CLINUVEL

A bid to summit

A clinical & financial update

Jefferies' Institutional Meetings

Sydney, 2 February 2026

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.

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

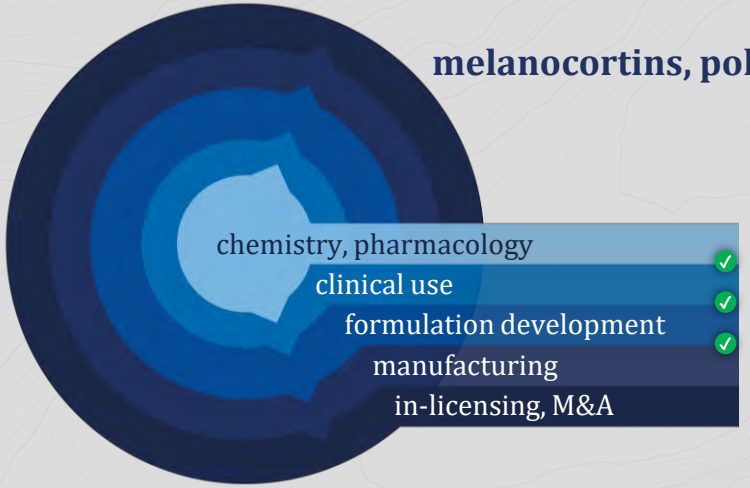
CLINUVEL ranked along <4% profitable biotechs

Chemistry & pharmacology

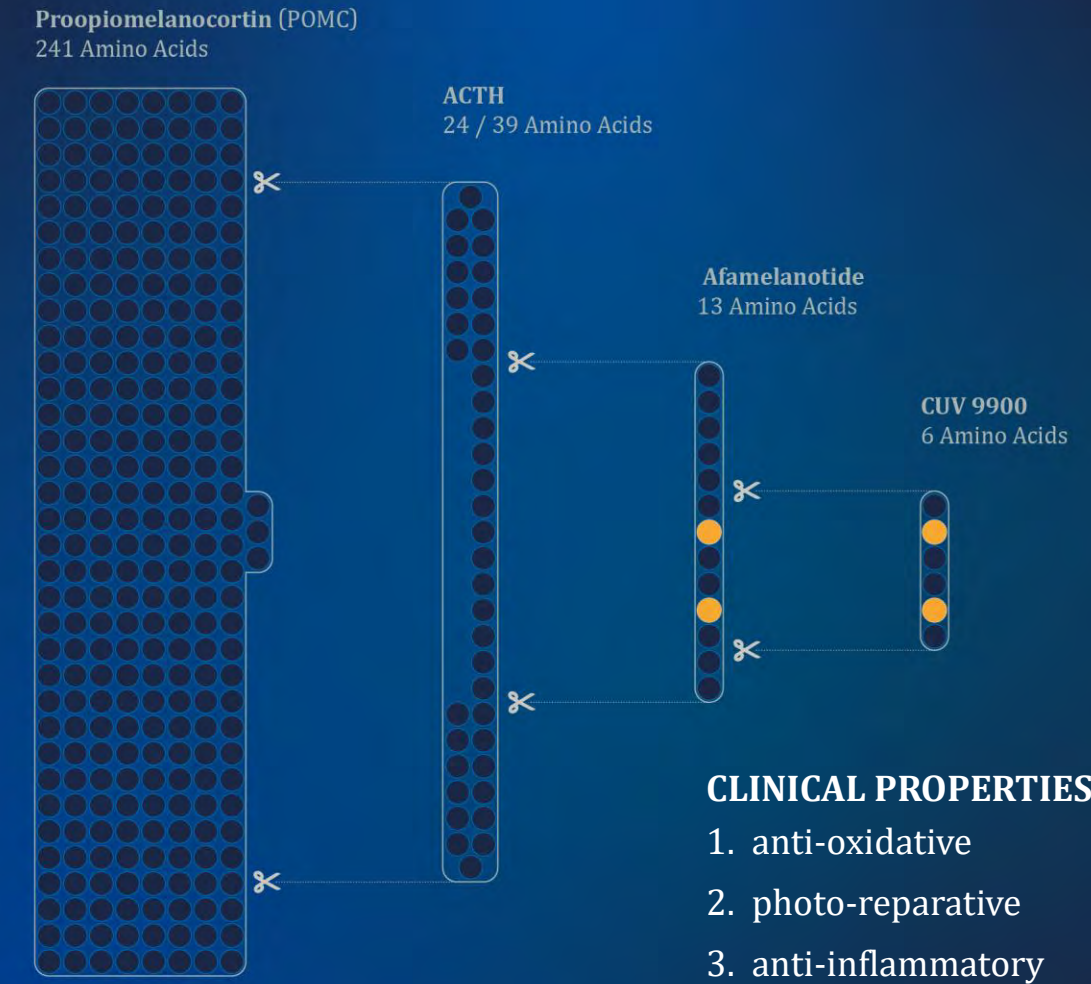
- 3 decades of clinical safety
- >21,500 doses administered
- efficacy validated by EMA, FDA, TGA, MoH IS

