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# CLINUVEL UPDATE: FINANCIAL PERFORMANCE AND STRATEGIC INITIATIVES

*Non-Deal Roadshow*

*Melbourne and Sydney, 27-28 February 2020*

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CLINUVEL PHARMACEUTICALS LTD  
ASX: CUV  
Nasdaq Int'l: CLVLY  
XETRA-DAX: UR9



CLINUVEL

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and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure to retain or attract key personnel and managerial talent; the impact of broader changes 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 2019 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.

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## CLINUVEL: Snapshot

- Specialty pharma
  - Develop and deliver novel treatments for severe genetic & skin disorders (unmet medical need)
- Developed and commercialised world's first systemic photoprotective drug, SCENESSE® (NME)
  - US & EU approved for EPP - rare genetic disorder, intolerance to visible light
- Self-distribution model Europe - USA next
- Fourth year profitable operations
- Product development pipeline supports future growth



## Approved Indication: Erythropoietic protoporphyria (EPP)

- Lifelong metabolic genetic disorder
  - FECH deficiency 18q21 in the haem biosynthesis pathway
- Intolerance to light
  - (blue/green/UV, peaking at 408nm)
- Phototoxicity – painful anaphylactoid reactions and burns
- Causes social isolation, anxiety and fear
- Rare disorder, not well characterised
  - Prevalence 10,000 worldwide
- One approved treatment therapy



Phototoxic reactions in EPP patients.  
Top image courtesy of the KE family.  
Bottom image courtesy of the patient.





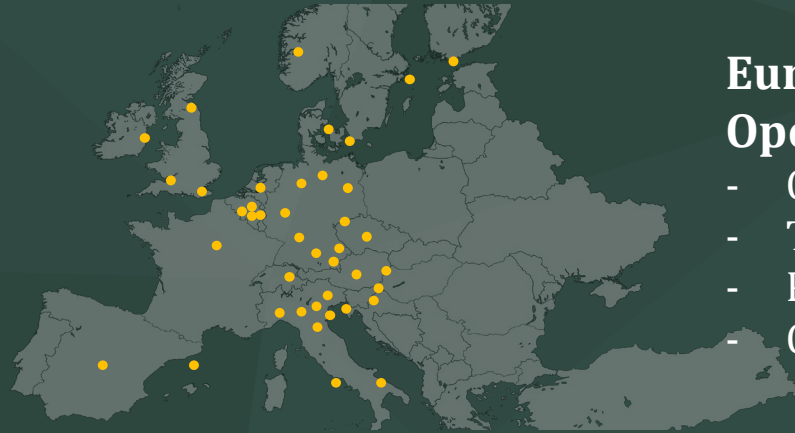
## Approved Treatment: SCENESSE<sup>®</sup> (afamelanotide 16 mg)

- World's first systemic photoprotective drug
- Afamelanotide induces melanogenesis, provides photoprotection
- Regulatory approval EU and USA
- Injectable implant every 60 days
- Rigorous pharmacovigilance EU
- Satisfactory real-world safety and effectiveness data
- Treatment continuation 94%



# Distribution Update: SCENESSE<sup>®</sup> for EPP

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**European Operations**

- Countries
- Treatments
- Patients
- Centres



**US Journey Pending**

## CLINUVEL SELF-DISTRIBUTION MODEL

- Long term shareholder return – not diluted by cost of licensing
- Relationship development - direct distribution to hospitals and doctors
- Controlled distribution - preferred by regulator
- Facilitates thorough patient safety profile – via rigorous pharmacovigilance

**ECONOMICS and PRACTICALITY**

## CLINUVEL GLOBAL UNIFORM PRICE

- Policy grounded in CLINUVEL's values of transparency, equity and fairness
- Social and political focus on lower drug prices
- Equitable treatment of all payors, hospitals and patients
- US Politics “no price rise higher than inflationary rate” [Prescription Drug Pricing Reduction Act, 2019]

