CLINUVEL

News Communiqué I

Melbourne, Australia, 07 January 2025
ASX: CUV | **Börse Frankfurt**: UR9 | **ADR Level 1**: CLVLY

Dear shareholders, friends,

The year 2025 is being prepared as one to stand out in terms of CLINUVEL's progress, news, and value for patients and shareholders.

I view investing in bio-pharmaceutical companies as an exercise where market participants are free to take a view on: 1) the value of a company long-term; 2) its ability to upset conventional wisdom and technologies; and 3) its sustainability to advance technologies to meaningful healthcare solutions.

As such, patience is asked from many of us within the firm, but also from those supporting it as investors. At the centre of our professional endeavours to build a for-profit organisation lies the notion of advancing *controversial ideas* in order to *access larger markets*, very well knowing that in a public setting expectations are high and memories short. We emphasise that, particular to bio-pharmaceuticals, entrepreneurship ought to be defined as putting earnings to work to generate future value and multiple revenue streams to diversify risk. Brick by brick we are building a house of viable, yet aligned objectives.

The Directors' view is that a financial basis to fund the next set of controversial concepts is key to CLINUVEL's long-term success. A deeper understanding of this approach is necessary to appreciate decisions to self-fund the development of melanocortins as the ultimate disruptive technology in repigmentation disorders (read: vitiligo) or in repairing skin's DNA (damaged by ultraviolet radiation). The uncertainty of institutional investors further funding melanocortins in vitiligo or other conditions would be too high under current market conditions and would therefore introduce existential risk. We believe that the upside of success will off-set the time value to reach North American vitiligo markets. CLINUVEL's current balance sheet strength reflects longitudinal decisions taken over the years.

Given the translational opportunity to use melanocortins not only in pharmaceuticals but also in PhotoCosmetics, higher visibility is needed among larger audiences, predominantly in North America. From January 2025, mainstream media and traditional industry press is expected to bring the Company and its story to the attention of US patient, consumer and investment audiences.

We will collectively draw a balance on the last day of the new year to evaluate whether this differing approach will have resulted in turning CLINUVEL into a wide-spread name known for its leadership in photomedicine.

With much excitement for 2025, I wish our patients, families and shareholders good health and fortune over the coming 12 months as you follow our odyssey.

Philippe Wolgen

Engaging the market

Lachlan Hay, COO; Peter Vaughan, CFO

With the addition of Myles Clouston in April to head up US Investor Relations, the IR team was able to connect with a considerably wider audience during 2024, familiarising and re-engaging North American institutions and analysts with the Company's story, while conducting roadshows in Australia and Europe and hosting our first Capital Markets Briefing in Sydney. The Company continues to receive coverage from nine analysts across Australia and Europe, with others following the story closely.

We enter 2025 with high expectations of our IR team, who have mapped out an extensive IR program for the year:

Period	**Events** (planned and actual)
January	JP Morgan Healthcare conference, San Francisco
February	Appendix 4D & Half Yearly Report Non-deal roadshow (NDR), Melbourne
March-April	Twilight Briefing, Melbourne NDR, Sydney Capital Markets Briefing, Germany NDR, Germany-Switzerland
May	Wilsons Rapid Insights Conference Capital Markets Briefing, Sydney
June	Jefferies Healthcare Conference, New York NDR, New York Capital Markets Briefing, New York NDR, San Francisco
August	Bioshares Summit, Hobart Appendix 4E & FY25 Annual Report NDR, Melbourne
September	NDR, Sydney NDR, Germany-Switzerland
October	Annual General Meeting (TBC)
November	Jefferies London Healthcare Conference Bell Potter Healthcare Conference

In addition to the above, the Company intends to publish quarterly News Communiqués and CBM Bulletins, increased social media updates, and key presentations throughout the year.

