CLINUVEL

Managing Director's address

Annual General Meeting

31 October 2023

ASX	CUV
Börse Frankfurt	UR9
Level 1 ADR	CLVLY

CLINUVEL GROUP

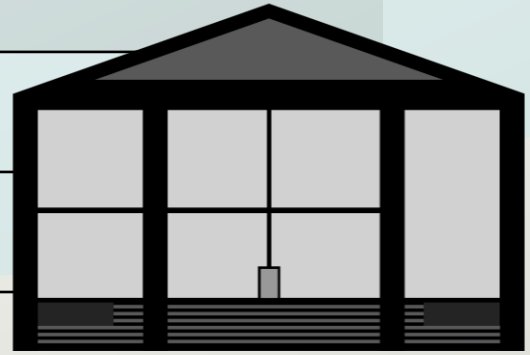
Forward-looking statement

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. 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 products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACÊLLE, PRÉNUMBRA® or NEURACTHEL®; 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, Israel, China and Japan 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® or NEURACTHEL® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology 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 and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2023 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.

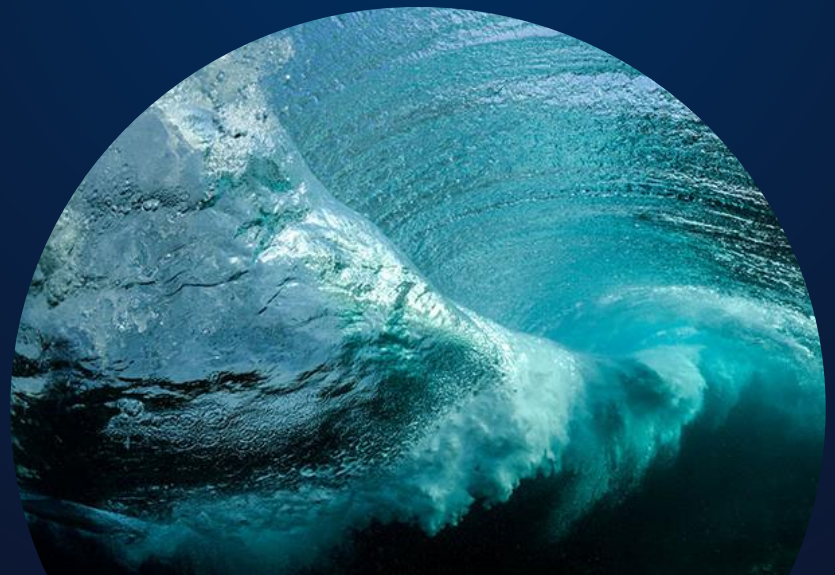
Catalysts

Timelines

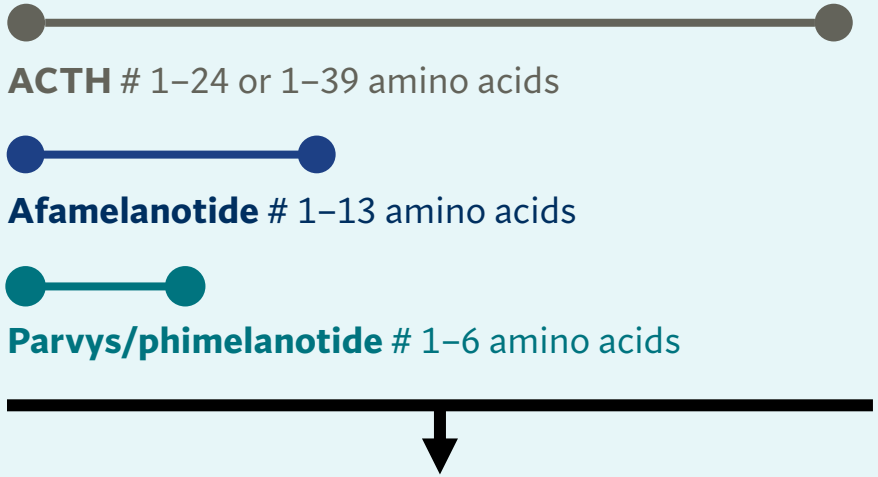
Next 12 months	
SCENESSE®	use in adolescents – EMA guidance regulatory filing Canada
Vitiligo	CUV105, n=200 – complete recruitment CUV107, n=200
XP – DNA Repair	CUV151-156 readouts CUV154-158 study start
VP	CUV040 – study complete
CNS disorders	CUV803 – readouts (PRÉNUMBRA®) new indication – study start
NEURACTHEL®	manufacturing progress
PhotoCosmetics	website launch; e-commerce CYACÊLLE global launch events
Finances	earnings growth



