

CLINUVEL

A bid to summit

A clinical & financial update

Jefferies' Institutional Meetings
Sydney, 2 February 2026



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), CYACÉLLE, 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®, CYACÉLLE, 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.

A unique business model

EXPERTISE

Peptides / Hormones

Melanocortins
Long-term safety

Formulation Development

Controlled-release
Inhouse development

Clinical Expertise

Porphyria, vitiligo
Central nervous system

Commercial Infrastructure

Direct distribution >15 countries
>150 centres active

Financial Management

9 yrs profitability
Cash reserves >A\$230m

Talent Management

Train & retain: CUV academy
Average tenure management > 9yrs

FISCAL PRUDENCE

CLINICAL FOCUS

STRATEGIC CONSISTENCY

FOCUS BEFORE DIVERSIFICATION | EARNINGS REINVESTED

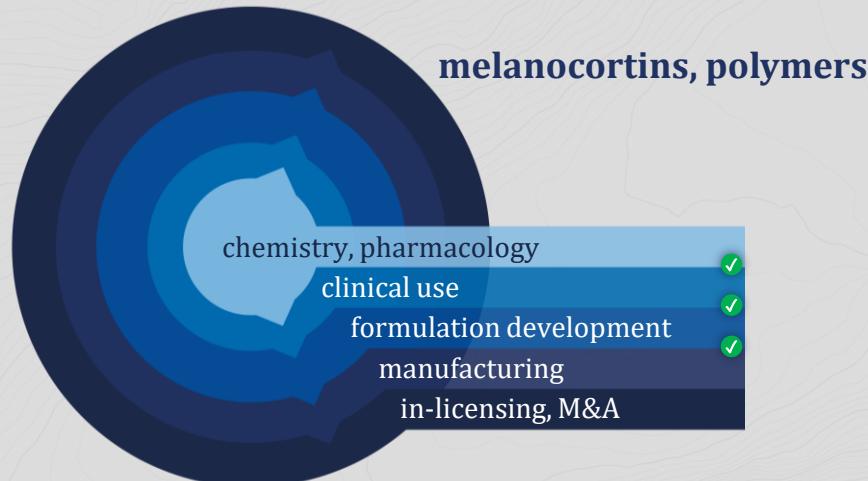
CLINUVEL ranked along <4% profitable biotechs

Chemistry & pharmacology

- 3 decades of clinical safety
- >21,500 doses administered
- efficacy validated by EMA, FDA, TGA, MoH IS
- CA pending
- 2 pharmacophores

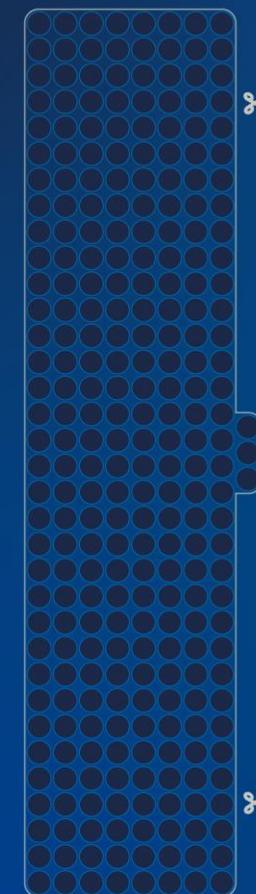


Risk management in research



MELANOCORTIN PORTFOLIO

Proopiomelanocortin (POMC)
241 Amino Acids



ACTH
24 / 39 Amino Acids



Afamelanotide
13 Amino Acids



CUV 9900
6 Amino Acids



CLINICAL PROPERTIES

1. anti-oxidative
2. photo-reparative
3. anti-inflammatory
4. photoprotective
5. repigmentation

