CLINUVEL

COMPANY ANNOUNCEMENT

Appendix 4C & Activity Report

Cash receipts increasing in a difficult operating environment

Melbourne, Australia, 29 April 2021	ASX: XETRA-DAX: NASDAQ INTERNATIONAL DESIGNATION:	CUV UR9 CLVLY

CLINUVEL PHARMACEUTICALS LTD today announced its Appendix 4C – Quarterly Cashflow Report and Activity Report for the period 01 January to 31 March 2021. All figures are rounded and reported in Australian dollars.

CLINUVEL MAINTAINS FOCUS

The coronavirus pandemic continues to have an adverse impact on healthcare services, chronically ill patients and the operating environment for companies worldwide. Whilst approved COVID vaccines are now being distributed in many countries, all continue to face human loss and ongoing economic disruption.

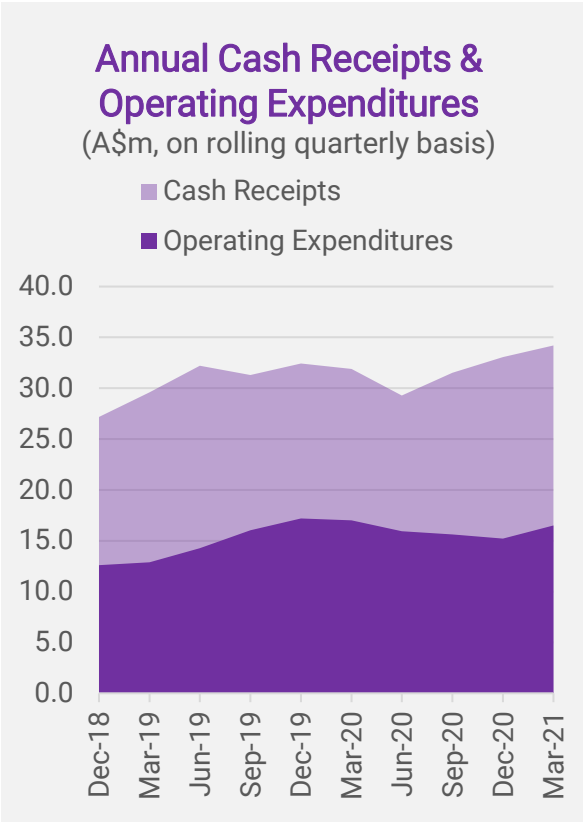
Despite the longer-term economic impact of the pandemic, CLINUVEL remains focussed on providing innovative solutions for patients and broader audiences. Under these adverse conditions, and throughout the current financial year, CLINUVEL has reported strong financial performance. The Company posted a tenth consecutive half year net profit in the six months to 31 December 2020, with an increase in net profit of 962% driven by a 58% increase in revenue. In the latest quarter of March 2021, the Company has continued to grow its receipts.

INCREASING CASH RECEIPTS AND POSITIVE NET CASH

CLINUVEL has reported cash receipts of $6,524,000 for the March quarter of 2021. This result reflects the increasing contribution from the commercial distribution of SCENESSE® (afamelanotide 16 mg)[1] in the European Economic Area and the United States for adult patients with the rare genetic and metabolic condition, erythropoietic protoporphyria (EPP). Net operating cash flows were $1,986,000 for the quarter.

After deferral of some orders or reduced order sizes during the outbreak of the coronavirus in Europe in 2020, demand seems largely normalised while patient adherence to SCENESSE® treatment remains very high. In the USA, 40 Speciality Centers are trained and accredited to administer SCENESSE® to EPP patients, exceeding the 30 which originally had been planned.

KEY CASH FLOW HIGHLIGHTS Q3 FY21	
Cash receipts	$6,524,000
Cash expenditures	$4,679,000
Net operating cash flow	$1,986,000



"*Our medical distribution model is effective in Europe and the US, which really needs to be seen against a challenging environment where lockdowns disrupt economic activity and the mobility of people*," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said.

"In alignment with our Strategic Updates, we focus on building the business through vertical integration of key functions to reach sustainability and self-reliance. As a result, the Company is controlling the increase of investments in a staged process to achieve these long-term goals," Mr Keamy said.

ORDERLY GROWTH IN EXPENDITURES

Annual operating expenditures are maintained to support the Group's future growth. Expenditures from net operating activities were $4,679,000 in the March quarter 2021. Key expenditures for this result included payments towards various annual corporate insurances, head count and formulation & manufacture. Future initiatives to support the achievement of the objectives, as outlined in Strategic Update II announced on 12 April 2021, will continue to play an important role in overall expenditure levels.

REVIEW OF KEY ACTIVITIES

In the March quarter 2021, the Group continued to progress commercial operations in Europe and the USA and maintain focus on the expansion of research and development activities. The Company's key activities in the quarter included:

- The grant of market access in Israel, with the Israeli Ministry of Health approving SCENESSE® as a first-line treatment for the prevention on phototoxicity in adult patients diagnosed with EPP. This opens the pathway for similar approvals in other countries in the Middle East. Preparations are underway to launch SCENESSE® in Israel.

- The DNA Repair Program which commenced in September 2020 was expanded, with the agreement of clinical and academic experts, to include patients with xeroderma pigmentosum variant (XP-V).

- Chairman Willem Blijdorp announced that CLINUVEL would establish a Manufacturing Division. This fourth division of the Group will focus on manufacturing novel formulations and products for CLINUVEL and offer research, development and production to other companies and research groups within the biopharmaceutical sector.

The Strategic Update II provides an overview of the new divisional structure of CLINUVEL and status of the expanded clinical program. Announcements on other events during the past quarter are available on the CLINUVEL website and CLINUVEL News.

Although the Company is not obligated to publish quarterly cash flow results, it elects to continue to do so to keep its global investors 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, $913,000 was paid in respect to Non-Executive Directors 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 and Australia as an orphan medicinal product for the prevention of 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.

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.

SCENESSE® and PRÉNUMBRA® are registered trademarks of CLINUVEL PHARMACEUTICALS LTD.

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 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 MARCH 2021

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	6,524	23,805
1.2	Payments for		
	(a) research and development	(65)	(611)
	(b) product manufacturing and operating costs	(907)	(3,467)
	(c) advertising and marketing	(51)	(169)
	(d) leased assets	(74)	(244)
	(e) staff costs	(2,278)	(6,051)
	(f) administration and corporate costs	(1,266)	(2,497)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	125	326
1.5	Interest and other costs of finance paid	(7)	(20)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	15	96
1.8	Other (provide details if material)	(30)	(8)
1.9	**Net cash from / (used in) operating activities**	**1,986**	**11,160**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(47)	(842)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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**	**(47)**	**(842)**

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	(59)	(192)
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**	**(59)**	**(1,427)**

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	72,918	66,747
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,986	11,160
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(47)	(842)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(59)	(1,427)
4.5	Effect of movement in exchange rates on cash held	95	(745)
4.6	**Cash and cash equivalents at end of period**	**74,893**	**74,893**

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	34,326	28,782
5.2	Call deposits	40,250	43,620
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	317	357
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**74,893**	**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	913
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)	1,986
8.2	Cash and cash equivalents at quarter end (item 4.6)	74,893
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (item 8.2 + item 8.3)	74,893
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: 29 April 2021

Authorised by: MR DARREN KEAMY
(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.