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Company Announcement

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

APPENDIX 4C AND ACTIVITY REPORT

Positive cash flow result, expanded research and development investment

Melbourne, Australia, 29 October 2020

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

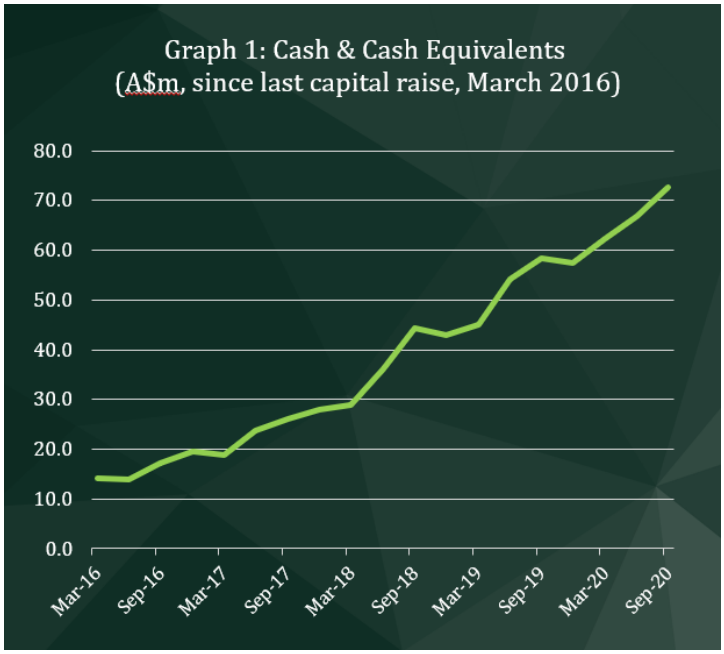
KEY HIGHLIGHTS: SEPTEMBER QUARTER 2020

- Cash receipts of $12,015,000
- Operating expenditures well controlled
- Net operating cash flow of $7,881,000
- Further capital invested in Singaporean Research, Development & Innovation Centre
- Dividend distribution to shareholders of $1,235,000
- Cash and cash equivalents on hand increased 9% to $72,759,000

POSITIVE CASH FLOW UNDER COVID RESTRICTIONS

CLINUVEL continued to progress the commercial distribution of SCENESSE® (afamelanotide 16mg)[1] in Europe and the USA in the September quarter 2020, despite a difficult operating environment. The quarter encompasses a period in the northern hemisphere where exposure to visible (HEV) and ultraviolet (UV) light pose the greatest risk to patients with erythropoietic protoporphyria (EPP), and thus treatment demand is generally higher.

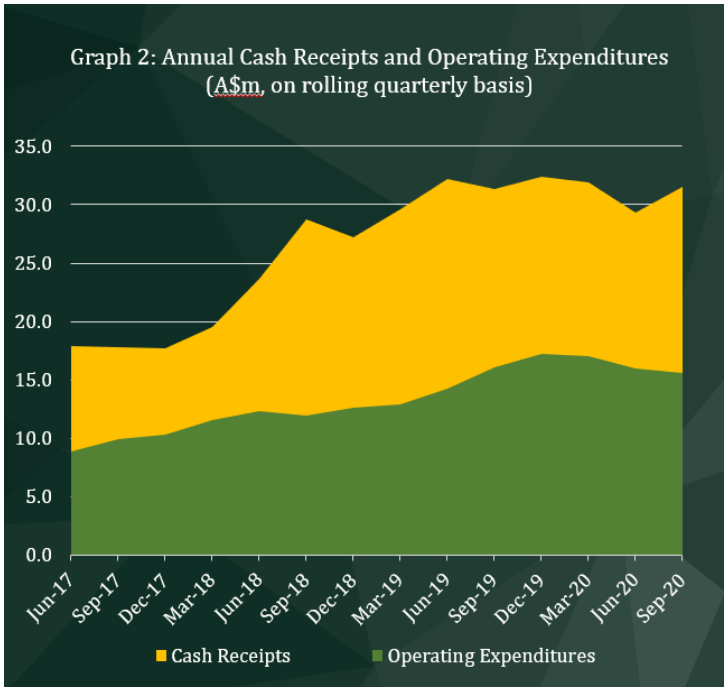
Cash receipts for the September quarter 2020 were $12,015,000, 22.8% higher than cash receipts of $9,782,000 in the same quarter of 2019. After expenditures on operating activities, net cash flow from operating activities was strong at $7,881,000 in the quarter. The stronger quarterly results in cash receipts reflect the first receipts from the commercial distribution of SCENESSE® in the US, along with European orders received and paid later in the calendar year due to impact of the coronavirus pandemic.



CLINUVEL's cash reserves have progressively increased since the commencement of commercial operations in June 2016 (refer **Graph 1**). After a 23% annual increase in the financial year ending 30 June 2020, cash reserves increased by a further 9% across the September 2020 quarter, to $72,759,000, continuing the trend of cash flows generated from operating activities. The 9% increase in cash reserves is after the distribution of a full-year dividend to shareholders of $1,235,000, being $0.025 per ordinary share. The full-year dividend distribution was the third consecutive full-year dividend paid to shareholders and serves as a continued appreciation of those who have supported the Company since 2005.

ANNUAL TREND IN CASH RECEIPTS AND EXPENDITURES

Graph 2 shows CLINUVEL's annual cash receipts at each quarterly timepoint since the June quarter 2017 (on a rolling annual basis). The increase from the June 2020 quarter indicates receipts from the distribution of SCENESSE® have been received later in the 2020 calendar year when compared to the prior year. This is largely attributed to changes in the timing of placing product orders by some treatment centres caused by the delay due to the COVID19 pandemic. The movement in the rolling annual cash receipts contrasts with the controlled growth in annual operating expenditures, where the Company has steadily increased investment to support future growth, including head count and the supply chain.



