ASX Announcement

27 Apr 2022

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Emyria commences Phase 1 trial for EMD-RX5; develops second ultra-pure CBD cannabinoid capsule EMD-RX7; expands MDMA analogue library; wins major IT award for Openly

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech developing multiple treatments for unmet needs powered by real-world patient data, is pleased to report on the Company's activities and strong cash position for the quarter ending March 31, 2022.

Highlights:

- **Commenced EMD-RX5 Phase 1 clinical trial** comparing Emyria's ultra-pure cannabidiol (CBD) capsule to Epidyolex oil - the sole registered CBD medicine in the US and Australia; interim results expected May 2022
- **Advanced pivotal Phase 3 clinical trial for EMD-RX5;** expected to commence this quarter
- **Launched EMD-RX7, Emyria's second ultra-pure CBD capsule** targeting registration as a prescription medicine for clinical indications requiring higher CBD doses; Phase 1 trial for EMD-RX7 in planning
- **Expanded proprietary MDMA analogue library** with University of Western Australia
- **Won a major, national IT award for Openly** - Emyria's digital health platform
- **Strong cash position of $6.66m** to advance multiple registration programs with the TGA and FDA

Emyria's Managing Director, Dr. Michael Winlo, said: "*This quarter, Emyria has made substantial progress towards the registration of over-the-counter EMD-RX5 with the commencement of an important Phase 1 study whilst advancing plans for the pivotal Phase 3 trial, expected to commence in the June Quarter.*

Emyria's proprietary dose form development program delivered EMD-RX7, a highly bioavailable capsule of ultra-pure cannabidiol. EMD-RX7 is targeting registration as a prescription medicine with major global regulators including the FDA. Further unique cannabinoid dose forms are in development, accelerated by targeting unmet clinical needs discovered through analysis of Emyria's proprietary, and growing, Real World data asset which is also backed by award-winning technology.

Emyria has also made great progress this quarter on the expansion and screening of a unique compound library, inspired by the molecule MDMA. This MDMA analogue library has the potential to yield next-generation psychedelic-assisted therapies and registered treatments for a range of neurological conditions and deepens Emyria's drug development pipeline."

