THE NEXT GROWTH PHASE

Investor Briefing – Non-Deal Roadshow
March 2019
Melbourne – Sydney

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ASX: CUV
Nasdaq Int'l: CLVLY
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CLINUVEL

Safe harbour statement

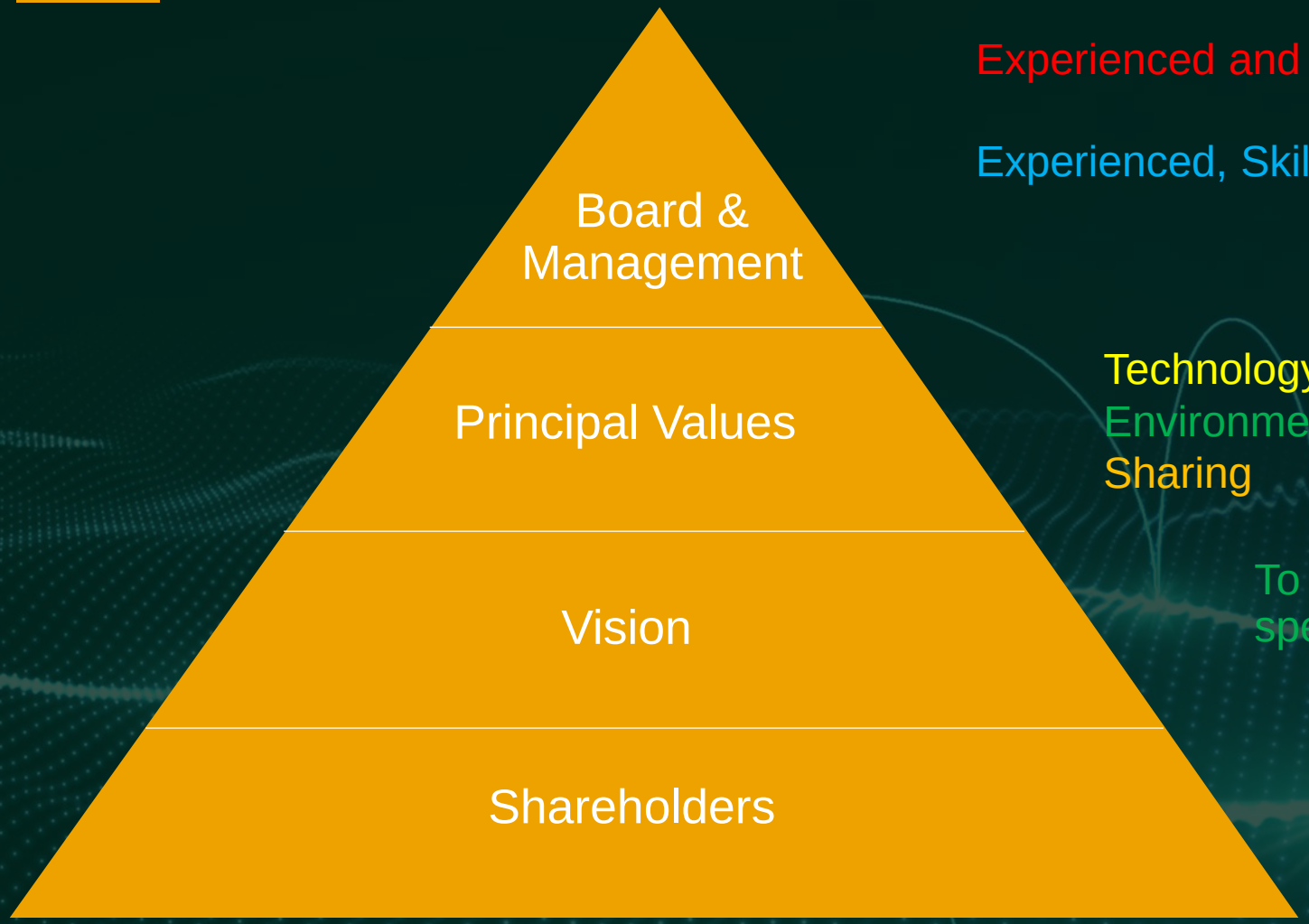
This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied 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.