Calendar & catalysts

2026

2027

	H1	H2	H1	H2
I SCENESSE®		Health Canada: Marketing Authorization decision		
		EMA filing SCENESSE: adolescent use in EPP		
CUV105 vitiligo	AAD'26 cases presented	Top line results	Complete results	
CUV107 vitiligo	EMA Scientific Advice Vitiligo	CUV107 Ph III → start recruitment	FDA vitiligo meeting	Recruitment completed
II ACTH-NEURACTHEL®		EU:1 st filing marketing authorisation		
III VLRX-L	Liquid controlled-release formulation top line preclinical results	Preclinical complete results	Liquid controlled-release in production [CDMO]	
IV Pipeline			New peptides in liquid controlled- release preclinical data	
V RD&I		VALLAURIX Singapore: complete construction of expanded RD&I Centre		
VII Finance, commercial	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	

Half year results (31 Dec 2025) published by 27 Feb 2026

Vitiligo – SCENESSE® (afamelanotide 16mg)

CUV102 Primary Endpoint

Extent of repigmentation Day 0 to Day 168

Fitzpatrick skin types IV-VI

Time to 1st repigmentation ~43 vs 68 days

Quality of Life

VASI p=0.025 VETF p=0.023

VASI p=0.046

VASI p=0.086

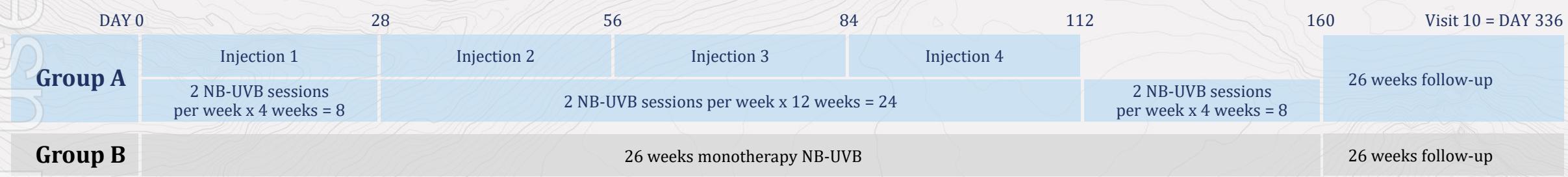
Publications:

Grimes et al (2013), *JAMA Dermatology*

Lim et al (2015), *JAMA Dermatology*

Toh et al (2020), *JAAD*

CUV102 results



Key take-aways CUV102

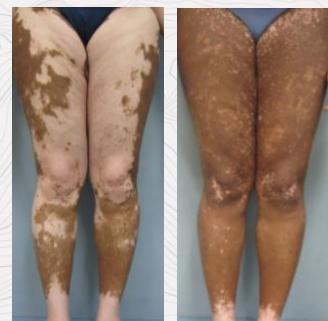
Adjunct therapy works well on all body sites (excl. hands & feet)

Initially skin gets darker before pigmentation in vitiligo occurs

Darker skin type reacts optimally

Patients & physicians swiftly become unblinded

Follicular & marginal repigmentation



Female patient in CUV102 at baseline (Day 0) and Day 179 after 40 NB-UVB treatments, 4 afamelanotide implants
Untouched, No-AI



F95% repigmentation

Male patient at baseline (Day 0) and Day 195 after 59 NB-UVB treatments, 4 afamelanotide implants
Untouched, No-AI

CUV105- Study design & results

Phase III, double arm, open label (n=210)

Inclusion criteria:

- Adults & adolescents (≥ 12 years)
- Generalised vitiligo, face & body (T-VASI ≥ 3)
- Fitzpatrick skin types III-VI

Primary Endpoint

T-VASI50 through centrally & locally assessed photographs

Secondary Endpoints

Efficacy:

- time to onset of repigmentation
- F-VASI25/50/75/90, T-VASI25/75/90
- QoL: VitiQoL, PGIC, PtGA, VNS

Pigmentation maintenance post-treatment period

Safety

	Day 0	20-week treatment	Day 140	24-week post-treatment observation	Day 308	20-week treatment	Day 448
Group A		Afamelanotide 16mg cr-injection every 21 days** NB-UVB 2x per week		No treatment		No treatment	
Group B		NB-UVB 2x per week		No treatment		Afamelanotide injection every 21 days NB-UVB 2x per week	

** afamelanotide 16mg implant formulation injected

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**
- approx. 20 sites (EU-NAM-MEA)

