

# 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), CYACËLLE, 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®, CYACËLLE, 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



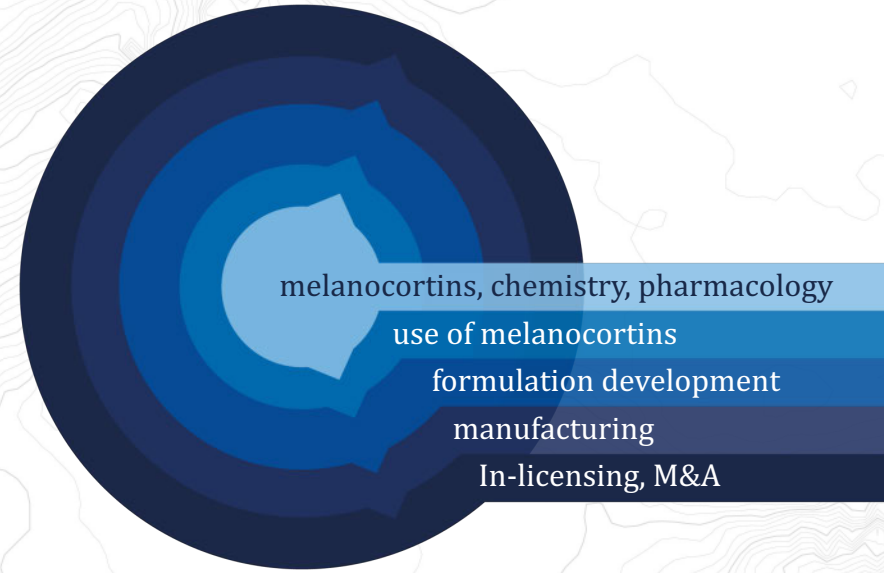
AMERICAN  
OPPORTUNITY

# Building a sustainable, integrated biopharmaceutical company

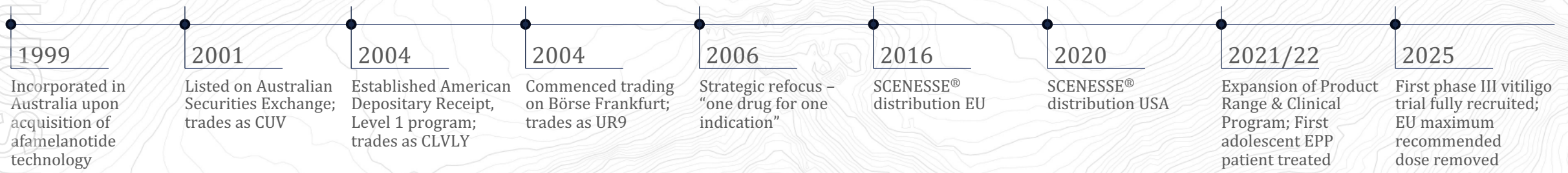


Focused, scalable, disciplined,

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



## Milestones



# Pipeline focus: melanocortins (Skin, CNS)

	Preclinical	Phase I	Phase II	Phase III	Commercial
SKIN	SCENESSE® (afamelanotide 16 mg) in adult EPP (EEA, UK, CH, USA, ISL, CAN, AUS)				
	SCENESSE® (afamelanotide 16 mg) in adolescent EPP				
	SCENESSE® (afamelanotide 16 mg) in adolescent and adult vitiligo				
	SCENESSE® (afamelanotide 16 mg) in variegate porphyria				
BRAIN	NEURACTHEL® instant – IS, MS				
	NEURACTHEL® modified release – CNS				

