CLINUVEL

First Half Results - FY2025

Financial and Operational Performance, six months to 31 December 2024

February / March 2025

Peter Vaughan, Chief Financial Officer & Malcolm Bull, Head of Investor Relations & Australian Operations

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 and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed and characterised by us as PhotoCosmetics; 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, the UK, Israel, China, Japan, and/or LATAM regions 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®, NEURACTHEL® or products developed as PhotoCosmetics which may lead to the Company being unable to launch, supply or serve its commercial markets, special access programs and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare, Medicaid, and U.S. Department of Veteran's Affairs) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology, cosmetic 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, cosmetic 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.

Strong Underlying Profit

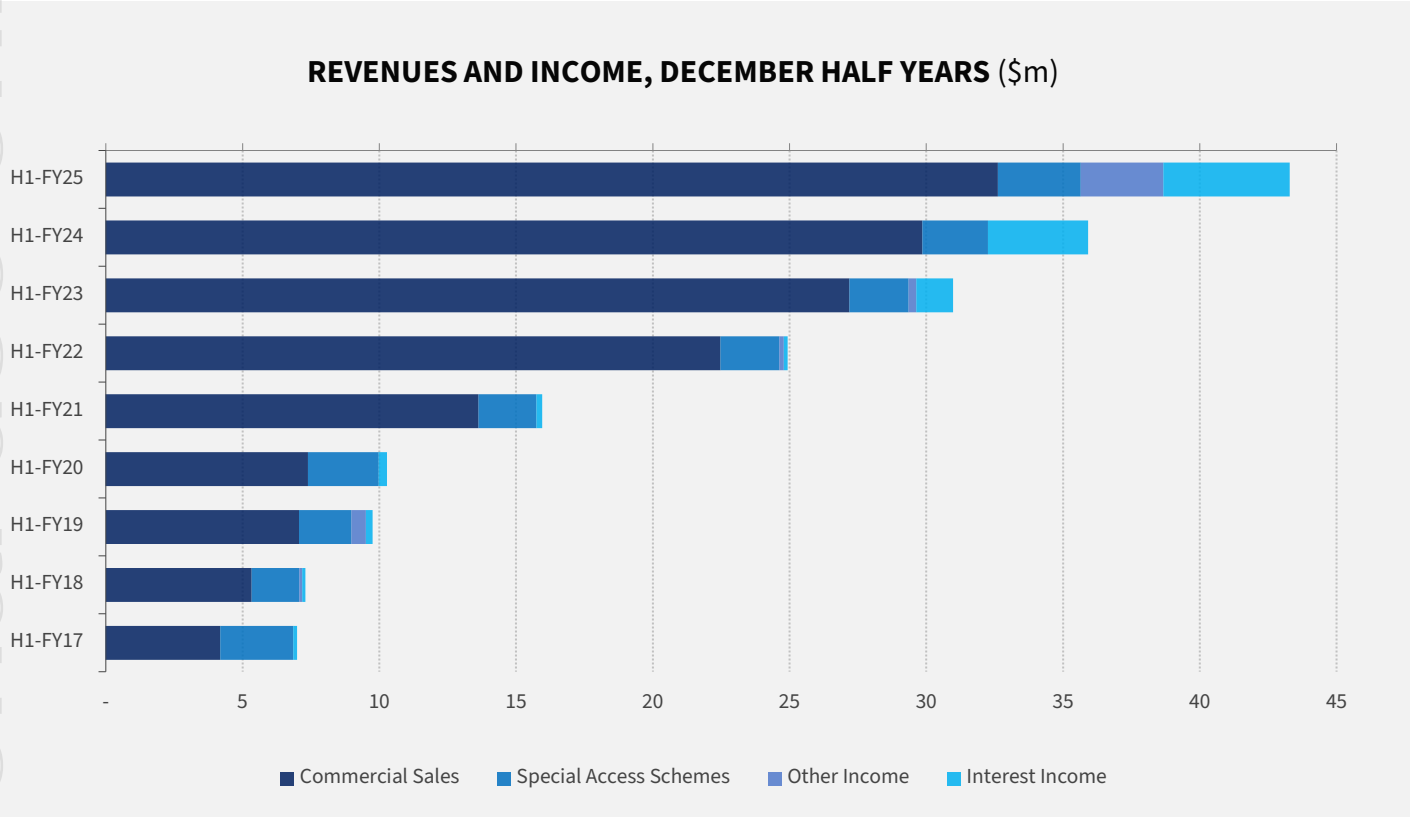
Half year ended 31 December 2024

	31 December 2024	31 December 2023	Change
REVENUES ($)	35,645,883	32,256,885	+10.5%
EXPENSES ($)	21,353,011	20,924,198	+2.0%
PROFIT BEFORE TAX ($)	21,932,314	14,805,699	+48.1%
PROFIT AFTER TAX ($)	14,075,335	10,936,043	+28.7%
BASIC EARNINGS PER SHARE ($)	0.28	0.22	+27.4%
CASH AND TERM DEPOSITS ($)	198,220,748	183,868,471*	+7.8%*

All figures reported in Australian dollars, $. *Balance as of and increase from, 30 June 2024.

