



# Proteomics International

LABORATORIES LTD

ASX Release  
28 April 2020

ASX code: PIQ

## Quarterly Business Update

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-month period to 31 March 2020.

- **Janssen study progresses and expands:** findings from first stage of collaboration with US big pharma to be presented at world's leading diabetes conference in June
- **CE Mark registration for PromarkerD:** high-throughput immunoassay kit, PromarkerD (IA), and PromarkerD Hub achieve CE Mark status in Europe allowing new prospective laboratories to process much higher numbers of samples at a more cost effective rate
- **Patent filed for diagnostic test for endometriosis:** newly identified biomarkers provide breakthrough for Proteomics International in the effort to create a world-first test for endometriosis
- **Diagnostics pipeline expanded:** Promarker™ R&D expands to include endometriosis, *Giardia* parasite, chronic lung conditions, cancer, oxidative stress, plant dieback, diabetic retinopathy and COVID-19
- **Strong cash balance:** all programs fully funded by existing cash reserves

### OPERATIONAL HIGHLIGHTS

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Proteomics International's activities fall into three key areas:

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

#### (i) Commercialisation of PromarkerD

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##### **Janssen study progresses and expands**

Proteomics International is collaborating with Janssen Research & Development to target treatment of diabetic kidney disease (DKD) [ASX: 26 November 2018]. The studies involve Proteomics International's scientific team working with Janssen scientists firstly to validate the effectiveness of PromarkerD as a DKD predictive diagnostic test across a completed Janssen clinical trial, and then to ascertain the relationship of PromarkerD to treatment.

[ASX: 31 March] The results of the first stage have been accepted for presentation at the world's leading diabetes conference, the 80th Scientific Sessions of the American Diabetes Association (ADA) in June 2020, and will be delivered jointly by the two teams. Janssen and Proteomics International have now agreed to extend the collaboration to examine the PromarkerD score in patient samples after treatment, to assess if patients display an improved prognosis .

Positive results from the collaborative study have the potential to fast-track the commercialisation of PromarkerD.

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## CE Mark registration for PromarkerD

[ASX: 14 January; 16 April] Proteomics International achieved CE Mark registration for the PromarkerD immunoassay (IA)<sup>#</sup>, the high-throughput kit version of the PromarkerD test system.

PromarkerD is the only test available in the Europe Union (EU) for predicting the onset of diabetic kidney disease, and PromarkerD (IA) will allow a greater number of prospective laboratories to process much higher numbers of samples at a more cost effective rate.

The Company also secured CE Mark registration for the PromarkerD Hub, a software tool used to calculate the risk of kidney disease. It follows CE Mark registration for PromarkerD (MS), the mass spectrometry version of the test, in the previous quarter [ASX: 12 November 2019].

The CE Mark provides a significant step for Proteomics International to license and sell PromarkerD throughout the European Union. It provides assurance to European consumers and potential licensing partners that the product has been developed and manufactured to meet EU safety, health and environmental protection requirements. Importantly, these registrations lay the groundwork for future regulatory approvals, including an application to the US FDA which Proteomics International intends to lodge mid-year 2020.

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

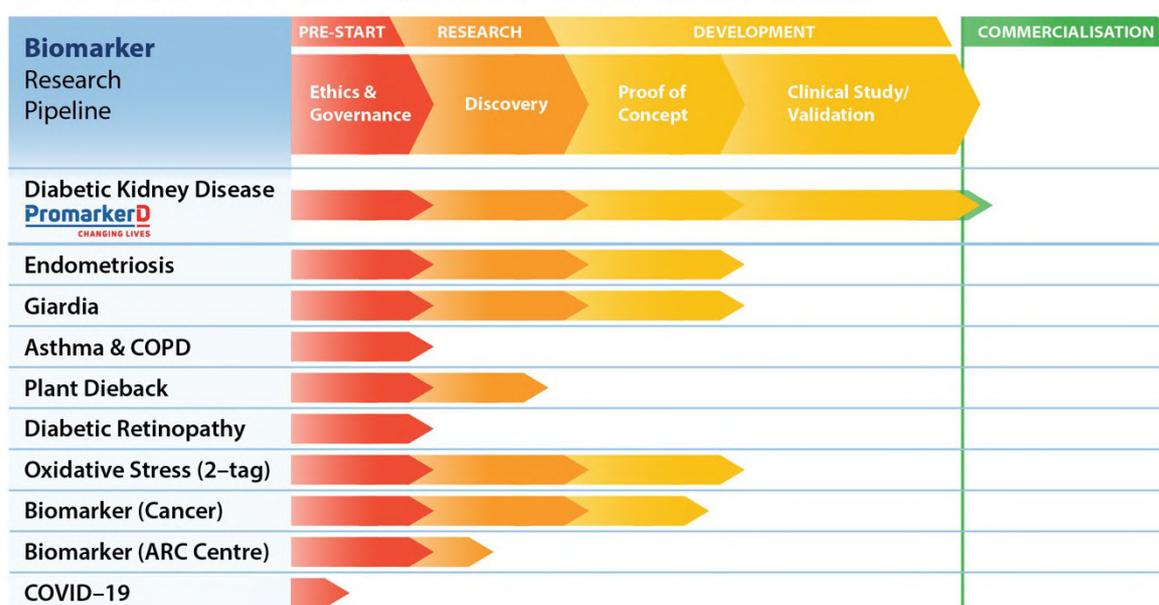
### Patent filed for diagnostic test for endometriosis

[ASX: 23 March] Proteomics International identified protein ‘fingerprints’ in the blood that could be used to test for endometriosis. The ‘fingerprints’—known as biomarkers—have potential to be developed into a simple blood test for the painful condition that occurs when the tissues that line the uterus spread outside of the uterine cavity.

Endometriosis affects one in nine Australian women and is currently diagnosed with a surgical procedure. Direct medical costs (outpatient and hospitalisation) associated with endometriosis in the United States surpass US\$17.3 (A\$27) billion annually. If successful, it would be the world’s first non-invasive test for endometriosis.

