CLINUVEL

# CLINUVEL PHARMACEUTICALS

## Investor Briefing Melbourne

20 October 2022

Philippe Wolgen – Chief Executive Officer

| | |
|---|---|
| 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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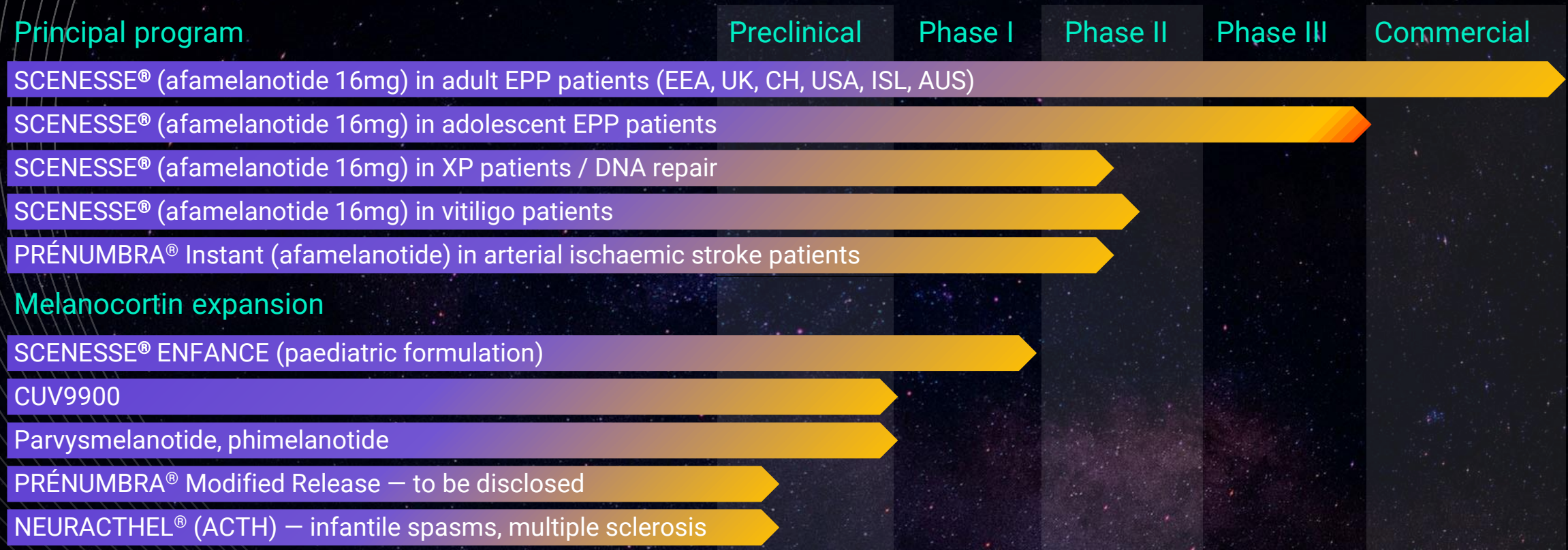
# Pipeline - melanocortins

