

ersonal use only

CLINUVEL

Pioneering treatments for patients with
significant unmet needs

Non-Confidential Presentation

June 2026

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



Safe harbor 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.

Profitable, focused, disciplined

Nine and a half years profitable (to 31 Dec 2025)

Growing revenue base

Strong balance sheet

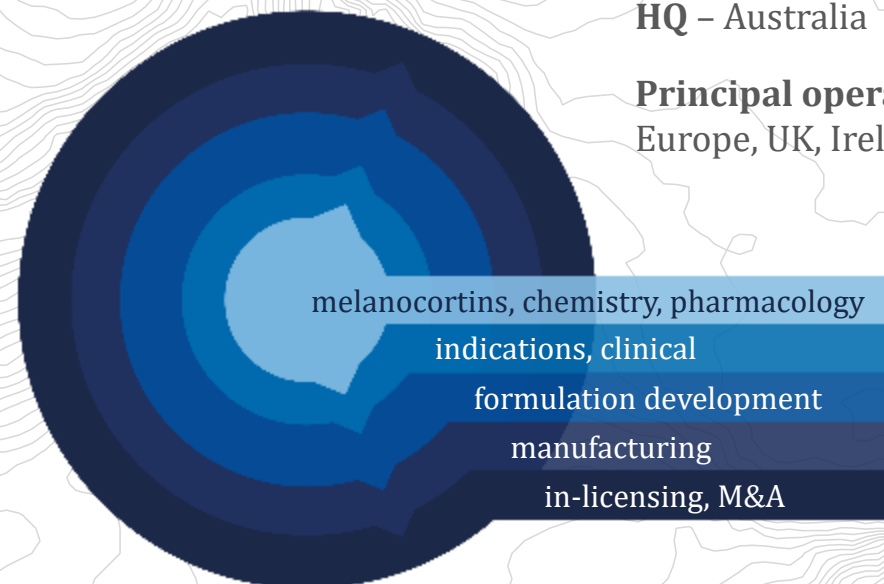
- zero debt
- cash reserves US\$155m (31 Dec 2025)
- 3+ year cash runway

Eight years dividends

Building a sustainable, integrated biopharmaceutical company

HQ – Australia

Principal operations – U.S.A, Europe, UK, Ireland, Singapore



Milestones

1999	2001	2004	2004	2006	2016	2020	2021/22	2025
Incorporated in Australia upon acquisition of afamelanotide technology	Listed on Australian Securities Exchange; trades as CUV	Established American Depository Receipt, Level 1 program; trades as CLVLY	Commenced trading on Börse Frankfurt; trades as UR9	Strategic refocus "one drug for one indication"	SCENESSE® distribution EU	SCENESSE® distribution USA	Expansion of Product Range & Clinical Program; First adolescent EPP patient treated	First phase III vitiligo trial fully recruited; EU maximum recommended dose removed

A distinct business model

EXPERTISE

Peptides / Hormones

- Melanocortins
- Long-term safety

Formulation Development

- Controlled-release
- In-house development

Clinical Expertise

- Porphyria, vitiligo
- Central nervous system

Commercial Infrastructure

- Direct distribution >15 countries
- >150 centres active

Financial Management

- 9½ years profitable (31 Dec 2025)
- Cash reserves US\$155m (31 Dec 2025)

