PIONEERING A NOVEL MEDICAL CONCEPT

CLINUVEL: from concept to commercialisation

04 April 2019

CLINUVEL PHARMACEUTICALS LTD
Darren Keamy, CFO

ASX: CUV
Nasdaq Int'l: CLVLY
Xetra-Dax: UR9

CLINUVEL

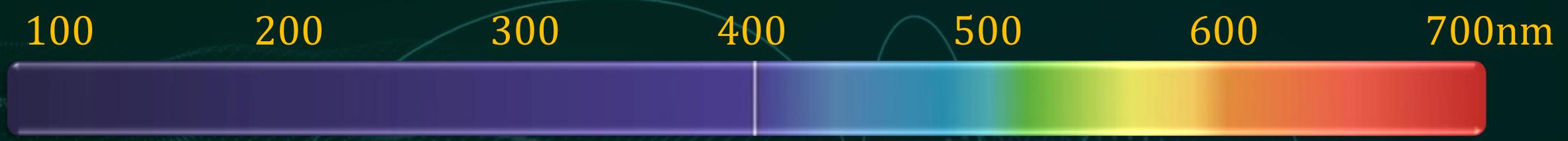
Safe harbour statement

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, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results 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 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® 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 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 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 2018 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 the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

CLINUVEL

- Pioneers of new medical concept – medicinal photoprotection
- Approved orphan product (NME) in Europe – SCENESSE®
  - First sales 2016
  - Generating Real World Evidence under “PASS”
- SCENESSE® PDUFA date 8 July
- Profits generated FY2017, FY2018
- Translational use and growth
  - Orphan indications and pigmentary disorder vitiligo (skin types IV-VI)
  - 2nd generation melanocortins – Rx
  - OTC products for larger audience

Health impacts of environmental and artificial light



<400nm: ultraviolet light

- Acute and chronic skin damage (cancer)
- Activates vitamin D production

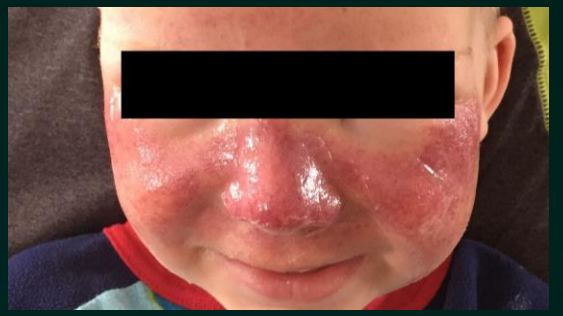
400-700nm: visible light

- Long-term health impacts not well understood

Video – erythropoietic protoporphyria

Erythropoietic protoporphyria (EPP)

- Rare metabolic disorder, 1:140,000
- Poorly understood and characterised disease
- Intolerance to blue/green/UVA/UVB light
- Phototoxicity – incapacitating anaphylactoid reactions and burns
- High unmet medical need (no alternative therapy)



Phototoxic reaction in an EPP patient.
Image courtesy of the Koerner family.

SCENESSE® (afamelanotide 16mg)

- New molecular entity (NME)
- Novel controlled-release injectable implant
- Stimulates melanin in skin to protect patients from light, prevent reactions
- Dosed every two months in spring and summer

- First-in-class application of peptide in treatment therapy for erythropoietic protoporphyria (EPP)
- World first systemic photoprotective

Afamelanotide has radically changed the way I approach my daily life…

This medicine has freed me from the debilitating consequences of EPP and from fear of suffering them.

Swiss erythropoietic protoporphyria (EPP) patient representative of 98.5% treatment continuation

SCENESSE® – Real World Evidence

- European patients in third year of post-authorisation treatment
- Data captured under Phase IV “PASS”
- Long-term treatment experience from clinical trials to post-authorisation use
  - Special access schemes since 2010
  - >5,100 doses to EPP patients across global program (>8,400 doses in total)
  - Cohort of EPP patients treated >10 years, >50 doses
- Safety profile maintained
  - Most common adverse reactions: nausea, headache, flushing
- Treatment continuation >95%
- RWE compiled for FDA submission, PDUFA date 8 July 2019

