



# Proteomics International

LABORATORIES LTD

ASX Release  
29 April 2021

ASX code: PIQ

## Quarterly Activities Report

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, is pleased to provide the following update on its business activities for the three months to 31 March 2021 and subsequent to the period end:

- **Proteomics International achieves ISO 13485 certification:** Key milestone underpins production and future global sales of the PromarkerD test for diabetic kidney disease
- **Promarker™ pipeline advances:** Several biomarker research programs progress to the next stage of development
- **Proteomics International files US FDA regulatory submission:** 513(g) application will allow the Company to determine the best product classification and FDA regulatory path for PromarkerD
- **Key Opinion Leader engagement:** PromarkerD to be showcased at global conferences throughout 2021
- **Executive Management personnel search underway:** The Company is set to bolster its team via the recruitment of a Chief Commercialisation Officer and Chief Financial Officer
- **Balance Sheet remains strong:** Proteomics International recorded receipts of \$332,000 for the quarter; cash reserves remain robust at \$7.06 million (December \$7.54 million)

### OPERATIONAL HIGHLIGHTS

Proteomics International's activities fall into three key areas:

- (i) commercialisation of PromarkerD
- (ii) R&D for new diagnostic tests using the Promarker™ pipeline
- (iii) analytical services on a commercial basis

#### (i) Commercialisation of PromarkerD

##### Proteomics International achieves ISO 13485 certification

[ASX: 23 April] Proteomics International received ISO 13485 certification, the most widely-used international standard for quality management systems in the manufacture of medical devices. The standard provides the foundation for regulatory requirements in the European Union, Australia, Japan, Canada and the United States, and is a key milestone underpinning production and future global sales of the PromarkerD test for diabetic kidney disease.

ISO 13485 certification is awarded to companies that can demonstrate an ability to produce safe, effective products that consistently meet the expectations of customers and regulators. The ISO 13485 certification will also apply to Proteomics International's pipeline of other diagnostics currently under development.

Proteomics International Laboratories Ltd

ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

T: +61 8 9389 1992 | E: [enquiries@proteomicsinternational.com](mailto:enquiries@proteomicsinternational.com) | W: [www.proteomicsinternational.com](http://www.proteomicsinternational.com)

### PromarkerD assay manufacture

[ASX: 23 April] The Company has instigated several processes that will facilitate the scale-up in production of the PromarkerD immunoassay reagents and kits. This includes production of specialist synthetic protein standards and stabilised recombinant versions of the antibodies (used to detect the target protein biomarkers). Proteomics International has also commenced discussions with selected Northern Hemisphere diagnostics manufacturers to scale and streamline future production for the European and US markets.

### Proteomics International files US FDA 513(g) regulatory submission

[ASX: 29 April] Proteomics International filed a 513(g) submission to the United States Food and Drug Administration (FDA) for the PromarkerD test for diabetic kidney disease. The application replaces the pre-submission package lodged with the FDA in February [ASX: 8 February], after the regulatory body took the unprecedented step of limiting the pre-submission route to urgent applications only due to the COVID-19 pandemic.

As with pre-submission, the 513(g) application will allow Proteomics International to determine the best regulatory path for PromarkerD - either the De Novo Classification or 510(k) route. The FDA is expected to assess the application and provide feedback within 60 days. The Company is preparing to file a full application in Q3 CY21, in line with previously stated timeframes.

### Key Opinion Leader engagement & Marketing activity

In parallel to achieving manufacturing and regulatory milestones for PromarkerD, Proteomics International continues to engage with Key Opinion Leaders (KOLs) through conference presentations and the publication of clinical results in leading scientific journals. KOLs and peer review publications are crucial in driving physician, payer and patient-advocate engagement, which in turn will drive adoption of PromarkerD.

