

CLINUVEL

Annual General Meeting

16 October 2024

ASX: CUV | **Börse Frankfurt:** UR9 | **ADR Level 1:** CLVLY

Forward-looking statement

CLINUVEL GROUP

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 2024 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.

CLINUVEL




Commoditising melanocortins



A PATIENT CENTRIC APPROACH

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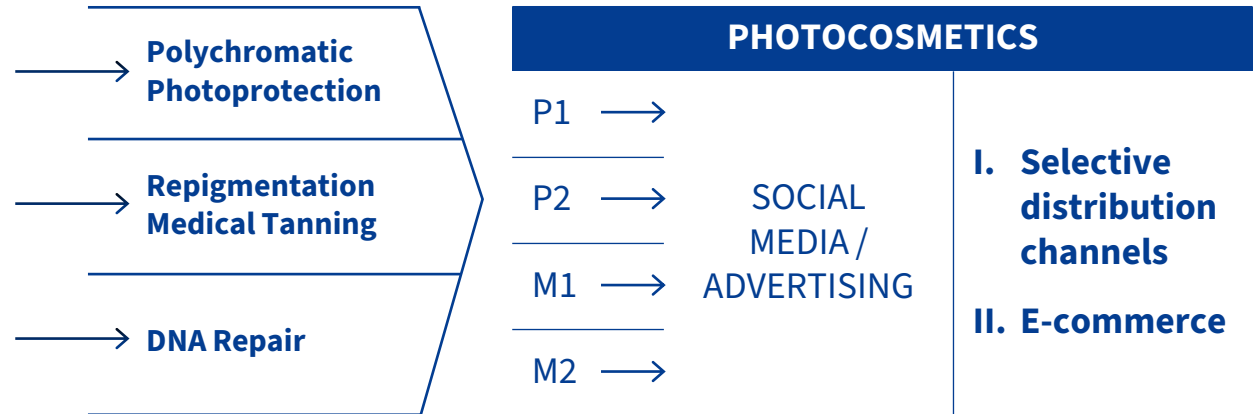
Melanocortin House

Rx Pharmaceutical Markets

			p^*
 SCENESSE® 0.5 mm 17 mm	EPP / VP	CUV network	N-AM 100%
			EEA 100%
	Vitiligo	CUV network	N-AM 60-70%
			EEA 60-70%
	XP	CUV network	N-AM 50%
			EEA 50%
			ME-AF 50%