FDA meeting 2027*

- discussion data

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*

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

20% Seeking treatment
65,900

9% Penetration Yr 1-2[†]
5,931

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

*Total vitiligo population FST IV-V-VI

[†]7-8 doses afamelanotide pp for >90%, repigmentation 47,448

EPP market longevity

Global

direct distribution to trained & accredited centres, hospitals
multidisciplinary care
long-term follow-up (>20yrs)

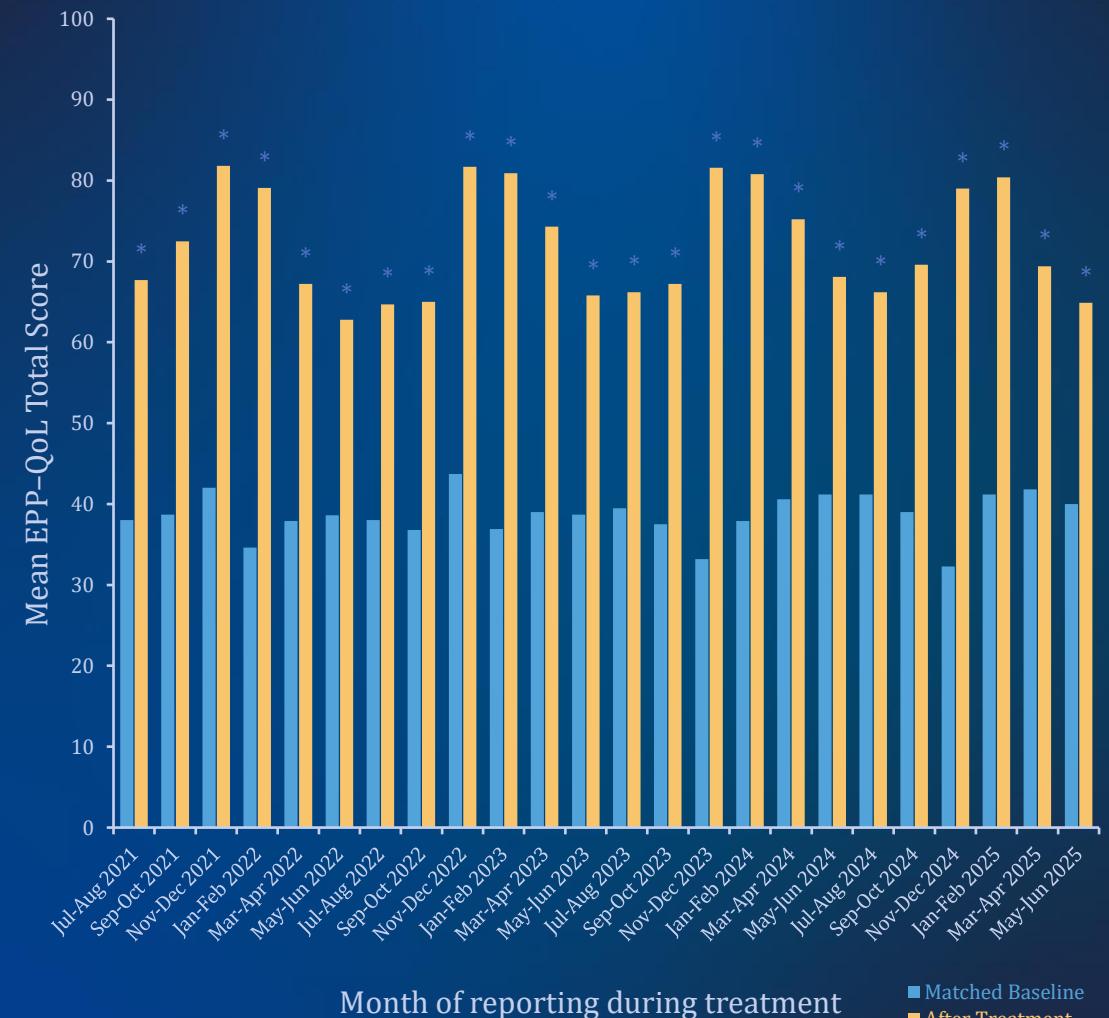
Europe 2016–2026

>30 EPP Expert Centres
rate of retention >90% 5 yrs
harmonised label in 2025: 6 injections p/a

