

# CLINUVEL

## First Half Results – FY2026

Investor Briefings - February and March 2026

**Lachlan Hay**, Chief Operating Officer

**Peter Vaughan**, Chief Financial Officer

**Malcolm Bull**, Head of Australian Operations and Investor Relations

ASX: CUV | Börse Frankfurt: UR9 | ADR Level I: CLVLY (uplist to Level II 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.

# Underlying profit maintained

Half year ended 31 December 2025

	31 December 2025 <sup>1</sup>	31 December 2024 <sup>1</sup>	Change
<b>Revenues<sup>2</sup></b>	36,930,512	35,645,883	+4%
<b>Expenses</b>	25,973,539	21,353,011	+22%
<b>Profit after tax</b>	10,442,705	14,075,335	-26%
<b>Basic earnings per share</b>	0.21	0.28	-26%
<b>Cash reserves<sup>3</sup></b>	232,999,375	224,105,942 <sup>4</sup>	+4% <sup>4</sup>

1. All figures reported in Australian dollars, \$A; 2. Revenues are commercial sales and special access schemes; 3. Balance of Cash & cash equivalents plus Cash held in term deposits; 4. As of and increase from 30 June 2025.

# Building a diverse, sustainable global business

## CLINUVEL

- Expertise in peptides, melanocortins
- Integrated 'in-house' business model
- Commercialised SCENESSE® for EPP<sup>1</sup>
- 9½ years revenues growth, profitability, self-financed expansion plan
- Long-term, focused management team
- Building 'house of melanocortins':
  - Porphyrias      ACTH - NEURACTHEL®
  - Vitiligo          PhotoCosmetics

## Key Activities and Outcomes – H1 FY2026

### Commercial

- EMA<sup>2</sup> approved year-round SCENESSE® treatment for EPP

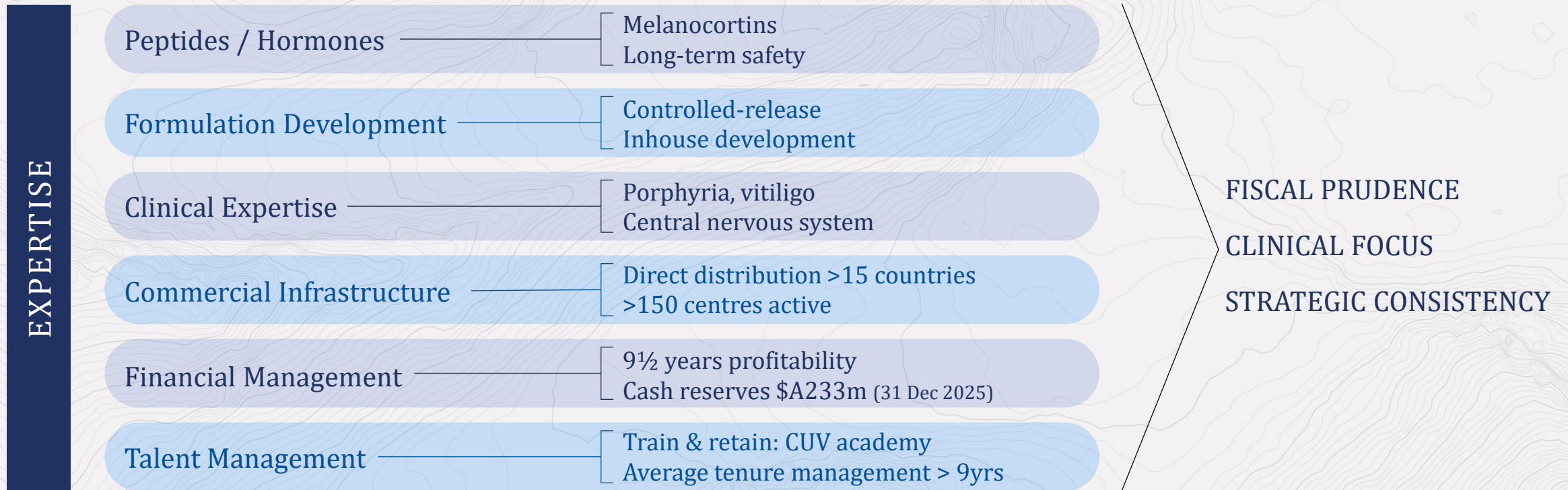
### Pipeline

- Ongoing Phase III vitiligo study – further positive case reports presented
- NEURACTHEL® Instant manufacturing process validated
- Controlled-release injectable peptide platform, developed in-house, enters preclinical program