Buoyant Revenues

Progressive rise in revenues from sales plus interest and other income

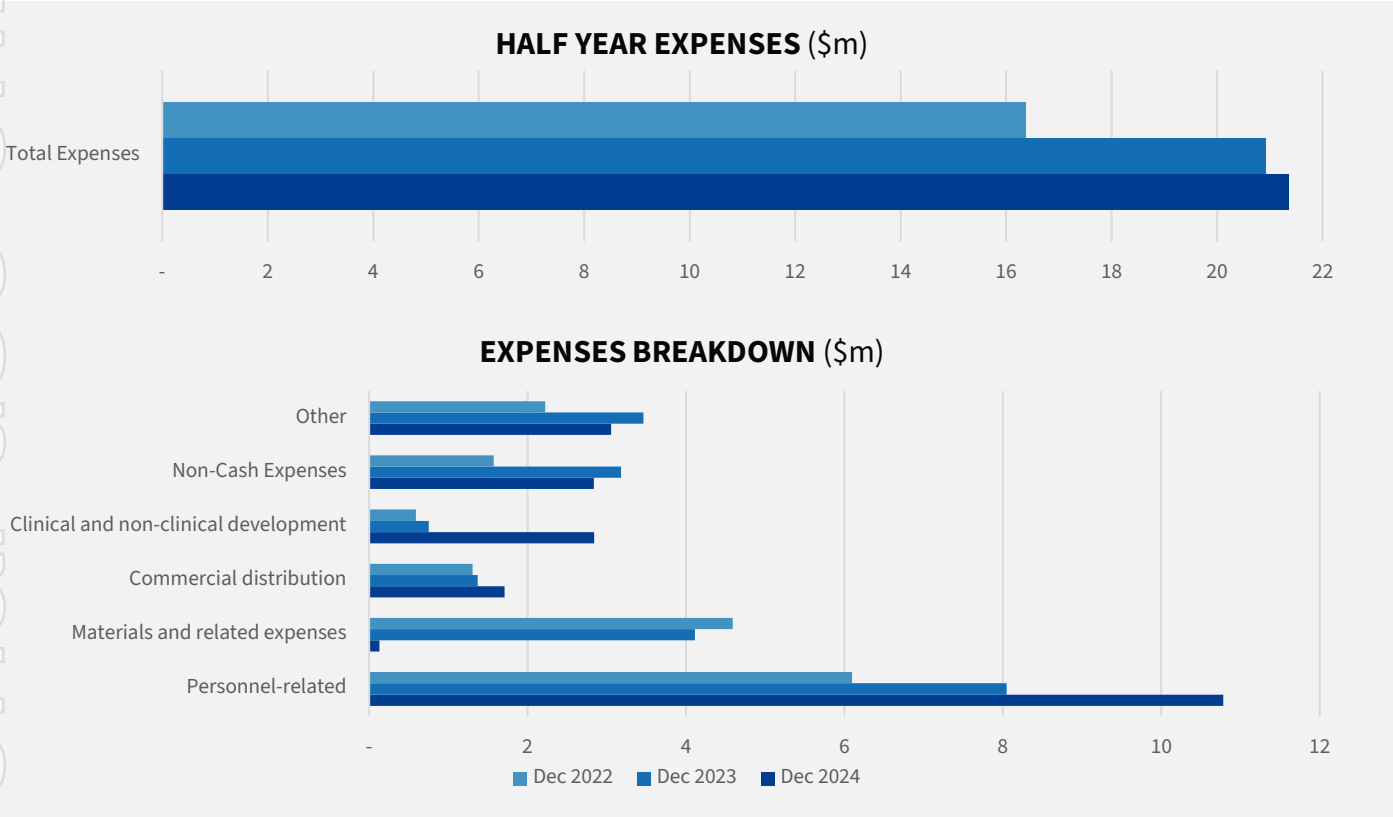


$m	Dec ’24	Dec ’23
Commercial	32.6 (+9.2%)	29.9
SAS	3.0 (+26.6%)	2.4
Interest	4.6 (+26.1%)	3.7
Other	3.0	(0.2)
Total	43.3 (+21.1%)	35.7

Total Revenues include commercial and SAS sales and interest and other income.

Controlled Expenses Support Expansion

Half year Dec ’24 expenses contained to 2% increase



GROWTH IN:

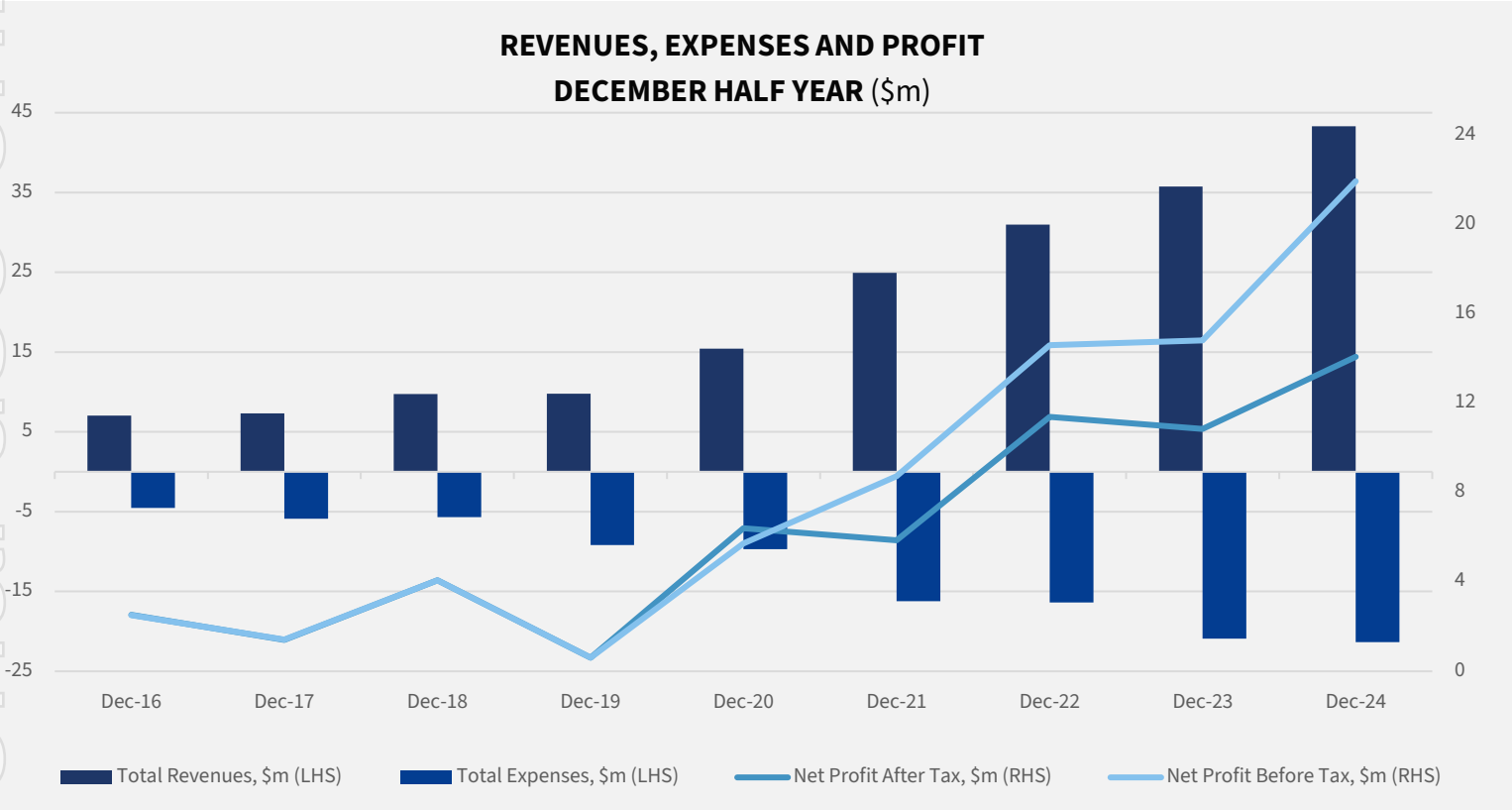
- Personnel related (+34.0%)
- Clinical and Non-Clinical Development (+277.4%)
- Commercial distribution (+24.7%)