North America 2020–2026

120 trained centres
>100 private insurers, Medicare, Medicaid, VA coverage
CPT® & J-codes established
clinical care team (5)
success rate Prior Authorization >95%
Patient Assistance Program for eligible patients

EU Post-authorisation safety study demonstrated continued positive effect on patient quality of life (QoL)



*EPP-QoL total score for treated patients and matched baseline from Jul-Aug 2021 to May-Jun 2025, represents a statistically significant difference ($p < 0.005$)

■ Matched Baseline
■ After Treatment

Experimental EPP treatments A look at the development landscape

COMPANY PROGRAM	TANABE PHARMACEUTICALS	DISC MEDICINE
Mechanism of action	Dersimelagon ("MT-7117"; since 2017); in-house development	Oral Glycine Transporter 1 (GlyT1) inhibitor - <i>unclear correlation between PPIX and phototoxicity</i>
Dose	Oral 200mg daily (previous 100/300mg evaluated) - low bioavailability	Oral 60mg daily (previous 20mg evaluated) - dosing from Roche different
Clinical Status	Two Phase III studies complete, only data from first study available	Data from two Phase II studies reported, Phase III ongoing
Regulatory status	FDA Fast Track Designation (2018)	FDA priority review ongoing Media report FDA concerns over "trial data and risk for abuse"
Known adverse events (AEs)	Dose dependency in Phase II Most common AEs seen in studies: - Nausea, Ephelides, Hyperpigmentation, Lip pigmentation, Fatigue, Photosensitivity reaction, Diarrhoea, Melanocytic nevus. Decreased appetite, Vomiting	Schizophrenia studies (dose dependency reported, max dose 20mg/day): Dizziness, Worsening of schizophrenia, Insomnia associated with schizophrenia, Somnolence EPP studies (dose dependency reported, up to 60mg/day): Dizziness (44-59% of patients; median duration 5 days in Phase II), Headache, Nausea No reports of CNS side effects - central effects obviously expected
Drug-drug restrictions	Patients excluded from clinical trials when using opioids, analgesics or NSAIDs. Caution use with statins: atorvastatin (Lipitor) and rosuvastatin (Crestor). - drug-drug interaction	Patients excluded from clinical trials if using: • CYP3A4 inhibitors and inducers, including common antibiotics (ciprofloxacin), antifungals (itraconazole), antivirals (ritonavir, Paxlovid), and barbiturates • Antipsychotic medication • Opioids
Safety profile – other	Patients excluded from clinical trials if there is history of melanoma or non-melanoma skin cancer Only patients willing/able to expose to sunlight during daylight hours are enrolled in Phase III - long-term safety not established	Patients excluded from clinical trials: HIV, active hepatitis B/C, pre/post liver transplant, low hemoglobin, pregnant/breastfeeding
Exposure	200 patients exposed across Phase II and first Phase III study, includes 25 adolescents Up to 16 weeks, 100, 200 or 300mg daily. - dose range studies unclear	98 patients exposed across two studies, includes 4 adolescents Up to 24 weeks in clinical trials, up to 28.7 months in open label - minimal Q of patients
Clinical endpoints	Light exposure: No significance in first Phase III study. Time to prodrome: Improvement at week 16 vs placebo, dose dependent. Primary Phase III endpoint. - weak endpoint, subjective	Light exposure: Dose dependent response demonstrated (significance vs baseline, not vs placebo). Co-primary in ongoing Phase III – average monthly time in sunlight Cumulative exposure used as secondary endpoint; endpoint not met in Phase II study Reduction in PPIX: Dose dependent response demonstrated, Co-primary in ongoing Phase III

