CLINUVEL

ESTABLISHING SUSTAINABLE VALUE

Bell Potter Healthcare Conference | 18 November 2024

Malcolm Bull – Head of Australian Operations & Investor Relations

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

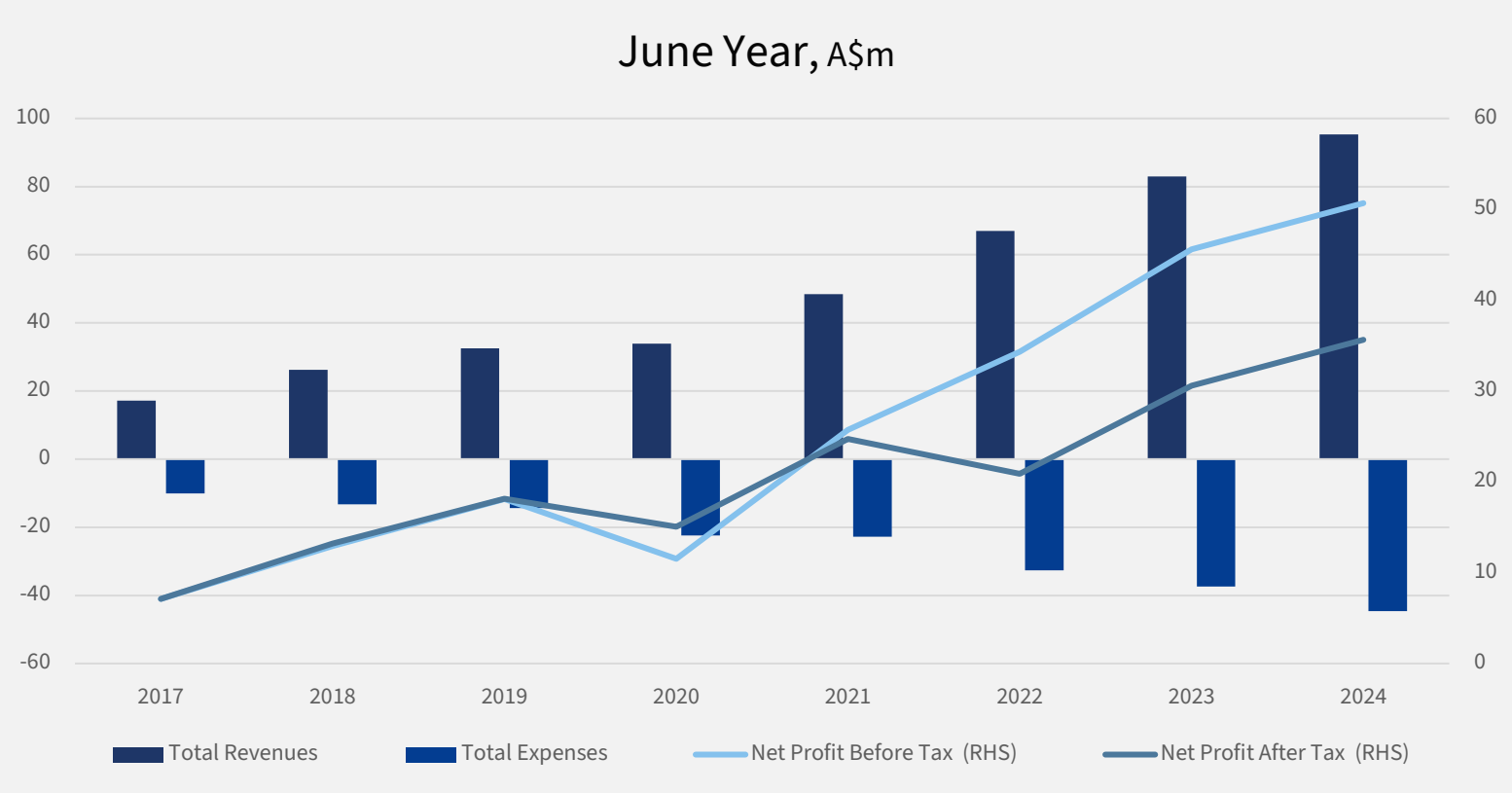
Forward-looking statement

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.

