Company Announcement

CLINUVEL

ASX: **CUV**
Nasdaq International Designation: CLVLY
XETRA-DAX: **UR9**

CLINUVEL REPORTS PROFIT, RE-INVESTING IN BUSINESS

Fourth consecutive annual positive net cash flow and profit before tax, unfranked dividend declared

An investor webinar will be held at 18:00 AEST today (27 Aug); see details below

Melbourne, Australia, 27 August 2020

CLINUVEL PHARMACEUTICALS LTD (CLINUVEL), a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and systemic disorders today announced its Appendix 4E and Preliminary Final Report (audited) for the year ending 30 June 2020 (FY2020).

GROWTH OF TREATMENT ACCESS

CLINUVEL is focused on expanding access to its novel drug SCENESSE® (afamelanotide 16mg) for adult erythropoietic protoporphyria (EPP) patients worldwide, while developing novel products for patients and consumers.[1] During FY2020, SCENESSE® was approved and launched in the USA and broader market access was facilitated in Europe, where the product has been available by prescription since 2016.

FINANCIAL SUMMARY

The Group has reported growth in total revenues of five percent, growth in cash reserves of 23 percent and a net profit before tax result of A$13.136 million. It is the fourth consecutive year CLINUVEL has recorded an annual profit. Today, an unfranked dividend of A$0.025 per share was declared, the third consecutive annual distribution of capital to CLINUVEL's supportive long-term investors.

All figures are rounded and reported in Australian dollars.

12 months ending	30 June 2020	30 June 2019
Key Financial Results	$ '000	$ '000
Total Revenues	32,565	31,048
Total Expenses	(20,773)	(14,384)
Net Profit Before Tax	13,136	18,115
Net Profit After Tax [a]	16,647	18,134
Operating Cash Flows	14,188	18,456
Cash and Cash Equivalents	66,747	54,269
Net Tangible Assets	73,669	57,180
Key Performance Statistics		
Current Ratio	11:1	12:1
Equity to Assets Ratio	0.9:1	0.9:1
Basic Earnings Per Share	33.8 cents	37.6 cents
Return on Equity	23%	32%
Share Price (CUV) Change	(24%)	206%
Unfranked Dividend Per Share	$0.025	$0.025

[a.] FY2020 NPAT includes income tax benefits of A$3.150m from the recognition of deferred tax assets in the balance sheet by bringing unused tax losses to account.

COMMERCIALISATION, RESEARCH AND DEVELOPMENT INVESTMENT

CLINUVEL has implemented a planned and focussed strategy of first commercialising and then investing in further follow-on research and development (R&D) of its pharmaceutical product SCENESSE® to maximise its value potential. In line with this strategy, CLINUVEL has increased its year-on-year investment in commercial, research and development activities, reflected in a controlled increase across most expenditure categories.

In FY2020 the Company expanded the number of staff in senior and support positions globally, with particular emphasis on widening its scientific, technological and commercial capabilities. The total expenditures on R&D and commercialisation costs, comprising clinical study costs, drug formulation research, manufacture and distribution, regulatory fees and research, development and commercialisation-specific overheads such as personnel, were A$9.630 million in FY2020, increasing 40% from A$6.871 million in FY2019. The net cash used in investing activities was A$0.889 million in FY2020, primarily on the capital expansion of the VALLAURIX laboratories in Singapore due to be completed in the current quarter.

COMMENTARY

"The Company has continued to meet its objectives to provide treatment despite the monumental societal changes which occurred in early 2020," CLINUVEL's CFO, Mr Darren Keamy said. "While many healthcare facilities came to a standstill and focussed on critically ill COVID-19 patients, we managed to continue the supply of SCENESSE® to EPP centres both in Europe and the USA."

"Today's results demonstrate not only an ability to maintain discipline in expenditure and cash management, but also a strength in managing our expenditure levels as a means to invest in future growth. In maintaining sufficient working capital to withstand adverse market conditions, and without further diluting shareholders or assuming debt, we have delivered a return on equity of 23 percent.

"The Board of Directors further recognise the supportive and long-term investors of CLINUVEL by declaring an annual dividend, a redistribution of profits consistent with FY2019. The financial results of 2020 demonstrate ongoing value creation, as we gradually expand the business, as well as CLINUVEL's stability during unsettling global conditions," Mr Keamy said.

Full details of the financial results are in the Appendix 4E and Preliminary Final Report announced separately.

CLINUVEL BRIEFING

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

Investor Zoom Webinar 18:00-18:30 AEST (10:00-10:30 CEST) today (27 Aug)

You are invited to register using this link:
https://us02web.zoom.us/webinar/register/WN_T5plWpuSSkSAs79J8VhHkA
Questions may be tabled as you register or during the webinar

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[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). SCENESSE® is approved in the USA to increase "pain-free" light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

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

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic, skin, and systemic disorders. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development initially has led to innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 and the US Food and Drug Administration in 2019 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). More information on EPP can be found at http://www.epp.care. CLINUVEL is advancing its portfolio of melanocortins, among which is PRÉNUMBRA® for the treatment of several critical disorders. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA. For more information please go to http://www.clinuvel.com.

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 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); our ability to achieve expected safety and efficacy results 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, 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® 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 based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure 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 2019 Annual Report and 2020 Preliminary Final 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 the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

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