FY2025

Strong, consistent financial performance

Increase in revenues, cash, NPAT

- global growth
- controlled expenses
- Reinvested in R&D for future revenues

9th consecutive annual profit

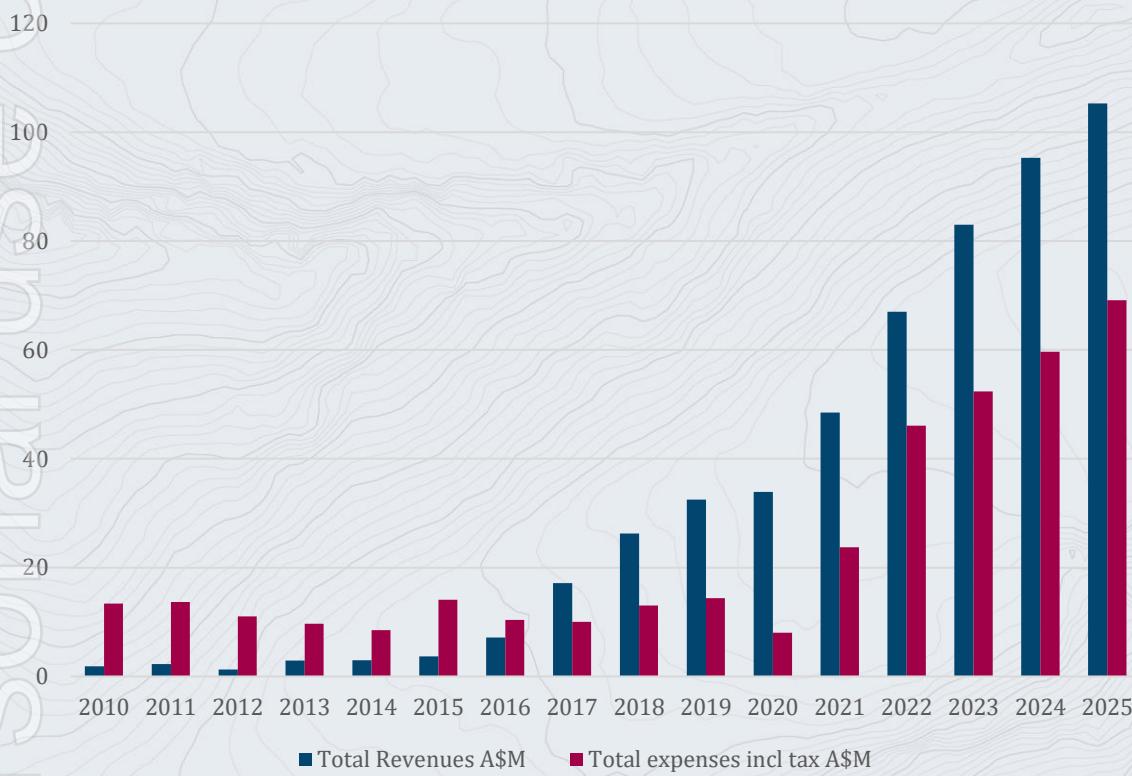
8th consecutive annual dividend

- fully-franked for 4th consecutive year
- A\$0.05 per ordinary share
- paid September 2025