The biomarkers were identified via the Promarker™ platform, and Proteomics International has filed a patent application for the invention. The Company is looking to partner with organisations with access to patient samples ahead of a large clinical study, which is anticipated to provide the basis for commercialisation.

### 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).

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### **Diagnostics pipeline expanded**

Alongside the recent significant upgrade in analytical capability [ASX 26 November 2019], Proteomics International proactively vetted biomarker discovery and diagnostics development opportunities. The Company targeted new diagnostic tests for chronic diseases with significant unmet need and market opportunity across medicine, veterinary and agriculture [ASX: 7 April].

This led to the expansion of diagnostics R&D pipeline using the Promarker™ platform. Alongside endometriosis, advances included achievement of proof-of-concept for a diagnostic to detect harmful strains of the *Giardia* parasite, the leading cause of infectious gastroenteritis worldwide. The Company will commence analysis into chronic lung conditions, and finalise advanced in-licensing and commercialisation opportunities in cancer and oxidative stress.

New biomarker discovery programs have been established in diabetic retinopathy and plant dieback disease. COVID-19 research programs have also been initiated to develop a rapid diagnostic test for the identification of the SARS-CoV-2 virus, and to isolate biomarkers that give insights into the progression of the COVID-19 disease. All programs are fully-funded.

### **FINANCIAL HIGHLIGHTS**

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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 rebate. This model continues to make optimum use of the Company's resources. The Company also completed an over-subscribed share placement in the December quarter.

Proteomics International achieved receipts from customers for the March quarter of \$930,000 (December quarter: \$74,000). They comprised receipts from Analytical Services, which were not materially affected by COVID-19, and an extraordinary payment of operating and co-investment funds for the expanded WA Proteomics Facility [ASX: 26 November 2019].

The net operating cash inflow for the March quarter was \$657,000 driven by the co-investment funds (December inflow: \$70,000). Expenditure was in line with budget and centred on the following areas:

- Development and manufacturing of test batches of the immunoassay (kit) version of PromarkerD
- Installation of new equipment to expand the Company's R&D capability for biomarker discovery and analysis
- Costs for seeking regulatory approvals to support PromarkerD commercialisation
- Business development and commercialisation costs for the roll-out of PromarkerD
- Expansion of the Promarker™ diagnostics R&D pipeline

### **ASX Listing Rule 4.7C**

Payments at item 6.1 of the Appendix 4C of \$121,000 relate to normal remuneration of Executive and Non-Executive Directors.

### **Cash position**

At 31 March 2020 the company had cash reserves of \$3.12 million (December \$2.45 million).

Authorised by the Board of Proteomics International Laboratories Ltd.

ENDS

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### **About PromarkerD ([www.PromarkerD.com](http://www.PromarkerD.com))**

The PromarkerD test system assesses the risk of diabetic kidney disease (DKD) in patients with type 2 diabetes. Chronic kidney disease is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant. PromarkerD is a simple blood test that uses a unique protein 'fingerprint' to provide an early detection of the onset of disease. In clinical studies published in leading journals PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years.

Further information is available through the PromarkerD web portal.

#### **# Definitions:**

"Promarker" - the proprietary technology used to discover and evaluate proteins for use as diagnostics

"PromarkerD/PromarkerD test system" - the patented predictive diagnostic test for Diabetic Kidney Disease

"PromarkerD (MS)" - the predictive diagnostic test for Diabetic Kidney Disease using Mass Spectrometry

"PromarkerD (IA)" - the predictive diagnostic test for Diabetic Kidney Disease using ImmunoAssay

"PromarkerD Hub" - the proprietary software tool used to calculate the risk of Diabetic Kidney Disease in diabetes patients

### **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 high-speed, low cost predictive 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:**

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## Appendix 4C

### Quarterly cash flow 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 2020**

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>1. Cash flows related to operating activities</b>		
1.1 Receipts from Customers	930	1,377
1.2 Payments for		
(a) research & development	(561)	(1,846)
(b) product manufacturing & operating costs	(54)	(191)
(c) advertising & marketing	(27)	(100)
(d) leased assets	0	0
(e) staff costs	(126)	(500)
(f) administration & corporate costs	(56)	(283)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	5	13
1.5 Interest & other costs of finance paid	0	(8)
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	16	1,151
1.8 Other (Deferred Grant Income)	530	530
<b>1.9 Net cash from / (used in) operating activities</b>	<b>657</b>	<b>143</b>
<b>2. Cash flows related to investing activities</b>		
2.1 Payments to acquire:		
(a) entities	0	
(b) businesses (see item 10)	0	0
(c) property, plant & equipment	(85)	(1,409)
(d) investments	0	0
(e) intellectual property	0	0
(f) other non-current assets	0	0
2.2 Proceeds from disposal of:	0	0
(a) entities		
(b) businesses (see item 10)	0	0
(c) property, plant & equipment	0	0
(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>(85)</b>	<b>(1,409)</b>

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	2	3,078
3.2 Proceeds from issue of convertible debt securities	0	0
3.3 Proceeds from exercise of options	0	68
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(12)	(221)
3.5 Proceeds from borrowings	0	0
3.6 Repayment of borrowings	18	(147)
3.7 Transaction costs related to loans & borrowings	0	0
3.8 Dividends paid	0	0
3.9 Other (provide details if material)	0	164
<b>3.10 Net cash from / (used in) financing activities</b>	<b>8</b>	<b>2,942</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash & cash equivalents at beginning of period	2,607	1,511
4.2 Net cash from / (used in) operating activities (see 1.9 above)	657	143
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(85)	(1,409)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	8	2,942
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>3,187</b>	<b>3,187</b>
<b>5. Reconciliation of cash &amp; cash equivalents</b> <i>at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts</i>	<b>Current Quarter \$A'000</b>	<b>Previous Quarter \$A'000</b>
5.1 Bank balance	1,087	2,557
5.2 Cash deposits	2,100	50
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>3,187</b>	<b>2,607</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	121	
6.2 Aggregate amount of payments to related parties and their associates included in item 2	0	
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		
Payments at 6.1 relate to normal remuneration of Non-Executive and Executive Directors		

<b>7. Financing facilities available</b>	<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>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
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.		
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)	657
8.2 Cash & cash equivalents at end of quarter (Item 4.6)	3,187
8.3 Unused financing facilities available at quarter end (item 7.5)	0
8.4 Total available funding (Item 8.2 + Item 8.3)	3,187
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>&gt;4*</b>
* Given the positive net cash flows from operating activities for the quarter, there are more than four Estimated quarters of funding available	
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:	
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:	
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:	

## 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: 28<sup>th</sup> April 2020

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.



