COMPANY ANNOUNCEMENT

Appendix 4C and Activity Report

CLINUVEL REPORTS HIGHEST ANNUAL ROLLING CASH RECEIPTS

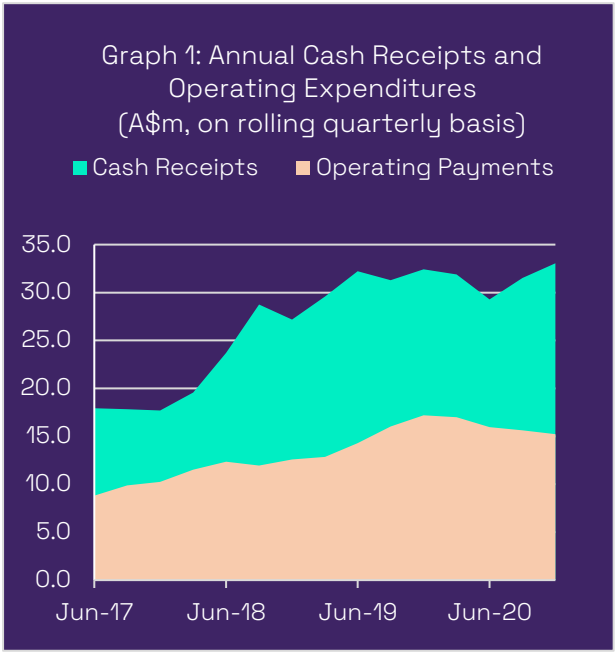
Melbourne, Australia, 28 January 2021

ASX:	CUV
XETRA-DAX:	UR9
NASDAQ INTERNATIONAL DESIGNATION:	CLVLY

CLINUVEL PHARMACEUTICALS LTD today announced its Appendix 4C – Quarterly Cashflow Report and Activity Report for the period 01 October to 31 December 2020. All figures are rounded and reported in Australian dollars.

KEY CASH FLOW HIGHLIGHTS Q2 FY21:

Cash receipts	$5,266,000
Net operating cash flow	$1,293,000
Cash Flow 01 Jan-31 Dec 2020	$33,053,000



OPERATING CONDITIONS AND THE GLOBAL ECONOMY

The coronavirus pandemic is causing anguish with the ongoing loss of human life, and the world is experiencing the largest contraction since the Great Depression of 1929. Despite some economies showing signs of resilience, the pace of recovery is proving to be disparate.

In this unprecedented environment where hospital and medical supplies face new challenges, CLINUVEL continues to strengthen its business and balance sheet. In the current financial year CLINUVEL has expanded both its commercial operation in the USA and its research and development program, without having to enter equity or debt financing. Following a fourth consecutive annual profit in the financial year ending 30 June 2020, and a positive cashflow outcome in the 2020 September quarter, the Company continues to record positive cash receipts in the 2020 December quarter leading to an increase in cash reserves.

COMMENTARY

"The continued performance of the Group stems from our measured strategy, consistent execution, and treatment demand from both the USA and Europe, which have contributed to a new high in annual cash receipts," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said.

"Against the ongoing backdrop of economic uncertainty, and in a quarter where cash receipts are historically lower, reflecting the seasonal demand, we have now been able to deliver a positive net cash result in the December quarter, the first since 2017.

"As of today, CLINUVEL is in a good position to pursue further investments in its R&D and clinical programs, aiming to deliver long-term value while building out the CLINUVEL Group of companies," Mr Keamy said.

STRONG CASH RECEIPTS AND NET CASH

Cash receipts of $5,266,000 reflects the contribution from the commercial distribution of SCENESSE® (afamelanotide 16 mg) in the United States and the European Economic Area. Net cash flow from operating activities was $1,293,000 in the quarter.

ANNUAL TREND IN CASH RECEIPTS AND EXPENDITURES

Graph 1 shows CLINUVEL's annual cash receipts at each quarterly timepoint since the June quarter 2017 (on a rolling annual basis). The last two quarters of 2020 includes cash receipts from the distribution of SCENESSE® in the US which commenced in April 2020. Rolling annual cash receipts to 31 December 2020 from the distribution of SCENESSE® were $33,053,000 – the highest since commercial operations commenced in June 2016.

Whilst distribution of SCENESSE® in the USA commenced in April 2020, the cash receipt cycle is longer than in Europe, in part due to the decentralised reimbursement system. As part of the administrative handling required by all parties in the billing and reimbursement process, CLINUVEL is recording cash receipts in cases which are longer than 90 days from invoice date. This period is expected to shorten as insurers include the new treatment within their administrative databases.

