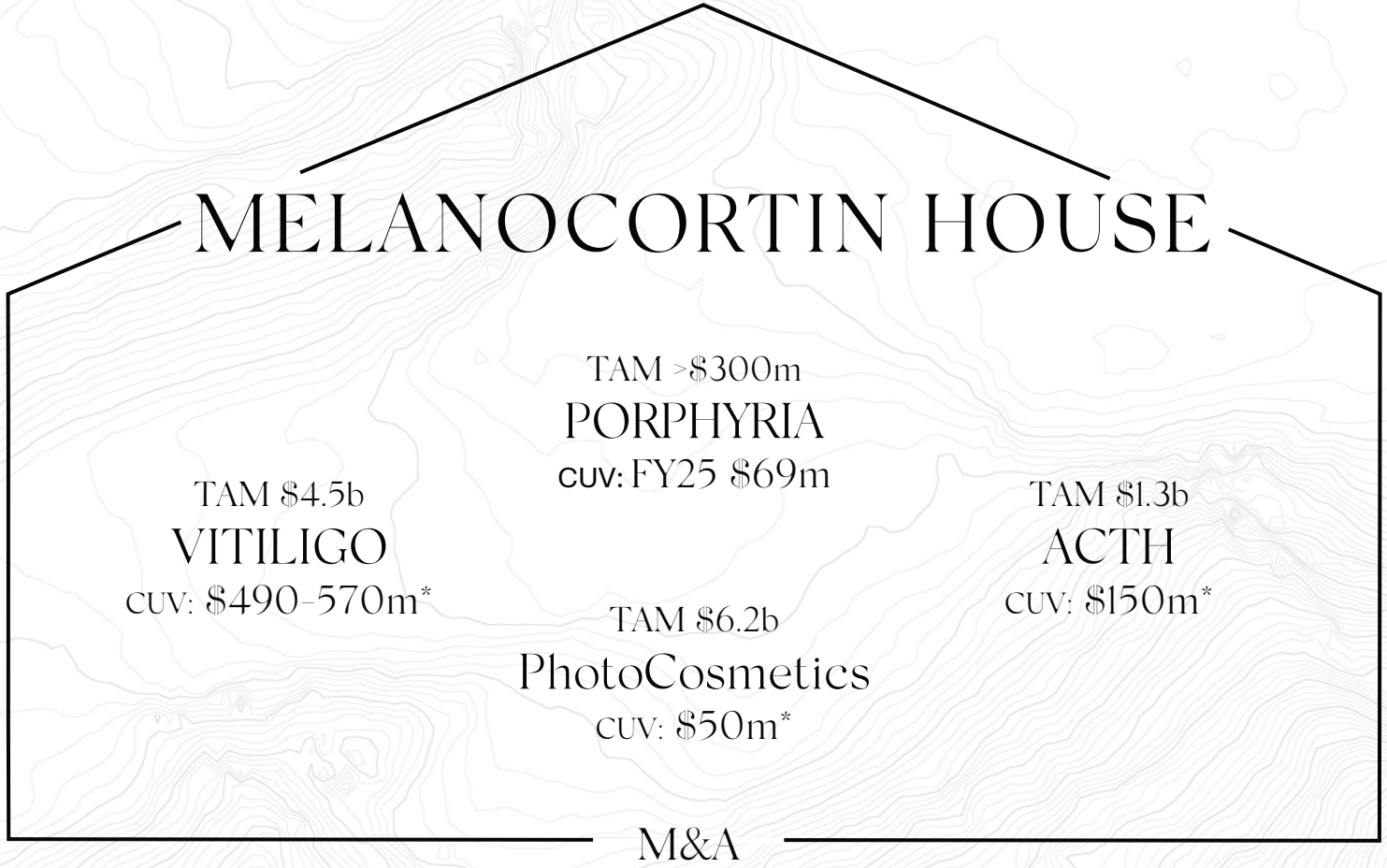
Vision of the Future

Foundation of 20 years

Products, indications & healthcare solutions
- 2 pharmaceutical products
- 5 conditions
- 3 PhotoCosmetic product lines

Advancing RD&I
- novel sustained-release liquid formulation

Capital management
- disciplined deployment of capital
- fiscal probity
- zero dilution – 10 yrs
- debt free



TAM and penetration figures are in US dollars. *CLINUVEL estimate. Year 1 and 2 “for vitiligo”.