# 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

## MELANOCORTIN HOUSE

TAM \$4.5b  
VITILIGO  
cuv: \$490-570m\*

TAM >\$300m  
PORPHYRIA  
cuv: FY25 \$69m

TAM \$1.3b  
ACTH  
cuv: \$150m\*

TAM \$6.2b  
PhotoCosmetics  
cuv: \$50m\*

M&A

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%

# FY2025 Profitability

## SCENESSE® in EPP – profitability

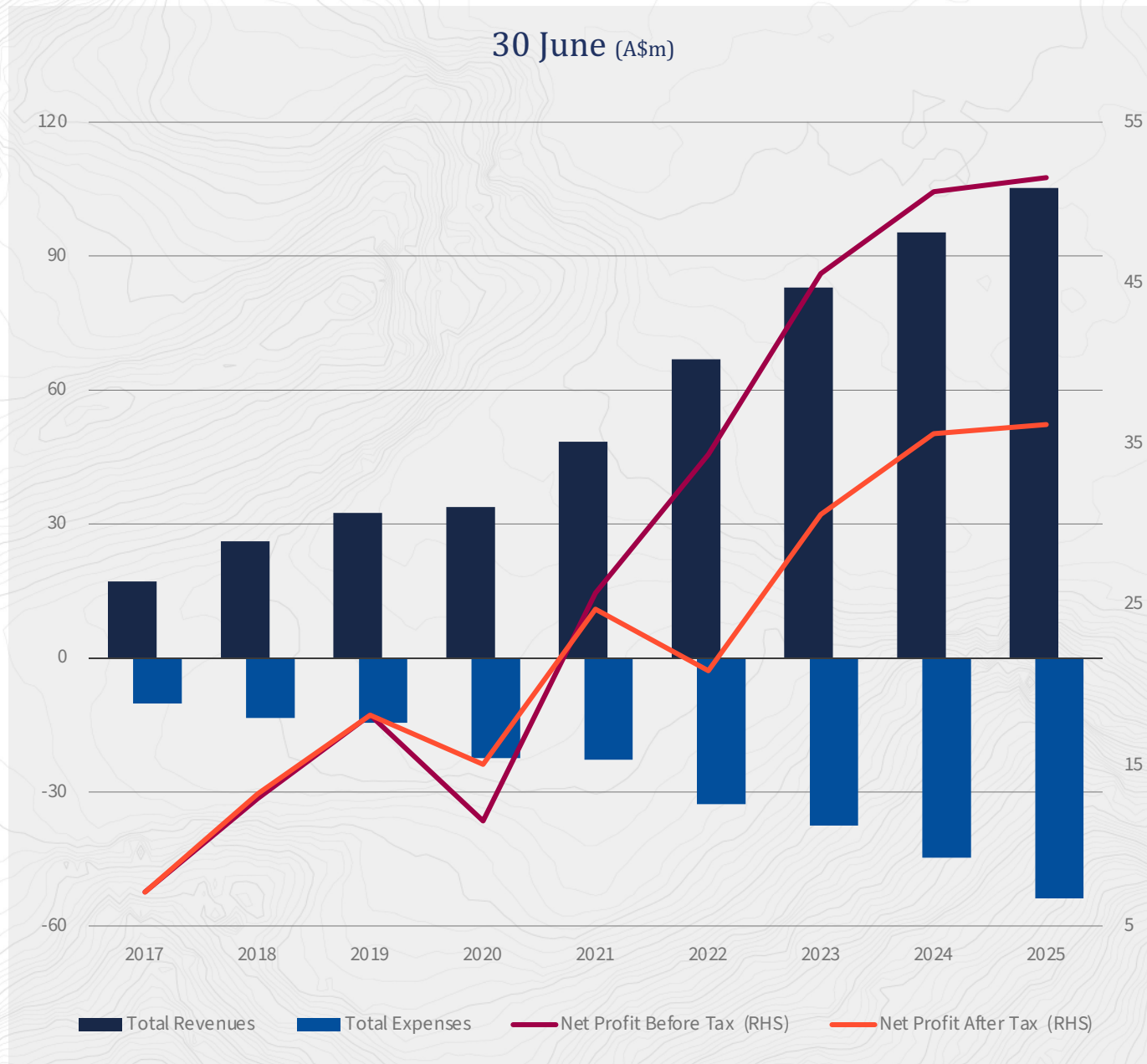
9 years of growth in revenues CAGR **35%**

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.