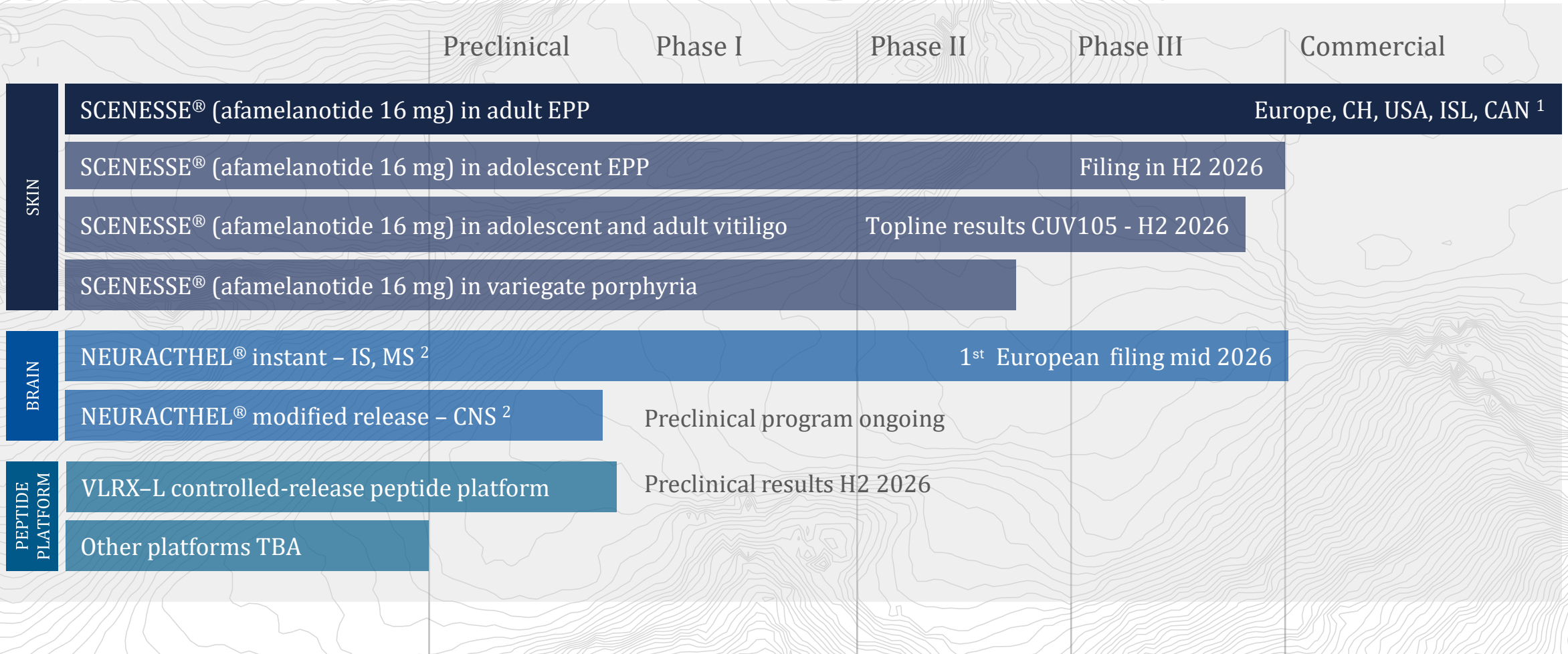
Talent Management

- Train & retain: CUV Academy
- Average tenure management > 9 yrs

FISCAL DISCIPLINE
CLINICAL FOCUS
STRATEGIC CONSISTENCY

FOCUS ON VIABILITY PRIOR TO REINVESTMENT OF EARNINGS TO DIVERSIFY

Commercial product and pipeline: melanocortins



1. Health Canada is currently evaluating SCENESSE® for adult EPP patients; 2. IS= infantile spasms; MS = multiple sclerosis; CNS = central nervous system.

FY2025

Financial performance

- disciplined and balanced approach
- 9 consecutive annual profits
 - continued in six months to 31 December 2025
- controlled expenses
- RD&I growth

CONSOLIDATED ENTITY	30 June 2025	Change
Revenues	US\$61m	+ 6%
Total Operating Expenses	US\$23m	+ 24%
Net Profit Before Income Tax	US\$33m	- 0.5%
Net Profit After Income Tax Expense	US\$23m	- 1%
Cash Reserves	US\$146m	+ 19%
Basic Earnings per Share	US\$0.46	- 2%

All figures originally released to Australian Securities Exchange in Australian dollars (A\$) for financial year ended 30 June 2025 and converted to United States dollars (US\$) in 20-F filing to U.S. Securities Exchange Commission.
Cash reserves equals Cash and cash equivalents plus Cash held in term deposits (i.e. short-term investments).