Orphan drug addressing unmet need in Europe

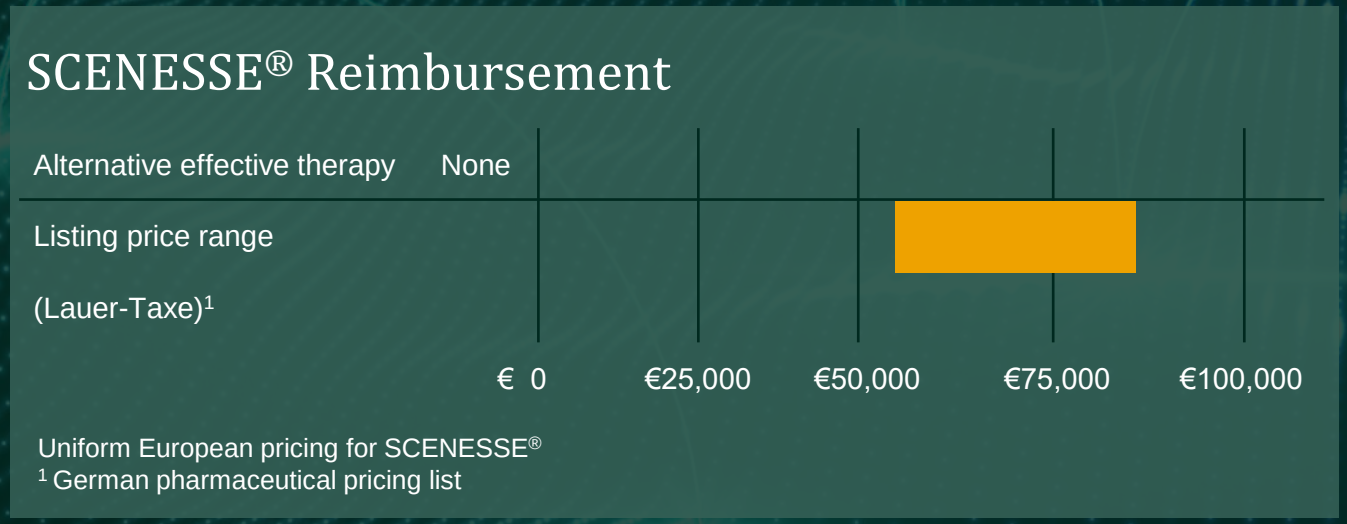
SCENESSE® accepted as standard of care for EPP in European nations

- 17 countries with known EPP patients, product being made available in up to 9 in 2018-19
- Ongoing supply under special access scheme in Switzerland

Commercial roll out with dedicated, specialised team

- Functions across pharmacovigilance, QA, clinical, regulatory, market access
- Cost effective model to be replicated in USA

- Uniform pricing strategy



SCENESSE® in vitiligo (1)

FACTS

- prevalence ~1%
  - addressable market 20-30%
- expression
  - generalised vs non-segmental
- pathophysiology
  - auto immune response
- standard of care
  - NB-UVB, mc transplants
  - steroids, mTOR-inhib.
- poor response rates[2]
  = unmet medical need

EFFECTIVENESS

CUV103 [2018]
CUV102 [2013]

- extent or repigmentation
  VASI ($p<0.025$)
- face: time to repigmentation
  ($p=0.01$)
- anatomical locations

