CLINUVEL UPDATE: FINANCIAL PERFORMANCE AND STRATEGIC INITIATIVES

Non-Deal Roadshow

Melbourne and Sydney, 27-28 February 2020

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CLINUVEL PHARMACEUTICALS LTD
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CLINUVEL

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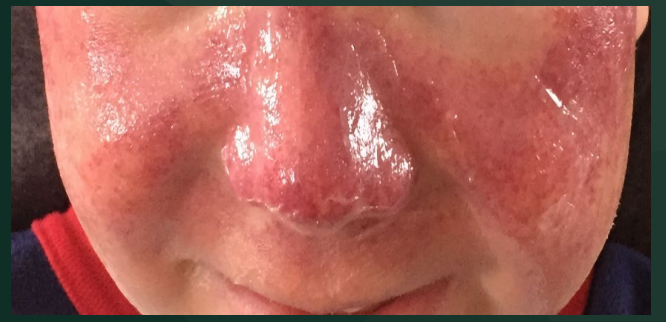
CONTENTS

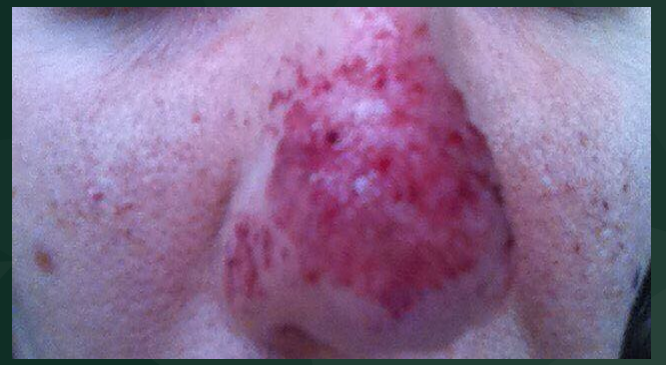
CLINUVEL: Snapshot

- 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



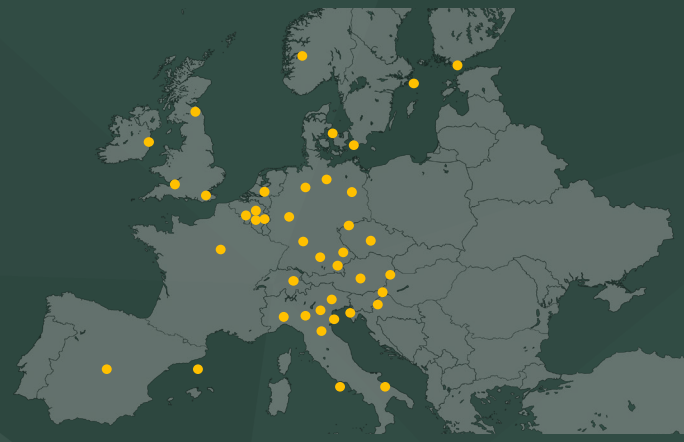


Phototoxic reactions in EPP patients.
Top image courtesy of the KE family.
Bottom image courtesy of the patient.

Approved Treatment: SCENESSE ® (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® for EPP



