

ASX Announcement

27 October 2021

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Business Update and September 2021 Quarter Cashflow

All figures in US\$

PCP = Previous Corresponding Period

Cogstate Ltd (ASX:CGS) has today released a business update and its Appendix 4C – Quarterly Cash Flow statement for the quarter ended 30 September 2021 (1Q22).

Highlights:

1Q22 REVENUE OF \$12.3M, A RECORD QUARTERLY RESULT, UP 99% COMPARED TO PCP

- Clinical Trials revenue of \$11.1m, up 93% compared to PCP
- Healthcare revenue of \$1.1m, up 255% compared to PCP*

CLINICAL TRIALS SALES CONTRACTS OF \$40.8M, A RECORD QUARTERLY RESULT, UP 391% COMPARED TO PCP

TOTAL REVENUE BACKLOG OF \$130 MILLION, A RECORD RESULT, UP 202% COMPARED TO PCP

- Clinical Trials revenue backlog of \$88.0 million, up 109% compared to PCP
- Healthcare revenue backlog of \$42.0 million

NET CASH OF \$23.4M AT 30 SEPTEMBER 2021**

- Cash inflow from operations of \$0.4m, excluding movements in passthrough costs paid on behalf of customers
- Net cash increased \$1.0m from \$22.4m at 30 June 2021, including proceeds from exercise of employee share options of \$0.97m

GUIDANCE IN RESPECT OF FY22 REMAINS UNCHANGED

- Clinical Trials revenue under contract as at 30 September 2021 is \$33.9m; Clinical Trials contribution margin expected to be consistent with FY21; Healthcare revenue under contract of \$4.2m and a contribution in the range of \$2.5 - \$3.0m; and Group EBIT margins in the range of 15-18%. Further details page 7.

	1Q22 US\$m	1Q21 US\$m	1Q22 vs 1Q21 %
Total revenue from ordinary activities	12.3	6.2	99%
- Clinical Trials revenue	11.1	5.8	93%
- Healthcare revenue	1.1	0.3	255%
- Research revenue	0.05	0.08	(45%)
Sales contracts executed	40.8	8.3	391%
Contracted future revenue	130.0	43.0	202%
Net operating cash flow	-0.3	-2.2	n/a
Total cash flow	0.4	-3.0	n/a
Net cash balance at end of period**	23.4	5.0	368%
Trade receivables	7.8	5.0	50%

*1Q21 numbers have been restated following a review of the application of the Group's accounting policy in respect of revenue relating to the grant of licences, provision of services and the provision of server access, in accordance with the requirements of AASB 15 Revenue from Contracts with Customers. These changes were implemented with the 1H21 result (see explanatory notes and reconciliation table below).

** Calculated as gross cash less borrowings and less cash receipts received in advance for future pass-through charges.

Explanatory Notes

- Sales contracts:** In the Clinical Trials division, Cogstate enters into contracts (“sales contracts”) with both pharmaceutical and biotechnology companies for the provision of Cogstate technology and services, for use in clinical research trials, to determine the extent to which their investigational compound is impacting the cognition of the patient population. The contract value will differ for each clinical trial, depending upon the scope of the technology and services provided by Cogstate, as well as the complexity and length of the trial. An increase in the total value of sales contracts executed will increase the revenue backlog and will, over time, result in an increase to revenue recognised by Cogstate.
- Calculation of revenue from Clinical Trials division:** Revenue from sales contracts is recognised over the life of the contract. The length of a clinical trial can vary from several months for a phase 1 study and up to 4-5 years for a phase 3 study. Revenue is recognised based upon achievement of pre-determined milestones. During each period, revenue may be recognised from (i) contracts in the backlog at the beginning of the period, as well as (ii) sales contracts executed during the period. Usually there is a time lag between an increase or decrease in the level of sales contracts executed and a corresponding change to recognised revenue.
- Contracted future revenue backlog:** Executed sales contract values that have not yet been recognised as revenue at period end are referred to as “contracted future revenue”. The revenue from these contracts will be recognised upon achievement of pre-determined milestones throughout the clinical trials. The contracted future revenue figure provides insight into future revenue performance.
- Healthcare revenue:** Cogstate has developed tools specifically designed to aid healthcare professionals, in general and specialist practice medicine, with objective assessments of cognition in patients. Cogstate’s Healthcare offering includes the system branded as Cognigram™, a medical device which allows for regular and standardised testing to assist in the early detection of cognitive decline that could be related to a range of factors, including neurodegenerative diseases such as Alzheimer’s disease. On 26 October 2020, Cogstate announced an exclusive global licensing agreement with pharmaceutical company Eisai (was previously just Japan), under which Eisai will market Cogstate technology as digital cognitive assessment tools targeting physicians, corporations, municipalities and also directly to consumers.

