Company Announcement

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

APPENDIX 4C AND ACTIVITY REPORT

Strong operating cash flow, increased cash balance in the midst of a global pandemic

Melbourne, Australia, 31 July 2020

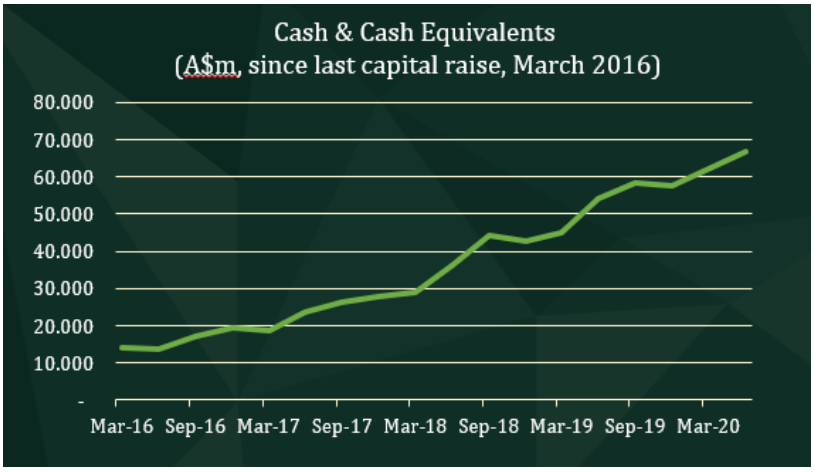
CLINUVEL PHARMACEUTICALS LTD today announced its Appendix 4C – Quarterly Cashflow Report and Activity Report for the period 01 April to 30 June 2020. All figures are rounded and reported in Australian dollars.

Key Highlights:

- Cash receipts $10,403,000 over the quarter
- Net cash flow of $7,175,000
- Cash and equivalents on hand increased 7% over the quarter
- A 44% compound annual growth rate over last 4 years
- Expenditures controlled, annual growth sustained
- Team expanded worldwide to support growth
- First US patients treated with SCENESSE® from April

CONTINUED CASH GENERATION IN A CHALLENGING OPERATING ENVIRONMENT

CLINUVEL completed the fourth full year of commercial operations in Europe and, in April 2020, started the distribution of SCENESSE® (afamelanotide 16mg)[1] in the USA. The coronavirus pandemic has caused the most significant worldwide economic contraction since the 1929 Great Depression, with many of the countries in which CLINUVEL operates still experiencing lockdowns and disruptions to daily life and commercial operations.



CLINUVEL continues to expand the supply of SCENESSE® in Europe. Cash receipts for the quarter were $10,403,000 constituting a net cash flow from operating activities of $7,175,000. All receipts relate to the supply of SCENESSE® to erythropoietic protoporphyria (EPP) Expert Centres across key European countries, including supply under special access to Switzerland.

For the quarter ending June 30, CLINUVEL booked a 7% increase in cash reserves. Since March 2016, when the Company last raised capital to launch SCENESSE® in Europe, CLINUVEL has increased its cash reserves from $14,170,000 to its 30 June level of $66,747,000, a 44% compound annual growth rate.

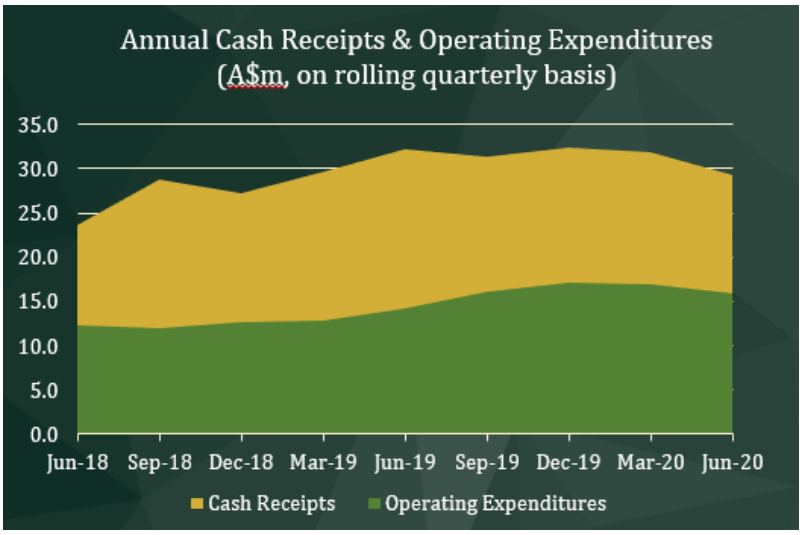
During the pandemic, the majority of Expert Centres continued prescription of SCENESSE® due to the ongoing clinical demand, while a small number of Centres either deferred orders or reduced order sizes in the initial months of the COVID infections. These few Centres were not able to provide treatment access to patients, or patients were unable to travel to Centres. Despite the uncertainty surrounding the pandemic, it was pleasing to learn that patient