Technology



The technology – melanocortins



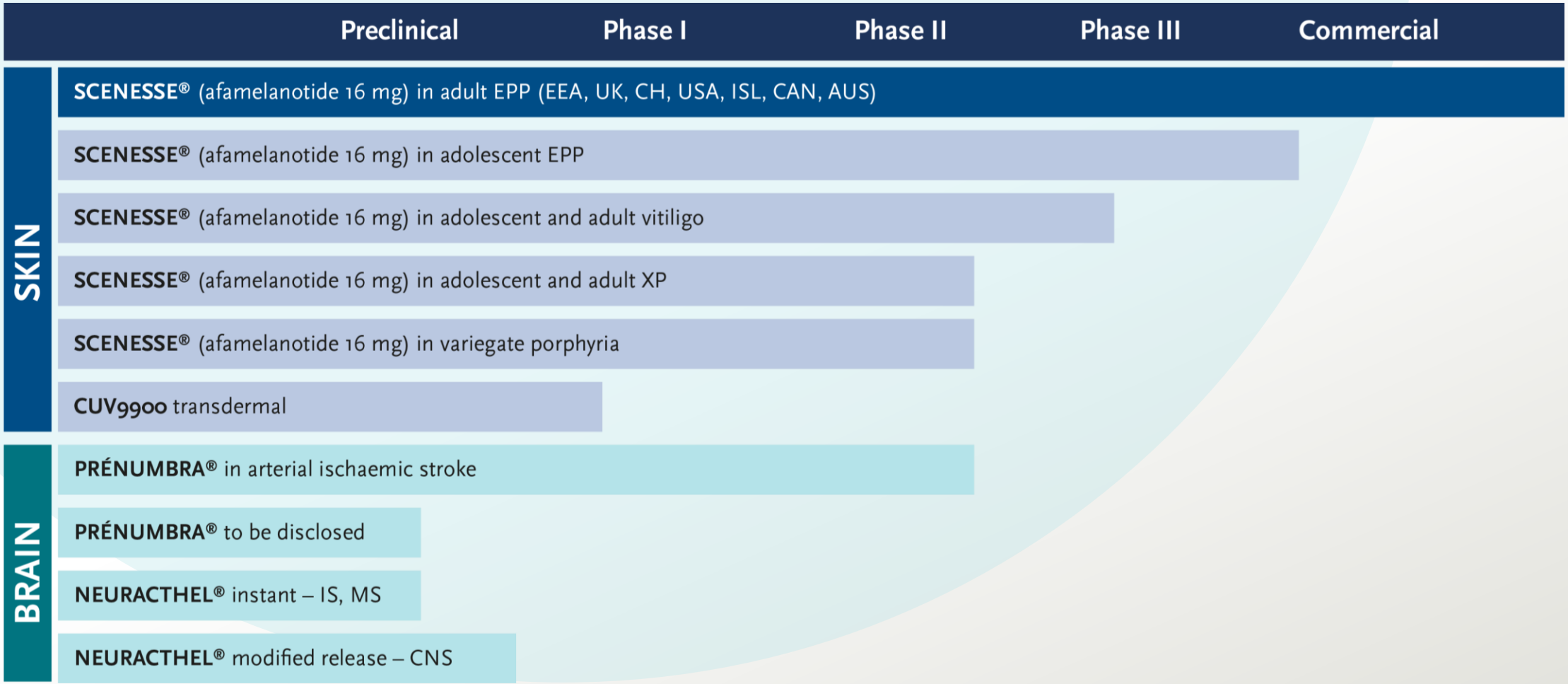
Active fragments	**– melanocortins**
His^{6}-Phe^{7}-Arg^{8}-Trp^{9}	**– melanogenesis**
Pro^{11}- Lys^{12}-Val^{13}	**– anti-inflammatory**
Afamelanotide	**– NLe^{4}-DPhe^{7}-α-MSH** **– hydrogen bond TM2**

COMPANY	YEAR*	RECEPTOR/S	STATUS
Merck	1999	MC4R	Abandoned
Basilea	2003	MC4R	Abandoned
Abbvie	2008	MC1R, MC3R, MC4R, MC5R	Abandoned
Novo Nordisk	2014	MC4R	Abandoned
Zengen	2007	MC1R	Abandoned
Aequus Bio.	2016	MC3R, MC4R	Research
U. Cincinnati (Abdel Malek)	2006	MC1R	Research
MC1R Ventures	2022	MC1R	Undisclosed
Crinetics Pharm.	2019	MC2R	Phase II
Santhera	2009	MC4R	Phase II
Synact	2015	MC1R, MC4R	Phase II
Mallinckrodt	1952	MC1R-MC5R	Chapter 11, ACTH
IPSEN	2007	MC4R	Licensed to Rhythm
Amphastar	1952	MC2R	Approved (sNDA): ACTH
ANI Pharma	1952	MC2R	Approved (sNDA): ACTH
Palatin Technology	1986	MC1R	Approved: HSDD
Rhythm Pharma	2008	MC4R	Approved: obesity/BBS
CLINUVEL	**1987**	**MC1R, MC3R, MC4R**	**Approved: afamelanotide** **In dev: ACTH, small molecule**

BBS: Bardet-Biedl syndrome | HSDD: hypoactive sexual desire disorder | ACTH: adrenocorticotropic hormone | * Year of initial development