Profitability

Revenue growth and profitability from distribution of SCENESSE® for EPP

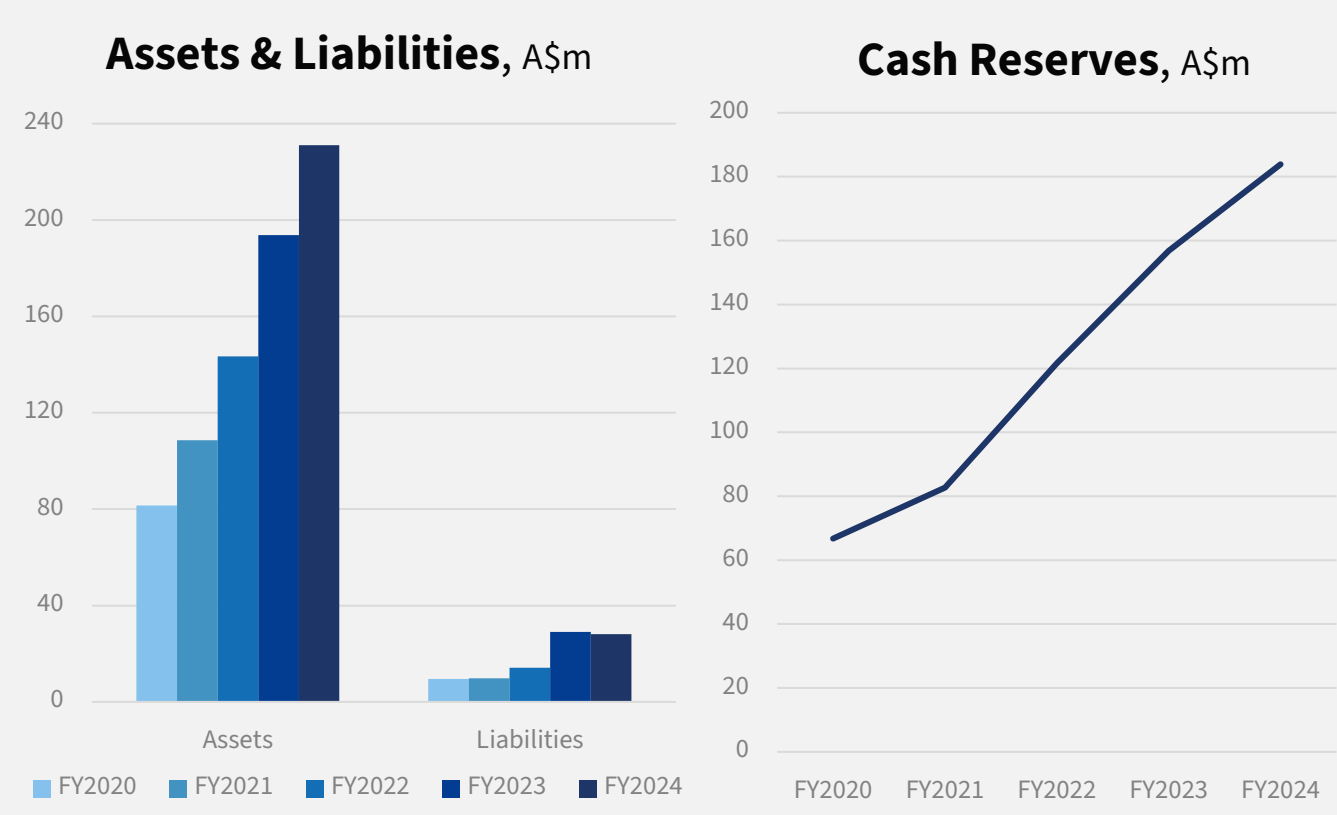


- 8 years consecutive annual revenues growth (CAGR 38%)
- Controlled fixed costs support expansion (expenses CAGR 20%)
- 8-year average EBIT Margin 48%, Profit Margin 45%
- 7 years consecutive annual dividend – FY24 A$0.05 fully franked
- Earnings per Share FY24: A$0.72
- Return on Equity FY24: 18%

Total Revenues include interest and other income.

