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Growth of a Specialty Pharmaceutical

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Morgans Scone Value in the Vines Conference

November 18th, 2022

Malcolm Bull

Head of Australian Operations and Investor Relations

ASX:	CUV
XETRA-DAX:	UR9
Level 1 ADR:	CLVLY

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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), 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®, 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 2022 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.

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Business Evolution – specialized in melanocortins

Date	Cumulative spend	Key activities	Addressable markets
1980–2005	AUS **$70m**	Invention aimed at lifestyle	US **$5bn**
2006–2016	AUS **$150m**	Restructure | Reformulation | Regulatory approvals | Market entry	
2017–2022	AUS **$320m**	Commercialisation | Profitability | Liquidity ratio ↑	US **$300m**
2023–2024	AUS **$495m**	Expansion | Scalability | **Targeted Technology Translation**	US **$12bn**

Core pharmaceutical business – 3 drugs

PHOTOMEDICINE
SCENESSE® – **EPP | vitiligo | XP**

PRÉNUMBRA® – Stroke | Vascular disorders

NEURACTHEL® – Infantile spasms | Relapsing multiple sclerosis

Consumer healthcare – 4 products

Highest risk skin cancer

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EPP Commercial Market

Safety – pharmacovigilance

- > 12,000 injections
- 1,300 patients
- Controlled distribution > 90 hospitals/clinics

Uniform pricing policy per jurisdiction

- Equitability, transparency to insurers
- No rebates, no discounts
- Disintermediation

45.5% CAGR revenue (6y 30 Jun 2022)

Integrated business

- Established inhouse specialty
- Market access, pricing – EU-CH-IL-US
- Pharmacovigilance – Longitudinal follow up

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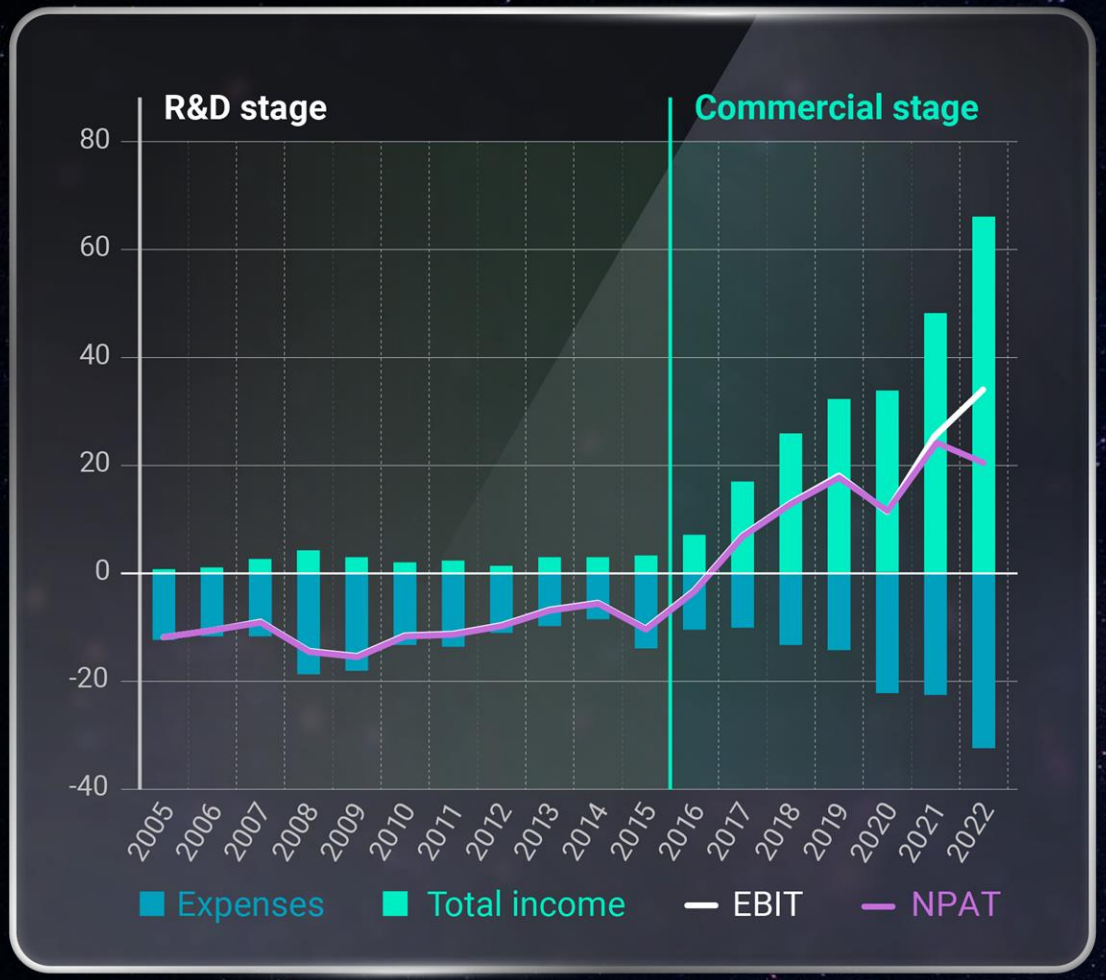
Financials 2005 – 2022