As part of this strategy, the Company will attend several global conferences in 2021. The latest results on PromarkerD will be presented in concert with these events:

CONFERENCE	REGION	CY'21	IMPACT
<b>Payors (Reimbursement)</b>			
Academy of Managed Care Pharmacy Virtual (AMCP)	US	April 12 <sup>th</sup> – 16 <sup>th</sup>	Showcased PromarkerD to health economics audiences
The Professional Society for Health Economics and Outcomes Research (ISPOR)	US	May 17 <sup>th</sup> – 20 <sup>th</sup>	Presenting PromarkerD health economics data (abstract accepted)
Academy of Managed Care Pharmacy Nexus (AMCP Nexus)	US	October 19 <sup>th</sup> – 22 <sup>nd</sup>	Presenting PromarkerD health economics data (abstract pending)
<b>Diabetes</b>			
Emirates Diabetes & Endocrine Virtual Congress (EDEC)	UAE	March 4 <sup>th</sup> – 5 <sup>th</sup>	Showcased PromarkerD at premier UAE diabetes conference
American Diabetes Association Scientific Sessions (ADA)	US	June 25 <sup>th</sup> – 29 <sup>th</sup>	Showcasing PromarkerD & presenting health economics data (abstract accepted)
Australasian Diabetes Congress (ADC)	AUS	August 11 <sup>th</sup> – 13 <sup>th</sup>	Presenting PromarkerD clinical results (abstract pending)
European Association for the Study of Diabetes (EASD)	EU	Sept 27 <sup>th</sup> – Oct 1 <sup>st</sup>	Showcasing PromarkerD & presenting clinical results (abstract submitted)
<b>Kidney/Nephrology</b>			
European Renal Association-European Dialysis and Transplant Association (ERA-EDTA)	EU	June 5 <sup>th</sup> – 8 <sup>th</sup>	Showcasing PromarkerD at premier dialysis conference
American Society of Nephrology Kidney Week (ASN)	US	November 2 <sup>nd</sup> – 7 <sup>th</sup>	Showcasing PromarkerD & presenting clinical results (abstract pending)
<b>Medical Science</b>			
Australian Institute of Medical and Clinical Scientists National Scientific Meeting (AIMS)	AUS	Aug 30 <sup>th</sup> – Sep 1 <sup>st</sup>	Research Manager presenting data on the PromarkerD platforms (Plenary talk)

### AMCP 2021 (Reimbursement) | 12-16 April 2021 | Virtual

This US-based conference is organised by the Academy of Managed Care Pharmacy, a professional association advocating for evidence-based medication use strategies. Proteomics International hosted a virtual booth promoting PromarkerD at this event.

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Virtual ISPOR 2021 (Reimbursement) | 17-20 May 2021 | Virtual

This US-based event is the world's leading health economics and outcomes research conference. Proteomics International has an abstract accepted for the event, and will host a virtual booth.

ERA-EDTA Congress (Clinical) | 5-8 June 2021 | In person (Berlin) and virtual

This European kidney congress run by the European Renal Association and the European Dialysis and Transplant Association typically attracts 9,000 participants from around the world. Proteomics International will host a virtual booth for the event, and staff from PromarkerD's Italian distributors (Medical Horizons SRT) will attend the physical conference.

ADA Scientific Sessions (Clinical) | 25-29 June 2021 | Virtual

This event run by the American Diabetes Association is the world's leading diabetes conference, with more than 12,500 participants in 2020. Proteomics International has an abstract accepted for the event, and will host a virtual booth.

Australasian Diabetes Congress (Clinical) | 11-13 August 2021 | In person (Brisbane)

This conference is a collaboration between the Australian Diabetes Society and Australian Diabetes Educators Association. Proteomics International is submitting an abstract, and will attend the event.

AIMS National Scientific Meeting (Clinical) | 30 August-1 September 2021 | In person (Melbourne)

This specialist clinical science conference is run by the Australian Institute of Medical and Clinical Scientists, the peak professional body for medical scientists working in medical laboratory science and laboratory medicine. Proteomics International research manager Dr Scott Bringans has been invited to give a plenary talk on the PromarkerD technology platforms.