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

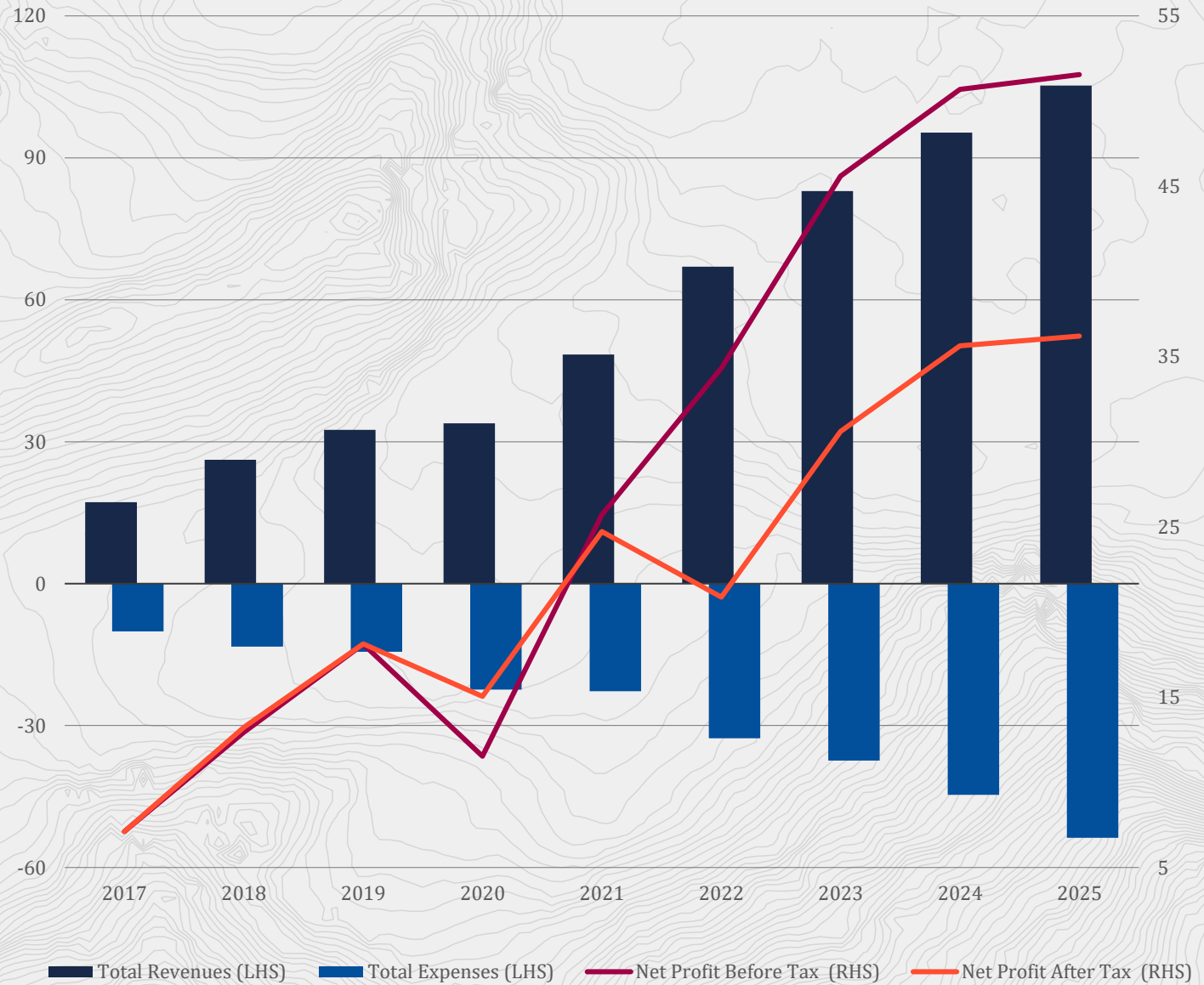
~40%

return on equity

16%

Total revenues include interest and other income.

30 June 2025 (A\$m)



Expanding presence: U.S.A.