FY'22 dividend	**10% of net profit**
<300% dilution	17 y
ROCE 27%	(6y)
Cash reserves	AUS **$137.6m** (30 Sept '22)
Expenses	AUS **$55.5m** (FY '21-22)
	AUS **$175m** (FY '21-25)

Exchange	Bio-pharmaceuticals	Profitability
Nasdaq, Main Board	798	67 (8.4%)
Nasdaq, NBI	274	25 (9.1%)
ASX	91	3 (3.2%)

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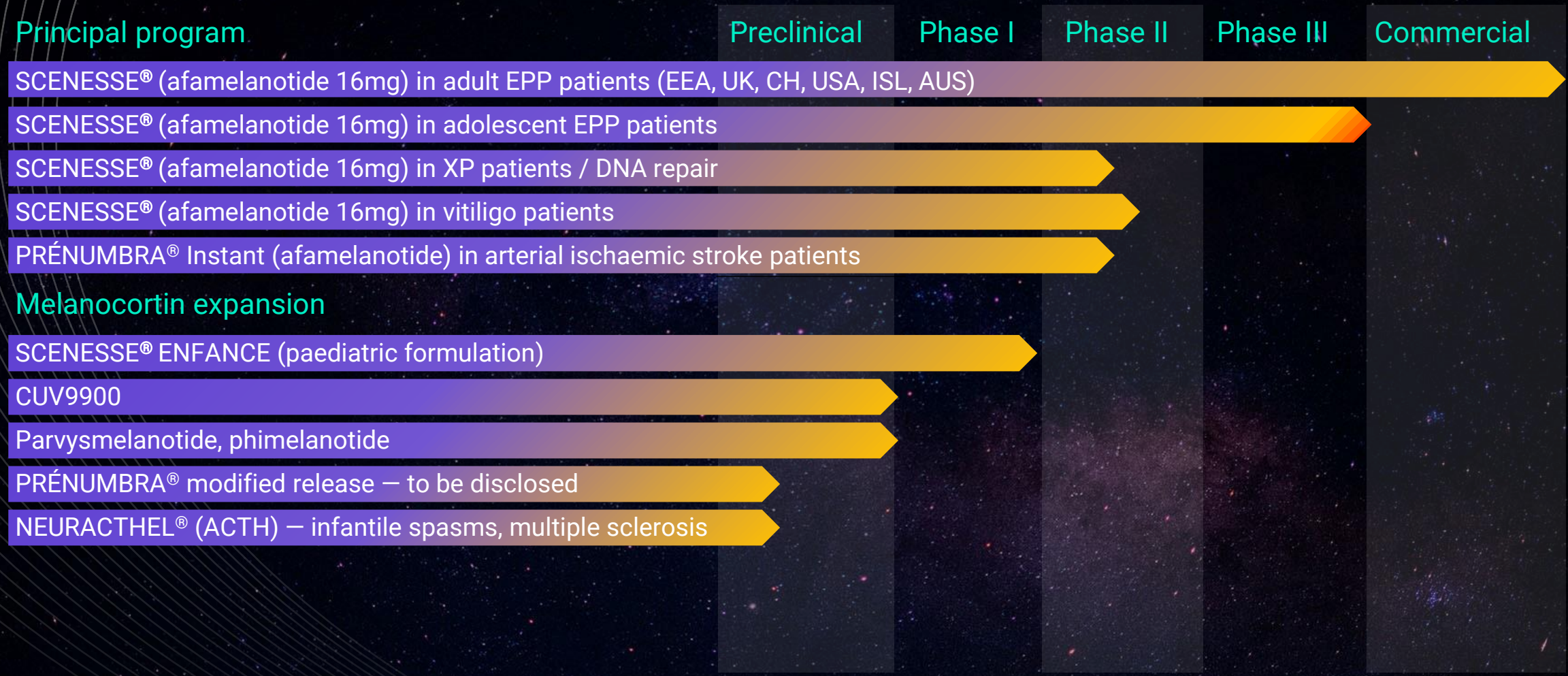
Pipeline - melanocortins