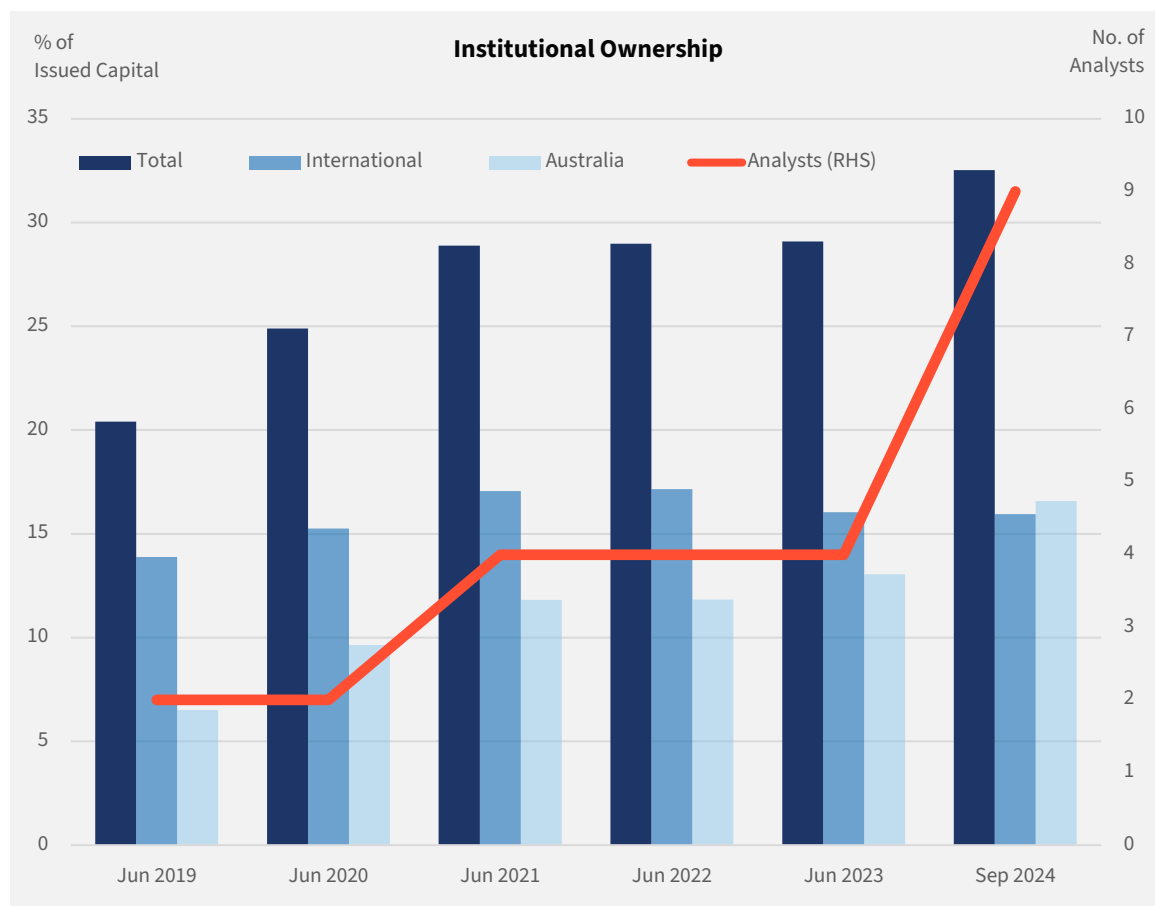
 NEURACTHEL®	MS/IS	Pharmacy	N-AM 60-70%
			EEA 60-70%
 PRÉNUMBRA®	Stroke (AIS)	Pharmacy	N-AM 30%
			EEA 30%
	Parkinson's Disease	Pharmacy	N-AM 20%
			EEA 20%

Specialised Skin Care



CLINUVEL develops and realises “controversial scientific concepts” while protecting against funding risk.