Increased American investor interest

- Phase III vitiligo – 1st systemic Rx [not immune suppressive]
- SCENESSE® in EPP - direct distribution >120 US centers
- US comprises >50% of revenue
- Nasdaq uplisting ADRs (Level II) – SEC filing pending



AMERICAN
OPPORTUNITY

Future outlook

Foundation of 20 years

Products, indications & healthcare solutions

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

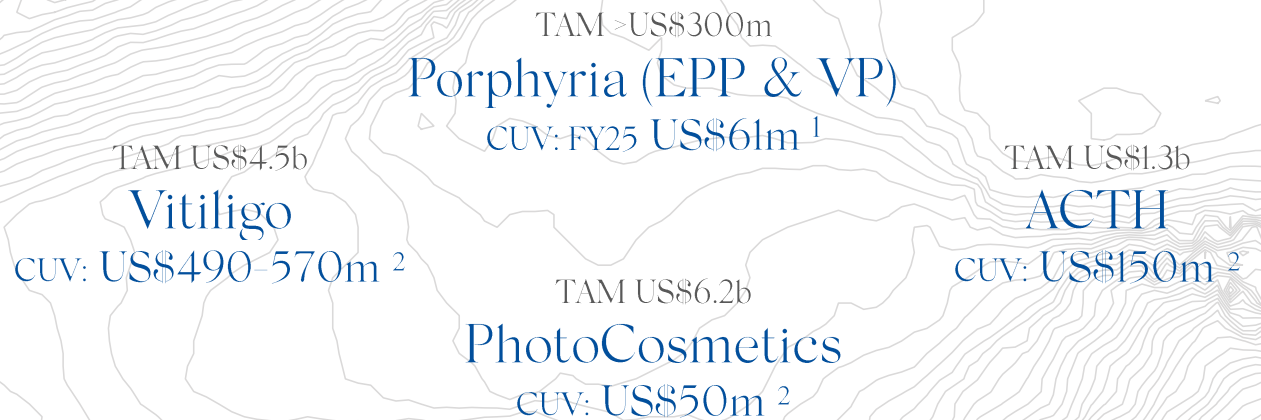
Advancing RD&I

- novel sustained-release liquid peptide formulations

Capital management

- disciplined deployment of capital
- zero dilution – 10 yrs
- debt free

MELANOCORTIN HOUSE



Vitiligo opportunity with Phase III top line data expected in H2 '26 represents a key value driver

TAM and penetration figures are in U.S. dollars. 1. Reflects EPP revenue in FY25. 2. CLINUVEL estimate, Year 1 and 2 for vitiligo.

Large unmet clinical need

Clinical problems solved:

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

>US\$300m

Total addressable market

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

Pep¹: reduction phototoxicity, blister formation

Patient population ~3-4K

US\$4.5b

Total addressable market

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 - 210 recruited

CUV107 - to commence

Pep¹: TVASI50

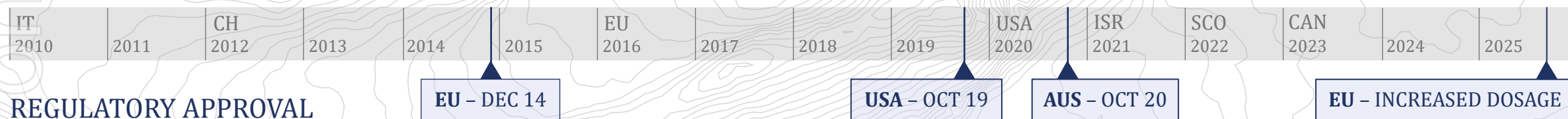
Sec²: 1st time to repigmentation, F-VASI25, QoL

Patient population ~3.3M

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

SCENESSE® first approved treatment for EPP

MARKETS ACCESSED



DISTRIBUTION

EU

Porphyria Centers, multiple countries
Year-round treatment, increased from 4 to 6 p.a. approved Sep '25

U.S.A.