ASX Release  
29 July 2020

ASX code: PIQ

# Proteomics International

LABORATORIES LTD

## 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-month period to 30 June 2020.

- **International study with global pharma validates PromarkerD test for diabetic kidney disease:** predictive power of PromarkerD confirmed in 3,000-strong clinical trial
- **CE Mark registration for PromarkerD:** high-throughput immunoassay kit, PromarkerD (IA), achieves CE Mark status in Europe, allowing prospective laboratories to process much higher numbers of samples at a more cost-effective rate
- **Intellectual Property portfolio expands:** now includes trade-secrets, plus patents and trademarks covering 273 million (59%) of the world diabetes population
- **COVID-19 research grants awarded:** \$200,000 in funding to support development of a rapid diagnostic test and isolate biomarkers that give insights into progression of the disease
- **Diagnostics pipeline expanded:** Promarker™ R&D expands to include endometriosis, *Giardia* parasite, chronic lung conditions, cancer, oxidative stress, plant dieback, diabetic retinopathy and COVID-19

### OPERATIONAL HIGHLIGHTS

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Proteomics International's activities fall into three key areas:

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

#### (i) Commercialisation of PromarkerD

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##### **International study with global pharma validates PromarkerD predictive test**

[ASX: 14 June] A global, multi-centre study of 3,000 people confirmed the effectiveness of PromarkerD as a predictive test for diabetic kidney disease. The collaborative study with Janssen Research and Development applied the PromarkerD test system to patient samples from the CANVAS completed phase 3 clinical trial. Retrospective analysis of blood samples from the completed clinical trial showed that patients predicted by PromarkerD to be at high-risk of chronic kidney disease were 13.5 times more likely than the low-risk group to develop the disease. The study provides international validation of previous findings that PromarkerD is able to correctly predict a clinically significant decline in kidney function up to four years in advance, paving the way for future FDA approval of the test.

The results were presented at the world's leading diabetes conference, the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA), in June. Proteomics International is now focused on partnering discussions with suitable organisations to bring PromarkerD to patients in the USA, and other major jurisdictions.

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### **CE Mark registration for PromarkerD**

[ASX: 16 April] As reported in the March Quarterly Business Update, Proteomics International achieved CE Mark registration for the PromarkerD immunoassay (IA)<sup>#</sup>. This high-throughput kit version of the PromarkerD test system will allow a greater number of prospective laboratories to process much higher numbers of samples at a more cost-effective rate.

It follows CE Mark registration for PromarkerD (MS), the mass spectrometry version of the test, and PromarkerD Hub, a software tool used to calculate the risk of kidney disease [ASX: 12 November 2019; 14 January]. The CE Mark provides a significant step for Proteomics International to license and sell PromarkerD throughout the European Union. PromarkerD is the only CE Mark approved predictive test for chronic kidney disease.

### **Reimbursement Code and Further Regulatory Approvals**

The Company is working with specialist consultants towards further regulatory approvals in appropriate jurisdictions and to secure a US medical reimbursement code for PromarkerD. Proteomics International will provide details on these activities in the coming quarter. Whilst these initiatives will enhance the overall commercial value of PromarkerD it should be noted that the test could currently be sold and marketed in the US as a Laboratory Developed Test (LDT) via any CLIA approved laboratory.

### **Intellectual Property portfolio expands**

Proteomics International continues to strengthen its intellectual property portfolio for PromarkerD. This IP, in the form of patents, trademarks and trade-secrets, provides the foundation for licensing discussions. New patents were recently secured for the potentially substantial markets of Brazil which has 16.8 million adults with diabetes, and Canada which has 2.8 million [ASX: 27 July]. Together the Company's granted patents and trademarks cover 273 million (59%) of the addressable diabetes patient population globally. As for any novel test, the level and timeframe of market penetration cannot be predicted accurately.

### **Business Model for PromarkerD**

Due to the prevalence of diabetes and diabetic kidney disease the potential revenue from a test for diabetic kidney disease is considerable.

Proteomics International is actively pursuing identified global and regional licensing opportunities for PromarkerD across jurisdictions covered by its patents and trademarks and is currently in commercialisation discussions with several different parties.

The Company's business model is to out-license its intellectual property to diagnostics providers and to receive a royalty on each test sold. Proteomics International will also sell the specialist reagents required to perform each test, whilst the PromarkerD hub regulates use of the test by each provider. Under this model the licensee will cover the capital expenditure to distribute and promote PromarkerD within their network, thus removing a significant cost burden from Proteomics International.

Proteomics International is targeting a test price to the patient of between US\$55 and US\$150 (test price of US\$55 is based on use of existing American Medical Association CPT billing codes for similar analytes to the PromarkerD panel; test price of US\$150 is based on stakeholder engagement responses (Proteomics International market access study conducted by independent US consultant)). Standard industry royalty rates for out-licensing of intellectual property for diagnostics typically range from 5-15%.

As part of the global launch for PromarkerD, the Company elected to first license in several smaller geographic jurisdictions, being Mexico (PromarkerD (MS)<sup>#</sup>), Dominican Republic (licence to develop own PromarkerD (IA)<sup>#</sup>) and most recently in Spain (PromarkerD (MS)<sup>#</sup>), however, sales of the test in these jurisdictions are on-hold with clinics and hospitals unable to offer the test due to the COVID-19 pandemic.

