



Company Announcement

CLINUVEL

NASDAQ INTERNATIONAL DESIGNATION VIRTUAL INVESTOR CONFERENCE PRESENTATION

Melbourne, Australia, and New York, USA, 20 September 2018

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION: CLVLY) presented to the Nasdaq Virtual Investor Conference on Wednesday 19 September. A copy of the presentation is appended. A webcast of the presentation can be found by [clicking here](#).

- End -

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at <http://www.epp.care>. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Switzerland, the US and Singapore, with the UK acting as the EU distribution centre.

For more information go to <http://www.clinuvel.com>.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

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Forward-Looking Statements

This release to the Australian Securities Exchange and to press may contain forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause CLINUVEL's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on

assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for SCENESSE®; that the FDA may not provide regulatory approval for any use of SCENESSE® or that the approval may be limited; that CLINUVEL may never file an NDA for SCENESSE® regulatory approval in the US; that the Company may not be able to access adequate capital to advance its vitiligo programs; that the Company may not be able to retain its current pharmaceutical and biotechnology key personnel and knowhow for further development of its product candidates or may not reach favourable agreements with potential pricing and reimbursement agencies in Europe and the US; 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.

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CLINUVEL PHARMACEUTICALS LTD

Nasdaq Virtual Investor Conference

New York, 19 September 2018

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ASX:
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Forward-looking statements, “safe harbor”

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 2017 Annual Report and 2018 Preliminary Financial 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.

Business Overview

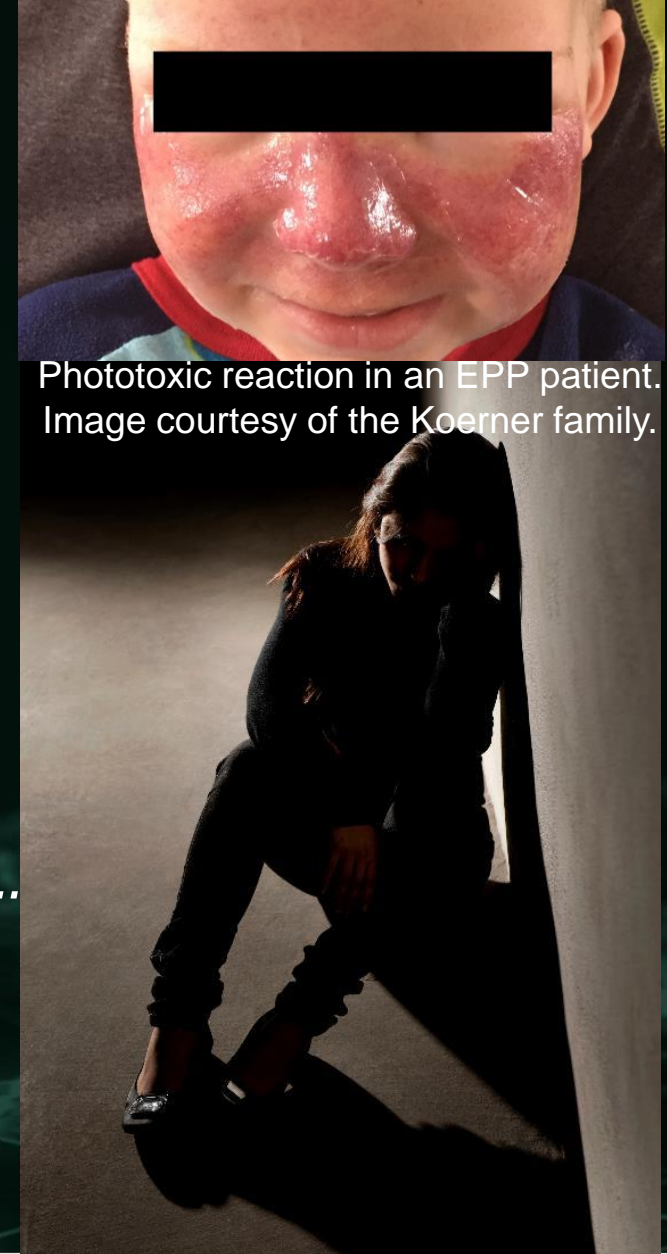
- Specialty pharmaceutical company
 - Longevity (14 years) – Management and Board
 - No alternative treatment to SCENESSE® (afamelanotide 16mg), no competition
- EU [EMA] approved product, awaiting PDUFA date [FDA] for orphan indication porphyria (EPP)
- Social responsibility to treat EPP children and depigmented patients (vitiligo)
- Growth through organic/inorganic expansion
 - Two additional indications
 - 2nd generation products – Rx
 - OTC products for larger audience
- Profitable since 2017, first dividend declared 2018



