



CLINUVEL

Company Announcement

ASX:

CUV

XETRA-DAX:

UR9

NASDAQ INTERNATIONAL DESIGNATION: CLVLY

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## APPENDIX 4C

*Latest quarterly receipts reflect seasonal demand and solid annual growth*

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Melbourne, Australia, 31 January 2020

### KEY HIGHLIGHTS:

- Annual receipts increased 19% year-on-year
- Annual growth sustained
- Cash on hand reduced by \$901,000
- Expenditures increase due to operational expansion

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 2019. All figures are rounded and reported in Australian dollars.

### December Quarter 2019 Result

Receipts from customers were \$3,734,000 for the quarter ending 31 December 2019 a 43% increase to the quarter ending 31 December 2018. For the 12 months to 31 December 2019, receipts from customers rose 19% when compared to the equivalent period ending 31 December 2018.

Cash and cash equivalents for the quarter ended 31 December 2019 finished at \$57,435,000, a reduction of \$901,000 from the previous quarter. The movement in cash was largely driven by net cash used in operating activities of \$635,000 which was broadly consistent to net cash used in operating activities for the same quarter last year (December 2018 quarter: \$625,000 reduction).

There were two key influences of the cash outcome for the December quarter 2019. First, the level of expenditures for the quarter reflects CLINUVEL's preparation to expand into new markets in 2020 and beyond. Second, unit orders of SCENESSE® (afamelanotide 16mg)<sup>1</sup> are expectedly lower during the northern hemisphere's winter months compared to spring and summer which cover the June and September quarters. Ambient light is stronger and the risk of phototoxicity to patients with the rare metabolic disorder, erythropoietic protoporphyria (EPP) is higher in the seasons of higher light intensity. This seasonal pattern to CLINUVEL's quarterly receipts is well established after more than three years of commercial operations in Europe.

### Details of Operating Payments – December Quarter 2019

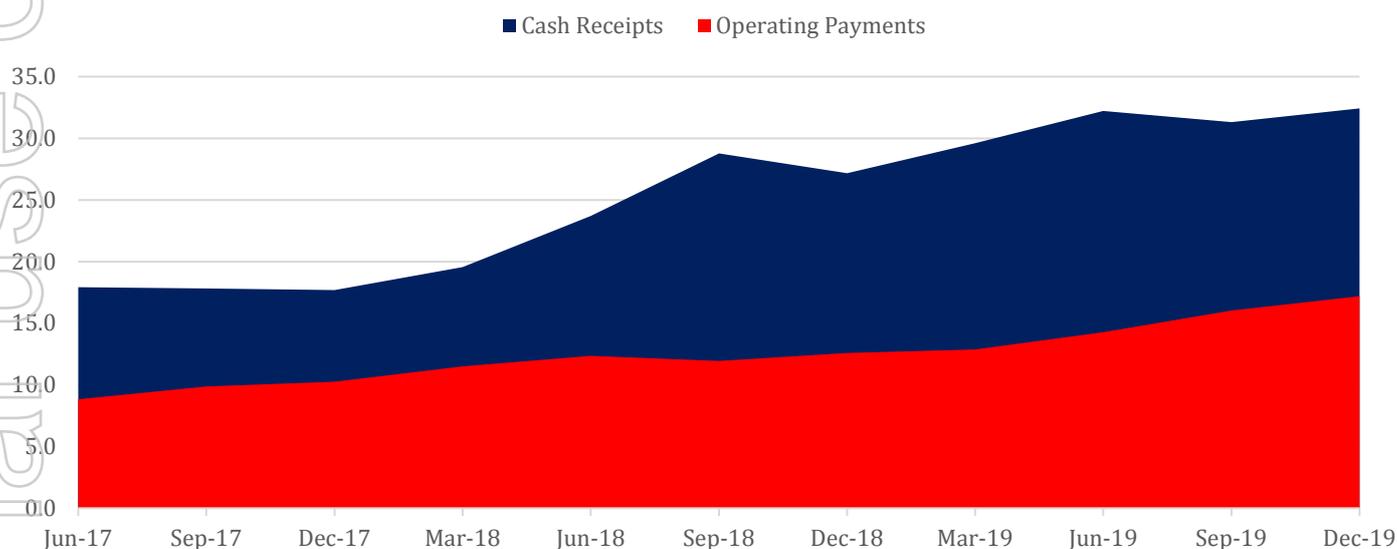
During the quarter ending 31 December 2019, the Company has been focussed on implementing its expansion plan in the USA following the approval on 08 October 2019 by the US Food & Drug Administration (FDA) to market SCENESSE® for the treatment of adult EPP patients. Administration and corporate costs increased from the prior quarter to support a number of activities including renewing key annual insurances and supporting various investor and public relations activities. Expenditures on product handling and distribution in Europe, as well as on the product supply chain to support raw material supply for coming years' anticipated demand, were key influences behind payments for product manufacturing and operating costs. Additionally, regulatory activities increased to support the submission of a dossier to the Australian Therapeutic Goods Administration for SCENESSE® to be listed