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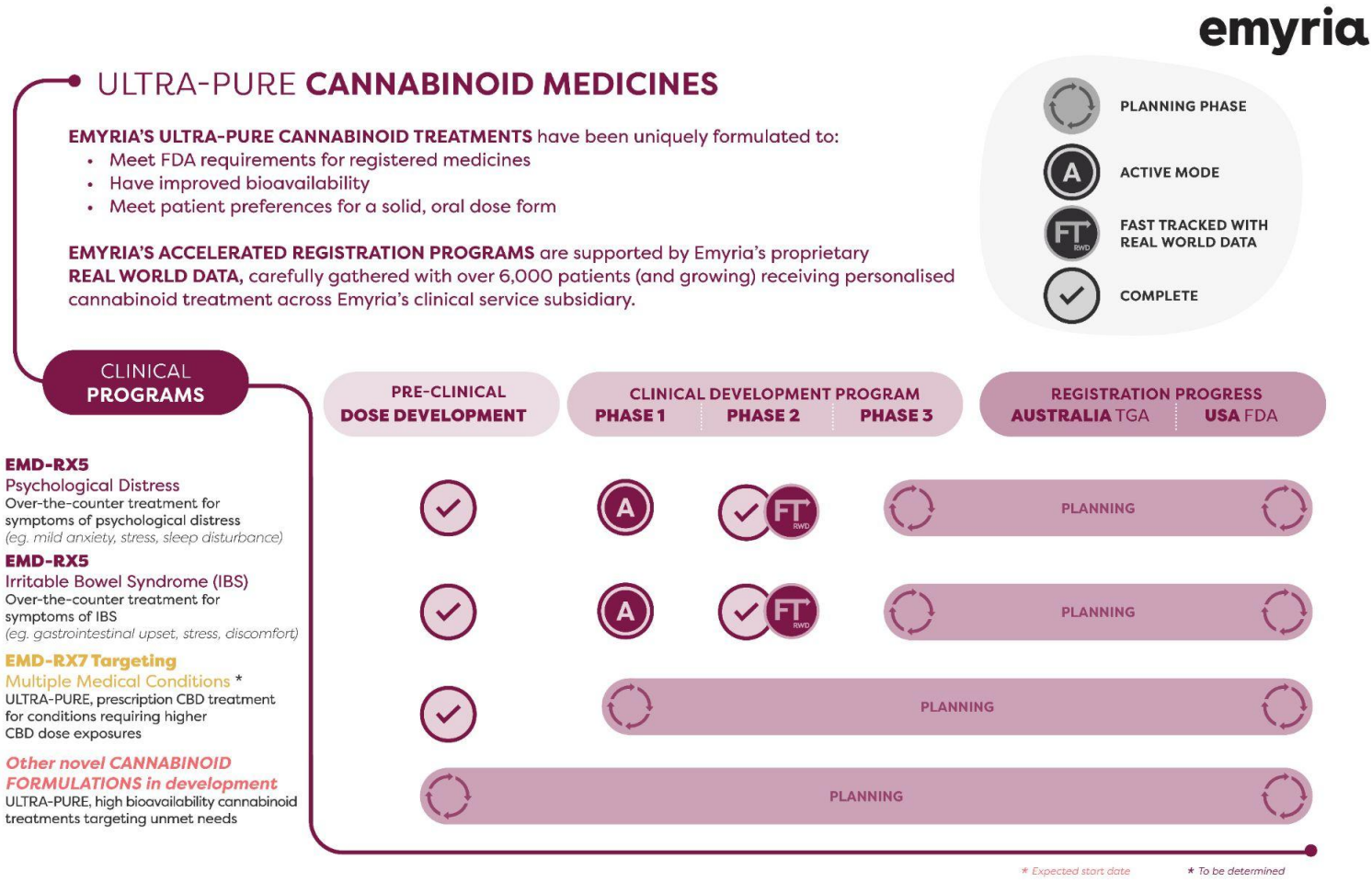
ADVANCING EMYRIA'S DRUG REGISTRATION PROGRAMS