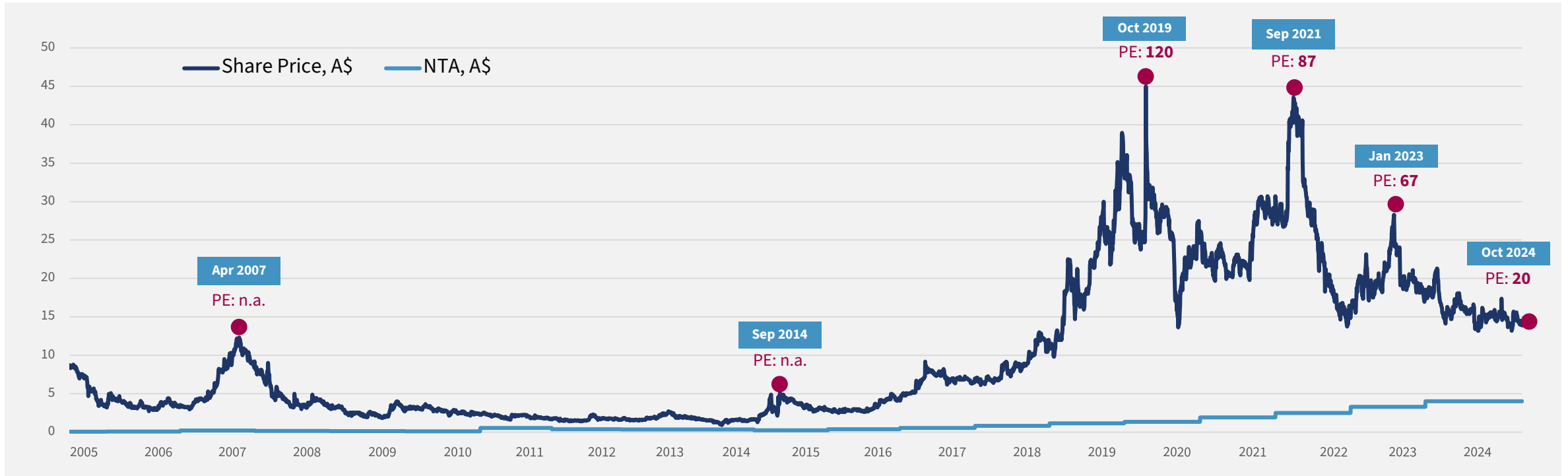
CLINUVEL's Institutional Ownership



Metric	FY2023 (no.)	FY2024 (no.)
Conferences, webinars, webcasts, investor briefings, non-deal roadshows	18	25
Investors reached through meetings hosted by analysts, one-on-one and group briefings	217	293

