

CLINUVEL

STRONG PERFORMANCE UNDERPINS EXPANSION STRATEGY

Financial Year Ended 30 June 2024

Investor Briefing : 29 August 2024

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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.

FY2024: Strong Financial Results

Consolidated Entity	30 June 2024	Change
Total Revenues, Interest and Other Income, \$m	95.306	up 15%
Total Expenses, \$m	44.627	up 19%
Net Profit Before Income Tax, \$m	50.679	up 11%
Net Profit After Income Tax Expense, \$m	35.636	up 16%
Cash Reserves, \$m	183.868	up 17%
Basic Earnings per Share, \$	0.72	up 15%
Net Tangible Assets Backing per Share, \$	4.02	up 22%
Dividend per Share Declared, \$	0.05	Steady

- Increase in revenues, net profit, cash
 - growth EPP market EU & US
 - controlled fixed costs
- 8th consecutive annual profit
- 7th consecutive annual dividend
 - fully franked for 3rd consecutive year
 - A\$0.05 per ordinary share
 - To be paid September 2024

Expansion Strategy

Since FY2021, diversification for long-term sustainability

Integration of key functions 'in-house'

Distribution SCENESSE®

Focus on increasing,
prescribers, treatment centres, patients

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New jurisdictions

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Adolescents (12-17 years)

Melanocortin product development, clinical studies

SCENESSE®, PRÉNUMBRA®, NEURACTHEL®

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CLINICAL STUDIES

1. DNA Repair-xeroderma pigmentosum
2. variegate porphyria
3. arterial ischaemic stroke
4. vitiligo
5. Parkinson's disease

Technology translation to PhotoCosmetic products

1. Polychromatic screen
CYACÊLLE &
CYACÊLLE Radiant

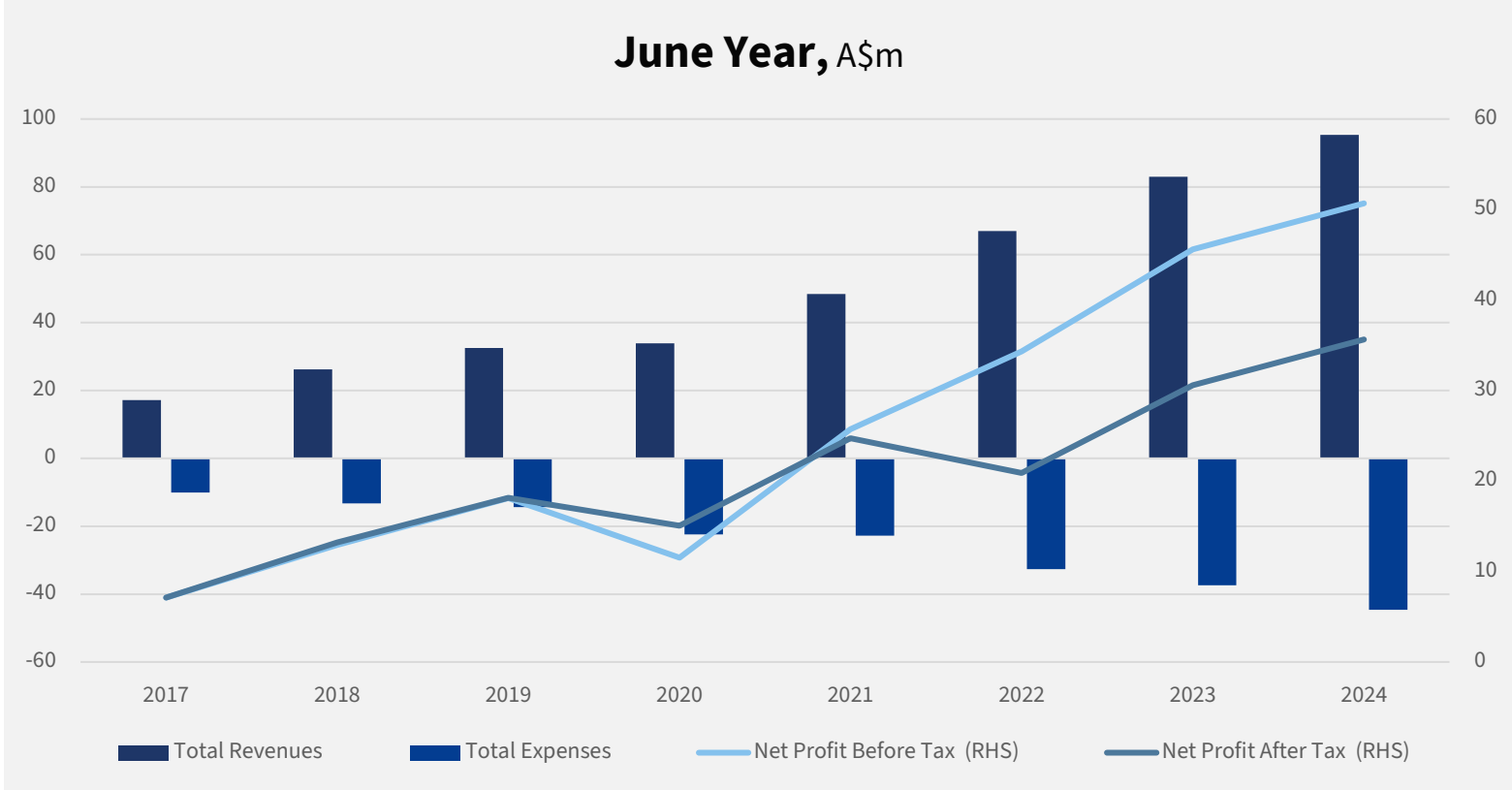
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2. DNA Repair – M1 range