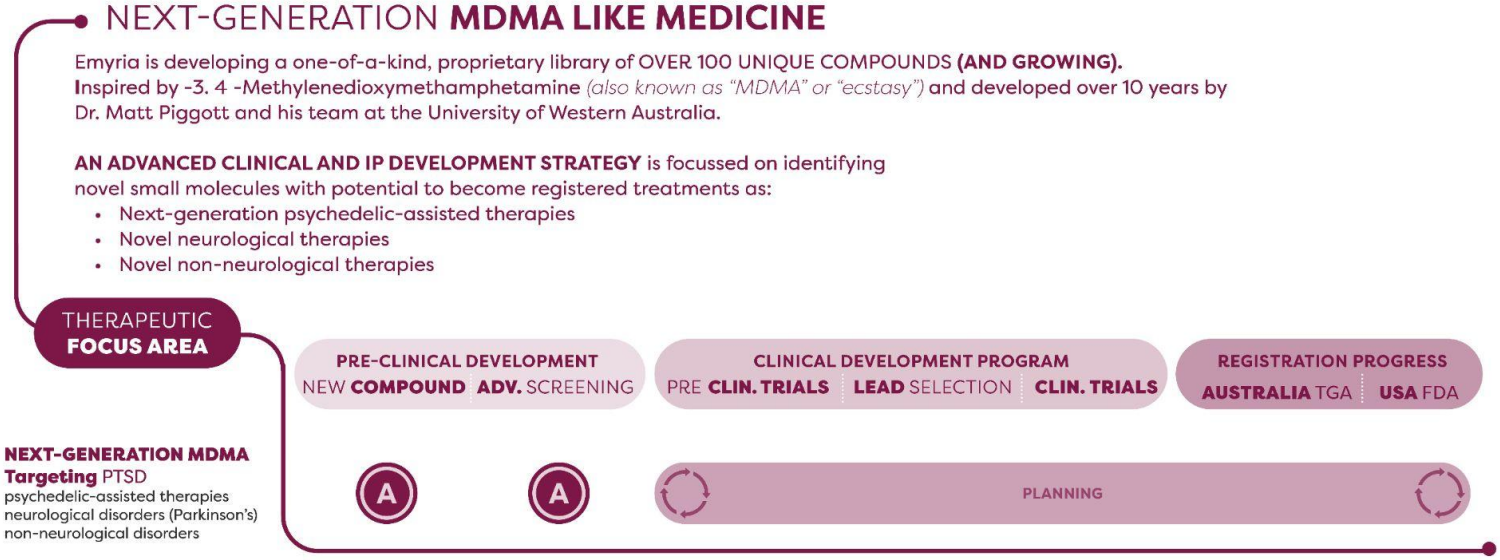


Fig 1. Emyria's drug development pipeline

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Ultra-pure cannabinoid development

Commenced Phase 1 clinical trial for EMD-RX5

EMD-RX5 is Emyria's first, wholly-owned proprietary formulation of ultra-pure cannabidiol (CBD). The Phase 1 clinical trial is assessing the safety, tolerability and bioavailability (a measure of the amount of the drug reaching the bloodstream) of EMD-RX5 capsules compared to Epidyolex oil in 12 healthy human volunteers. Epidyolex is sold by Jazz Pharmaceuticals (NASDAQ: JAZZ) and is the sole CBD medicine registered with both the TGA and FDA.

[See ASX release 17 Mar 2022]

EMD-RX5 was uniquely formulated to:

- Improve the bioavailability and tolerability of CBD
- Create a convenient, solid oral dose form for patients
- Meet FDA requirements for ingredient purity by using ultra-pure CBD
- Meet TGA requirements for "over-the-counter" (OTC) registration
- Address clinical indications where low doses of CBD appear to be effective.

EMD-RX5 is initially targeting registration with Australia's Therapeutic Goods Administration (TGA) as an over-the-counter (Schedule 3) treatment for the symptoms of psychological distress which includes mild anxiety, stress and sleep disturbance (amongst others). Phase 1 results are expected in May 2022. The pivotal Phase 3 clinical trial required to support registration is well advanced and expected to commence this quarter pending successful ethics approval.

Mild anxiety, stress and sleep disturbance affect about 15% of the adult population with a higher prevalence in patients with chronic disease and a rising prevalence [1]. There is currently no over-the-counter treatment available for this grouping of symptoms.