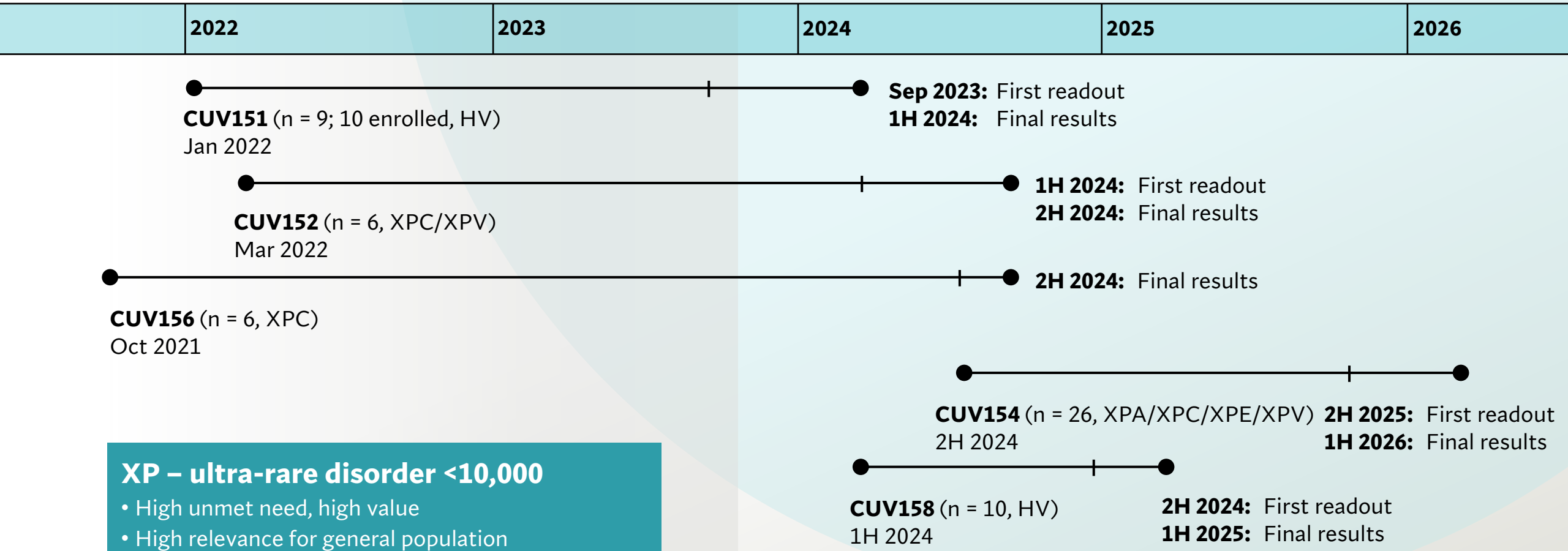
Clinical programs

Pharmaceutical pipeline



XP; xeroderma pigmentosum | IS; infantile spasms | MS; multiple sclerosis | CNS; central nervous system.

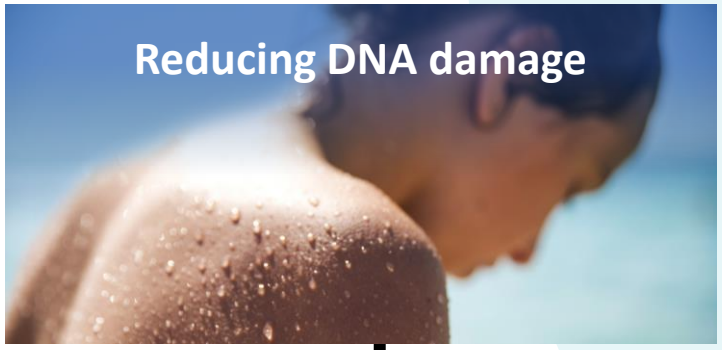
XP trials – clinical timelines



XP – ultra-rare disorder <10,000

- High unmet need, high value
- High relevance for general population

Evaluating XP – DNA Repair – clinical endpoints



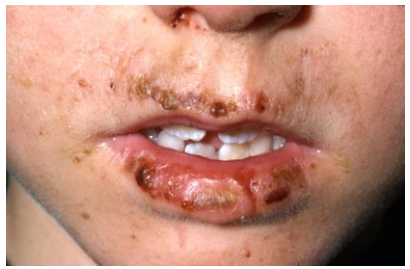
		CUV156	CUV151
DNA repair markers	• Photoproducts (CPDs) • γ-H2AX • P53	- reduction - increase - variable, increase	- reduction at 15 mins (p=0.0039) - pending - pending
Quality of life	Validated questionnaires	pending	
Safety	Treatment-emergent adverse events Clinical & laboratory evaluations	safety profile maintained	
Erythema response **Severity** **Melanin density**	Minimal Erythemal Dose (MED) Patient & physician assessments Spectrophotometry	- variable - pending - increase	- reduction (p=0.018) - increase (p<0.05)