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3. Melanogenesis – M2 range

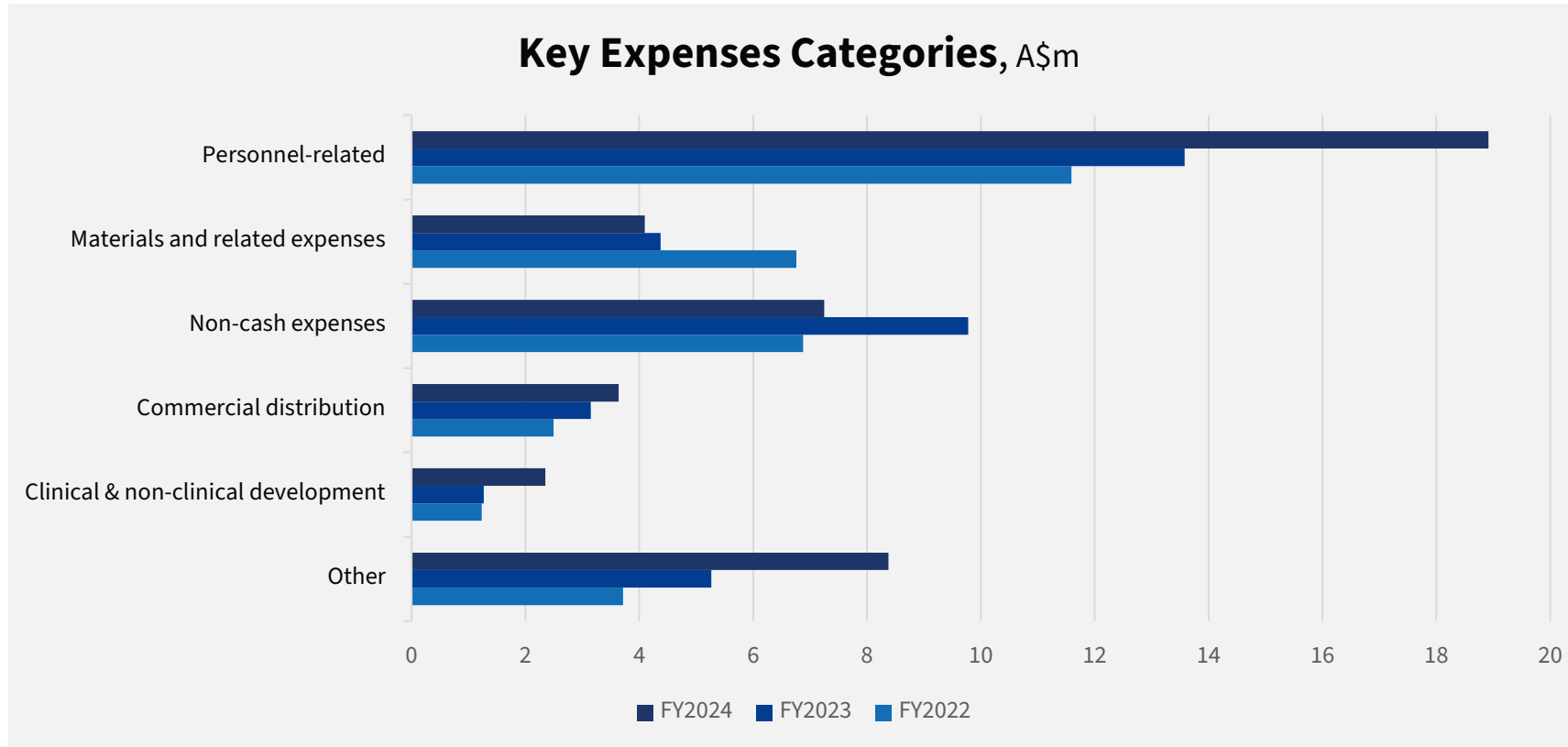
Long-term Profitability



- 8 years consecutive annual growth in revenues (CAGR 38%)
- Controlling fixed costs supports expansion initiatives (CAGR 20%)
- YoY growth EBIT, NPAT
- Debt to Equity Ratio: 14%
- Return on Equity: 18%

Total Revenues include interest and other income.