OFFSET BY:

- Materials and related expenses (-96.8%)
- Non-cash expenses (-10.8%)
- Other (-11.8%)

Revenues, Expenses and Profit

Revenues growth and controlled expenses underpin earnings growth

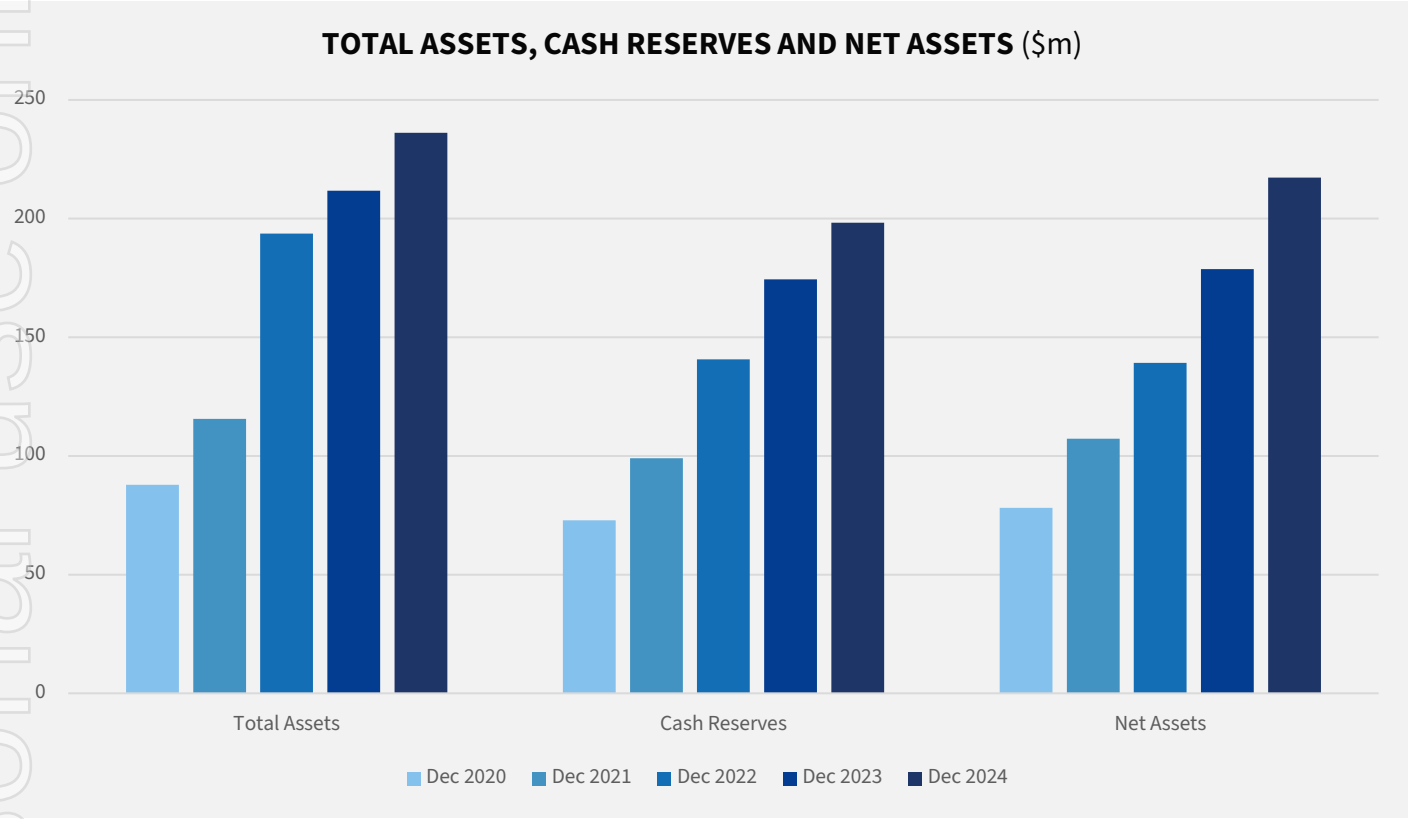


- All revenues from distribution of SCENESSE® for EPP
- Consecutive half year revenues growth since commencement of commercial operations
- Expenses for expansion offset by reductions in materials and non-cash expenses
- Positive trend in underlying profit
- Earnings per Share
  - Dec ’24: $0.28
  - Dec ’23: $0.22

Total Revenues include interest and other income.

Balance Sheet Strength

Enables self-financing expansion



$m	31 Dec ’24	30 Jun ’24
Total Assets	236.2m (+2.2%)	231.1m
Cash Reserves	198.2m (+7.8%)	183.9m
• covers OPEX for 2-3 yrs • enables continued pipeline development • provides buffer from externalities • finances $20m 12-month share buy-back (28/03/24) • finances value-adding asset acquisition		
Total Liabilities	18.9m (-32.7%)	28.1m
• trade creditors, suppliers • debt-free		
Net Assets	217.3m (+7.0%)	203.0m

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

Focused Expansion strategy

Integration of key functions 'in-house'

Distribution SCENESSE®	Melanocortin product development, clinical studies	Translation of technology to PhotoCosmetic products	M&A
Focus on increasing patients, prescribers, treatment centres – New jurisdictions – EPP adolescents (12-17 years) – SCENESSE® dosage (EU)	PRÉNUMBRA® and NEURACTHEL® – CLINICAL STUDIES vitiligo variegate porphyria CNS	1. Polychromatic screen CYACÊLLE & CYACÊLLE Radiant – 2. DNA Repair – 3. Melanogenesis	Vertical integration – Innovative technologies