JP Morgan's Healthcare Conference – starting next week – is widely recognised as one of the largest events on the corporate life sciences calendar. Hosted annually, it is generally seen as setting the agenda and identifying trends for the coming year, as well as an opportunity for companies to engage the investment community afresh after the year end break. We will publish a summary update shortly after the JP Morgan conference to share some thoughts on what is expected for the industry.

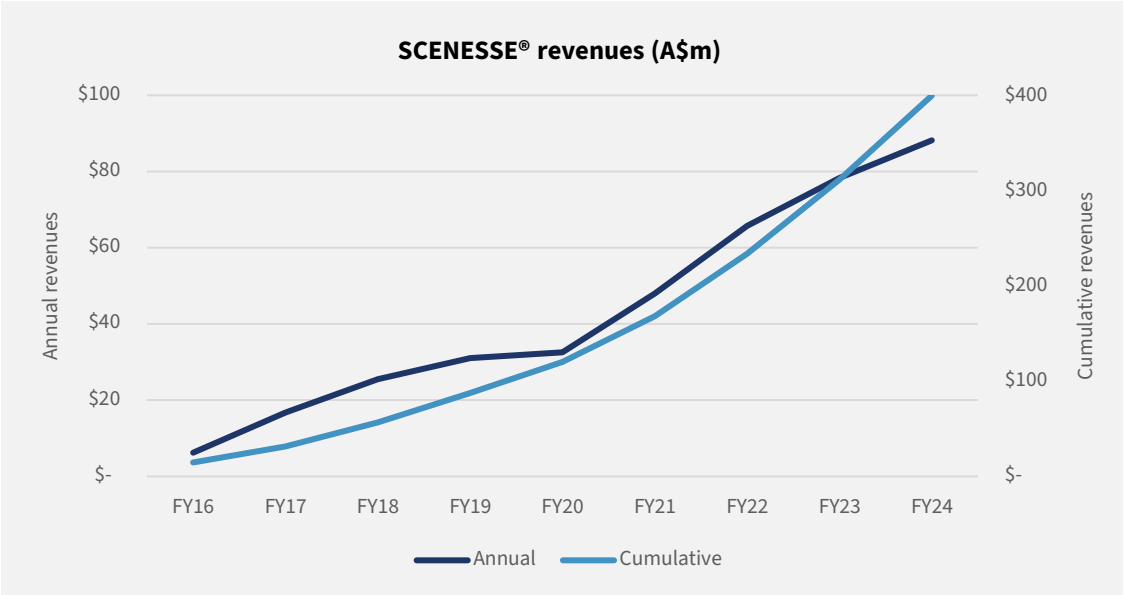
Strengthening the foundations of the melanocortin house

In May 2010, CLINUVEL announced that the Italian health authorities (AIFA) would commence reimbursement of SCENESSE® for the treatment of Italian erythropoietic protoporphyria (EPP) patients. With supply heavily subsidised by the Company, we reported our first A$1m in cumulative revenue from the Italian program some 13 months later.

The Italian program (expanded two years later into Switzerland, both prior to any marketing authorisation) gave the team confidence that there was a commercial proof-of-concept, that the use of melanocortins to treat a rare metabolic disorder was acceptable to regulators, to physicians and –

perhaps above all – to patients. It also established some conventions which we now see as rules as to how we approach commercialisation: work collaboratively with experts to provide longitudinal care; collect data and knowledge from ongoing use; maintain control over the supply chain to ensure only patients receive treatment and that we're not at the mercy of intermediaries dictating commercial terms; and approach product pricing in a fair, transparent manner. While this is not an exhaustive list, it has given our team beacons by which to navigate growth and helped colour our thinking in the long-term as well.

The commercial success of FY24 is the direct result of both long- and mid-term planning, consistency of approach, and knowledge developed globally. During FY24, we generated A$88m in SCENESSE® sales, treating more patients than any year to date, across more centres, and trending towards higher dose administrations per patient per annum, reflecting ongoing demand. The CLINUVEL team delivered a 13% year-on-year revenue increase. Cumulative revenues from SCENESSE® supply to 30 June 2024 total A$400m.