Strong Balance Sheet

Enables self-financing expansion



As of 30 June	2023	2024
Total Assets	**$193.7m**	**$231.1m** (+19%)
Total Liabilities	**$29.1m**	**$28.1m** (-3%)

- trade creditors, suppliers
- debt-free

Cash Reserves	**$156.8m**	**$183.9m** (+17%)

- covers OPEX for 2-3 yrs
- enables continued pipeline development
- provides buffer from externalities
- finances A$20m 12-month share buy-back (28/03/24)
- finances value-adding asset acquisition

Cash Reserves equals Cash & cash equivalents plus Cash held in term deposits.

Focused Expansion strategy

Integration of key functions 'in-house'

Distribution SCENESSE®

Focus on increasing patients, prescribers, treatment centres

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New jurisdictions

–

EPP adolescents (12-17 years)

Melanocortin product development, clinical studies

PRÉNUMBRA® and NEURACTHEL®

–

CLINICAL STUDIES

1. vitiligo
2. variegate porphyria
3. CNS

Translation of technology to PhotoCosmetic products

1. Polychromatic screen CYACÊLLE & CYACÊLLE Radiant

–

2. DNA Repair

–

3. Melanogenesis

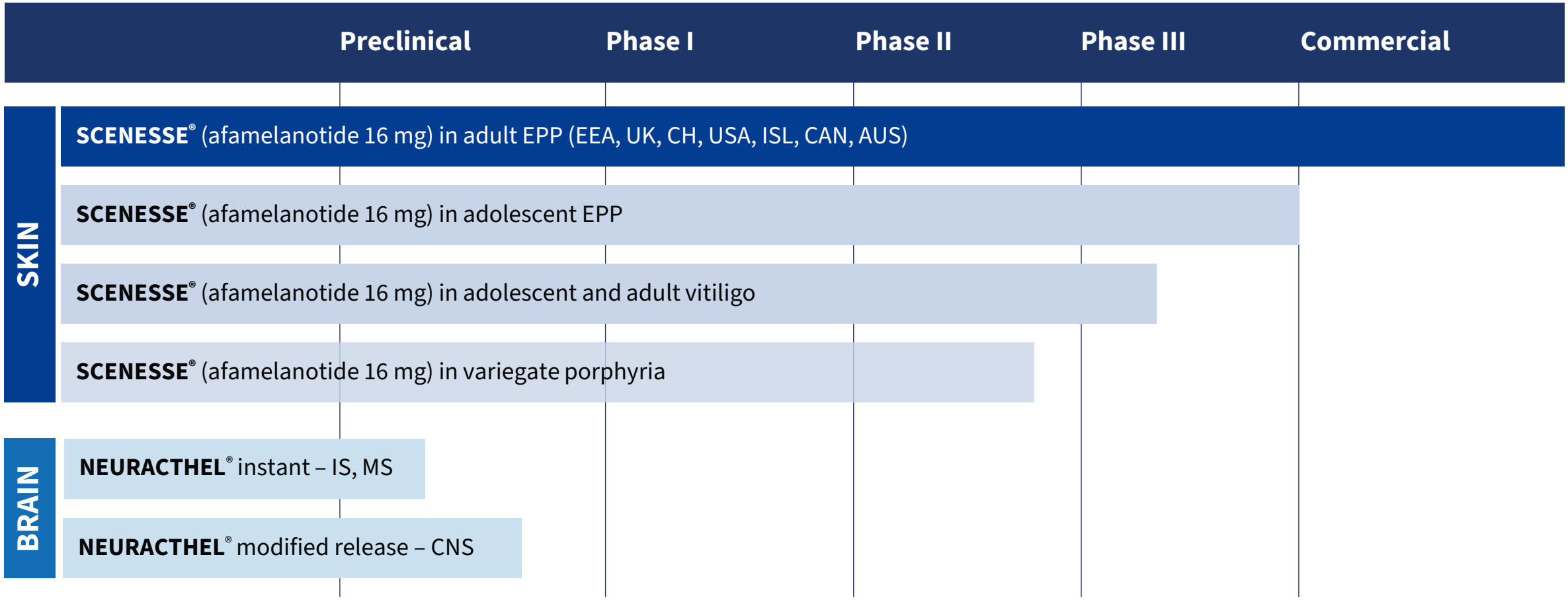
M&A

Vertical integration

–

Innovative technologies

Clinical pipeline: skin and brain



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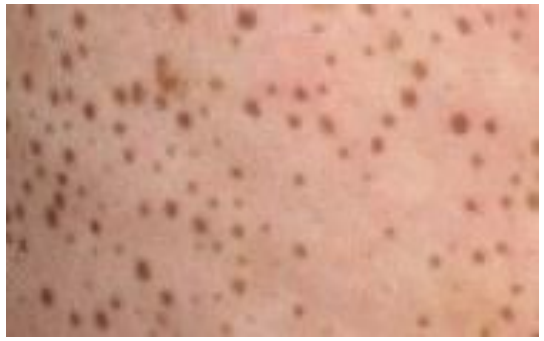
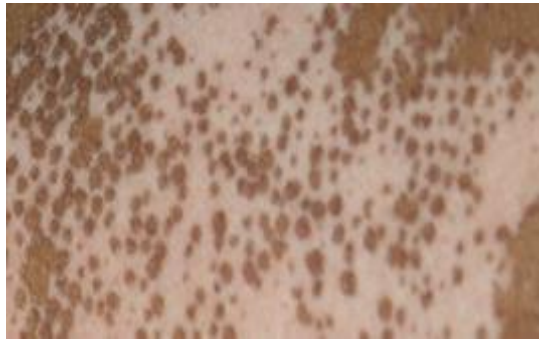
XP = xeroderma pigmentosum | IS= infantile spasms | MS = multiple sclerosis | CNS = central nervous system.

Vitiligo

Path to market, affects 1-2% of global population



NB-UVB treatment



NB-UVB treatment + afamelanotide

CUV102 +NB-UVB, n = 56

↓

CUV103 +NB-UVB, n = 21

↓

CUV104 monotherapy, n = 6

↓

CUV105 +NB-UVB, n = 200

↓

CUV107 +NB-UVB, n = 200

↓

FDA submission[1]

Step 1	Safety profile established • >17,000 doses afamelanotide administered [2]
Step 2	CUV102, 103, 104
Step 3	2022: FDA set precedent for NB-UVB combination therapy
Step 4	2022: Insurers providing reimbursement codes
Step 5	2023: Vitiligo Expert Panel
Step 6	2023: Commencement Phase III clinical studies
Step 7	2025: Train & accredit 120 US centers

