CLINUVEL

COMPANY ANNOUNCEMENT

CLINUVEL REPORTS TENTH CONSECUTIVE HALF YEAR NET PROFIT

Melbourne, Australia, 24 February 2021	ASX: XETRA-DAX: NASDAQ INTERNATIONAL DESIGNATION:	CUV UR9 CLVLY

KEY HIGHLIGHTS, HALF YEAR ENDED 31 DECEMBER 2020

Consolidated Entity	Result	Change from same period 2019
Total Revenues	$15,743,000	Up 58%
Total Expenses	$9,621,000	Up 5%
Net Profit before income tax	$5,811,000	Up 852%
Profit after income tax expense	$6,487,000	Up 962%
Basic Earnings per share	$0.133	Up 956%
Net Tangible Assets backing per share	$1.481	Up 10%

All figures reported in Australian dollars. Refer to the Appendix 4D Half Year Report released to the Australian Securities Exchange for details.

CLINUVEL today announced its tenth consecutive half year net profit, released in its Half Yearly Report for the six months ended 31 December 2020. The Company achieved revenues for the period of $15.743 million and posted a half year net profit before tax of $5.811 million.

"CLINUVEL's long-term strategy and focus has been reaffirmed by today's results," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said. "Despite ongoing global economic uncertainty, our team has expanded distribution of our lead drug SCENESSE® in both the USA and Europe through our efficient business model and by exercising financial restraint and control.

"The Company is in a sound financial position to continue to grow and fund its expansion. We are investing in our R&D and clinical programs and progressing our evolution into a diversified pharmaceutical company," Mr Keamy said.

COMMERCIAL AND CLINICAL PROGRESS AND GROWTH

CLINUVEL continues to strengthen its business despite the operating challenges of the pandemic and the world's largest economic contraction since the Great Depression in 1929.

During the December 2020 half year period, CLINUVEL increased access to its drug SCENESSE® (afamelanotide 16mg)[1] for patients with the rare metabolic disorder, erythropoietic

protoporphyria (EPP) in both Europe and the USA. SCENESSE® was also approved to be listed on the Australian Therapeutic Goods Register by the Therapeutic Goods Administration in October 2020.

CLINUVEL has expanded its clinical development plans for SCENESSE®, announcing two new clinical programs. The Company's DNA Repair Program seeks to confirm the drug's ability to repair ultraviolet-induced DNA damage in patients with the rare disorder xeroderma pigmentosum (XP) and healthy volunteers with fair skin. CLINUVEL is also evaluating SCENESSE® in patients with arterial ischaemic stroke (AIS) in the innovative CUV801 study, expected to commence shortly.

In October 2020 CLINUVEL released a Strategic Update, outlining its plans to translate the Company's melanocortin technology from medicinal products to healthcare solutions for wider audiences. The expanded Group is structured with three divisions – Pharmaceuticals, Healthcare Solutions and Communications, Branding & Marketing – linked by the Research, Development & Innovation Centre at the VALLAURIX subsidiary in Singapore.

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CLINUVEL's Appendix 4D is available on the Company's website, www.clinuvel.com. CLINUVEL will release an Operations Update Webinar on its website on 25 February.

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product and the world's first systemic photoprotective pharmaceutical 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. SCENESSE® is approved in Australia for the prevention of phototoxicity in adult patients with EPP. SCENESSE® is approved in Israel as a first line treatment for the prevention of phototoxicity to all adult patients diagnosed with EPP. 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 and diversified biopharmaceutical company focused on developing and commercialising treatments for patients with genetic, metabolic, and life-threatening disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair and acute or life-threatening conditions. 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, the US Food and Drug Administration in 2019 and the Australian Therapeutic Goods Administration in 2020 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. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA. For more information, please go to http://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 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 2020 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 the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

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