Company Announcement

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

QUARTERLY ACTIVITY REPORT AND APPENDIX 4C

CLINUVEL posts positive operating cash flows during period of expansion and growth in midst of COVID-19 pandemic

Melbourne, Australia, 28 April 2020

CLINUVEL PHARMACEUTICALS LTD**,** a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic metabolic and systemic disorders, today announced its Appendix 4C – Quarterly Cashflow Report and Activity Report for the period 01 January to 31 March 2020. All figures are rounded and reported in Australian dollars.

EXECUTIVE SUMMARY ACTIVITY REPORT QUARTER ENDING 31 MARCH 2020

Key Activity Highlights:

- Continued supply of SCENESSE® in Europe
- SCENESSE® launch in USA following Prior Authorization by US insurers
- Expansion of in-house R&D capabilities, Singaporean government provides financial incentives

Throughout the quarter CLINUVEL has continued to focus on expanding its business activities during a time when the COVID-19 pandemic has affected all global business.

CLINUVEL's drug SCENESSE® (afamelanotide 16mg)[1] is approved in Europe and the USA for the prevention of phototoxicity and anaphylactoid reactions in adult patients with the metabolic disorder erythropoietic protoporphyria (EPP). The Company is currently evaluating SCENESSE® and other novel pharmaceutical products as treatments for patients with high unmet medical needs.

Supply of SCENESSE® to European EPP Expert Centres, including supply to Switzerland under a special access program, continued in the March quarter. Patient demand for SCENESSE® is seasonally variable, reflecting the impact of the intensity of ambient light to patients at risk of phototoxic reactions and anaphylactoid reactions.

SCENESSE® was approved by the US Food and Drug Administration (FDA) in October 2019. During the March quarter the Company progressed its commercialisation plans in the USA, announcing a three-phase distribution plan. Discussions with US insurer groups continued which has led to more than 30 insurers providing the prescriptive drug on Prior Authorization or formulary lists. Recommended US product and billing codes were finalised for SCENESSE®.

Work commenced to further expand the Group's Singapore laboratory capabilities, with the objective of bringing all analytical services inhouse. A new location was secured to establish state of the art and expanded laboratories which will work according to both ISO17025 and Good Laboratory Practice (GLP) specifications. The Economic Development Board of Singapore, under its Research Incentive Scheme for Companies initiative, awarded the Group's Singaporean entity up to S$500,000 over three years to support its expansion plan to progress its product pipeline.

During the quarter the Group confirmed the Australian Therapeutic Goods Administration (TGA) has accepted the registration dossier for SCENESSE®. CLINUVEL is responding to the TGA's questions as it progresses under the Priority Registration pathway to make SCENESSE® available as first line therapy for adult EPP patients.

A Type C meeting is scheduled to be held with the FDA in late April 2020 to discuss the design of a multicentre Phase IIb vitiligo clinical study (CUV104) and the future data package necessary to support a supplemental New Drug Application filing for SCENESSE® in vitiligo. In addition to vitiligo, the Group has also been working towards clinical evaluation the use of SCENESSE® in DNA repair.

The Group continues to be active in its pipeline development of a paediatric formulation of SCENESSE®, its next generation products based on melanocortin analogues CUV9900, parvysmelanotide, and phimelanotide with the intention of developing these analogues as medicinal agents for topical use, and its over-the-counter product range for general photoprotective application.

EXECUTIVE SUMMARY APPENDIX 4C QUARTERLY FINANCIAL REPORT

Key Cash Flow Highlights:

- Quarterly receipts $5,369,000
- Annual receipts increased 8% year-on-year, continued growth
- Reduction in quarterly expenditures from prior quarter
- Expenditures continue to support Group expansion
- Cash on hand increased $4,894,000
- Cash equivalents $62,329,000
- Positive effect on cash held in non-Australian dollar currency

March Quarter 2020 Result

Receipts from customers were $5,369,000 for the quarter ending 31 March 2020. The quarterly receipts mirror the established pattern of nearly four years of commercial operations in Europe where seasonal fluctuations in unit orders for EPP treatment are reported. For the 12 months to 31 March 2020, receipts from customers rose 8% when compared to the equivalent period ending 31 March 2019.

Cash and cash equivalents for the quarter ended 31 March 2020 finished at $62,329,000, an increase of $4,894,000 from the previous quarter. The movement in cash was made up of a positive net cash flow from operating activities result of $2,169,000, combined with a positive effect of movement in exchange rates on cash held of $2,971,000. The severe weakening of the Australian dollar due to the global economic uncertainty from COVID-19 at the end of the quarter resulted in a positive revaluation of $2,971,000 from translating Euro and Swiss currency held in cash into Australian dollars.

Consistent with previous years, the cash result this quarter was positively impacted by a 24% reduction in expenditures from operating activities, from $4,497,000 to $3,398,000 compared to the December quarter.