  CA pending
- 2 pharmacophores

Risk management in research



MELANOCORTIN PORTFOLIO



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:1st 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

	DAY 0	28	56	84	112	160	Visit 10 = DAY 336
Group A	Injection 1		Injection 2	Injection 3	Injection 4		26 weeks follow-up
	2 NB-UVB sessions per week x 4 weeks = 8		2 NB-UVB sessions per week x 12 weeks = 24			2 NB-UVB sessions per week x 4 weeks = 8	
Group B	26 weeks monotherapy NB-UVB						26 weeks follow-up

Key take-aways CUV102

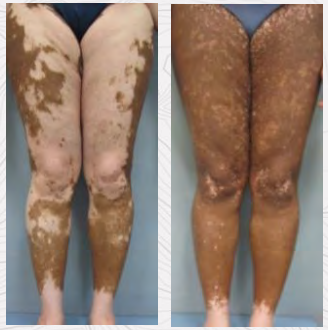
Adjunct therapy works well on all body sites (excl. hands & feet)

Initially skin gets darker before pigmentation in vitiligo occurs

Darker skin type reacts optimally

Patients & physicians swiftly become unblinded

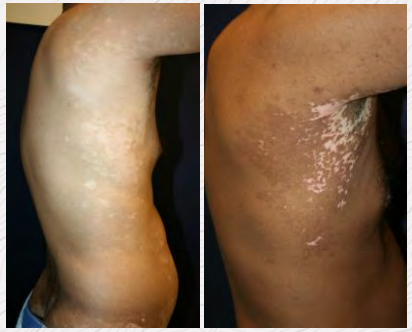
Follicular & marginal repigmentation



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

* Pending ongoing interactions
** Select centres are supplied NB-UVB equipment

Vitiligo U.S. Market

significant market opportunity

Commercial preparation
establish systems, NB-UVB

↓

Distribution
national team (20)

