ASX Release
30 July 2021

ASX code: PIQ

Quarterly Activities Report

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a medical technology company at the forefront of precision medicine and predictive diagnostics, is pleased to provide the following update on its business activities for the three months to 30 June 2021:

- **Diabetes treatment lowers PromarkerD risk score:** Positive results from study with US pharmaceutical company Janssen to be presented at Australasian Diabetes Congress in August
- **PromarkerD manufacturing, regulatory and reimbursement updates:** the global commercialisation strategy for PromarkerD is on track, with the Company continuing to make advances across accreditation and regulatory approvals, manufacture and kit assembly, and distribution
- **Major analytical services contract in pharmacokinetic testing:** the Company secures largest single analytical services contract to date
- **CCO and CFO bolster executive team:** Appointments of leading executives follow a worldwide executive search
- **PromarkerD roll-out being accelerated by short-term increased expenditure in key areas:** Strong cash position enables acceleration of expenditure on business development, manufacturing, reimbursement and regulatory approvals

OPERATIONAL HIGHLIGHTS

Proteomics International's activities fall into three key areas:

(i) commercialisation of PromarkerD, the predictive test for diabetic kidney disease (DKD)
(ii) R&D for new diagnostic tests using the Promarker^{TM} pipeline
(iii) analytical services on a commercial basis

(i) Commercialisation of PromarkerD

Diabetes treatment lowers PromarkerD risk score

[ASX: 16 July] A collaborative study conducted by Proteomics International and Janssen Research & Development found a significant reduction in the PromarkerD risk scores of patients with type 2 diabetes taking canagliflozin, an SGLT2-inhibitor diabetes drug.

The study was the second stage of the collaboration between Proteomics International and Janssen [ASX: 31 Mar 2020; 15 Jun 2020], in which the companies examined the association between canagliflozin, an approved diabetes therapy with additional renal benefits, and change in PromarkerD score. The research measured PromarkerD scores in blood samples from more than 2,000 patients in the completed CANVAS clinical trial.

The research found the average PromarkerD risk score of patients taking canagliflozin dropped during the three-year trial, while the average risk score of patients taking a placebo rose. The biggest reductions were seen in the patients classified by PromarkerD at the start of the trial as at high risk

of developing diabetic kidney disease. The results will be presented at the Australasian Diabetes Congress in August 2021.

PromarkerD assay manufacturing update

[ASX: 23 April; 22 July; 28 July] The Company has instigated several processes that will facilitate the scale-up in production of the PromarkerD immunoassay reagents and kits. This includes the production of specialist synthetic protein standards and stabilised recombinant (synthetic) versions of the antibodies (used to detect the target protein biomarkers). Proteomics International is also engaging with selected Northern Hemisphere diagnostics manufacturers to scale and streamline future production for the European and US markets.

[ASX: 23 April] As reported in the March quarterly update, Proteomics International has 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 international 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 13845 certification will also apply to Proteomics International's pipeline of other diagnostics currently under development.

PromarkerD regulatory update

[ASX: 29 April] As reported in the March quarterly update, 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 will determine the best regulatory path for PromarkerD - either the De Novo Classification or 510(k) route. The FDA normally assesses applications within 60 days, however, it has advised all responses are delayed due to the COVID-19 pandemic. The Company is preparing to file a full application once the required pathway for PromarkerD is determined. The route to market in the US remains the LDT (laboratory developed test) path through CLIA certified labs [ASX: Investor presentation 20 July], which allows sales to commence prior to FDA approval.

PromarkerD reimbursement update

[ASX: 2 July] Proteomics International is set to seek a reimbursement code for the PromarkerD test for diabetic kidney disease following extensive engagement with expert panels representing physicians, laboratories and payors, conducted alongside comprehensive economic health benefit modelling.

Reimbursement codes and payer coverage in the US are initiated through the American Medical Association (AMA) and its Current Procedural Terminology (CPT) Editorial Panel. This code, known as a CPT Proprietary Laboratory Analyses (PLA) code, uniquely identifies a test for the laboratory and the payors.

A payer budget impact study was conducted by US based consultant Boston Healthcare Associates to demonstrate the potential economic health benefit of the PromarkerD test compared to the current standard of care. All companies seeking reimbursement for any new test are required to provide a dossier demonstrating the potential economic health benefit of the test. The second element to achieving reimbursement is demonstrating the clinical utility of PromarkerD, namely the impact of PromarkerD on patient treatment decisions by primary care physicians and specialist endocrinologists. A clinical utility study on PromarkerD has also been conducted by Boston Healthcare Associates and is currently subject to peer review prior to publication.

Further information about PromarkerD is available through the web portal (www.PromarkerD.com).

To visit the PromarkerD virtual product display please see: www.PromarkerD.com/product

(ii) Diagnostics & (iii) Analytical Services

Major analytical services contract in pharmacokinetic testing

[ASX: 18 May] Proteomics International secured a major pharmacokinetic testing contract with Australia's largest clinical trial contract research organisation, Avance Clinical. The contract engages Proteomics International to perform advanced pharmacokinetic testing of a novel drug for lysosomal storage disorder. It is the Company's largest single analytical services contract to date, with a value of $243,000.