### Corporate & finance

- Applied to SEC<sup>3</sup> to uplift ADRs<sup>4</sup> to Level II, Nasdaq listing

# A unique business model



FOCUS ON VIABILITY PRIOR TO REINVESTMENT OF EARNINGS TO DIVERSIFY

CLINUVEL ranked along <4% profitable biotechs

# Revenues, expenses and profit

Revenues growth with controlled expansionary expenses underpin consistent and stable earnings

Revenues include commercial sales and special access schemes.

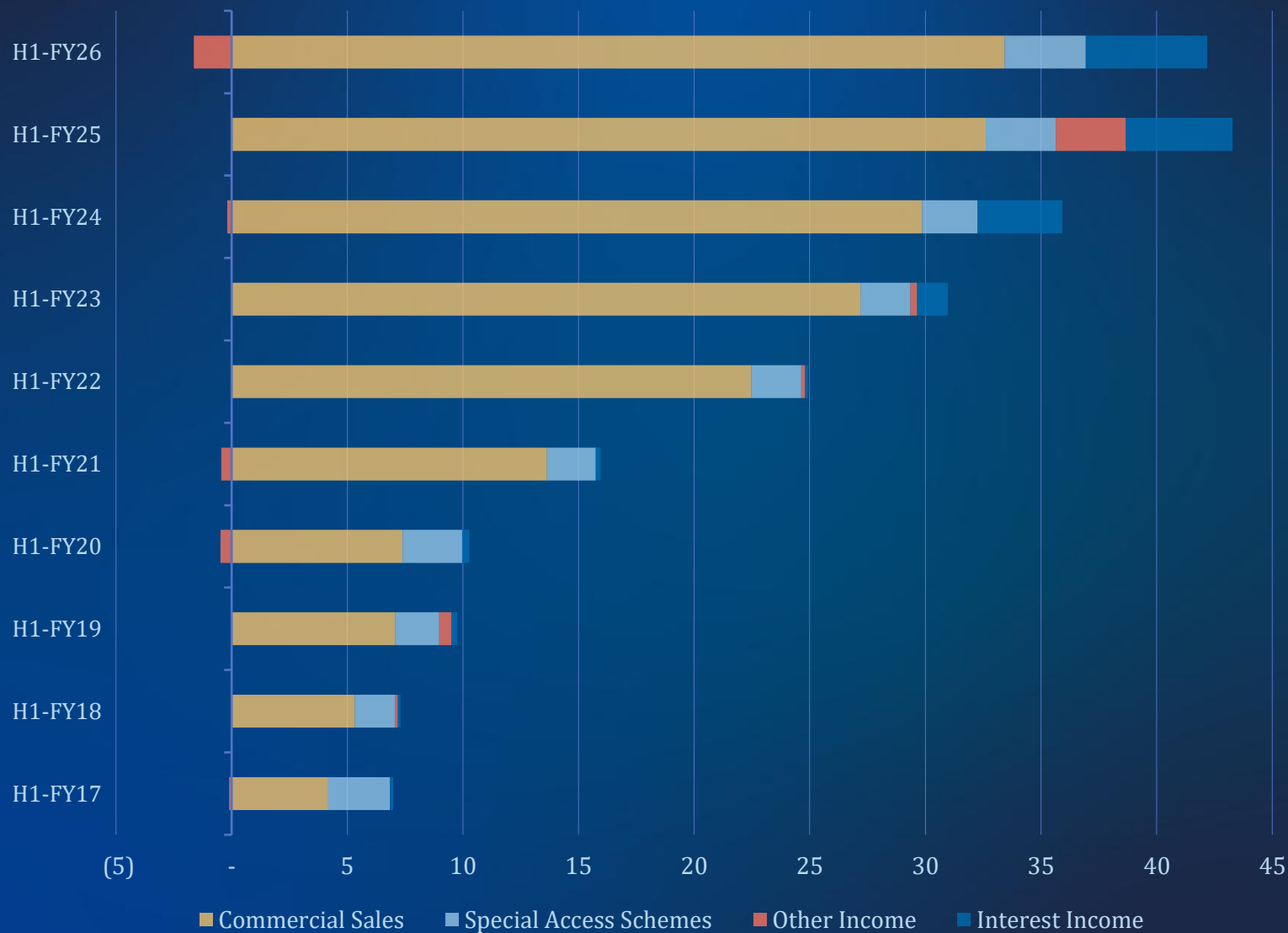


# Buoyant Revenues

Progressive sales revenues plus interest income with variable other income contribution

\$Am	Dec '25	Dec '24
Commercial	33.4 (+3%)	32.6
SAS	3.5 (+15%)	3.0
<b>Revenues</b>	<b>36.9 (+4%)</b>	<b>35.7</b>
Interest Income	5.3 (+14%)	4.6
Other Income	(1.6)	3.0
<b>Total Revenues and Income</b>	<b>40.6 (-6%)</b>	<b>43.3</b>

Revenues and Income, December Half Years (A\$m)



# Controlled Expenses Support Expansion

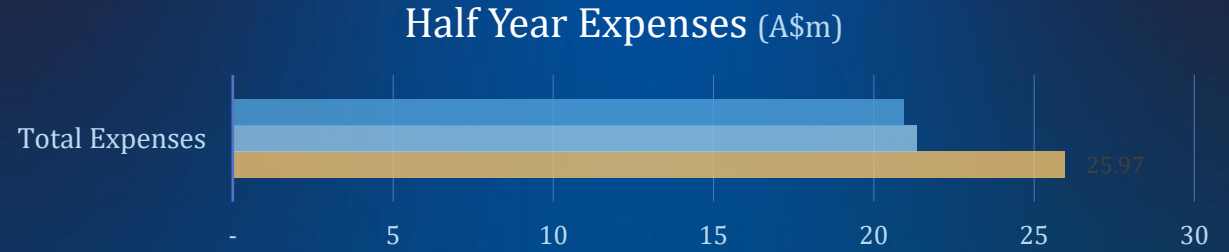
Half year Dec '25 expenses increase 22%

## Growth In:

- Personnel-related (+16%)
- Clinical and Non-Clinical Development (+19%)
- Commercial distribution (+42%)
- Finance and corporate & Legal and insurance (+47%)