Total addressable market: <US$100m

Europe | USA | Africa | Middle East | S&C America

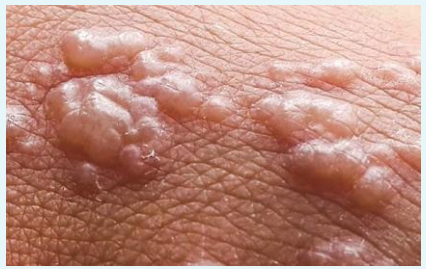
~1,300 XP patients worldwide

Cutaneous porphyrias



Erythropoietic protoporphyria

- Expansion for adolescent patients
- Single dose study CUV052
- Expansion population ~21%



Variegate porphyria

- CUV040 study ongoing
- Regulatory assessment – SCENESSE® label

Total addressable market: US$300m

2023

CUV040 VP (n = 6)
Jan 2022

2024

1H 2024: Final results

EMA guidance adolescent EPP
1H 2024

CUV052 (adolescent EPP n = 12)
Start 1H 2024

2H 2024: First readout

Health Canada submission EPP
1H 2024, decision timelines determined by regulator

2026

Regulatory filings	EPP, VP
Specialty Network	120 USA
Payor engagement	EU-USA
Paediatric dose	EU-USA

Arterial Ischaemic Stroke

Targeted product position

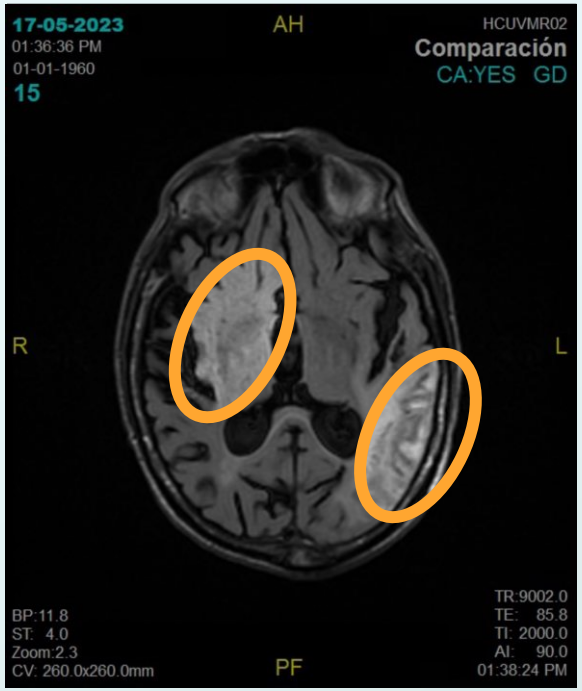
A hormonal treatment to assist hypoxic brain

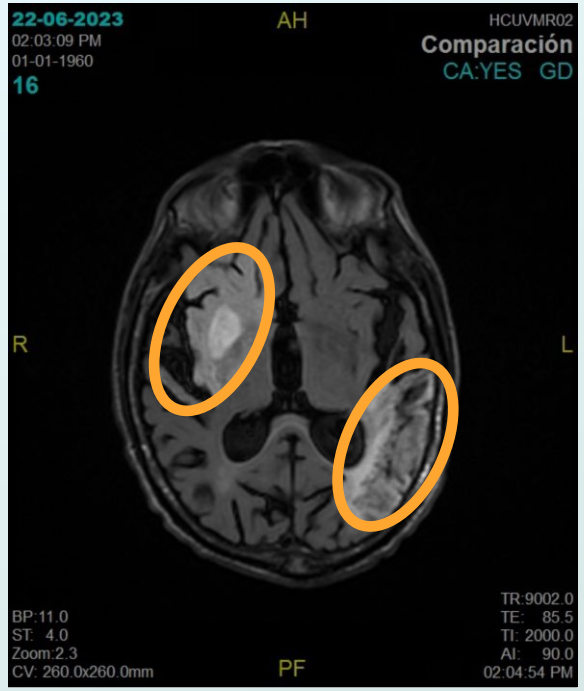
Study CUV801 (n = 6) proof of concept – afamelanotide

- open-label, up to 4 doses: days 0, 1, 7, 8; evaluation at day 42
- occlusion higher regions: > M1
- functional recovery in 5 patients; NIHSS ≥ 4 (4/6)
- cerebral perfusion improved per MRI-FLAIR (CBF, Tmax)

Study CUV803 (n = 12) first patient treated March 2023

- moderate & severe patients
- occlusion higher regions: > M2/A2/P2
- higher, more frequent dosing, PRÉNUMBRA®
- safety
- neurological functionality (NIHSS)
- perfusion of penumbra, oligemic zone





Total addressable market: US$31B
Penetration US$1.98-2.23B
- USA + EU + AU

NIHSS: National Institutes of Health Stroke Scale | CBF: cerebral blood flow

Vitiligo – global Phase III study (CUV105)