Due to the significance of the global licensing agreement, the group announced in its 1H21 results that it had reviewed the application of its accounting policy in respect of revenue relating to the grant of licences, provision of supporting services and the provision of server access, in accordance with the requirements of AASB 15 Revenue from Contracts with Customers.

The group considers that recognising the upfront cash payments received From Eisai (\$1m in Dec 19 for Japan and \$15m in Dec 20 for Global (ex Japan)) as revenue on a straight-line basis over the licence periods better reflects its performance in providing access to the licences, continuing support services and servers. As required by the accounting standards, this change is applied retrospectively, and as a result, the group has restated comparative figures. This resulted in a \$0.03m increase in Healthcare revenue in 1Q21 from a reported \$0.29m to a restated \$0.32m. This restatement has no impact on cash. See reconciliation table below.

	(Restated) 1Q21 US\$	Adjustment	(As Previously Reported) 1Q21 US\$
Healthcare Revenue	0.32	0.03	0.29

Under the 10-year global (ex-Japan) agreement between Eisai and Cogstate executed on 26 October 2020:

- In addition to the upfront payments from Eisai of US\$15 million, Cogstate is also due to receive an ongoing royalty on revenue derived by Eisai from the sale of Cogstate technology. Over the course of the 10-year global agreement, the contractual terms prescribe that the royalty payments shall not be less than an additional \$30 million (\$10 million over years 1-5 and \$20 million over years 6-10).
- The full \$45m (upfront payment of \$15m plus the minimum royalties of \$30m due over the course of the global license agreement) is being amortised on a straight-line basis over 11 years (10-year term + 12 months to commence). Actual cash royalties paid in each period will be the higher of (i) royalty amount calculated based on sales of product or (ii) minimum annual cash royalty, which ramp up over the contract period.

Revenue

Cogstate reported a record quarterly revenue of \$12.3 million for 1Q22, up 99% on pcp (1Q21 \$6.2m) and 23% higher than the prior quarter (4Q21 \$10.0m).

Revenue	1Q22 US\$ m	1Q21 US\$ m	Variance %
Clinical Trials	11.1	5.8	93%
Healthcare	1.1	0.3	255%
Research	0.05	0.08	(45%)
Total Revenue	12.3	6.2	99%

Clinical Trials revenue in 1Q22 was \$11.1m, up 93% on pcp and 26% higher than 4Q21, benefitting from the strong growth in new Clinical Trials Sales contracts executed in recent periods. Revenue in the quarter also benefited from strong software license revenue relating to recent new business signings.