Contents

Company Overview

- Developing and delivering treatments for patients with severe genetic and skin diseases
- Leader in melanocortins and expert in interaction of “light” and “skin”
- Foundations of business established
  - Navigated from R&D pharmaceutical product development to commercial operations
- Profitable commercial operations: Europe
- Ongoing R&D: new products, new clinical applications
- Melbourne HQ: global presence
- Next phase of expansion, growth

Execution of a Vision



Experienced and Cohesive Board

Experienced, Skilled, Committed Management & Staff

Technology, Respect & Appreciation, People & Environment, Approach, Knowledge Building & Sharing

To excel in scientific innovation in specialized domain

Core, long term, aligned with socially responsible strategy

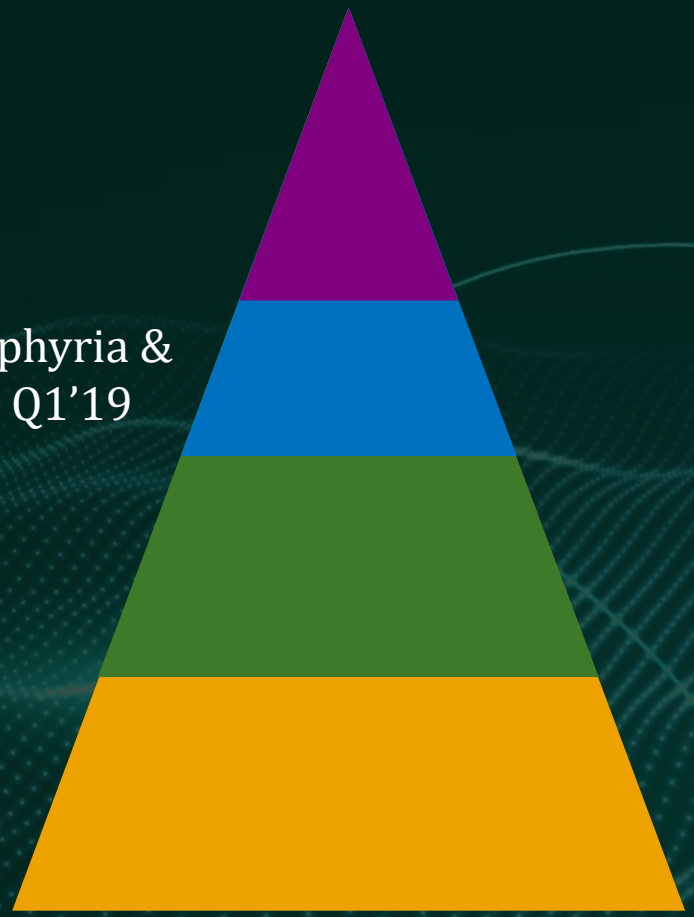
Medicinal photoprotection

EPP

Variegate porphyria & 2nd indication Q1’19

Vitiligo

General population



Proof of concept in porphyrias (EPP)

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

Photoprotection, DNA repair

Systemic repigmentation (total body)

- First pharma company to address loss of pigmentation
- Positive early safety/efficacy data

Systemic & topical photoprotection

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

SCENESSE® for EPP

- Erythropoietic protoporphyria (EPP)
  - Rare genetic disorder, affecting 1:140,000
  - Expressed as severe phototoxic “burns” and anaphylactoid reactions to light (~408nm)
- SCENESSE® (afamelanotide 16mg)
  - Novel controlled release injectable implant
  - Activates melanin in skin to protect patients from light, prevent reactions
  - Dosed every two months in spring and summer
  - >6,000 doses to >900 individuals
- First-in-class application of peptide in treatment therapy for EPP
- Foundation of the business: world first systemic photoprotective

SCENESSE® Pathway to Market

- December 2014 – European Commission ratified marketing authorisation in Europe
- June 2016 – product launch EU
- Safety focus Risk Management Plan & registry – rigorous pharmacovigilance programme for life
- Self-distribution EU
- Uniform pricing policy
- Real world experience to date – safety profile maintained, >95% treatment continuation year on year

Patient Testimonials:

- "SCENESSE® has really changed my life!"
- "With SCENESSE® my life has become so positive!"

