The year 2024.

Esteemed shareholders, friends

To our teams, the start of a calendar year reflects three prior months of planning, resource allocation and setting of objectives. Come the 1st of January, we aim to have formulated realistic goals for the year advancing the Company, whereby the fundamental drive remains research, clinical development, commercial operations and communication. Our direction and technologies are distinct from peers, and long-termism dominates our thinking.

For 2024, the fulcrum of clinical development is found in two arms: **photomedicine and central nervous system**.

In **photomedicine** the **Phase III vitiligo clinical trial (CUV105)** remains the talking point of patients and shareholders. We are conducting a randomised study evaluating afamelanotide in combination with narrowband UVB (NB-UVB) against NB-UVB alone, the current standard of care. The effects of treatments will swiftly become visible to patients who undergo combination therapy. Dr Teng will report on technical progress, with the last patients to enrol in Q4. Simultaneously, the US team is training and accrediting centers to prepare for future distribution in vitiligo. Our first target number shared with you is 120 American accredited centers trained to prescribe SCENESSE®. A further Phase III study (CUV107) is being established to integrate first key learnings from CUV105 and prepare a robust registration dossier for global regulators. Literally, after decades of preparation, it moves us to seize the opportunity to therapeutically assist large number of patients who lost their colour and identity.

In parallel, much excitement is derived from the **xeroderma pigmentosum-DNA repair program** (CUV156-CUV154-CUV152-CUV151). Two further XP studies, CUV158 and CUV159 are in planning to evaluate the PRÉNUMBRA® Instant dose, with a view to offer dosing flexibility in the future. The first genetic analyses, from the control study CUV151 are due. A drug's ability to positively affect repair of damaged skin following UV irradiation would have high relevance to millions of people, specifically those at highest risk of UV photodamage and skin cancer. The downstream potential of this clinical research spills over to our PhotoCosmetic product line, since melanocortins engender a potential to assist repair of DNA damage.

As a final part of the photomedicine program, we await final data from **CUV040**, a study analysing the effects of the drug in **variegate porphyria** (VP), a genetic disease-causing fragility, blistering and ulcers of the skin. Coordinated by Dr Bilbao, analyses and next steps to market will be released with an aim to extend the existing label of SCENESSE®.

Switching to the program of afamelanotide in diseases of the **central nervous system**, the **stroke trial CUV803** is currently recruiting the last three patients who incurred a severe infarct. Subsequently, we will evaluate the safety and efficacy in this group with moderate and severe stroke. As an extension of afamelanotide formulations, the PRÉNUMBRA® Instant formulation is used in CUV803, allowing the administration of the drug in higher frequency and dosing.

I believe that by the end of 2024, we will have a clear understanding of timelines and chances of securing further regulatory approvals in major markets, while our regulatory team headed by Drs Quadbeck-Diel and Wright are frequently engaging with the authorities. Dr Hamila coordinates Quality Affairs, involving both product manufacturing, testing and release, as well as clinical matters, while keeping the Company audit-ready in seven jurisdictions.

A stone throw away from pharmaceuticals, yet still highly related to our clinical programs, we are preparing the **PhotoCosmetic ranges**, M1 and M2 lines, skin care products containing melanocortin peptides. The Communications, Branding & Marketing (CBM) team are first introducing the polychromatic lines, CYACÊLLE and – shortly – CYACÊLLE RADIANT, to select communities and patients in need.

These two first products are to generate visibility for Group's activities and engage target audiences before the long-anticipated **M-serums and M-lotions** are launched. At present, the team is preparing its labelling, packaging, product placement and global presentation, whereby the goal is to differentiate in all its facets from other brands. Production is being prepared by an external manufacturing partner.

The phenomenon of a pharmaceutical company branching out in cosmetics is somewhat against convention, but given the attributes of our melanocortin technology, it is a strategy perfectly making sense though requiring much communication. As part of global campaigns, the coming year will unveil events pre-empting the future of the M-lines.

Ms Bibiloni and her team are giving shape to the brand, as seen in the recently launched CLINUVEL website. Mass-market oriented activities, proxy to the pharmaceutical business, necessitated the recruitment of an inhouse CBM team. Complementing this team, we recruited two experienced journalists coming from the Financial Times and The Economist, and who are tasked to generate further content and narrative around our products and activities.

Deliberately, we have taken a **multipronged approach to corporate communication**, seeing that all news to public markets is written at various depth and in more than one format.