The launch into these initial jurisdictions has allowed Proteomics International to create brand awareness and prove PromarkerD in real-life clinical settings, both of which are important for future licensing opportunities in larger geographic areas.

Importantly, on the back of recent key milestones of immunoassay development, CE Mark registration, and the successful international study with Janssen, Proteomics International is receiving strong interest for PromarkerD from more advanced markets and will update the ASX accordingly as and when events occur.

#### # Definitions:

- "Promarker" - the proprietary technology used to discover and evaluate proteins for use as diagnostics
- "PromarkerD/PromarkerD test system" - the patented predictive diagnostic test for Diabetic Kidney Disease
- "PromarkerD (MS)" - the predictive diagnostic test for Diabetic Kidney Disease using Mass Spectrometry
- "PromarkerD (IA)" - the predictive diagnostic test for Diabetic Kidney Disease using ImmunoAssay
- "PromarkerD Hub" - the proprietary software tool used to calculate the risk of Diabetic Kidney Disease in diabetes patients

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

### Diagnostics pipeline expanded

[ASX: 7 April] As reported in the March Quarterly Activities Report, Proteomics International expanded its diagnostics R&D pipeline using the Promarker™ platform. The Company is targeting new diagnostic tests for chronic diseases with significant unmet need and market opportunity across medicine, veterinary health and agriculture. Fully-funded research programs are now in place for endometriosis, the *Giardia* parasite (the leading cause of infectious gastroenteritis worldwide), chronic lung conditions, cancer, oxidative stress, diabetic retinopathy, plant dieback disease and COVID-19.

### COVID-19 research grants awarded

[ASX: 25 May] Proteomics International was awarded two grants worth a combined \$200,000 under the Western Australian COVID-19 Research Grants Program. The grants will support the Company's recently announced COVID-19 research programs to develop a rapid diagnostic test for the identification of the SARS-CoV-2 virus, and to isolate biomarkers that give insights into the progression of the COVID-19 disease. Both areas of research are aimed at improved medical treatment of patients to assist in the re-opening of Australian and global borders. The research is ongoing and expected to be completed over the next 8-12 months.

### 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). Updated 30<sup>th</sup> June 2020.

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## FINANCIAL HIGHLIGHTS

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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's receipts from customers for the year to 30 June of \$1.75 million showed good resilience despite difficult market conditions at the end of the financial year (FY19: \$1.73 million). June quarter receipts were \$375,000 (March quarter: \$930,000), and included a sharp drop in turnover in April which made the group eligible for State and Federal COVID-19 stimulus packages. Receipts continue to be driven by revenue from Analytical Services and Proteomics International has observed a strong rebound in demand across all sectors in the last two months.

The net operating cash outflow from operating activities for the year to 30 June was \$783,000 (FY19: \$1.74 million). June quarter cash outflow was \$926,000 (March inflow: \$657,000). Expenditure remained in line with budget and centred on the following areas:

- Business development and commercialisation costs for the roll-out of PromarkerD
  - Seeking a reimbursement code in the USA to support PromarkerD commercialisation
  - Seeking regulatory approvals to support PromarkerD commercialisation
- Development and manufacturing of test batches of the immunoassay (kit) version of PromarkerD
- Expansion of the Promarker™ diagnostics R&D pipeline

### ASX Listing Rule 4.7C

Payments at item 6.1 of the Appendix 4C of \$121,000 relate to normal remuneration of Executive and Non-Executive Directors.

### Cash position

At 30 June 2020 the Company had cash reserves of \$2.37 million (March \$3.12 million). These reserves will be strengthened by an estimated R&D tax incentive rebate of \$1.2 million expected to be received in the first half of the new financial year, and based on average quarterly net spend provides the Company greater than 12 months cash runway.

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 high-speed, low cost predictive 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:

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**Proteomics International Laboratories Ltd**

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## Appendix 4C

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

**Name of entity**

<b>Proteomics International Laboratories Ltd</b>
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**ABN**

<b>78 169 979 971</b>
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**Quarter ending ("current quarter")**

<b>30 June 2020</b>
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<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>1. Cash flows related to operating activities</b>		
1.1 Receipts from Customers	375	1,752
1.2 Payments for		
(a) research & development	(962)	(2,808)
(b) product manufacturing & operating costs	(85)	(276)
(c) advertising & marketing	(14)	(114)
(d) leased assets	0	0
(e) staff costs	(262)	(762)
(f) administration & corporate costs	(167)	(450)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	8	21
1.5 Interest & other costs of finance paid	(6)	(14)
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	100	1,251
1.8 Other (Deferred Grant Income)	87	617
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(926)</b>	<b>(783)</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	(35)	(1,444)
(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	0	0
(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>(35)</b>	<b>(1,444)</b>

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	(2)	3,076
3.2 Proceeds from issue of convertible debt securities	0	0
3.3 Proceeds from exercise of options	155	223
3.4 Transaction costs related to issues of equity securities or convertible debt securities	4	(217)
3.5 Proceeds from borrowings	0	0
3.6 Repayment of borrowings	(18)	(165)
3.7 Transaction costs related to loans & borrowings	0	0
3.8 Dividends paid	0	0
3.9 Other (provide details if material)	0	164
<b>3.10 Net cash from / (used in) financing activities</b>	<b>139</b>	<b>3,081</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash & cash equivalents at beginning of period	3,187	1,511
4.2 Net cash from / (used in) operating activities (see 1.9 above)	(926)	(783)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(35)	(1,444)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	139	3,081
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>2,365</b>	<b>2,365</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	910	1,087
5.2 Cash deposits	1,455	2,100
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>2,365</b>	<b>3,187</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	121
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	

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

7. Financing facilities available <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>	Total facility amount	Amount drawn
	at quarter end	at quarter end
	\$A'000	\$A'000
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; padding: 5px; min-height: 40px;">N/A</div>	

8. Estimated cash outflows for next quarter	\$A'000
8.1 Net cash from / (used in) operating activities (see 1.9 above)	926
8.2 Cash & cash equivalents at quarter end (Item 4.6)	2,365
8.3 Unused financing facilities available at quarter end (item 7.5)	0
8.4 Total available funding (Item 8.2 + Item 8.3)	2,365
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>3</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?	
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?	
Answer: These cash reserves will be strengthened by an estimated R&D rebate of \$1.2 million in the first half of the new financial year.	
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:	
<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> July 2020

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.



