15 October 2019

Dear All,

In my career in life sciences, I have served on public Boards, was part of the management team that led CSL to its position and oversaw several executive transitions in our beloved Company, first at Epitan and last, but not least, at CLINUVEL.

Saddled with a difficult technical dossier on afamelanotide which had not passed any of the entry criteria of the FDA in 1995 (Melanotan Inc.), a molecule which had been rejected for its investigational new drug (IND) applications in 2003 and again early in 2004 (Epitan Ltd), there was still some hope left in the melanocortin project, but must I admit very few sparkles of it. The Board in 2004 needed to identify a competent and ingenuous management team to turn the tide, otherwise Epitan would fail in its endeavours.

In past letters, I have covered the merits and achievements of our current management team, the one we put in place in November 2005. What is relevant today, is to outline the extra dimension it took to combat two negative US regulatory outcomes. When Dr Wolgen (at the time shoulder to shoulder with the late Dr Hank Agersborg) and his team presented their strategy, the Board was not only unsure about the unconventional and tortuous transition it would take to gain US approval for the technology, but also about the costs, since the Company essentially was on the brink of bankruptcy.

The management team came up with a novel formulation, new chemistry, a new indication, new understanding of pharmacology, mode of cellular action and regulatory approach. Those around the Board table at the time were sceptical and some even reluctant to accept the business plan. Yet there was no other avenue than to adopt a left-field approach and restructure Epitan into CLINUVEL. There were a series of unconventional decisions the Managing Director and the management team had to make, but suffice to say, the elements of the new strategy needed to be legitimate, ethical and within the confines of the pharmaceutical sector.

Fast forward five years to 2010, and the program in erythropoietic protoporphyria (EPP) was well underway, patients were responsive and the medical community supportive. Although the share price was languishing, we had understood that with the notable meltdown of one of our largest German shareholders in 2007 much of the CLINUVEL registry needed attention and cleaning up. For this, there was once again a new strategy.

Moving forward again to July 2014, we faced the sadness of the unexpected passing of my respected fellow Board member Jack Wood and at the same time, encountered a new challenge in the form of a US based non-friendly take-over proposal. Our management team had done their homework precisely and implemented a strategic plan that refuted the opportunistic bid 90 days before the European Medicines Agency approved SCENESSE® (afamelanotide 16mg) for distribution in the European Union.[1] As an active Board, we wholeheartedly supported the direction the management team had taken.

Turn the pages to a further three years, and the Company finds itself in feverish discussions with the US Food and Drug Administration (FDA) on the merits of melanocortins, EPP and its clinical strategy. Due to the attention it had brought once again to the FDA, the Agency agreed to invite 150 families to Maryland for a one-day seminar for patients to express their symptoms, handicaps and frustrations. From then onwards, the FDA came to understand not only the need to treat, but also the place of afamelanotide as a new therapeutic class to help those with the EPP disorder.

In my mind, the historic crossroads occurred in two parts. First, on the day of the plenary session of the EMA in London where I witnessed one of the greatest debates and oral pleadings I had ever seen. Our Managing Director presented the favourable versus unfavourable arguments of not only the pharmaceutical technology,

but also its decision-making processes which had taken place during nine consecutive years. The EMA's approval on 24 October 2014 marked the full circle this team had come on merits alone. The second part of the journey to me was the large meeting in Silver Spring, as the FDA was now actively pursuing an interest in EPP. Burdened by the past failures of Melanotan and Epitan and IND rejections, the October meeting set a fresh start to positive interactions between our management team and the FDA which has since been well maintained.

One of the critical decisions our Managing Director made was to organise a team of professionals around Dr Dennis Wright, with whom I had worked during my CSL days – an experienced pharmaceutical professional, who had the intellect and calmness to oversee a complex development program. With Agersborg, Wright and Wolgen, we now had a team which remained unflinched by any critique or scepticism. We had Darren Keamy, the ever-reliable CFO who looked after our spending and finance impeccably, and the rest has become part of Australian life science history. But really the entire team, support staff, management and juniors have all contributed to this glorious outcome; all have been part of it.

In my extensive research, this is the first Australian team to have taken a new chemical entity in an orphan disorder rescued from the edge of bankruptcy to success, on its own merits and with its own integrated team. The Australian life sciences need successes, and this approval will give a boost to many other start-ups to enter the drug development field.

The FDA's monumental decision is the culmination of over a decade of research and development and regulatory liaison on the safety and efficacy of SCENESSE®. As I said in my April 2019 letter, an approval will be our 'crowning glory' as a company, as a cohesive team of individuals who kept 'hacking at the rock until it became silicate'. The teams will progress immediately to implement our distribution strategy to provide treatment on the ground in the US. But let's take a moment to savour the immense satisfaction all stakeholders of the Company feel in this significant regulatory achievement.

For US patients and their families and supportive porphyria associations, the FDA's decision means the long wait for treatment is nearly over. It must understate their feelings of the situation somewhat, if I empathise that they had an anxious and frustrating time in the waiting room, particularly in the most recent years as European patients with EPP were being treated with positive reports. We are most pleased to share in their elation that the treatment is finally on its way.

For the many practicing physicians and medical academics who advocated and supported our application to regulators, you should be proud of your role in this outcome and we offer you our heartfelt thanks.
For Mrs Desiree Lyons, the former head of the American Porphyria Foundation, a vocal advocate and a formidable woman who has devoted her life to all porphyrias, our appreciation to all you have done for patients.

Our suppliers and service partners, who work with us side-by-side in active collaboration, share our pride and satisfaction in achieving the FDA marketing approval. We appreciate your service and support.

As our Managing Director has said, the FDA took the courage and leadership in this dossier, and the FDA's Division of Dermatology and Dental Products deserve a big round of applause, often forgotten.

Last but certainly not least, thank you to our shareholders, particularly those who have travelled the path with the Company for more than a decade. There is much pleasure you should have and relish in seeing the US regulatory approval.

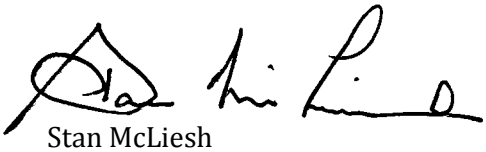
We will be communicating our outlook in the weeks to come and perhaps will see the interest of new investors reflected in CLINUVEL's share registry.

As my time at the Company comes to an end, very few things remain on my list to do. I shall devote my time to hand over the corporate knowledge to our new Board member and effect a professional handover to my

replacement in due course. To have been Chairman and part of this journey gives me a deep sense of pride and satisfaction.

I wish all stakeholders of the business well in life and with your partnership with the Company.

Yours sincerely,



Stan McLiesh
Chair
CLINUVEL Group

– End –

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. SCENESSE® is approved in the USA to increase pain free light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at 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 treatment(s) 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 adult patients with the genetic metabolic disorder 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 go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

Head of Investor Relations
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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 Preliminary Final 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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