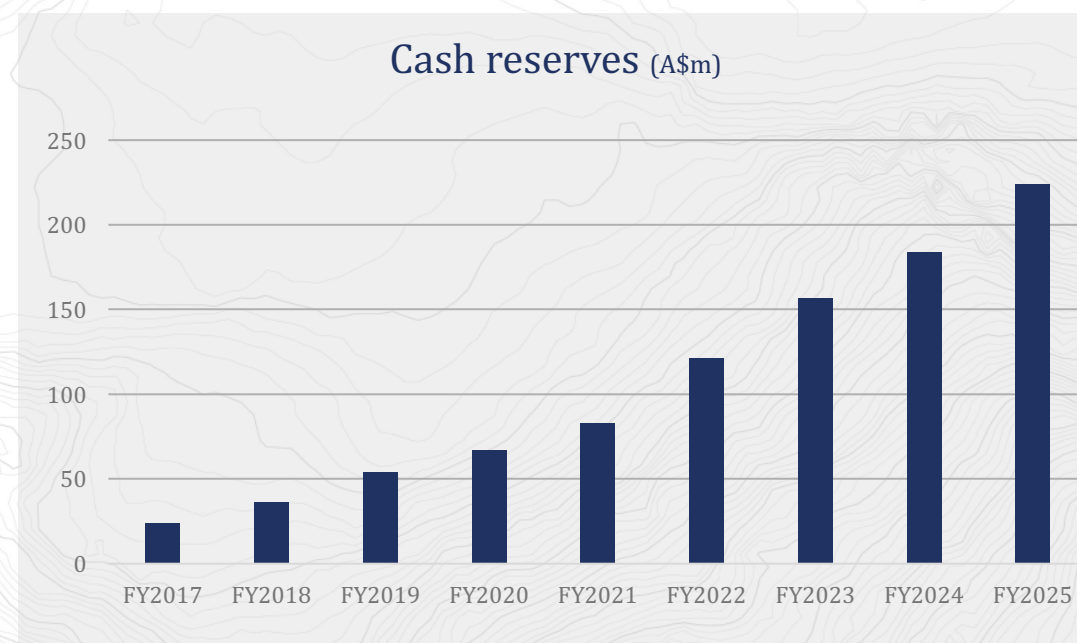
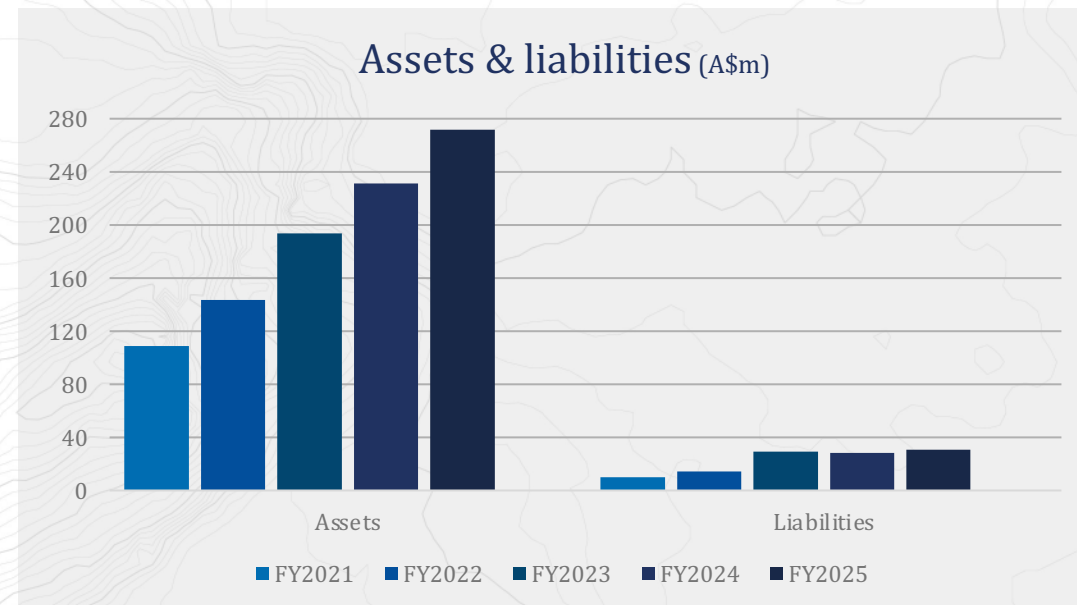
FY2025

# Strongest balance sheet ['05-'25]

On 30 June, in Australian dollars	2024	2025	△
<b>Total assets</b>	A\$231.1m [US\$152.5m]	A\$271.8m [US\$179m]	<b>+18%</b>
<b>Total liabilities</b>	A\$28.1m [US\$18.5m]	A\$30.9m [US\$20.4m]	<b>+10%</b>
<ul style="list-style-type: none"> <li>• trade creditors</li> <li>• debt-free (20<sup>th</sup> year)</li> </ul>			
<b>Cash reserves</b>	A\$183.9m [US\$121.3m]	A\$224.1m [US\$148m]	<b>+22%</b>

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

## >US\$300m

Total addressable market (US\$)