120+ Specialty Centers
>110 insurers
Unique drug and treatment codes
Year-round treatment, up to 6 doses
CLINUVEL Assistance Program

Rigorous pharmacovigilance program
EPP patient registry

Standard of care, safety record
>21,700 administrations to EPP patients

Vitiligo market: U.S.A.

significant opportunity

1% Prevalence
3,295,000

Total addressable market
US\$4.5b

Commercial preparation
establish systems, NB-UVB

Distribution
national team (20)

Prescribers
target 190 trained & accredited centres

Market access
reimbursement extensive vitiligo

Market penetration
~6,000 patients in years 1-2

25% Eligible
823,750¹
40% (0.5% BSA, 0.2% H/N)
329,500
20% Seeking treatment
65,900

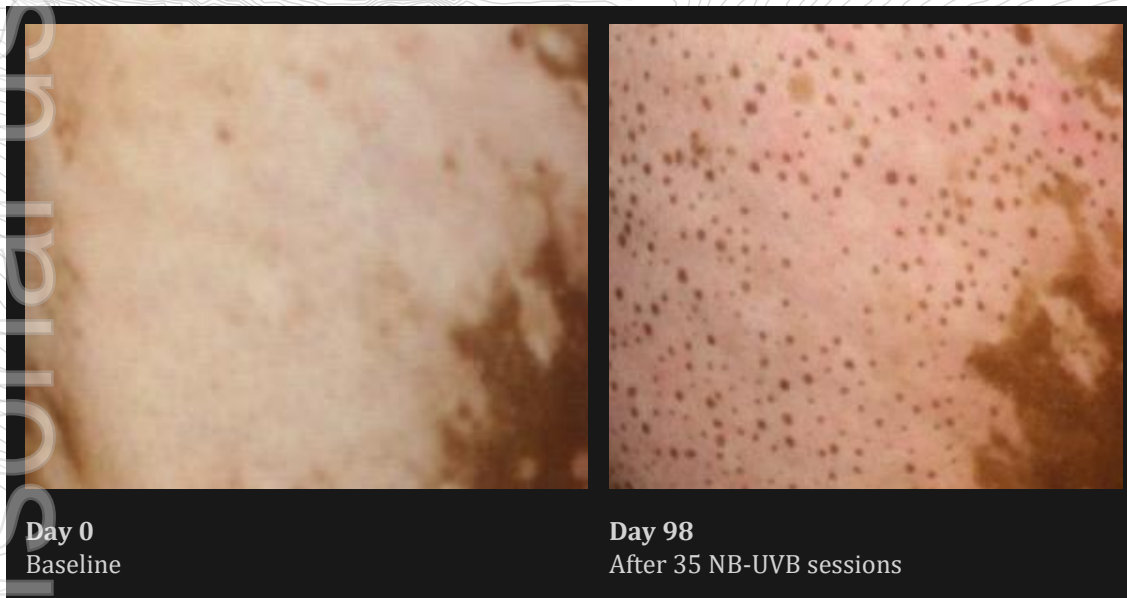
9% Penetration Yr 1-2²
5,931

Market penetration, year 1-2
US\$490-570m

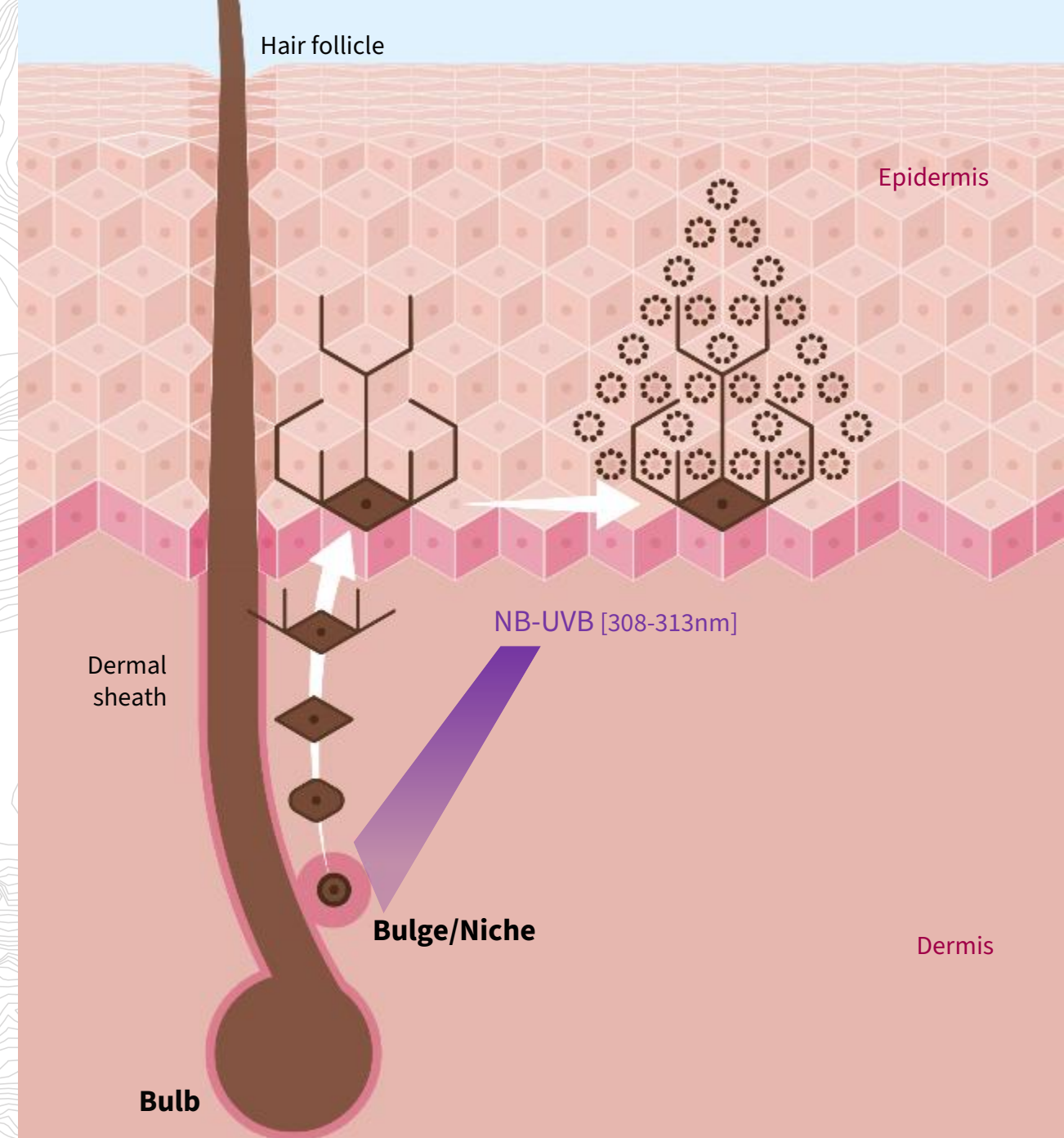
