CLINUVEL

5 September 2025

Fellow Shareholders,

In a global biotechnology sector characterised by binary outcomes and significant capital demands, CLINUVEL's performance in FY2025 stands as testament to disciplined execution and strategic foresight. Our results reflect a rare profile within the industry: a profitable, commercial-stage company with a robust and de-risked balance sheet. We present these achievements not in isolation, but against the performance of platform-product focused peers in the U.S.A., Europe, and Australia – few of whom have delivered such consistent returns. And in all this we are proud of the business we have built and the point at which we have arrived.

Once again, our business model has proven its validity with A$105 million in revenues, A$35.6 million in net profit after tax, and an eighth consecutive dividend (A$0.05 per share), entirely funded through operating cash flow. Notably, we maintained cumulative R&D and commercial expenditure over the past five years at A$171.2 million, underbidding our initial forecast of A$175 million. This precision in financial management has not gone unnoticed – as one analyst aptly noted, our team's discipline offers significant confidence in CLINUVEL's future. This outcome is deliberate, not incidental.

Following these results, the Board has undertaken a thorough evaluation of the Company's position and prospects. Today, I am sharing key aspects of that review with you.

Quantified Risk Assessment: CLINUVEL vs. Sector Norms

Platform-product biotechnology companies inherently face multiple risks. At CLINUVEL we have adopted a structured strategy to mitigate these challenges:

1. Regulatory & Commercialisation Risk

- *sector norm* shows the probability of a clinical product advancing from Phase III to approval is approximately 58% (as per the Tufts Center for the Study of Drug Development). Achieving commercial success post-approval remains even more uncertain.
- *CLINUVEL's positioning around SCENESSE®*: an already approved and commercially established drug in key markets including the U.S. and EU. Its long-term use provides a validated safety profile, and our teams are confident of its potential for expansion into further indications, such as vitiligo.

2. Financial & Dilution Risk

- *sector norm* shows that more than 75% of pre-profit biotechs on the ASX and NASDAQ require dilutive capital raises every 18–24 months to fund operations.
- *CLINUVEL's position:* to date we have limited our need for external funding and not raised funds since 2016. With cash reserves of A$224 million (a 22% year-on-year increase), zero debt, and self-funded operations, we remain insulated from equity market gyrations. Our cash reserves underpin a net tangible asset value of approximately A$4.80 per share.

3. Pipeline & Growth Dependency Risk

- *sector norm* shows that companies reliant on a single revenue stream often trade at a discount, with pipeline assets heavily discounted until de-risked.
- *CLINUVEL's position:* we are actively de-risking our growth strategy. Our vitiligo programme is funded through operational cash flow. Furthermore, historical R&D efficiency – achieving outcomes with an investment of A$405 million, compared to an industry norm exceeding A$2 billion – enables us to advance new indications without diluting shareholders.
- development of ACTH (NEURACTHEL®) continues to proceed favourably, and we anticipate providing a commercialisation timeline when validation of manufacturing has concluded.
- our unique PhotoCosmetic programmes are advancing through formulation refinement and regulatory planning, with the aim of finding new audiences and diversifying revenue streams.

4. Execution & Margin Risk

- *sector norm* shows that gross margins for commercial biotechs typically range between 70–85%, though high SG&A costs frequently result in negative operating margins post-launch.
- *CLINUVEL's position:* to date we have been able to achieve a sustained revenue scale while controlling costs, maintaining a gross margin near 50% and achieving a net profit margin of 34% - a clear indicator of commercial and operational efficiency.
- our business development team actively evaluates strategic acquisition opportunities, and we are optimistic that one of these may soon materialise, adding further value to the Company.

5. CEO Succession Planning

- the Board is engaged in structured succession planning to ensure continued leadership stability. An update will be provided to shareholders early in 2026.

The Anomaly and the Opportunity

I typically refrain from public commentary on valuation, but in light of thoughtful questions raised during our Investor Webinar on 28 August, I feel it necessary to address our perspective directly.

CLINUVEL's investment thesis is straightforward, yet the Australian market continues to apply a generic, high-risk biotech valuation framework to a company that has transitioned into a profitable, lower-risk commercial entity.

We are acutely aware that our share price does not yet reflect the value being built. We hear the concerns of some shareholders and take them seriously. We also recognise that certain market participants remain focused on perceived risks including competitive threats, pricing pressures, and the high barriers to success in this sector. These concerns are not lost on us; they are realities we engage with daily. Dr Wolgen addressed the topic of potential competition in detail during the recent webinar.

It is worth noting that U.S. listed platform-product companies with financial profiles similar to CLINUVEL's often trade at enterprise value-to-revenue multiples between 4x and 6x. CLINUVEL currently trades at a discount to this range. Conservative application of a 4.5x multiple – accounting for geographic and product concentration – would imply a materially higher enterprise valuation, even before attributing value to our pipeline or cash holdings.

Our mandate remains clear: to continue delivering commercial results, advance our clinical pipeline with discipline, and communicate our value proposition to a broader investor base, particularly in markets such as the U.S., where profitable growth is appropriately valued. Our recently announced intention to pursue a Level II ADR listing on NASDAQ is designed to increase visibility among U.S. investors.

Finally, I wish to recognise the renewed energy and capability of our executive team, including Dr Wolgen's return and the emergence of strong leadership within the ranks. There should be no doubt: this team is positioned to deliver on all fronts, and we expect this to be reflected in the share price in due course.

I leave you with this thought: I would far rather own CLINUVEL's operations, prospects, and balance sheet at a depressed share price, than hold the position of most of our international peers.

Thank you for your continued support.

Sincerely,

Professor Jeffrey V. Rosenfeld
Chairman
CLINUVEL PHARMACEUTICALS LIMITED

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL I: CLVLY; Börse Frankfurt: UR9) is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for specialised populations. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, assisted DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel, and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA. For more information, please go to https://www.clinuvel.com.

Authorised for ASX release by the Board of Directors 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. All statements other than statements of historical or current facts made in this document are forward-looking. We identify forward-looking statements in this document by using words or phrases such as "anticipate," "believe," "consider," "continue," "could," "estimate," "expect," "foresee," "intend," "likely," "may," "objective," "potential," "plan," "predict," "project," "seek," "should," "will" and similar words or phrases and their negatives. Forward-looking statements reflect our current expectations and are inherently uncertain. Actual outcomes or results could differ materially for a variety of reasons. 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; the COVID-19 pandemic and/or other world, regional or national events affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed and characterised by us as PhotoCosmetics; our ability to achieve expected safety and efficacy results in a timely manner 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, the UK, Israel, China, Japan, and/or LATAM regions 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®, CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed as PhotoCosmetics which may lead to the Company being unable to launch, supply or serve its commercial markets, special access programs and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare, Medicaid, and U.S. Department of Veteran's Affairs) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology, cosmetic and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; our ability to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry, cosmetic industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2025 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 preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

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