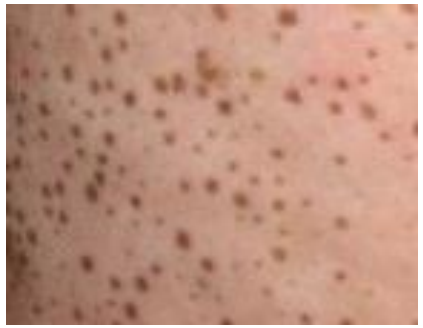
	CLINUVEL CUV105 Phase III	Pfizer pivotal Phase III oral JAK inhibitor*
Study population	N=200, adults and adolescents (≥12 years) highest unmet need: darker skin (Fitzpatrick IV-VI)	
Inclusion	≥0.3% body surface area with facial vitiligo: T-VASI ≥0.3 & F-VASI ≥0.3	
Primary endpoint	rate of repigmentation of total body surface (T-VASI50)	proportion of participants achieving F-VASI75
Secondary endpoint/s	evaluate repigmentation of the face, maintenance of repigmentation	proportion of participants achieving T-VASI50
Randomisation	1:1 to SCENESSE® + NB-UVB vs NB-UVB monotherapy	
Treatment duration	20-week treatment phase, six-month follow up	
Sites	expert treatment centres globally	
Status	12-month recruitment (to October 2024)	

"Once on the market, SCENESSE® will clinically become the pigment booster"

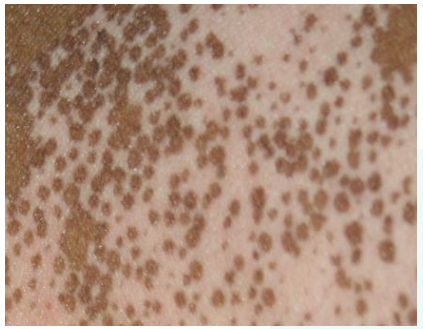
Vitiligo Expert Panel member

* Source: ClinicalTrials.gov

Vitiligo – path to market



NB-UVB treatment



NB-UVB + afamelanotide

CUV102
+NB-UVB n = 56

CUV103
+NB-UVB n = 21

CUV104
monotherapy n = 6

CUV105 2023
+NB-UVB n = 200

CUV107 2024
+NB-UVB n = 200

FDA submission[1] 2026

Step 1 **>15,200 doses afamelanotide administered[2]**
- Safety profile accepted

Step 2 **NB-UVB combination**
- program planning resulted in savings $75 – 145M

Step 3 **2022** **FDA – precedent for NB-UVB as combination therapy**

Step 4 **2022** **Insurers providing reimbursement codes**

Step 5 **Project finance - clinical trials A$77m**

Step 6 **2023** **Vitiligo Expert Panel**

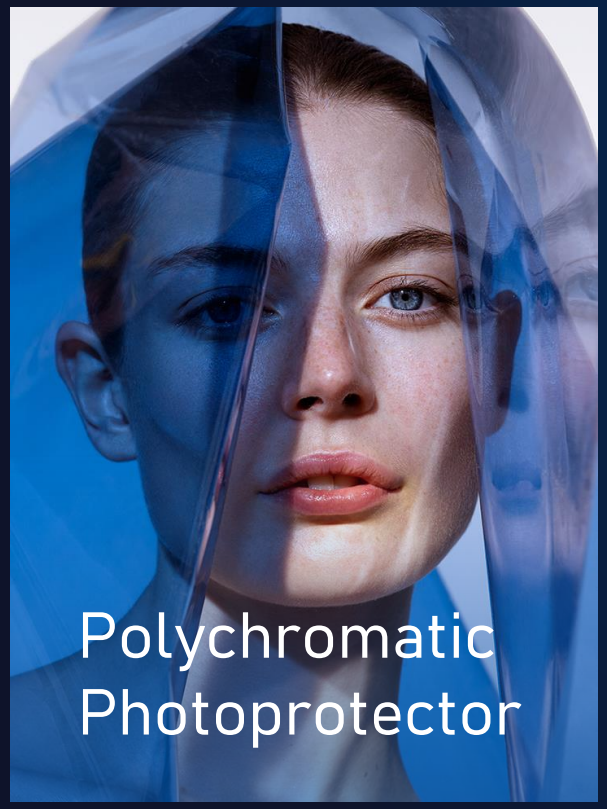
Step 7 **Train & accredit 120 US centres pre-marketing**

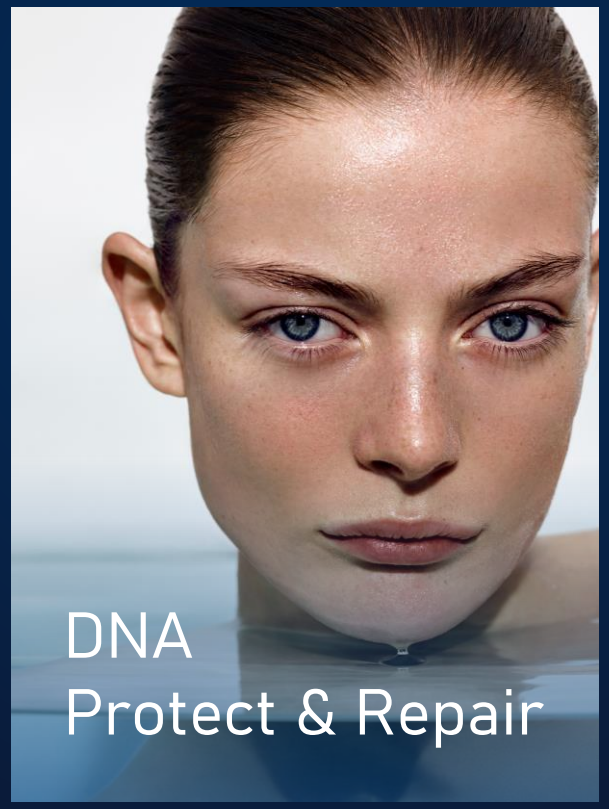
Total addressable market NAM: US$490-570m
- Penetration 9% TAM, yr 1-2