FY2025

Financial excellence – a distinct model

- disciplined and balanced approach
- 9th consecutive annual profit
- controlled expenses
- RD&I growth

CONSOLIDATED ENTITY		30 June 2025	Change
Total Revenues, Interest and Other Income	A$m	105.3 [US$70m]	+ 10%
Total Expenses	A$m	53.7 [US$35m]	+ 20%
Net Profit Before Income Tax	A$m	51.6 [US$34m]	+ 2%
Net Profit After Income Tax Expense	A$m	36.2 [US$24m]	+ 2%
Cash Reserves	A$m	224.1 [US$148m]	+ 22%
Basic Earnings per Share	A$	0.72 [US$0.48]	+ 1%

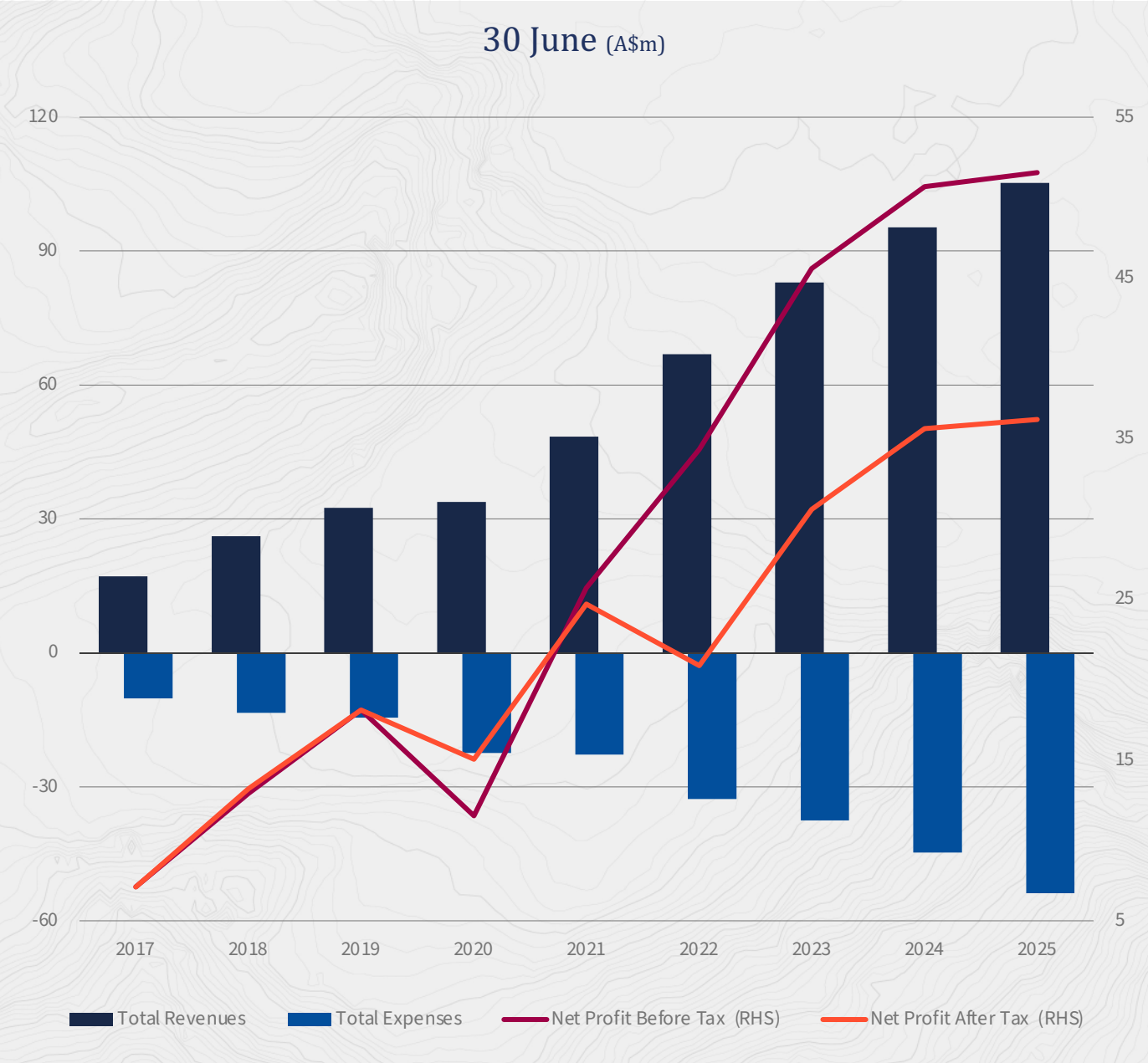
All figures reported in Australian dollars for financial year ended 30 June 2025. Refer to the Appendix 4E and Annual Report released to the Australian Securities Exchange for details. Cash reserves equals Cash and cash equivalents plus Cash held in term deposits.