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# Arterial Ischaemic Stroke

## Targeted product position

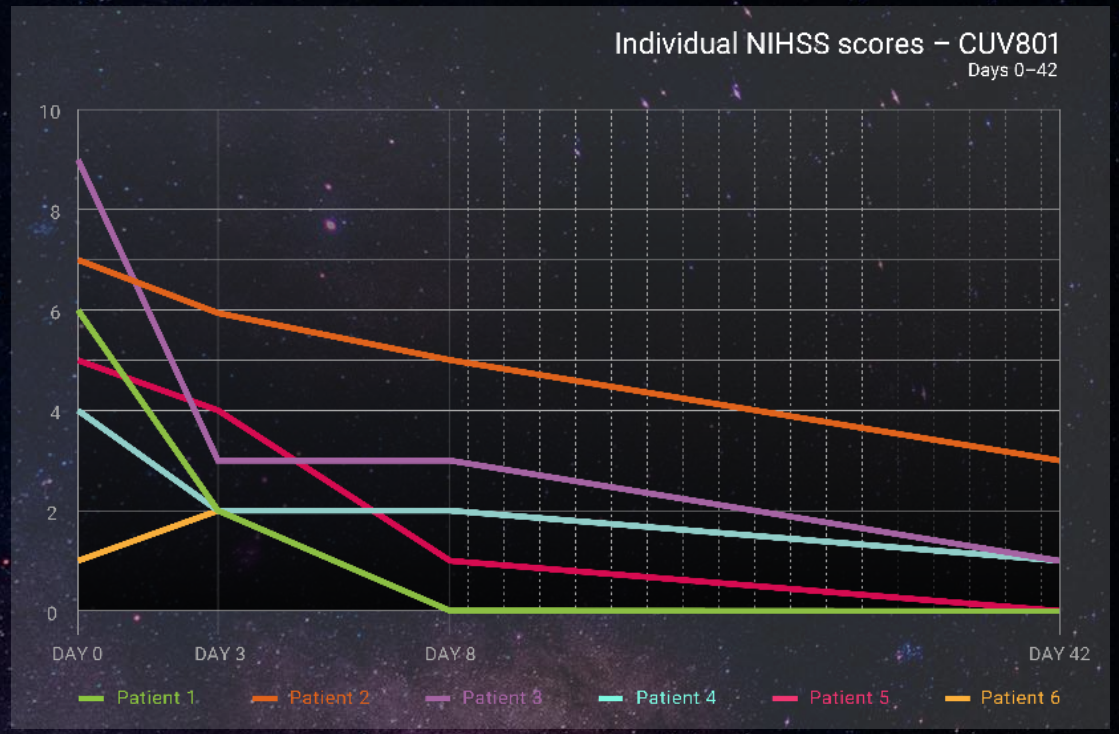
*A hormonal treatment to assist hypoxic brain.*

## 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)

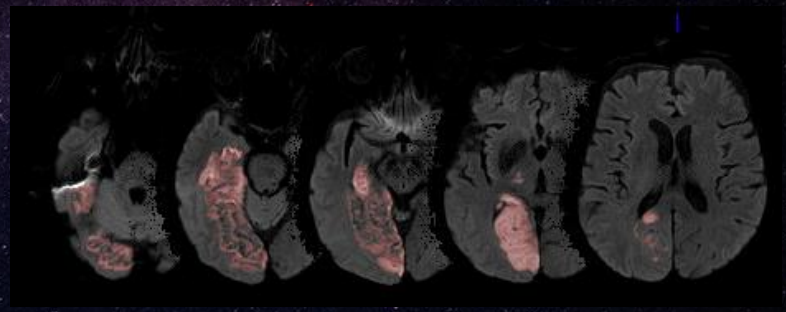
## Study CUV803 (n=12): planned 2H 2022 - afamelanotide

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




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

*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) – shortened life expectancy

## Addressable Market

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

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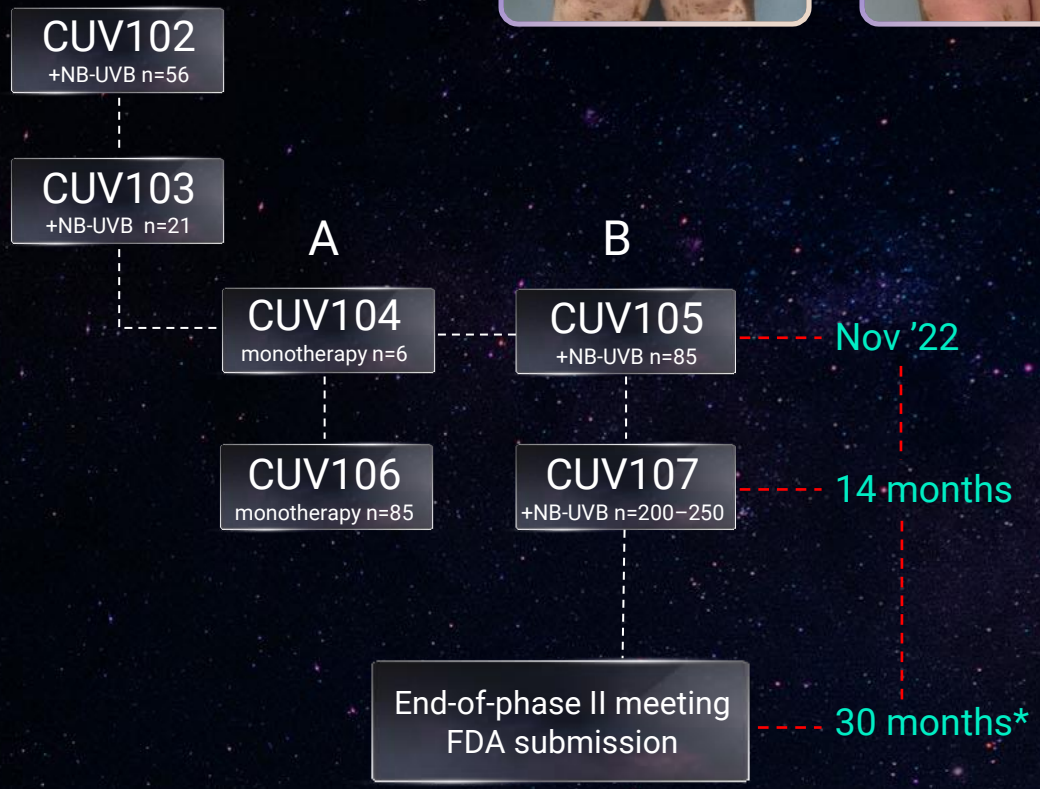
# Vitiligo