**CLINUVEL LEADING THE WAY**

## Key Milestones

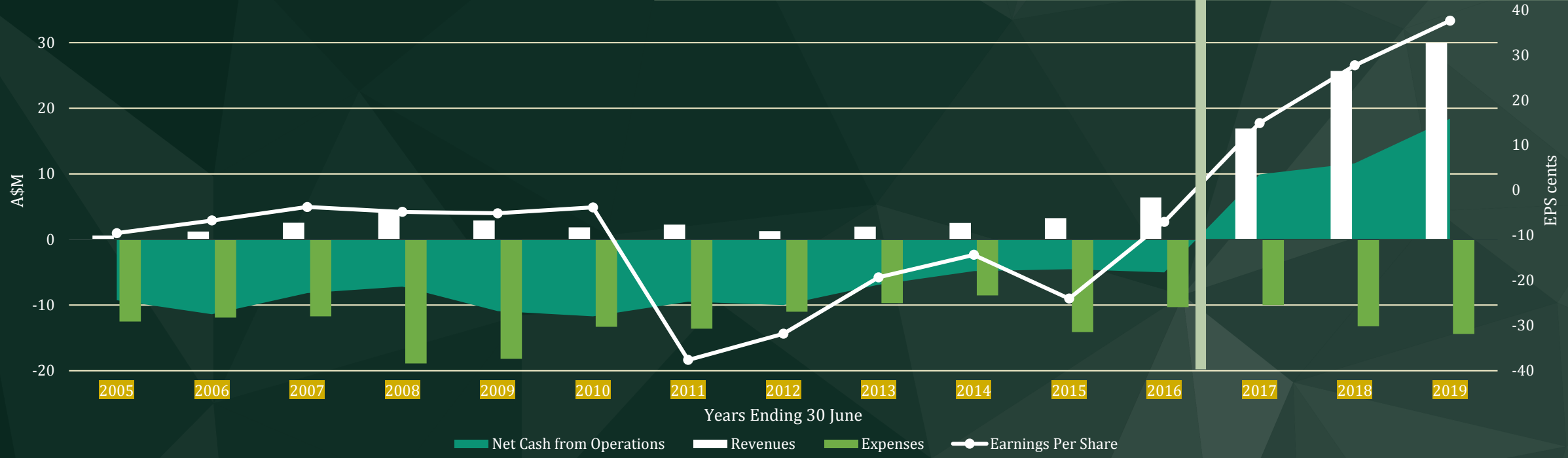
- 2005 • New executive management team, focus on medicinal photoprotection
- 2006 • First EPP study, Switzerland
- 2007 • First cross-over design study
- 2009 • IND approved by US FDA, commenced confirmatory Phase II/III studies USA/EU, first EPP study published in *New England Journal of Medicine*
- 2010 • Listing Italian 648/96 program, SCENESSE® supplied and reimbursed, financial proof of concept
- 2012 • Expansion of reimbursement program under special access in Switzerland
- 2013 • Positive results in final Phase III US study
- 2014 • European marketing authorisation - approved October, ratified December
- 2015 • Confirmatory Phase III USA/EU studies published in *New England Journal of Medicine*
- 2016 • First commercial launch, Europe
- 2019 • FDA approval, 8 October
- 2006-2019 • SCENESSE® maintains positive safety profile
- 2016-2019 • European commercial distribution, acceptance as standard of care for EPP



# Financial Dynamics

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R&D 2005-2016	COMMERCIAL 2017-2019
- cost-management	- cost-management
- self-arranged equity financing	- cash positive
- never below critical cash	- profitable
- financial proof of principle 2010	- debt-free
- R&D cost SCENESSE <sup>®</sup> , A\$153.5m	- dividend FY18 & FY19



Note: CUV continues quarterly reporting of cash flows; these reflect seasonal fluctuations due to cyclical treatment demand