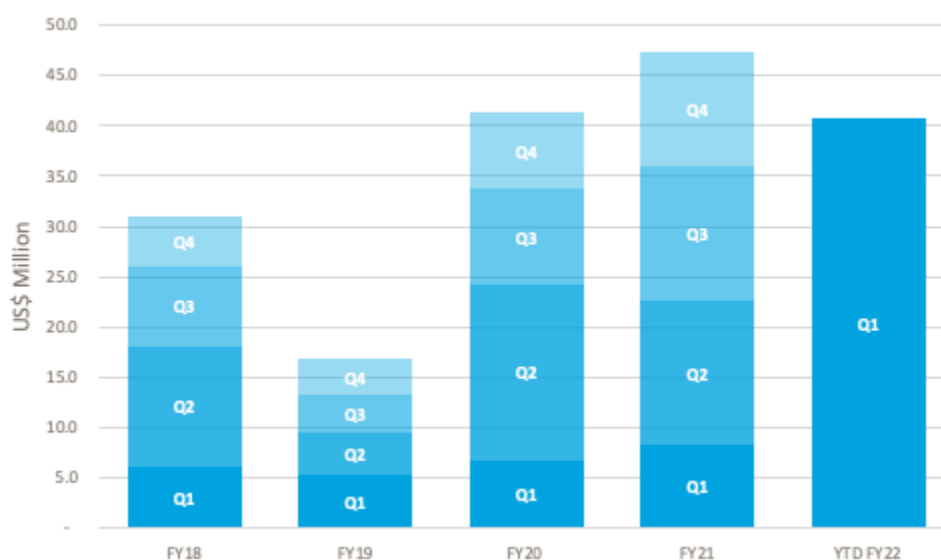
In Healthcare, 1Q22 revenue was \$1.1m, up 255% on pcp (as previously noted, revenue in the prior period was restated up from \$0.29m to \$0.32m to reflect the change in revenue recognition policy). The 1Q22 revenue was primarily the recognition of approximately \$1.1m of deferred revenue associated with the Eisai licencing agreement. Cogstate continues to work in partnership with Eisai, with product launch in the USA and several Asian countries imminent.

Sales Contracts Executed

For the quarter ended 30 September 2021, Cogstate executed \$40.8 million of Clinical Trials sales contracts, a record quarter, including a large phase 3 Alzheimer's disease trial where Cogstate digital assessments will be used as important endpoints in the trial. Overall, 97% of the \$40.8m of contracts executed during the quarter was in respect of Alzheimer's disease trials. Clinical Trials sales contracts executed in 1Q22 were up 391% on 1Q21, and up 257% on 4Q21.

The gross total of new sales contracts executed was \$44.3 million and includes several new sales contracts. The net total of \$40.8 million includes the cancellation of one ongoing trial and reconciliations at the completion of a small number of other trials.

Clinical Trials Sales Contracts Executed



For context, a history of Clinical Trials sales contracts executed, per quarter, since 1 July 2020 is provided below:

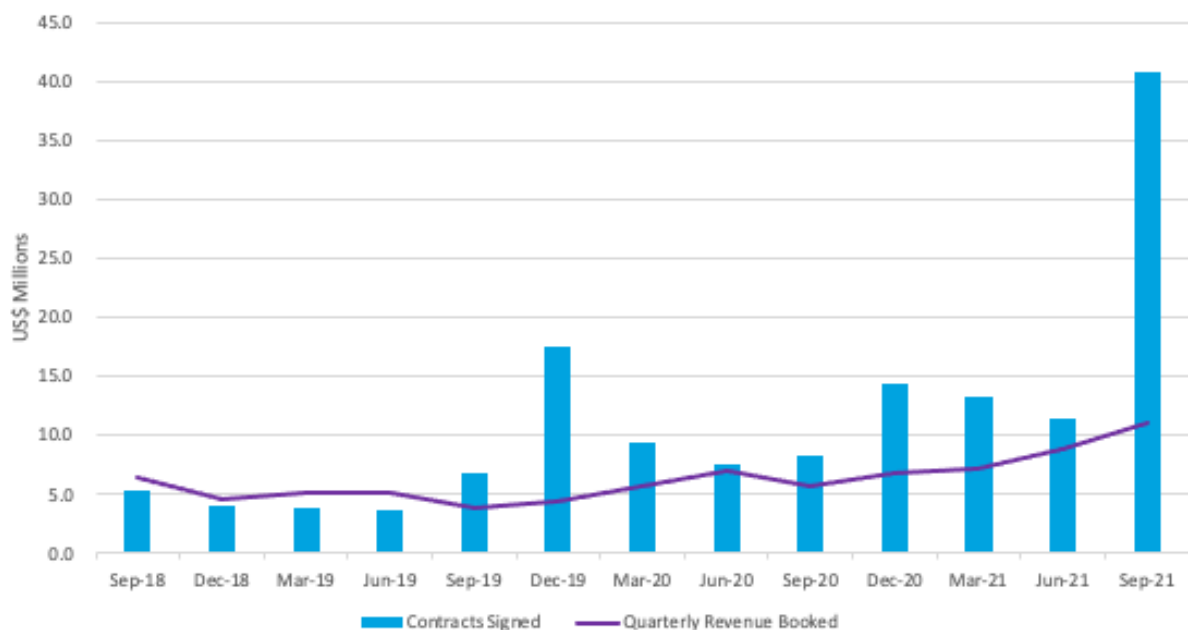
	Sep Quarter US\$m	Dec Quarter US\$m	1 st Half US\$m	Mar Quarter US\$m	Jun Quarter US\$m	2 nd Half US\$m	Financial Year US\$m
FY22 YTD	\$40.8						
FY21	\$8.3	\$14.3	\$22.6	\$13.3	\$11.4	\$24.7	\$47.3
FY20	\$6.7	\$17.5	\$24.2	\$9.5	\$7.6	\$17.1	\$41.3