In FY21 – amidst the disruption of the pandemic – we began discussing publicly how we might arrive at the foundations now in place and ensure a larger number of patients receive melanocortin treatment. This included shoring up the value chain, expanding patient access, mapping out an expanded clinical program, and establishing a target rate of expenditure (A$175m over five years) which could be justified by our internal forecasts of revenue growth. Put bluntly, how could CLINUVEL insulate itself from any further global disruptions whilst setting a formidable foundation to achieve its objectives? Five years later, much of this foundation is built, with around $200m in cash reserves at the end of December 2024 to construct the next layers.

Greater treatment access for EPP patients is one clear objective. Regulatory initiatives in Europe aim to facilitate more year-round treatment for those patients who demand it, aligning the US and European labels. Data are being generated and analysed to strengthen the case for adolescent use of SCENESSE®, while our team in Singapore develop and refine next generation approaches to melanocortin formulation and delivery, with a view to treatment regimens appropriate for paediatric patients. CLINUVEL's partnership with Valentech in Latin America has laid groundwork for patient treatment, while our commercial team are continuously evaluating similar opportunities in other jurisdictions. As announced in late December, we also expect a formal decision on Canadian marketing authorisation during calendar year 2025.

The Company's cash position allows us to invest aggressively, but selectively, in ongoing R&D programs, with a particular focus on vitiligo. 2025 will see us complete recruitment for the ongoing CUV105 study and commence a further Phase III study (CUV107), incorporating key learnings from the program. The American Academy of Dermatology Meeting – held in Orlando in March this year – will provide a global platform for our teams to engage the broader dermatology community like never before, with over 20,000 healthcare professionals expected to attend.

Our financial position also provides us with optionality to actively pursue and take advantage of opportunities as they arise. Our team are consistently evaluating potential transactions, assets, partnerships and novel development approaches to grow our pipeline and revenue streams over time. Any such additions need to be aligned with our thinking and trajectory and, importantly, we need to ensure they are value accretive, worthy of investment of resource and energy.

Systems upgrades

CLINUVEL is making an investment over the next six months to evolve its systems to effectively support both current and future commercial growth. In particular, we are enhancing our financial and operational infrastructure by integrating advanced automation and real-time data analytics – tools that will allow our managers to more easily assess and analyse how environmental or operational shifts and decisions may impact the business and grasp longer-term trends. The system upgrades are focused to streamline key reporting processes, minimise manual intervention, and provide immediate access to vital financial and commercial insights. Once complete, we expect to have built a solid basis for well-informed, agile decision-making, to drive operational efficiency. Most importantly, these systems are designed for scale with our organisation enabling the business to support larger, more complex operations globally.

This approach will also further fortify our risk management and compliance frameworks to maintain robust visibility and control across all our business units. While supporting our existing and future business, these measures will also facilitate a smooth integration of any strategic acquisitions while preserving financial discipline and ensuring adherence to regulatory requirements.

The traditional drug development model relies upon heavily outsourced operations, particularly for clinical trial management where clinical research organisations (CROs) add considerable cost and timeline burdens. CLINUVEL has always maintained that an in-house team can deliver a more cost-effective result, so we have made the strategic decision to build a team capable of managing our clinical trials and global reporting processes in-house. In doing so, one of our divisions is becoming an operation resembling a CRO, using integrated software to track and report our clinical programs to gain real-time, actionable insights for improved data-capture for enrolment monitoring, patient attendance, financial commitments, and logistics reducing our reliance on costly third-party providers. This reduced, risk-based, remote approach to clinical trial management allows for reduced in-person site and patient monitoring reducing costs and staff travel requirements.

These system enhancements will lay the foundations for a scalable, efficient, and cost-effective operational model positioning us for sustainable growth as we continue to expand across our global markets.

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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, 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.

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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 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.

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