Key Outcomes

Half Year to December 2024

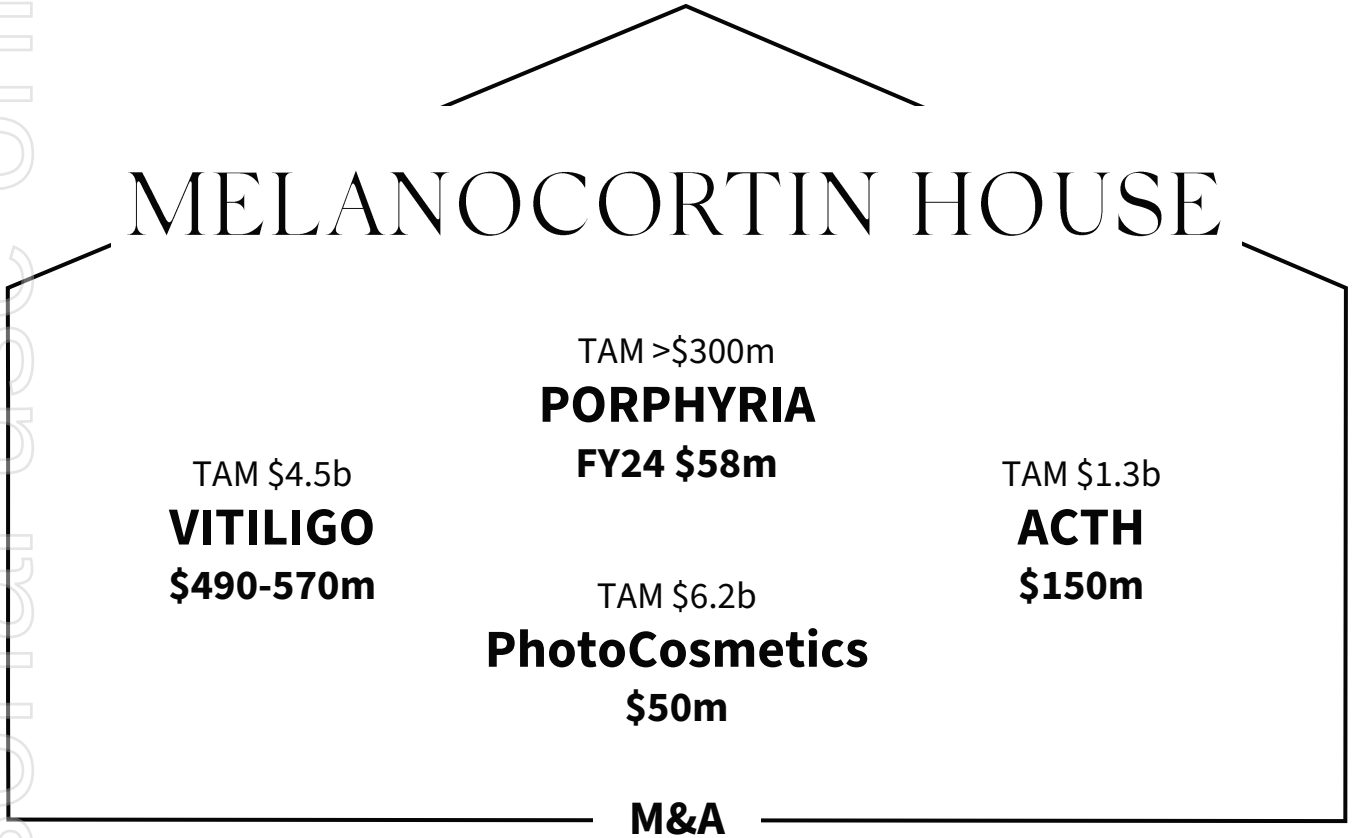
Objective	Progress	
Building long-term value	• Strong financial performance achieved – highest 1HFY underlying profit to date • Seventh consecutive dividend declared and paid following FY2024 results	• Prioritisation of strategic programs: vitiligo, ACTH & porphyrias • Board renewal: three new Non-Executive Directors appointed • Restructured clinical team
Growing commercial distribution of SCENESSE® for EPP	• Treated more patients and distributed more SCENESSE® implants than any 1HFY to date • 93 North American Specialty Centers established (89 USA, 4 Canada)	• New Drug Submission to Health Canada for adult EPP patients, outcome expected in Q4 CY2025 • Submitted variation to European label to allow year-round EPP patient treatment, outcome expected Q1 CY2025
Developing melanocortins	• Vitiligo: CUV105 study inclusion criteria relaxed; extension treatment offered to patients assigned NB-UVB monotherapy; completion of recruitment targeted 30 June 2025 • Variegate porphyria: Positive Phase II results in CUV040	• DNA repair: Positive final Phase II results from CUV151 presented to British Association of Dermatologists Meeting; afamelanotide shown to assist DNA repair after UV damage (UV-irradiated skin) • PhotoCosmetics: Advancing three cosmetic product lines; first “M line” containing melanocortins due to release in 2026
Increasing visibility	• Sponsored 2024 International Congress of Porphyrias & Porphyrins (ICPP) • Presentation of CUV040 results to ICPP	• Extensive preparations for upcoming American Academy of Dermatology Annual Meeting, Orlando, March 2025
Global IR engagement	• Research coverage initiated by Dr Kalliwoda Research and Parmantier & Co (nine analysts now cover CLINUVEL) • Conference presentations: Bioshares Biotech conference; Biotech Showcase Melbourne; Bell Potter Healthcare Conference	• Non-Deal Roadshows: Melbourne-Sydney and Switzerland-Germany • Increased stakeholder engagement USA • 2024 Annual General Meeting

Catalysts 2025

Objective	Event
Growing commercial distribution of SCENESSE® for EPP	• Engagement EMA on CUV052 and adolescent EPP patient use of SCENESSE® • EMA decision on SCENESSE® dosage for EPP patients • Expand to 120 North American Specialty Centers • Health Canada decision on marketing authorisation, SCENESSE® for EPP
Developing melanocortins	• Vitiligo - Complete recruitment CUV105 study - Commence study CUV107 • Variegate porphyria - Regulatory feedback and commence CUV053 • Stroke - CUV803 results • NEURACTHEL® manufacturing update
Increasing visibility	• American Academy of Dermatology Meeting • CYACÉLLE next generation product launch
Global IR engagement	• FY2025 results and non-deal roadshows • Annual General Meeting