Contracted Future Revenue

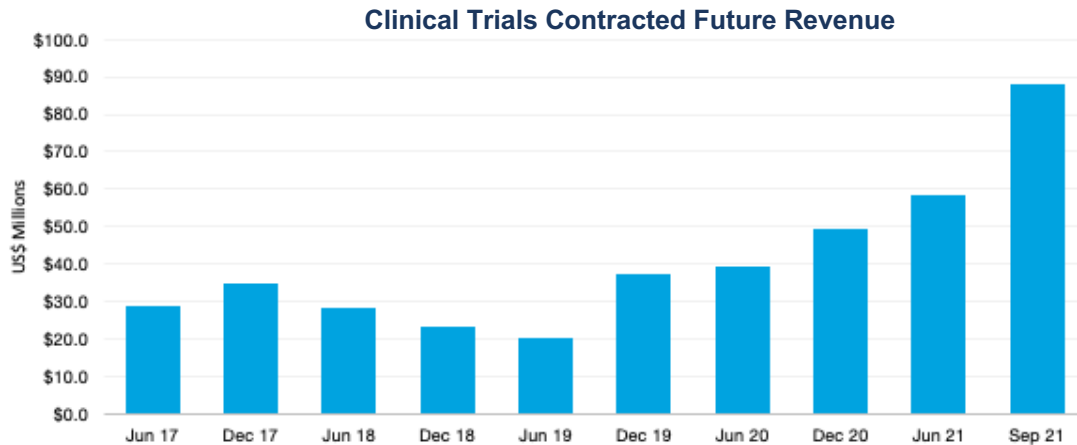
Total Contracted future revenue increased to \$130.0m as at 30 September 2021 vs \$101.5m as at 30 June 2021 and \$43.0m in pcp. The contracted future revenue figure provides insight into future revenue performance of the Group.

In Clinical Trials, contracted future revenue increased during 1Q22 with the value of contracts executed (\$40.8m) exceeding Clinical Trials revenue recognised (\$11.1m). The value of new contracts signed has now exceeded revenue recognised in each of the last 9 consecutive quarters.

Clinical Trials Sales Contracts vs Revenue Recognised



This has in turn driven a further expansion in the backlog of Clinical Trials contracted future revenue to a record of US\$88.0m. The graph below shows contracted future Clinical Trials revenue as at the end of each half year period since June 2017, as well as the September 2021 quarter.