- Clinical Objectives
  1. repigmentation face/H&N
  2. follicular response

MODE OF ACTION

Hypothesis 1

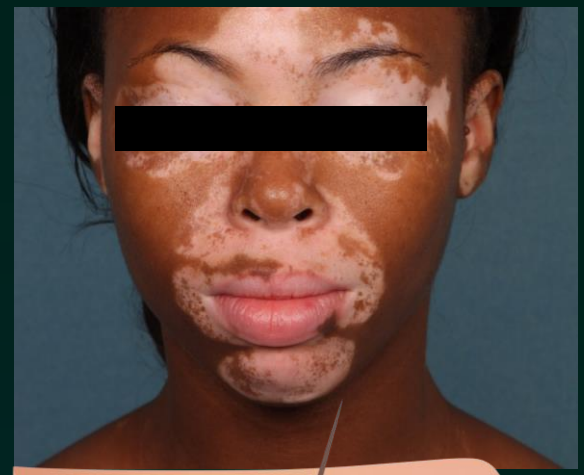
SCENESSE® + NB-UVB activates

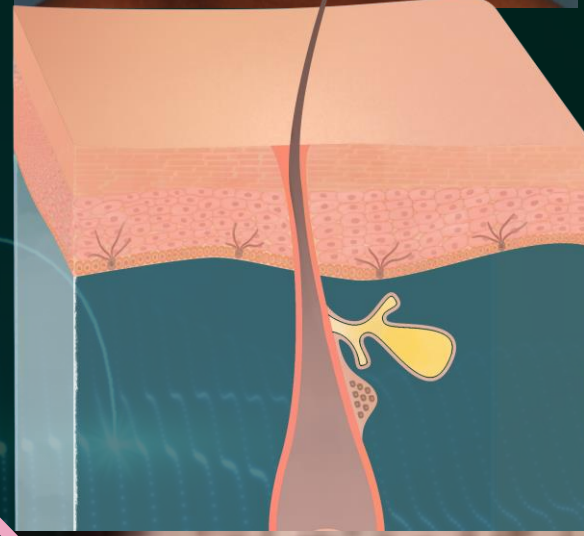
- differentiated stem cells
- melanoblasts to migrate
- **follicular repigmentation**