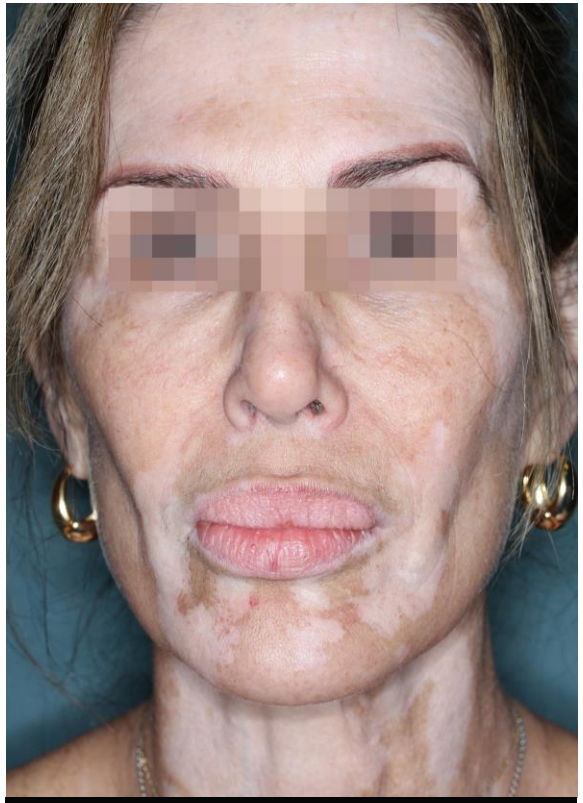
Total addressable market USA: US$4.5bn

~6,000 patients in years 1-2 of treatment
= revenues of US$490-570m

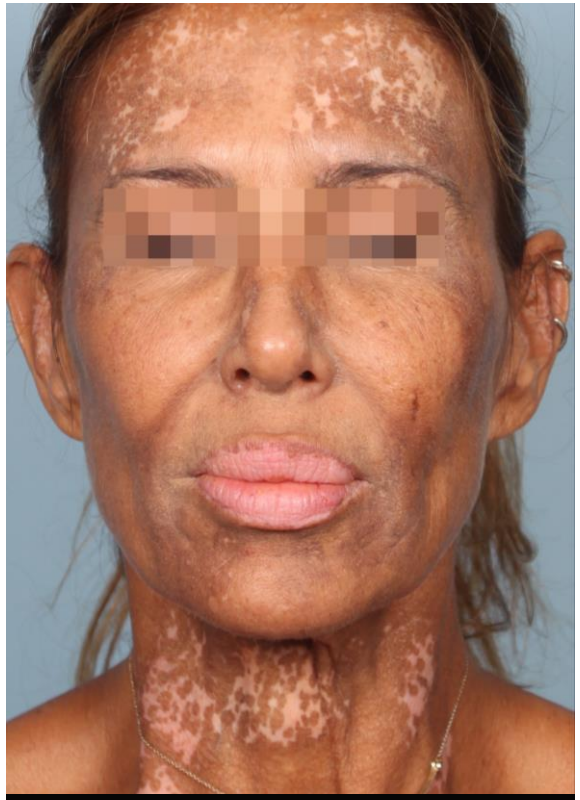
[1] Completion of clinical studies determine timing of regulatory filing | [2] All indications | Clinical images courtesy of CUV102 investigators

SCENESSE® (afamelanotide) for vitiligo

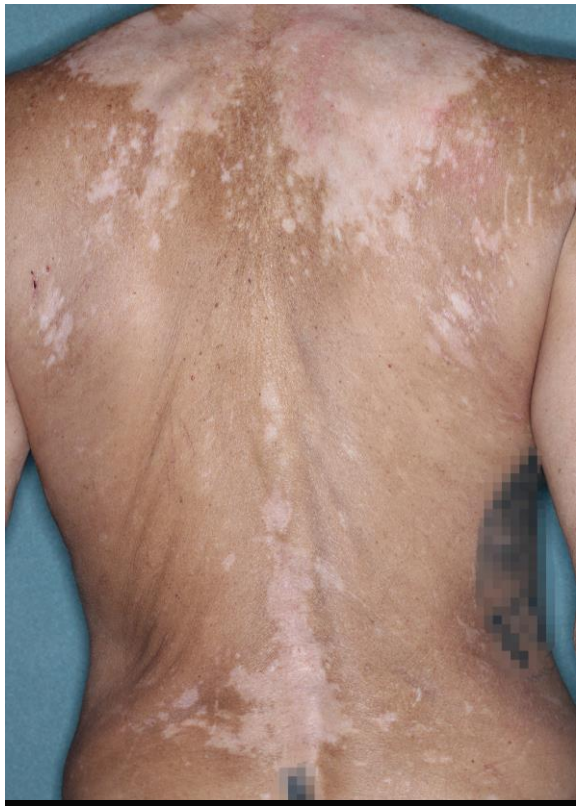
Case study presented to 2024 American Academy of Dermatology (FST IV)