## Checkpoint in CLINUVEL's Journey

- Progressing a longstanding strategy
- European business generated record profit (A\$18.1m FY19)
- Positioning for sustainability by investing in the business to support future growth
- FDA approval (October 2019) of SCENESSE® for EPP enables:
  - expansion into USA; and
  - progression of product pipeline
- Evolving to an integrated biopharmaceutical business for sustained long-term growth
  - various business functions executed in-house
  - treatments for multiple indications

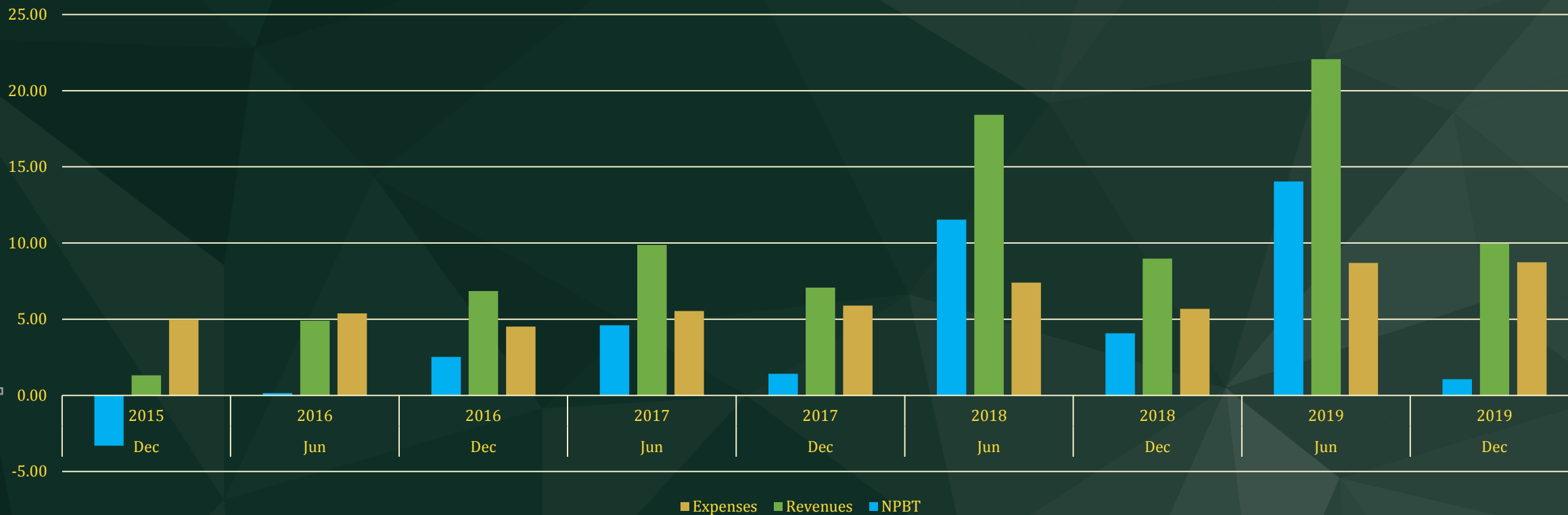
## Financial Results: Half Year Ended December 2019

- Revenues
  - 11% growth
- Expenses
  - Increased investment across the business, including manufacturing supply and distribution, marketing and personnel
- NPBT
  - Eighth consecutive half year profit
- Cash Balance
  - Solid foundation to finance growth

Key Financials	December 2019	December 2018	Change, %
Revenues, \$m	9.971	8.981	+11
Expenses, \$m	8.741	5.683	-54
NPBT, \$m	1.059	4.075	-74
Cash, \$m	57.432	42.826	+34
Equity, \$m	58.027	43.128	+35
Cash from Operations, \$m	4.747	7.247	-34
Net Increase in Cash, \$m	3.186	6.102	-48
Basic EPS, cents	2.2	8.5	-74
Net Tangible Assets Backing per Share, \$	1.18	0.90	31