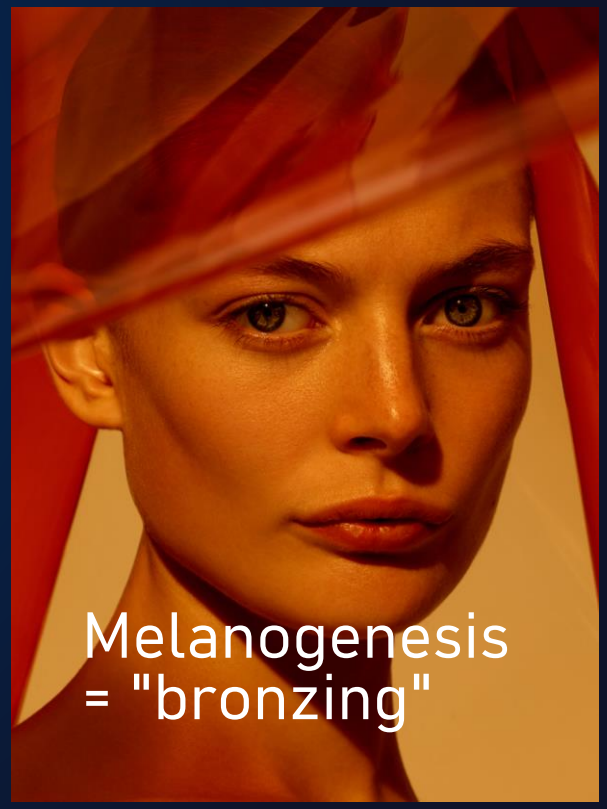
[1] Regulatory timelines are dictating timings and progress of filings | [2] All indications | Clinical images courtesy of CUV102 investigators

Targeted Technology Translation

PhotoCosmetics

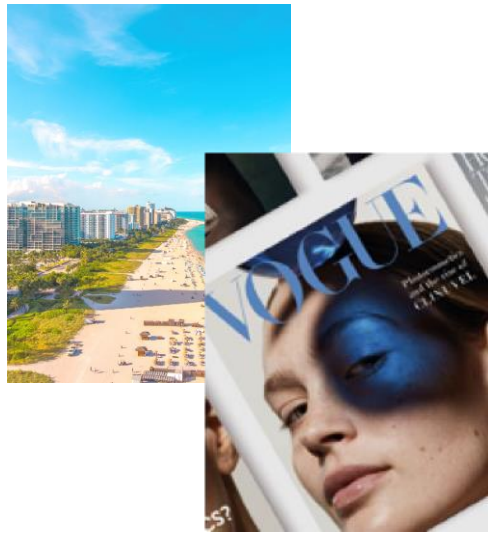






PhotoCosmetics

CYACÊLLE
Polychromatic screen



CYACÊLLE
Radiant

Identity & visibility
- architecture
- launch events 2024-25-26

Advocacy
- CUVA (60)
- CUVIP (10)
- social media

Digital Campaigns
- multi-channel
- new digital platform
- cost of customer acquisition
- click through rate (target 3.2%)
- conversion rate (1.8-2.3%)

Distribution
- medical
- e-commerce
- high-end retail

Total addressable market (sunless tanning)
US$6.2B
Penetration yr 1-5: 1% = US$60M

Investor Relations & Finance

Investor Relations Activities

INVESTOR RELATIONS TEAM

1 Australia | 1 Europe | 1 US (pending) | 1 Consultant | 2 External Partners

1 **NDRs by Banks and Brokers**

2 **Institution and Analyst Meetings**

3 **CLINUVEL Events**

Summary of activities			
	FY22	FY23	FY24
Roadshows & conferences	13	9	13
Institutional & analyst contacts	131	183	+300
CLINUVEL events	6	10	10
Newsletters, Strategic updates, CEO & Chair letters	13	12	13