↓

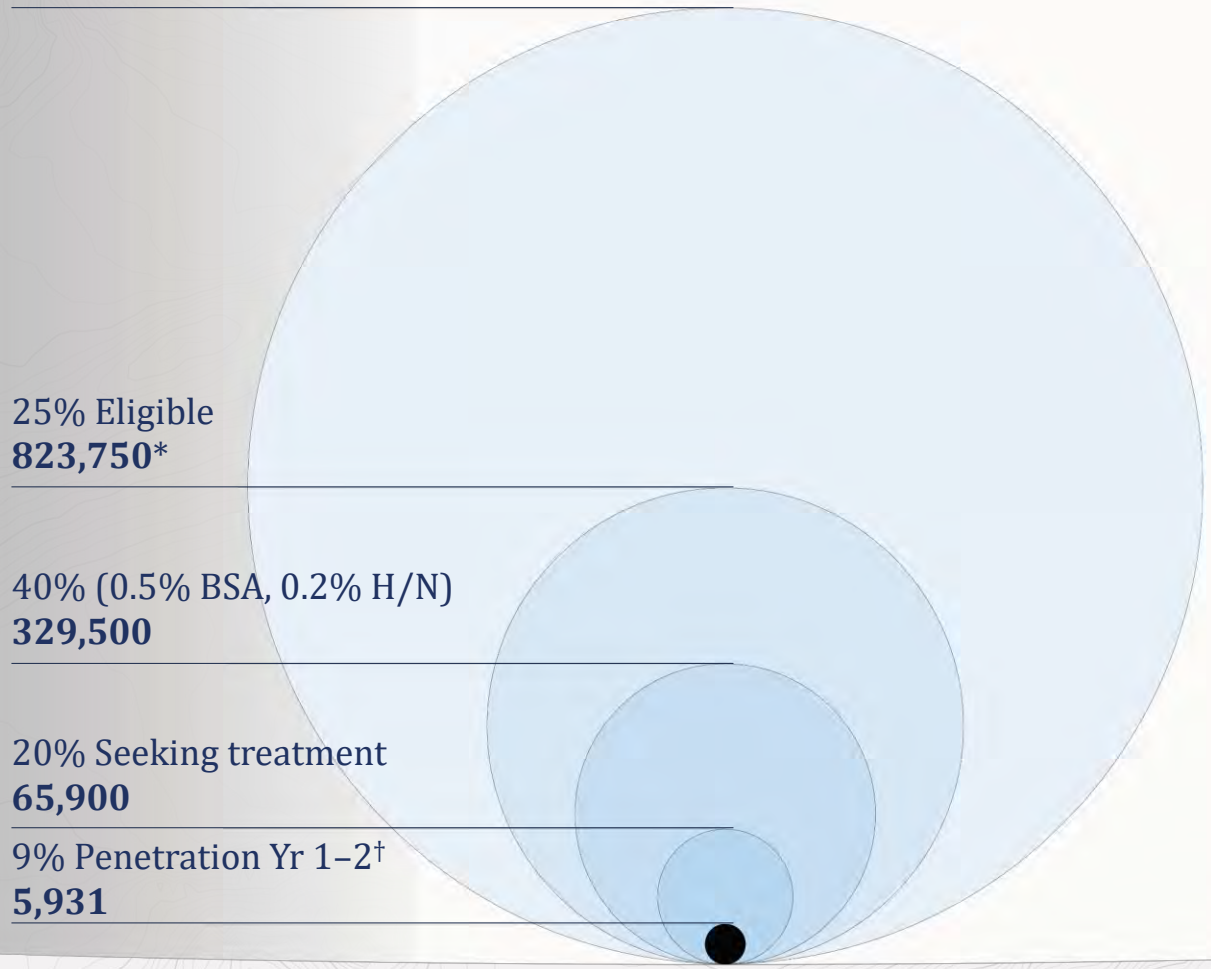
Prescribers
target 190 trained & accredited centres