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

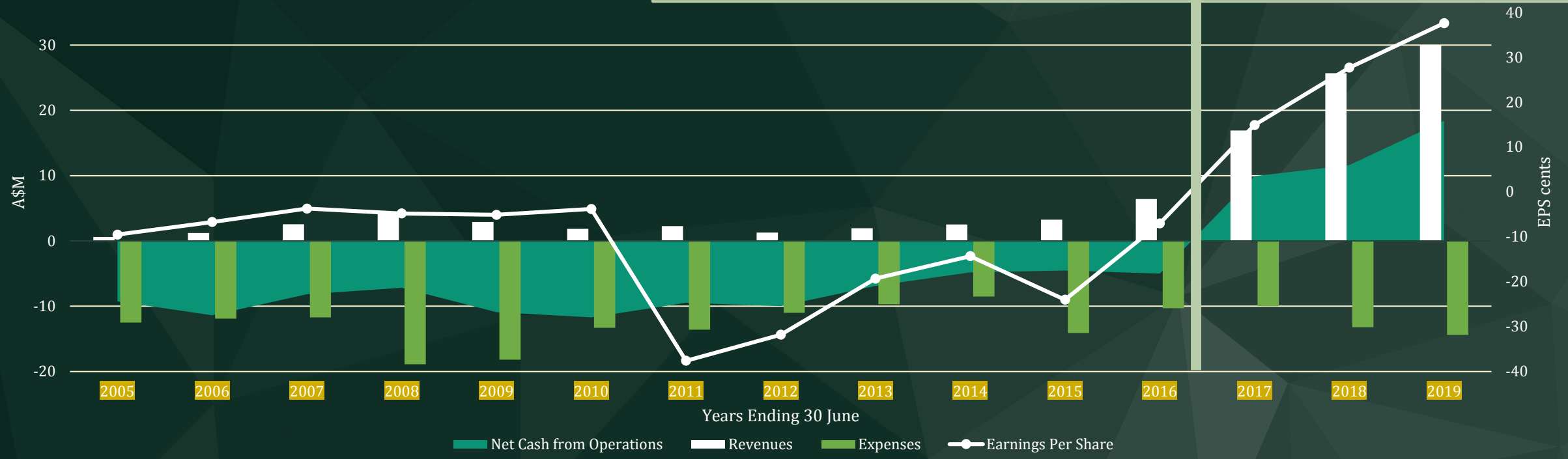
Financial Dynamics

R&D 2005-2016

- cost-management
- self-arranged equity financing
- never below critical cash
- financial proof of principle 2010
- R&D cost SCENESSE®, A$153.5m

COMMERCIAL 2017-2019

- cost-management
- cash positive
- profitable
- debt-free
- 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

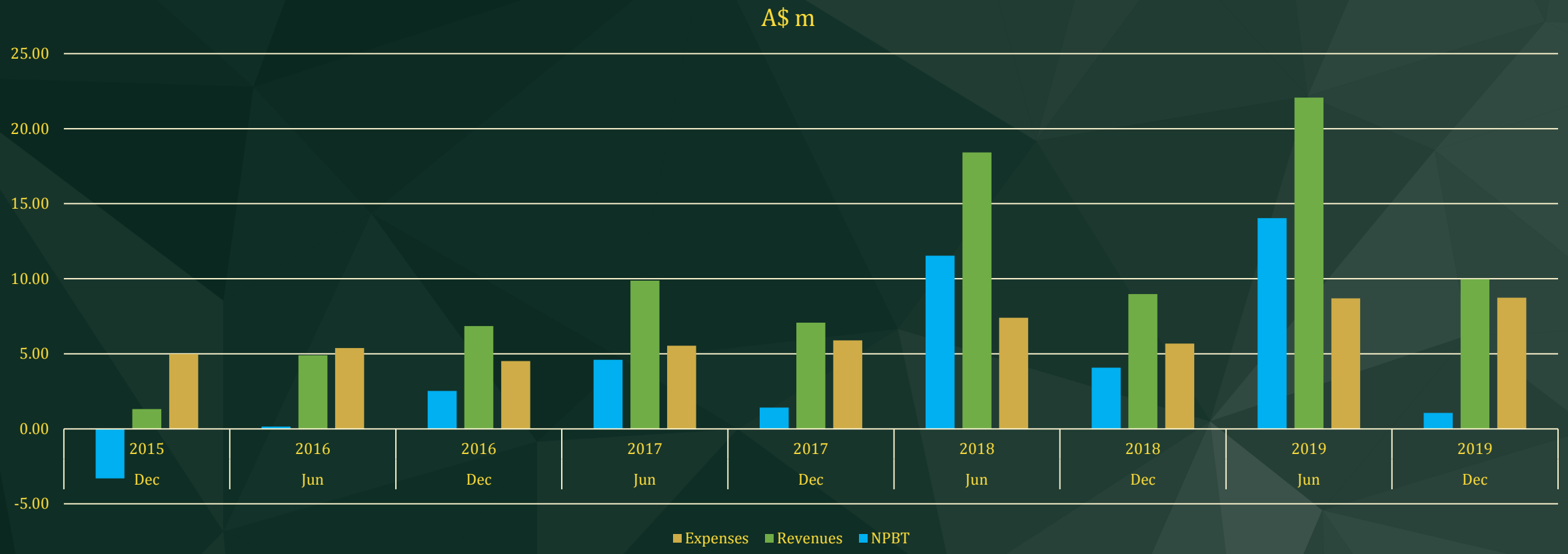
Financial Results: Half Year Ended December 2019

