CLINUVEL

COMPANY ANNOUNCEMENT

Appendix 4C & Activity Report

CLINUVEL's clinical operations treat more patients and achieve record cash receipts

Melbourne, Australia, 29 July 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 April to 30 June 2021. The Company enabled treatment for a record number of erythropoietic protoporphyria (EPP) patients in the quarter, resulting in the growth of cash receipts.

KEY CASH FLOW HIGHLIGHTS
Q4 FY21*

Cash receipts	**$14,918,000**
Cash expenditures	**$6,885,000**
Net operating cash flow[1] [1]Operating cash flow excludes non-cash items.	**$8,102,000**
Cash reserves[2]	**+ 10.4%**
Debt-free	

*01 April – 30 June 2021. All dollar figures in this release are rounded and reported in Australian dollars.
[2] % increase in cash reserves compared to previous quarter.

Operational progress continues in Europe and United States due to treatment efficacy

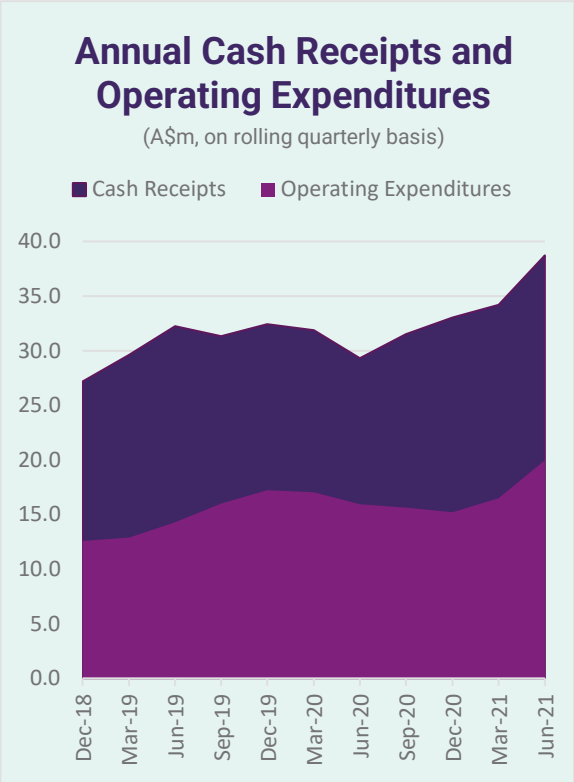
- Cash receipts increase, positive net cash result
- Expenditures in manufacturing, reinvestments in R&D
- Operational focus, cost containment

OPERATIONAL FOCUS IN MOST CHALLENGING ENVIRONMENT

Despite adverse market conditions prevailing throughout the financial year ending 30 June 2021, CLINUVEL's commercial operations have continued to deliver outstanding results.

CLINUVEL has focused upon the clinical care of EPP patients requesting effective treatment to lead a normal outdoors life. The Company has continued its operations, managed its supply chain, and collaborated with individual clinical centres to ensure continuation of SCENESSE® (afamelanotide 16mg) treatment while lockdowns and restrictions applied in Europe, the United States and Israel.

In the context of the global economic slowdown, prudent management of costs and giving priority to patients, enabled the Company to post its tenth consecutive half year net profit in the six months to 31 December 2020. An increase in net profit of 962% was driven by a 58% increase in revenue. In the second half of the financial year to 30 June 2021, the Company continued to grow its operations and cash receipts.



In keeping with its public commentary, the Company maintained a uniform European price policy and has not raised its drug price within the European Economic Area since 2016 despite rising prices from suppliers, operational costs, and inflationary pressure.

INCREASING CASH RECEIPTS AND POSITIVE NET CASH

CLINUVEL has reported cash receipts of $14,918,000 for the June quarter of 2021. These receipts are the highest recorded for the April to June quarter, reflecting:

1) Persistently strong treatment demand from EPP patients in the months of more intense light exposure
2) The expansion of distribution of SCENESSE®

Net operating cash flows were $8,102,000 for the quarter.

FINANCIAL COMMENTARY ON RESULTS

"Demand for SCENESSE® remains cyclical, with the highest number of patient treatments seen in the spring and summer months as light intensity increases," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said. ***"There is now, however, a gradual trend of porphyria patients requesting treatment all year round as they are able to gradually enjoy a newly found freedom, by being able to change their life-long learned behaviour of avoiding light at the risk of burns.***

This quarter we continued to increase our investments in product manufacturing and R&D. Consistent with CLINUVEL's business model, our R&D expenditure consisted of product

formulation development, and production and staffing costs to grow our pipeline in-house, rather than relying on third party suppliers.

"However, one most important factor is that we are able to grow CLINUVEL whereby we are keeping our promises to state and private health insurers by maintaining uniform price levels year-on-year and by not exceeding national volumes of drug supply. This conscientious approach enables us to economically reinvest in care products for children and in the next generation of solutions," Mr Keamy said.