- Other (+191%)

## Reduction In:

- Non-cash expenses (-31%)



# Balance Sheet Strengthens

Enables self-financing expansion

## Cash Reserves<sup>1</sup> of \$A233m:

- cover OPEX for 3+ yrs
- enable continued pipeline development
- provide buffer from externalities
- finance value-adding asset acquisition

**Debt-free balance sheet**

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

Cash Reserves and Net Assets (A\$m)



# Pipeline: melanocortins

	Preclinical	Phase I	Phase II	Phase III	Commercial
SKIN	SCENESSE® (afamelanotide 16 mg) in adult			EPP Europe, CH, USA, ISL, CAN <sup>1</sup>	
	SCENESSE® (afamelanotide 16 mg) in adolescent EPP			Filing in H2 2026	
	SCENESSE® (afamelanotide 16 mg) in adolescent and adult vitiligo		Topline results CUV105 - H2 2026		
	SCENESSE® (afamelanotide 16 mg) in variegate porphyria				
BRAIN	NEURACTHEL® instant – IS, MS <sup>2</sup>			1 <sup>st</sup> European filing mid 2026	
	NEURACTHEL® modified release – CNS <sup>2</sup>				
PLATFORM	VLRX-L controlled-release peptide platform		Preclinical results H2 2026		
	Other platforms TBA				
B2C	PhotoCosmetics			Pre-launch in progress	

