CLINUVEL

MEDIA RELEASE

# Global SCENESSE® demand drives increased CLINUVEL revenues, earnings

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| **Melbourne, Australia, 24 February 2023** | ASX: | CUV |
| | Börse Frankfurt: | UR9 |
| | ADR Level 1: | CLVLY |

## Executive summary

### Positive Results in the Half Year to 31 December 2022

- 19% increase in revenues from clinical demand for SCENESSE® (afamelanotide 16mg).
- 94% increase in NPAT; 67% increase in EBIT.
- Net assets increased by 11%; 16% growth in cash to $140.7 million since the start of the reporting period.

*Increases year on year compared to six months to 31/12/21, unless stated otherwise.*
*All figures reported in Australian dollars, $.*

| | 31 December 2022 | 31 December 2021 | Change |
|---|---|---|---|
| Revenues, $ | 29,355,042 | 24,631,266 | +19.2% |
| Profit after tax, $ | 11,387,665 | 5,870,380 | +93.9% |
| Basic Earnings per share, $ | 0.230 | 0.119 | +93.3% |
| Cash, $ | 140,703,376 | | +15.8%* |

**Increase from 30 June 2022.*

For the six months ended 31 December 2022, CLINUVEL is pleased to record a 19% increase in its revenues, and 94% increase in net earnings after tax, or $11.39 million.

*"Today's excellent figures are the result of years of focus and financial discipline, while operationally facilitating supply of SCENESSE® to patients in Europe and the USA,"* CLINUVEL's Chief Financial Officer, Mr Darren Keamy said.

*"The number of prescriptions for, patients receiving, and expert centres administering the therapy have all increased over the period.*

*"The performance exceeds our expectations, thereby precipitating the financial basis to expand our portfolio of melanocortins, diversify markets, and become a self-sufficient company.*

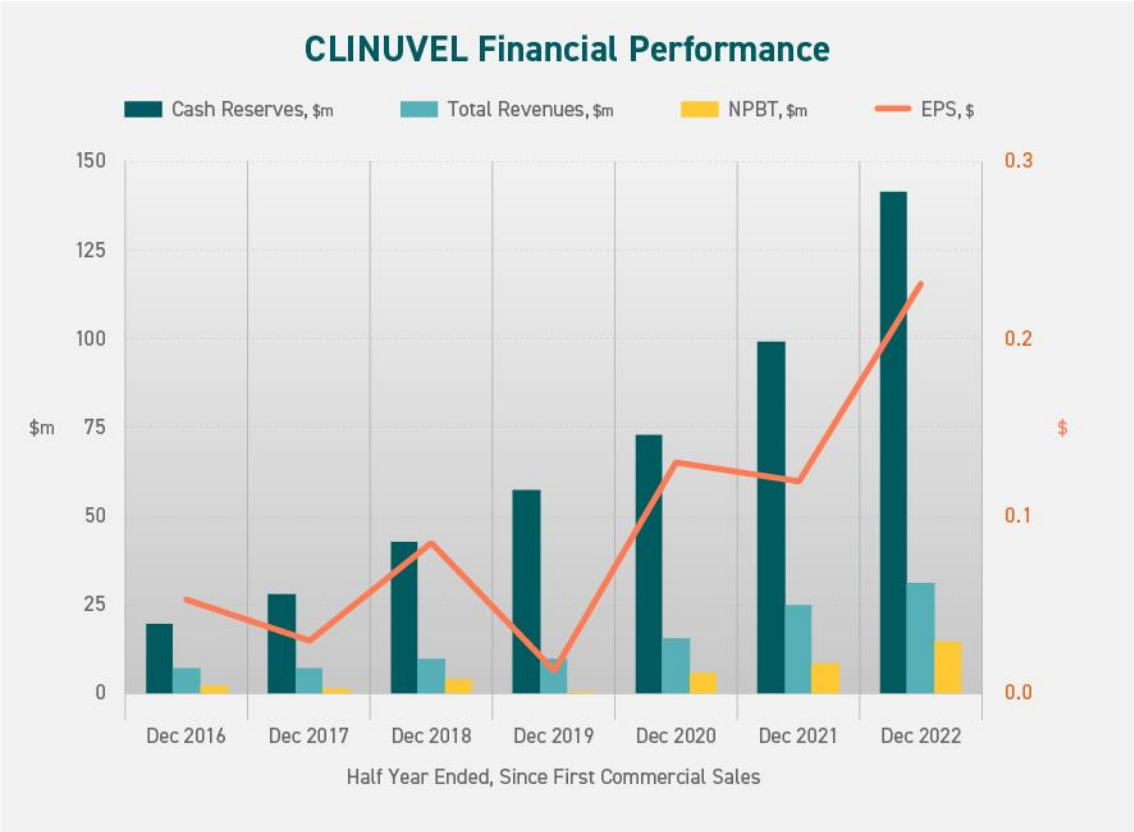
*"Working within our set budgets, we are now focused on bettering our results for the financial year end. It is an exciting moment in the history of the Company."*

Alongside the revenue result, CLINUVEL contained its expenses during the half year period to achieve a negligible rise of 1%, furthering its balance sheet. As of 31 December, CLINUVEL held

cash and cash equivalents of over $140 million, a 16% increase from 30 June, with total assets above $160 million.

*"We have actively managed CLINUVEL's commercial programs, translating to a steady increase in liquid assets, as well as earnings per share,"* Mr Keamy said.

*"In parallel, we have made necessary investments to advance clinical research and new product development, while placing emphasis on cost control. There is not much debate around prudent fiscal management in a climate of macroeconomic uncertainty, therefore we keep a balance between strengthening the Group's commercial basis and expansion. Most of all, I am pleased for patients and our shareholders, as our financial record and stability provides options for pursuing our long-term objectives."*




## Financial performance

The 67% increase in net profit before tax was the fourteenth consecutive half year profit since the commencement of CLINUVEL's commercial operations in June 2016. The 94% rise in net profit after tax achieved is the highest recorded by the Group for a December half year.

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. Half-way along this timeline, total expenditures have reached approximately 41% of the Group's target.

The Company maintained a balance sheet free from external borrowings, with a rise in total assets of 11.4% to $160.3 million. CLINUVEL will report its full financial year results in August 2023.

**– END –**

**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 the general population. 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, 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.

SCENESSE®, PRÉNUMBRA®, and NEURACTHEL® are registered trademarks of CLINUVEL.

**Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD**

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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 2022 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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