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

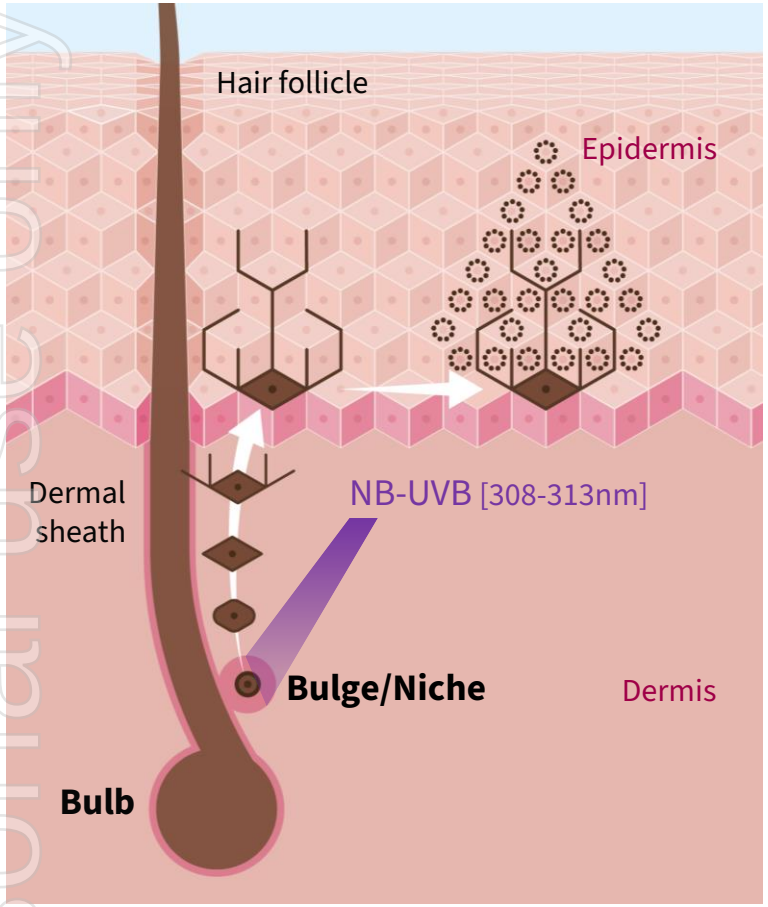
CLINUVEL will

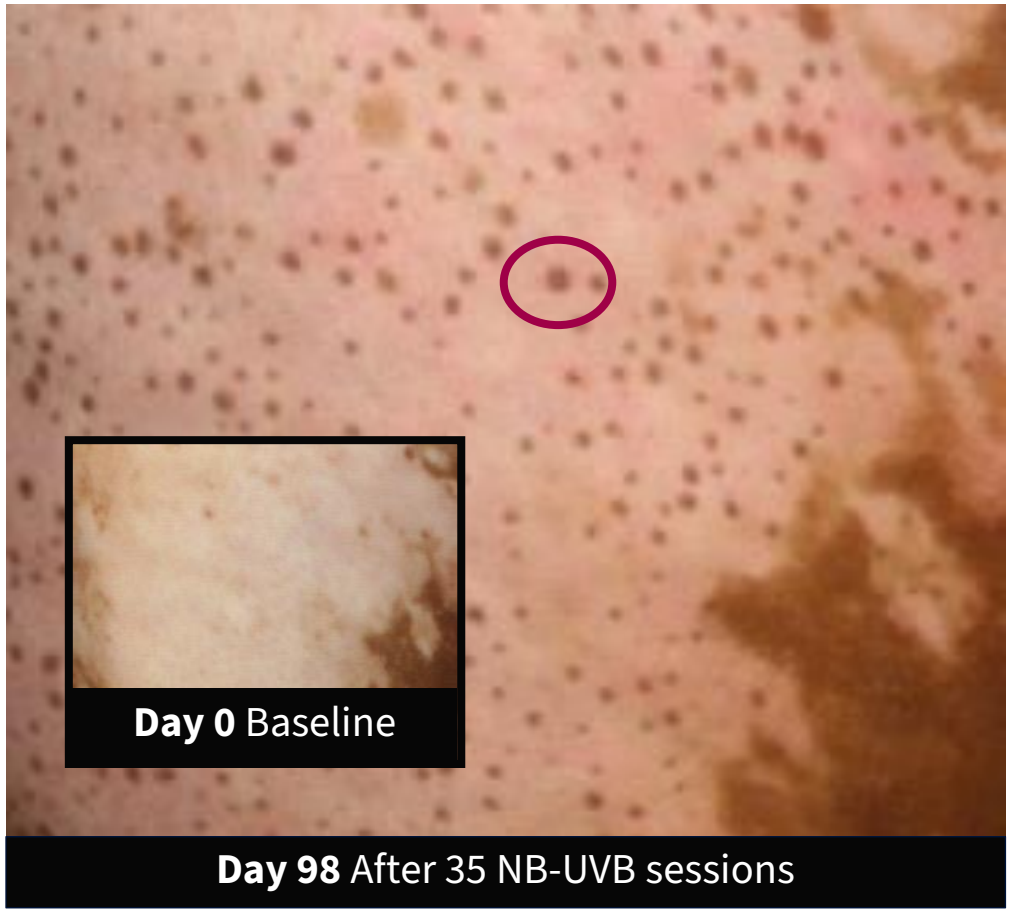
- develop new formulations & products
- treat new indications
- integrate in-house manufacturing
- maintain financial performance
- exercise disciplined deployment of capital
- become a household name

TAM and penetration figures are in US dollars.

