



CLINUVEL

Company Announcement

ASX:

CUV

XETRA-DAX:

UR9

NASDAQ INTERNATIONAL DESIGNATION: CLVLY

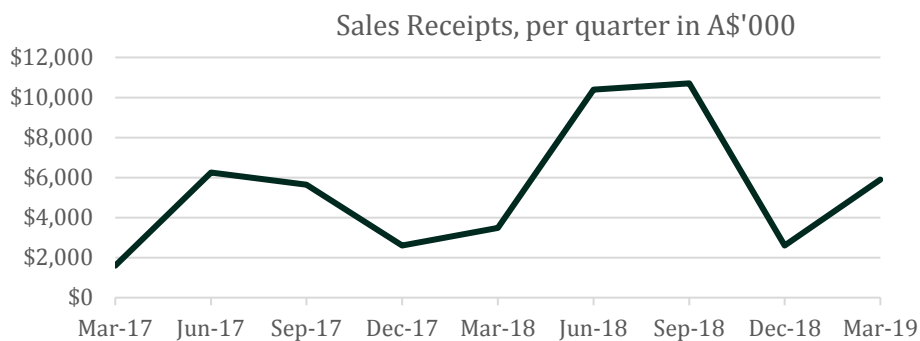
APPENDIX 4C

Melbourne, Australia, 30 April 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 January to 31 March 2019. All figures are rounded and reported in Australian dollars.

Cash Receipts for the quarter were \$5,898,000, an increase of 126% on the December quarter 2018 (\$2,608,000) and up 70% compared to the March quarter 2018 (\$3,480,000). Financial year-to-date cash receipts to March 2019 of \$19,211,000 were 44% higher than for the prior corresponding period to March 2018.

All Cash Receipts were earned from the SCENESSE® (afamelanotide 16mg)¹ treatment provided in the European Union and Switzerland for patients with the rare metabolic disorder erythropoietic protoporphyria (EPP). Unit sales of SCENESSE® are generally lower in the winter months due to the lower intensity of ambient light. This results in a mean lower 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 financial year-to-date cash receipt result reflects the growth in the commercial distribution program in Europe in terms of more EPP centres willing to prescribe and more patients seeking treatment and alleviating the impact of sales fluctuations on company cashflow.

Net Operating Payments for the March quarter 2019 were \$3,584,000 compared to \$3,331,000 in the December quarter 2018 and \$3,302,000 in the March quarter 2018. The 7% increase from the December quarter 2018 is due to increases in product manufacturing expenditures to prepare for an expected increase in sales as we progress into the spring and summer seasons in the northern hemisphere. Taking into account the rise in product manufacturing expenditures, the overall modest difference in these cash outflows across the comparative periods reflects the stable operating cost base of the business and cautious cost management.

Net Cash from Operations was positive by \$2,516,000 in the March quarter 2019. Net Cash from Operations for the nine months to 31 March 2019 was \$9,764,000 compared to \$4,253,000 in the same period to 31 March 2018. As a result of the positive cashflow in the quarter, the Cash Balance as at 31 March 2019 increased to \$44,975,000, compared to \$42,826,000 as at 31 December 2018 and \$28,915,000 as at 31 March 2018.

During the March quarter 2019, CLINUVEL remained focused on the management of its European business and responding to the US Food and Drug Administration (FDA) on its New Drug Application for approval to distribute the first-in-class treatment, SCENESSE® to EPP patients in the USA. The FDA is currently assessing CLINUVEL's application under a Priority Review with an advised date (PDUFA) of 8 July 2019 for its decision.

COMMENTARY

"Whilst our quarterly cashflow results are influenced by the seasonality of demand of European patients, our volume growth year on year is trending positively", CLINUVEL's Chief Financial Officer Mr Darren Keamy said. "This, coupled with consistent cost management, has driven the positive cashflow outcome and improved cash balance in the March quarter of 2019. Our European office has prepared itself for the impending spring and summer months where, as seen in recent years, sales orders for SCENESSE® tend to increase."

- 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.

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

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Australia

Melbourne, Australia, 30 April 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")

31 MARCH 2019

| 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 | 5,898 | 19,211 |
| 1.2 Payments for | | |
| (a) research and development | (19) | (199) |
| (b) product manufacturing and operating costs | (1,132) | (1,911) |
| (c) advertising and marketing | (65) | (218) |
| (d) leased assets | (126) | (333) |
| (e) staff costs | (1,334) | (4,456) |
| (f) administration and corporate costs | (686) | (2,393) |
| 1.3 Dividends received (see note 3) | - | - |
| 1.4 Interest received | 202 | 332 |
| 1.5 Interest and other costs of finance paid | (4) | (10) |
| 1.6 Income taxes paid | - | - |
| 1.7 Government grants and tax incentives | - | - |
| 1.8 Other/including GST & VAT | (218) | (259) |
| 1.9 Net cash from / (used in) operating activities | 2,516 | 9,764 |
| 2. Cash flows from investing activities | | |
| 2.1 Payments to acquire: | | |
| (a) property, plant and equipment | (27) | (215) |
| (b) businesses (see item 10) | - | - |
| (c) investments | - | - |

| Consolidated statement of cash flows | Current quarter \$A'000 | Year to date (9 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 | (27) | (215) |

| | | |
|---|----------|--------------|
| 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 | 0 | (957) |
| 3.9 Other (provide details if material) | - | - |
| 3.10 Net cash from / (used in) financing activities | 0 | (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 | 42,827 | 36,198 |
| 4.2 Net cash from / (used in) operating activities (item 1.9 above) | 2,516 | 9,764 |
| 4.3 Net cash from / (used in) investing activities (item 2.6 above) | (27) | (215) |

| Consolidated statement of cash flows | | Current quarter \$A'000 | Year to date (9 months) \$A'000 |
|---|--|------------------------------------|--|
| 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 | (341) | 185 |
| 4.6 | Cash and cash equivalents at end of quarter | 44,975 | 44,975 |

| 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 | 22,764 | 22,364 |
| 5.2 | Call deposits | 22,125 | 20,375 |
| 5.3 | Bank overdrafts | | |
| 5.4 | Other (Security Deposits) | 86 | 87 |
| 5.5 | Cash and cash equivalents at end of quarter (should equal item 4.6 above) | 44,975 | 42,826 |

| 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 | 310 |
| 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 <i>Add notes as necessary for an understanding of the position</i> | 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 | (70) |
| 9.2 | Product manufacturing and operating costs | (1,815) |
| 9.3 | Advertising and marketing | (90) |
| 9.4 | Leased assets | (135) |
| 9.5 | Staff costs | (1,375) |
| 9.6 | Administration and corporate costs | (790) |
| 9.7 | Other/including GST & VAT | 275 |
| 9.8 | Total estimated cash outflows | (4,000) |

| 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: 30 April 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.