



# CLINUVEL

05 October 2018

Dear All,

This is a thank you to shareholders, investors, patients, clinicians, and all those who have continued to support CLINUVEL together with new shareholders who have recently gained confidence to join the CLINUVEL register. The Company's performance of the past years, the first ever dividend declared, and progress towards US market entry are some of the main motivations to support the Company's course at this point in time.

Looking back at the past financial year and preliminary results which were reported on 29 August, one can draw a line by stating that the strategy CLINUVEL has executed over many years – actually spanning more than a decade – has been worthwhile and rewarding for our longer-term shareholders. These members have now had the choice to either stay with our story or take profits after years of waiting for success. For the benefit of those new shareholders who recently took a position in CLINUVEL I will provide some background on our current status.

The second year of profitability of this specialty pharmaceutical company is remarkable for a great number of reasons, and the positive bottom line allows us to further pursue additional medical solutions of children and other patient groups who are not yet treated, and to expand the Company's portfolio. Our Board of Directors has consistently put at the centre of our activities continued funding of pharmaceutical development, since in today's environment we must take a view to reinvest a significant percentage of our profits. Without companies such as ours there will be no progress for unattended patient groups. We are not only responsible for making a drug available to them, but also to provide hope and maintain faith in our ability to provide care to adult and juvenile patients and their families while monitoring safety long-term.

To be able to supply the pharmaceutical innovation (or even to have contributed in some capacity) is a privilege and the result of much effort. If one would take away the hallmarks of this Company, namely true persistence and intelligence, many thousands of patients would instantly lose this hope. Hence, I want to see our teams continue their campaign to take SCENESSE® and follow-on products to hospitals and their patients. I am of the opinion that, from various viewpoints, being associated with the CLINUVEL story is most gratifying.

Following the recent increase in enterprise value CLINUVEL has become an attractive investment for those professional investors who seem to appreciate the years of working towards building our pharmaceutical venture. My present fellow Board members, as well as the late Jack Wood and Hank Agersborg, all encouraged the management team to keep working towards the corporate objectives without being distracted for market appreciation to follow sooner or later. Going forward, I wish to see the same attitude and approach to the clinical, regulatory, financial and executional aspects of our business, while keeping in sight the new corporate objectives with an aim to grow the Group. In any of the expansions we seek, patients will always deserve our priority and attention and medical care will remain at the core of our existence. Most of us at some time in our lives will find ourselves in the role of being a patient. At such times we all will want to receive an effective treatment, and if this therapy does not yet exist we would at least want the hope that a new one is being developed by a company such as CLINUVEL. In the future, I am certain the need for medical research and for effective drugs will remind us all of the challenging path we have followed over the past decades.

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The calendar year 2018 has shown us how all European and Swiss expert centres continue to prescribe SCENESSE® to their erythropoietic protoporphyria (EPP) patients, while this is driven purely by clinical demand without the Company actively promoting the drug or engaging in medical marketing campaigns. This approach provides us clean analytical data to understand the percentage of patients requesting treatment year on year. As reported earlier this year, the rate of continuation of EPP patients is higher than 95%, an unusual high percentage in ethical pharmaceuticals. This begs different questions as to their reasons for seeking treatment, motivation to take time off from work, impact of treatment and professional medical attitude towards a novel medical therapy such as SCENESSE®. Analyses of these data are ongoing for satisfying annual European (EMA) submissions, and for the benefit of our discussions with regulatory agencies (currently the US FDA) but also with insurance groups throughout Europe and the United States.

Since the sign-off of the recent audited financial results, we gradually increase our R&D investments to speed up our pipeline of products, the next generation therapies coming from the melanocortin family and beyond. However, the main and long-awaited objective is to gain marketing authorisation for SCENESSE® in the United States. Despite our potential to immerse ourselves in large clinical trials in vitiligo and other indications, we need to see the US EPP dossier closed before we turn our attention to the next challenges. As the US Food and Drug Administration is concerning itself at present with the innovative technology in EPP, the very same key decision makers across the desk will also be involved in reviewing SCENESSE® in other indications. Therefore, we must complete one regulatory dossier before we open the next one. I fully subscribe to this “single-minded” strategy, having been in the industry for four decades now. Pharmaceutical companies need to be clear in their strategy and dialogue with leading regulatory authorities. Regulatory authorities consist of skilled professionals with a narrow and dedicated focus on new drug treatments and drug developers need to take into account the views and perception of authorities deciding on scientific innovation. Therefore, we will first await an FDA outcome on EPP before we proceed with other US indications for SCENESSE®. Our Board of Directors has a clear rationale for staying with our current development strategy and expanding our focus for SCENESSE® once FDA clearance is provided for the drug in EPP. May I add that the current strategy has served CLINUVEL well over a long period of focus.

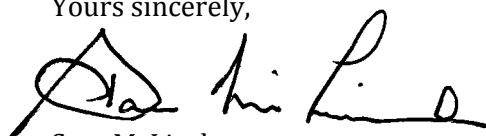
Back in 2011 a mainstream Australian journalist wrote that the future for CLINUVEL would be uncertain. She questioned whether we would have the stamina to see the development and distribution through, suggesting that the Company would fall prey, as many other Australian biotechs have, to a foreign buyer capitalising on the domestic work. Despite regulatory and other significant obstacles, we have diligently worked at overcoming each individual challenge in a successful manner. Being privy to the daily work by our management, I can clearly see the traits that has made this Company where it is today and one of the few Asia-Pacific pharma successes: unabating, relentless perseverance, patience and associated wisdom in executing the tasks at hand.

Recently I stated that I would stand down as Chair. After much thought and discussion with my fellow Board members, members of the management team and some of our larger investors, I have agreed to hand over the chairmanship immediately following a successful FDA outcome, which I expect somewhere in 2019 if all stars remain aligned. A US entry of SCENESSE® would most likely be one of the pinnacles of my professional career, a long-fulfilled dream and possibly the most significant event in the history of CLINUVEL. Having seen how the failed US regulatory attempts in the past had caused our current teams legacy issues to overcome with the US regulatory agency, I truly believe that this current regulatory approach is the only way to allow access to the drug for US EPP patients, first adults and later children who desperately await treatment. The latest series of requests for information from the FDA were expected, part of the preparation and assurance to the FDA that the US product complies with US regulatory standards. A possible NDA granted will mark success of the goals we set some eight years ago and with pride I will hand over the responsibilities to my successor.

One of my tasks remaining is to complete the executive contracts of our key personnel, CFO and CEO, since the Board of Directors and our larger institutional investors are unanimous in their wish to see a further term under this leadership team. The discussions with Dr Wolgen have progressed slowly since he devotes all his time in operational matters to lead the Company overseas, whereas the discussions with the CFO are taking place as we speak. I am hopeful that we will conclude all executive matters within weeks to be able to provide long term stability to the Company.

I look forward to meeting our new shareholders at CLINUVEL's Annual General Meeting on 21 November in Melbourne.

Yours sincerely,



Stan McLiesh  
Chair  
CLINUVEL Group

<sup>1</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).

#### **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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