Afamelanotide for vitiligo

NB-UVB – follicular repigmentation



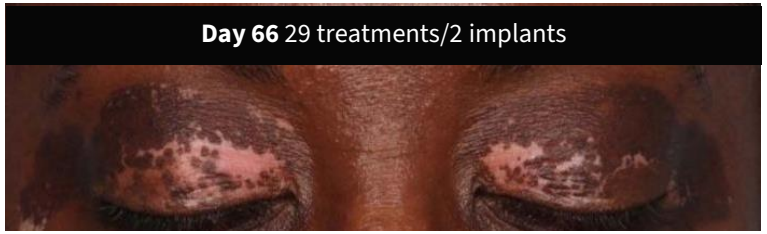


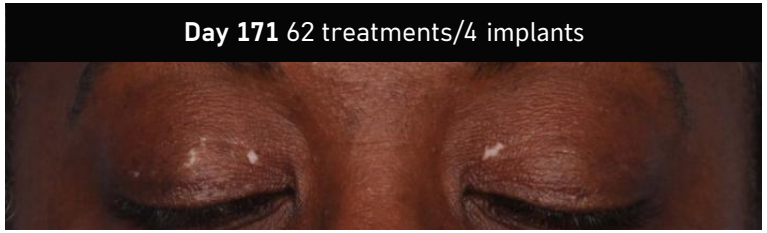
NB-UVB differentiating follicular stem cells

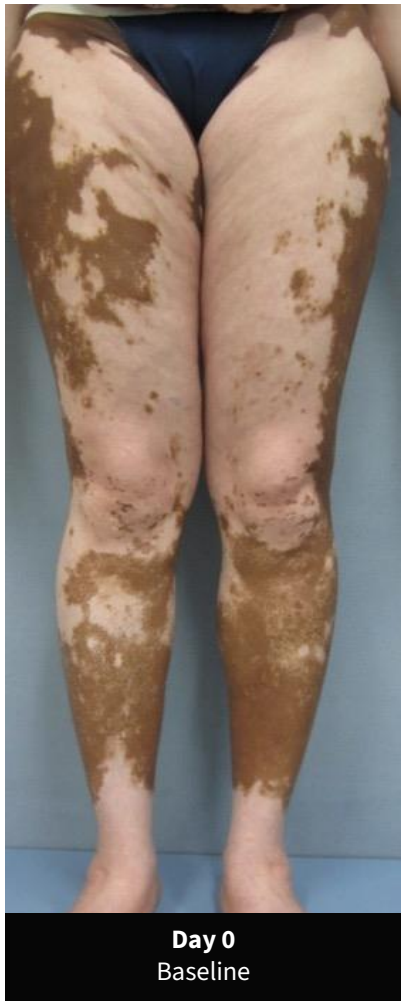
Melanoblasts migrating, become fully functioning melanocytes

Afamelanotide acting as agonist to MC1R expressed

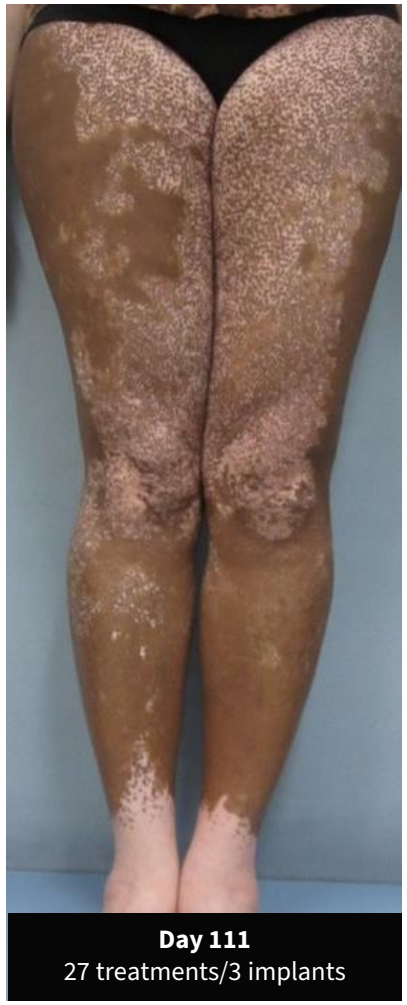
CUV102 Phase II study results



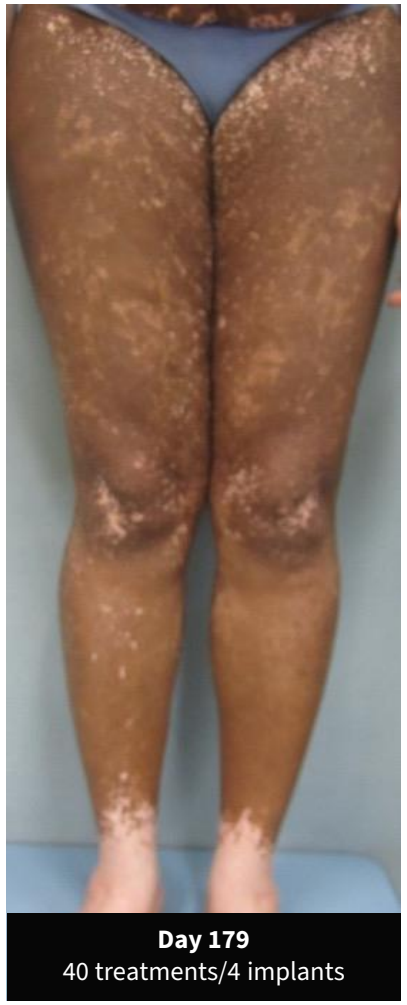




Day 0
Baseline



Day 111
27 treatments/3 implants



Day 179
40 treatments/4 implants

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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.

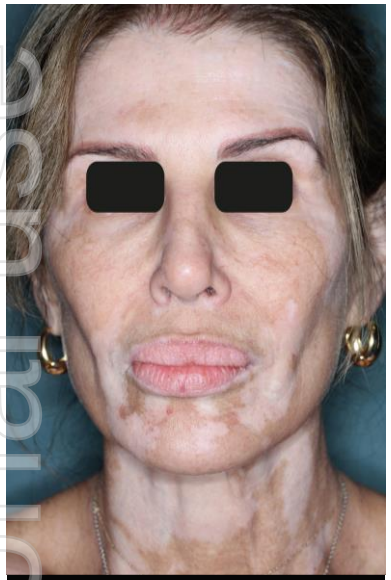
CUV105 Phase III study – first clinical observations

CASE REPORT 1

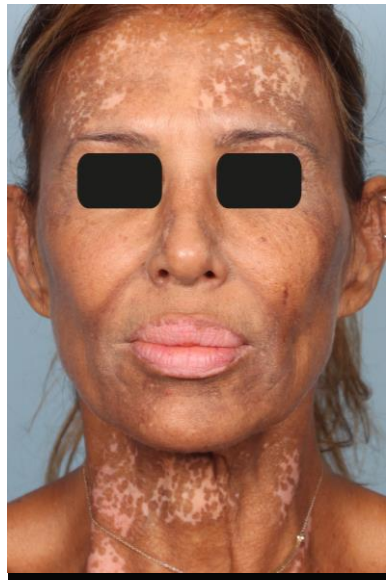
- Female, 55 years old, Skin Type IV
- Diagnosed with vitiligo in 2006, slowly progressive disease activity, no previous episodes of repigmentation, and no family history of vitiligo. Unresponsive to previous vitiligo treatments.