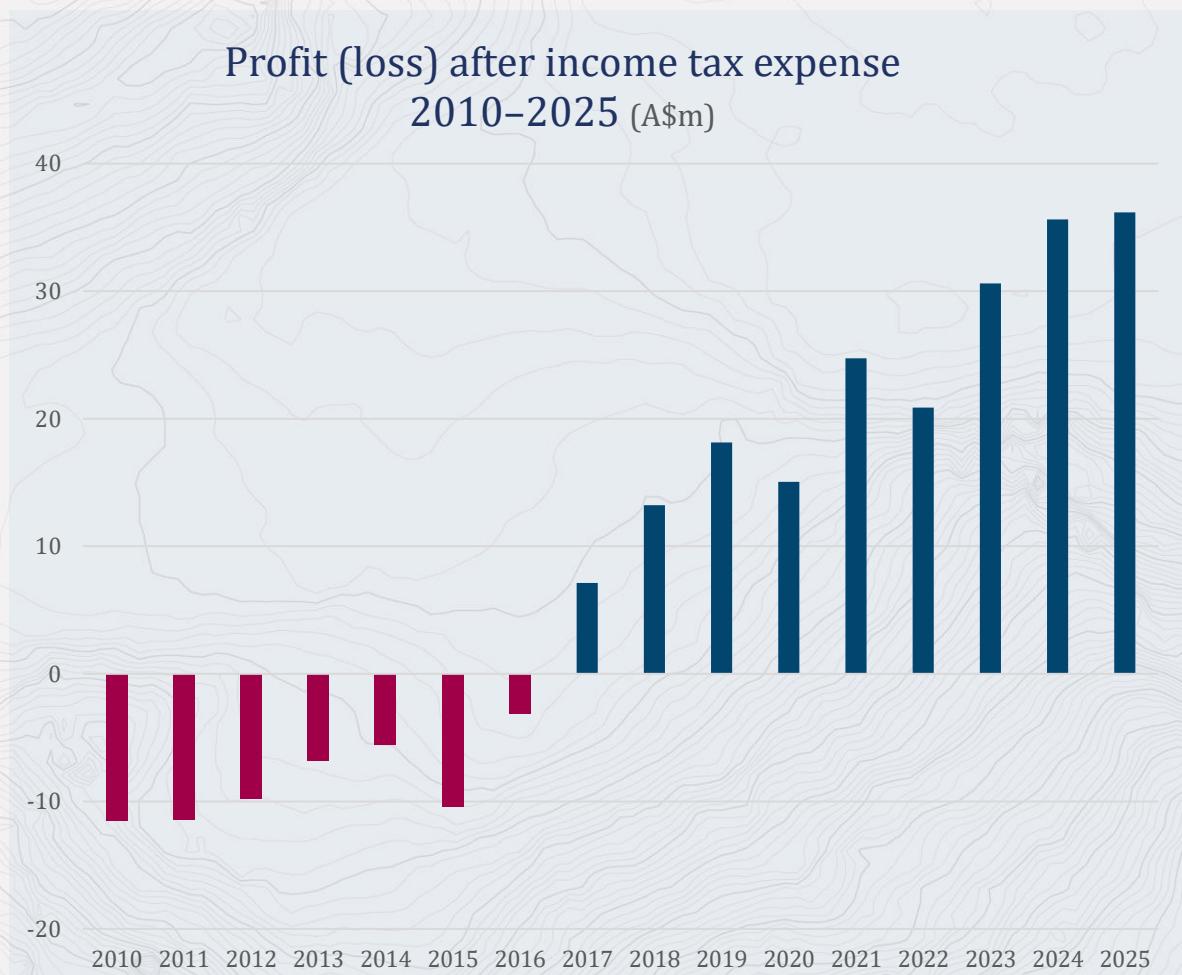
CONSOLIDATED ENTITY	30 June 2025 (A\$)	Change
Total Revenues, Interest and Other Income	105.3m	+ 10%
Total Expenses	53.7m	+ 20%
Net Profit Before Income Tax	51.6m	+ 2%
Net Profit After Income Tax Expense	36.2m	+ 2%
Cash Reserves	224.1m	+ 22%
Basic Earnings per Share	0.72	+ 1%
Net Tangible Assets Backing per Share	4.77	+19%
Dividend per Share Declared	0.05	Stable

Revenues, expenses and profit FY2010–2025

Revenues and expenses 2010–2025 (A\$m)



Profit (loss) after income tax expense
2010–2025 (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**
	SCENESSE® (afamelanotide 16 mg) in adolescent EPP				Filing in H2 2026
	SCENESSE® (afamelanotide 16 mg) in adolescent and adult vitiligo			Topline results CUV105 - H2	
	SCENESSE® (afamelanotide 16 mg) in variegate porphyria				
BRAIN	NEURACTHEL® instant – IS, MS*			1 st European filing mid 2026	
	NEURACTHEL® modified release – CNS				
PLATFORM	VLRX-L controlled-release peptide platform				
	Other platforms TBA				
B2C	PhotoCosmetics			Pre-launch in progress	

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

** Health Canada is currently evaluating SCENESSE® for adult EPP patients

Future outlook, clear objectives

ersonal
national
international
vision

Vitiligo

- significant market
- preparation of distribution systems
- CUV105 topline results
- CUV107 start