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

# Calendar & catalysts

## 2026

## 2027

	H1	H2	H1	H2
<b>I SCENESSE®</b>		Health Canada: Marketing Authorization decision		
		EMA filing SCENESSE®: adolescent use in EPP		
<b>CUV105 vitiligo</b>	AAD'26 cases presented	Top line results	Complete results	
<b>CUV107 vitiligo</b>	EMA Scientific Advice Vitiligo	CUV107 Ph III → start recruitment	FDA vitiligo meeting	Recruitment completed
<b>II ACTH-NEURACTHEL®</b>		EU:1 <sup>st</sup> filing marketing authorisation		
<b>III VLRX-L</b>	Liquid controlled-release formulation top line preclinical results	Preclinical complete results	Liquid controlled-release in production [CDMO]	
<b>IV Pipeline</b>			New peptides in liquid controlled- release preclinical data	
<b>V RD&amp;I</b>		VALLAURIX Singapore: complete construction of expanded RD&I Centre		
<b>VII Finance, commercial</b>	FY'26 Half Year Results (31/12/25)	FY'26 Financial Year Results (30/6/26)	FY'27 Half Year Results (31/12/26)	FY'27 Financial Year Results (30/6/27)
	Commercial update EPP-Vitiligo			
	SEC review: Nasdaq, ADR upgrade		AAD'27 San Francisco	

# Regulatory strategy vitiligo

## Proof of concept

CUV101-102-103 SCENESSE® adjunct NB-UVB



**CUV104 SCENESSE®**  
monotherapy



**CUV105 Ph III**  
SCENESSE®-NB-UVB ongoing



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

## 2026 EMA/FDA IRB/Ethics/DMSB

### Data Monitoring Surveillance Board

- CUV105 data lock, data integrity (H2 '26)

### EMA meeting: Scientific Advice (pending)

- CUV107 protocol validation
- adults, children >12 y
- dark skin III-IV-V-VI (Fitzpatrick)

### Start CUV107

- NB-UVB equipment supplied <sup>1</sup>
- approx. 20 sites (EU-NAM-MEA)

### FDA meeting 2027 <sup>2</sup>

- discussion data

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

# Vitiligo U.S. Market

*significant market opportunity*

**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

1% Prevalence  
**3,295,000**

Total addressable market  
**US\$4.5b**

25% Eligible  
**823,750<sup>1</sup>**

40% (0.5% BSA, 0.2% H/N)  
**329,500**

20% Seeking treatment  
**65,900**

9% Penetration Yr 1-2<sup>2</sup>  
**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.

# Future outlook, clear objectives

Vitiligo	<ul style="list-style-type: none"><li>- significant market</li><li>- preparation of distribution systems</li><li>- CUV105 topline results</li><li>- CUV107 start</li></ul>	US\$490m <sup>1</sup> 20 staff  2H 2026
EPP	<ul style="list-style-type: none"><li>- superior technology</li><li>- long-term treatment &amp; safety</li></ul>	US\$300m <sup>2</sup>
RD&I	<ul style="list-style-type: none"><li>- new controlled-release formulation</li><li>- preclinical read out</li></ul>	H1 2026
Funds	<ul style="list-style-type: none"><li>- sufficient to run program to</li></ul>	2028
Manufacturing	<ul style="list-style-type: none"><li>- planned</li></ul>	2026

## A team which

- developed, completed clinical programs
- commercialised SCENESSE® in EPP
- completes a global program for the 2<sup>nd</sup> time
- executed a financial strategy
- will integrate all functions, skills

1. Total penetration U.S.A. first two years of distribution; 2. Addressable market porphyrias.

# 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