FY2025

Profitability

SCENESSE® in EPP – profitability

9 years of growth in revenues	CAGR **35%**
controlled increase of expenses	CAGR **20%**
net profit margin	**34%**
reinvestment RD&I	**~40%**
return on equity	**16%**



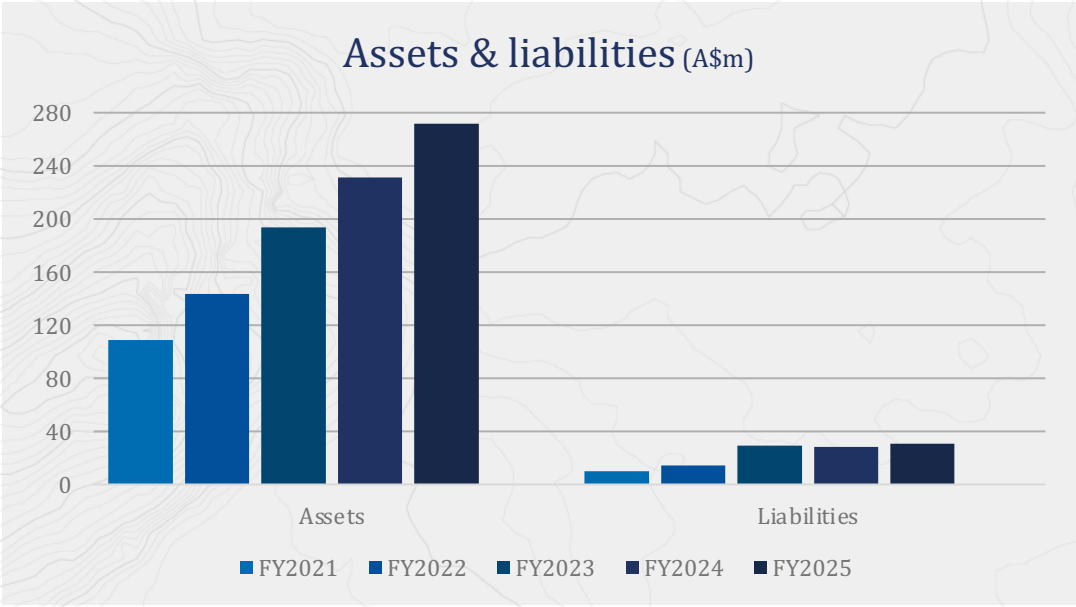
Total revenues include interest and other income.

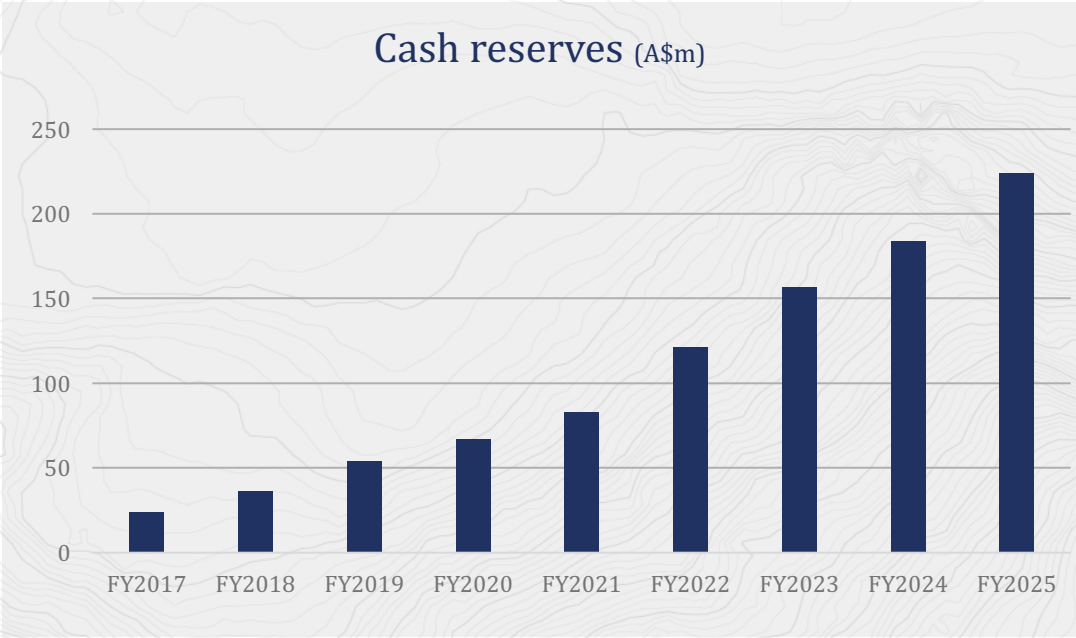
FY2025

Strongest balance sheet ['05–'25]

On 30 June, in Australian dollars	2024	2025	△
Total assets	A$231.1m [US$152.5m]	A$271.8m [US$179m]	+18%
Total liabilities • trade creditors • debt-free (20th year)	A$28.1m [US$18.5m]	A$30.9m [US$20.4m]	+10%
Cash reserves	A$183.9m [US$121.3m]	A$224.1m [US$148m]	+22%

1. OPEX , CAPEX
2. finance vitiligo program
3. reinvest high-NPV R&D projects
4. integrate supply chain, next-generation formulations
5. absorb negative externalities





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

Large unmet clinical need

Clinical problems solved:

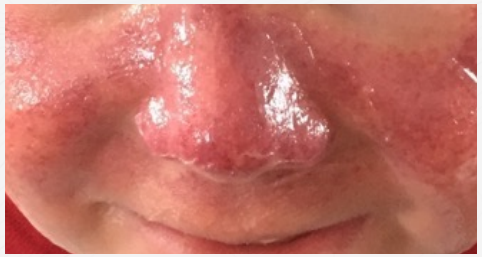
- EPP & VP - phototoxicity
- Vitiligo - systemic loss of pigmentation

>U$300m

Total addressable market (US$)

EPP Erythropoietic Protoporphyria

Genetic disorder: absolute light intolerance, phototoxicity

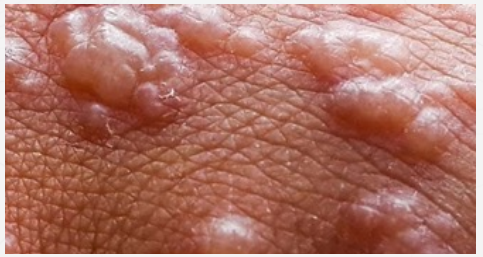


Expansion SCENESSE® adolescents 12–17 years, n=28 (CUV052) – complete, analysis underway

Patient population ~10K

VP Variegate Porphyria

Genetic disorder: blister, phototoxicity after UV–HEV exposure



Ph II/III: n=12 patients (CUV040) – complete, review endpoints

Pep[1]: reduction phototoxicity, blister formation

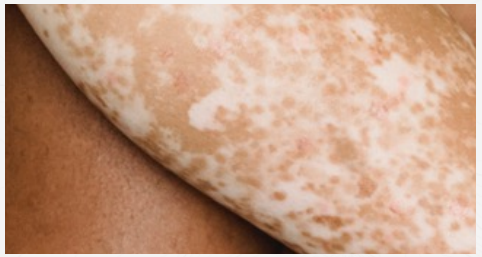
Patient population ~3-4K

U$4.5b

Total addressable market (US$)

Vitiligo

Gradual loss of skin pigmentation: Patient loss of identity (QoL). Afflicts 1% of world's population



Ph II: n=58, CUV102, combination

Ph II: n=6, CUV104, monotherapy

Ph III: n=200, combination, CUV105 – recruited, CUV107 – to commence

Pep[1]: TVASI50

Sec [2]: 1st time to repigmentation, F-VASI25, QoL

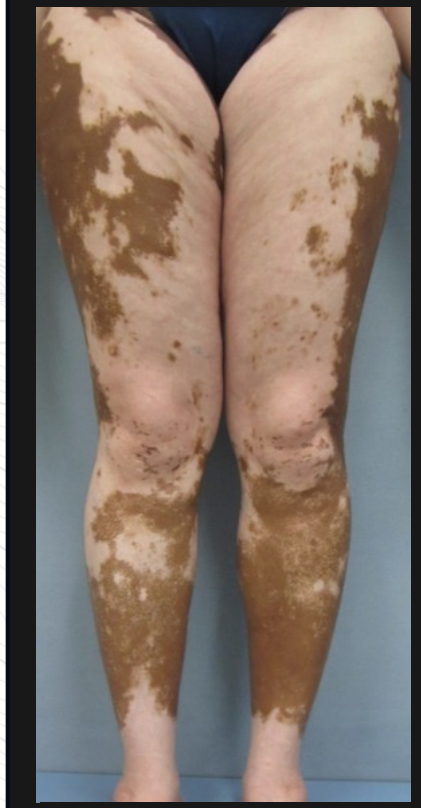
Patient population ~3.3M

*EPP image courtesy of the Koerner family; [1]Pep = primary endpoint, [2] Sec = secondary endpoint/s.