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CLINUVEL's business focus - *systemic photoprotection*

- Genetic metabolic disorder(s)
- Intolerant to light emission (blue-green/UVB/UVA)
- High unmet medical need(s)
- No alternative therapy, no benchmark
- Afamelanotide 16mg, family of melanocortins (POMC)
- Rx/ SCENESSE® approved by EMA '14
- World's first **systemic photoprotective drug**



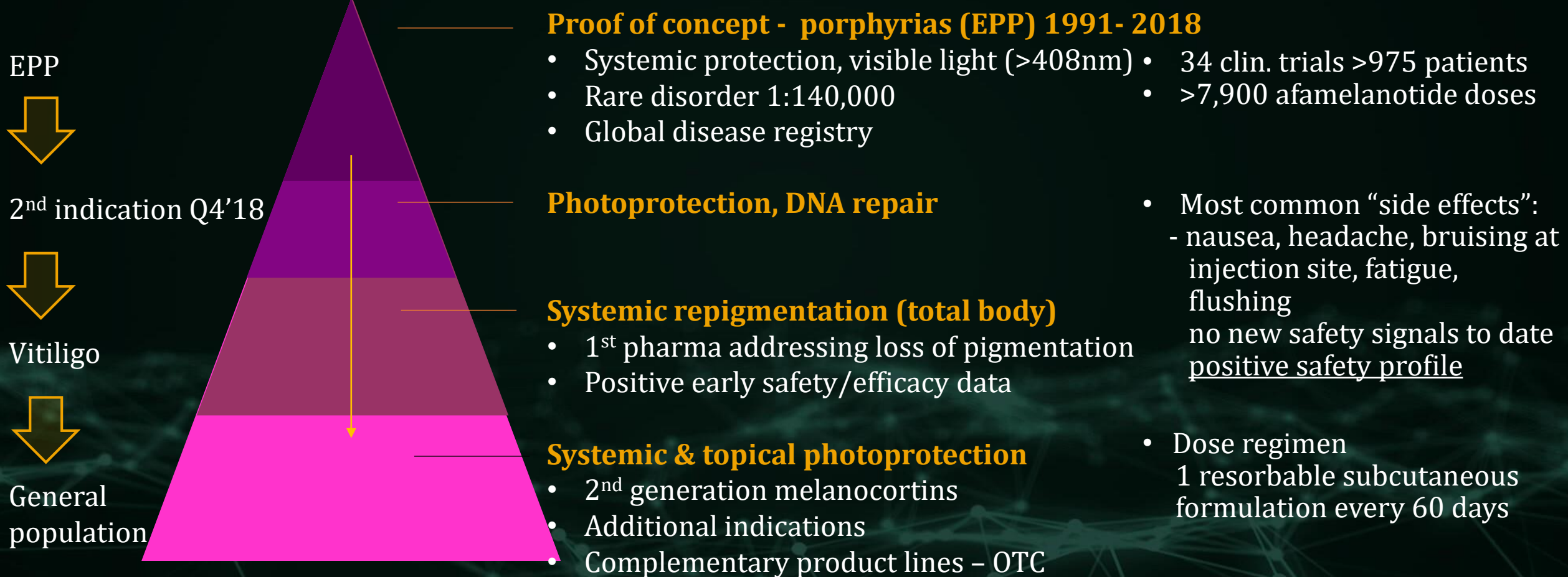
Phototoxic reaction in an EPP patient.
Image courtesy of the Koerner family.

*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% treatment continuation**

SCENESSE® - medical innovation/breakthrough

FLOW OF KNOWHOW ON MELANOCORTINS



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CLINUVEL's European operations



How does CLINUVEL commercialize its technology?