		As of Jun 2019	As of Sep 2024	Change
International	% issued capital	13.9	16.0	+2.1
Australia	% issued capital	6.5	16.6	+10.1
Total	% issued capital	20.4	32.6	+12.2

CLINUVEL Share Price vs Fundamentals



Apr 2007	
Cash:	A\$8.6m
Revenues:	A\$1.2m
Earnings:	A\$(10.8)m
Products:	Nil
Pipeline:	Nil

Sep 2014	
Cash:	A\$14.6m
Revenues:	A\$2.5m
Earnings:	A\$(5.5)m
Products:	Nil
Pipeline:	1 + 1

Oct 2019	
Cash:	A\$54.3m
Revenues:	A\$31.0m
Earnings:	A\$18.1m
Products:	1
Pipeline:	1

Sep 2021	
Cash:	A\$82.7m
Revenues:	A\$48m
Earnings:	A\$24.7m
Products:	1
Pipeline:	2

Jan 2023	
Cash:	A\$121.5m
Revenues:	A\$65.7m
Earnings:	A\$20.8m
Products:	1
Pipeline:	3

Oct 2024	
Cash:	A\$183.9m
Revenues:	A\$95.3m
Earnings:	A\$35.9m
Products:	2
Pipeline:	9

Value to Profitability

Listed bio-pharmaceuticals with <\$5b vs >\$5b MCAP

RUSSELL 3000 (n=135) + **NBI** (n=213) + **EU Biopharma** (n=289)

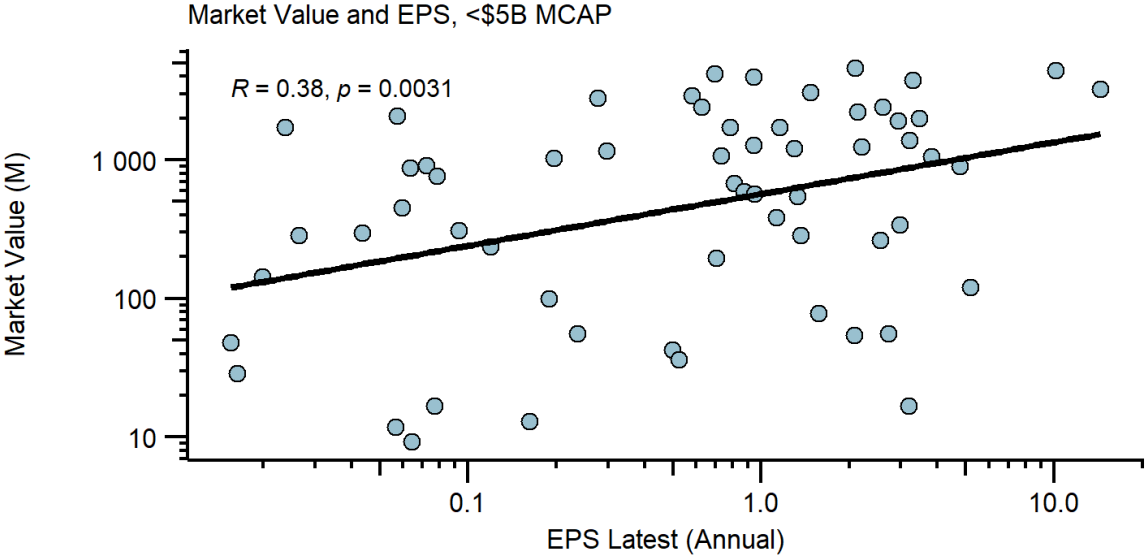
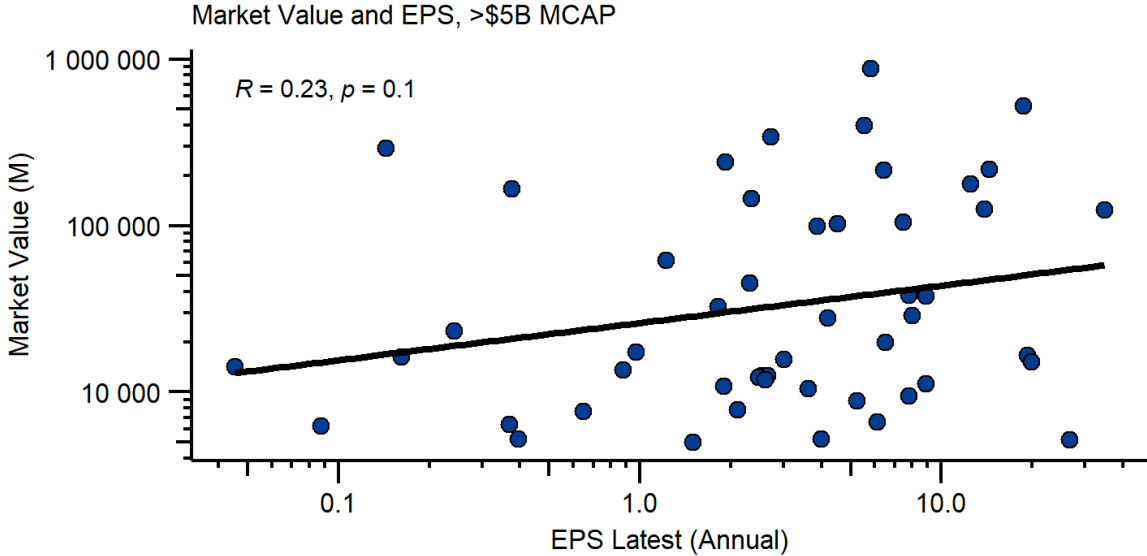
ENTITIES	PROFITABLE	EARNINGS GROWTH 7-yr	CUV BENCHMARKED
> \$5B	50	35	
< \$5B	60	30	✓
< \$1B	34	13	✓
Total	110	65	