EASD Annual Meeting (Clinical) | 27 September–1 October 2021 | Virtual

The largest diabetes conference in Europe, this event run by the European Association for the Study of Diabetes typically attracts more than 15,000 delegates from over 130 countries. Proteomics International has submitted an abstract, and will host a virtual booth.

AMCP Nexus (Reimbursement) | 17-22 October 2021 | In person (Denver) and virtual

Like AMCP 2021, this US-based virtual health economics and managed care conference is run by the Academy of Managed Care Pharmacy. Proteomics International intends to submit an abstract, and will host a booth.

ASN Kidney Week (Clinical) | 2-7 November 2021 | In person (San Diego)

This large US-based kidney conference is run by the American Society of Nephrology. Proteomics International intends to submit an abstract, and will host a booth.

Further information about PromarkerD is available through the web portal ([www.PromarkerD.com](http://www.PromarkerD.com)).

To visit the PromarkerD virtual product display please see: [www.PromarkerD.com/product](http://www.PromarkerD.com/product)

## **(ii) Diagnostics & (iii) Analytical Services**

### **Promarker™ pipeline advances**

Proteomics International is beginning to reap the benefits of the Company's strategy to expand its diagnostic development pipeline in 2020. Proteomics International is engaged with a number of regional and international partners who have been affected by the Covid-19 pandemic, which has slowed progress in some programs. Nonetheless, the Company does not consider any delays to be material, with several biomarker research programs progressing to the next stage of the

**Proteomics International Laboratories Ltd**

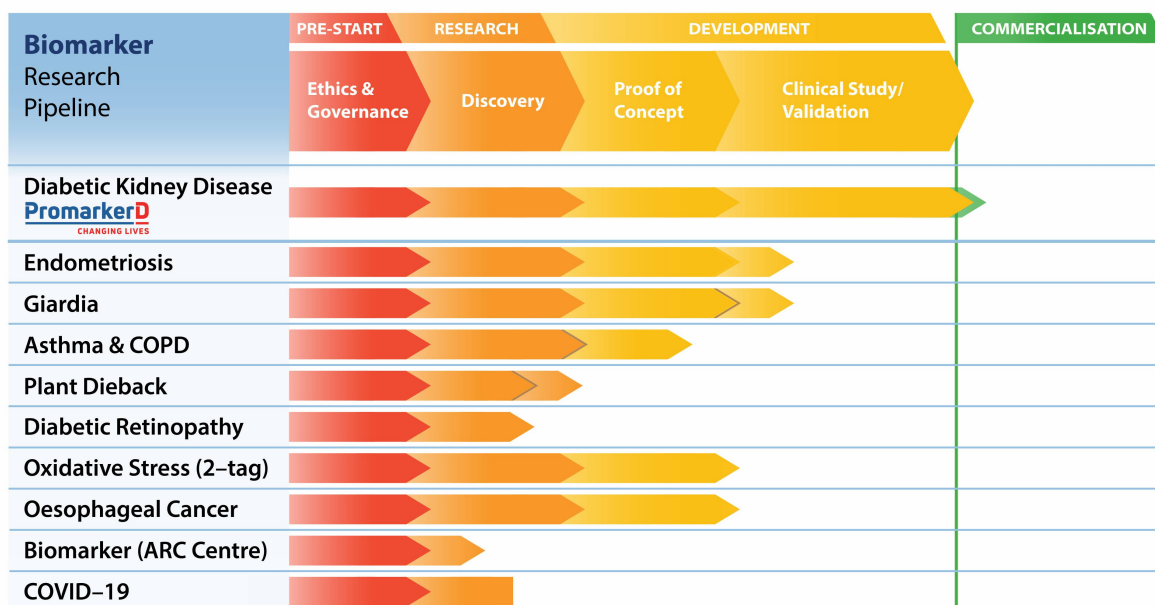
ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

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Promarker™ pipeline, including four at the ‘clinical validation’ stage. All programs are in areas of unmet need and have the potential to deliver significant value for the Company.

#### DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



The Promarker™ R&D pipeline and typical timeline is as follows: Ethics & governance approval (3 months), Discovery (6 months), Proof of concept (6 months), Clinical studies/Validation (12 months).

#### Endometriosis

*Status update: Agreements to access samples for Clinical Validation study being finalised; Clinical Validation study pending.*

Proteomics International has identified and filed a patent application describing a panel of novel protein biomarkers with the potential to be developed into a simple blood test for endometriosis. Endometriosis occurs when the tissues that line the uterus spread outside of the uterine cavity and surround other organs. The debilitating disease affects one in nine Australian women, with the current gold standard for detection being a surgical procedure. Given the large unmet medical need and the only existing diagnostic tool being invasive surgery, Proteomics International believes there will be significant commercial interest in this program post successful clinical study validation.

#### Giardia (causing gastroenteritis)

*Status update: Results from Validation study under analysis.*

Proteomics International continues its development of an improved diagnostic test for the parasite *Giardia* in collaboration with the Murdoch University Veterinary School and a leading US veterinary company. *Giardia* is a leading cause of infectious gastroenteritis worldwide and one of the most common parasitic human diseases. Proteomics International has identified strain specific *Giardia* targets and developed a prototype immunoassay, which is pending validation using field samples. This aspect was delayed by the COVID-19 pandemic.

#### Asthma & COPD

*Status update: Results from Proof-of-Concept study under analysis.*

Proteomics International is working to identify biomarkers for asthma and chronic obstructive pulmonary disease, which cost healthcare systems tens of billions of dollars a year. The study is in collaboration with the Busselton Population Medical Research Institute, which gives Proteomics International access to the globally-recognised Busselton Health Study, first established in 1966 and one of the longest running epidemiological research programs in the world.

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## **Plant dieback**

*Status update: Results from Discovery study under analysis.*

Proteomics International has an ongoing collaboration with the Centre for Crop and Disease Management (Curtin University) to target the plant pathogen *Phytophthora cinnamomi*, which is responsible for plant dieback that affects a wide variety of native plant species and premium crops such as avocados and macadamias. Current investigations are focused on proteomic analysis (determining the protein maps) of the life stages of the organism and how it infects its host. This may lead to a field test for the easier detection of infected soil, and has the potential to identify weaknesses in the pathogen that could be targeted to help eradicate this disease.

## **Diabetic retinopathy**

*Status update: Discovery study ongoing.*

Following the success of its diabetic kidney disease project, Proteomics International signed a new collaboration agreement with The University of Western Australia to seek early markers for diabetic retinopathy, the major cause of blindness in the US. This collaboration is applying the Promarker™ platform to look for prognostic markers in the blood that can identify patients at risk of retinopathy, especially sight-threatening retinopathy. The program will again utilise the Fremantle Diabetes Study which provided the rich sample repository that led to PromarkerD.

## **Oxidative stress (2-tag)**

*Status update: Validation studies pending; Commercialisation discussions underway.*

Proteomics International has been in a long-term collaboration with The University of Western Australia to develop methodology that could become the next generation of medical diagnostic tests. The patented technology called "2-tag" measures the oxidative stress in a system. Proteomics International is currently in commercial negotiations to unlock value from this innovative technology.

## **Oesophageal cancer**

*Status update: Technology transfer ongoing; Clinical Validation pending.*

Proteomics International has joined forces with QIMR Berghofer Medical Research Institute to improve detection of oesophageal adenocarcinoma, the most common form of oesophageal cancer in Australia. Proteomics International is employing its Promarker™ platform to analytically and then clinically validate a panel of biomarkers - protein 'fingerprints' in the blood - that QIMR Berghofer researchers found are associated with early stages of the cancer. The aim is to develop a simple blood test for oesophageal adenocarcinoma.

