



CLINUVEL

Company Announcement

ASX:

CUV

XETRA-DAX:

UR9

NASDAQ INTERNATIONAL DESIGNATION: CLVLY

## APPENDIX 4C

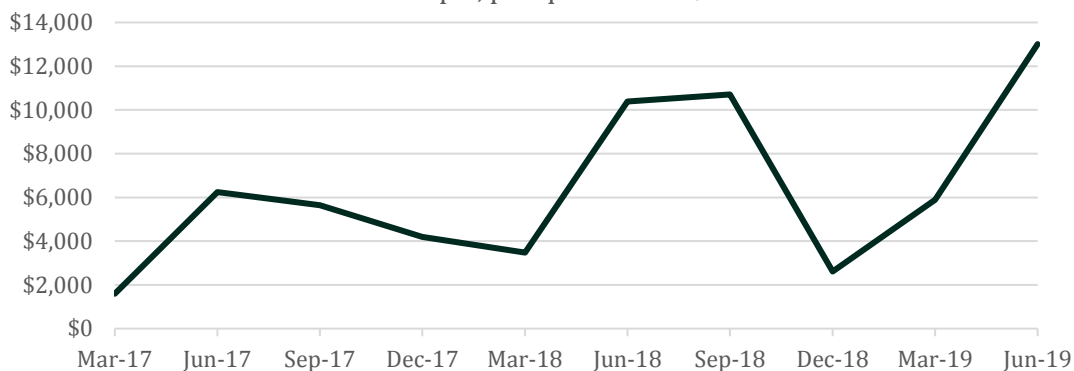
Melbourne, Australia, 31 July 2019

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 April to 30 June 2019. All figures are rounded and reported in Australian dollars.

Cash Receipts for the quarter were \$13,010,000, an increase of 121% on the March quarter 2019 (\$5,898,000) and 25% on the June quarter 2018 (\$10,388,000). Financial year-end Cash Receipts to June 2019 of \$32,221,000 were up 36% compared to the prior financial year (to June 2018).

All Cash Receipts were earned from the provision of SCENESSE® (afamelanotide 16mg)<sup>1</sup> in the European Union and Switzerland to patients with the rare metabolic disorder, erythropoietic protoporphyria (EPP). Unit orders of SCENESSE® are generally lower in the northern hemisphere winter months due to the lower intensity of ambient light. This results in a lower average clinical demand in most countries receiving SCENESSE® during this period. Conversely, stronger clinical demand in the northern hemisphere spring and summer positively impacts Cash Receipts in the June and September quarters. The June quarter 2019 Cash Receipts reflect this stronger seasonal demand.

Sales Receipts, per quarter in A\$'000



The financial year-to-date Cash Receipts reflect the growth in the commercial distribution program in Europe where EPP Expert Centres were willing to prescribe SCENESSE® and more patients are seeking treatment for their condition, thus alleviating the impact of sales fluctuations on Company cashflow.

Net Operating Payments for the June quarter 2019 were \$4,501,000 compared to \$3,584,000 in the March quarter 2019 and \$3,090,000 in the June quarter 2018. The 26% increase from the March quarter 2019 is primarily due to further increases in product manufacturing expenditures to meet the clinical demand for SCENESSE® in the months

of higher light intensity in the northern hemisphere and to respond to the ongoing risk management commitments imposed by the European Medicines Agency as part of the marketing authorisation.

Net Cash from Operations was positive by \$8,618,000 in the June quarter 2019. Net Cash from Operations for the twelve months to 30 June 2019 was a positive \$18,382,000 compared to a positive \$11,693,000 in the same twelve-month period to 30 June 2018. Favourable exchange rate movements on foreign currencies held also provided a positive impact of \$718,000 to the total Cash Balance at the end of the quarter. As a result of the combination of positive cashflows from operations and exchange rate movements in the quarter, the Cash Balance as at 30 June 2019 increased to \$54,269,000, compared to \$44,975,000 as at 31 March 2019 and \$36,198,000 as at 30 June 2018.

#### **COMMENTARY**

“The June quarter 2019 marks the completion of three full years of distribution of SCENESSE® in Europe,” CLINUVEL’s Chief Financial Officer Mr Darren Keamy said. “Despite seasonal fluctuations, CLINUVEL has experienced a positive trend in Cash Receipts over this period. This indicates that more EPP patients in Europe are receiving treatment with SCENESSE® and we look forward to the time the same treatment access can be provided to American EPP patients who have no current alternatives.”

- End -

<sup>1</sup> SCENESSE® (afamelanotide16mg) 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](http://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.

#### **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, 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.

[www.clinuvel.com](http://www.clinuvel.com)

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Australia

Melbourne, Australia, 31 July 2019

## 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**

88 089 644 119

**Quarter ended ("current quarter")**

30 JUNE 2019

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	13,010	32,221
1.2 Payments for		
(a) research and development	(54)	(253)
(b) product manufacturing and operating costs	(2,270)	(4,181)
(c) advertising and marketing	(69)	(287)
(d) leased assets	(124)	(457)
(e) staff costs	(1,355)	(5,811)
(f) administration and corporate costs	(936)	(3,329)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	109	441
1.5 Interest and other costs of finance paid	(5)	(15)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other/including GST & VAT	312	53
<b>1.9 Net cash from / (used in) operating activities</b>	<b>8,618</b>	<b>18,382</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	(42)	(257)
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(42)</b>	<b>(257)</b>
<b>3. Cash flows from financing activities</b>		
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	0	(957)
3.9 Other (provide details if material)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>0</b>	<b>(957)</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	44,975	36,198
4.2 Net cash from / (used in) operating activities (item 1.9 above)	8,618	18,382
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(42)	(257)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	0	(957)
4.5	Effect of movement in exchange rates on cash held	718	903
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>54,269</b>	<b>54,269</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	25,599	22,764
5.2	Call deposits	28,525	22,125
5.3	Bank overdrafts		
5.4	Other (Security Deposits)	145	86
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>54,269</b>	<b>44,975</b>

**6. Payments to directors of the entity and their associates**

- |     |  | <b>Current quarter<br/>\$A'000</b> |
|-----|--|------------------------------------|
| 6.1 | Aggregate amount of payments to these parties included in item 1.2                                   | 313                                |
| 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

<b>7.</b>	<b>Payments to related entities of the entity and their associates</b>	<b>Current quarter \$A'000</b>
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	

<b>8.</b>	<b>Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
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.		

<b>9.</b>	<b>Estimated cash outflows for next quarter</b>	<b>\$A'000</b>
9.1	Research and development	(70)
9.2	Product manufacturing and operating costs	(2,050)
9.3	Advertising and marketing	(200)
9.4	Leased assets	(140)
9.5	Staff costs	(2,000)
9.6	Administration and corporate costs	(950)
9.7	Other/including GST & VAT	(50)
<b>9.8</b>	<b>Total estimated cash outflows</b>	<b>(5,460)</b>

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 July 2019

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.