Special Access Schemes since 2010

SCENESSE® commercially distributed since 2016

Direct, controlled EU distribution to EPP expert centres

EMA risk management plan, global disease registry, "PASS"

Results to date

66.1% increase in patient treatments 2016 to 2017

98% treatment continuation rate reported in EU/CH

US patients flying to Switzerland to seek treatment

SCENESSE® Uniform Price

Alternative effective therapy¹ None

Listing price range

(Lauer-Taxe)²

€ 0

€25,000

€50,000

€75,000

€100,000

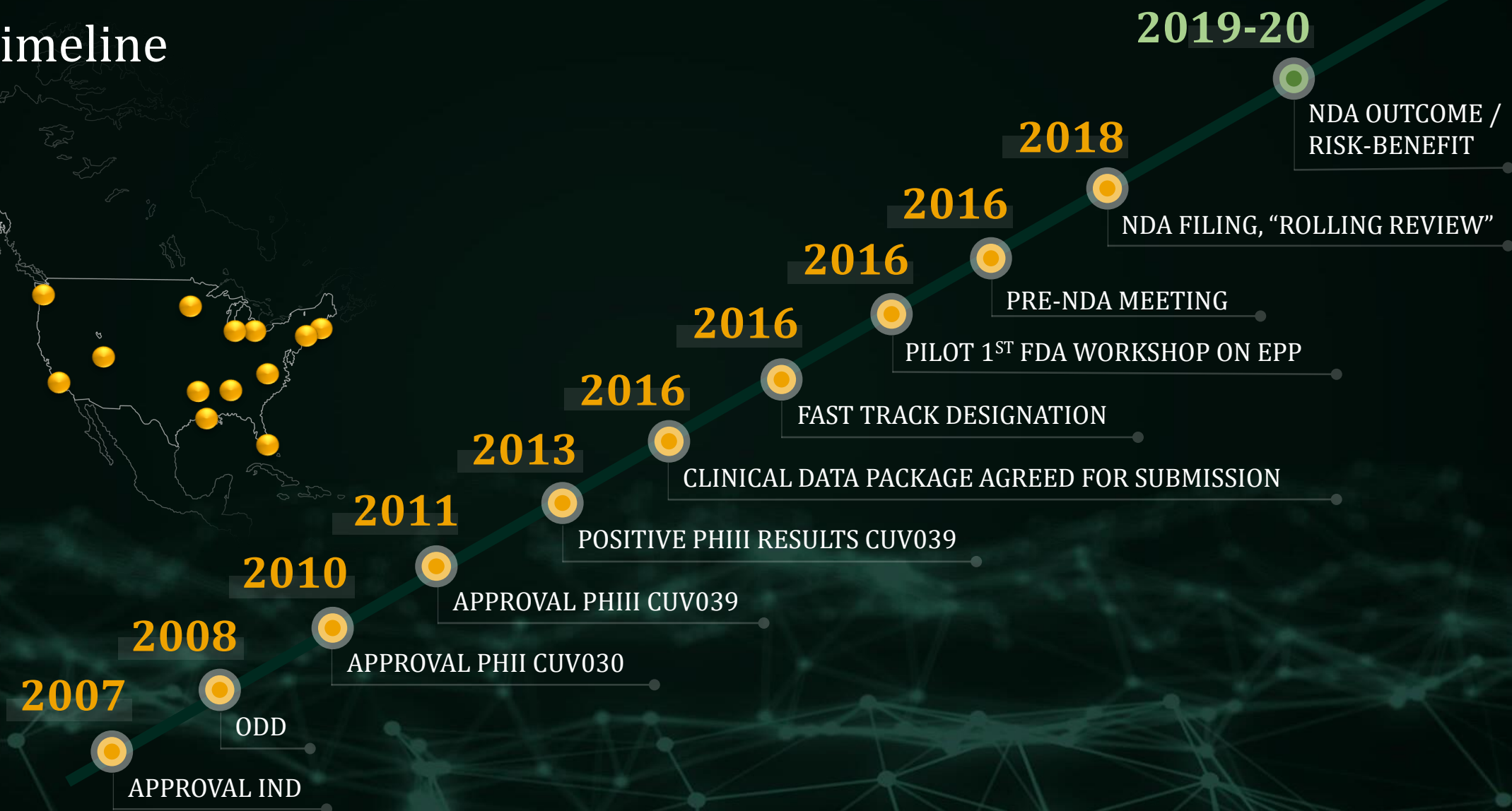
¹No alternative effective therapy exists for SCENESSE®