Correlation between Market Value and Profitability

Indicates decoupling between Market Value and Profitability

Weak correlation between Market Value and EPS in companies with >\$5B MCAP

Weak correlation between Market Value and EPS in companies with <\$5B MCAP

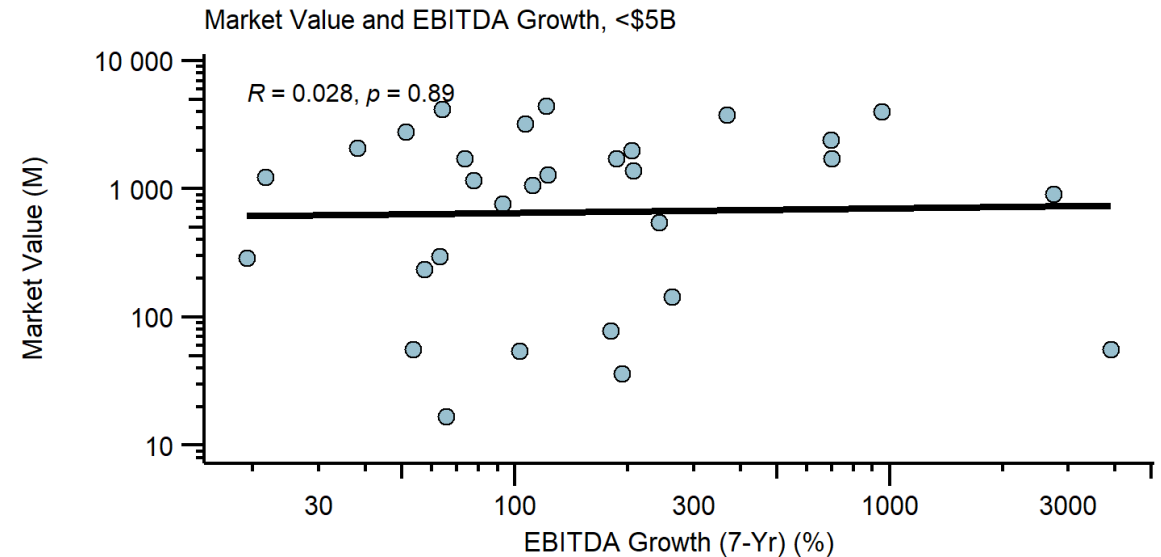
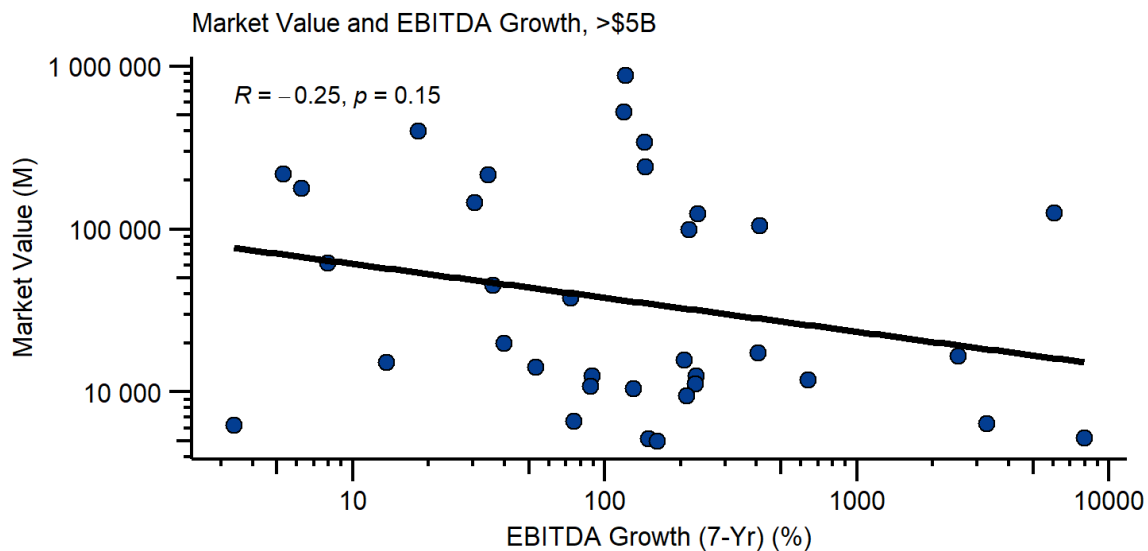


Correlation between Market Value and Earnings Growth over 7 Years

Indicates decoupling between Market Value and Earnings Growth

Weak correlation between Market Value and EBITDA Growth in companies with >\$5B MCAP