demand for SCENESSE® remained high, with existing patients continuing to seek treatment and new patients receiving treatment for the first time.

The cash receipts continued the positive trend seen in recent years, where the number of unit orders progressively increases when patients become more prone to exposure to stronger ambient light sources in the spring and summer months. The price of SCENESSE® was uniform across Europe throughout the quarter.

ANNUAL TREND IN CASH RECEIPTS AND EXPENDITURES

The adjacent graph illustrates the rising and progressive trend in annual cash receipts over the past eight successive rolling quarters. The controlled increases to annual net operating expenditures are assessed and balanced on a rolling annual basis to manage and support the growth and R&D investments of the Group.



Cash inflows are predominantly in Euro and Swiss currency. For accounting purposes, at the end of the quarter when translating cash into Australian currency the value of cash held by the Group in Euro and Swiss currency was revalued down by $2,261,000. On 31 March, cash was positively revalued by $2,971,000.

CONTROLLED GROWTH IN EXPENDITURES

Expenditures from net operating activities in the quarter were according to the Company's business plans and broadly in line with the prior quarter, increasing by 1% to $3,433,000. These do not include the impact of any interest received from placing excess funds in term deposit, along with payments received from various government business support or stimulus packages in response to the coronavirus pandemic. The product manufacturing and operating cost category was $1,054,000, rising 64% when compared to the prior quarter, reflecting the increase in payments to support distribution and supply of the product into Europe and the USA meeting, cyclical and seasonal demand in the northern hemisphere. Staff costs for the June quarter do not include annual remuneration-related payments to staff.

On an annual basis, as part of the planned expansion of the Group, total net expenditures from operations rose 11.7% in the year to 30 June 2020, with product manufacturing and operating costs, and staff costs each rising by 16%.

SCENESSE® DISTRIBUTION USA

In April 2020, CLINUVEL commenced distribution of SCENESSE® for adult EPP patients with the first US insurance companies initiating reimbursement for treatment under Prior Authorization. Cash receipts for the June quarter 2020 did not include any receipts from the supply of SCENESSE® in the US market. The Company expects, in these early stages of US launch, that payment terms may be longer in duration than the 30 to 60 days average length of payment term in Europe.

REVIEW OF OTHER KEY ACTIVITIES

The Group saw continued progress in its corporate, clinical and research and development work throughout the quarter despite an adverse operating environment.

While the expansion of the Group's Singapore laboratory was affected by government's circuit-breaker to contain the pandemic, most of the $466,000 in cash outflows from investing activities was incurred for this expansion and development work was largely unaffected. It is expected the new facilities will be completed by the end of the third quarter of calendar year 2020 to further progress R&D on novel melanocortins, and prescription and over-the-counter products.

The Group continues to work with the Therapeutic Goods Administration (TGA) as it evaluates SCENESSE® under a priority registration pathway as the first proposed therapy for adult patients with EPP in Australia. A series of exchanges have occurred between CLINUVEL and the TGA, as is usually expected under a scientific review, and the Group expects the TGA to conclude its evaluation by the end of calendar year 2020.

