



CLINUVEL

Company Announcement

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## CLINUVEL sustains profitability first-half of year

*Financial performance to reinvest in global expansion*

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### EXECUTIVE SUMMARY

- total revenues: A\$7.19 million<sup>1</sup>
  - 3% increase in total revenues PRP
  - commercial sales revenues: A\$5.33 million
  - cash increase from 30 June 2017: A\$4.19 million
  - net profit after tax: A\$1.41 million (44% decrease PRP)
  - growth in number of expert treatment centres prescribing SCENESSE®
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**28 FEBRUARY 2018, MELBOURNE** - CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY) today announced financial results for the half year ended 31 December 2017, reporting net profit after tax of A\$1.41m, and total revenues of A\$7.19m.

### FINANCIAL RESULT

The financial result reflects overall increased revenues of 3% compared to the previous reporting period (PRP) to the half year ended 31 December 2016 and an increase of 28% for the commercial sales of SCENESSE® (afamelanotide 16mg) compared to the PRP (A\$5.33 million in 2017 against A\$4.18 million in 2016). The number of expert centres prescribing SCENESSE® increased to 13 centres in comparison to 4 centres for the PRP. Total revenues were A\$7.19 million for the period. Cash and cash equivalents increased by A\$4.19 million for the six months to 31 December 2017.

As a result of an increase in overall expenses across the Group's global operations, the net profit of A\$1.41 million for the period was down 44% compared to the PRP. The increase in expenses were primarily associated with the distribution activities for making SCENESSE® available to a growing number of expert centres which provide treatment to patients with the rare genetic disorder erythropoietic protoporphyria (EPP).<sup>2</sup> Increased staff numbers and key personnel remuneration-related costs was also a contributing factor, resulting in a 27% increase in general operations (A\$2.73 million in 2017 compared to the PRP of A\$2.15 million). CLINUVEL is currently preparing to file a New Drug Application (NDA) with the US Food and Drug Administration (FDA) aiming to obtain marketing approval. Costs related to regulatory and non-clinical work for the NDA contributed to an increase of 86% in regulatory and non-clinical expenses compared to the PRP (A\$0.91 million in 2017 against A\$0.49 million in 2016).

CLINUVEL's CEO, Dr Philippe Wolgen said "In remembering where this program started in 2005 with a mere scientific concept requiring ample equity funding and the objectives we had set ourselves, we are pleased to report sustained half year profits for the Group. The focus remains to advance the market access to European - and eventually to US - EPP patients who have no other therapeutic options."

"We have sufficient grounds to maintain our reputed cost management while maximizing the output. As we see more prescriptions of SCENESSE® we will progressively be in the position to broaden the infrastructure enabling growth on multiple fronts. CLINUVEL's mandate is to substantially reinvest in novel products and services, and therefore the obligatory art is to balance cash flows with expenditures required for long term growth. Overall, we

are on track against our own financial expectations, comfortable with financial ratios we adhere to and optimistic for the future direction of the company.” Dr Wolgen said.

<sup>1</sup> Figures in this release are presented in Australian dollars and may not reflect reporting due to rounding. See the Company’s Appendix 4D for exact figures.

<sup>2</sup> SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on CLINUVEL’s website at [www.clinuvel.com](http://www.clinuvel.com).

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#### **About SCENESSE®**

SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with EPP. The innovative nature of the therapy in an orphan disorder, the lack of available scientific instruments to adequately measure the therapy, ethical considerations and the drug’s positive safety profile were some of the factors which led to the European marketing authorisation of SCENESSE®. Information on the product can be found on CLINUVEL’s website at [www.clinuvel.com](http://www.clinuvel.com)

#### **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 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. 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.

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