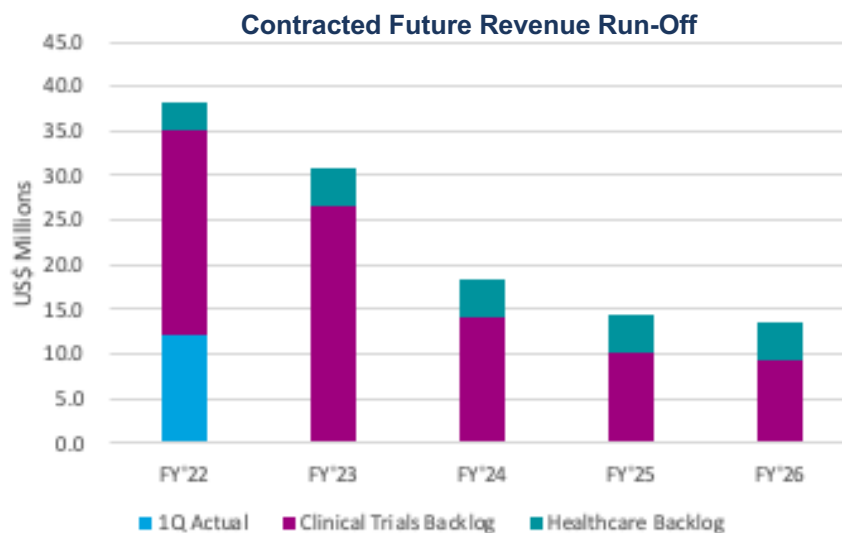
Cogstate continues to win work across a number of different indications, but Alzheimer's disease is a significant contributor, now representing 70% of contracted future Clinical Trials revenue.

In Healthcare, a further \$42.0m of payments remains to be recognized in relation to the Eisai Global partnerships over the license periods.

The revenue backlog for both the Clinical Trials and Healthcare segments are highlighted in the table below.

	30 Sep 21	30 Jun 21	30 Sep 20
	US\$	US\$	US\$
Contracted Clinical Trials Revenue	88,015,983	58,424,721	42,062,088
Eisai Licence – Global (commercial years 1-10)	41,180,936	42,211,299	-
Eisai Licence – Japan (10 year licence)	790,309	815,494	890,227
Total Contracted Future Revenue	129,987,228	101,451,514	42,952,315

The expected run-off of future revenue backlog is shown in the chart below:



Operating Cash Flow

The table below summarises the cashflow for the quarter, while separating the cash flows that relate to pass-through expenses paid on behalf of Cogstate customers. The summary shows a total operating cash inflow of \$0.4 million during the quarter for Cogstate, this is before accounting for -\$0.7 million related to pass-through costs, which is a timing difference for Cogstate.

	Cogstate Operations	Customer Related Pass-Through Expenses	Total
	US\$m	US\$m	US\$m
Cash at 01 July 2021	22.4	1.2	23.6
Cash flow from operations			
Eisai upfront payment (net of costs)	-	-	-
Cash flow from ordinary operations	0.4	(0.7)	(0.3)
Total cash flow from operations	0.4	(0.7)	(0.3)
Cash flow from investing			
Capitalised software development	-	-	-
Property, Plant & Equipment	(0.1)	-	(0.1)
Grant funds received	-	-	-
Total cash flow from investing	(0.1)	-	(0.1)
Cash flow from financing			
Proceeds from the exercise of options	1.0	-	1.0
Principal portion of lease payments	(0.2)	-	(0.2)
Total cash flow from financing	0.8	-	0.8
Cash at 30 September 2021	23.4	0.5	24.0

- Net cash, excluding amounts on behalf of customers for payment of pass-through expenses, increase by \$1.0 million during the quarter, to \$23.4 million.
- Cash receipts from customers totalled \$9.7 million for the quarter up from \$7.2 million in the prior corresponding period, but consistent with the previous quarter (up 2%).
- There were no cash receipts from Eisai during the quarter. Cogstate will begin invoicing Eisai for minimum royalty payments under the Global Agreement (excl. Japan) during 2Q22.
- Staffing levels and staff costs have not varied substantially from March to September. Cash outflows relating to staff costs for the September quarter (\$6.5m) were higher than the March and June 2021 quarters, reflecting:
 - All software development costs were expensed during 1Q22;
 - Based on 2 weekly pay-cycle in the USA, the September quarter included an additional pay run (approx. \$0.4 million per USA pay cycle) in July 2021; and
 - Payment of annual bonuses in September 2021 (approx. \$2.4 million).

