CLINUVEL

COMPANY ANNOUNCEMENT

Appendix 4C & Activity Report

Record December Quarter Caps Strong Annual Rise
in Cash Inflows for CY2021

Melbourne, Australia, 31 January 2022	ASX: XETRA-DAX: ADR Level 1:	CUV UR9 CLVLY

CLINUVEL PHARMACEUTICALS LTD today announced its Appendix 4C – Quarterly Cashflow Report and Activity Report for the period 01 October to 31 December 2021.

HIGHLIGHTS CASH FLOW

	Q2 FY2022[1]	CY2021
Cash receipts	**$13,120,000**	**$52,348,000**
Cash expenditures	**$7,624,000**	**$25,485,000**
Net operating cash flow[2]	**+$5,746,000**	**+$26,075,000**
Cash reserves[3]	**+6.0%**	**+35.8%**
Debt-free		

The table provides context of the quarterly results ending 31 December 2021to the overall results of calendar year 2021.
1. Period 01 October to 31 December 2021. All dollar figures in this release are rounded and reported in Australian dollars.
2. Operating cash flow excludes non-cash items.
3. % increase in cash reserves compared to previous quarter, or year on year.

COMMERCIAL OPERATIONS ENABLING GROWTH AND EXPANSION STRATEGY

Patient demand for treatment with CLINUVEL's innovative drug SCENESSE® (afamelanotide 16mg) has increased year-on-year, with growth seen in both Europe and the USA throughout 2021. The drug – the world's only approved therapy for the rare metabolic disorder erythropoietic protoporphyria (EPP)[1] – was also made available to patients in Israel for the first time in 2021, following its addition to the Israeli National Health Basket.

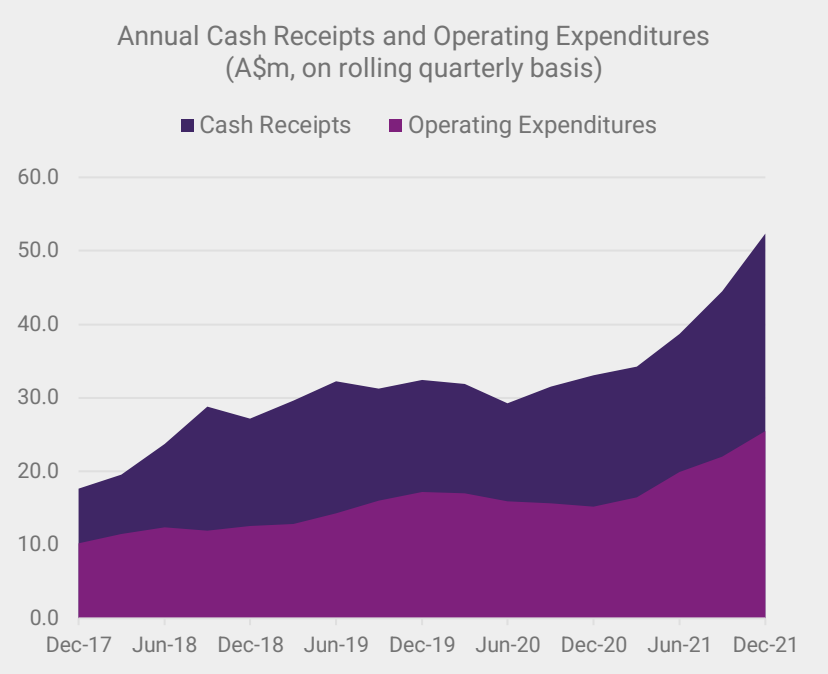
Increasing demand for CLINUVEL's commercial product underlies the rising trend in the Company's cash receipts which continued in the December quarter to round-out a strong 58.4% increase for the 2021 calendar year. This is despite the ongoing impact of COVID-19 on the operating environment with disrupted supply chains and stress on the healthcare sector to maintain ongoing treatments.

CLINUVEL's cash receipts, coupled with prudent control of expenditures, are enabling the progress of a multi-pronged strategy to:

- Grow commercial operations based on SCENESSE® for EPP patients;
- Develop innovative melanocortin products to treat a range of indications with an unmet medical need;
- Provide non-prescription healthcare solutions to individuals in the wider population at high risk of exposure to ultraviolet (UV) and high energy visible light (HEV); and
- Further integrate critical parts of its value chain.

This strategy is in place to build a diversified and sustainable specialty pharmaceutical group and to enhance the quality of life and well-being of many patient groups and individuals in the wider population.