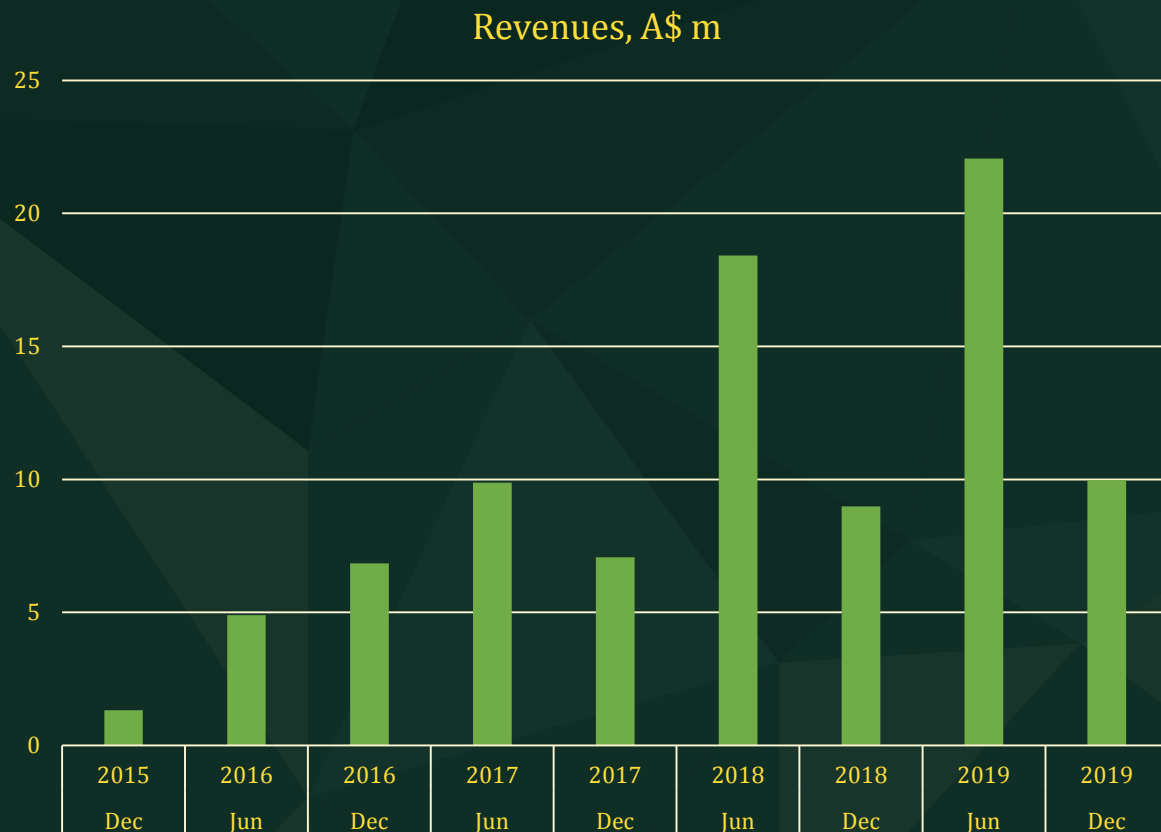
# Eighth Consecutive Half Year Profit Since SCENESSE® EU Launch

A\$m



Total revenues from operations, excludes other income. NPBT includes revenues and other income.