Day 0
Baseline



Day 134
7 implants, 39 NB-UVB sessions



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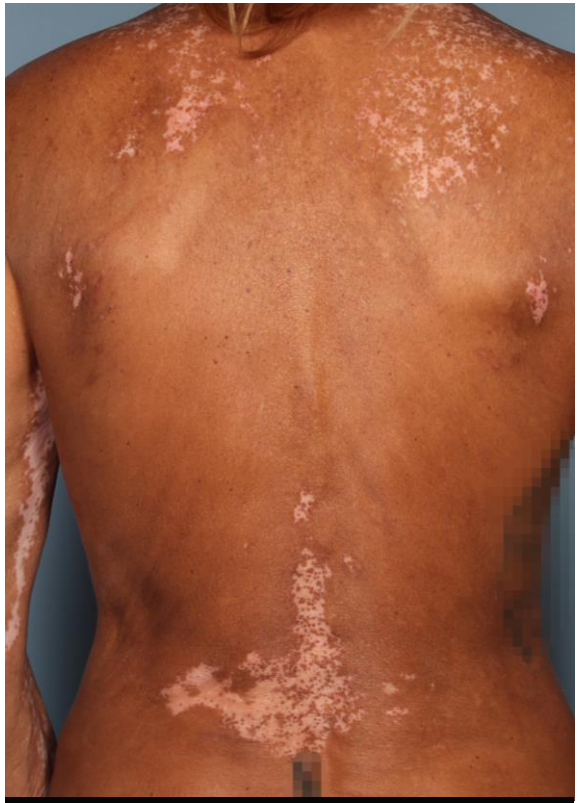

Day 134
7 implants, 39 NB-UVB sessions

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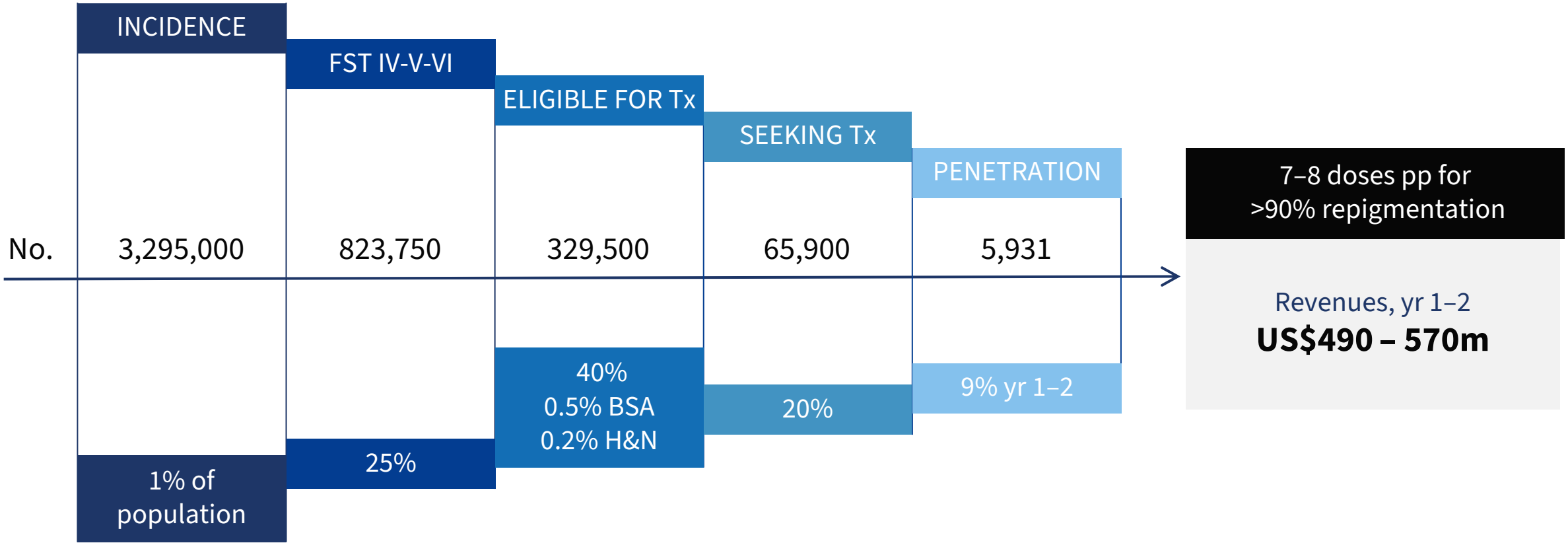
Images have been amended/cropped and pixelated to protect the patient's privacy but are otherwise unaltered.
Images courtesy of the investigator