SOLID INCREASES IN CASH RECEIPTS AND NET CASH



CLINUVEL recorded cash receipts of $13,120,000 and net operating cash flows of $5,745,000 for the December quarter of 2021. The cash receipt result is more than double the highest cash receipt result recorded in a December quarter by the Company. The increase reflects firmer demand for SCENESSE® in Europe and consistent growth in the treatment of patients in the United States throughout the 2021 calendar year. Patient treatment in the US is being facilitated by a larger network of Specialty Centers than originally anticipated, as well as acceptance by US insurers to reimburse the drug under Prior Authorization arrangements and include it on formulary lists. This has facilitated greater year-round access to treatment for US patients. Cash inflows from European Expert Centres were also strong, with higher-than-expected collections in the quarter. As witnessed in prior years, European orders tapered off in the December quarter due to lower seasonal demand in the months of less light exposure.

EXPENDITURES AND REINVESTMENTS

Expenditures from operating activities were $7,624,000 in the December quarter. Payments towards manufacturing and supply costs of raw materials and finished goods continued at levels recorded in recent quarters, as part of a program to fortify stock levels to meet expected future patient demand and to support the expanded range of R&D initiatives. These expenditures were complemented by costs associated with data mining and collection from the use of SCENESSE® in EPP patients. Increasing and preserving staff head count in an environment where the demand for talent is intensifying has been a constant focus for management as it strives to have the dedicated resources in place to support its expansion plans. Expenses towards a non-clinical study – part of progressing the Company's product formulation portfolio – were also recorded. Corporate and investor relations related expenses typically incurred in the December quarter contributed to an increase in administrative expenses compared to the prior quarter.

In the December quarter the Company, through its Singapore subsidiary entity VALLAURIX PTE LTD, received its first Research Incentive Scheme grant payment under the 2020 award from the Singapore Economic Development Board.

FINANCIAL COMMENTARY ON RESULTS

"The success of the Company's deliberate long-term strategy to establish SCENESSE® as the global standard of care for EPP patients is evident in the 58% growth in cash receipts achieved in the 2021 calendar year," CLINUVEL's Chief Financial Officer, Mr Darren Keamy said.

"The Company has built a strong cash position to support the planned organic growth and to also provide a financial buffer to respond to unforeseen impacts like COVID-19 and any adverse changes in the economic environment.

"The Group's growth and expansion strategy to become a diversified and sustainable specialty pharmaceutical business requires ongoing reinvestment in a considered and careful manner in an ever-challenging operating environment. This reinvestment is impacting our overall expenditure base, but this is being more than sufficiently financed by the growth in cash flows generated from our commercial operations," Mr Keamy said.

KEY ACTIVITIES - DECEMBER QUARTER 2021

The primary focus of CLINUVEL's commercial distribution of SCENESSE® for EPP in Europe, the USA and Israel during the quarter was to:

- work with porphyria treatment centres and suppliers to ensure continuous supply of the drug to patients;
- manage the ongoing reimbursement of the cost of treatment; and
- undertake key data collection, compliance, and reporting activities associated with CLINUVEL's obligations under marketing approvals.

Having established itself as a world expert in photomedicine and melanocortin drug development, CLINUVEL is conducting clinical trials to evaluate the safety and efficacy of afamelanotide for a range of patients with genetic, metabolic, systemic, and life-threatening, acute disorders. The expanded clinical program was also progressed during the quarter with key developments in individual programs reported below.

DNA Repair Program

- The DNA Repair Program aims to assess the ability of afamelanotide to play a role in the repair of DNA of skin damaged by UV radiation and visible light. This clinical focus is relevant to over two billion people worldwide who have some sort of inefficiency in their natural DNA reparative processes (nucleotide excision repair and basic excision repair).
- The initial focus of the DNA Repair Program is on patients with the rare genetic disorder xeroderma pigmentosum (XP), a life-threatening disorder caused by an inability to repair UV-provoked DNA skin damage.
- The Company announced early in the quarter that all necessary regulatory and ethics committee approvals to commence a new and world first study (CUV156), had been granted. Subsequently, the first two patients with the XP-C complementation were treated with no adverse reactions reported. As this study progressed, the Company also continued to prepare to commence a new study (CUV151) involving healthy volunteers of fair complexion as a control group.

Arterial Ischaemic Stroke (AIS)

- Globally, at least ten million people per annum suffer an ischaemic stroke and are ineligible for treatment with existing therapies. Afamelanotide is known to offer neuroprotection and act as a

potent anti-oxidative hormone. The drug therapy is assessed on its ability to improve blood flow and increase the delivery of oxygen and nutrients to deprived brain tissue in stroke patients.

- Three AIS patients had been treated with afamelanotide in the CUV801 study before COVID-19 related lockdowns impacted progress at the treating hospital in Australia in the September quarter and into the December quarter.
- The Company announced the completion of enrolment in the CUV801 study in January 2022. Importantly, no drug related adverse reactions were reported in the six patients treated. The study will now be completed and analysed, with results expected later in the year.

Vitiligo

- Vitiligo affects up to 45 million individuals worldwide, with no current approved therapy. In initial studies, afamelanotide has been shown to repigment vitiliginous lesions as a combination therapy.
- Towards the end of the quarter, the Company announced agreement with the US Food and Drug Administration (FDA) on the design of a new North American vitiligo study. The focus is on patients of darker skin complexion (Fitzpatrick IV-VI), for whom the need for repigmentation treatment is regarded as the greatest due to visible disease causing a loss of identity in this group. CLINUVEL will now proceed to commence a study (CUV104) to assess the role of afamelanotide as a monotherapy to repigment the skin and improve the quality of life of patients.

