CLINUVEL

COMPANY ANNOUNCEMENT

Melbourne, Australia, 22 February 2024 ASX: CUV | Börse Frankfurt: UR9 | ADR Level 1: CLVLY

CLINUVEL Delivers Increased Revenues, Solid Earnings in December 2023 Half Year

An Investor Webinar will be held today (22 February) at 18:00–18:30 AEDT (08:00–08:30 CET) to discuss the half year results – refer below.

EXECUTIVE SUMMARY

Results: Half Year to 31 December 2023

- Revenues up 10%
- Net assets increased 9%; cash and term deposits up 11% from 30 June 2023 to \$174.5m
- NPBT \$14.8m, up 1% with controlled 28% expenses increase
- NPAT \$10.9m, lower by 4% from increased income tax expense

Increases compared to six months to 31/12/22, unless stated otherwise. All figures reported in Australian dollars, \$

	31 December 2023	31 December 2022	Change
Revenues, \$	32,256,885	29,355,042	+9.9%
Expenses, \$	20,924,198	16,376,227	+28.0%
Net Profit before tax, \$	14,805,699	14,599,951	+1.4%
Net Profit after tax, \$	10,936,043	11,387,665	-4.0%
Basic earnings per share, \$	0.22	0.23	-3.9%
Cash and term deposits, \$	174,449,193	156,813,537*	+11.2%*

*Increase from 30 June 2023.

CLINUVEL has today reported a 10% increase in revenues and a 1% rise in underlying earnings before tax for the half year to 31 December 2023, with the Group delivering a net profit after tax.

"Today's results reflect the consistent and resilient nature of CLINUVEL's business, based on strong ongoing demand for SCENESSE" treatment by patients in Europe and the USA," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said.

"We have invested heavily in people, property, and clinical programs over the last six months to ensure long-term returns, while increasing our cash and term deposit position by 11% over the period to provide a reinforced foundation."

Increased revenues – generated from sales of CLINUVEL's photoprotective drug SCENESSE[®] (afamelanotide 16mg) – were driven by an increase in patients receiving treatment for the first time in North America where CLINUVEL has established a network of Specialty Centers to provide continuing clinical care.

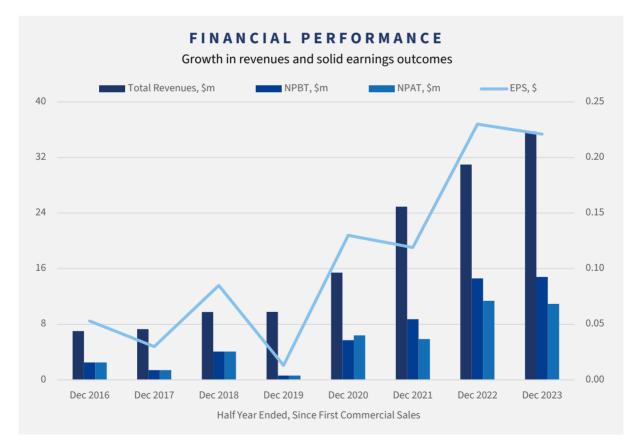
The period-on-period increase in expenses (28%) reflects the expansion of activities across the Group and includes a 10% rise in employee head count. The Company has also invested in a new commercial office facility to support an expanding workforce. Underlying earnings before tax grew to \$14.8m, up 1% compared to the six months to December 2022. Deferred tax benefits brought to account in the prior period resulted in a higher income tax expense result in this period reducing the comparative net profit after tax result.

"CLINUVEL has been able to achieve growth in underlying earnings whilst increasing expenditures to advance its accelerating diversification strategy. This is an excellent outcome," Mr Keamy said.

"We strive to maintain an equilibrium between prudent fiscal management and expanding the Group's commercial foundations by re-investing in our operations. We believe the right balance is being achieved, with constant review and adjustment as needed."

Financial performance

This is the fifteenth consecutive half year profit since the commencement of CLINUVEL's commercial operations.



"CLINUVEL is on track to remain within its projected overall expenditures of \$175 million for the five financial years ending June 2025, excluding investments of a capital nature. Seventy percent of the way into this timeline, accumulated expenditures have reached two-thirds of the Group's target," Mr Keamy said.

The Company maintained a balance sheet free from external borrowings, with a rise in total assets of 9% to \$211.7 million.

CLINUVEL will report its full financial year results in August 2024.

CLINUVEL Investor Webinar

CLINUVEL will host an investor and analyst webinar at 18:00 AEDT today to review the half year results to December 2023. Participants can register using the link below:

INVESTOR WEBINAR 22 February 2024 18:00-18:30 AEDT (08:00-08:30 CET)

To participate, please register using this link:

https://us06web.zoom.us/webinar/register/WN_ZaXcveRpSOefaZd1tb1I-w#/registration

Questions may be tabled as you register, and during the webinar.

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CLINUVEL's Appendix 4D Half Yearly Report is available on the Company's website, www.clinuvel.com.

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.

Contact:

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