Physician's report

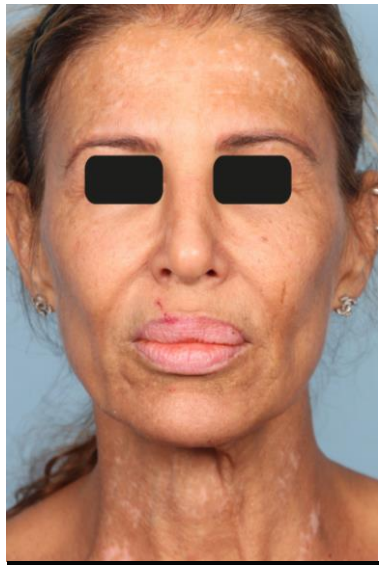
80-90% repigmentation seen after Day 140 but near total repigmentation achieved after continued NB-UVB monotherapy.



DAY 0
Baseline



DAY 134
7 afamelanotide implants
39 NB-UVB treatments



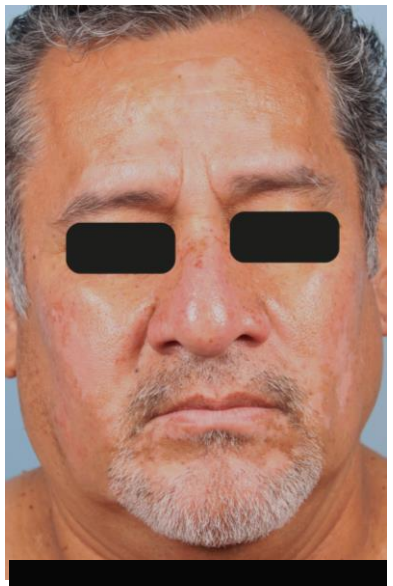
DAY 222
82 days after completing study
53 NB-UVB treatments

CASE REPORT 2

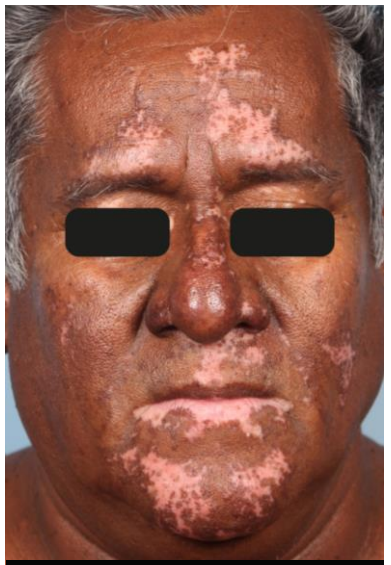
- Male, 52 years old, Skin Type IV
- Diagnosed with vitiligo in 2023, progressive disease activity, no previous episodes of repigmentation, and no family history of vitiligo. No history of previous vitiligo treatments.

Physician's report

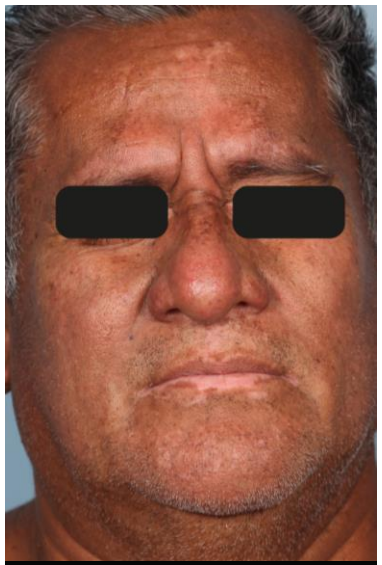
The patient and our team are pleased with the results. Patient reports greater self esteem post-treatment.



DAY 0
Baseline



DAY 140
7 afamelanotide implants
40 NB-UVB treatments



DAY 170
30 days after
completing study
no further therapy

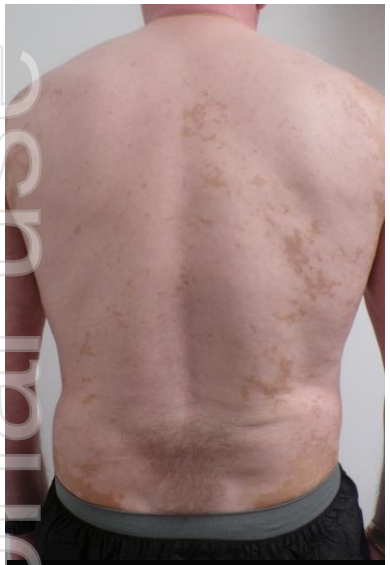
CUV105 Phase III study – first clinical observations

CASE REPORT 3

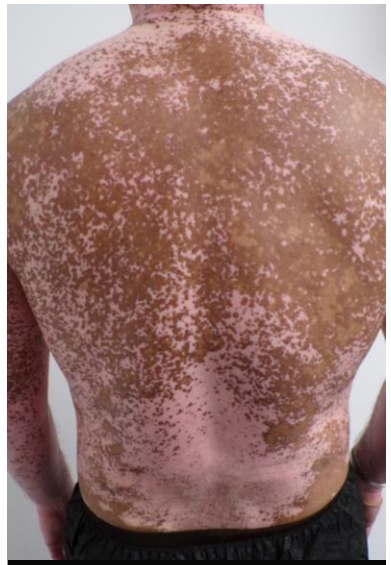
- Male, 56 years old, Skin Type IV
- Diagnosed with vitiligo in 1999

Physician's report

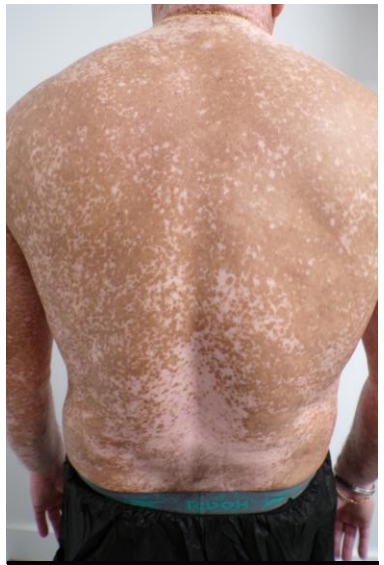
First repigmentation seen around day 42, considerable repigmentation seen by day 106. Patient continued to repigment after conclusion of treatment protocol with no further therapy.



