

CLINUVEL

ASX ANNOUNCEMENT

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

CLINUVEL considers Nasdaq listing, ASX delisting

Headquarters relocating to the United States

EXECUTIVE SUMMARY

- Board of Directors considering transaction to list all ordinary shares on Nasdaq under a foreign entity
- existing shareholders to receive ordinary shares representing an equivalent proportionate economic interest in Nasdaq listed company
- transaction remains subject to final Board decision, finalisation of structure and documentation, and all necessary shareholder and regulatory approvals
- operational headquarters relocating to the United States
- further information to be made available to shareholders

Melbourne / New York – 27 August 2026 – CLINUVEL PHARMACEUTICALS LTD (ASX: CUV | Nasdaq: CUVL) today announced that its Board of Directors is considering a transaction under which CLINUVEL would change its group holding structure, seek a listing of its ordinary shares on the Nasdaq Stock Market (“Nasdaq”), and delist from the ASX.

Proposed transaction reflects CLINUVEL’s global operations

CLINUVEL’s main research activities are currently undertaken in Singapore, while its commercial and clinical operations are managed from the United Kingdom, European Union and United States. The Company is also establishing its new headquarters in the United States, effective from 1 January 2027.

The proposed Nasdaq listing reflects the increasing significance of CLINUVEL’s current and future operations in the United States, the largest global market in scientific innovation.

Process subject to ongoing diligence, final Board approval

The transaction would be implemented by way of a Scheme of Arrangement under Part 5.1 of the Corporations Act 2001 (Cth), which would be subject to shareholder and Court approval.

Under the transaction, a foreign holding company (“New HoldCo”) would become the new parent company of the CLINUVEL Group. Current shareholders of CLINUVEL would receive ordinary shares in New HoldCo representing an equivalent proportionate economic interest to their existing interest in CLINUVEL (subject to the rounding of fractional entitlements). New HoldCo would seek to list on the Nasdaq (Global Select Market).

A final Board decision has not yet been made to proceed with the transaction and due diligence continues with input from global counsel and auditors. Any decision to proceed will be subject to finalisation of the transaction structure and documentation and, if pursued, the transaction will remain subject to the necessary shareholder, Court, ASX and regulatory approvals.

Shareholders do not need to take any actions at this time and all existing security holdings are unaffected. Further information regarding the transaction, its structure and implementation, including the discontinuation of CLINUVEL’s ASX listing and German trading through Börse Frankfurt, will be provided to shareholders in due course.

Commentary

“We have methodically and gradually worked towards the moment whereby the Company has reached maturity of its operations, R&D capabilities and balance sheet to support consideration of gaining access to a larger life sciences capital market” said Dr Philippe Wolgen, CLINUVEL’s Chief Executive Officer.

“All of CLINUVEL’s revenues are generated in Europe and North America, our future pharmaceutical activities targeted are on North America, and the majority of our senior executives based outside Australia. We believe it is thus appropriate to consider whether a U.S. focused group and Nasdaq listing better align with the Company’s future operations and strategic direction.”

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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 Managing Director on behalf of 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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