Related Party Transaction

- As noted in item 6 of the Appendix 4C Cashflow Statement, payments made to related parties and their associates total \$917,393 for the quarter. The payments relate to:
 - Non-executive directors' fees paid to Martyn Myer, David Dolby, Richard Mohs, Richard van den Broek, Ingrid Player and Kim Wenn totalling \$108,991.
 - Salary and wages remuneration (including payment of FY21 bonuses) to executive director (CEO – Brad O'Connor) and other related party individuals totalling \$808,402.
 - All noted remuneration is on commercial terms.

Investing Cash Outflow

- No software development costs were capitalised during 1Q22 as we continue to reallocate resource to different projects across the business and conduct an assessment of what costs qualify for capitalisation.

Cash Flow From Financing:

- Net financing cash inflow of \$0.775 million includes proceeds from exercise of options of \$0.968 million offset by principal portion of lease payments of \$0.193 million.

FY22 Outlook.

FY22: GUIDANCE IN RESPECT OF THE FULL FINANCIAL YEAR

Market conditions remain positive, with Alzheimer's R&D expected to increase over coming years as approved treatment(s) provide regulatory path to market, and the increased adoption of decentralized trials design provides sales opportunities for digital assessments.

At this stage, we re-iterate our full year guidance provided on 24 August 2021:

- Clinical Trials revenue under contract at 30 September 2021 of \$33.9m
- Additional revenue will be generated from contracts executed 2Q22 – 4Q22
- Expect FY22 Clinical Trials contribution margin to remain consistent with FY21 performance, allowing for investment in technology to support the shift to decentralised trials
- Healthcare: Contracted revenue of \$4.2m, producing a segment contribution in the range of \$2.5m - \$3.0m
- Research: segment contribution consistent with FY21 result
- Operating expenses: as a percentage of operating revenue are expected to be in a range of 31-33%.
- Group EBIT margins expected to be in the range of 18-20%
- Underlying operating cash flow expected to be 30-35% of EBITDA, allowing for amortisation of Eisai revenue as well as amortisation of software development at an amount consistent with FY21.

About Cogstate

Cogstate Ltd (ASX:CGS) is the neuroscience technology company optimising brain health assessments to advance the development of new medicines and to enable earlier clinical insights in healthcare. Cogstate technologies provide rapid, reliable and highly sensitive computerised cognitive tests across a growing list of domains and support electronic clinical outcome assessment (eCOA) solutions to replace costly and error-prone paper assessments with real-time data capture. The company's clinical trials solutions include quality assurance services for study endpoints that combine innovative operational approaches, advanced analytics and scientific consulting. For 20 years, Cogstate has proudly supported the leading-edge research needs of biopharmaceutical companies and academic institutions and the clinical care needs of physicians and patients around the world. In the Healthcare market, in August 2019 Cogstate entered into an exclusive licensing agreement with the pharmaceutical company Eisai, under which Eisai will market Cogstate technologies as digital cognitive assessment tools in Japanese markets. In October 2020, Cogstate extended its agreement with Eisai to the Rest of the World. The product, branded as NouKNOW, launched in Japan on 31 March 2020 (nouknow.jp). For more information, please visit www.cogstate.com.

For further information contact:

Brad O'Connor, Chief Executive Officer, boconnor@cogstate.com

Quarterly Report – 30 September 2021

Summary Financial Table

	Quarter Just Completed	Previous Quarter Completed	Previous Corresponding Quarter
	30-Sep-21 US\$ million	30-Jun-21 US\$ million	30-Sep-20 US\$ million
<u>Receivables</u>			
Opening balance	7.85	7.45	4.21
Closing balance	7.84	7.85	5.00
Net Increase/(Decrease) in Receivables	(0.01)	0.40	0.79
<u>Payables</u>			
Opening balance	(5.66)	(4.29)	(7.05)
Closing balance	(3.14)	(5.66)	(3.41)
Net Increase/(Decrease) in Payables	(2.52)	1.37	(3.64)
<u>Cash Flow</u>			
Cash receipts from customers	9.71	9.50	7.19
Cash payments to employees	(6.53)	(3.55)	(5.01)
Cash payments to suppliers	(3.45)	(1.74)	(4.43)
Cash receipts, non-trading	0.00	0.00	0.03
Net Operating Cash In/(Out) Flows	(0.27)	4.21	(2.22)
Net Investing Cash In/(Out) Flows	(0.13)	(0.57)	(0.55)
Net Financing Cash In/(Out) Flows	0.77	(0.16)	(0.18)
Foreign exchange movement	-	-	-
Net Increase/(Decrease) in cash held	0.37	3.48	(2.95)