CLINUVEL does not edit or moderate physicians' declarations or patient testimonies

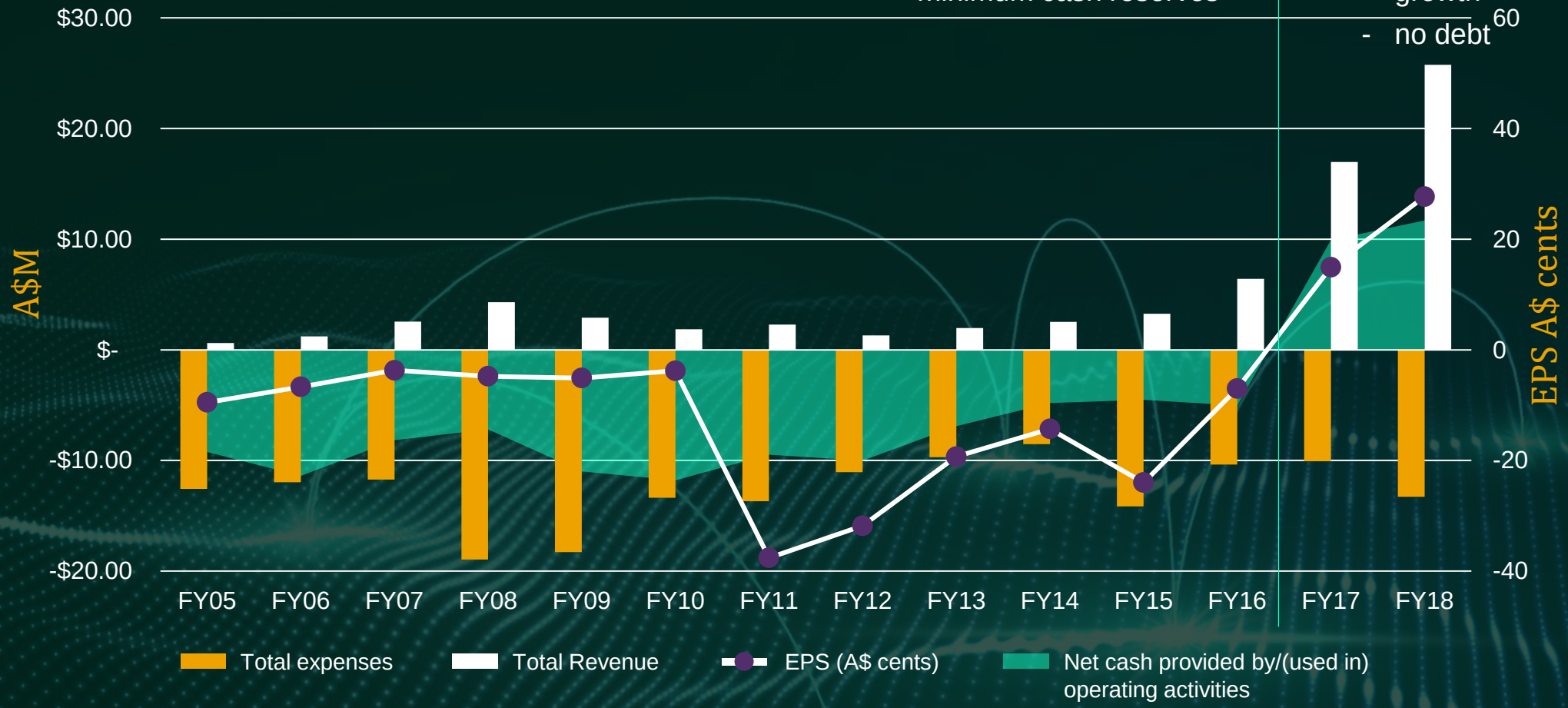
Financials

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



CUV continues quarterly reporting

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

FY2019 Half Year results

- The 6 months to 31 December 2018 were positive for CLINUVEL:
  - Revenues, $8.981m, up 27% on 6 months to December 2017
  - Expenses ($5.683m) responsibly managed in growth phase of the business
  - Net Profit, $4.076m, up 189% on 6 months to December 2017
  - Basic EPS, $0.085 representing growth of 283%

- Features of the half-year:
  - Seasonality of demand in Europe reflected in variability of quarterly cash flows
  - Payment of first unfranked dividend (A$0.02 per share, $0.957m total)
  - CUV in S&P/ASX 300
  - Focus to manage Brexit
  - Preparation for US expansion

What's Next?