Launched second, ultra-pure CBD medicine, EMD-RX7

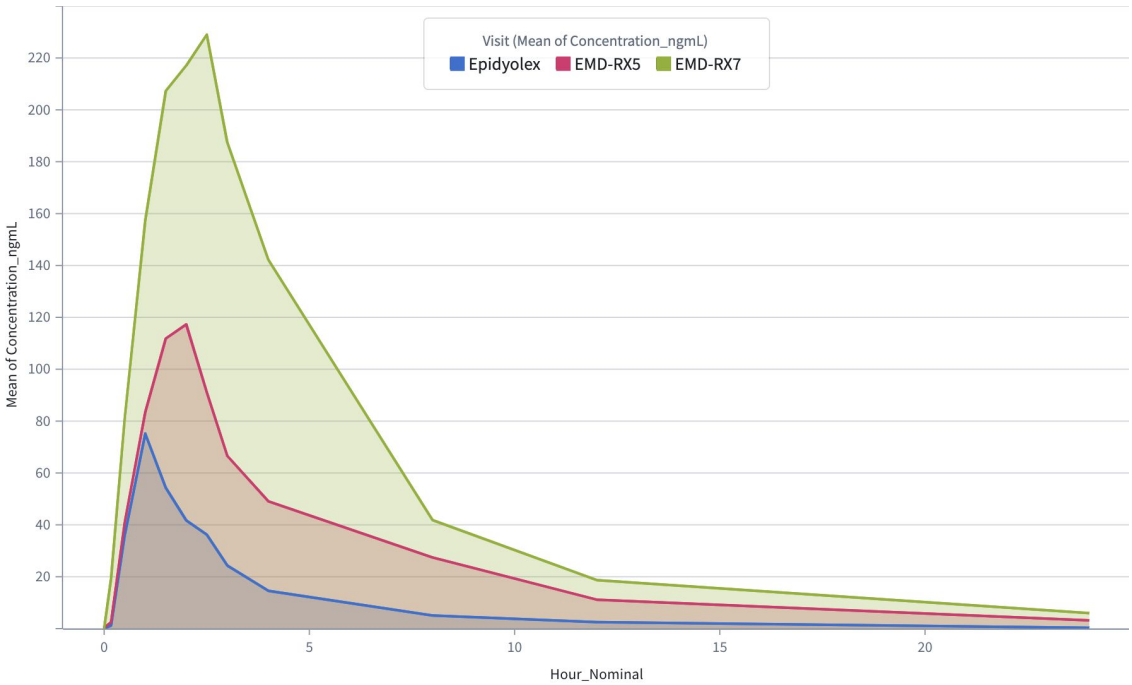


Fig 2. Mean concentration (ng/ml) of CBD : Epidyolex vs EMD-RX5 & EMD-RX7 over 24 hours

EMD-RX7 is Emyria's second, 100% owned, ultra-pure CBD dose form and follows the successful development of EMD-RX5.

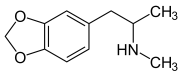
Preclinical studies demonstrated EMD-RX7 has more than 4 times the bioavailability compared to Epidyolex *(see Figure 2)* meaning lower doses of EMD-RX7 may be required to achieve clinical results for indications where high CBD has been shown to be effective.

[See ASX release 22 Mar 2022]

EMD-RX7 will target indications responsive to higher CBD exposures as guided by Emyria's extensive Real World Data gathered with 6,000 patients. A Phase 1 clinical trial is in development and expected to commence in 2022.

Table 1: Emyria's current ultra-pure CBD portfolio

	Emyria's ultra-pure CBD dose form	
Feature	**EMD-RX5**	**EMD-RX7**
Active pharmaceutical ingredient	Ultra-pure CBD	Ultra-pure CBD
Dose form	Oral capsule	Oral capsule
Bioavailability advantage over equivalent Epidyolex dosing in animal models	> 2 times greater	> 4 times greater
Ownership	100% Emyria owned	100% Emyria owned
Scheduling focus	Over-the-counter, low-dose (<150mg / day CBD)	Prescription scheduling, high-dose (>150mg /day CBD)
Convenient dosing regime	1-3 small capsules per day	1-3 small capsules per day
Target clinical indications	*Multiple*: Starting with: - psychological distress - irritable bowel syndrome - others in planning	*Multiple*: to be announced following completion of Phase 1 clinical trial
Clinical development stage	Phase 1: active Phase 2: *not required due to Real World Data* Phase 3: Expected to commence H1, 2022	Phase 1: Expected to commence H2, 2022 Phase 2: *not required due to Real World Data* Phase 3: In development



MDMA analogue development progress

Expanded MDMA analogue library

Emyria, and partner the University of Western Australia, substantially expanded their proprietary MDMA analogue library by adding 17 additional compounds. The compound synthesis program - which generates new chemical entities - is ongoing and guided by the successful screening results received in December, 2021. All new compounds are being screened by partner Eurofins and **a second MDMA-analogue patent family** is being prepared for filing.

A technique to isolate analogues into individual enantiomers was developed which, when applied, has the potential to double the size of the current library and provide more selective compounds.

A collaboration between Emyria and Professor Iain McGregor (University of Sydney) was also formed to support follow-on screening assessments to help identify compounds with the greatest potential to help patients in need by becoming registered therapeutics.