1. Total vitiligo population FST IV-V-VI; 2. 7-8 doses afamelanotide pp for >90%, repigmentation 47,448.

NB-UVB – follicular repigmentation

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



NB-UVB = Narrowband ultraviolet B.



CUV102 vitiligo study

Phase II study results

- Scientific basis for phase III



Day 0 Baseline



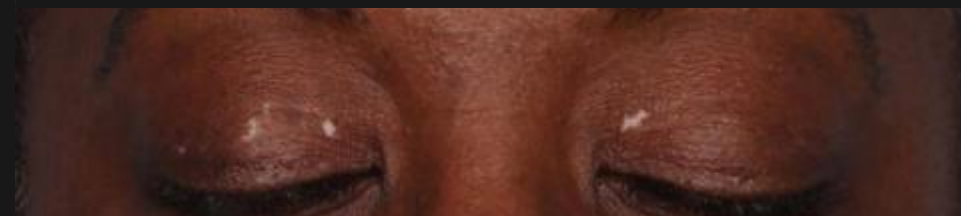
Day 35 - 15 treatments/1 implant



Day 66 - 29 treatments/2 implants



Day 171 - 62 treatments/4 implants



CUV105 vitiligo phase III study – 12 case reports published¹

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

CASE REPORT 9

- Male, 42 years old, Skin Type V
- Diagnosed with vitiligo in 2015, patient previously seen spontaneous repigmentation but had not previously had therapy.

Physician's report

Patient highly satisfied with treatment. Patient returned to normal baseline colour after cessation of treatment.