Vitiligo

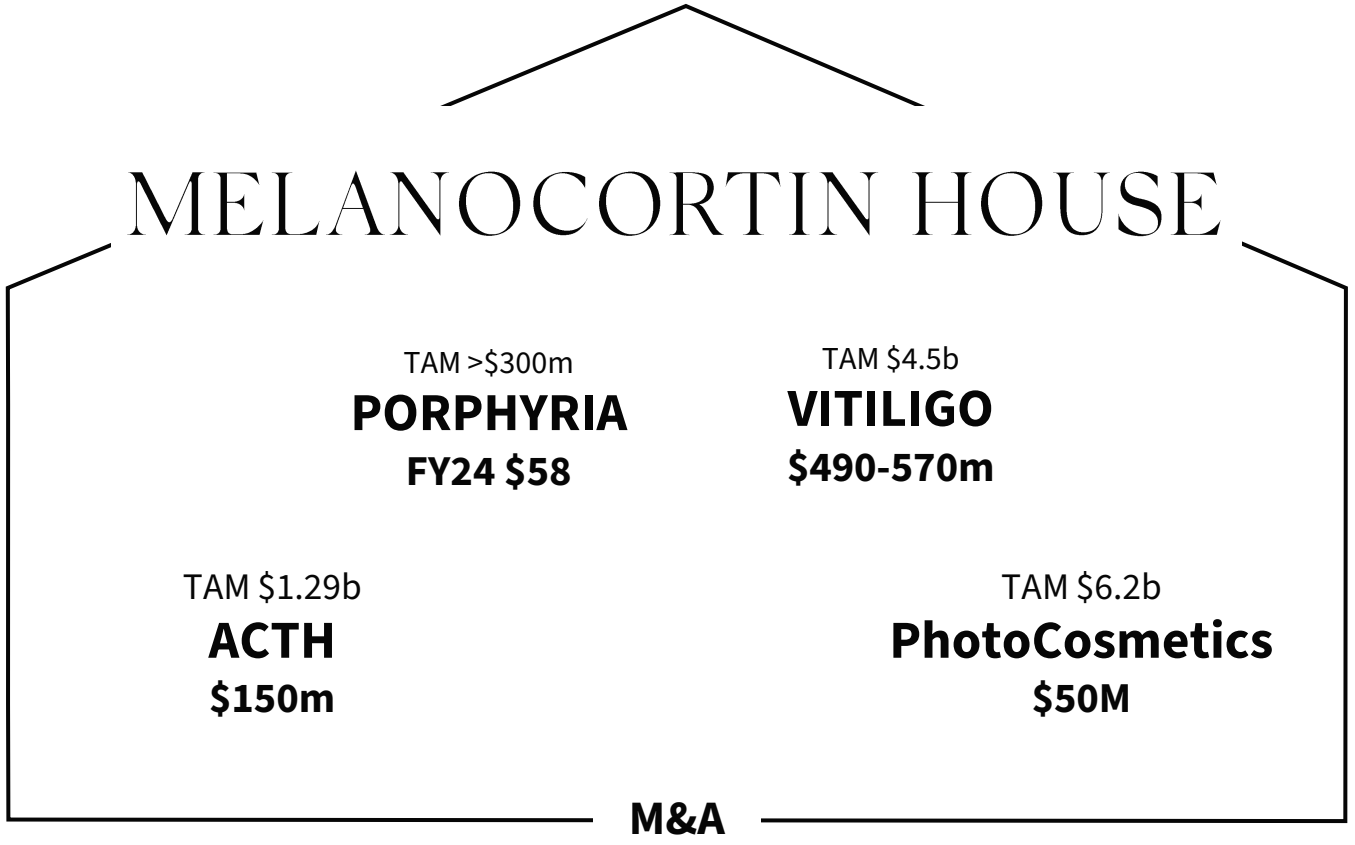
Addressable Market USA – afamelanotide for FST IV-V-VI



*Abbreviations. FST = Fitzpatrick Skin Type; Tx = treatment; BSA = body surface area; H&N = head and neck.

Vision of the Future

A house of melanocortins



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

Products, indications & healthcare solutions

- 3 pharmaceutical products
- 5 conditions treated
- 3 PhotoCosmetic product lines

CLINUVEL will

- develop new formulations & products
- treat new indications
- integrate in-house manufacturing
- maintain financial performance
- exercise disciplined deployment of capital
- become a household name

TAM = Total Addressable Market. All figures in US$.

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Thank you for your interest

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

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