Analyst coverage initiated

Registry 2023

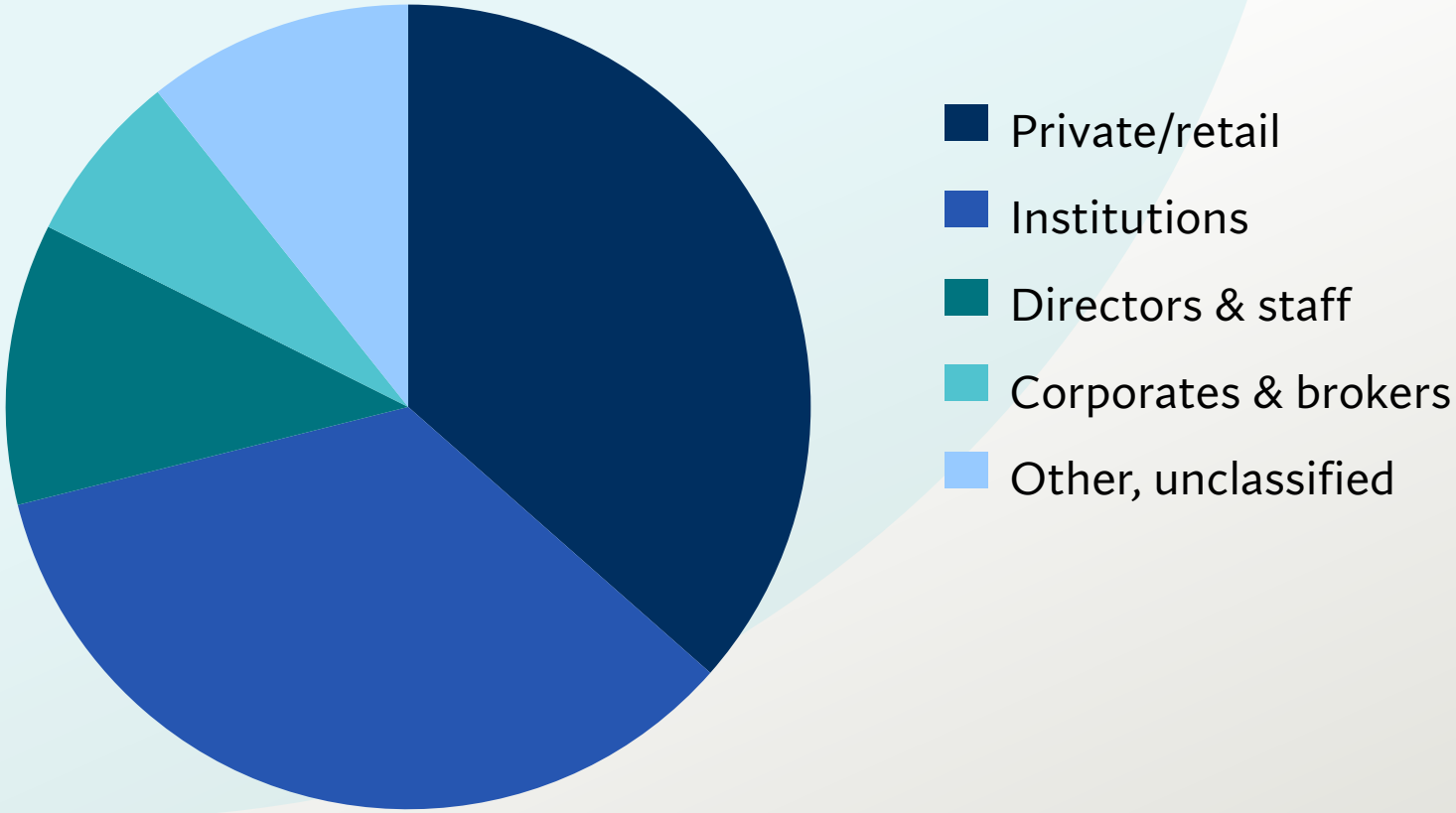
Australia and New Zealand Institutions

September 2023

- 30 total ANZ institutions
- 14.2% of issued capital

CLINUVEL Shareholders by Type

% of Issued Capital, September 2023



Finance

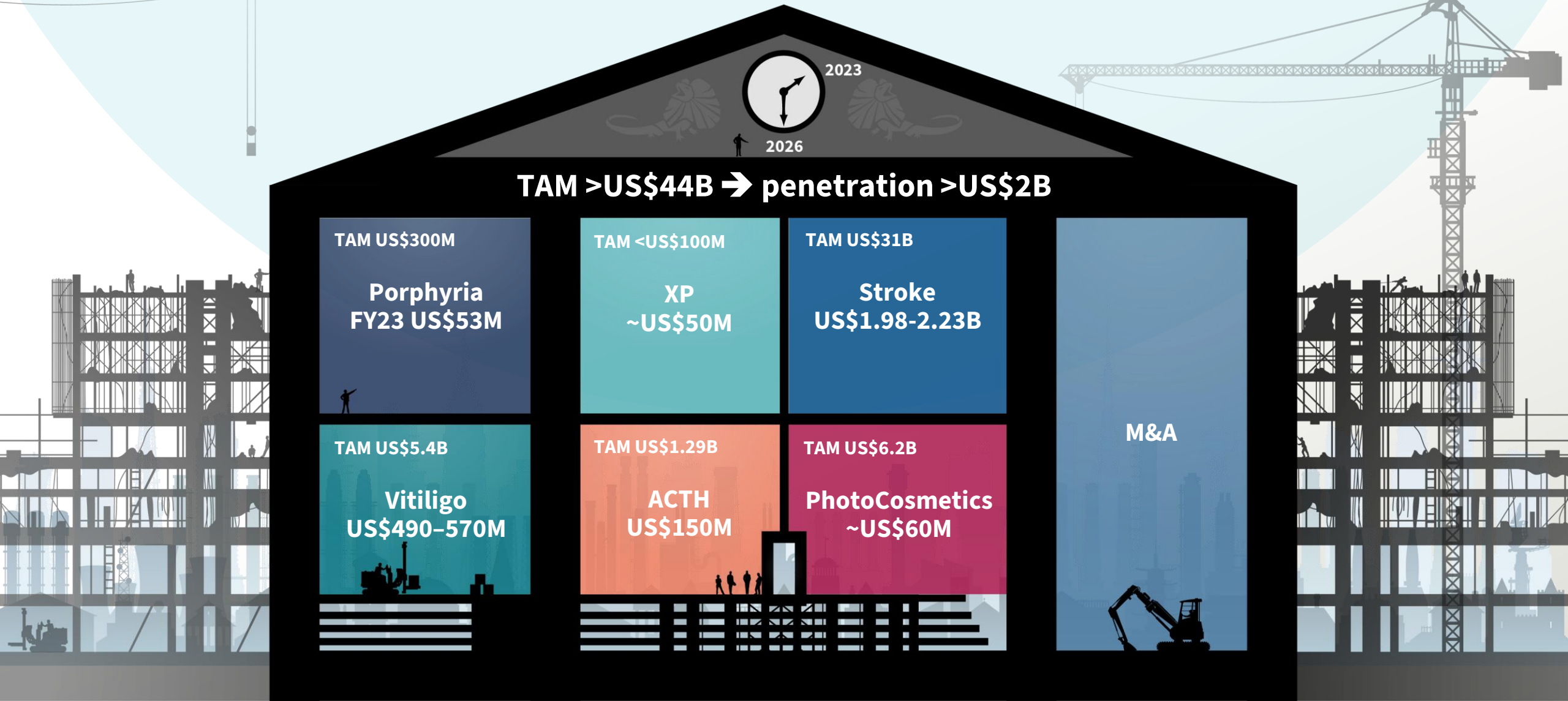
Code	Company	Mkt Cap (A$m)	FY24e EV/EBITDA	FY24e P/E
AUS Established Med Tech Companies*				
ASX:CSL	CSL Limited	$113,080.6	16.4x	24.2x
ASX:RMD	ResMed Inc.	$31,170.6	14.1x	18.8x
ASX:COH	Cochlear Limited	$15,887.4	27.1x	43.2x
	Average		**19.2x**	**28.7x**
	Median		**16.4x**	**24.2x**

Code	Company	Mkt Cap (A$m)	FY24e EV/EBITDA	FY24e P/E
US Profitable Biopharma Companies - Directly Commercialising Novel Drugs in US/EU*				
NASDAQ: AMGN	Amgen Inc.	$220,196.8	9.2x	13.2x
NASDAQ: BIIB	Biogen Inc.	$53,452.5	9.3x	14.5x
NASDAQ: REGN	Regeneron Pharmaceuticals, Inc.	$129,267.3	12.2x	16.3x
NASDAQ: INCY	Incyte Corporation	$18,529.2	6.9x	11.1x
NASDAQ: JAZZ	Jazz Pharmaceuticals plc	$12,526.5	6.1x	5.5x
NYSE: ABBV	AbbVie Inc.	$385,924.0	11.5x	12.6x