↓

Market access
reimbursement extensive vitiligo

↓

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



*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

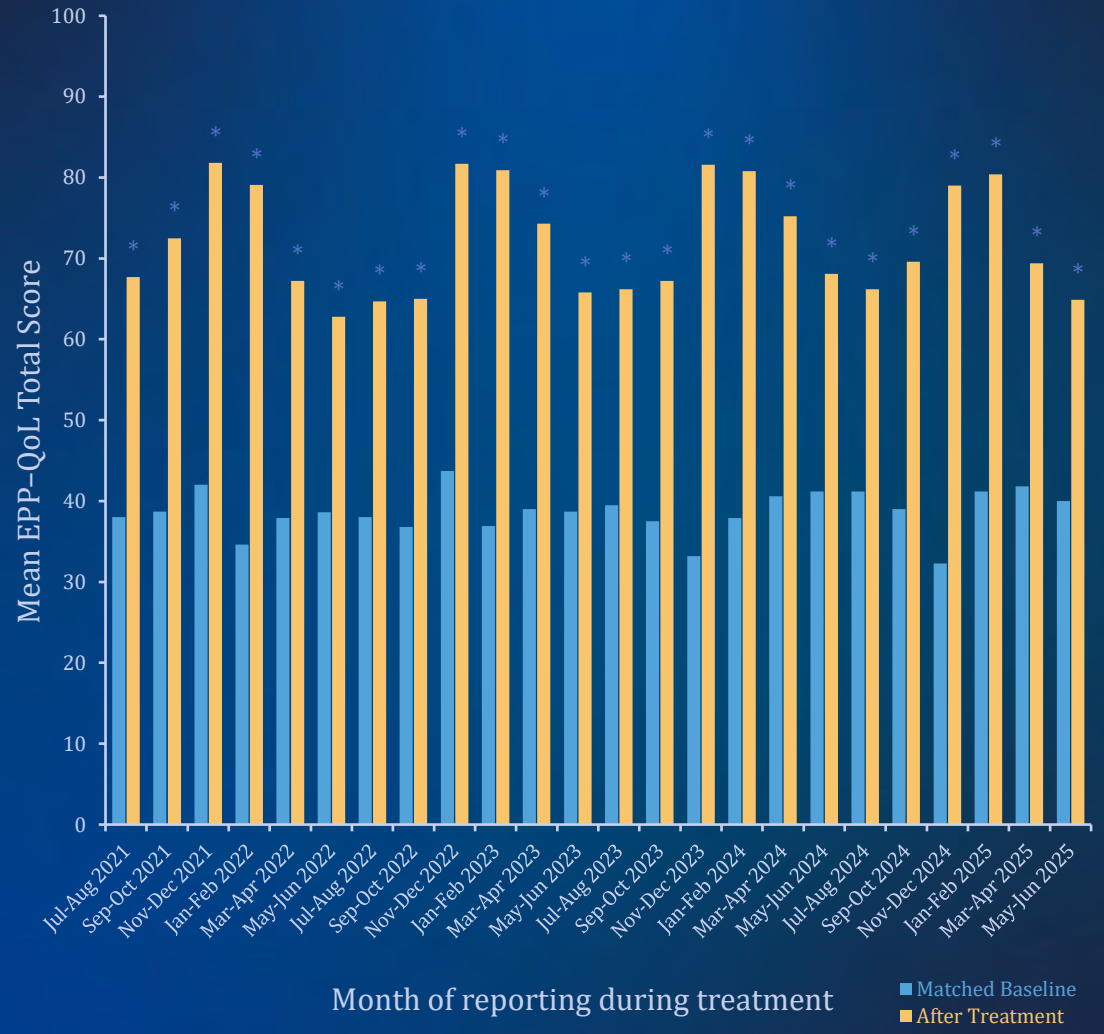
CPT® & J-codes established

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)

Experimental EPP treatments A look at the development landscape

COMPANY PROGRAM	**TANABE PHARMACEUTICALS** **Dersimelagon** ("MT-7117"; since 2017); in-house development	**DISC MEDICINE** **Bitopertin** ("DISC-1459", "RG1678", "RO4917838"; since 2022); repurposed from Roche after failed trials for schizophrenia
Mechanism of action	Oral synthetic MC1R agonist,: - ***lower binding affinity to MC1R than afamelanotide***	Oral Glycine Transporter 1 (GlyT1) inhibitor - ***unclear correlation between PPIX and phototoxicity***
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

