



Company Announcement

CLINUVEL

ASX: CUV  
Nasdaq International Designation: CLVLY  
XETRA-DAX: UR9

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## Chair's Address to the Annual General Meeting

Melbourne, Australia, 20 November 2019

### A MOMENTOUS ACHIEVEMENT

Looking at the year in retrospect, I draw a balance on the overall resources it took to achieve one of the greatest successes in Australian pharmaceutical history. At a relatively low expense of under A\$139 million, we arrived at a commercial product to serve the needs of EU and US patients. Whilst I try to temper my euphoria, the 8 October FDA approval of a new molecular entity (NME), a first-in-class therapy, is a rarity in the Asia Pacific region, and the world in general. It is also the most momentous achievement in CLINUVEL's history. I am delighted to have been part of this as Chairman of a brilliant team and congratulate the entire CLINUVEL staff, the patients, the carers, the physicians and the long-standing shareholders.

### ORIGINS OF SUCCESS

A promising story which had started three decades ago, afamelanotide really only got started when this management team took over the reins and executed the most ambitious, and at times seemingly hopeless, task of overturning negative US regulatory decisions issued in the nineties and at the turn of the century. When I first came across the current leadership, I now readily admit that I wasn't convinced they could succeed. I remember well the first time I met Dr Wolgen in 2005. Although I had understood the long-term vision and future plans, I had had my doubts he and his managers could see it through. In November 2005, my fellow Board members shared the same sentiment, but as US and Australian managers up to then had left behind a trail of unsuccessful footprints, the Board all agreed that a fresh approach was the only way to rescue the molecule and above all the Company. As the operations unfolded and the development of SCENESSE® progressed, we started to see the intelligence and persistence of a cohesive team willing to fight every decision along the way. We had departed from the lowest base with Epitan facing bankruptcy, having no viable strategy, program or pharmaceutical formulation. We saw the turning of a new chapter under CLINUVEL in January 2006. I must add that Hank Agersborg, who had a distinguished career in pharmaceutical research and development, provided an outstanding partnership with Philippe Wolgen.

### STEADFAST FOCUS ON THE PLAN

A number of retail shareholders have approached me in the past few years to question the pathway, the strategy and pace, and call for changes which they believed would speed the process and create value. Long-term larger shareholders on our register remained steadfast in their belief and supported the strategy and management team. Without these majority shareholders and their intricate understanding of how the Company intended to grow and deliver, the Company would not be where it is today. More likely, an alternative approach would have strayed from its mainstream strategy, raising further capital at increasingly diluted terms and losing value along the way. I am grateful that the Board followed managements' analyses, vision and professional intuition to stick with the execution of a well-designed plan. I express my special gratitude to the loyal Swiss, Austrian, German, US and Australian institutions and individuals who have given support.

I have seen each individual obstacle; I have lived the CLINUVEL story along each step and have shared some difficult moments. It goes beyond the realm of this evaluation to share all the resistance the CLINUVEL team has faced, but I summarise it by stating that the persistence and execution of the managers, particularly the CFO and CSO, have surpassed what one could have asked of a pharmaceutical team. The CEO has been inspirational at all times, and particularly when required to be resourceful and find solutions when others could not or did not. Without this resolve, the company would be insolvent today.

## **A POSITIVE FUTURE**

We celebrate the long-awaited FDA approval, and I am certain the Company will go from strength to strength. It is profitable, has the support of long-term shareholders, is attracting new shareholder interest across the globe, continues to operate responsibly, and manages its cash prudently serving as an example in our industry. There is no doubt in my mind, CLINUVEL will expand and build a larger group of companies to feature on the Asia-Pacific pharmaceutical landscape.

I'm certain, however, that it will be this management team which will deliver on the next stages for CLINUVEL, and our approach as a Board and as shareholders must be to ensure they have the support and assurances necessary to succeed.

## **SHAREHOLDER VALUE AND COMPANY COMMUNICATIONS**

Per the graph on screen we have seen substantial gains in shareholder value under the current management team, with share price increases of 206%, 58% and 62% in the last three financial years, respectively and the growth of the Company to one of the 200 largest on the Australian Securities Exchange.

Every shareholder has the free will to invest in CLINUVEL and we aim to attract like-minded and compatible long-term shareholders; we also reserve the right to not respond to those who ignore their obligations and lack the graciousness to communicate in a civil fashion and cannot share our strategy. Our philosophy is to advise the market, and thus all small and large shareholders, of developments and progress of the Company on a timely basis.

An interesting analysis is that in the last few years CLINUVEL compares well to a group of eight ASX peers in terms of total announcements and voluntary announcements such as newsletters, specific events and developments in the business. This analysis reflects a company that takes the provision of information and continuous disclosure to its stakeholders very conscientiously.

## **PASSING THE BATON**

One of my final tasks as Chairman has been to secure continuation of the Company under a competent management team. I am very pleased that the CEO, CFO and CSO have recently been persuaded and agreed to continue to advance the strategy of the Company.

I have had the good fortune to work quite closely with two brilliant CEOs of pharmaceutical companies, CSL and CUV. Both have become significant shareholders in their respective companies per medium of incentive programs designed to stretch management to almost breaking point if they achieve targets which will guarantee success for the Company and its shareholders in the process. In respect of CLINUVEL, there would be no business today if it had been left to any one of the previous four CEO's and most likely a new incoming one at this stage.

Philippe and his management team have been challenged on many occasions and found answers to a litany of issues raised in two of the world's most competitive environments as they progressed to approval for EPP and progressed to potentially new applications and designs for afamelanotide.

Moving forward, it is in all shareholders' interest to have a management team who are capable of overcoming these challenges and have their incentives aggressively aligned with our interests.

My decision to step down from the Company after 17 years as a Director is with mixed feelings, but a certain degree of pride in our achievements. I also have the secure knowledge that the new Chair, Mr Willem Blijdorp, will continue and strengthen the Board with commercially savvy directors, such as Sue Smith, our most recently appointed Director. Willem is an entrepreneur well known for his instinctive management, his ability to grow businesses and influence as a strong Chair provides a positive path for the Company. His vision to expand the Company on more than one track is refreshing and coincides with the long-held vision of our CEO. Together they work well, and the security of the tenure of Darren Keamy and Dennis Wright bodes well for us shareholders.

I am fully aware that CLINUVEL is only at the start of further successes given the pipeline of products and projects, expansion plans, its assets and most of all, the pool of impressive professionals we have in the Company. It has been my pleasure and honour to have served as Chair. To shareholders and staff, I thank you for your support.

**- 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 and the US Food and Drug Administration in 2019 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, Singapore and the USA. For more information please go to <http://www.clinuvel.com>.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

#### **Head of Investor Relations**

Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

#### **Investor enquiries**

<https://www.clinuvel.com/investors/contact-us>

#### **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; 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 2019 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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