Hypothesis 2

SCENESSE®

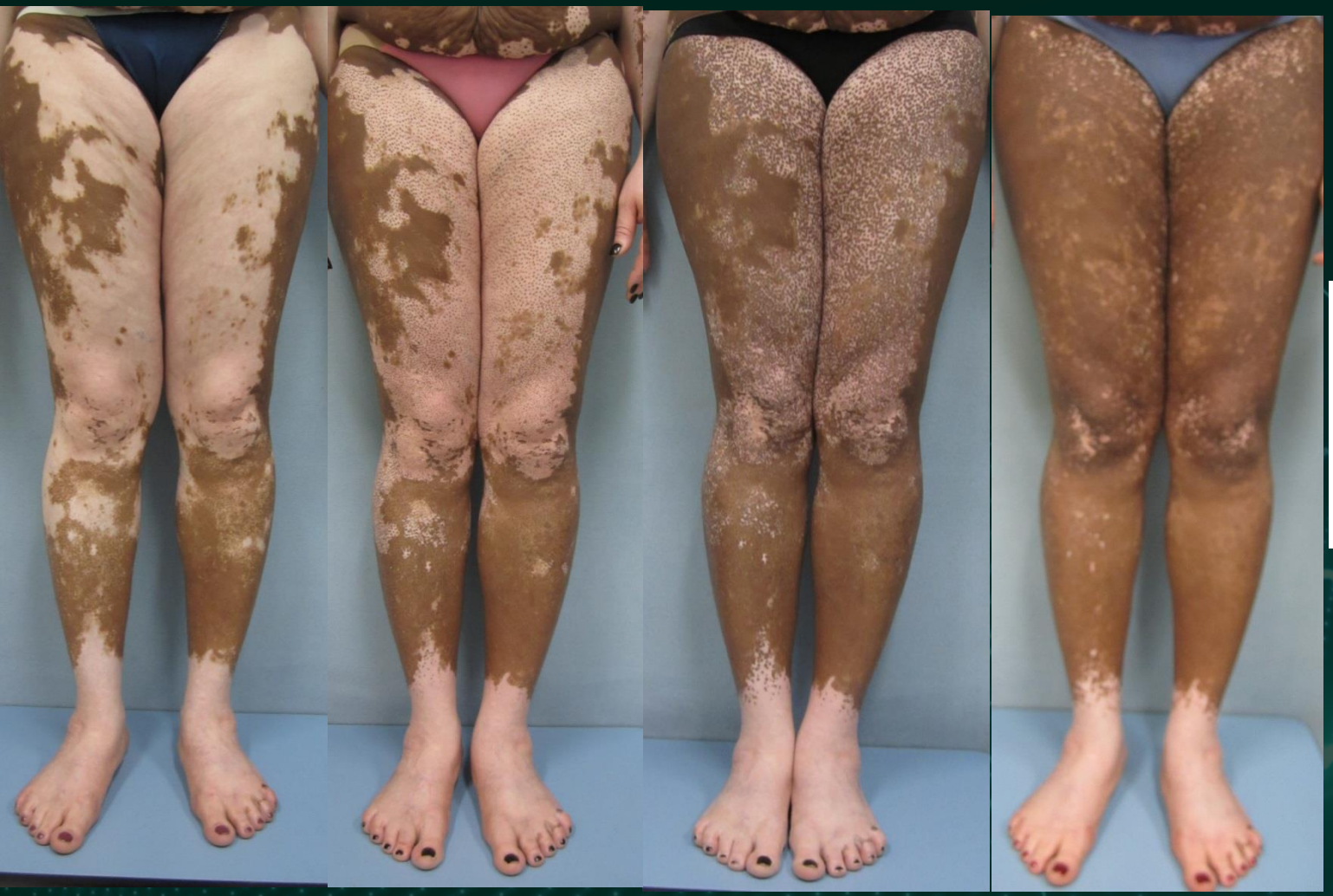
- monotherapy is effective





[1]*Ezzedine et al. Vitiligo. The Lancet, 2015.*
[2]*Rodrigues et al. Current and emerging treatments for vitiligo. JAAD, 2017.*
Patient images courtesy of Phase II vitiligo study medical specialists

SCENESSE® in vitiligo (2)



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

CLINUVEL Group - business growth

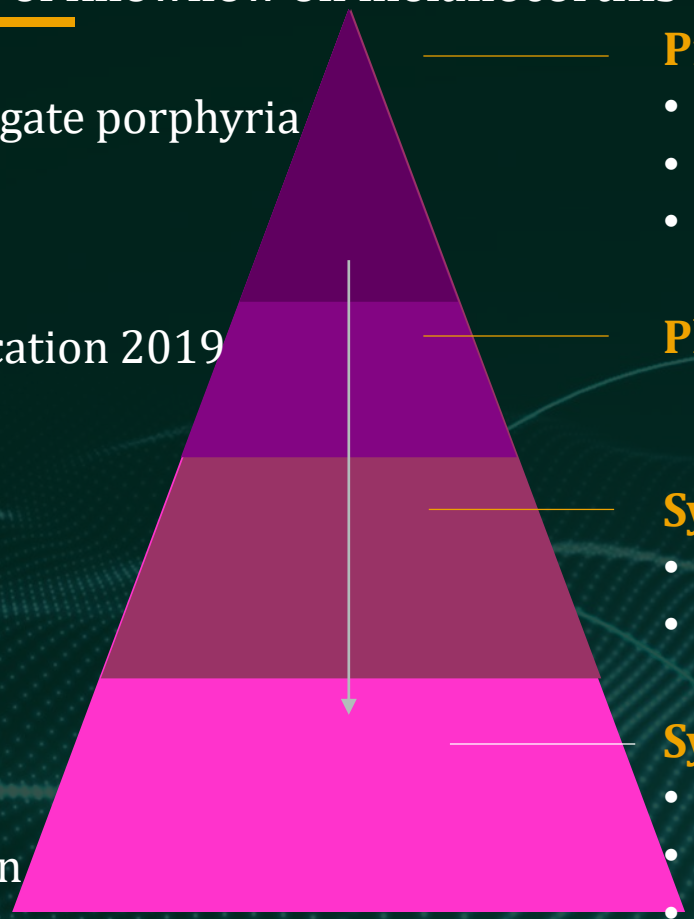
Flow of knowhow on melanocortins

EPP, variegate porphyria

New indication 2019

Vitiligo

General population



Proof of concept - porphyrias (EPP) 1991- 2018

- Systemic protection, visible light (>408nm)
- Rare disorder 1:140,000
- Global disease registry

Photoprotection, DNA repair

Systemic repigmentation (total body)

- 1st pharma addressing loss of pigmentation
- Positive early safety/efficacy data