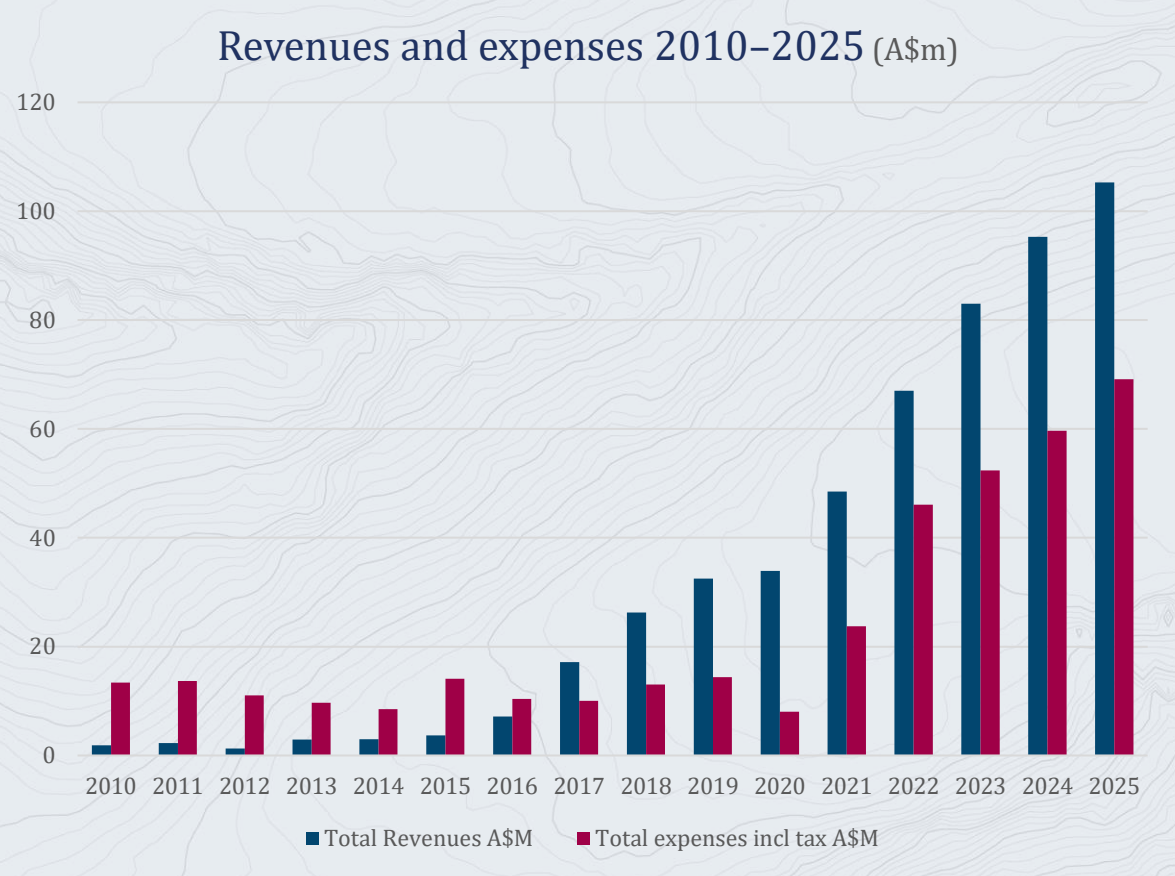
8th consecutive annual dividend

- 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

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.