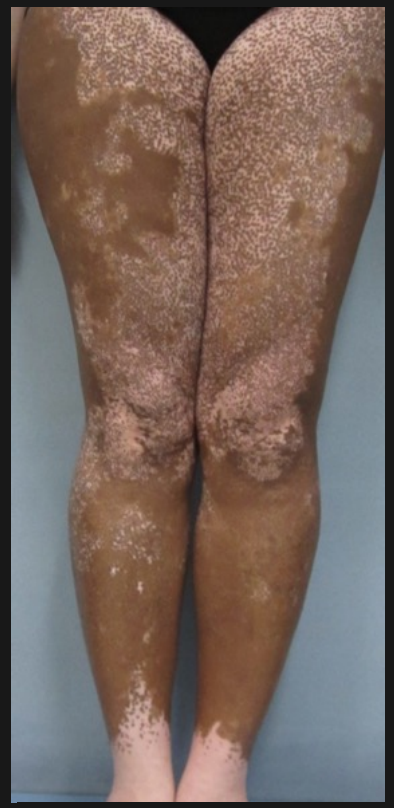
CUV102

Phase II study results

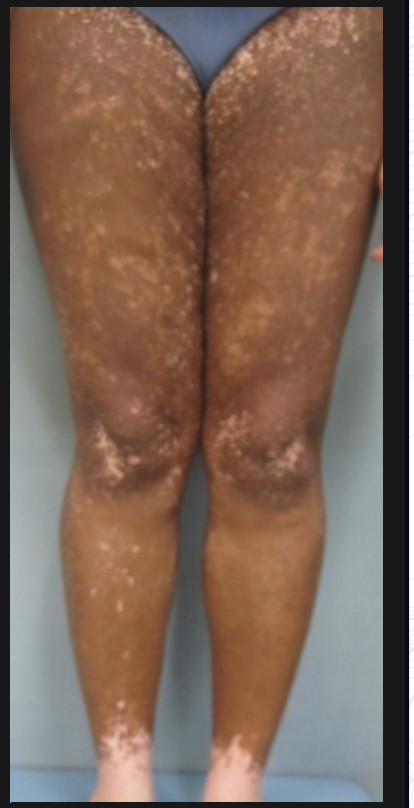
- Scientific basis for phase III



Day 0
Baseline



Day 111
27 treatments/3 implants



Day 179
40 treatments/4 implants

Day 0 Baseline

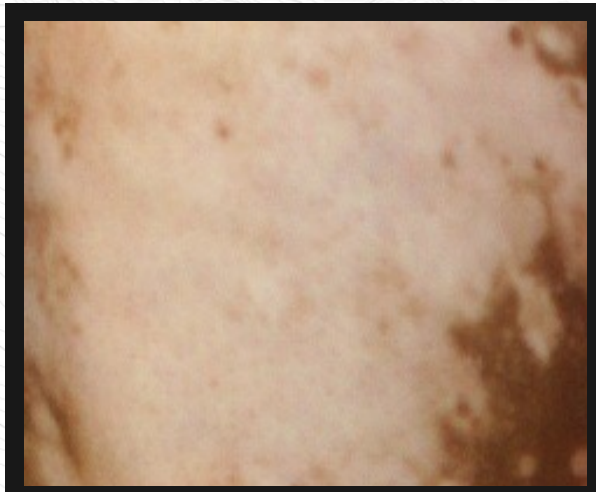
Day 35 – 15 treatments/1 implant

