

CLINUVEL PHARMACEUTICALS LTD COMPANY ANNOUNCEMENT

Appendix 4C

31 January 2018 Melbourne, Australia and Leatherhead, UK

CLINUVEL PHARMACEUTICALS LTD **(ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY),** a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe and therapeutically unmet genetic disorders today announced its Appendix 4C – Quarterly Cashflow report for the period 01 October to 31 December 2017.¹

The cash balance as at 31 December 2017 was \$27,938,000, an increase of \$1,758,000 to the 30 September 2017 cash balance and an increase of \$4,186,000 to the 30 June 2017 cash balance.

Cash receipts for the quarter were \$4,199,000 compared to \$5,638,000 for the previous quarter. The cash receipts reflect the cyclical demand for SCENESSE® (afamelanotide 16mg) in the northern hemisphere where orders for SCENESSE® increase in spring and summer when EPP patients are at a heightened risk of phototoxic reactions. Cash receipts are expected to fluctuate in the following quarterly reporting periods, reflecting the timing of customer payments following sales orders received for SCENESSE®.

Net operating payments for the quarter were \$2,694,000 compared to \$3,269,000 for the previous quarter. The decrease in net operating payments from the previous quarter was primarily due to increased personnel costs occurring in the prior quarter following the 30 June financial year end. Reclaiming of indirect taxes paid in prior quarters was partially offset by increased working capital spending on global insurances, patent fees, legal and professional advisor fees. The combination of cash receipts and expenditures contributed to a net operating activity positive cash flow of \$1,553,000 for the quarter ended 31 December 2017 (30 September 2017: \$2,470,000).

The increase in cash reserves is primarily generated from its operations, reflecting the Company's first full calendar year in generating revenues from launching a novel drug in a new therapeutic "orphan" area, whilst continuing to control overall costs.

CLINUVEL has spent over \$170 million to date on its novel drug SCENESSE[®], with the product approved in the European Union as the only treatment for the ultra-rare disorder erythropoietic protoporphyria (EPP).²

- End -

¹ All figures are reported in Australian dollars.

² 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 <u>www.clinuvel.com</u>.

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 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 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 <u>http://www.clinuvel.com</u>.

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; 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 2017 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 2017

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	4,199	9,837
1.2	Payments for		
	(a) research and development	(150)	(230)
	(b) product manufacturing and operating costs	(697)	(1,481)
	(c) advertising and marketing	(55)	(120)
	(d) leased assets	(91)	(179)
	(e) staff costs	(1,231)	(2,927)
	(f) administration and corporate costs	(658)	(1,140)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	48	149
1.5	Interest and other costs of finance paid	(3)	(10)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other/including GST & VAT	191	124
1.9	Net cash from / (used in) operating activities	1,553	4,023
2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(3)	(16)
	(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	(3)	(16)
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	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	-	<u> </u>
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	26,180	23,752
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,553	4,023
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(16)

Cons	solidated 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)	-	-
4.5	Effect of movement in exchange rates on cash held	208	179
4.6	Cash and cash equivalents at end of quarter	27,938	27,938

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	17,624	16,917
5.2	Call deposits	10,250	9,200
5.3	Bank overdrafts		
5.4	Other (Security Deposits)	64	63
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	27,938	26,180

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	281
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
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6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Managing Director salary and non-Executive Directors' fees

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 Add notes as necessary understanding of the position	available for an	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	(315)
9.2	Product manufacturing and operating costs	(750)
9.3	Advertising and marketing	(80)
9.4	Leased assets	(90)
9.5	Staff costs	(1,490)
9.6	Administration and corporate costs	(535)
9.7	Other/including GST & VAT	40
9.8	Total estimated cash outflows	(3,220)

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:

(Director/Company secretary)

Date: 31 January 2018

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.