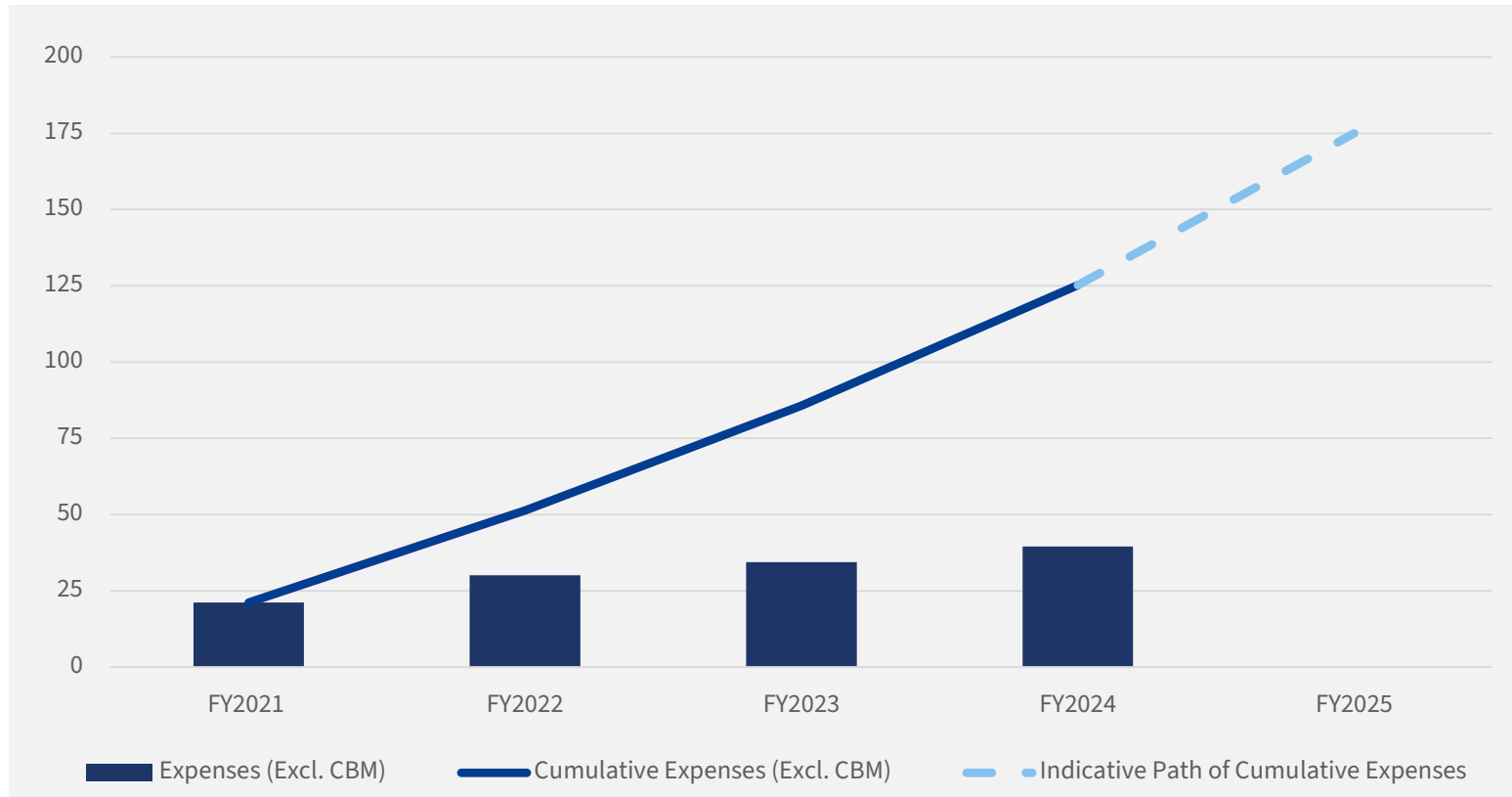
Analyses of Expenses FY22-23-24



- total increase OPEX 19%
- personnel-related increase integrating key functions in-house
- materials and related expenses offset by changes in inventories
- lower non-cash expenses due to reduction share-based payments to staff

