



11 January 2018

Dear Shareholders,

Whilst the Board of CLINUVEL looks back on a very successful 2017 it must now look forward to exciting times ahead. The Group will engage in many activities on several continents, and we are expecting to see the first fruits of internal research coming to the public eye.

Insurers and payors worldwide continue to restrict availability of reimbursements to patients needing “orphan drugs”. Nonetheless, as a counter-measure, we continue to broadcast the clinical successes achieved in the countries that do offer financial support for erythropoietic protoporphyria (EPP) patients¹ in recognition of SCENESSE® (afamelanotide 16mg) as a treatment.

The long-awaited highlight for 2018 will be the final submission to the US Food and Drug Administration (FDA) of what has been a challenging SCENESSE® dossier as part of the new drug application (NDA). Activating pigmentation by way of a hormonal therapy in light-deprived patients – EPP – has proven a difficult task for even the most experienced scientific regulators and consultants. However, as the European and Swiss patients have shown, our concept is not only effective but also of long-term benefit, it is hoped that the FDA will not wish for North American patients to be excluded.

CLINUVEL’s clinical and regulatory team have adopted a strategy of full and open communication with regulatory bodies, and the FDA has signalled receptiveness by having first accepted the clinical data for submission, then waived carcinogenicity studies, granted Fast Track Designation, and organised three meetings with relevant patients and experts while the formal scientific review is yet to be concluded. This persistent approach taken by our management team has brought us to where we are today as a company. Those that operate in our industry will have insight as to when the theoretical diverges from what is practical and optimal and so will better understand and support the decision pathways of CLINUVEL. It has not gone amiss that the Company’s application to the FDA is to be submitted during these politically and economically sensitive times, and we continue to take technical and substantive measures to best position the Company’s application.

2018 will be my last full year as Chair of CLINUVEL and I would certainly prefer to exit my role as Chair with the knowledge that shareholders, active investors and the domestic business community view CLINUVEL as a successful Australian pharmaceutical entity, and one of the few to have withstood the test of time while taking a New Molecular Entity from concept to patients in two major global markets.

It is essential that CLINUVEL is positioned to ensure that continuity and stability of success are guaranteed long-term. Having worked with previous executive teams, and certainly at CSL one led by one of Australia’s greatest CEOs, I have come to appreciate up close the efforts and accomplishments of our current CLINUVEL management against significant odds and challenges. In golfing parlance they are certainly besting par on the biotechnology course.

As Chair of the Board I have led and participated in intense deliberation on the positioning and vision for the future of the Company to ensure they are consistent with the interests of our stakeholders. All knowledgeable consultants and key investors in our industry have made it clear that continuity under current management is preferred and mandatory for us to reach our long-term objectives. As a Board we are privy to key management decisions, and it has become obvious to us, and those with a standing in the sector, that Dr Wolgen’s intelligence, vision and forthright manner will succeed where others may well have walked away. This approach has taken CLINUVEL to the success it enjoys today.

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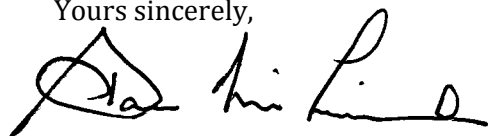
At this critical point in time the Board considered it absolutely essential to persuade our Managing Director to sign one final employment agreement to prepare the Company for a handover by 2021. With Dr Wolgen's commitment to guide CLINUVEL through the next three years, as Chair I believe it secures the interests of those stakeholders who have provided funding for our programmes over the past several years.

Together with the retention of the Managing Director's services and the need to retain key personnel and have a succession plan in place for senior staff, the Company has put in place a Professional Development Program for senior managers. As part of that program Dr Emilie Rodenburger will be assisted and guided by our Acting CSO Dr Dennis Wright to become the Company's next Chief Scientific Officer.

CLINUVEL will attract a wider audience in 2018, not the least by diversifying its product offerings to new markets. The knowledge gained as a specialty pharmaceutical company, and the confidence gained among the top academic experts worldwide, will need to be translated into a continuum benefiting a wider market. CLINUVEL will launch its premiere non-pharmaceutical product lines under private label. These dermatological products will be complementary to SCENESSE®. Fitting our 2018 strategy, CLINUVEL will exhibit its first conference display in Asia and Europe, our main targeted markets. This will be discussed by our Managing Director in more detail over coming months.

For the next twelve months Management and Board will give its best to achieve our objectives, and it gives me a sense of great pride and humility to have served as Chair over the past years. May we all look forward to an exciting 2018.

Yours sincerely,



Stan McLiesh
Chair
CLINUVEL Group

¹ 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.

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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