## Revenue Analysis: Half Year Comparison



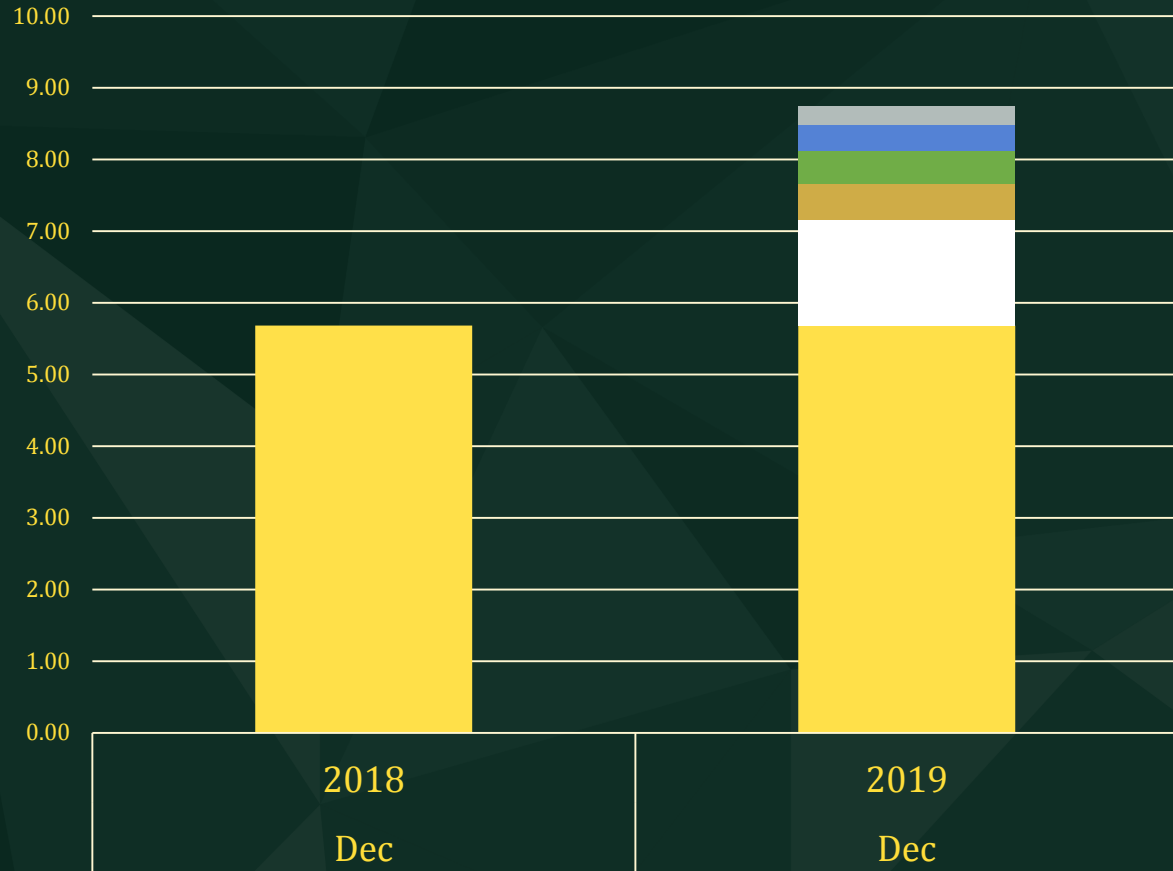
- Robust growth continues
  - 11% by value
  - 7% by volume
  - Dampened by timing of orders
- Price stable, some exchange rate impact
- Seasonally lower half
- Stable retention of patients in countries supplied