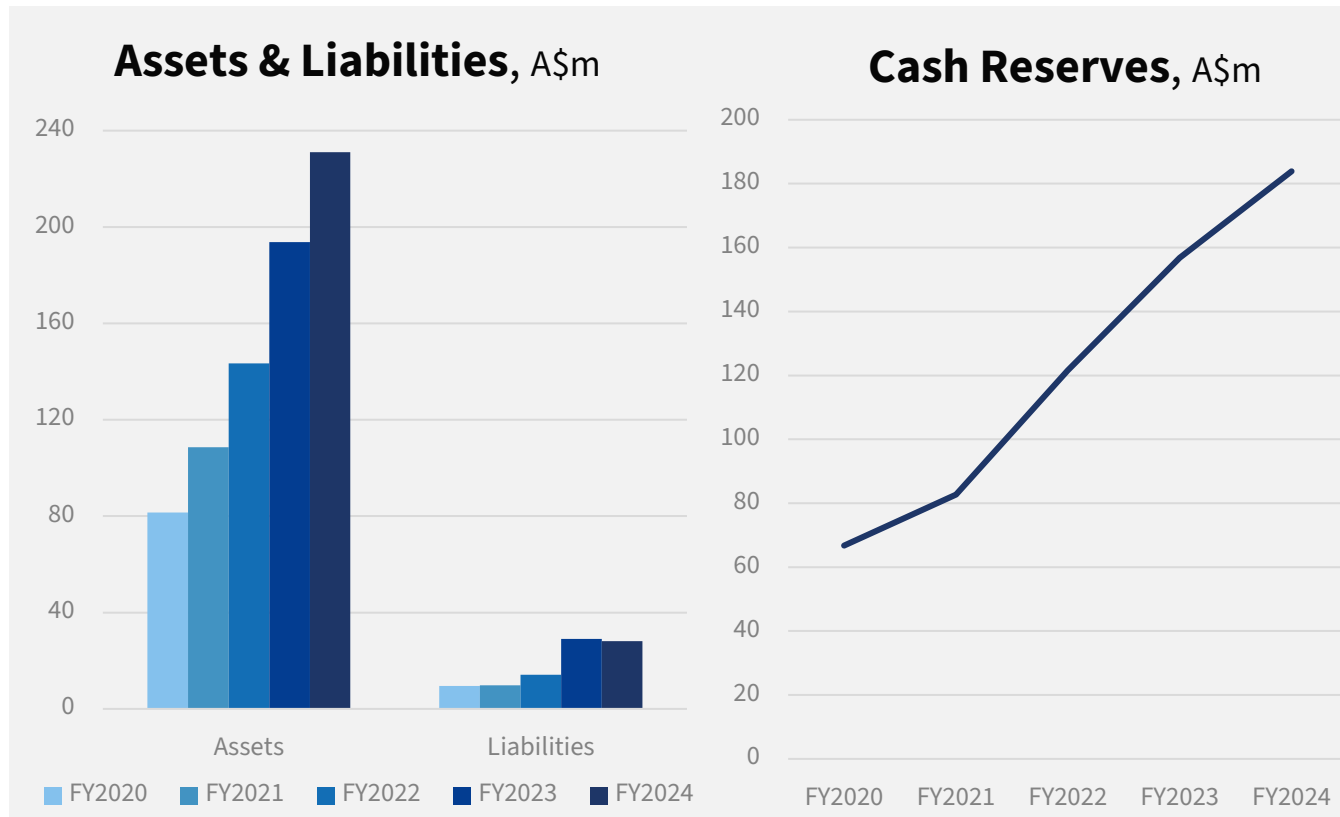
Expenses Plan

5-Years to 30 June 2025 (A\$175.0m forecast)



- controlled increase in expenses to support growth
- 4 years cumulative expenses, excluding CBM expenses, = 72% of five-year plan achieved = A\$125.2 m spent to 30 June '24
- new 3-year expenses plan to be announced in December '24

Strong Balance Sheet



On 30 June	2023	2024
Total Assets	\$193.7m	\$231.1m (+19%)
Total Liabilities	\$29.1m	\$28.1m (-3%)
		<ul style="list-style-type: none"> • trade creditors, suppliers • debt-free
Cash Reserves	\$156.8m	\$183.9m (+17%)
		<ul style="list-style-type: none"> • funding OPEX (2-3 yrs) • to continue pipeline development • as buffer from externalities • A\$20 million 12-month share buy-back (28/03/24) • to finance value-adding asset acquisition

Clinical Pipeline: skin and brain

Melanocortin based pharmaceuticals for unmet needs

	Preclinical	Phase I	Phase II	Phase III	Commercial
