

CLINUVEL

ASX ANNOUNCEMENT

ASX: CUV | Nasdaq: CUVL | Börse Frankfurt: UR9

CLINUVEL implements strategic reorganisation to refocus on U.S. markets

Melbourne / New York – 23 July 2026 – CLINUVEL PHARMACEUTICALS LTD (ASX: CUV | Nasdaq: CUVL) today announced a strategic reorganisation of its operations and workforce, effective 1 January 2027, concurrent with the relocation of its corporate headquarters to the United States.

"We have long contemplated a U.S. listing and concluded that the Company has reached a stage of maturity sufficient to attract the attention of U.S. investors," said Mr Lachlan Hay, CLINUVEL's Chief Operating Officer. "Based on feedback from recent non-deal roadshows, CLINUVEL's profile is seen as distinct from many U.S. biopharmaceuticals, while many U.S. investors expressed a preference to invest in U.S.-focused and listed companies. Since our future operations will be centred in the United States, we are now positioning the business functions for these next phases."

Restructuring Highlights

- **Headquarters Relocation:** CLINUVEL's corporate headquarters and key functions will transition to the U.S., effective 1 January 2027, to strengthen regulatory engagement and commercial partnerships.
- **Workforce Reduction:** the Company is reducing its global workforce by approximately 10%-20% and relocating select functions to the U.S. This reflects a necessary realignment of operating expenditure with current revenue generation and near-term clinical and commercial priorities.
- **U.S. Market Focus:** operational resources will be pivoted exclusively toward the U.S. pharmaceutical pipeline and commercial strategy. The U.S. represents over 40% of the global pharmaceutical market by value and is the primary ecosystem for premium pricing, regulatory advancement, and M&A activity.
- **Capital Access:** the restructuring is a prerequisite to unlocking deeper, more liquid capital pools in the U.S.

Strategic Rationale

Capital Markets Conditions

The current macroeconomic environment has constrained liquidity in the Australian and broader Asia-Pacific markets. Over 66% of CLINUVEL's shareholder register is currently held by foreign investors, with the majority of new shareholders originating from North America and Europe.

Valuation Alignment

U.S.-listed specialty pharmaceutical companies with comparable revenue and pipeline profiles typically trade at materially higher enterprise value-to-revenue multiples relative to their ASX-listed counterparts. This valuation differential is driven by deeper sector-specific knowhow, analyses, greater institutional participation, and a more developed ecosystem for specialty pharma financing.

Pipeline Commercialisation

The Company's late-stage programs, particularly in vitiligo, are primarily targeted at the U.S. patient population, which is estimated at approximately six million affected. The U.S. market for systemic vitiligo therapeutics is projected to be sizable over the coming decade. Relocating the current base and operational

headquarter to the U.S. positions the Company to access distribution, and potential partnership infrastructure, required to capture the opportunity. Additional pipeline activities are all targeted to serve U.S. pharmaceutical markets.

Shareholder Composition

Foreign investors have dominated CLINUVEL's register for an extended period, reflecting the global appeal of the Company's assets. The U.S. focus formalises current shareholder composition and provides a structural pathway to expand the investor base to include leading global healthcare funds and institutional investors that preferentially allocate capital to U.S.-headquartered companies.

Management Commentary

"The Board has initiated this transformation because it believes that a U.S. focus of our operations is the single most effective means to unlock the intrinsic value of our assets," Mr Hay added. "This restructuring positions the Company for a future of growth and will benefit shareholders, patients, and stakeholders over the long-term."

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About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL is a global biopharmaceutical company focused on developing and delivering innovative therapies for patients with genetic, metabolic, and dermatological disorders. The Company's portfolio is centred around melanocortin peptides, with programs advancing in photomedicine and vitiligo. CLINUVEL is listed on the Australian Securities Exchange (ASX: CUV) and the Nasdaq Stock Market (Nasdaq: CUVL).

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Canada, 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). For further information, visit 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 but are not limited to risks relating to: our ability to develop and commercialise pharmaceutical products; pandemics, epidemics, public health emergencies, geopolitical conflicts, trade restrictions, natural disasters and other disruptions affecting global supply chains, including our ability to develop, manufacture, market and sell biopharmaceutical and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACELLE, 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®, CYACELLE, 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 including the risk factors described in the Company's Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission, together with the Company's announcements lodged with the Australian Securities Exchange. Forward-looking statements speak only as of the

date on which they are made, and the Company undertakes no obligation except as required by applicable law, the rules of the Australian Securities Exchange, the U.S. Securities and Exchange Commission, Nasdaq, or other applicable regulatory requirements, 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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