Appendix 4C

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

Name of entity

Cogstate Limited

ABN

80 090 975 723

Quarter ended ("current quarter")

30 September 2021

Consolidated statement of cash flows		Current quarter \$US	Year to date (3 months) \$US
1.	Cash flows from operating activities		
1.1	Receipts from customers	9,712,317	9,712,317
	Pass through receipts	347,218	347,218
1.2	Payments for		
	(a) research and development	(156)	(156)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(30,771)	(30,771)
	(d) leased assets (refer to 3.9)	-	-
	(e) staff costs	(6,527,747)	(6,527,747)
	(f) administration and corporate costs	(2,011,849)	(2,011,849)
	(g) pass through payments	(1,015,521)	(1,015,521)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received (refer to 2.5)	-	-
1.5	Interest and other costs of finance paid	(12,468)	(12,468)
1.6	Income taxes paid	(1,382)	(1,382)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)		
	Other professional fees (incl. accounting & audit)	(254,905)	(254,905)
	Computer costs	(396,209)	(396,209)
	Advisory fees	-	-
	Legal costs, including patent costs	(48,010)	(48,010)
	Listing fees & Associated costs	(26,052)	(26,052)
	Travel Costs	(641)	(641)
1.9	Net cash from / (used in) operating activities	(266,176)	(266,176)

+ See chapter 19 for defined terms.

	Current quarter \$US	Year to date (3 months) \$US
2. Cash flows from investing activities	-	-
2.1 Payments to acquire:		
(a) entities		
(b) businesses	-	-
(c) property, plant and equipment	(143,103)	(143,103)
(d) investments	-	-
(e) intellectual property	-	-
(f) capitalised software development	-	-
2.2 Proceeds from disposal of:		
(g) entities	-	-
(h) businesses	-	-
(i) property, plant and equipment	-	-
(j) investments	-	-
(k) intellectual property	-	-
(l) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	-	-
2.5 Interest Received	8,428	8,428
2.6 Net cash from / (used in) investing activities	(134,675)	(134,675)
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	968,196	968,196
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Principal portion of lease payments	(193,182)	(193,182)
3.10 Net cash from / (used in) financing activities	775,014	775,014

+ See chapter 19 for defined terms.

		Current quarter \$US	Year to date (3 months) \$US
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	23,640,789	23,640,789
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(266,176)	(266,176)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(134,675)	(134,675)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	775,014	775,014
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	24,014,952	24,014,952

		Current quarter \$US	Previous quarter \$US
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		
5.1	Bank balances	24,014,952	23,640,789
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	24,014,952	23,640,789

6. Payments to related parties of the entity and their associates

6.1 Aggregate amount of payments to related parties and their associates included in item 1

6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current quarter
\$US

917,393

Nil

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

Answer

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.

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

Total facility amount at quarter end \$US	Amount drawn at quarter end \$US
96,016	65,448
96,016	65,448

7.5 Unused financing facilities available at quarter end

30,569

- 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.

Bank Guarantee of US\$64k (A\$88k) and credit card facility of US\$32k (A\$45k).

8. Estimated cash available for future operating activities

\$US

8.1	Net cash from / (used in) operating activities (Item 1.9)	(266,176)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	24,014,952
8.3	Unused finance facilities available at quarter end (Item 7.5)	30,569
8.4	Total available funding (Item 8.2 + Item 8.3)	24,045,521
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	90.34

- 8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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

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

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

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: 27 October 2021

Authorised by: Darren Watson
On behalf of the Board of Cogstate Ltd

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.

+ See chapter 19 for defined terms.