# Proteomics International

LABORATORIES LTD

ASX Release  
28 October 2020

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 30 September 2020 and subsequent to the period end:

- **First distribution agreement for easy-to-use, high volume immunoassay version of PromarkerD:** world's first predictive test for diabetic kidney disease to be made available in Italy through innovative distributor Medical Horizons SRL
- **Licence/Partnering discussions focused on PromarkerD immunoassay technology:** negotiations with prospective licensees/partners aim to bring simple, easy-to-use PromarkerD technology platform to patients around the world
- **PromarkerD international validation study:** results published in internationally peer-reviewed *Journal of Clinical Medicine* following joint clinical study with global pharma
- **Intellectual Property portfolio expands:** now includes trade-secrets, plus patents and trademarks covering 273 million (59%) of the world diabetes population
- **Partnership with QIMR Berghofer Institute to target oesophageal cancer:** new collaboration to develop a simple blood test to expand the Promarker™ diagnostics pipeline
- **Heavily-oversubscribed Placement raises \$6 million:** New UK and Australia-based institutions join the Company's share register.

### OPERATIONAL HIGHLIGHTS

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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

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##### **First distribution agreement for easy-to-use immunoassay version of PromarkerD test**

[ASX: 16 October] Proteomics International signed a distribution licensing agreement for the immunoassay version of the PromarkerD predictive test for diabetic kidney disease. The agreement with innovative medical distributor Medical Horizons SRL will see the blood test made available to patients in Italy, where 3.7 million people, or one in 12 adults, have diabetes.

The distribution agreement with Medical Horizons is for two years, exclusive to Italy, and exclusive to PromarkerD (IA)<sup>#</sup>. Proteomics International will receive payment for each kit sold, which results in potential revenue to the Company in line with previously stated royalty models. As for any novel test, market penetration cannot be predicted accurately, hence for the new licence it is not possible to quantify the financial impact on Proteomics International in any given timeframe.

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Medical Horizons have already completed registration of PromarkerD with the Italian Ministry of Health (allowing the test to be sold) and are now engaged with a number of Italian Key Opinion Leaders for early adoption of the test by major hospitals.

### Licence/Partnering discussions focused on PromarkerD immunoassay technology

Proteomics International is continuing discussions with diagnostic and pharmaceutical companies in multiple countries to bring the immunoassay kit version of the PromarkerD test to patients. This simple technology platform is cost-effective and standard to clinical diagnostics laboratories around the world. The format allows hundreds of blood samples to be analysed quickly as part of a panel of routine blood tests. Proteomics International is also currently renegotiating deals with the Company’s existing PromarkerD partners, allowing them to access the immunoassay version of the test.

### PromarkerD international validation study results published in Journal of Clinical Medicine

[ASX: 12 October] The findings of a major multi-centre clinical study confirming the effectiveness of PromarkerD as a predictive test for diabetic kidney disease were published in the internationally peer-reviewed *Journal of Clinical Medicine*. The paper titled ‘PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)’<sup>1</sup> was the first external validation study of PromarkerD, and was jointly authored by Proteomics International, The University of Western Australia Medical School and Janssen Research and Development.

Peer-reviewed publications form an essential component of PromarkerD's adoption by Key Opinion Leaders and the wider diabetes community.

### PromarkerD in the clinic

[ASX: 31 August] As presented in the Annual Report, the PromarkerD predictive test employs a “traffic light” scoring system for patient reports. The test results provide patients and their doctors with a risk score based on the likelihood they will develop diabetic kidney disease within the next four years. The score is based on a combination of a simple blood test that measures three plasma proteins combined with three commonly measured clinical factors (age, cholesterol and eGFR).

Patients with a moderate to high risk score now have new treatment options available to them via the gliflozin (SGLT2 Inhibitor) class of drugs. The first SGLT2 Inhibitor to be FDA approved as displaying renal protective properties was Canagliflozin (Invokana™) (see Proteomics International Investor Presentation August [ASX: 26 August]).