- 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

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

Eighth Consecutive Half Year Profit Since SCENESSE® EU Launch



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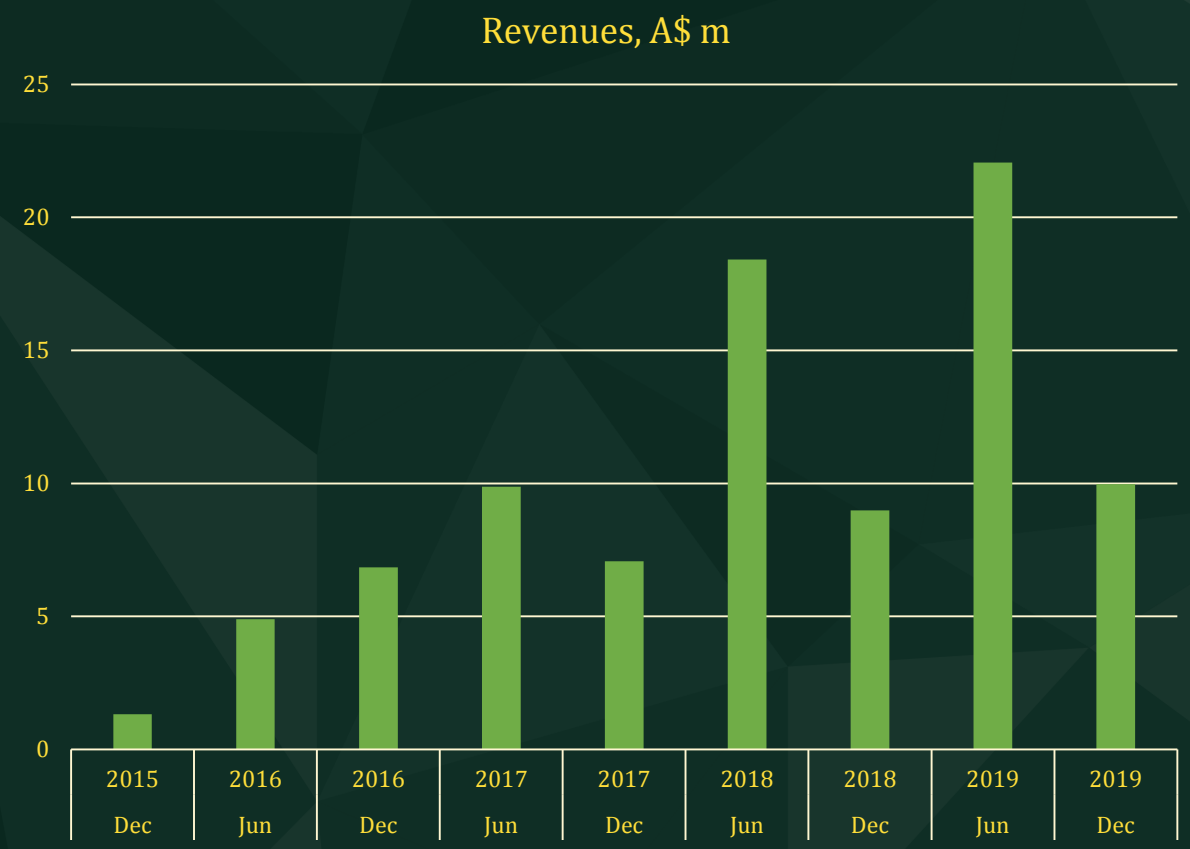
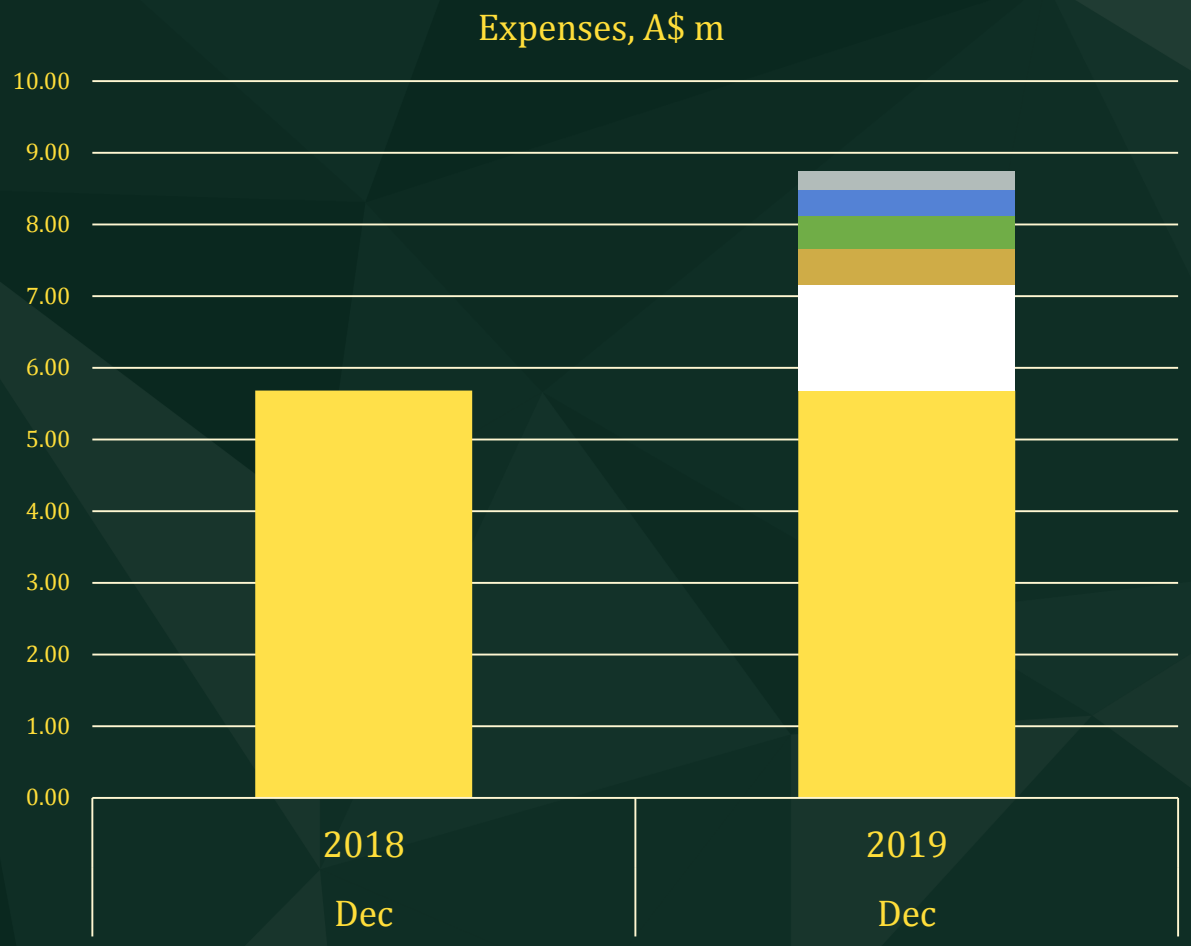
Revenue Analysis: Half Year Comparison