### EPP

Erythropoietic Protoporphyrria

**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<sup>1</sup>:** reduction phototoxicity, blister formation

**Patient population ~3-4K**

## US\$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<sup>1</sup>:** TVASI50

**Sec<sup>2</sup>:** 1st time to repigmentation, F-VASI25, QoL

**Patient population ~3.3M**

# CUV102

Phase II study results

- Scientific basis for phase III



Day 0 Baseline



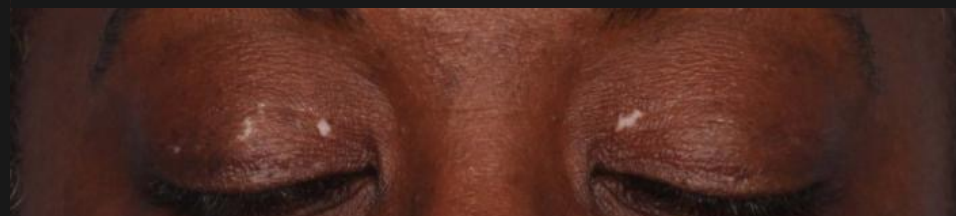
Day 35 - 15 treatments/1 implant



Day 66 - 29 treatments/2 implants

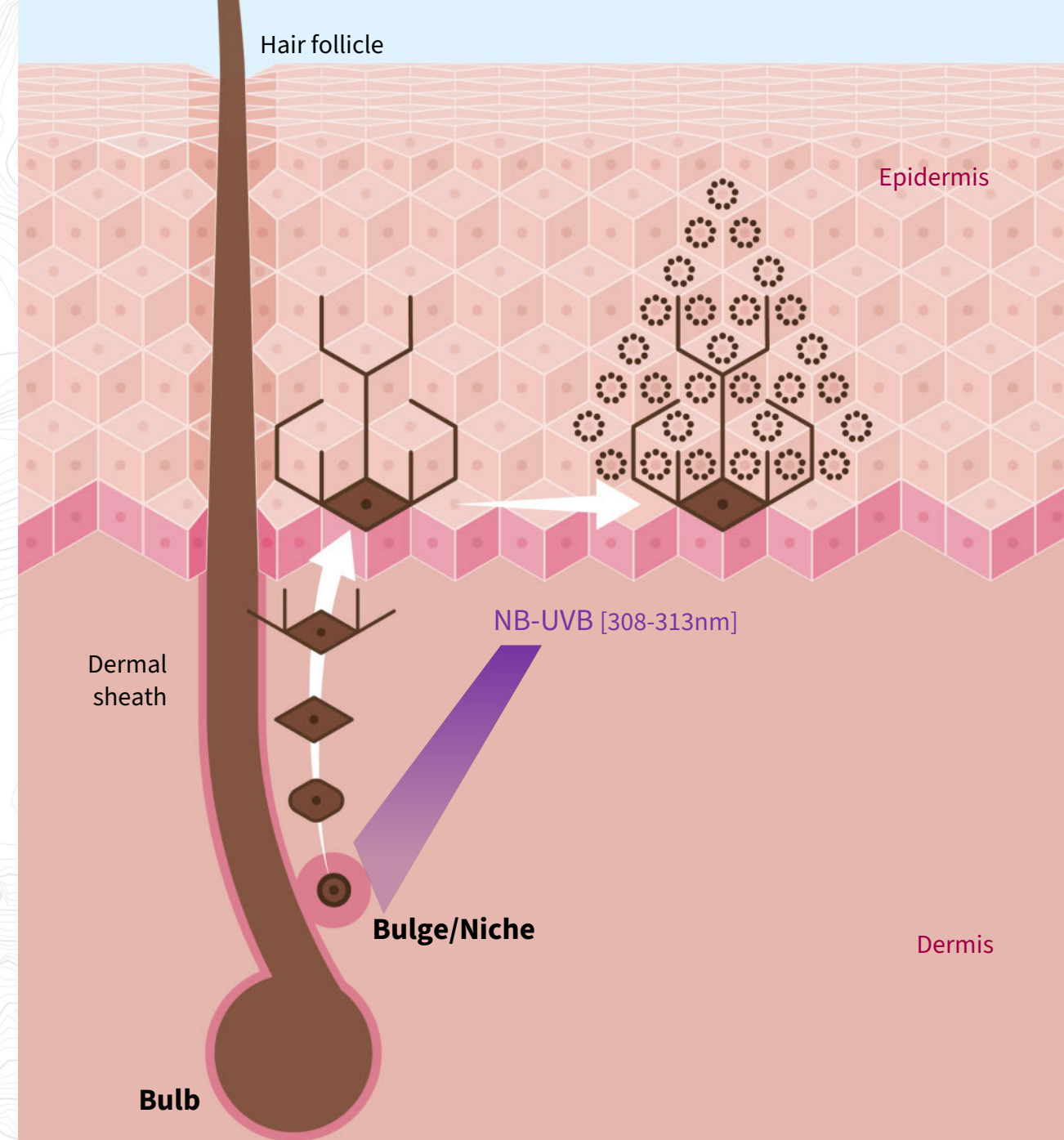
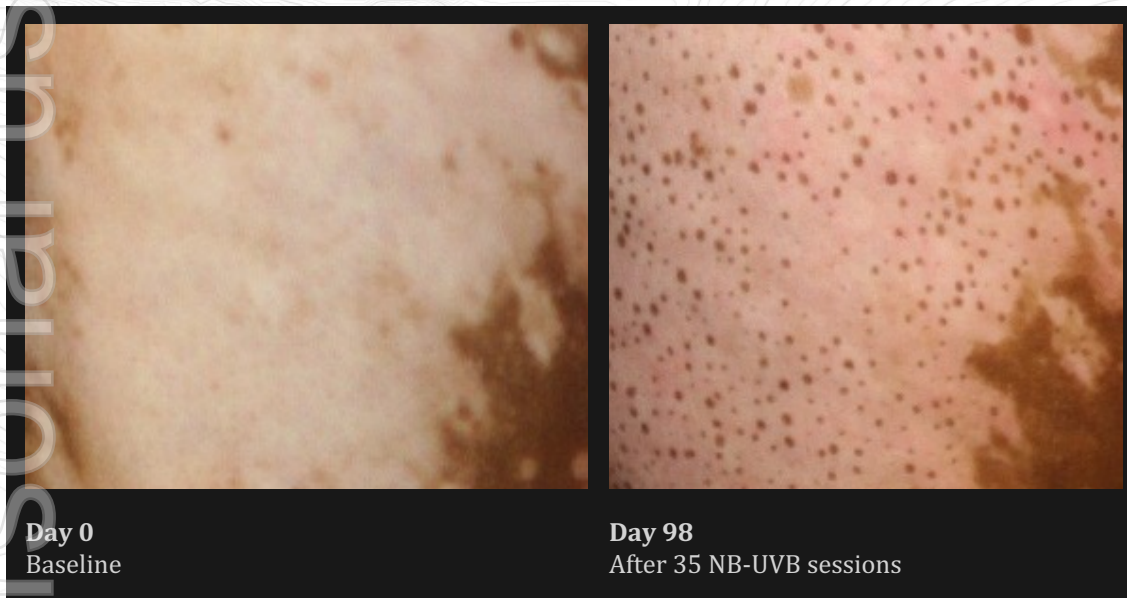


