Company Announcement

ASX: **CUV**

XETRA-DAX: **UR9**

NASDAQ INTERNATIONAL DESIGNATION: CLVLY

APPENDIX 4C

Melbourne, Australia and Leatherhead, UK, 31 January 2019

CLINUVEL PHARMACEUTICALS LTD**,** a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders, today announced its Appendix 4C – Quarterly Cashflow report for the period 01 October to 31 December 2018. All figures are rounded and reported in Australian dollars.

Cash receipts for the quarter were $2,608,000, a 38% decrease compared to the same quarter of 2017 ($4,199,000). The quarter's reduction in cash receipts when compared to the October to December 2017 period was impacted by a combination of fluctuation in seasonal demand and timing of customer payments, with the current customer mix having paid in a more timely manner than during the same period last year. Orders received from European Erythropoietic Protoporphyria (EPP) Expert Centres (EEECs) continue to reflect the seasonal demand for SCENESSE® (afamelanotide 16mg) in the northern hemisphere which increases in spring, summer and autumn when EPP patients are at a heightened risk of phototoxic and anaphylactoid reactions.[1] Cash receipts from sales orders received are expected to continue to vary in the quarterly reporting periods owing to the timing of customer payments following cyclical (and seasonal) sales orders received for SCENESSE®. All revenues in the quarter were generated from the CLINUVEL Group's innovative technology being used to treat an ''orphan" indication, whilst the Group continued to focus on managing its overall cost base.

Net operating payments for the quarter increased 24% to $3,332,000 compared to $2,694,000 for the same quarter last year. The increase in net operating payments period-on-period was characterised by expenditures in meeting US FDA drug filing and review activities, in responding to European pricing and market access activities, and also meeting commitments towards annual insurances and ongoing product development work.

The combination of cash receipts and expenditures contributed to a net operating activity negative cash flow of $625,000 for the quarter ended 31 December 2018. The decrease in cash reserves is reflective of the cyclical nature to the ordering of SCENESSE® throughout the year whilst managing its cost base as the Group's overall activities continue to progress.

The cash balance as of 31 December 2018 was $42,827,000, a decrease of $1,564,000 to the 30 September 2018 cash balance but is $14,888,000 above the 31 December 2017 cash balance. Sixty one percent (61%) of the decrease in cash reserves for the quarter was resultant of CLINUVEL acknowledging the long-term support of all its investors by paying a first-time unfranked dividend distribution of $0.02 per share on 8th October 2018.

The CLINUVEL Group has incurred costs of over $185 million to date on developing and commercialising its novel drug SCENESSE®, with the product approved in the European Union as the only available and first-line therapy for the treatment of EPP. A New Drug Application has been submitted to the US Food and Drug administration for the use of SCENESSE® in the treatment of EPP and is currently under Priority Review with an expected PDUFA date of 8 July 2019.

COMMENTARY

"The Group continues to push ahead, advancing its activities during the winter months of the northern hemisphere where revenues and their consequent sales receipts are expected to taper off," CLINUVEL's Chief Financial Officer

Mr Darren Keamy said. “Our intention to focus on our US filing, European distribution, and increasing product development activities is demonstrated by our recent spend. As we move into the 2019 calendar year the constant attention to operational cost management remains unchanged.”

- End -

[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. 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 treatment(s) 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 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, Switzerland, the US and Singapore.
For more information go to http://www.clinuvel.com.
SCENESSE® is a registered trademark 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, 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 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 2018 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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+Rule 4.7B

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity	
CLINUVEL PHARMACEUTICALS LIMITED	
ABN	**Quarter ended ("current quarter")**
88 089 644 119	31 DECEMBER 2018

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	2,608	13,313
1.2	Payments for		
	(a) research and development	(75)	(180)
	(b) product manufacturing and operating costs	(593)	(779)
	(c) advertising and marketing	(96)	(153)
	(d) leased assets	(106)	(207)
	(e) staff costs	(1,322)	(3,122)
	(f) administration and corporate costs	(1,033)	(1,707)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	98	130
1.5	Interest and other costs of finance paid	(3)	(6)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other/including GST & VAT	(103)	(41)
1.9	**Net cash from / (used in) operating activities**	**(625)**	**7,248**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(148)	(188)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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**	**(148)**	**(188)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	(957)	(957)
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**(957)**	**(957)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter/year to date	44,391	36,198
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(625)	7,248
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(148)	(188)

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(957)	(957)
4.5	Effect of movement in exchange rates on cash held	166	526
4.6	**Cash and cash equivalents at end of quarter**	**42,827**	**42,827**

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	22,365	26,080
5.2	Call deposits	20,375	18,225
5.3	Bank overdrafts		
5.4	Other (Security Deposits)	87	86
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**42,827**	**44,391**

6.	**Payments to directors of the entity and their associates**	**Current quarter $A'000**
6.1	Aggregate amount of payments to these parties included in item 1.2	306
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Non-Executive Directors' fees and Managing Director salary

7.	Payments to related entities of the entity and their associates	Current quarter $A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	-
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

8.	Financing facilities available *Add notes as necessary for an understanding of the position*	Total facility amount at quarter end $A'000	Amount drawn at quarter end $A'000
8.1	Loan facilities	-	-
8.2	Credit standby arrangements	-	-
8.3	Other (please specify)	-	-

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

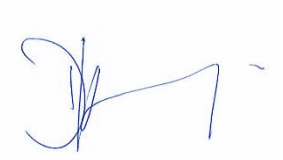
9.	Estimated cash outflows for next quarter	$A'000
9.1	Research and development	(80)
9.2	Product manufacturing and operating costs	(1,320)
9.3	Advertising and marketing	(90)
9.4	Leased assets	(125)
9.5	Staff costs	(1,340)
9.6	Administration and corporate costs	(725)
9.7	Other/including GST & VAT	35
9.8	**Total estimated cash outflows**	**(3,645)**

10.	**Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**	**Acquisitions**	**Disposals**
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

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.



Sign here: ..... Date: 31 January 2019

(~~Director~~/Company secretary)

Print name: DARREN KEAMY

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.