## **Novel disease biomarkers - ARC Centre for Personalised Therapeutics Technologies**

*Status update: Agreement to access samples being finalised; Discovery study ongoing.*

The Australian Research Council Centre for Personalised Therapeutics Technologies is a \$3.1 million Federally funded Industrial Transformation Training Centre (ITTC) in which Proteomics International is working alongside leading university-based researchers to apply the Promarker™ technology to Complementary Diagnostics. The Company will provide further details as this project develops.

## **COVID-19**

*Status update: Development study completed, project suspended.*

Last year, Proteomics International was awarded two grants under the Western Australian COVID-19 Research Grants Program to support research into COVID-19 biomarkers and diagnostics. The development studies were completed, however, the research programs have been suspended in light of the extensive resources directed at COVID-19 worldwide.

## **OPERATIONS - Executive Management personnel search underway**

Proteomics International has engaged international recruitment companies to bolster its Executive/Upper-Management via the appointment of a Chief Commercialisation Officer (CCO) and

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Chief Financial Officer (CFO). These appointments are nearing completion and will help drive the next phase of the Company's expansion strategies to accelerate its growth in global markets.

## FINANCIAL HIGHLIGHTS

Proteomics International's business model is to continue the commercialisation of PromarkerD whilst using its Promarker™ technology platform to create a pipeline of novel diagnostic tests, and offset the cash burn from R&D and product development through its analytical services revenue, coupled with the R&D tax incentive rebate. This diversified model has shown its strength in the current economic climate and enables the group to continue to make optimum use of its resources.

Proteomics International achieved receipts from customers for the March quarter of \$332,000 (December quarter: \$186,000). Receipts continue to be driven by revenue from analytical services.

The net operating cash outflow for the March quarter was \$471,000 (December inflow \$205,000). Expenditure was in line with budget and centred on the following areas:

- Business development and commercialisation costs for the roll-out of PromarkerD
- Manufacturing costs for the PromarkerD immunoassay kit
- Regulatory and reimbursement activities in the USA to support PromarkerD commercialisation
- R&D for projects in the Promarker™ diagnostics pipeline

### Cash position

At 31 March 2021 the Company had cash reserves of \$7.06 million (December \$7.54 million).

Authorised by the Board Proteomics International Laboratories Ltd (ASX:PIQ).

ENDS

### About Proteomics International Laboratories (PILL) ([www.proteomicsinternational.com](http://www.proteomicsinternational.com))

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on Perth's QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the Company's world-leading test for diabetic kidney disease, PromarkerD. The Company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

### For further information please contact:

Dr Richard Lipscombe  
Managing Director  
Proteomics International Laboratories Ltd  
T: +61 8 9389 1992  
E: [enquiries@proteomicsinternational.com](mailto:enquiries@proteomicsinternational.com)

Dirk van Dissel  
Corporate Advisor & Investor Relations  
Candour Advisory  
T: +61 408 326 367  
E: [dirk@candouradvisory.com.au](mailto:dirk@candouradvisory.com.au)

Kyle Moss  
Corporate Advisor  
Euroz Hartleys  
T: +61 8 9488 1400  
E: [kmoss@euroz.com](mailto:kmoss@euroz.com)

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ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

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## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

Name of entity

Proteomics International Laboratories Ltd

ABN

78 169 979 971

Quarter ending ("current quarter")