²Price in Lauer-Taxe is published by IFA GmbH



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US FDA timeline

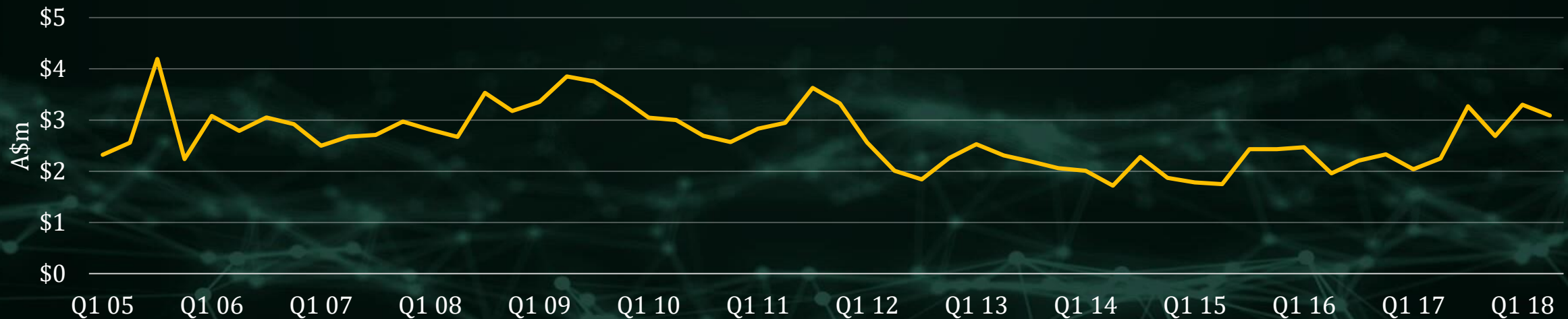


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Financials I CLINUVEL's DNA

- Disciplined financial management 2005-2018
- Debt-free
- Expertise in house

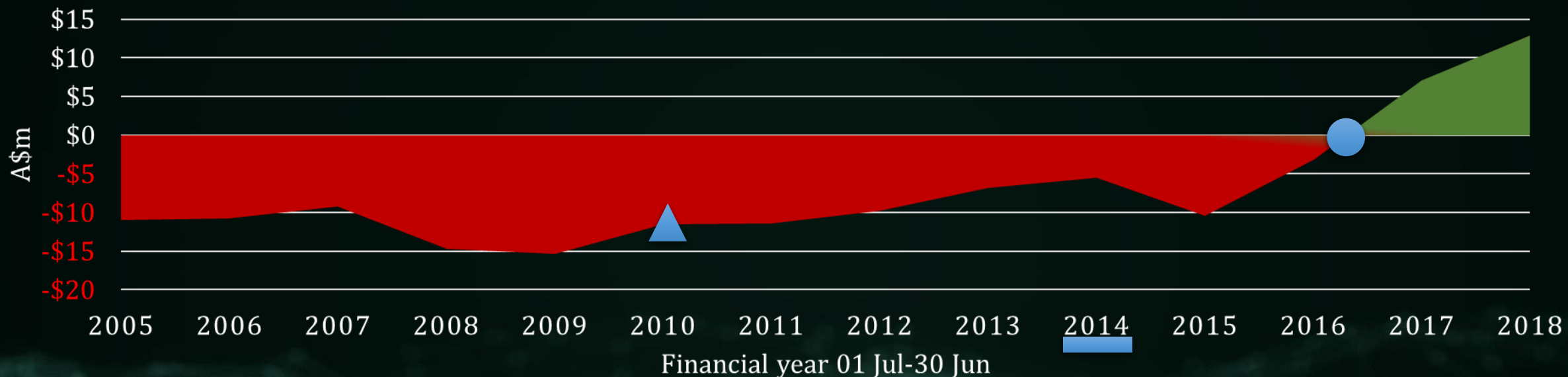
Quarterly Operating Cash Outflows



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Financials II P&L – medical innovation SCENESSE®