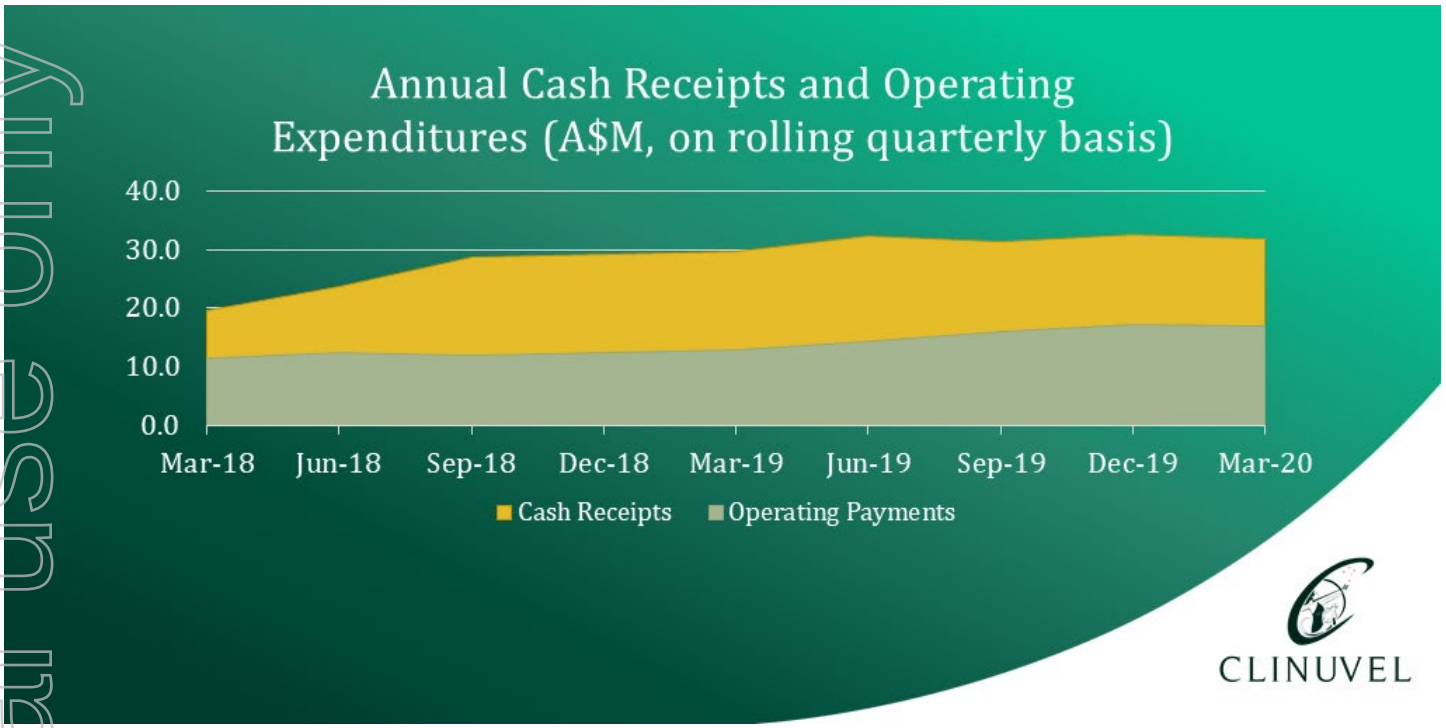
Details of Operating Payments – March Quarter 2020

Administration and corporate costs decreased from the previous quarter which was punctuated by expenditures to renew key annual insurances and to support various investor and public relations activities. Expenditures on product handling and distribution in Europe was down from the previous quarter, which has included initial payments towards product supply chain development to meet coming years' anticipated treatment demand.

In addition to cash used in operating activities, cash used in investing activities increased, representing initial capital expenditures incurred as part of the expansion of CLINUVEL's R&D facilities in Singapore.

As disclosed in Item 6.1 to the Appendix 4C report, directors' fees including CEO remuneration were included in this quarter.

Trend in Annual Receipts and Net Operating Payments
The graph below illustrates the rising and progressive trend in annual receipts over the past eight successive quarters strengthening CLINUVEL's balance sheet. The controlled increases to annual net operating payments are balanced on a rolling basis to manage and support the growth of the Company.



CLINUVEL has provided this ASX release under ASX Listing Rule 4.7C. The requirement to report an Appendix 4C cash flow report for each quarter ended in 2018, but the Company has elected to continue to provide the report to its shareholders.

A copy of the Appendix 4C – Quarterly Cash Flow Report for the March quarter FY2020 is attached below.

- 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.

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 and skin disorders. 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 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. Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information please go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

Head of Investor Relations

Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

Investor enquiries
https://www.clinuvel.com/about-clinuvel/investor-relations-contact-form

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	31 MARCH 2020

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	5,369	18,885
1.2	Payments for		
	(a) research and development	(101)	(287)
	(b) product manufacturing and operating costs	(641)	(3,798)
	(c) advertising and marketing	(89)	(425)
	(d) leased assets	(115)	(322)
	(e) staff costs	(1,771)	(5,327)
	(f) administration and corporate costs	(754)	(2,694)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	198	542
1.5	Interest and other costs of finance paid	(4)	(13)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (including GST/VAT)	77	357
1.9	**Net cash from / (used in) operating activities**	**2,169**	**6,918**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(217)	(423)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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**	**(217)**	**(423)**

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	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	(1,224)
3.9	Other (Lease Liabilities)	(29)	(159)
3.10	**Net cash from / (used in) financing activities**	**(29)**	**(1,383)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	57,435	54,269
4.2	Net cash from / (used in) operating activities (item 1.9 above)	2,169	6,918

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(217)	(423)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(29)	(1,383)
4.5	Effect of movement in exchange rates on cash held	2,971	2,948
4.6	**Cash and cash equivalents at end of period**	**62,329**	**62,329**

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	29,682	25,962
5.2	Call deposits	32,325	31,325
5.3	Bank overdrafts	-	-
5.4	Other (Security Deposits)	322	147
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**62,329**	**57,434**

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	461
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)	2,169
8.2	Cash and cash equivalents at quarter end (Item 4.6)	62,329
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	62,329
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: .28 April 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.