

# CLINUVEL

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15 January 2026

Fellow shareholders, friends, partners,

We enter the year 2026 with unbridled optimism. This sentiment is borne out of intimate knowledge that data generated by our teams point to the possibility of realising greater ambitions: to develop new technologies for many patients in need. I believe this year will define CLINUVEL for many years to come. The Group's value lies in the quality of data it produces, the cash flows it prepares, and the size of the next markets it plans to enter.

One could imagine four questions in assessing CLINUVEL's identity and performance setting it apart from the majority of biotechnology firms globally.

One: what defines this Company?

Two: what can be expected in 2026 from its teams?

Three: is the excitement around the Company published by 10 analysts justified?

And last: why does it take time for the Company to share data, results?

## **CLINUVEL's Value, Facts and Fiction**

Research is a non-linear process whereby discoveries need time to mature to viable products. In a public setting that is increasingly difficult because the next set of new ideas lure away the investment attention from qualified investors as they hope to discover nearer-term value recognition. In that sense, CLINUVEL is approaching realisation of key activities (milestones) as more data will be made public. We bridged these times of low frequency in news flow by ensuring we had cashflows from our commercial operations to fund the research and innovation cycles without needing external funding. In executing this plan, we were able to save shareholders hundreds of millions of dollars in dilutionary capital.

I see the notion of market value as a still photograph of a company at any given time. It is perhaps better to place full emphasis on a company's intrinsic value, something along the lines of a reel of fragments being edited to a feature film, dynamic and more relevant to the longer durability of a going concern.

Underlining the belief we now hold in our technologies, we recently agreed a five-year investment plan in the VALLAURIX Research, Development and Innovation (RD&I) Centre in Singapore with the Singaporean Economic Development Board. This investment expands the RD&I Centre footprint, facilitating the acquisition of more equipment and recruitment of further qualified talent. The Singaporean funding authorities based their decision on diligence made on the Company's technologies, prospects, and confidence to further generate meaningful data leading to commercial products.

To fuel public investors' sentiment, progress will be shared when intellectual property is secured. The main objective in our preclinical and clinical research is to develop new pharmaceutical products which serve larger, non-orphan markets and address unmet need, with a focus on our core expertise in peptides, including melanocortins. In all these deliberations, the search has been to add substantial and non-obvious advantage over existing technologies or methodologies. In my view, it is the sole approach in this sector to secure future reimbursement from insurers and payors, who are increasingly scrutinising and shunning pharmaceutical products. We review many of the opportunities and technologies presented to us, and the majority do not hold the prospect of future cash flows. We regard these interesting research projects as far from commercial reality. Our task is to stay the course and invest in opportunities closest to markets.

## The Year 2026 and Time

When a publicly listed biotechnology firm approaches anticipated catalysts and news flow, one usually sees renewed investor attention, trading volumes increasing. In 2026 – as seen from the first two weeks – we will have plenty of activities which may interest public markets, certainly those investors who have done some work on CLINUVEL.

Formulation platforms and knowhow are increasingly becoming core assets of the Group. It has taken more than a decade to arrive at the new systemic pharmaceutical formulations, but I believe it will have been worth the painful and arduous journey to bring these innovations to market from organic research efforts. CLINUVEL's approach here is perhaps different to that of public life-science companies where large gambles are taken, but we have avoided large capital errors necessitating the shuttering of centi-million dollar programs by focusing on cost efficiency and ensuring minimal value erosion.

Value and knowledge are tightly connected in our case. In past years, I have made retention of critical knowledge a top priority across the Company. By building out our core research teams, we were ensuring that each member was passing on knowledge to newly recruited members. A process of methodical knowledge transfer seems logical but is far from what one sees in pharmaceutical practice; I now believe our decisions around knowledge protection have made the Company less vulnerable to loss of key knowhow, since there is a processed and steady transfer of information, approach and understanding among expanding teams.