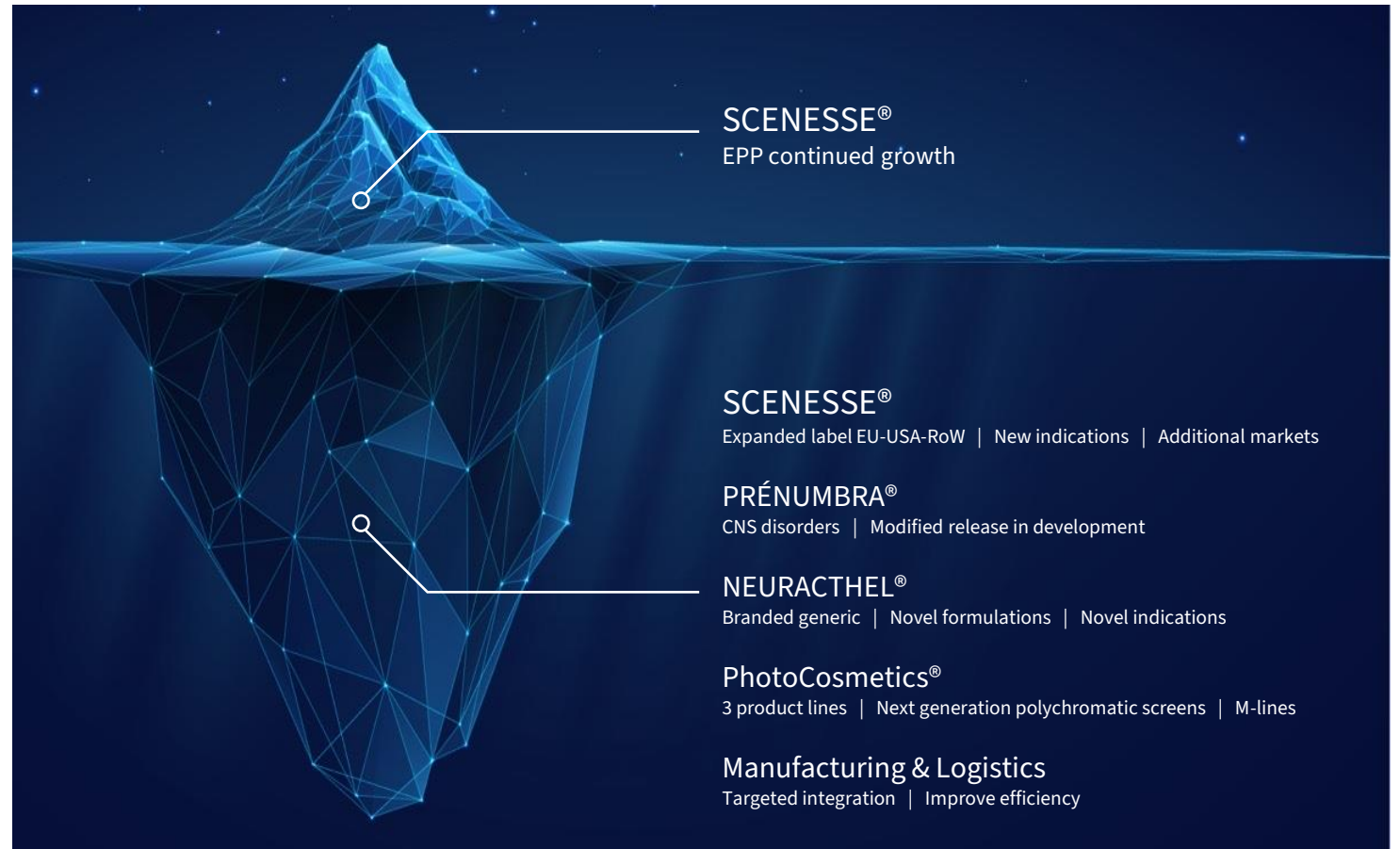
No correlation between Market Value and EBITDA Growth in companies with <\$5B MCAP



Emerging value...

Catalysts 2024–25

- 1 EPP: Complete CUV052, re-engage regulators on adolescent use SCENESSE®*
- 2 VP: regulatory feedback, commence CUV053
- 3 Stroke: CUV803 results*
- 4 Vitiligo: CUV105 recruitment*
- 5 Vitiligo: commence CUV107 study*
- 6 Establish 120 Specialty Centers in North America
- 7 EPP: Health Canada marketing authorisation outcome
- 8 EPP: European Medicines Agency decision on label variation (4-6 implants)
- 9 NEURACTHEL – manufacturing update*
- 10 CYACËLLE next generation range launch, media campaigns
- 11 American Academy of Dermatology Meeting 2025
- 12 Fortifying value chain
- 13 Financial growth Half-Year & Financial Year



VITILIGO IS UNIQUE

...symptomatology is visible...

...the negative is visible...

...treatment effect must provoke a positive...

New Treatment Algorithm Vitiligo

		NB-UVB	Topical	Topical JAK	Oral JAK	SCENESSE®
		LOCALISED ←→			SYSTEMIC	
Segmental	10%					
Generalised	90%	✓	✓	✓	✓	✓
Localisation	Face, Head and Neck Trunk (including genitalia) Limbs Hands and Feet	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓
Skin Type	Fitzpatrick I – White Fitzpatrick II – Fair Fitzpatrick III – Average Fitzpatrick IV – Light Brown Fitzpatrick V – Brown Fitzpatrick VI – Black	✓ ✓ ✓ ✓ ✓ ✓	✓ ✓ ✓ ✓ ✓ ✓	✓ ✓ ✓ ✓ ✓ ✓	✓ ✓ ✓ ✓ ✓ ✓	✓ ✓ ✓ ✓ ✓ ✓
Systemic Disease	Immunocompromised Diabetes Eczema Other	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓
Extent	<10% Face, Head and Neck Trunk (including genitalia) Limbs	✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓
	>10% <50% Face, Head and Neck Trunk (including genitalia) Limbs	✓ ✓ ✓		✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓
	>50% Face, Head and Neck Trunk (including genitalia) Limbs	✓ ✓ ✓		✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓
Psychological Impact	Very High High Moderate Low None				✓ ✓ ✓ ✓	✓ ✓ ✓ ✓