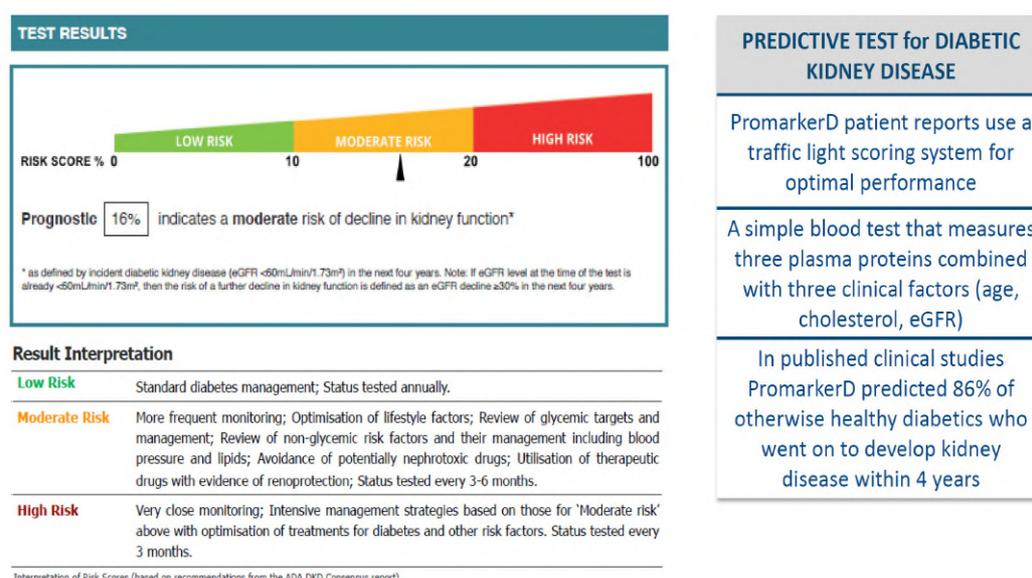
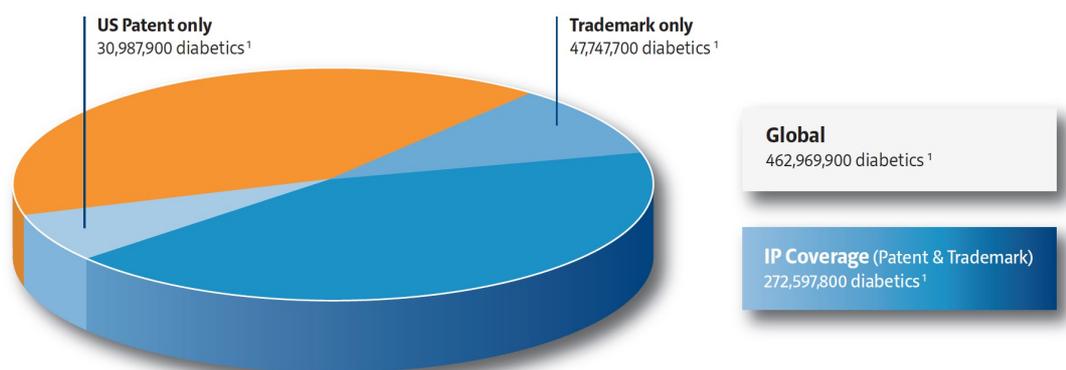


Figure 1: The PromarkerD test employs a “traffic light” scoring system

<sup>1</sup> J. Clin. Med. (2020) 9, 3212; doi.org/10.3390/jcm9103212



Assumptions: <sup>1</sup> International Diabetes Federation (IDF) Atlas 9th Edition 2019 [Age group 20-79 years; Total = Diagnosed (48.7%) + Undiagnosed (51.3%)].

Figure 2: Number of adults with Type-2 diabetes covered by PromarkerD patents and Promarker trademark

### Intellectual Property portfolio expands

[ASX: 27 July] New patents were secured for the potentially substantial markets of Brazil which has 16.8 million adults with diabetes, and Canada which has 2.8 million. As reported in the Company's Annual Report, Proteomics International has established a strong intellectual property portfolio for PromarkerD. This IP, in the form of patents, trademarks and trade-secrets, provides the foundation for on-going licensing discussions. Together the Company's granted patents and trademarks cover 273 million (59%) of the addressable diabetes patient population globally.

#### # Definitions:

- "Promarker" - the proprietary technology used to discover and evaluate proteins for use as diagnostics
- "PromarkerD/PromarkerD test system" - the patented predictive diagnostic test for Diabetic Kidney Disease
- "PromarkerD (MS)" - the predictive diagnostic test for Diabetic Kidney Disease using Mass Spectrometry
- "PromarkerD (IA)" - the predictive diagnostic test for Diabetic Kidney Disease using ImmunoAssay
- "PromarkerD Hub" - the proprietary software tool used to calculate the risk of Diabetic Kidney Disease in diabetes patients

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

#### Partnership with QIMR Berghofer Institute to target oesophageal cancer

[ASX: 9 October] Proteomics International has joined forces with QIMR Berghofer Medical Research Institute (QIMR Berghofer) to improve detection of oesophageal adenocarcinoma, the most common form of oesophageal cancer in Australia. The collaboration is part of Proteomics International's strategy to continually expand its diagnostics portfolio to target commercial opportunities in areas of significant unmet need.

Further details on the Company's Promarker™ R&D pipeline will be provided in the December quarter.

### 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.

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Proteomics International achieved receipts from customers for the September quarter of \$543,000 (June quarter: \$375,000). Receipts continue to be driven by revenue from Analytical Services and Proteomics International is observing strong demand across all sectors.

The net operating cash outflow for the September quarter was \$624,000. Expenditure was in line with budget and centred on the following areas:

- Business development and commercialisation costs for the roll-out of PromarkerD
- Seeking a reimbursement code in the USA to support PromarkerD commercialisation
- Expansion of the Promarker™ diagnostics R&D pipeline

### **Heavily-oversubscribed Placement raises \$6 million**

[ASX: 23 October] A successful placement brought new UK and Australia-based institutions onto the Company's share register. The Placement raised \$6 million (before costs) through the issue of 12.5 million shares at \$0.48 per share, a discount of 14.9% to the 20-day VWAP. The heavily-oversubscribed Placement was supported by institutions and sophisticated professional investors, and closed early due to overwhelming investor response.

Funds from the Placement will drive the delivery of the ground-breaking PromarkerD test in major global markets, following the recent achievement of a number of milestones for the test. The funds received will also strengthen Proteomics International's balance sheet for future licensing negotiations, and assist in accelerating the diagnostic pipeline.

### **ASX Listing Rule 4.7C**

Payments at item 6.1 of the Appendix 4C of \$103,000 relate to normal remuneration of Executive and Non-Executive Directors.

### **Cash position**

At 30 September 2020 the Company had cash reserves of \$1.74 million (June \$2.37 million), which excludes \$6 million (before costs) to be received from the Placement. These reserves will be further strengthened by an estimated R&D tax incentive rebate of \$1.1 million expected to be received in the December quarter.