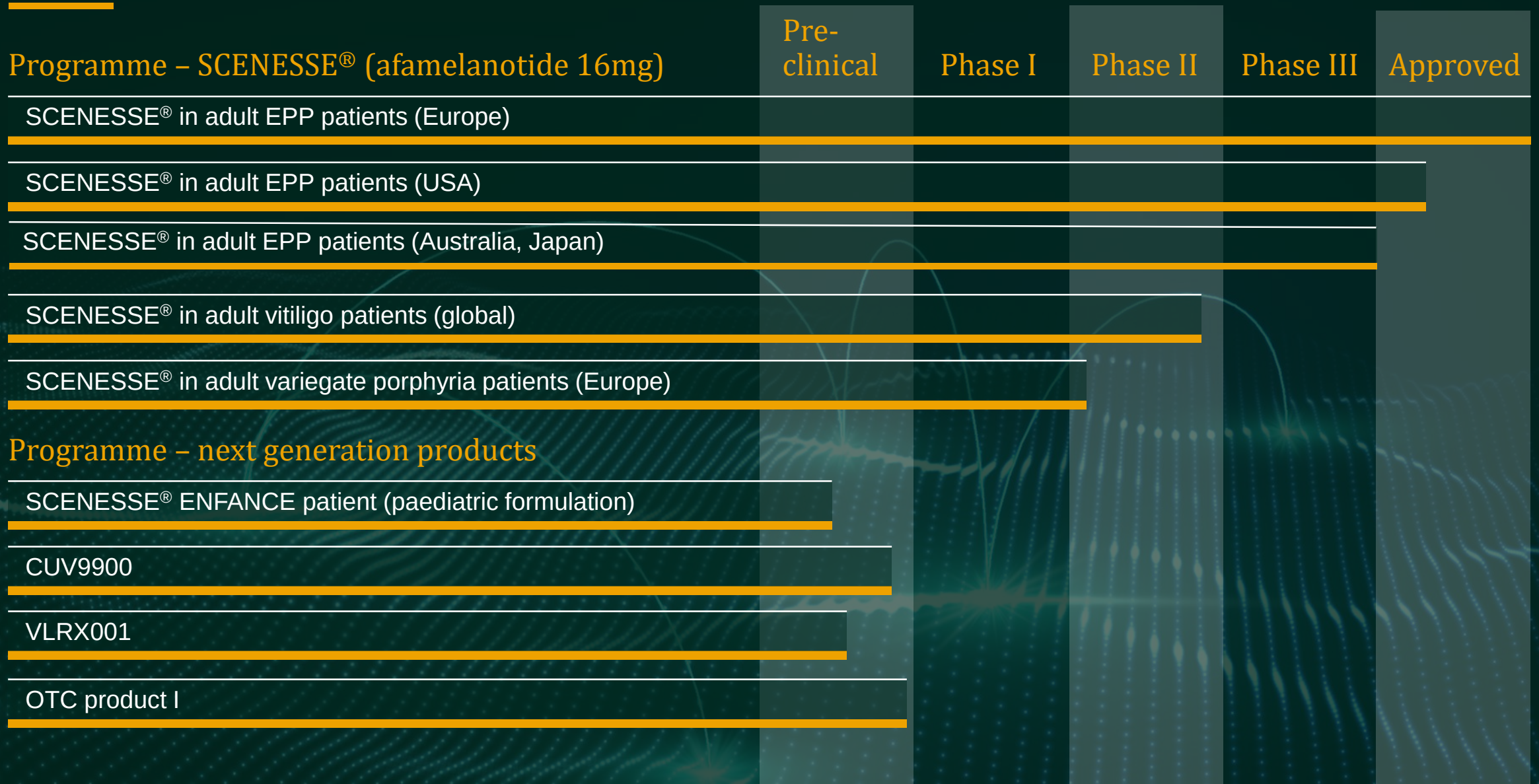
1. EU Expansion
   - Additional expert centres to meet patient & physician demand