LOCALISED



SYSTEMIC

SCENESSE® for vitiligo patients with highest burden

≥ 10% BSA ✓ | F-H-N-genitals ✓ | darker skin complexion (IV-V-VI) ✓



Commercial Infrastructure I

North America

	ACTUAL	TARGET
Staff	20	27
Distribution Centers	3	2
Shipping	2	3

Commercial Infrastructure II

North America

	ACTUAL	TARGET
Training / Recommended Clinics	85	120
Average Capacity	50%	50%
Patient Fitzpatrick Skin Types	IV-VI	IV-VI

Commercial Infrastructure III

North America

	ACTUAL	TARGET
Medicare	YES	-
Medicaid/340B Program	YES	-
Veterans Administration (VA)	YES	-
Commercial Health Insurers	YES	✓*

*Insurers are familiar with the SCENESSE® implant in dermatology

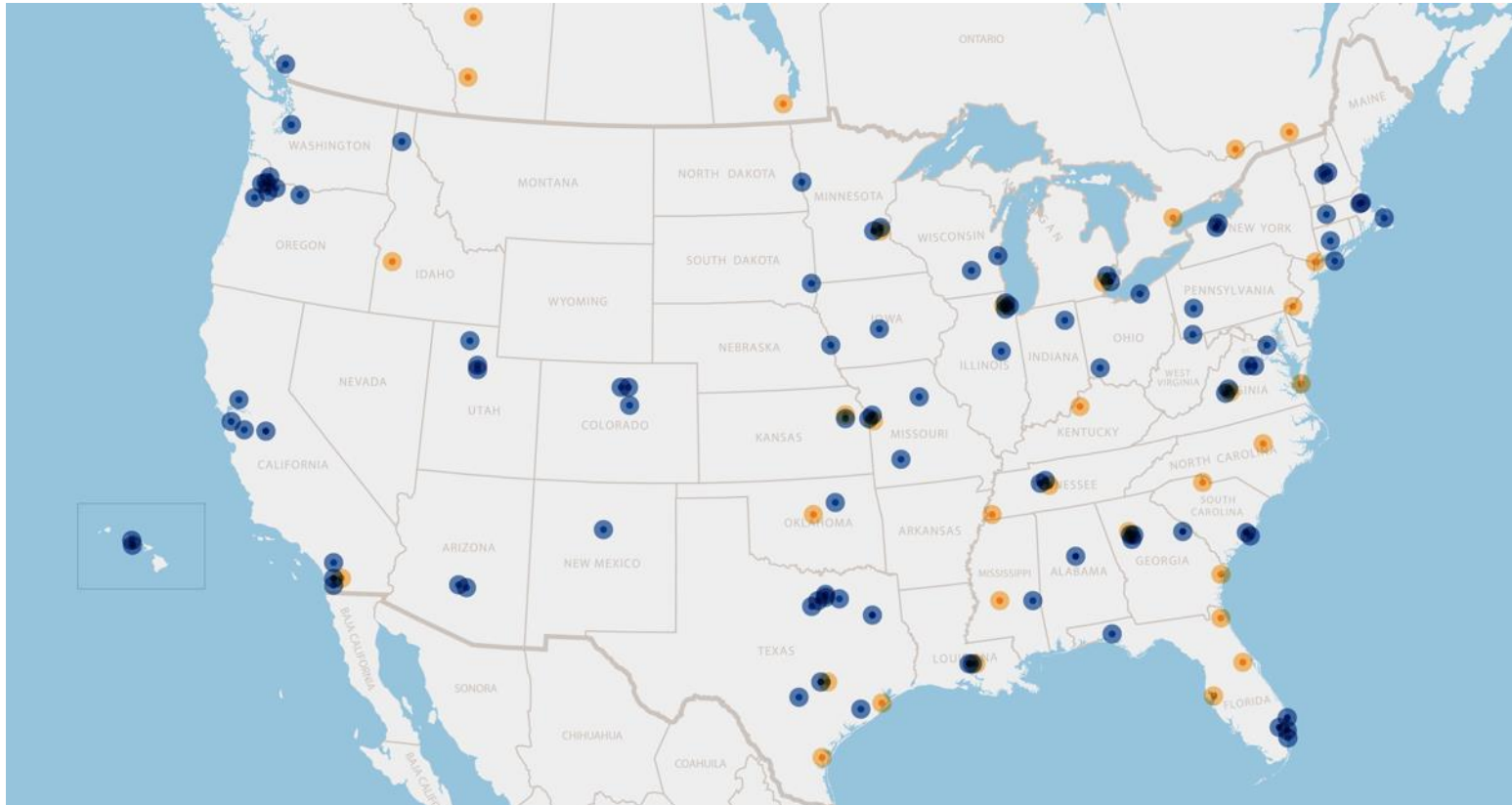
Commercial Infrastructure IV

North America

	ACTUAL	TARGET
J Codes	J7352	✓
CPT® Codes	11981	✓
Prior Authorization	YES	✓

Commercial Infrastructure V

North America – Current Clinics and Targets



71% of target achieved

74% of CUV team established

Treatment codes in place

2025-2026 dermatology campaigns

OBJECTIVE

CLINUVEL to be dominant in North American vitiligo market

CLINICAL EVIDENCE

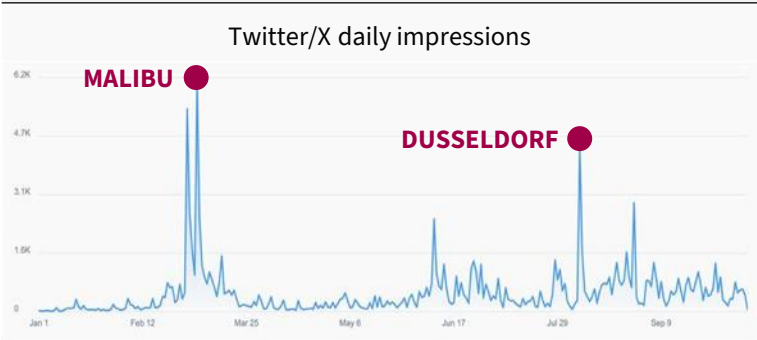
VITILIGO.....*its visible impact is high...*

SCENESSE®.....*its efficacy is highly visible...*

Social media = visibility

January – October 2024

Impressions	75,346,483
Instagram views	51,991,821
Reach	14,132,293
Profile visits	119,000
New followers	1,353



“LADY GAGA EVENT” 2024 MALIBU

Reach	3.5m
Impressions	> 11m
Attendee followers reach	10.6m

PRESS COVERAGE

The Business of Fashion	> 500,000