EXPENDITURES AND REINVESTMENTS

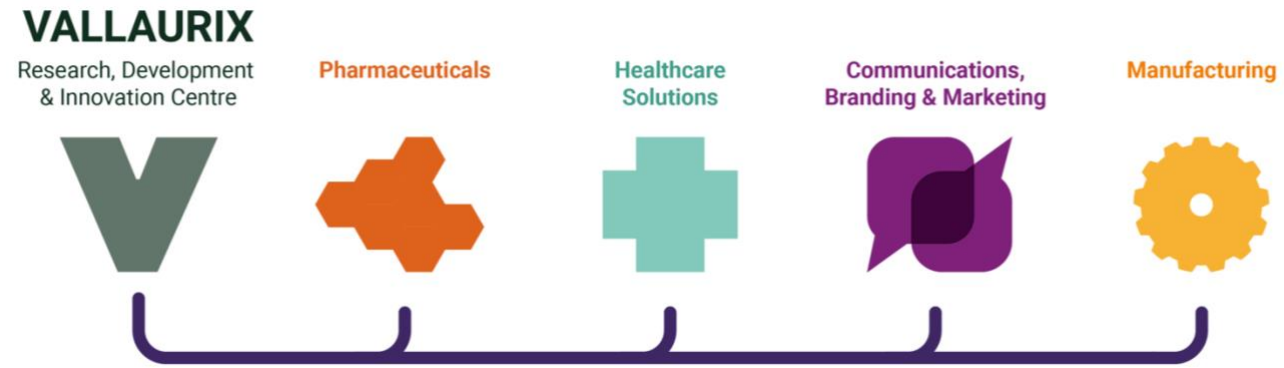
Expenditures from net operating activities were $6,885,000 in the June quarter 2021. Key reasons for the increase were rising manufacturing and supply costs of raw materials. In the current global environment, the Company needs to build inventories to meet expected future patient demand and support the R&D initiatives. At the same time, supply chain costs have increased. Other direct and indirect personnel-related costs also impacted staff costs in the quarterly report.

The overall expenditure levels for initiatives that will require ongoing support and influence have been outlined in Strategic Update II, announced on 12 April 2021.

REVIEW OF KEY ACTIVITIES THIS QUARTER

In the June quarter 2021, the Group continued to manage and progress commercial operations in Europe, the USA and Israel. The Group maintained its focus on driving the expansion of research and development activities on new indications for patient groups and healthcare solutions for the general population. Key activities in the past quarter included:

- Activities to increase SCENESSE® inventories to meet rising patient demand, which is reflected in product manufacturing and operating costs.
- Announcement of a new organisational structure of four divisions to support the growth of the Company.
- An extensive update on the status of the expanded clinical and research program in Strategic Update II.



DNA Repair Program

- Agreement was reached with clinical and academic experts to proceed clinical work in the genetic disorder xeroderma pigmentosum (XP), focusing on patients with the XP-C and XP-V variants. Three trials (CUV150-152-153) have been designed to assess ultraviolet (UV) induced DNA damage and oxidative stress of skin surface in XP patients. Dosing of the drug will occur at variable intervals for a maximum four months. A fourth trial, CUV151, is designed to assess DNA repair in healthy volunteers.

Arterial Ischaemic Stroke

- Due to the pandemic, the speed of the start of the clinical trial in stroke patients (study CUV801) incurred a delay, and eventually the first AIS patient was treated with afamelanotide in June 2021.

All of the Company's announcements in the June quarter 2021 are available on the CLINUVEL website, with further updates posted to the CLINUVEL News website.

Although the Company is no longer obligated to publish quarterly cash flow results, it elects to continue to do so to keep its global investors regularly 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, $1,676,000 (inclusive of non-monetary benefits valued according to international accounting standards) were recorded in respect to Non-Executive Directors' fees, Managing Director's fees and non-monetary benefits.

– End –

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.

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

Media Enquiries
Monsoon Communications
Mr Rudi Michelson, 61 411 402 737, rudim@monsoon.com.au

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.

www.clinuvel.com

Level 11
535 Bourke Street
Melbourne - Victoria, Australia, 3000

T +61 3 9660 4900

F +61 3 9660 4999

Appendix 4C

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

Name of entity
CLINUVEL PHARMACEUTICALS LIMITED

ABN
88 089 644 119

Quarter ended ("current quarter")
30 JUNE 2021

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	14,918	38,724
1.2	Payments for		
	(a) research and development	(123)	(734)
	(b) product manufacturing and operating costs	(2,059)	(5,526)
	(c) advertising and marketing	(47)	(216)
	(d) leased assets	(109)	(354)
	(e) staff costs	(4,038)	(10,115)
	(f) administration and corporate costs	(566)	(3,063)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	65	391
1.5	Interest and other costs of finance paid	(6)	(27)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3	99
1.8	Other (provide details if material)	61	80
1.9	**Net cash from / (used in) operating activities**	**8,102**	**19,262**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(13)	(854)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**(13)**	**(854)**

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	(53)	(245)
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**	**(53)**	**(1,480)**

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	74,893	66,747
4.2	Net cash from / (used in) operating activities (item 1.9 above)	8,082	19,242
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(13)	(854)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(53)	(1,480)
4.5	Effect of movement in exchange rates on cash held	(238)	(984)
4.6	**Cash and cash equivalents at end of period**	**82,691**	**82,691**

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	36,816	34,326
5.2	Call deposits	45,550	40,250
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	325	317
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**82,691**	**74,893**

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	1,676
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)	8,102
8.2	Cash and cash equivalents at quarter end (item 4.6)	82,691
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (item 8.2 + item 8.3)	82,691
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 July 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.