Day 0
Baseline



Day 134
7 afamelanotide implants
39 NB-UVB treatments



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



Day 0
Baseline



Day 140
7 afamelanotide implants
39 NB-UVB treatments



Day 224
no further therapy

1. Accessible on CLINUVEL's website, ASX Announcements – CLINUVEL, refer announcements on 20 Jan 2025 (4 reports), 7 May 2025 (1 report), 19 Sep 2025 (3 reports), and 08 Jan 2026 (4 reports).

Regulatory strategy vitiligo

Proof of concept

CUV101-102-103 SCENESSE® adjunct NB-UVB



CUV104 SCENESSE®
monotherapy



CUV105 Ph III
SCENESSE®-NB-UVB ongoing – topline results H2 2026



CUV107 Ph III
SCENESSE®-NB-UVB - start H2 2026

2026 EMA/FDA IRB/Ethics/DMSB

EMA scientific advice (April 2026)

- Emphasised “totality of evidence” approach
- Central photographic review and validated disease assessment tools agreed
- Acknowledged benefit to darker skin types (Fitzpatrick IV-V-VI)
- CUV107 study size, n=300; adults and adolescents >12 yrs

Data monitoring surveillance board

- CUV105 data lock, data integrity (H2 2026)

Start CUV107

- NB-UVB equipment supplied ¹
- Approx. 20 sites (EU-NAM-MEA)

FDA meeting 2027 ²

- Discussion data

1. Select centres are supplied NB-UVB equipment. 2. Pending ongoing interactions.

NEURACTHEL®

- ACTH generic product manufacturing validation completed
- Three validated batches, stability supports product dossiers
- NEURACTHEL® Instant validated with European partner
- Stock is available for clinical use, pending regulatory approval
- European regulatory filing H2 2026
- NEURACTHEL® Modified-release in development
- Clinical programme planned for West Syndrome (infantile spasms) and Relapsing MS

Total Addressable Market **US\$1.3b**



Calendar & catalysts

	2026 H1	H2	2027 H1	H2
SCENESSE®		Health Canada: Marketing Authorization decision		
		EMA filing SCENESSE®: adolescent use in EPP		
Phase III, CUV105 vitiligo	AAD'26 cases presented ✓	Top line results	Complete results	
Phase III, CUV107 vitiligo	EMA Scientific Advice ✓	Start recruitment	FDA vitiligo meeting	Recruitment completed
ACTH-NEURACTHEL®		EU:1 st filing marketing authorisation		
VLRX-L		Liquid controlled-release formulation first preclinical results	Liquid controlled-release in production [CDMO]	
Pipeline			New peptides in liquid controlled-release preclinical data	
RD&I		VALLAURIX Singapore: complete construction of expanded RD&I Centre		
Finance, commercial	FY'26 Half Year Results (31 Dec '25) ✓	FY'26 Financial Year Results (30 Jun '26)	FY'27 Half Year Results (31 Dec '26)	FY'27 Financial Year Results (30 Jun '27)
	Commercial update EPP-Vitiligo			
	SEC review: Nasdaq, ADR upgrade		AAD'27 San Francisco	

Targeted technology translation

PROTECT-PRESERVE-BRONZE

Translating our technology & knowhow to develop a range of PhotoCosmetic products to assist people in need of photoprotection, DNA repair and melanogenesis