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:**

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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")**

**30 September 2020**

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>1. Cash flows related to operating activities</b>		
1.1 Receipts from Customers	543	543
1.2 Payments for		
(a) research & development	(717)	(717)
(b) product manufacturing & operating costs	(62)	(62)
(c) advertising & marketing	(29)	(29)
(d) leased assets	0	0
(e) staff costs	(224)	(224)
(f) administration & corporate costs	(158)	(158)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	3	3
1.5 Interest & other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	20	20
1.8 Other (Deferred Grant Income)	0	0
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(624)</b>	<b>(624)</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	(2)	(2)
(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	0	0
(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>(2)</b>	<b>(2)</b>

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	0	0
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	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>0</b>	<b>0</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash & cash equivalents at beginning of period	2,365	2,365
4.2 Net cash from / (used in) operating activities (see 1.9 above)	(624)	(624)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(2)	(2)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	0	0
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>1,739</b>	<b>1,739</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	785	910
5.2 Cash deposits	954	1,455
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>1,739</b>	<b>2,365</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	103
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.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount	Amount drawn
	at quarter end	at quarter end
	\$A'000	\$A'000
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; padding: 5px; min-height: 40px;">                     N/A                 </div>	

8. Estimated cash outflows for next quarter	\$A'000
8.1 Net cash from / (used in) operating activities (see 1.9 above)	(624)
8.2 Cash & cash equivalents at quarter end (Item 4.6)	1,739
8.3 Unused financing facilities available at quarter end (item 7.5)	0
8.4 Total available funding (Item 8.2 + Item 8.3)	1,739
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>3*</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; padding: 5px; min-height: 30px;">                     Answer:                 </div>	
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; padding: 5px; min-height: 30px;">                     Answer: * Excludes funds of \$6 million (before costs) to be received from Placement [ASX 23 October] and estimated R&amp;D tax incentive rebate of \$1.1 million expected to be received in the December quarter.                 </div>	
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; padding: 5px; min-height: 30px;">                     Answer:                 </div>	
<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: 28<sup>th</sup> October 2020

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.



# Proteomics International

LABORATORIES LTD

ASX Release  
28 January 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 December 2020:

- **First and second distribution agreements for PromarkerD immunoassay test:** Italy and Israel become first markets for easy-to-use, high volume technology platform
- **Licence/Distribution discussions for PromarkerD Immunoassay continue:** Proteomics International is in discussions with various prospective partners and continues to receive significant inbound interest for PromarkerD
- **PromarkerD validation and clinical performance results published:** Key Opinion Leader (KOL) engagement has continued with the publication of three studies in internationally peer-reviewed journals *Clinical Proteomics*, *Proteomes* and the *Journal of Clinical Medicine*
- **Regulatory and reimbursement pathways pursued:** the Company is actively engaged with a number of regulatory/reimbursement bodies in a number of jurisdictions
- **Partnership with QIMR Berghofer Institute to target oesophageal cancer:** collaboration to develop a simple blood test to expand the Promarker™ diagnostics pipeline
- **Heavily-oversubscribed Placement raises \$6 million:** new UK and Australia-based institutions join the Company's share register
- **Proteomics receives \$1.1 million in R&D tax incentive:** cash reserves boosted by Australian Government rebate

### OPERATIONAL HIGHLIGHTS

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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

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##### First distribution agreements for PromarkerD immunoassay test

[ASX: 16 October, 12 November] Italy and Israel became the first markets for the easy-to-use immunoassay version of the PromarkerD test for diabetic kidney disease. As reported in the September quarterly update, Proteomics International signed a distribution licensing agreement with innovative medical distributor Medical Horizons SRL in October to bring PromarkerD (IA) to patients in Italy. The country is home to 3.7 million people with diabetes, or one in 12 adults.

Medical Horizons have completed registration of PromarkerD with the Italian Ministry of Health and are now engaged with a number of Italian Key Opinion Leaders for early adoption of the test by major hospitals.

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In November, Proteomics International appointed Zotal Ltd as the exclusive distributor for PromarkerD in Israel, a country recognised as a global leader in the life-science industry and renowned for its early adoption of cutting-edge medical technologies. One in eight adults in Israel has diabetes, and the disease is the country's fifth leading cause of death.

Zotal will now complete product registration and reimbursement applications for PromarkerD with the Israeli Department of Medical Devices, Ministry of Health and engage with Israeli Key Opinion Leaders for the promotion and early adoption of the test by major hospitals.

Both distribution agreements are for two years, exclusive to their respective countries and exclusive to PromarkerD (IA). Proteomics International will receive payment for each kit sold. As for any novel test, market penetration cannot be predicted accurately, hence for the new licences it is not possible to quantify the financial impact on Proteomics International in any given timeframe.

### **PromarkerD validation and clinical performance results published**

[ASX: 12 October, 5 November] An international validation study and additional clinical assay performance results for the PromarkerD test were published in three peer-reviewed scientific journals. As advised in the previous quarterly update, the findings of a global multi-centre clinical study confirming the effectiveness of PromarkerD as a predictive test for diabetic kidney disease were published in the *Journal of Clinical Medicine*. The paper was the first external validation study of PromarkerD, and was jointly authored by Proteomics International, The University of Western Australia Medical School and Janssen Research and Development.

The publication of PromarkerD clinical results in major scientific journals is a key component of the Company's strategy to engage with Key Opinion Leaders (KOLs). Clinical practitioners and industry partners rely on the peer-reviewed system to prove the utility of novel tests such as PromarkerD.

Two further studies demonstrating the robust technical performance of the test were published in the journals *Clinical Proteomics* and *Proteomes*. The results form an essential basis for further regulatory approvals of the PromarkerD test system and its adoption by pathology laboratories worldwide.

### **Roll-out of a novel chronic disease diagnostic test during a global pandemic**

The necessity for clinical pathology laboratories to focus testing on the SARS-CoV-2 virus has naturally restricted testing for other diseases. This has presented limitations for the immediate roll-out of the novel PromarkerD test, and there have been impacts in each country (Spain, Mexico, Dominican Republic, Italy, Israel) where Proteomics International has a licence or distribution agreement.