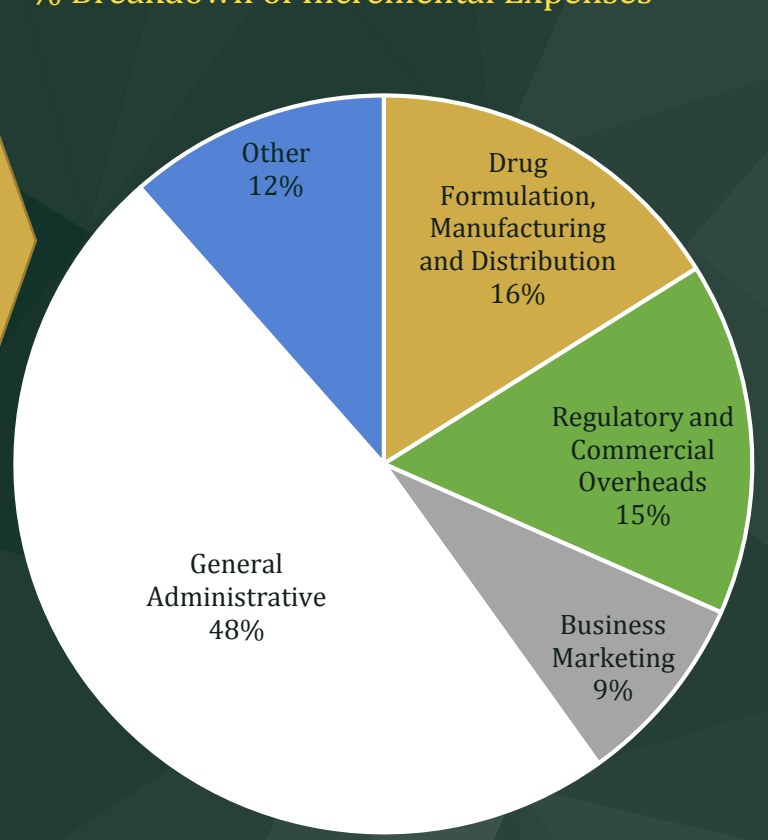
- Robust growth continues
  - 11% by value
  - 7% by volume
  - Dampened by timing of orders
- Price stable, some exchange rate impact
- Seasonally lower half
- Stable retention of patients in countries supplied