Revenues, expenses and profit FY2010–2025



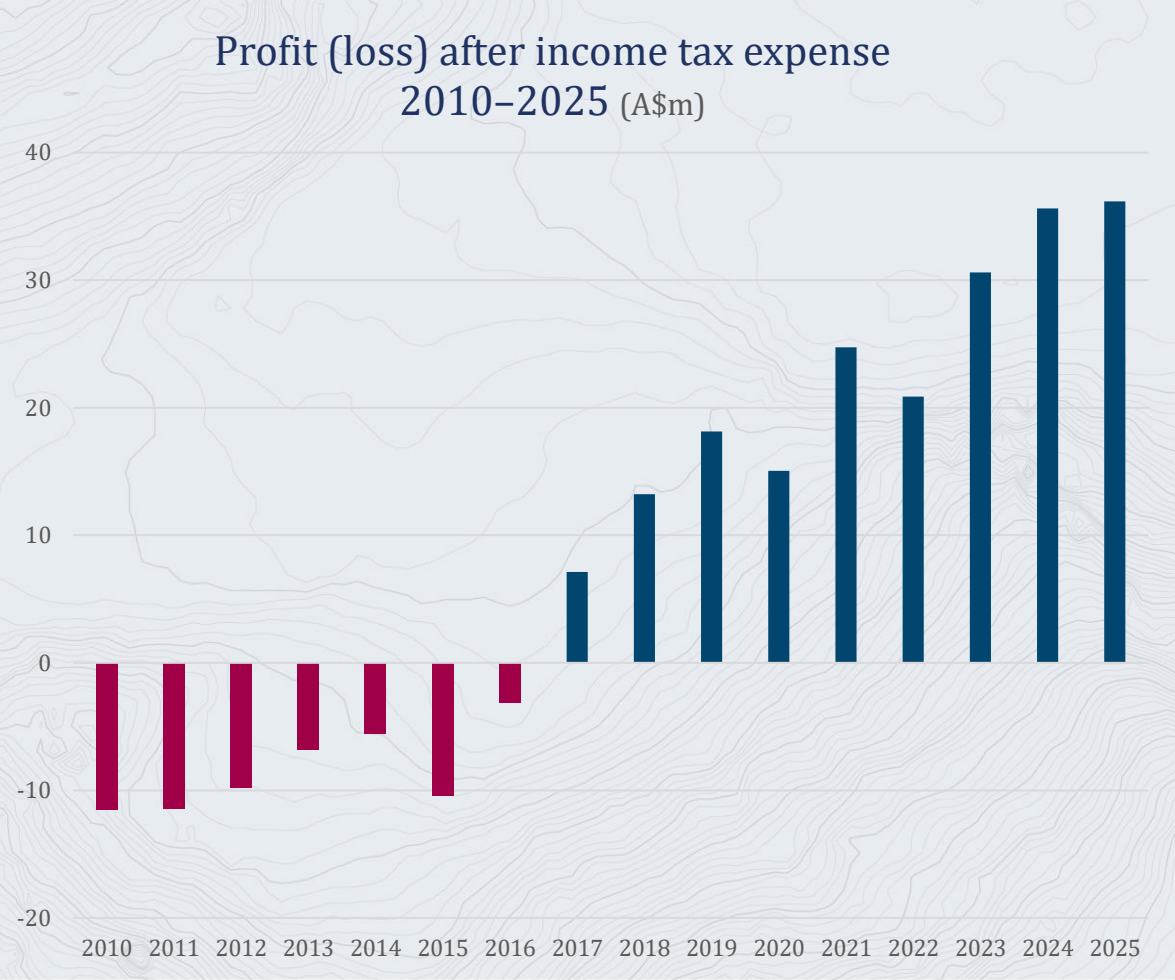
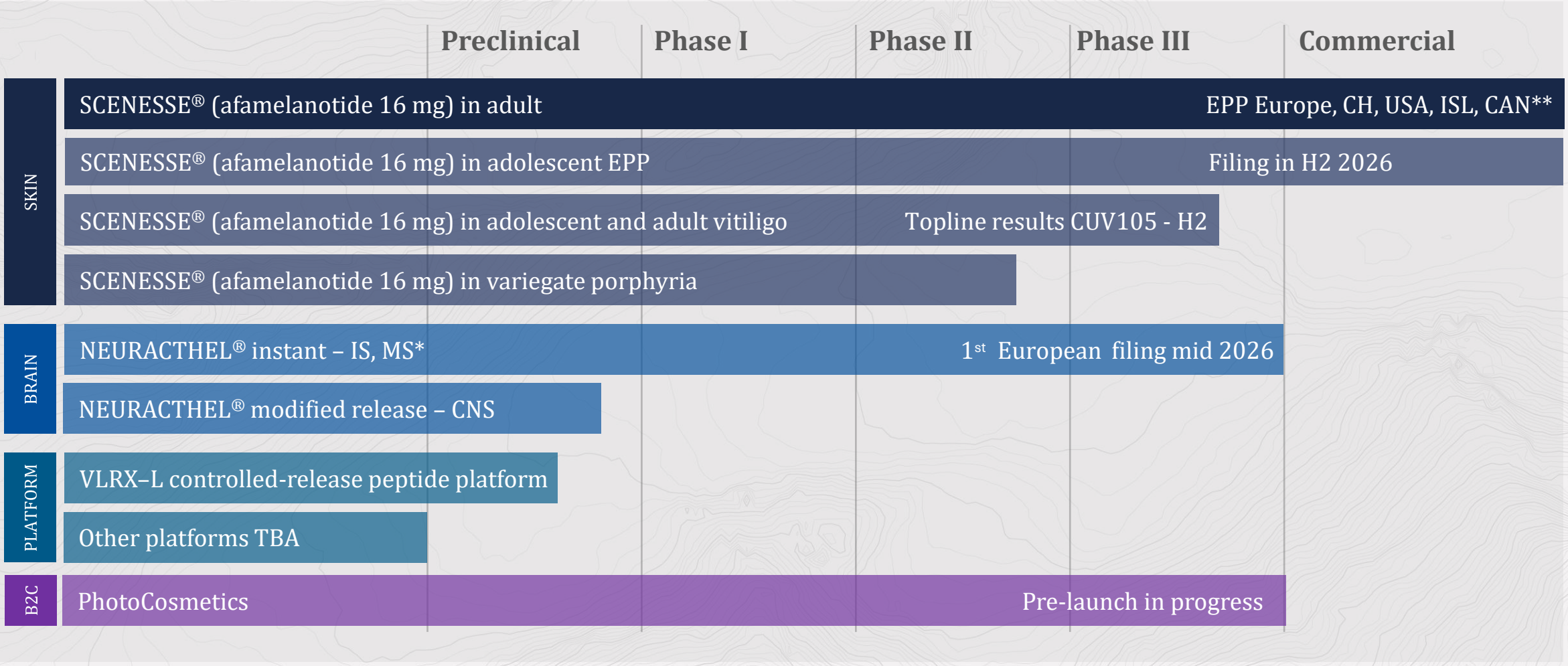