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Arterial Ischaemic Stroke

Targeted product position

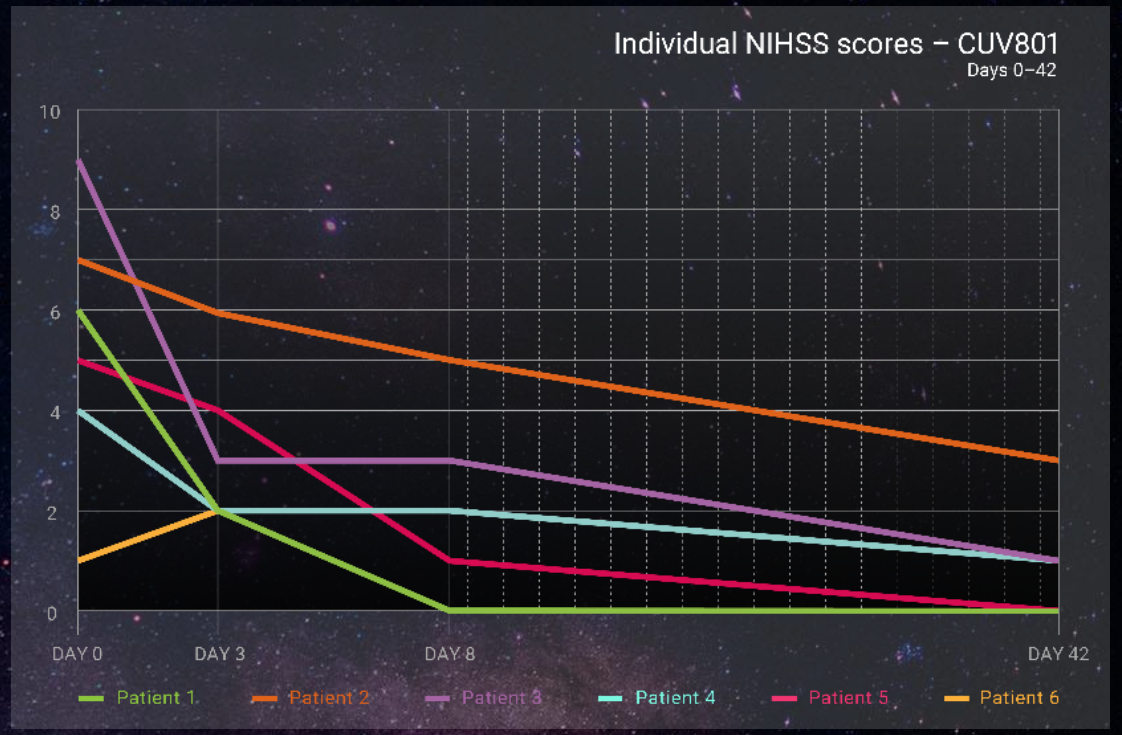
A hormonal treatment to assist hypoxic brain.

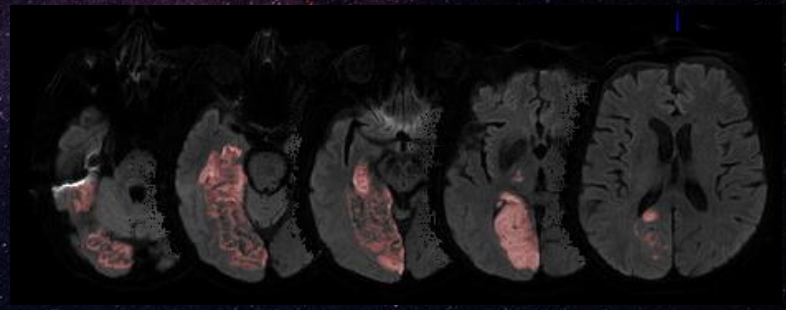
Study CUV801 (n=6): Proof of Concept - afamelanotide

- open-label, up to 4 doses: days 0, 1, 7, 8; evaluation at day 42
- occlusion higher regions: > M2/A2/P2
- functional recovery in 5 patients; NIHSS ≥4 (4/6)
- cerebral perfusion improved per MRI-FLAIR (CBF, Tmax)

Study CUV803 (n=12): planned 2H 2022 - afamelanotide

- occlusion higher regions: > M2/A2/P2
- higher, more frequent dosing of afamelanotide
- safety
- neurological functions (NIHSS)
- perfusion of penumbra, oligemic zone





MRI-FLAIR: changes in affected areas in CUV801 study.

Image courtesy of the study investigator.