SKIN	SCENESSE® (afamelanotide 16 mg) in adult EPP (EEA, UK, CH, USA, ISL, CAN, AUS)				
	SCENESSE® (afamelanotide 16 mg) in adolescent EPP				
	SCENESSE® (afamelanotide 16 mg) in adolescent and adult vitiligo				
	SCENESSE® (afamelanotide 16 mg) in adolescent and adult XP				
	SCENESSE® (afamelanotide 16 mg) in variegate porphyria				
	CUV9900 transdermal				
BRAIN	PRÉNUMBRA® in arterial ischaemic stroke				
	PRÉNUMBRA® in Parkinson's Disease				
	NEURACTHEL® instant – IS, MS				
	NEURACTHEL® modified release – CNS				

Catalysts

2024

SCENESSE® adolescent use – EMA outcome ✓ | adolescent PK study CUV052 – start ✓ | regulatory filing Canada ●●●

Vitiligo CUV105, n=200 ASX 21 Aug '24: extended recruitment, relaxation inclusion criteria
CUV107, start n=200 ●●●

XP – DNA Repair CUV151-156 readouts ✓ | CUV154 -158 study start ●●●

VP CUV040 – study complete ✓

CNS disorders CUV803 – readouts (PRÉNUMBRA®) ●●● | New Indication: Parkinson's Disease – study start ✓