Hello! Magazine	> 7,000,000
La Maison Gaga	> 15,000,000
Metro	> 18,600,000
r/LadyGaga	> 495,000

INFLUENCERS

(cosmetics/fashion) x 7 > 4.5m

PhotoCosmetics

Acquiring leadership in photomedicine requires maximum visibility
in the largest pharmaceutical markets

AAD 2025 preparation – 20,000 delegates



M-lines disruptive concept



PhotoCosmetics

CLINUVEL as a brand

2024

Q1

2026

Q4

Malibu



Radiant/
E-commerce



DNA
Social Media



Times
Square Film



AAD



Media
Press Event



**LAUNCH
CLINUVEL
PROTECT –**
Polychromatic
Photoprotection
(Monaco
yacht show)



Press event (US)
Ambassador
Campaign



**LAUNCH
CLINUVEL
PRESERVE –**
Assisted
DNA Repair



**LAUNCH
CLINUVEL
BRONZE –**
Melanogenesis



Summer
of CLINUVEL



Focus
on Retail



SUMMARY

Institutional ownership +12.2%

–

Price vs value decoupled in bio-pharmaceuticals <US\$5b

–

13 catalysts 2025 (5/16 carried over from 2024)

–

Vitiligo – commercial preparation N-AM – 75% in place

–

Social media central in building global CLINUVEL brand

–

Financial strength provides optionality for 2025

IN MEMORY OF
Professor Marcus Maurer – Aug'24



“a revolutionary thinker in dermatology, an inspiration and statue of optimism for all who had met Marcus”

CLINUVEL

Thank you

We thank CLINUVEL's long-term supporters,
Board of Directors and most of all, our highly committed staff

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CLINUVEL

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

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