CONTROLLED GROWTH IN EXPENDITURES

Annual operating expenditures have been controlled and gradually increase over time to support the Group's future growth, including head count and supply chain costs. Expenditures from net operating activities were $4,111,000 in the December quarter 2020; these do not include the impact from other receipts, such as interest received from placing cash reserves on term deposit. Further growth in the business, including the preparation of its clinical program in DNA regeneration and stroke (AIS) and research & development are in line with the Company's strategic plan. **Graph 1** illustrates the expected upward growth to overall operating expenditures to realise CLINUVEL's plans.

REVIEW OF KEY ACTIVITIES

The Group continued to develop its commercial operations in the December quarter 2020 in Europe and the USA. Research and development activities were expanded with a focus on novel treatments for patients with severe genetic and vascular disorders who lack therapeutic alternatives.

After some deferral of orders or reduced order sizes in the initial months of 2020 due to the coronavirus pandemic in Europe, demand has largely normalised and patient adherence to SCENESSE® treatment remains high.

The Company's key activities in the quarter included:

- Progress in the DNA Repair Program with the completion of treatment of the first xeroderma pigmentosum (XP) patient with SCENESSE® to evaluate the product's safety and satisfy the request from authorities. The XPC patient tolerated treatment well, providing the basis on which a Phase II study (CUV150) will proceed in a group of six XP-C patients, subject to ethics committee and other approvals to start during the COVID pandemic.
- Approval of SCENESSE® by the Australian Therapeutic Goods Administration to treat adult patients with EPP.
- Expansion of the research and development program to evaluate the effects of afamelanotide, the active ingredient in SCENESSE®, in patients suffering from arterial ischaemic stroke (AIS). Pending COVID restrictions, a pilot Phase II study (CUV801) will commence to administer afamelanotide to up to six AIS patients to evaluate its safety and effectiveness.

- A strategic update (26 October 2020) to outline the Group's new divisional structure and expanded research and development program to support the diversification and growth of the Group in pharmaceutical products for unmet medical needs and non-pharmaceutical products for wider healthcare use.

The Company's announcements on each of these events are available on the CLINUVEL website.

Although the Company is not obligated to publish quarterly cash flow results, it elects to continue to do so to keep its investors regularly and periodically updated. A copy of the Appendix 4C – Quarterly Cash Flow Report for the second quarter of FY2021 is attached.

Pursuant to Listing Rule 4.7C and as disclosed in Item 6.1 to the attached Appendix 4C, $338,000 was paid in respect to Non-Executive Director and Managing Director fees, while this figure is inclusive of the value of non-monetary benefits.

- End -

[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. 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.

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 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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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
CLINUVEL PHARMACEUTICALS LIMITED	
ABN	**Quarter ended ("current quarter")**
88 089 644 119	31 DECEMBER 2020

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	5,266	17,281
1.2	Payments for		
	(a) research and development	(154)	(545)
	(b) product manufacturing and operating costs	(1,317)	(2,561)
	(c) advertising and marketing	(97)	(118)
	(d) leased assets	(84)	(170)
	(e) staff costs	(1,861)	(3,773)
	(f) administration and corporate costs	(587)	(1,231)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	95	201
1.5	Interest and other costs of finance paid	(6)	(13)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	43	81
1.8	Other (provide details if material)	(5)	22
1.9	**Net cash from / (used in) operating activities**	**1,293**	**9,174**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(145)	(795)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	-
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(145)**	**(795)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(74)	(133)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	(1,235)
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**(74)**	**(1,368)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	72,759	66,747
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,293	9,174
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(145)	(795)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(74)	(1,368)
4.5	Effect of movement in exchange rates on cash held	(915)	(840)
4.6	**Cash and cash equivalents at end of period**	**72,918**	**72,918**

5.	**Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	30,448	28,782
5.2	Call deposits	42,168	43,620
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	302	357
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**72,918**	**72,759**

6.	**Payments to related parties of the entity and their associates**	**Current quarter $A'000**
6.1	Aggregate amount of payments to related parties and their associates included in item 1	338
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	
8.2	Cash and cash equivalents at quarter end (item 4.6)	
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	n/a

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?
Answer:	
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?
Answer:	

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: .....28 January 2021.....

Authorised by: Board of Directors of CLINUVEL PHARMACEUTICALS LTD

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(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.