Chart years refer to financial years ended 30 June

Pipeline: melanocortins



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

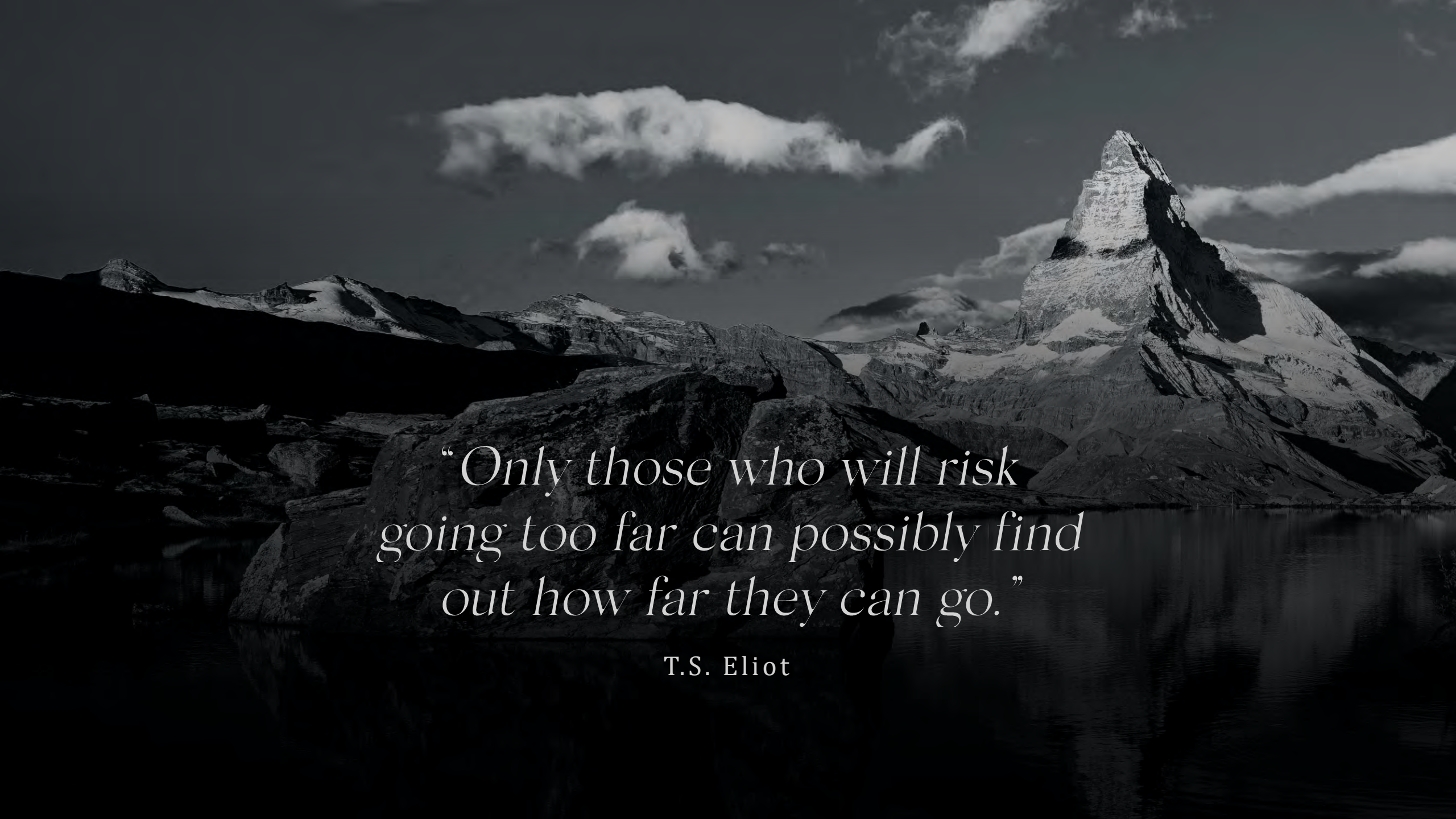
Future outlook, clear objectives

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

*Total Addressable Market U.S.A., est 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


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

CLINUVEL

Thank You

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