Net Profit (Loss) Before Tax (AUD)



Total funds committed to SCENESSE® program to date:

A\$172m

Industry standard development costs

US\$600-800m

Profit after tax (FY18)

A\$13.224m

Unfranked dividend per ordinary share (FY18)

\$A0.02



CLINUVEL

Financials III ASX: CUV – 12 months



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CLINUVEL Group ownership

ASX:
XETRA-DAX:
ADR:

CUV
UR9
CLVLY (Nasdaq International Designation)

Market Cap (17 September)

A\$873.9m

52 week high-low

A\$6.40-\$18.89

Board, management and staff

8.87%

Lagoda Investment Management

7.12%

FIL

4.99%

Ender1 LLC

5.43%

Family offices Switzerland/Germany/Asia

13%

Private investors UK/Netherlands/Austria

~5%

Australian institutions

2%

Rest of World/Unanalyzed

12.7%

Asia
8.8%

Australia
28.4%

North America
27.4%

Europe
22.8%

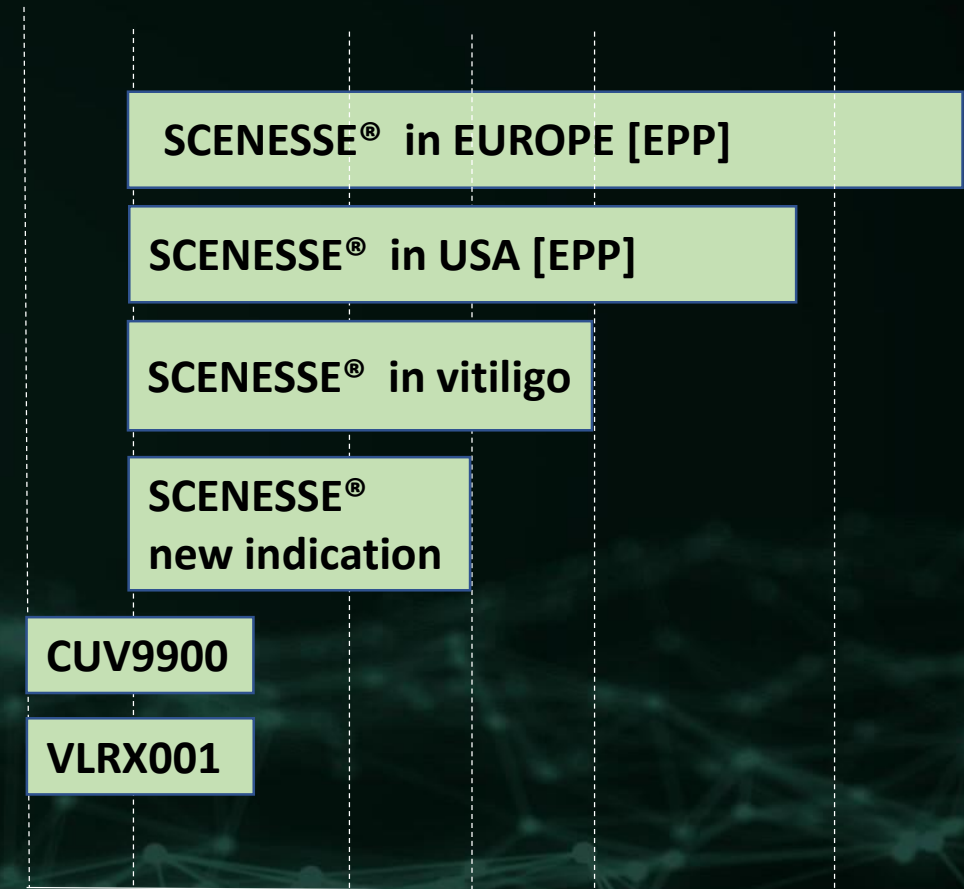


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Conclusions CLINUVEL

POC PRECLIN PI PII PIII COMMERCIAL

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Q&A

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