Day 66 – 29 treatments/2 implants

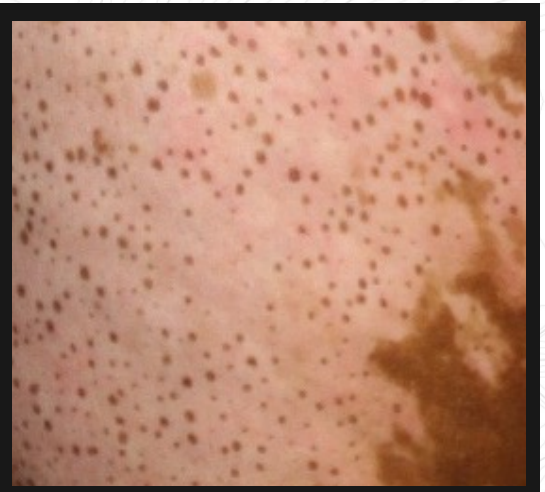
Day 171 – 62 treatments/4 implants

NB-UVB – follicular repigmentation

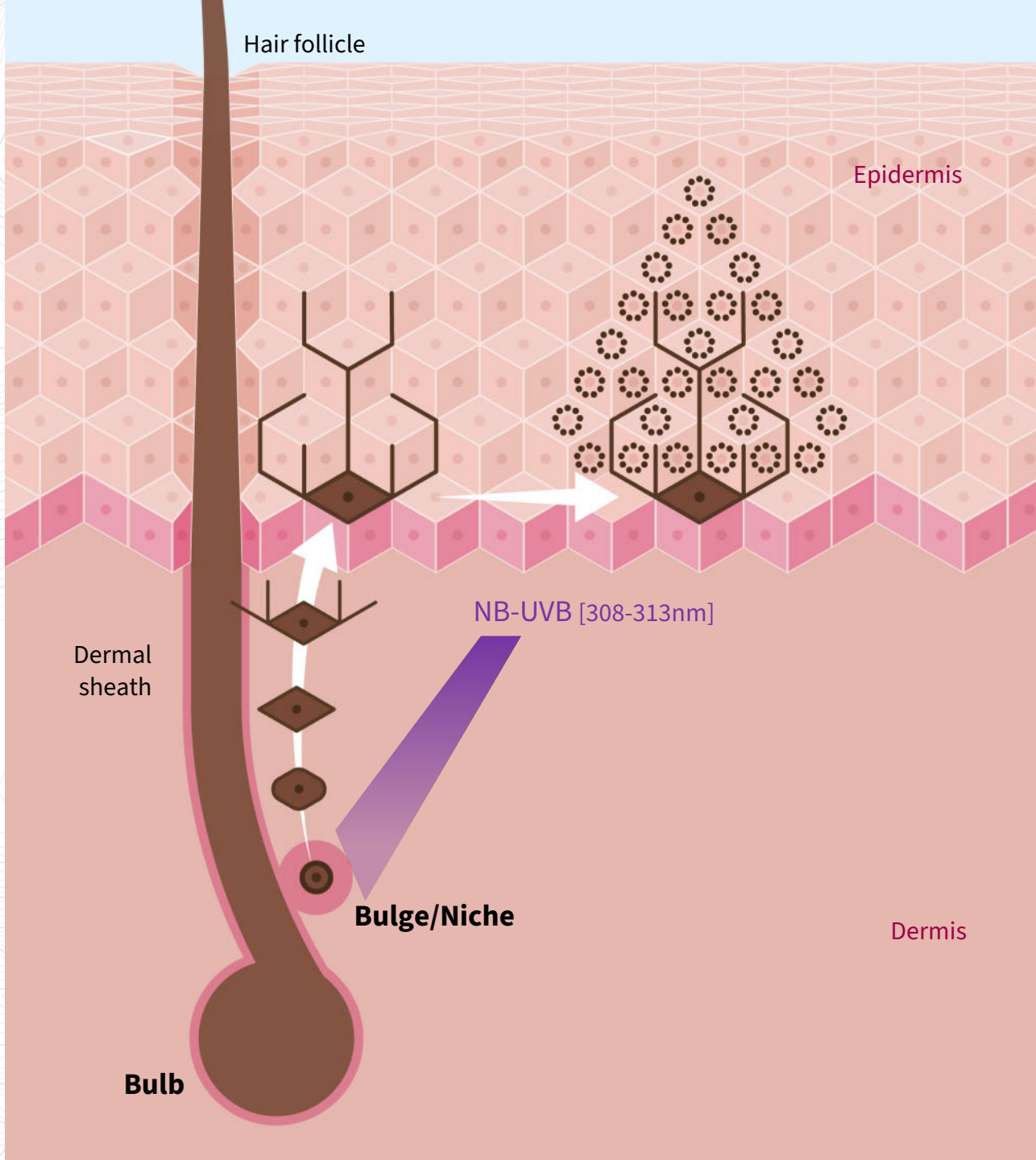
- NB-UVB differentiating follicular stem cells
- Melanoblasts migrating, become fully functioning melanocytes
- Afamelanotide acting as agonist to MC1R expressed