as part of the Australian Register of Therapeutic Goods. Ongoing growth in staff headcount and renewal of executive contracts saw further increases to payments for staff costs, impacting net operating payments.

### Trend in Annual Receipts and Net Operating Payments

The graph below illustrates the rising and progressive trend in annual receipts over successive rolling quarters, a driving force behind CLINUVEL's cash flow and profitability. The controlled increases to annual net operating payments is balanced on a rolling annual basis to manage and support the growth of CLINUVEL.

Annual Receipts and Operating Payments in A\$m  
(on rolling quarterly basis)



### COMMENTARY

"We are starting to witness an annual trend in our sales receipts through the European winter months, while we expect to receive more orders as spring and summer approaches," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said.

"Following FDA approval, we are fully committed to our growth plans in the US and to progress our product pipeline. This commitment will be balanced with the careful and deliberate cashflow management that CLINUVEL has demonstrated over years of research and development and commercial operations. This will be a primary focus in 2020," Mr Keamy said.

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

- End -

<sup>1</sup> 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](http://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 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, 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 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.

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

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## 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")**

31 DECEMBER 2019

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	3,734	13,516
1.2 Payments for		
(a) research and development	(114)	(186)
(b) product manufacturing and operating costs	(1,289)	(3,157)
(c) advertising and marketing	(119)	(336)
(d) leased assets	(134)	(208)
(e) staff costs	(1,945)	(3,556)
(f) administration and corporate costs	(1,095)	(1,940)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	128	345
1.5 Interest and other costs of finance paid	(4)	(9)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other/including GST & VAT	203	280
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(635)</b>	<b>4,749</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	(15)	(206)
(b) businesses (see item 10)	-	-
(c) investments	-	-

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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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(15)</b>	<b>(206)</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 and lease liabilities	(40)	(130)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	(1,224)
3.9 Other (provide details if material)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>(40)</b>	<b>(1,354)</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	58,336	54,269
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(635)	4,749
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(15)	(206)

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<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(40)	(1,354)
4.5	Effect of movement in exchange rates on cash held	(211)	(23)
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>57,435</b>	<b>57,435</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	25,963	27,400
5.2	Call deposits	31,325	30,825
5.3	Bank overdrafts		
5.4	Other (Security Deposits)	147	111
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>57,435</b>	<b>58,336</b>

<b>6.</b>	<b>Payments to directors of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to these parties included in item 1.2	629
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

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<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)	-	-

8.4h 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	(125)
9.2	Product manufacturing and operating costs	(1,600)
9.3	Advertising and marketing	(130)
9.4	Leased assets	(90)
9.5	Staff costs	(2,200)
9.6	Administration and corporate costs	(930)
9.7	Other/including GST & VAT	60
<b>9.8</b>	<b>Total estimated cash outflows</b>	<b>(5,015)</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 January 2020

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.

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