2. US Expansion
   - PDUFA date – 8 July 2019
   - Approval would potentially double our EPP addressable market
   - Replicate EU operating model

3. Ongoing Progression of our Development & Regulatory Pipeline
   - SCENESSE® for EPP in other "tier 1" countries
   - SCENESSE® evaluation in variegate porphyria, vitiligo & new indications
   - Topical formulations of melanocortins for wider use

4. Evaluating inorganic growth opportunities

Product Pipeline



SCENESSE® in vitiligo

FACTS

- prevalence ~1%[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 analyses in progress

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

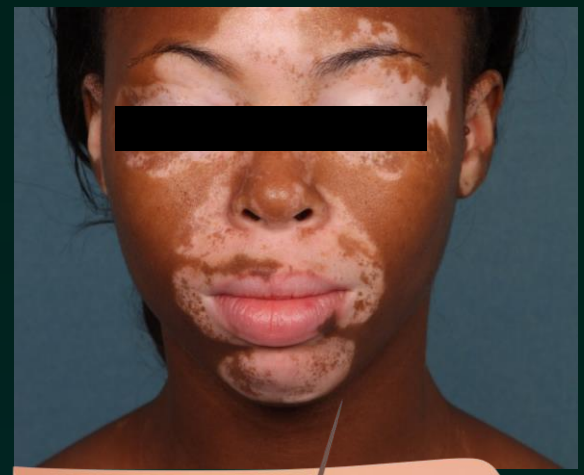
SCENESSE® + NB-UVB activates

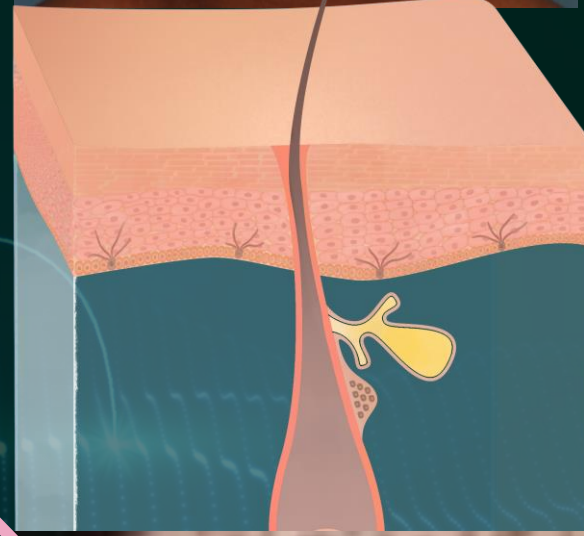
- differentiated stem cells
- melanoblasts to migrate
- **follicular repigmentation**

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.*

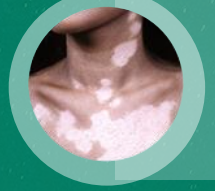
Patient images courtesy of Phase II vitiligo study medical specialists

SCENESSE® *NME world's first systemic photoprotective*

1988-2019

EFFECTIVENESS

EPP

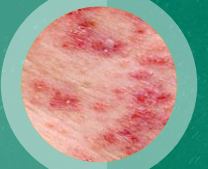


Vitiligo

- Human volunteers: melanogenesis
- reduction in apoptotic epidermal cells
- EPP: reduction in phototoxicity
  reduction in anxiety, increased freedom
- Solar Urticaria: reduction in wheal formation
- AK/SCC in OTRs: no malignancies
- Vitiligo: repigmentation

>1,200 patients exposed, ~8,200 doses

VP



Paediatric

- **TOXICOLOGY**
- **CLINICAL SAFETY**
- **LONG-TERM USE**
- **LONG-TERM MONITORING**

DNA REPAIR

PHOTOPROTECTION

SAFETY

World's first locoregional photoprotective

TOPICAL MELANOGENESIS

CUV9900

VLRX001

FIRST-IN-MAN

Summary

1. Foundations for growth established
2. Profit Trending Upward
3. Growth Outlook
4. 8 July 2019 – FDA: PDUFA date