US\$490m*
20 staff
H2
2026

EPP

- superior technology
- long-term treatment & safety

US\$110m*

RD&I

- new controlled-release formulation
- preclinical read out

H1

Funds

- sufficient to run program to

2028

Manufacturing

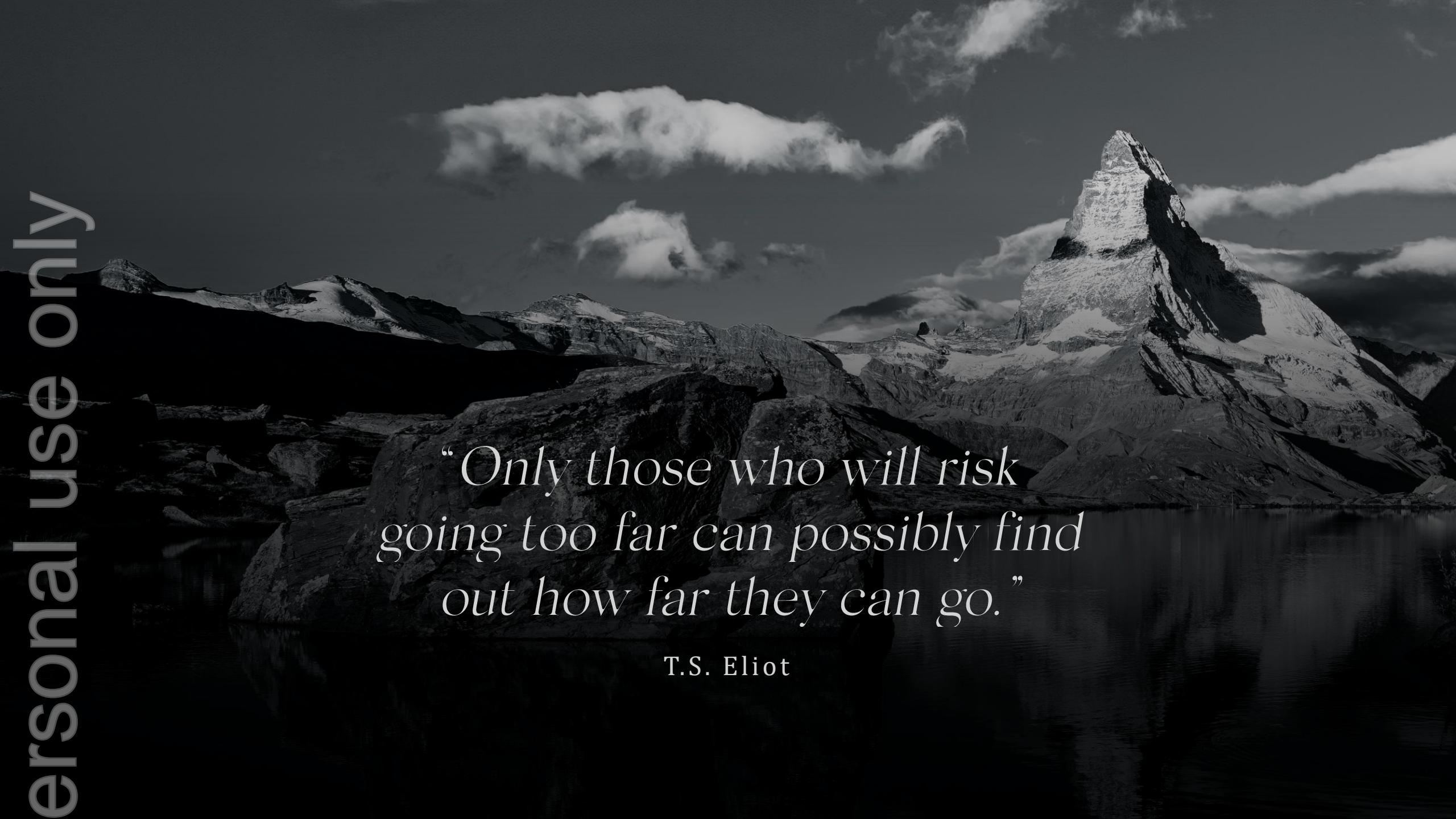
- planned

2026

A team which

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

ersonal use only



“Only those who will risk
going too far can possibly find
out how far they can go.”

T.S. Eliot

personal use only

CLINUVEL

Thank You

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

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