FINANCIAL AND CORPORATE 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 June quarter of $395,000 (March quarter: $332,000). Receipts continue to be driven by revenue from analytical services.

The net operating cash outflow for the June quarter was $1.44 million (March quarter: $471,000). Expenditure was in line with budget, plus included accelerated spending 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 to support PromarkerD commercialisation
- R&D for projects in the Promarker™ diagnostics pipeline

CCO and CFO appointed to bolster executive team

[ASX: 10 June] The executive team was expanded with the appointments of Vik Malik as Chief Commercialisation Officer (CCO) and Jacqueline Gray as new Chief Financial Officer (CFO), following a worldwide executive search. Mr Malik, a medical technologies commercialisation veteran, will lead the commercial roll-out of the Company's innovative diagnostic products centred on the PromarkerD predictive test for diabetic kidney disease. Ms Gray, a well-credentialed finance professional with experience across global brands, including in the technology, healthcare and media sectors, will have responsibility for Proteomics International's finance, accounting and financial strategy development.

ASX Listing Rule 4.7C

Payments at item 6.1 of the Appendix 4C of $140,000 relate to normal remuneration of Executive and Non-Executive Directors.

Cash position

At 30 June 2021 the Company had cash reserves of $5.6 million (March $7.06 million). These reserves will be strengthened by an estimated R&D tax incentive rebate of $1.1 million expected to be received in the first half of the new financial year. The Company notes that the next quarterly spend is budgeted to be lower than the current quarter as one-off costs are not repeated and consequently the Company is in a strong financial position to fund its objectives for FY22.

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

ENDS

About Proteomics International Laboratories (PILL) (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.

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Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Name of entity

Proteomics International Laboratories Ltd

ABN	**Quarter ending ("current quarter")**
78 169 979 971	**30 June 2021**

Consolidated statement of cash flows		**Current Quarter $A'000**	**Year to date $A'000**
1.	**Cash flows related to operating activities**		
1.1	Receipts from Customers	395	1,456
1.2	Payments for		
	(a) research & development	(1,148)	(3,066)
	(b) product manufacturing & operating costs	(85)	(263)
	(c) advertising & marketing	(59)	(132)
	(d) leased assets	0	0
	(e) staff costs	(338)	(947)
	(f) administration & corporate costs	(214)	(597)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	10	14
1.5	Interest & other costs of finance paid	0	(3)
1.6	Income taxes paid	0	0
1.7	Government grants & tax incentives	0	1,209
1.8	Other (Deferred Grant Income)	0	0
1.9	**Net cash from / (used in) operating activities**	**(1,439)**	**(2,329)**

2.	**Cash flows related to investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	0	0
	(b) businesses (see item 10)	0	0
	(c) property, plant & equipment	(160)	(205)
	(d) investments	0	0
	(e) intellectual property	0	0
	(f) other non-current assets	0	0
2.2	Proceeds from disposal of:		0
	(a) entities	0	0
	(b) businesses (see item 10)	0	0
	(c) property, plant & equipment	0	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)		
2.6	**Net cash from / (used in) investing activities**	**(160)**	**(191)**

Consolidated statement of cash flows		Current Quarter $A'000	Year to date $A'000
3.	**Cash flows from financing activities**		
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	150	150
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(7) 0	(391) 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
3.10	**Net cash from / (used in) financing activities**	**143**	**5,759**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	7,060	2,365
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(1,439)	(2,329)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(160)	(191)
4.4	Net cash from / (used in financing activities (item 3.10 above)	143	5,759
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	**Cash & cash equivalents at end of quarter**	**5,604**	**5,604**

5.	**Reconciliation of cash & cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	**Current Quarter $A'000**	**Previous Quarter $A'000**
5.1	Bank balance	554	1,010
5.2	Cash deposits	5,050	6,050
5.3	Bank overdrafts	0	0
5.4	Other (provide details)	0	0
5.5	**Cash & cash equivalents at end of quarter (should equal item 4.6 above)**	**5,604**	**7,060**

6.0	**Payments to related parties of the entity & their associates**	**Current Quarter $A,000**
6.1	Aggregate amount of payments to related parties and their associates included in item 1	140
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

7.	**Financing facilities available** *Note: the term "facility" includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end** **$A'000**	**Amount drawn at quarter end** **$A'000**
7.1	Loan facilities	0	0
7.2	Credit standby arrangements	0	0
7.3	Other(please specify)	0	0
7.4	**Total financing facilities**	**0**	**0**

7.5	**Unused financing facilities available at quarter end**	**0**

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

8.	**Estimated cash outflows for next quarter**	**$A'000**
8.1	Net cash from / (used in) operating activities (see 1.9 above)	(1,439)
8.2	Cash & cash equivalents at quarter end (Item 4.6)	5,604
8.3	Unused financing facilities available at quarter end (item 7.5)	0
8.4	Total available funding (Item 8.2 + Item 8.3)	5,604
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**3.9**

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

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

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

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 it's business objectives and, if so, on what basis?

Answer:

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

Compliance Statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 30 July 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 acitivities 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 proisions 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.