In April 2020, CLINUVEL entered a Collaboration Agreement to launch SCENESSE® (afamelanotide 16mg) under a Named Patient Program (NPP) for the treatment of EPP patients in the People's Republic of China. The collaboration with HK Winhealth Pharma Group Co. Limited focuses on facilitating early access for Chinese EPP patients while collecting data for a new drug application (NDA) to the Chinese National Medical Products Administration (NMPA). Safety and effectiveness data captured under the NPP will be included in a Chinese NDA alongside data captured from CLINUVEL's clinical trial and pre- and post-authorisation programs in Europe and the USA.

The Group continued work to plan and prepare for future clinical initiatives to develop novel treatments for patients with severe genetic and skin disorders who lack therapeutic alternatives. A Type C Guidance meeting was held with the US Food and Drug Administration (FDA) on 29 April 2020 to seek agreement on the design of a multicentre Phase IIb clinical study and the data package necessary to support a supplemental New Drug Application filing for SCENESSE® in the pigment loss disorder vitiligo. There are no approved pharmaceutical treatments for vitiligo, a disease which affects between 0.5% and 2% of the US population, where various mechanisms result in the loss of pigment producing cells. The Company is working with clinical experts to finalise clinical study protocols. Further clinical and regulatory work is underway to establish a new program to evaluate afamelanotide in DNA repair.

Post the June quarter 2020, this month the Group announced the development of a second formulation of afamelanotide, PRÉNUMBRA®. This liquid controlled-release formulation is to be evaluated in clinical trials for acute disorders and vascular anomalies.

COMMENTARY

"Against the global economic contraction, CLINUVEL is best positioned to invest in its planned growth and expansion, and patient demand for treatment has been largely unaffected, a testament to the impact of EPP on patients' lives and their need for ongoing treatment," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said.

"Looking back, we have had a clear, long-held, view on how to optimise our resources and prepare for adverse economic conditions. By maintaining a strong cash position, we are able to respond to changes quickly and nimbly, limiting the need to return to investors to access capital and allowing us to focus on the long-term growth of the Group," Mr Keamy said.

Although the Company is not obligated to publish quarterly cash flow results, it elects to do so to keep its investors periodically updated. A copy of the Appendix 4C – Quarterly Cash Flow Report for the fourth quarter of FY2020 is attached.

Pursuant to Listing Rule 4.7C and as disclosed in Item 6.1 to the attached Appendix 4C, $100,000 was paid in respect to non-executive Director and Managing Director fees.

- End -

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of phototoxicity in adult patients with 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 vascular 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.

SCENESSE® and PRÉNUMBRA® are registered trademarks 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 2019 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	30 JUNE 2020

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	10,403	29,288
1.2	Payments for		
	(a) research and development	(102)	(388)
	(b) product manufacturing and operating costs	(1,054)	(4,852)
	(c) advertising and marketing	(63)	(488)
	(d) leased assets	(139)	(462)
	(e) staff costs	(1,429)	(6,757)
	(f) administration and corporate costs	(714)	(3,408)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	94	637
1.5	Interest and other costs of finance paid	(8)	(21)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	121	121
1.8	Other (including GST/VAT)	66	423
1.9	**Net cash from / (used in) operating activities**	**7,175**	**14,093**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(466)	(889)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(f) other non-current assets	-	-
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**	**(466)**	**(889)**

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	(30)	(189)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	(1,224)
3.9	Other (Lease Liabilities)	-	-
3.10	**Net cash from / (used in) financing activities**	**(30)**	**(1,413)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	62,329	54,269
4.2	Net cash from / (used in) operating activities (item 1.9 above)	7,175	14,093

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(466)	(889)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(30)	(1,413)
4.5	Effect of movement in exchange rates on cash held	(2,261)	687
4.6	**Cash and cash equivalents at end of period**	**66,747**	**66,747**

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	25,385	29,682
5.2	Call deposits	41,095	32,325
5.3	Bank overdrafts	-	-
5.4	Other (Security Deposits)	267	322
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**66,747**	**62,329**

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	100
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)	7,175
8.2	Cash and cash equivalents at quarter end (Item 4.6)	66,747
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	66,747
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** * The entity generated cash from its operating activities in the current quarter	n/a *

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

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: N/A

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: N/A

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: N/A

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: .31 July 2020.....

Authorised by: By the Board

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.