31 March 2021

Consolidated statement of cash flows	Current Quarter \$A'000	Year to date \$A'000
<b>1. Cash flows related to operating activities</b>		
1.1 Receipts from Customers	332	1,061
1.2 Payments for:		
(a) research & development	(512)	(1,918)
(b) product manufacturing & operating costs	(51)	(178)
(c) advertising & marketing	(32)	(73)
(d) leased assets	0	0
(e) staff costs	(169)	(609)
(f) administration & corporate costs	(86)	(383)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	0	4
1.5 Interest & other costs of finance paid	(3)	(3)
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	50	1,209
1.8 Other (Deferred Grant Income)	0	0
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(471)</b>	<b>(890)</b>
<b>2. Cash flows related to investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	0	0
(b) businesses (see item 10)	0	0
(c) property, plant & equipment	(28)	(45)
(d) investments	0	0
(e) intellectual property	0	0
(f) other non-current assets	0	0
2.2 Proceeds from disposal of:		
(a) entities	0	0
(b) businesses (see item 10)	0	0
(c) property, plant & equipment	14	14
(d) investments	0	0
(e) intellectual property	0	0
(f) other non-current assets	0	0
2.3 Cash flows from loans to other entities	0	0
2.4 Dividends received (see note 3)	0	0
2.5 Other (provide details if material)		
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(14)</b>	<b>(31)</b>

Consolidated statement of cash flows		Current Quarter \$A'000	Year to date \$A'000
<b>3. Cash flows from financing activities</b>			
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	0	6,000
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	0	0
3.4	Transaction costs related to issues of equity securities or convertible debt securities	3	(384)
		0	0
3.5	Proceeds from borrowings	0	0
3.6	Repayment of borrowings	0	0
3.7	Transaction costs related to loans & borrowings	0	0
3.8	Dividends paid	0	0
3.9	Other (provide details if material)	0	0
<b>3.10 Net cash from / (used in) financing activities</b>		<b>3</b>	<b>5,616</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>			
4.1	Cash & cash equivalents at beginning of period	7,542	2,365
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(471)	(890)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(14)	(31)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3	5,616
4.5	Effect of movement in exchange rates on cash held	0	0
<b>4.6 Cash &amp; cash equivalents at end of quarter</b>		<b>7,060</b>	<b>7,060</b>
<b>5. Reconciliation of cash &amp; cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		<b>Current Quarter \$A'000</b>	<b>Previous Quarter \$A'000</b>
5.1	Bank balance	1,010	587
5.2	Cash deposits	6,050	6,955
5.3	Bank overdrafts	0	0
5.4	Other (provide details)	0	0
<b>5.5 Cash &amp; cash equivalents at end of quarter (should equal item 4.6 above)</b>		<b>7,060</b>	<b>7,542</b>
<b>6.0 Payments to related parties of the entity &amp; their associates</b>			<b>Current Quarter \$A,000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1		120
6.2	Aggregate amount of payments to related parties and their associates included in item 2		0
<i>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</i>			
Payments at 6.1 relate to normal remuneration of Non-Executive and Executive Directors			



<b>7. Financing facilities available</b> <i>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.</i>	<b>Total facility amount</b>	<b>Amount drawn</b>
	<b>at quarter end</b>	<b>at quarter end</b>
	<b>\$A'000</b>	<b>\$A'000</b>
	0	0
7.1 Loan facilities	0	0
7.2 Credit standby arrangements	0	0
7.3 Other (please specify)	0	0
<b>7.4 Total financing facilities</b>	<b>0</b>	<b>0</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>0</b>
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.		
<div style="border: 1px solid black; height: 20px; width: 100%;"></div> N/A		

<b>8. Estimated cash outflows for next quarter</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (see 1.9 above)	(471)
8.2 Cash & cash equivalents at quarter end (Item 4.6)	7,060
8.3 Unused financing facilities available at quarter end (item 7.5)	0
8.4 Total available funding (Item 8.2 + Item 8.3)	7,060
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>15</b>
<i>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.</i>	
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?	
<div style="border: 1px solid black; height: 30px; width: 100%;"></div> Answer:	
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?	
<div style="border: 1px solid black; height: 30px; width: 100%;"></div> Answer:	
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?	
<div style="border: 1px solid black; height: 30px; width: 100%;"></div> Answer:	
<i>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.</i>	

## 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: 29<sup>th</sup> April 2021

Authorised by: The Board  
(Name of body or officer authorising release - see note 4)

### Notes

1. The quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entities 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 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 - e.g. 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.