Total Addressable Market **US\$6.2b**



PHOTOMEDICINE —————>>> PhotoCosmetics

ERYTHROPOIETIC PROTOPORPHYRIA

Intolerance to all types of light

1

POLYCHROMATIC PHOTOPROTECTION

Advanced solar shield

XERODERMA PIGMENTOSUM

Severe photodamage and skin cancer

2

DNA REPAIR

Preserves and repairs the skin's DNA

VITILIGO

Loss of pigmentation in the skin

3

MELANOGENESIS

Activates pigmentation

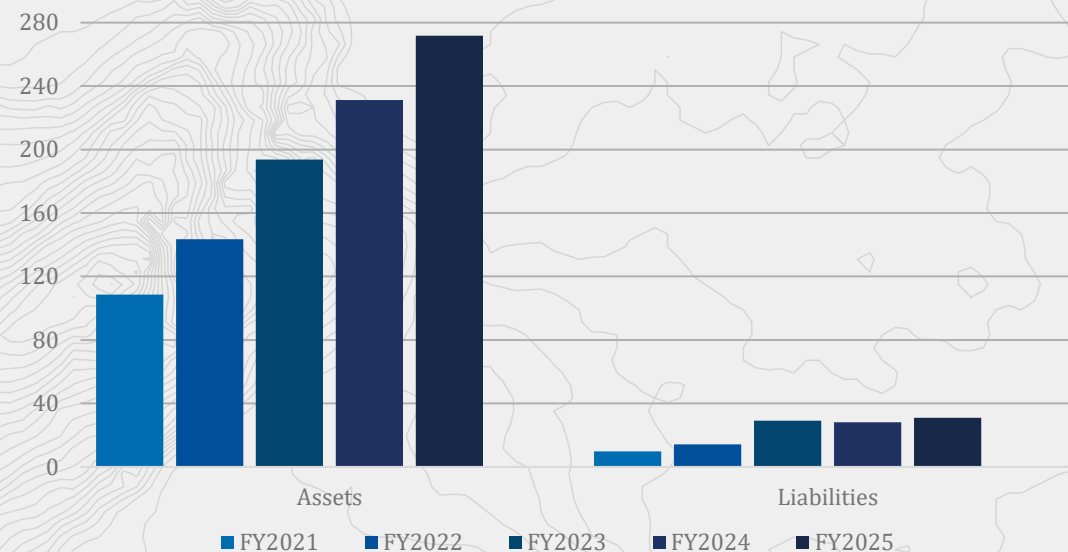
FY2025

Strong balance sheet

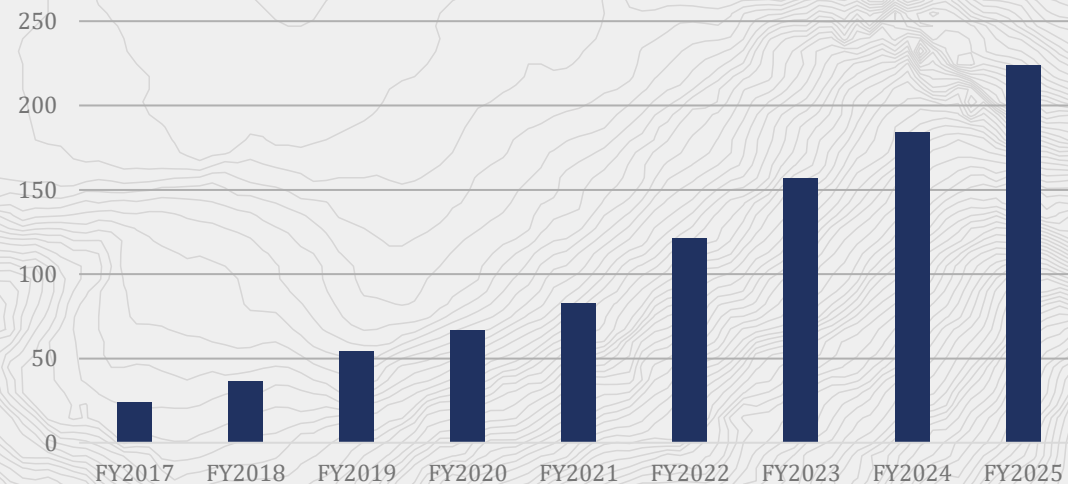
June 30, in US\$	2024	2025	△
Total assets	US\$154m	US\$177m	+15%
Total liabilities			
• trade creditors	US\$19m	US\$20m	+7%
• debt-free (20 th year)			
Cash reserves	US\$122m	US\$146m	+19%

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

Assets & liabilities (A\$m)



Cash reserves (A\$m)



Figures for the financial years ended 30 June 2024 and 2025 are converted to United States dollars (US\$) in 20-F filing to U.S. Securities Exchange Commission. Cash reserves equals Cash and cash equivalents plus Cash held in term deposits (i.e. short-term investments).

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

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