Day 0
Baseline

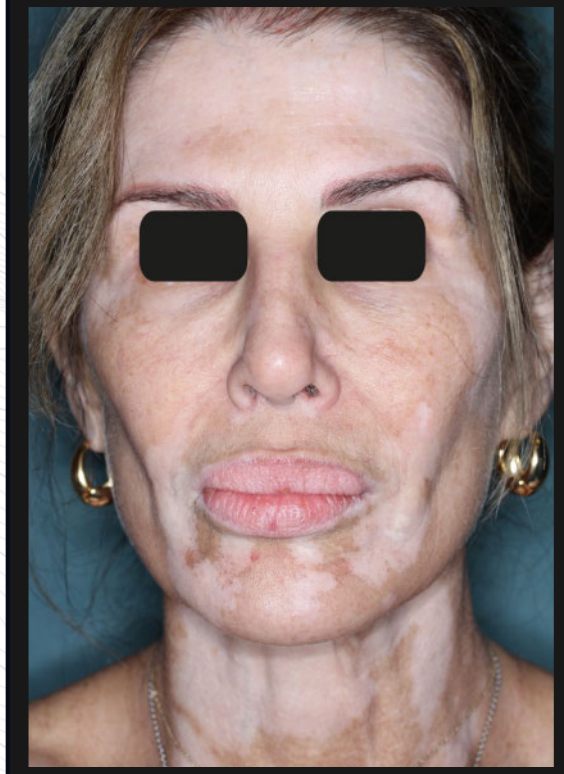


Day 98
After 35 NB-UVB sessions

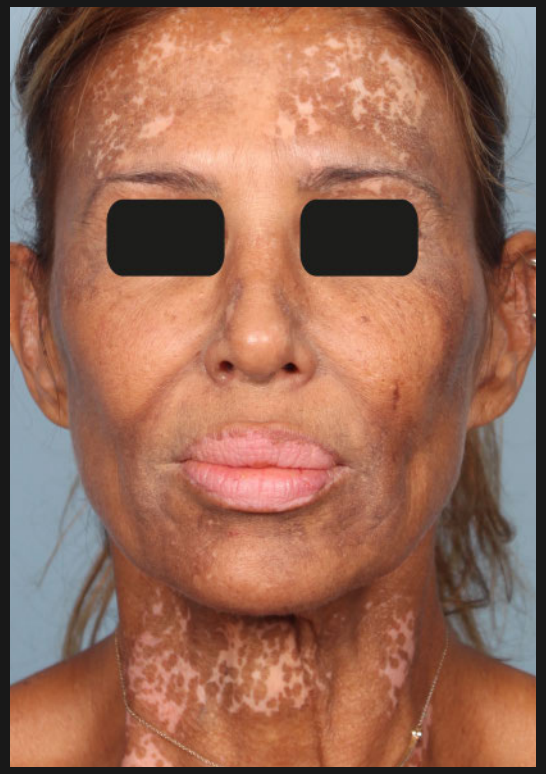


CUV105

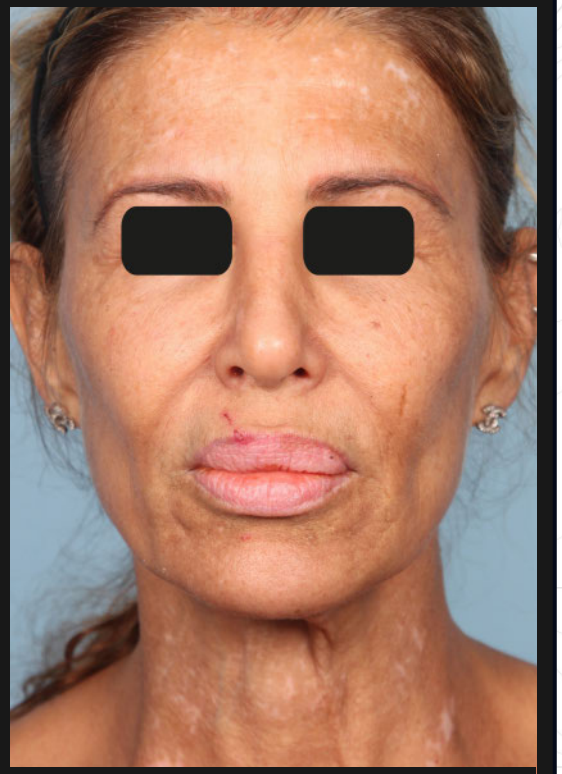
First Phase III study



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 1

Female, 55 years old, Skin Type IV

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

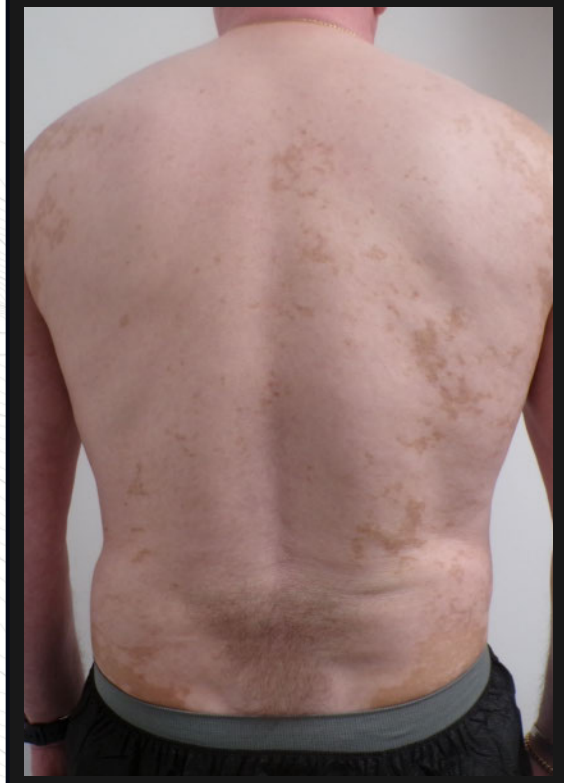
Physician's report

80–90% repigmentation seen after Day 140 but near total repigmentation achieved after continued NB-UVB monotherapy.