# Expense Analysis: Half Year Comparison

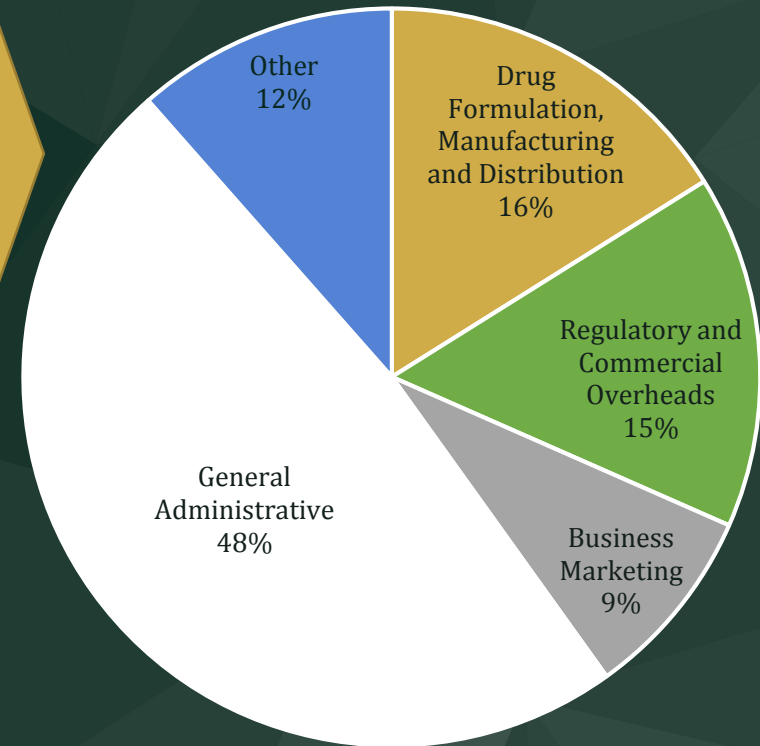
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Expenses, A\$ m



Increase of A\$3.06m

% Breakdown of Incremental Expenses



# Strategic Initiatives 2020

## GROWTH EUROPE

- Fourth year of commercial operations
- Increase patient treatment access
  - existing and new countries and centres

## EXPANSION USA

- CEO lead executive implementation team
- Establish Business Infrastructure
- Expand US team
- Activate network of hospitals and doctors
- Negotiate reimbursement of treatment cost with insurers
- Planned sales by end 2020

## PROGRESS PIPELINE

- EPP
  - New regulatory approvals
  - Paediatric formulation
- Vitiligo
  - Skin depigmentation disorder
  - 0.5-2% prevalence
  - Phase II studies - promising results
- Topicals
  - Pharmaceutical use
  - OTC products
- Medicinal Photoprotection
  - Effectiveness of melanocortins

## INORGANIC GROWTH

- Open to value adding opportunities
- Synergistic benefits
- Management to complement CLINUVEL team and culture

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# SCENESSE® for Vitiligo



Day 0  
Baseline

Day 55  
After 15 NB-UVB  
treatments, 1 implant

Day 111  
After 27 NB-UVB  
treatments, 3 implants

Day 176  
After 40 NB-UVB  
treatments, 4 implants

## Original Investigation

# Afamelanotide and Narrowband UV-B Phototherapy for the Treatment of Vitiligo A Randomized Multicenter Trial

Henry W. Lim, MD; Pearl E. Grimes, MD; Oma Agbai, MD; Iltefat Hamzavi, MD; Marsha Henderson, MD;  
Madelaine Haddican, MD; Rita V. Linkner, MD; Mark Lebwohl, MD



## VITILIGO JAMA Study

2 Groups:

Light Therapy

Light Therapy and Afamelanotide

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INSIDE YOUR  
HEALTH



# Product Pipeline



- EPP
  - TGA reviewing SCENESSE® for EPP in Australia
  - Developing paediatric formulations

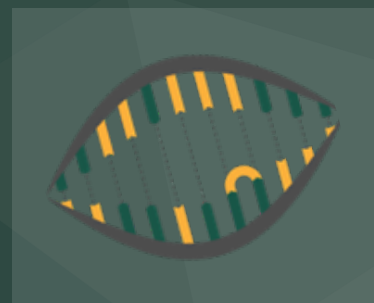
SCENESSE® Enfance 



- Topicals
  - Focus of Singapore subsidiary, VALLAURIX
  - Pharmaceutical application for vitiligo
  - Developing OTC skin care products



- Vitiligo
  - Type C Guidance meeting with FDA requested
  - Larger Phase IIb study in US planned



- Medicinal Photoprotection
  - Assessing effectiveness of melanocortins
  - New indication soon

# THANK YOU

*...Questions*

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