Proteomics International believes that there is strong, pent-up demand for screening for major diseases neglected during the pandemic, including diabetes and its complications such as chronic kidney disease. Diagnostics companies will also be strongly positioned with additional testing capacity, alongside a community now more aware of the importance of early testing for disease.

Taken together, this has provided the opportunity for Proteomics International to prepare PromarkerD so that it is market ready as the pandemic comes under control. To this end Proteomics International is in discussions for the manufacture of PromarkerD to be relocated to the northern hemisphere, and is pursuing regulatory and reimbursement pathways in a number of jurisdictions. The Company will adjust timelines and provide details where they are material to achieving roll-outs in a specified time period.

#### **# Definitions:**

"Promarker" - the proprietary technology used to discover and evaluate proteins for use as diagnostics

"PromarkerD/PromarkerD test system" - the patented predictive diagnostic test for Diabetic Kidney Disease

"PromarkerD (MS)" - the predictive diagnostic test for Diabetic Kidney Disease using Mass Spectrometry

"PromarkerD (IA)" - the predictive diagnostic test for Diabetic Kidney Disease using ImmunoAssay

"PromarkerD Hub" - the proprietary software tool used to calculate the risk of Diabetic Kidney Disease in diabetes patients

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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**

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### **Partnership with QIMR Berghofer Institute to target oesophageal cancer**

[ASX: 9 October] As reported in the September quarterly update, Proteomics International has joined forces with QIMR Berghofer Medical Research Institute (QIMR Berghofer) to improve detection of oesophageal adenocarcinoma, the most common form of oesophageal cancer in Australia. The collaboration is part of Proteomics International's strategy to continually expand its diagnostics portfolio to target commercial opportunities in areas of significant unmet need.

### **Promarker™ pipeline advances**

Important for the future commercial application of potential new Promarker™ derived biomarkers, the above PromarkerD assay performance studies also illustrate the potential for adoption of Proteomics International's Promarker™ mass spectrometry diagnostics platform in future clinical practice. The Company has positioned its R&D arm at the forefront of this technological approach, which has the potential to overtake current immunoassay technology and assume mainstream use in clinical pathology laboratories. Exemplifying this, the *Clinical Proteomics* publication [ASX: 5 November] is one of the first validations of a proteomics derived multi-biomarker diagnostic test in a clinical setting.

Several diagnostics projects in the Promarker™ pipeline are at pivotal stages in their development. Proteomics International is engaged with a number of global partners and collaborators who have been affected by the Covid-19 pandemic, and this has slowed progress on some fronts. Nonetheless, the Company does not consider any delays to be material and it will continue to provide updates on its diagnostics pipeline as milestones are achieved, with a number of significant milestones expected to occur in the current and subsequent quarters.

## **FINANCIAL HIGHLIGHTS**

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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 December quarter of \$186,000 (September quarter: \$543,000). Receipts continue to be driven by revenue from analytical services.

The net operating cash inflow for the December quarter was \$205,000 (September outflow \$624,000). Expenditure was in line with budget and centred on the following areas:

- Business development and commercialisation costs for the roll-out of PromarkerD
- Seeking a reimbursement code in the USA to support PromarkerD commercialisation, specifically, market engagement studies through specialised consultants addressing:
  - Economic Health Benefit (Payer Budget Impact study) for insurers/payers
  - Clinical Utility (Decision Impact study) for test adoption by health professionals
- Expansion of the Promarker™ diagnostics R&D pipeline

### **Heavily-oversubscribed Placement raises \$6 million**

[ASX: 23 October, 2 November] A successful placement brought new UK and Australia-based institutions onto the Company's share register. The heavily-oversubscribed Placement raised \$6 million (before costs) and closed early due to overwhelming investor response. Funds from the

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Placement will drive the delivery of the PromarkerD test in major global markets, strengthen Proteomics International's balance sheet for future licensing negotiations, and assist in accelerating the diagnostic pipeline.

#### **Proteomics receives \$1.1 million in R&D tax incentive**

[ASX: 3 November] The Company's cash reserves were further strengthened by the receipt of \$1.1 million in research and development tax incentive. In 2019-20, Proteomics International spent \$2.62 million on R&D, which enabled the company to receive an Australian Government rebate of \$1,138,815 for the 2020 financial year.

#### **ASX Listing Rule 4.7C**

Payments at item 6.1 of the Appendix 4C of \$110,000 relate to normal remuneration of Executive and Non-Executive Directors.

#### **Cash position**

At 31 December 2020 the Company had cash reserves of \$7.54 million (September \$1.74 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:**

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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 December 2020**

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>1. Cash flows related to operating activities</b>		
1.1 Receipts from Customers	186	729
1.2 Payments for		
(a) research & development	(689)	(1,406)
(b) product manufacturing & operating costs	(65)	(127)
(c) advertising & marketing	(12)	(41)
(d) leased assets	0	0
(e) staff costs	(216)	(440)
(f) administration & corporate costs	(139)	(297)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	1	4
1.5 Interest & other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	1,139	1,159
1.8 Other (Deferred Grant Income)	0	0
<b>1.9 Net cash from / (used in) operating activities</b>	<b>205</b>	<b>(419)</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	(15)	(17)
(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	0	0
(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>(15)</b>	<b>(17)</b>

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	6,000	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	(387)	(387)
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>5,613</b>	<b>5,613</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash & cash equivalents at beginning of period	1,739	2,365
4.2 Net cash from / (used in) operating activities (see 1.9 above)	205	(419)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(15)	(17)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	5,613	5,613
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>7,542</b>	<b>7,542</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	587	785
5.2 Cash deposits	6,955	954
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>7,542</b>	<b>1,739</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		110
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>	<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>
<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>		
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.		
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)	205
8.2 Cash & cash equivalents at quarter end (Item 4.6)	7,542
8.3 Unused financing facilities available at quarter end (item 7.5)	0
8.4 Total available funding (Item 8.2 + Item 8.3)	7,542
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>N/A</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?	
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?	
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?	
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>	

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Date: 28 January 2021

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

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