Systemic & topical photoprotection

- 2nd generation melanocortins
- Additional indications
- Complementary product lines – OTC

Most common “side effects”:

- nausea, headache, bruising at injection site, fatigue, flushing
- no new safety signals to date

positive safety profile

Dose regimen

1 resorbable subcutaneous formulation every 60 days

Product Pipeline

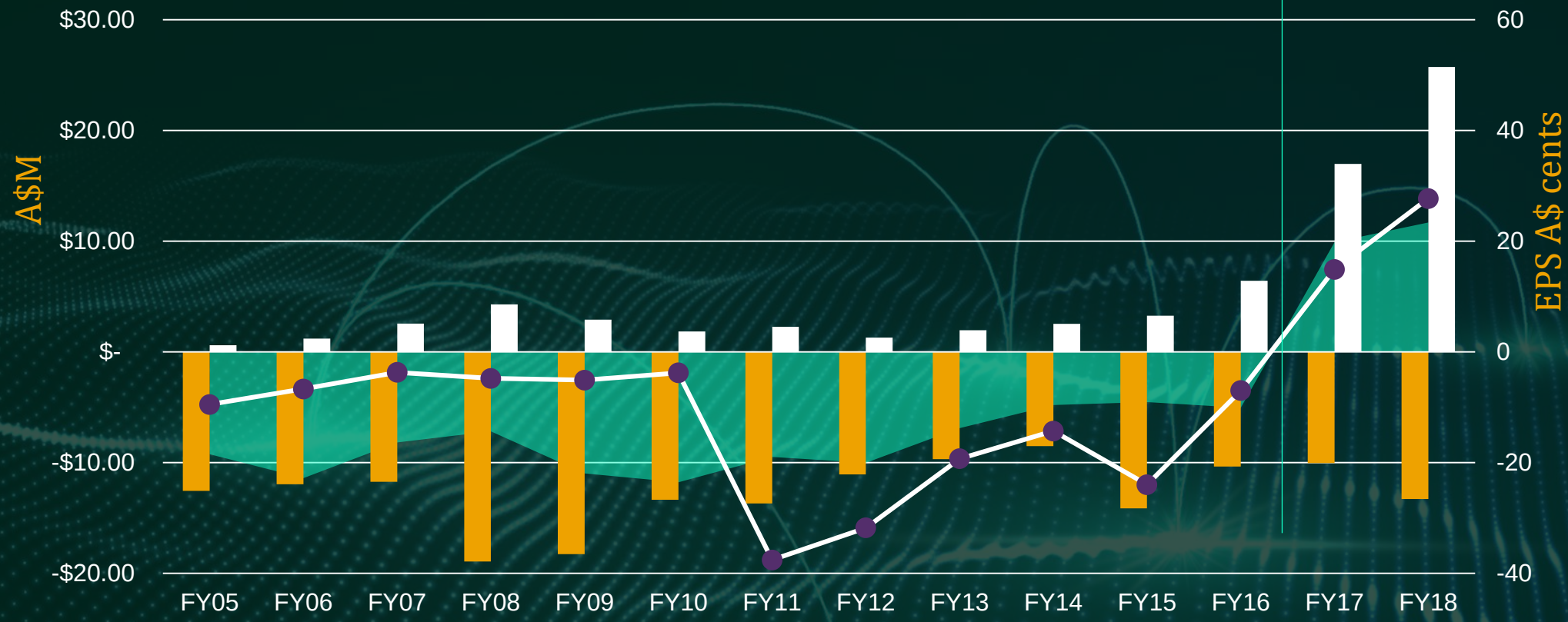
Financials

R&D 2005-2016

- cost-management
- equity financing
- financial proof of principle
- minimum cash reserves

COMMERCIAL 2016 ONWARDS

- cost-management
- cash positivity
- profitability
- growth
- no debt
- first dividend FY18



CUV continues quarterly reporting

Cash flow statement will reflect seasonal fluctuations due to cyclical treatment period

Summary – CLINUVEL

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- SCENESSE® PDUFA date set for 8 July
- Profits generated from EU sales FY2017, FY2018
- Future focus on translational use and growth to increase