

## Chair's address to the Annual General Meeting

Melbourne, Australia 28 November 2017

Coming from the background of an ethical pharmaceutical company I had some misgivings 15 years ago of joining the board of a company with a 'tanning' drug. Here we are today, a genuine biopharmaceutical company having posted revenues of AUD\$17.3m on a single drug used to treat an unusual orphan disorder.

The pathway through the FDA to the North American market is the next peak we have to scale and this requires diligence and care with the application of additional data we have gathered from our European experience. It's not often one has a chance to quote Lady Macbeth but her response to her husband's doubts was "screw your courage to the sticking place and we'll not fail", and dare I say we are well screwed.

The ability to offer a novel and effective technology to a patient community that has no alternative therapy is rewarding, and gives a great sense of satisfaction. Regrettably the bureaucrats do not easily accept innovation, and when they finally do, they have no willingness to pay for it. The negotiation of a uniform European price for SCENESSE® has been met with stubborn resistance. The chicanery displayed by insurers, national advisors and payors has been of an incredible scale. The final arbitration in Germany required our indomitable CEO to present in German, not his native tongue, which is akin to me being asked to present to you in Swahili which would not be pleasant for any of us.

As Chair I worry about operational, economic and national issues and I have a strong desire to ensure prudent governance is applied in the manner in which the Company deals with those issues. We have a management team in place who have, essentially, travelled the road to registration and revenue generation together. However, there is still a constant need to replenish, rejuvenate, and augment our staff to meet new challenges. This requires regular review and maintenance of contracts for senior staff to ensure we have the best resources available. A highly intelligent gentleman once said: If A is success in life, then  $A=X$  plus Y plus Z. Work is X, Play is Y, and Z is to keep investors and shareholders happy, which is very important at certain times. Thank you, Albert Einstein.

At the conclusion of formal business our incredibly diligent and hard-working CEO Dr Wolgen will paint a canvas of the next chapters in the CLINUVEL story. May I take this opportunity to thank you for your commitment and interest in the well-being of CLINUVEL, and also thank you for your attendance at our Annual General Meeting.

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### **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 product, 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 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; 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. 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.

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