## Clinical Program




## Addressable Market

- US$490-570m

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

FDA sets precedent for NB-UVB as combination therapy

First topical treatment approved

SCENESSE® 1st 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

Add to Pharmaceuticals, Healthcare Solutions

## 2. Melanocortins

Use in non-prescription products

## 3. Populations at Highest Risk of photodamage - UV/HEV (λ)

3 populations unaddressed with high need

## 4. Dermatocosmetic Product Portfolio

## 5. Targeted Digital Marketing

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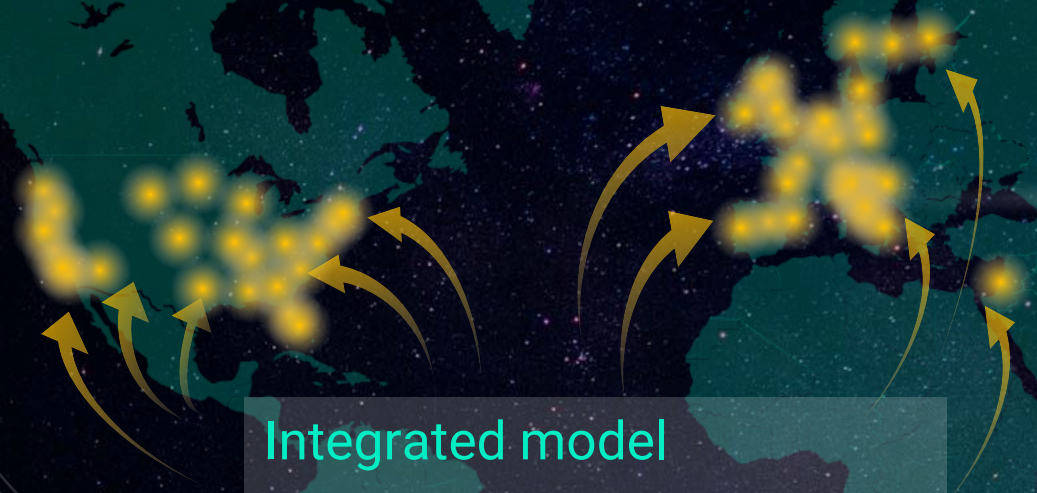
# EPP Commercial Market

