



# CLINUVEL

24 April 2019

Dear All,

On a continent where very few biotechnology and pharmaceutical companies have ever succeeded in taking a first-in-class and first-in-line therapy from concept to commercialisation, CLINUVEL has all the makings of becoming a lasting success story in Australian life sciences. It will become a Company serving many different patient populations. At my stage of life it is rewarding to be engaged in a meaningful mission from which thousands of patients and their families will benefit and, in doing so, to see shareholder value being created.

While still in no position to accurately predict the outcome, nevertheless in 2019 the Board of Directors hope to see the crowning glory of our objectives so far with the Company reaching a US Food and Drug Administration (FDA) approval through a New Drug Application. Literally around the clock, our teams are collaborating with the FDA to answer the frequent queries arising from the scientific review process, such that a controlled post-licensing (post-marketing) follow-up of patients is put in place in the US. After 14 years of incessant work and relentless efforts, I have seen up close the exceptional managerial focus, from key managers not willing to let go of the 'prime objective' until they see their ambitions realised.

In order to put the FDA filing in some broader perspective, when I first joined the Epitan Board of Directors in 2002 quite a different strategy had been followed in the attempt to obtain US regulatory clearance for the molecule now known as afamelanotide. It appeared that the organisation was bent on a belief that afamelanotide would be successfully positioned as a lifestyle agent designed to provide millions of fair-skinned people with a "healthy tan" and possible protection from the sun. From a lifetime spent in the pharmaceutical industry it was quite obvious that this strategy would never produce a successful regulatory outcome, nor provide the foundation for growth of the Company.

It was only after the Board had voted in favour of the current CEO and Dr Agersborg as CSO late in 2005 that a meaningful medical application for the drug would be found and a rigorous strategy developed. The chief executive set out to radically change the management and Board, whereby CSO Dr Wright and CFO Mr Keamy became pivotal executive managers. From then onwards in restructuring the management team the CEO established a Company able to advance a clinical-regulatory-financial program along set objectives and within numerous constraints. For both the older management members and the shareholders of the time, CLINUVEL's new strategy in November 2005 was a hard sell. By optimising the chemistry, reformulating the drug product, and gaining interest from academia to collaborate, the Company had only a fighting chance to progress in the face of regulatory and academic resistance, along with critique from the financial sector. The challenge was compounded by a market which had lost faith in the story.

It was the current CEO who came up with a detailed (but unconventional) plan to capitalise the business in a most efficient and anti-dilutive manner which would enable the Company to reach today's valuation. His unflinching conviction and energy to defy all critics and non-believers was needed to overturn two previous decades of a company floundering and not taking advantage of its technology and intellectual property. I remember all too well that in 2005 the Board and shareholders held an initial healthy scepticism, but continued to support the strategy as it was presented as the most viable longer term solution and option to build an enterprise. As it has evolved, the realisation of Dr Wolgen's early vision for the Company long-term has been met with enormous success. Both as a Non-Executive Director and shareholder I am indeed grateful for the attitude the current management has displayed over the years. Suffice to say this is strengthened by the knowledge that unlike other biotechs, CLINUVEL has never been the recipient of financial grants from the local or central government agencies, nor has it reverted to debt financing along its path.

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It's quite noticeable that Australian institutions are now starting to pay attention to CLINUVEL as it approaches its commercial and regulatory goals, a recognition for a dozen years of concentration of resources in the creation of a profitable and sustainable enterprise. Essential in the Company's execution was to establish an organisation whereby variable costs could be contained and fixed components minimised. The current strategy proves rewarding, particularly given there are few examples of pharmaceutical and biotechnology companies succeeding in the grass-root innovation of scientific technology in Australia and New Zealand, propagating a reluctance of professional investors to seek out opportunities in the area. It appears CLINUVEL's cost-effective and financially responsible approach has piqued the interest of domestic managers and buy-side analysts of superannuation and pension funds. A deeper understanding of the fluctuating and recurrent cash flows from our seasonal business has clearly contributed to the institutional enquiries we have received lately. Projecting along a straight line, there is a confidence that the Company will attract much more interest from a larger pool of superannuation funds.

Before passing on my role as Chair, I wish to see the finalisation of executive employment agreements in line with international standards to ensure we retain the services of our first-class management team. There are also clinical agreements to be executed on a new indication for SCENESSE® (afamelanotide 16mg).<sup>1</sup> Infrastructure and financial planning for CLINUVEL's business expansion needs to be in place and, most certainly, I wish to witness the FDA approval of SCENESSE®, one of the most significant milestones for the whole CLINUVEL team and patients.

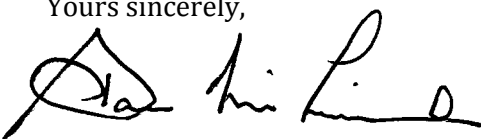
At the base, as a unified Board we wish to see the longer-term commitment of current executives as an ultimate signal that they will pursue the objective of setting up a diversified portfolio for the future. In securing the services of the management team we strive for continuation of the current clinical and regulatory strategy. On that note, in my position I am very pleased to state that nine key personnel have grown and remained at CLINUVEL longer than ten years. Specific knowhow is being retained among the broader management team.

We eye expansion as the next stage of the Company's organic and inorganic growth. There are inherent dangers coming with mergers and acquisitions. Within the organisation we are aligned on the need for a structure which allows growth and minimises risk. Infrastructure, systems, and procedures have been put in place by senior management prior to embarking on an expansion strategy and integration. It could be said we are nearing the moment where CLINUVEL is ready to expand beyond its core activities while maintaining its focus on afamelanotide and melanocortins. In our chief executive we identify an experienced individual who recognises the importance of building functional teams and remains aware of the dangers of ill-planned and ill-timed expansions.

CLINUVEL has done well over the past two years in improving shareholder value and consolidating strong market performance. Equally important is that we have performed well against our own set of objectives and made a critically sound decision to directly distribute the main pharmaceutical product rather than rely on commonly used pharmaceutical distribution chains. There is always room for improvement, but all in all when all of my final objectives have been met, I will retreat in the notion that CLINUVEL will have all key ingredients to become a company of an order of magnitude larger than what it is now, and an enrichment for the Pacific region.

I conclude in stating that the organisation as a whole appreciates the support given by long-term friends and shareholders and those who more recently have taken such a keen interest in the organisation.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Stan McLiesh', written in a cursive style.

Stan McLiesh  
Chair  
CLINUVEL Group

- End -

<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 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 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.

#### **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 2018 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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