CLINUVEL announced the expansion of its melanocortin drug portfolio during the quarter with the addition of NEURACTHEL®, a novel formulation of the melanocortin adrenocorticotropic hormone (ACTH), under a supply agreement with a strategic partner. NEURACTHEL®, will be evaluated for patients with neurological, endocrinological and degenerative disorders, who lack alternative therapy. Further updates on this initiative can be expected.

The Company also held the Annual General Meeting of Shareholders in virtual format on 10 November. A record number of shareholders voted on the resolutions of the Meeting which were all voted in favour of the Directors' recommendations. The Chair and Managing Director presented to the Meeting and the Board of Directors answered shareholder questions. An Operations Update, Investor Webinar and Strategic Update were issued during the quarter and CLINUVEL presented at key conferences, specifically the Morgans Value in the Vines Conference and the Jefferies London Healthcare Conference.

All of the Company's announcements and key media interviews in the December quarter 2021 are available on the CLINUVEL website, with other updates available on the CLINUVEL News website.

Although the Company is no longer obligated under ASX Listing Rules to publish quarterly cash flow results, it elects to continue to do so to keep its global investors updated regularly. A copy of the Appendix 4C – Quarterly Cash Flow Report for the second quarter of FY2022 is attached.

Pursuant to Listing Rule 4.7C and as disclosed in Item 6.1 to the attached Appendix 4C, $1,134,000 (inclusive of non-monetary benefits and long accrued leave entitlement to Managing Director) were recorded in respect to Non-Executive Directors' fees, Managing Director's fees and non-monetary benefits.

– End –

[1] SCENESSE® (afamelanotide 16mg) is approved in the European Union and Australia as an orphan medicinal product for the prevention of prevention of phototoxicity in adult patients with erythropoietic protoporphyria (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 (ASX: CUV; ADR LEVEL 1: CLVLY; XETRA-DAX: UR9) is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for the general population. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore and the USA. For more information, please go to https://www.clinuvel.com.

SCENESSE®, PRÉNUMBRA®, and NEURACTHEL® are registered trademarks of CLINUVEL.

Authorised for ASX release by the Board of Directors 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; the COVID-19 pandemic and/or other world, regional or national events affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg), PRÉNUMBRA® or NEURACTHEL®; our ability to achieve expected safety and efficacy results in a timely manner 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, Israel, China 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®, PRÉNUMBRA® or NEURACTHEL® 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 and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; our ability 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 2021 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 preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

www.clinuvel.com

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity
CLINUVEL PHARMACEUTICALS LIMITED

ABN
88 089 644 119

Quarter ended ("current quarter")
31 DECEMBER 2021

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	13,120	30,905
1.2	Payments for		
	research and development	(366)	(572)
	product manufacturing and operating costs	(2,986)	(5,659)
	advertising and marketing	(105)	(174)
	leased assets	(87)	(160)
	staff costs	(3,227)	(5,800)
	administration and corporate costs	(1,029)	(1,766)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	50	113
1.5	Interest and other costs of finance paid	(6)	(17)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	200	210
1.8	Other (provide details if material)	182	226
1.9	**Net cash from / (used in) operating activities**	**5,746**	**17,306**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	businesses	-	-
	property, plant and equipment	(35)	(56)
	investments	-	-
	intellectual property	-	-
	other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(b) entities	-	-
	businesses	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	property, plant and equipment	-	-
	investments	-	-
	intellectual property	-	-
	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**	**(35)**	**(56)**

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(69)	(131)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	(1,235)
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**(69)**	**(1,366)**

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	93,383	82,691
4.2	Net cash from / (used in) operating activities (item 1.9 above)	5,746	17,306
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(35)	(56)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(69)	(1,366)
4.5	Effect of movement in exchange rates on cash held	(32)	418
4.6	**Cash and cash equivalents at end of period**	**98,993**	**98,993**

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	39,864	39,307
5.2	Call deposits	58,800	53,800
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	329	276
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**98,993**	**93,383**

6.	**Payments to related parties of the entity and their associates**	**Current quarter** $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	1,134
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end** $A'000	**Amount drawn at quarter end** $A'000
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		
7.5	**Unused financing facilities available at quarter end**		
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8.	**Estimated cash available for future operating activities**	$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	17,306
8.2	Cash and cash equivalents at quarter end (item 4.6)	98,993
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (item 8.2 + item 8.3)	98,993
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
	8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?
	Answer: N/A	
	8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?
	Answer: N/A	
	8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?
	Answer: N/A	

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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.

Date: 31 January 2022

Authorised by: MR DARREN KEAMY

(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.