Initial screens have not raised any safety concerns, and have identified several compounds of interest for further therapeutic potential as:

- "Second-generation MDMA" for psychedelic assisted therapy
- Novel neurological and non-neurological treatments

[See ASX announcements 08 Dec 2021 and 22 Feb 2022]

TECHNOLOGY

Openly wins the national "Service Transformation for the Digital Consumer" award

The ACS Digital Disruptor Awards are led by the Australian Computer Society (ACS) to celebrate *"the outstanding tech talent in the Australian industry by recognising innovators, disruptors, leaders, emerging professionals, and tech superstars who are making a difference."*

The Service Transformation for the Digital Consumer Award recognises a project that *"uses innovative ways to change how an organisation provides their services to the consumer with measurable controls and outputs."*

Openly is registered as a Class II medical device and provides medical grade remote monitoring powered by a smartphone. Openly is part of Emyria's Real-World Data capture platform and was built in close collaboration with partners Happitech and WeGuide.

CORPORATE

Emyria has $6.6M cash on hand as of 31 March 2022.

The board of directors were paid $319,000 for the quarter ended 31 March 2022 (as disclosed in section 6 of the 4C quarterly report) and this comprised wages, fees and superannuation.

Outlook

Advancing the registration of EMD-RX5 remains the Company's top priority. A pivotal Phase 3 clinical trial has been planned and expected to commence immediately following the successful completion of the Phase 1 study. Leading Contract Research Organisation (CRO) and Site Management Organisation (SMO), Clinitrials, have recently been appointed to manage the Pivotal Phase 3 across 5-6 sites in Australia. *(See ASX release 13 APR 2022).*

Emyria's wholly-owned clinical service subsidiary, already operating across Australia, is expected to further accelerate recruitment by helping identify suitable patients who will be referred for formal screening at independent sites managed by Clinitrials.

Emyria continues to evaluate FDA pathways for its proprietary cannabinoid programs leveraging the Company's proprietary Real World patient data for insights.

In parallel, the company continues to pursue an extensive synthesis, screening and evaluation program for its novel MDMA analogue library with partner the University of Western Australia in order to identify families of compounds with potential to become next generation psychedelic-assisted therapies as well as treatments for major mental health illnesses and neurological disorders.

The Company will provide further updates to the market accordingly.

PROMOTIONS DURING QUARTER

Presentation: Hidden Gems
https://emyria.com/2022/03/07/sharecafe-small-cap-hidden-gems-webinar-recording/

Presentation: Broker Briefing
https://wcsecure.weblink.com.au/clients/emyria/headline.aspx?headlineid=61083316

This announcement has been approved and authorised for release by the Board of Emyria Limited.

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REFERENCES:

[1] Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221. Canberra: AIHW.

About Emyria (www.emyria.com)

Emyria Limited is a clinical stage biotech developing multiple treatments for unmet needs powered by real-world patient data. Emyria's model is aimed at accelerating treatment development and improving patient care.

Emyria's Treatments target unmet needs and are focused on obtaining approval from major global regulators. Emyria's drug development programs are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - www.emeraldclinics.com.au)

Emyria Data provides deep treatment insights and is therefore a source of unique IP, strategically designed drug development and personalised care programs.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represents the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Appendix 4C

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

Name of entity	
EMYRIA LIMITED	
ABN	**Quarter ended ("current quarter")**
96 625 085 734	31 March 2022

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	407	1,268
1.2	Payments for		
	(a) research and development	(430)	(1,298)
	(b) product manufacturing and operating costs	(449)	(1,662)
	(c) advertising and marketing	(75)	(296)
	(d) leased assets	(154)	(285)
	(e) staff costs	(503)	(1,359)
	(f) administration and corporate costs	(265)	(1,290)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	11
1.5	Interest and other costs of finance paid	(10)	(15)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,162
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,477)**	**(3,764)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(8)	(37)
	(d) investments	-	-
	(e) intellectual property	(556)	(1,106)
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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**	**(564)**	**(1,143)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	5,032
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	7	7
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	Other – net payments from cash backed guarantees	-	1
3.10	**Net cash from / (used in) financing activities**	**7**	**5,040**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,696	6,529
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,477)	(3,764)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(564)	(1,143)

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)	7	5,040
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
4.6	**Cash and cash equivalents at end of period**	**6,661**	**6,661**

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	6,661	8,696
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)**	**6,661**	**8,696**

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	319
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)	(1,478)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,661
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,661
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	4.5

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: 27 April 2022

Authorised by: Simon Robertson
(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.