Total Revenues from operations, excludes other income.

Expense Analysis: Half Year Comparison



Increase of A$3.06m



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

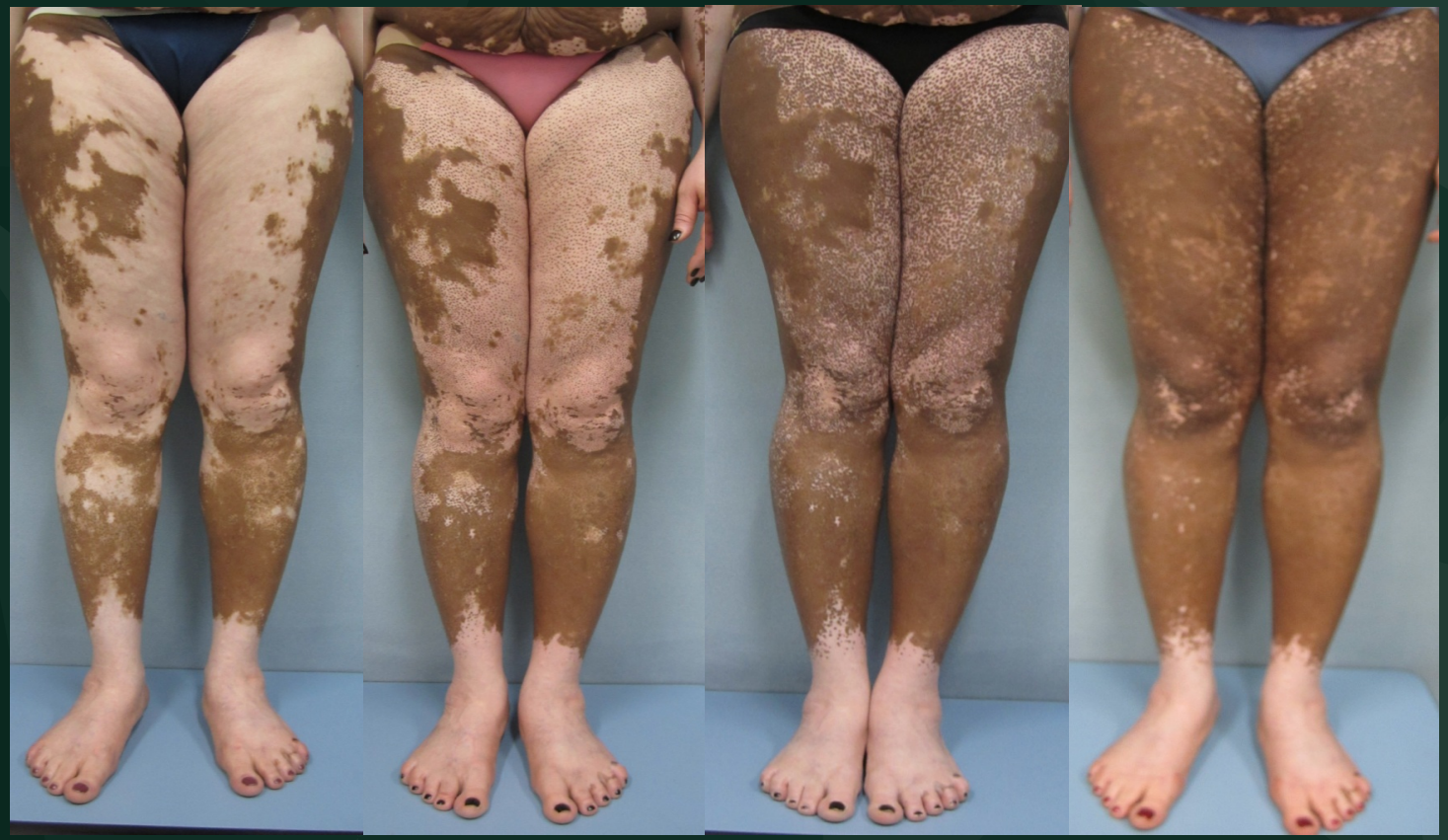
PROGRESS PIPELINE

- 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

SCENESSE® for Vitiligo



Day 0
Baseline

Day 55
After 15 NB-UVB
treatments, 1 implant

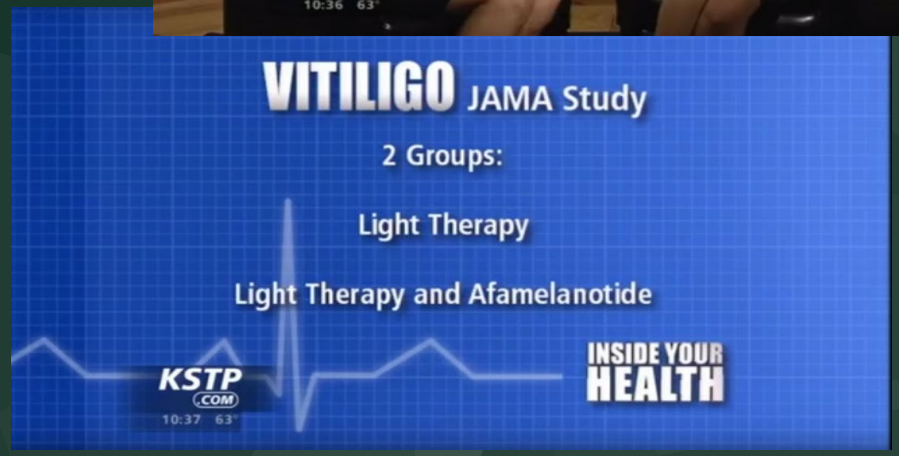
Day 111
After 27 NB-UVB
treatments, 3 implants

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

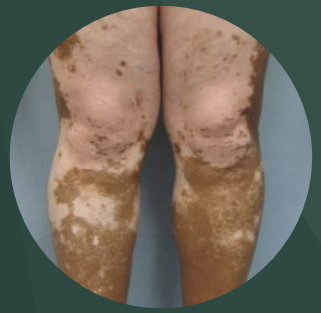


Product Pipeline

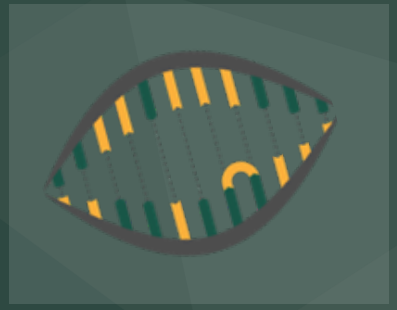
- EPP
  - ➢ TGA reviewing SCENESSE® for EPP in Australia
  - ➢ Developing paediatric formulations

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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Authorised for ASX release: Managing Director on behalf of CLINUVEL PHARMACEUTICALS LTD

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