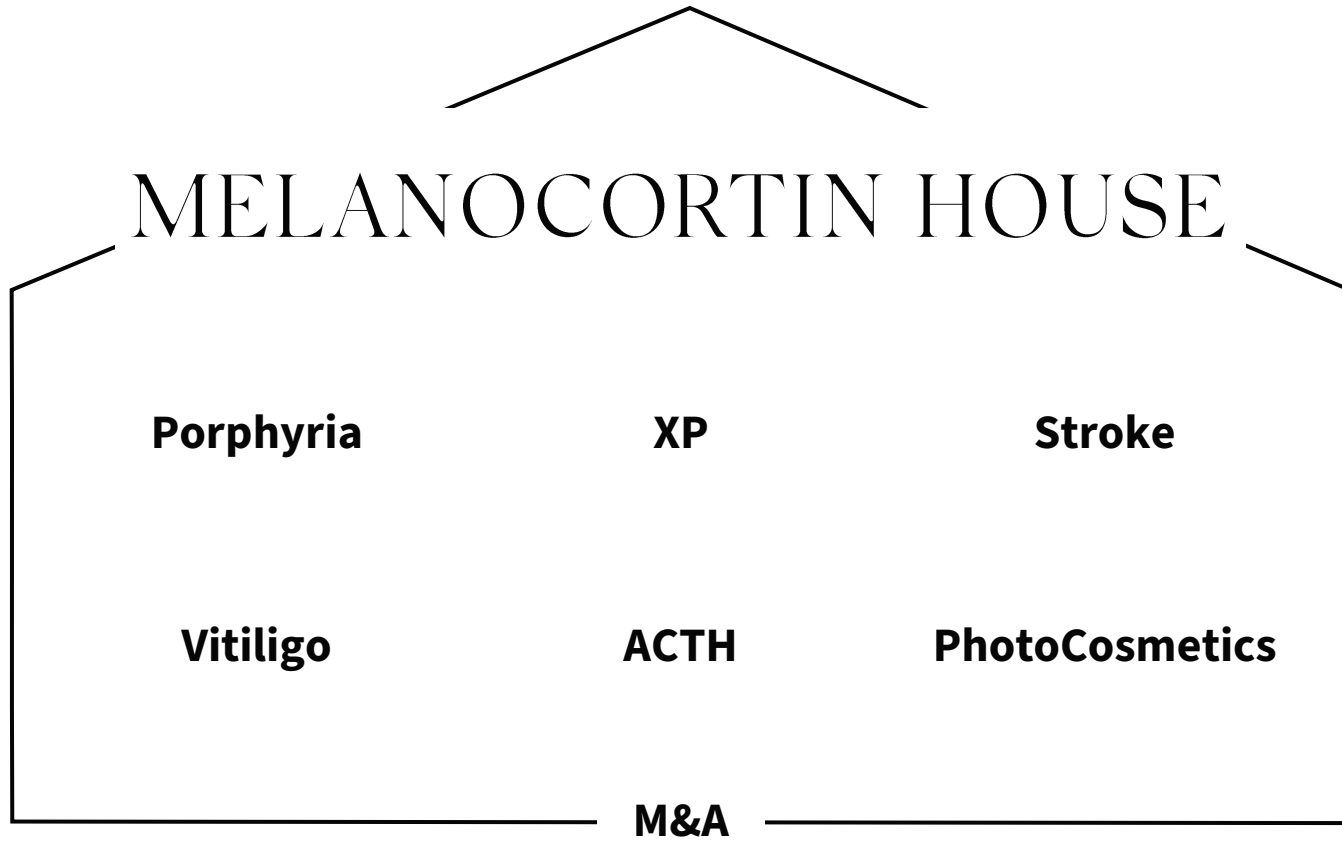
NEURACTHEL® manufacturing progress ●●●

PhotoCosmetics website launch ✓ | e-commerce ✓ | CYACÊLLE global launch – prelaunch initiated ✓

Finances earnings growth, half year ✓ | full year ✓

Looking Forward: 2025 and Beyond

Building a melanocortin house



A pharmaceutical group, diversified-integrated to sustain long-term performance

Products for multiple indications and healthcare solutions

- 3 pharmaceutical products
- 8 conditions treated
- 3 PhotoCosmetic products

CLINUVEL will

- execute R&D into new formulations, products, indications
- integrate in-house manufacturing capabilities
- maintain its financial performance
- exercise disciplined deployment of capital
- become a household name

Q&A

DISCUSSION

CLINUVEL

Thank you for your interest

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

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