## Uniform pricing policy per jurisdiction

- Equitability, transparency
- No rebates, no discounts

## 45.5% revenue CAGR

6 years to 30 June 2022



## Integrated model

- Direct distribution network
- Market access
- Price negotiations

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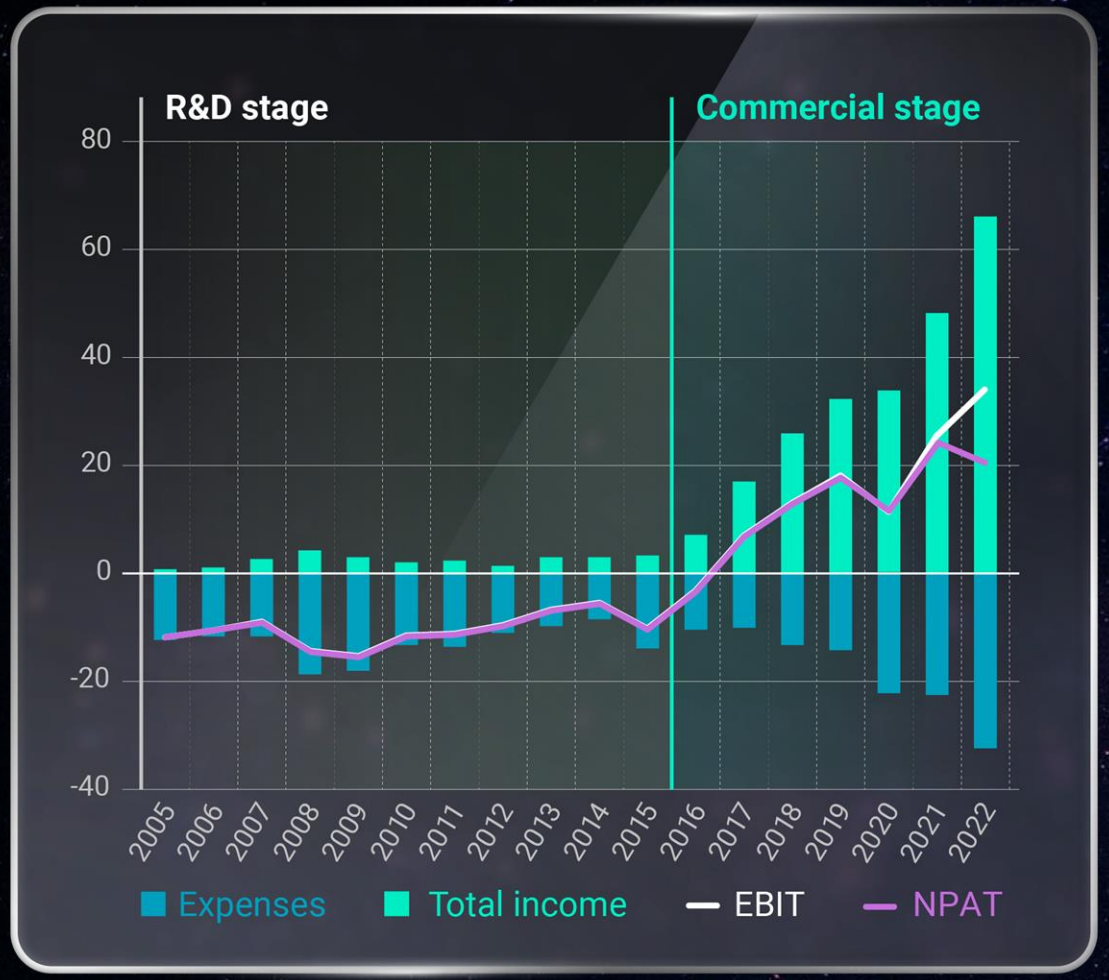
# Financials 2005 – 2022




| | |
|---|---|
| FY'22 dividend: | **10% of net profit** |
| <300% dilution | |
| ROCE 27% | (6yrs) |
| Cash reserves: | AUS **$121m** (30 June '22) |
| Expenses: | AUS **$55.5m** (FY '21-22) |
| | AUS **$175m** (FY '21-25) |

| Nasdaq '22* | Bio-pharmaceuticals | Profitable |
|---|---|---|
| Main board | 798 | 67 (8.4%) |
| NBI | 274 | 25 (9.1%) |
| ASX | 91 | 3 (3.2%) |

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# Summary

## Pharmaceuticals

| | | |
|---|---|---|
| 1 | Stroke – reduction in penumbra, NIHSS | (1 trial) |
| 2 | Xeroderma pigmentosum – assisted DNA repair | (3 trials ongoing) |
| 3 | Vitiligo - afamelanotide monotherapy + combination therapy | (2 trials) |
| | I. SCENESSE® | commercial US-EU-CH-IS |
| | II. PRÉNUMBRA® | in manufacturing |
| | III. NEURACTHEL® | in manufacturing |

## Healthcare Solutions

| | | |
|---|---|---|
| A | R&D: 4 OTC product lines | CYACÊLLE (1st product) |

## Communications Program

| | | |
|---|---|---|
| 1 | IR, traditional roadshows, conferences | meeting cycles p/a |
| 2 | targeted events | global events, soirées |
| 3 | CBM team established | increased social media |

## Finance

| | | |
|---|---|---|
| | stability, counter cyclical buffer | financial discipline |

## CATALYSTS 2022-2023

XP/DNA repair read out Ph II

Start Ph II trial vitiligo

Start Ph II stroke high/freq dosing

I. SCENESSE® expansion adolescents

II. PRÉNUMBRA® to be used in stroke

III. NEURACTHEL® manufacturing

## HEALTHCARE SOLUTIONS

Launch CYACÊLLE

## COMMUNICATIONS

6 – 8 cycles next 12 months

13 events in 16 months

Increased social media CUVA/CUVIPs

## FINANCE

Growth

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

**Head of Investor Relations**

Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

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