In 2026, the Company will become more U.S. focused, allocating more resources to expand our staff on the East and West Coast, with more U.S. based senior managers. In parallel, Dr Teng continues to expand the number of North American Specialty Centers in preparation of a prospective vitiligo market. We have achieved our end of 2025 target of 120 Centers, and the next target is 190 trained and accredited Centers by the end of June 2027. This dispersion of treatment points will give us sufficient exposure and prescribers to reach vitiligo patients once SCENESSE® is ready for market entry.

As to the vitiligo program, based on clinical feedback, we hold a strong belief we have a significant drug product in SCENESSE® to assist patients of darker complexion regaining their lost skin colour. The most recent images from Fitzpatrick skin type VI patients hold promise as to the efficacy of treatment. Read-outs of the CUV105 trial in the second half of 2026, and a further CUV107 clinical study, will show whether and when we can file a new dossier with global regulatory agencies.

As we are nearing the end of the vitiligo trial CUV105, we see that the field is evolving. For instance, we witness how trial designs are harmonised in Europe and U.S.A., with equivalent endpoints (study objectives), and regulatory agencies becoming better at understanding the treatment opportunities in non-segmental vitiligo.

ACTH (NEURACTHEL®) has been in manufacturing for more than three years, and in the European summer we plan to file its dossier for first regulatory review. ACTH is a melanocortin and universally used for diagnostic and therapeutic purposes; we plan to enter global markets focusing on its dual mechanism. This product aims to secure CLINUVEL's second stream of cash flows.

Amidst the expansion thrift, we closely monitor the executive orders and negotiations led by Robert F Kennedy Jr on U.S. pricing of pharmaceuticals. I expect pricing pressure to mount in the coming years in the U.S., starting with the most expensive and highest budget impact drugs per unit first. Thus far, we do not anticipate an impact on the distribution of SCENESSE®.

## Market Reports, Excitement

External analysts of CLINUVEL are generally positive about the stock with target prices above our current share price. This reflects recognition of the intrinsic value created. New investors – institutions, high net worth individuals and family offices – uniformly express excitement about the future of CLINUVEL and this is a significant spur to our investor relations activities. Stakeholders can expect investor relations outreach in 2026 to extend across Australia, Asia, Europe and North America.

Given this attention, we have long since posed ourselves a fundamental question: what are the odds in the sector of repeating commercial success by the same team, given the rarity of turning a biotechnology venture financially viable and independent? Despite the odds, we think we can and are striving to do so.

## Conclusion

I believe I have answered four relevant questions as we enter 2026. In all our endeavours, we are asked to be flexible, allowing for changing of plans, not being too dogmatic and allowing for unexpected events, but most of all, at all times being focused on possible risks.

From market analyses over the years, I firmly believe that CLINUVEL can realistically attain a valuation north of A\$7.5B or US\$5B, given the prospect of the vitiligo, ACTH, EPP markets, formulation platforms, and the probity of financial management maintained over the past two decades. Further, I believe such a valuation is justified and justifiable. It is easy in this sector to be self-delusional about goals and valuations, and I tend to think we are realistic about our ambitions as long as we continue to be solely focused on building an enduring firm. There are specific areas where those who follow us closely will see change in the near-term. For further success and higher valuation, for example, we will need to upscale our communications to reach wider audiences. It is my unwavering aim to realise a diversified group maintaining a higher valuation, as I believe it is within reach.

Many shareholders have bought our common stock on-market and remain invested in CLINUVEL with the expectation that one day the stock will return back to levels seen in 2019 and 2021, and above. Many of you (approximately 40%) are lifetime shareholders in CLINUVEL, and as the largest individual shareholder I don't take lightly the task of expanding CLINUVEL to become a great business. I can now say it has been our life's work to leave behind a sound business with a deep pipeline of promising treatments.

Very much reflecting how I view our challenges the next calendar year, I wish to end up with one memorable quote from Winston Churchill made in Northwest London in 1941; when reading the passage please think of it in the context of time and subsequent outcomes:

*“Never give in. Never give in. Never, never, never, never, in nothing, great or small, large or petty, never give in, except to convictions of honour and good sense.”*

I wish you a year of full health and harmony.

Philippe

### 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), CYACËLLE, 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®, CYACËLLE, 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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