Day 171 - 62 treatments/4 implants



# NB-UVB – follicular repigmentation

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



# CUV105

First Phase III study



## 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.

# CUV105

First Phase III study



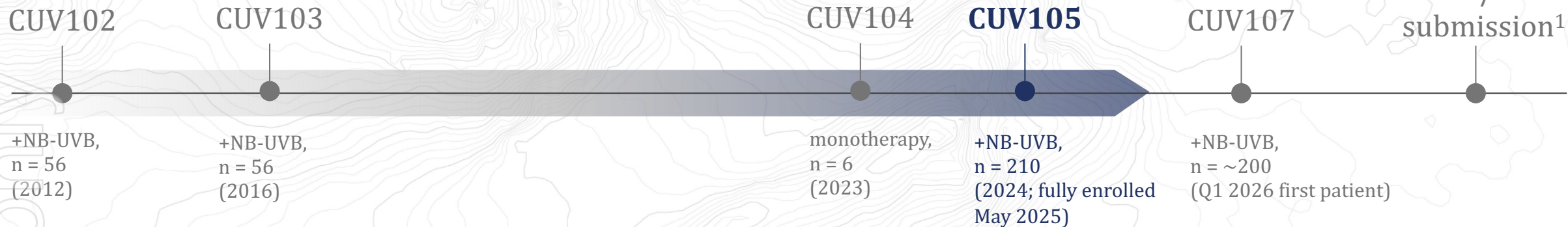
## CASE REPORT 2

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.



# Vitiligo – path to market

Safety profile established  
>20,500 doses administered

STEP 1

CUV102, CUV103, CUV104

STEP 2

2022: FDA set precedent for NB-UVB combo therapy

STEP 3

2022: Insurers providing reimbursement codes

STEP 4

2023: Vitiligo Expert Panel

STEP 5

2024/2025: Commencement Phase III clinical study

STEP 6

2025: Train/accredit 120 U.S. centers

STEP 7

## CATALYSTS

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

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

ersonal use only

# 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

[www.clinuvel.com](http://www.clinuvel.com)

ASX: CUV | Börse Frankfurt: UR9 | ADR Level I: CLVLY