Xeroderma Pigmentosum (XP)

Clinical Program – DNA Repair

CUV156 XP-C n=6	**CUV151** Disease-free subjects n=10
CUV152 XP-V, XP-C n=6	**CUV153** XP-V, XP-C n=6
CUV154 XP-V, XP-C n=20	

Clinical Profile

- Gene defects: 3p25, 6p21
- Highest rate of skin cancer(s) – short life expectancy

Addressable Market

- 1,000 EU/US/LATAM/MENA patients

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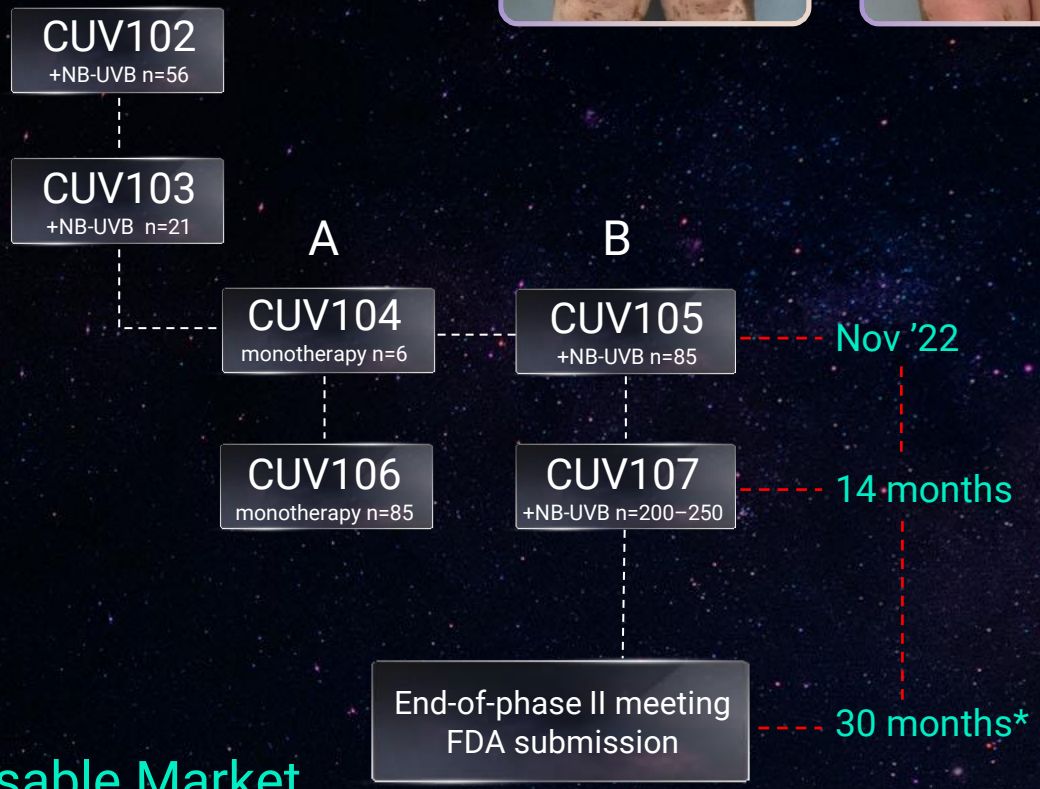
Vitiligo

Clinical Program



Addressable Market

- US$490-570m

2022: >12,700 doses FDA accepts safety profile afamelanotide

FDA set precedent for NB-UVB as combination therapy

First topical treatment approved

SCENESSE® first systemic treatment

➢ Non immunogenic

Regulatory pathways are either A+B or B

1. A+B: projected expenditures $96m
2. B: projected expenditures $77m

Healthcare Solutions

1. Targeted Technology Translation

   Pharmaceuticals to Healthcare Solutions

2. Melanocortins

   Use in non-prescription products

3. Populations at Highest Risk of Exposure to UV/HEV λ

   3 unaddressed categories

4. Dermatocosmetic Product Portfolio

5. Targeted Digital Marketing

   Social media through CUVAs and CUVIPs

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Summary

	Pharmaceuticals	Catalysts 2022-23
	I. SCENESSE®	Commercial distribution in EPP: US-EU-CH-IL Expansion to adolescents
	II. PRÉNUMBRA®	First use in Stroke trial
	III. NEURACTHEL®	in manufacturing: 2023
1	Stroke – reduction in penumbra, NIHSS	1 trial
2	Xeroderma pigmentosum – assisted DNA repair	3 trials, read-outs 2022-2023
3	Vitiligo - afamelanotide monotherapy + combination therapy	2 trials: 2022-2023
	Healthcare Solutions	
	R&D: 4 OTC product lines	Launch CYACÊLLE 1st March '23 (1st product)
	Communications Program	
1	IR, traditional roadshows, conferences	6 – 8 news cycles p.a., multiple conferences
2	Targeted events	global events, soirées family offices
3	CBM team established	social media – CUVA / CUVIP programs
	Finance	
	Stability, counter cyclical buffer	Growth with financial discipline

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

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