When we started this strategy in 2019, the Company was anticipating FDA approval for SCENESSE® (afamelanotide 16mg). At that time, we had one analyst coverage in spite of regulatory and commercial success in Europe. We attracted Mr Bull as IR manager, and today we see **seven different banks and brokers covering the Company**, with two more in preparation. We have teamed up with banks and brokerage houses and participate in multiple institutional roadshows per year. These one-on-one presentations are the best yardstick to learn from portfolio managers and analysts across how they view the Company, its direction and current leadership. Following feedback, we adapt our course and tone for future meetings.

In addition, our IR team, Mr Keamy, CFO, and other managers frequently meet individual investors, shareholders, and fund managers to present the story as it unfolds. Away from the exchange with institutions, we have added a program tailored to reach family offices, high net worth and retail investors.

On **29 February**, the Company is invited to present at a meeting attended by Silicon Valley entrepreneurs, technology investors in Los Angeles, on **27 March** to German investors in Duesseldorf, in June at the Jefferies Conference in New York and throughout the year at various healthcare conferences. Early **May**, we are hosting a Capital Markets Day in Sydney, discussing our programs and future.

As part of increasing the online **visibility of CLINUVEL**, we will engage with high profile intriguing personalities (**10 CUVIPs**), who cover wider audiences, ranging from established classical music lovers to younger fans. All artists publicly speak about their support for CLINUVEL's mission. In our social media campaigns, we will have 60 ambassadors (**CUVAs**) with authentic – non-AI generated - stories on solar risk, photodamage and skin cancers supporting the mission of the Company.

A new platform is the **Photomedicine Foundation**, an initiative to give back to communities who cannot afford health care, such as those affected by vitiligo, albinism and XP in Tanzania, Kenya, Tunesia, Saudia Arabia and Brazil. In putting all these initiatives together and maintaining them long term, will lead to CLINUVEL becoming a name globally recognised for developing new therapies, luxury products and reploughing profits back to neglected patient communities. In this sense we link our photocosmetic venture to benefit patient communities.

At this point in time, it is imperative to realize that this strategy and myriad of parallel activities is only made possible owing to our team's focus, discipline and long-term mission to grow a commercial footprint and preserve funds. Without two decades of concentration towards this one gaol, we would not be where we are.

Our commercial activities continue to grow, enabling more patients to receive treatment with SCENESSE®. Mrs Colucci is responsible for growing markets, while Mr Hay has the global chair to oversee operations. Gradually our shareholders will see the fruits of these efforts, results not expected overnight but longitudinally based on consistency and a clear vision to establish a global brand.

Also in 2024, we will provide more colour on our long-desired goal to incorporate manufacturing of formulations. We have established an inhouse team of analysts in charge of new business development, led by Mr Ellison scanning the world for new opportunities and working closely with our banking partners.

I leave you with some thoughts.

From my position, I characterise CLINUVEL as a commercially successful company which tests its **technologies under extreme conditions** to make these available to wider use. That particular model led to profitability and cash buffers enabling the Company to grow its pipeline. Our approach to complex matters differs from our peers, and sometimes may not easily be recognisable for public markets but obviated the need to return to market for funding.

The foundation of a melanocortin house is formed by a group of nine executive managers who have stayed together for a median 16 years, new senior managers coming through and an attitude of permanence throughout the Company which is the cementum of success for years to come. The diverse Board of Directors critically oversees this process of building a construct, testing the premises of managerial decisions.

There is absolutely no guarantee in biopharmaceuticals that a model works. I do wish to share a discussion held on **5 February**, a US tech investor from California and shareholder of 18 years captured during a video call:

> *"…if I had known the abysmal percentage of success in pharmaceuticals and new molecules, 4% of the new compounds coming to market, I would never have invested. However, I am grateful for what the CUV team has done, I made much money and am increasing my holdings to 1% of the Company."*

The establishment of a sustainable bio-pharmaceutical company, one which survives the attrition of time is an essential goal. The learnings and adaptations of working with specific and unique

technology are paramount to new insights how to translate these to value — patience is painful but inevitable. With vitiligo, XP, VP, stroke and PhotoCosmetics on the board, I believe that the very same team who has brought SCENESSE® to market has a better than fair chance of replicating this once, twice, and thrice.

We shall speak soon.

Philippe

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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 products; competition for our products, especially SCENESSE® (afamelanotide 16mg), PRÉNUMBRA® or NEURACTHEL®; 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, Israel, China and Japan 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®, PRÉNUMBRA® or NEURACTHEL® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology 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 and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2023 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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