



CLINUVEL

Company Announcement

ASX:

CUV

XETRA-DAX:

UR9

NASDAQ INTERNATIONAL DESIGNATION: CLVLY

APPENDIX 4C

September quarter 2019 cash flow boosts cash balance to \$58.3m

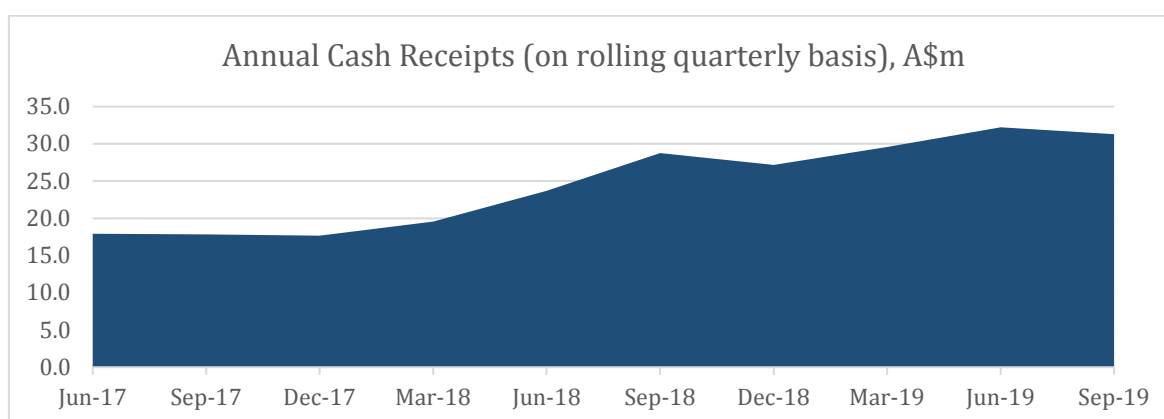
Melbourne, Australia, 31 October 2019

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 July to 30 September 2019. All figures are rounded and reported in Australian dollars.

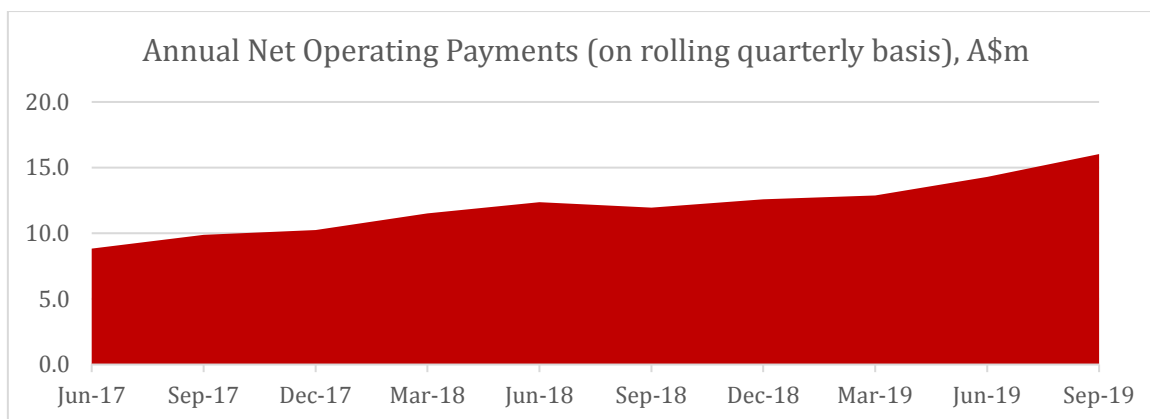
Cash receipts were \$9,782,000 for the quarter ending September 30, 2019, whereby the combination of Cash Receipts and Net Operating Payments has resulted in Net Cash from Operating Activities increasing by \$5,385,000. Cash reserves were impacted by CLINUVEL paying, on 19 September 2019, a second consecutive full year unfranked dividend distribution of \$0.025 per share, translating to a \$1,224,000 distribution to shareholders out of the prior year profit.

Overall cash flows continue to be positive, with cash and cash equivalents for the quarter increasing by \$4,067,000 to \$58,336,000.

Cash Receipts in the June and September quarters of each year reflect the strong clinical demand for SCENESSE® (afamelanotide 16mg)¹ throughout the northern hemisphere spring and summer by patients in the European Union and Switzerland with the rare metabolic disorder, erythropoietic protoporphyria (EPP). Unit orders of SCENESSE® are generally lower in the northern hemisphere during winter months due to the lower intensity of ambient light and less risk of phototoxicity.



In the quarter ending September 30, 2019, product manufacturing expenditures were incurred to meet the clinical demand for SCENESSE® and operating costs were maintained to meet the ongoing post-authorisation commitments coming with the European marketing authorisation for SCENESSE®. Staffing costs and expenditures towards Company promotional activities at key conference industry events also contributed to the 2% increase quarter-on-quarter.



COMMENTARY

“The cash flow result for the quarter continues to be reflective of the seasonal nature of distributing SCENESSE® into Europe, where patients are more exposed to ambient light in the summer months and the demand for the drug increases,” CLINUVEL’s Chief Financial Officer, Mr Darren Keamy said.

“The Company will continue to be most disciplined in the approach to its cash flow management as it nears the northern hemisphere winter months and taking into account that following the 8 October approval of SCENESSE® by the US Food and Drug Administration, the Company will progress its implementation of the distribution plan to bring the treatment to EPP patients in North America,” Mr Keamy said.

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

- End -

¹ 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.

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

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Australia
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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")

30 SEPTEMBER 2019

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	9,782	9,782
1.2 Payments for		
(a) research and development	(71)	(71)
(b) product manufacturing and operating costs	(1,868)	(1,868)
(c) advertising and marketing	(217)	(217)
(d) leased assets	(74)	(74)
(e) staff costs	(1,611)	(1,611)
(f) administration and corporate costs	(845)	(845)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	217	217
1.5 Interest and other costs of finance paid	(5)	(5)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other/including GST & VAT	77	77
1.9 Net cash from / (used in) operating activities	5,385	5,385
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(191)	(191)
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 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	(191)	(191)
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 and lease liabilities	(90)	(90)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	(1,224)	(1,224)
3.9 Other (provide details if material)	-	-
3.10 Net cash from / (used in) financing activities	(1,314)	(1,314)
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	54,269	54,269
4.2 Net cash from / (used in) operating activities (item 1.9 above)	5,385	5,385
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(191)	(191)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1,314)	(1,314)
4.5	Effect of movement in exchange rates on cash held	187	187
4.6	Cash and cash equivalents at end of quarter	58,336	58,336

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	27,400	25,599
5.2	Call deposits	30,825	28,525
5.3	Bank overdrafts		
5.4	Other (Security Deposits)	111	145
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	58,336	54,269

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	245
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	(80)
9.2	Product manufacturing and operating costs	(1,100)
9.3	Advertising and marketing	(80)
9.4	Leased assets	(110)
9.5	Staff costs	(2,230)
9.6	Administration and corporate costs	(870)
9.7	Other/including GST & VAT	150
9.8	Total estimated cash outflows	(4,320)

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 October 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.