NASDAQ: AZN	AstraZeneca PLC	$300,041.2	11.7x	14.5x
NYSE: BMY	Bristol-Myers Squibb Company	$163,381.4	7.0x	6.9x
NASDAQ: GILD	Gilead Sciences, Inc.	$150,250.1	7.8x	10.5x
NYSE: NVS	Novartis AG	$300,212.6	10.7x	13.4x
NYSE: PFE	Pfizer Inc.	$267,545.8	8.3x	9.4x
	Average		**9.2x**	**11.6x**
	Median		**9.2x**	**12.6x**
ASX:CUV	**Clinuvel Pharmaceuticals Limited**	**$756.5**	**12.7x**	**21.2x**

* Company data from Bell Potter Equity Markets

CLINUVEL in 2026

Total addressable markets



Conclusions

Catalysts next 12 months	**16**
Prudent fiscal management	**CAGR 30%, net assets 31%, cash A$156.8 (FYE ‘23)**
Australian institutions	**14%**
Pharma + PhotoCosmetic	**Pipeline, commercial launches 2024-25-26**
Analyst coverage	**Independent reports published**
TAM	**>US$2B**

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

Head of Investor Relations
Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD
https://www.clinuvel.com/investors/contact-us

www.clinuvel.com
Level 11, 535 Bourke Street
Melbourne - Victoria, Australia, 3000
T +61 3 9660 4900 F +61 3 9660 4909