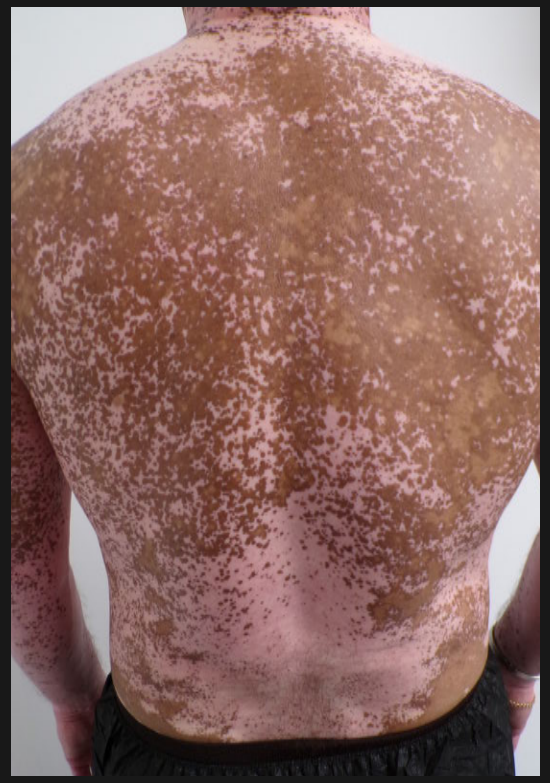
*5 Case reports presented to-date

CUV105

First Phase III study



Day 0
Baseline



Day 134
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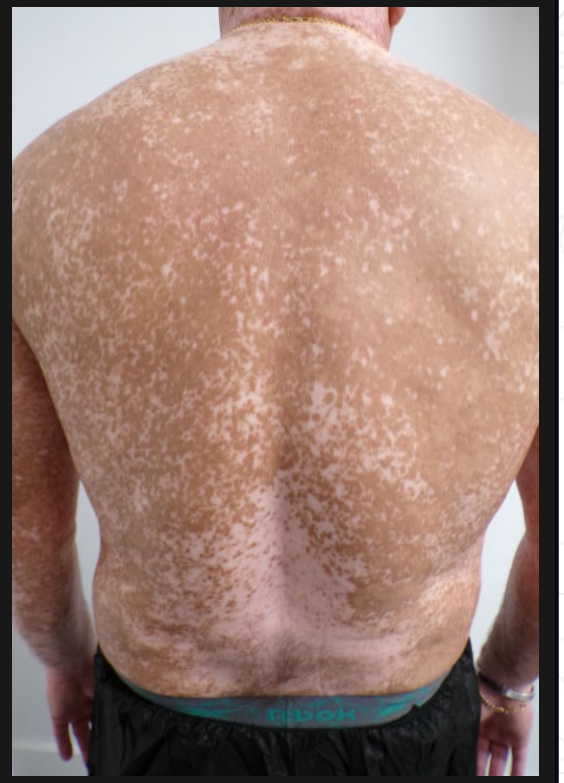


Day 308
168 days after completing study
no further therapy

CASE REPORT 2

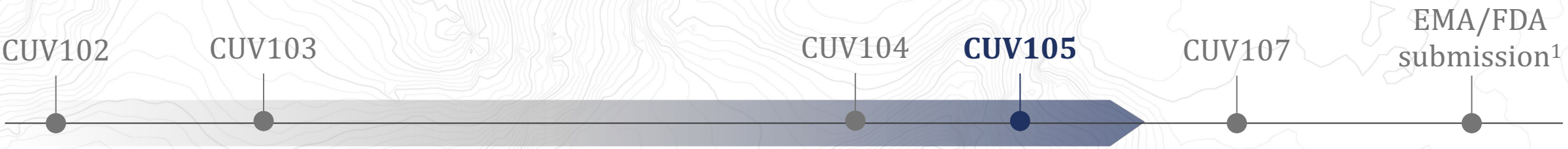
Male, 56 years old, Skin Type IV

Diagnosed with vitiligo in 1999

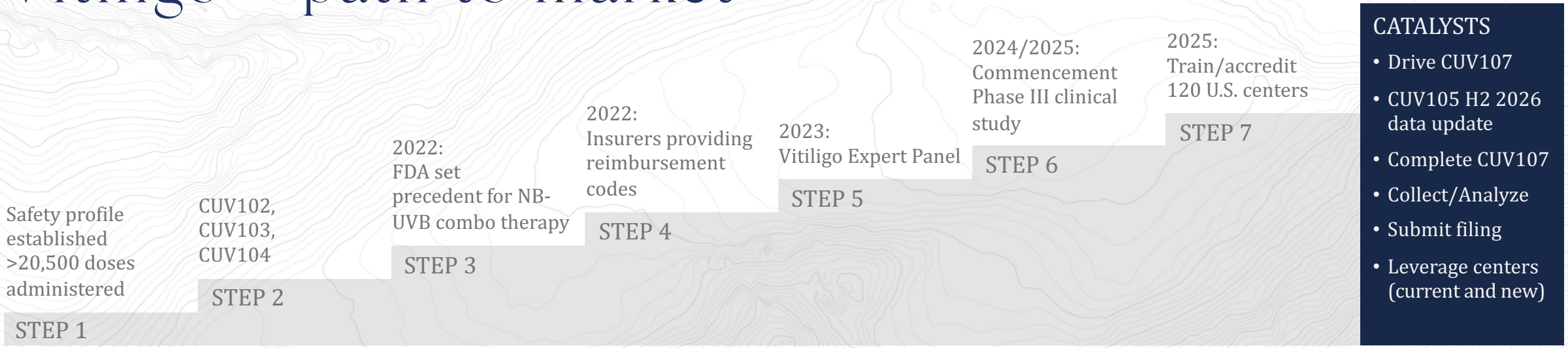
Physician's report

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.

*5 Case reports presented to-date



Vitiligo – path to market



CATALYSTS

- Drive CUV107
- CUV105 H2 2026 data update
- Complete CUV107
- Collect/Analyze
- Submit filing
- Leverage centers (current and new)

1.Based on collective CUV105 and CUV107 completion, data collection and analysis, and submission to regulatory authorities.

CLINUVEL

Thank You

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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