# CLINUVEL

28 February 2025

# Message from the Chair

Fellow shareholders,

With financial results for the six months ending 31 December 2024 released yesterday, we are pleased to have delivered seventeen consecutive half year profits. Underlying profit in the reporting period was the highest December half year outcome to date. The key results compared to the corresponding period of 2023 are:

- buoyant revenues growth of 10.5%;
- containment of expenses growth to 2.0%, without compromising the Company's R&D initiatives;
- underlying profit (before tax) of \$21.9 million, up 48.1%;
- profit after tax of \$14.1 million, up 28.7%;
- a rise in earnings per share of 27.4% to \$0.28; and
- increases in total assets and cash reserves of 2.2% and 7.8%, respectively, with a 7.0% rise in net assets, since 30 June 2024, free of external borrowings.

The Board has the privilege of understanding the operational decisions and challenges which management has, and is, overcoming to steer us to this stage of financial strength. There is no complacency, but we can be proud of CLINUVEL's progress, particularly when the pendulum of current success could easily have swung the other way. As part of our planning, the Board considers various scenarios on current funds and future cash flows to understand the adequacy to finance our clinical and commercial programs. With \$198.2 million in cash reserves, as reported at 31 December 2024, we project to have sufficient funds to complete clinical research, scale-up distribution activities in North America and provide for unforeseen events.

# **Focus versus expansion**

The past six months we have decided to concentrate our efforts on vitiligo and the development of NEURACTHEL®, two markets which remain underserved. With this choice, we see a need to secure a strong commercial footprint in North America. As a result, we are accrediting many more centres to enable treatment access, with a commensurate expansion of personnel in Palo Alto.

As I alluded to at the last Annual General Meeting, we will expand the Company, strengthening it even more by investing wisely in facilities and technologies for future operations and the growth of our business.

# **North American prominence**

We are hosting, for the first time, a large pavilion at the American Academy of Dermatology Annual Meeting (7-11 March in Orlando), a global conference where 20,000 delegates are gathering to hear and see the latest developments in dermatology and skin care. With the vitiligo program underway, we believe that North America will soon be our main focus and largest market. Shareholders will see daily social media updates on the conference and activities, while media activities will be revealed in support of our efforts. Our aim is to make CLINUVEL a familiar name among thought leaders and prescribers, to attract interest in our systemic medical solution in vitiligo.

One of the main tasks of a Board is to ensure executive management is – and remains – in place, but particularly to see a new CEO be attracted to continue CLINUVEL's success. An executive search is underway, and our preference is to see an American leader navigate the Company through its next phase of growth.

### **Progress and price**

Against all the positive developments, growth, and financial strength, we have been aware of forced sellers depressing CLINUVEL's share price. However, we firmly believe that a strong rebound will follow once more commercial and clinical research progress is shared with capital markets. The support from brokers, banks, fund managers and analysts seem unwavering, as gauged from the sell-side reports written on the Company. Now, time and patience are required to see the Group emerge from its current weakness in share price. Looking at CLINUVEL's past but also closely watching peers, strong recoveries are seen as investors discover an opportunity and upcoming news catalysts.

In directly interacting with financial institutions and investment banks, executive managers and I obtain a fairly good view on how outside professionals regard CLINUVEL. By and large, American, European, and Asian institutions positively comment on the commercial model we are following. Some are following the Company longer-term for its expansion plans and potential future financing required. Overall, there is widespread support for CLINUVEL to continue its current journey and approach, as many companies in life sciences find it increasingly difficult to attract funding for their next set of ideas. To be in this position is not only one of envy but also one not to take for granted.

We are grateful for your ongoing support as we look forward to a year of exciting developments for CLINUVEL.

Jett my Mosufeld

Jeffrey Rosenfeld Chairman

#### About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: 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. 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 2024 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.

Contact:

Tel: +61 3 9660 4900 Fax: +61 3 9660 4909 Email: <u>mail@clinuvel.com</u>

Australia (Head Office), Level 22, 535 Bourke Street, Melbourne, Victoria, 3000, Australia