DAY 0
Baseline



DAY 134
7 afamelanotide implants
39 NB-UVB treatments



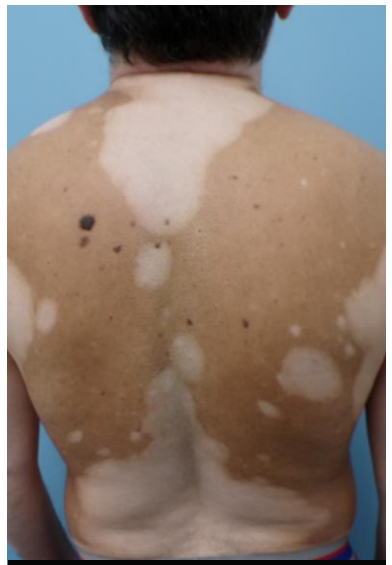
DAY 308
168 days after completing study
no further therapy

CASE REPORT 4

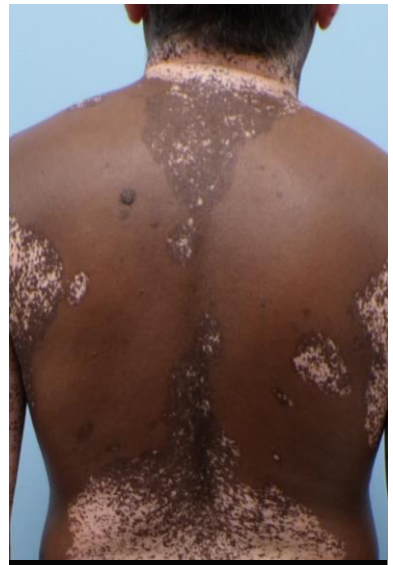
- Male, 56 years old, Skin Type IV
- Diagnosed with vitiligo in 1986

Physician's report

Due to extensive depigmentation, patient is yet to fully repigment. Patient continued to receive NB-UVB treatment following the study and continued to repigment (not shown).



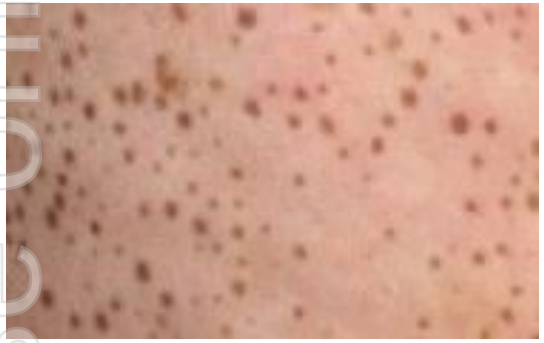
DAY 0
Baseline



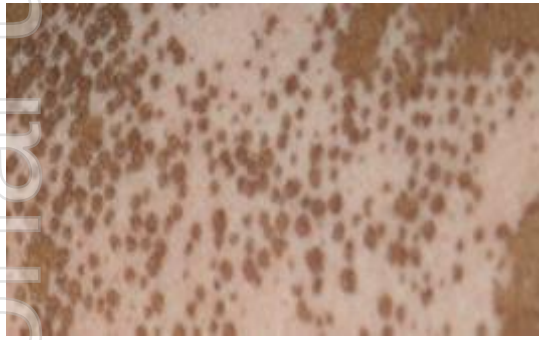
DAY 140
7 afamelanotide implants
40 NB-UVB treatments

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, CUV103, CUV104
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

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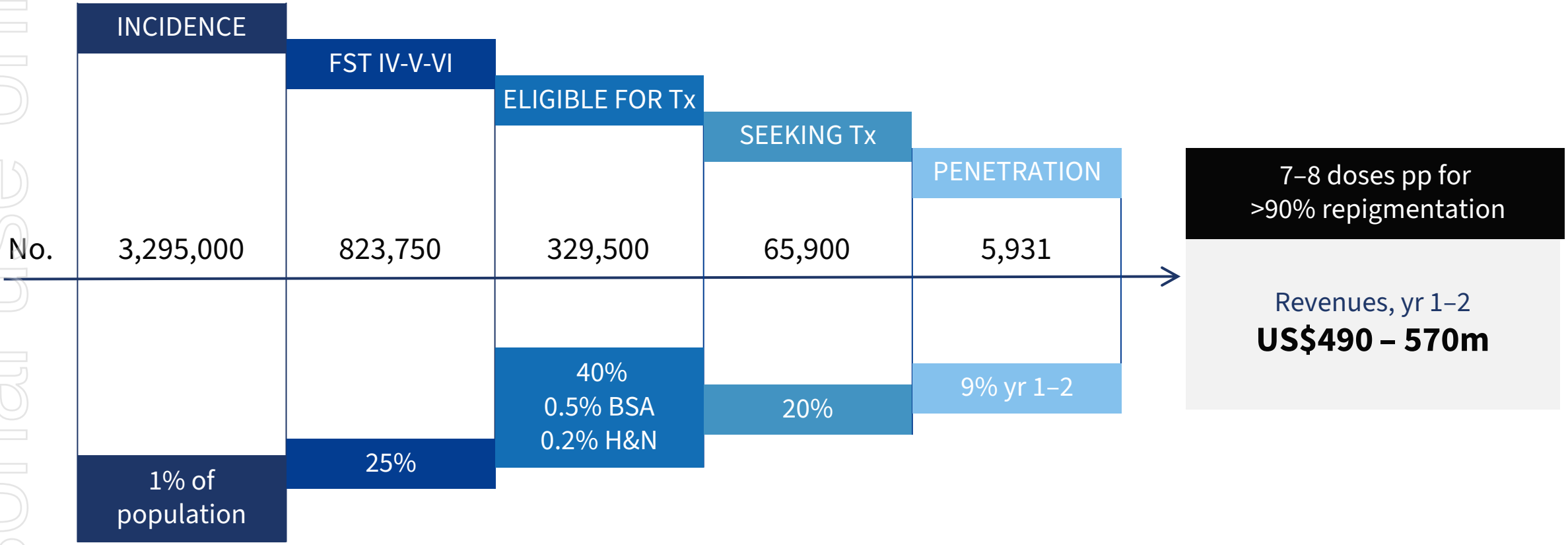
[1] Completion of clinical studies determine timing of regulatory filing | [2] All indications | Clinical images courtesy of CUV102 investigators.

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.

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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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