Cash inflows are predominantly in Euro currency, but more recently in other currencies as well. For accounting purposes, at the end of the September quarter 2020, cash held in foreign currencies were translated to Australian dollars, resulting in an upwards revaluation of $75,000.

CONTROLLED GROWTH IN EXPENDITURES

Expenditures from net operating activities rose by 24.6% to $4,277,000 in the September quarter 2020. These do not include the impact of other receipts, such as interest received from placing cash reserves on term deposit with financial institutions. Staff costs rose by 33.8% to $1,912,000, reflecting the timing of annual remuneration-related payments. Payments for materials and services attached to the Company's product pipeline, including PRÉNUMBRA® and the topical formulations under development, saw research and development costs rise from $102,000 in the June quarter 2020 to $391,000 in the September quarter 2020.

REVIEW OF KEY ACTIVITIES

Despite the adverse operating environment in the September quarter 2020, the Group continued to grow its commercial operations in Europe and the USA, and expand the research and development activities focussed on novel treatments for patients with severe genetic, skin and vascular disorders who lack therapeutic alternatives.

Throughout the calendar year, the majority of Expert Centres in Europe have continued to prescribe SCENESSE® to meet ongoing patient demand for treatment. A small number of Centres had either deferred orders or reduced order sizes in the initial months of the pandemic, but in more recent months access to patients has resumed with easing of restrictions across Europe. Despite the ongoing uncertainty surrounding the pandemic, patient demand for SCENESSE® has remained high and Expert Centres are working to facilitate ongoing treatment.

In the USA, the distribution of SCENESSE® has progressed ahead of the Company's planning. Twenty-six Specialty Centers (30 were planned by July 2021) have been trained and accredited to administer SCENESSE® and over 55 national and local private insurers have agreed to reimburse SCENESSE® either under Prior Authorization arrangements, acceptance as a special drug or as part of their formulary listing.

The Company's key activities in the quarter included:

- Progress in the development of a second formulation of afamelanotide, PRÉNUMBRA®. Announced in July, this liquid controlled-release formulation is to be evaluated in clinical trials for acute disorders and vascular anomalies;

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- The completion of the Group's new Research, Development & Innovation Centre in Singapore (VALLAURIX SG) which opened at the end of August 2020 and accounted for the majority of the cash outflows from investing activities in the quarter;
- The announcement of an innovative DNA Repair Program in September which aims to confirm that intervention with SCENESSE® enhances the elimination of photoproducts and regeneration of DNA. This concept is being assessed first in the rare genetic disorder xeroderma pigmentosum (XP). Treatment of the first XP-C patient also commenced in September to confirm the product's safety. After satisfactory monitoring and assessment, the program shall proceed to a Phase II pilot study involving six XP-C patients and a control study of 10 healthy volunteers.

The Company also continued its exchanges with the Therapeutic Goods Administration (TGA) on its application submitted under a priority registration pathway for SCENESSE® to be the first therapy for adult EPP patients in Australia. The TGA advised its decision to approve the application for marketing authorisation of SCENESSE® in Australia on 26 October 2020. Work also continued during the quarter with clinical experts on the protocol of a multicentre Phase IIb clinical study of SCENESSE® in combination with narrowband UVB phototherapy, to treat the pigment loss disorder vitiligo.

COMMENTARY

"The continued demand for SCENESSE® from EPP patients in Europe and the USA bolstered the Group's cash receipts in the September quarter," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said.

"The further rise in our cash reserves after the payment in the quarter of a third annual dividend as the northern hemisphere winter months approach is welcome in the context of the adverse operating environment and the ability it provides to self-finance the growth of commercial operations and the expansion of our research and development activities, " Mr Keamy said.

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 first quarter of FY2021 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 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.

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

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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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Appendix 4C

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

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Name of entity

CLINUVEL PHARMACEUTICALS LIMITED

ABN	**Quarter ended ("current quarter")**
88 089 644 119	30 SEPTEMBER 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	12,015	12,015
1.2	Payments for		
	(a) research and development	(391)	(391)
	(b) product manufacturing and operating costs	(1,243)	(1,243)
	(c) advertising and marketing	(21)	(21)
	(d) leased assets	(86)	(86)
	(e) staff costs	(1,912)	(1,912)
	(f) administration and corporate costs	(644)	(644)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	106	106
1.5	Interest and other costs of finance paid	(7)	(7)
1.6	Income taxes paid	0	0
1.7	Government grants and tax incentives	37	37
1.8	Other (provide details if material)	27	27
1.9	**Net cash from / (used in) operating activities**	**7,881**	**7,881**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(649)	(649)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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**	**(649)**	**(649)**

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)	(59)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	(1,235)	(1,235)
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**(1,294)**	**(1,294)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	66,747	66,747
4.2	Net cash from / (used in) operating activities (item 1.9 above)	7,881	7,881
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(649)	(649)

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1,294)	(1,294)
4.5	Effect of movement in exchange rates on cash held	75	75
4.6	**Cash and cash equivalents at end of period**	**72,759**	**72,759**

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	28,782	25,385
5.2	Call deposits	43,620	41,095
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	357	267
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**72,759**	**66,747**

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.

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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)	7,881
8.2	Cash and cash equivalents at quarter end (item 4.6)	72,759
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	72,759
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: n/a

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: n/a

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: n/a

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.

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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: ..29.10.2020.....

Authorised by: MR DARREN KEAMY (Company Secretary)
.....
(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 – e.g. 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.

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