Proteomics International
LABORATORIES LTD

ASX Release
26 October 2023

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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 September 2023 and subsequent to the period end.

- **US Medicare sets reimbursement price for PromarkerD and Australian regulatory decision:** Major commercial milestone achieved with the diabetic kidney disease (DKD) test assigned a payment rate of US$390 in the United States
- **Oesophageal cancer test presented at World Congress for Esophageal Diseases:** Promarker*Eso* blood test shows strong discrimination of oesophageal adenocarcinoma - analysis commenced to confirm the clinical performance of the test in independent cohorts
- **OxiDx technology secures patent in Japan:** Landmark patent is the first to grant of a new family of patents which greatly extend the intellectual property protection for OxiDx's next-generation diagnostics technology
- **Sector related developments for PromarkerD:** Complementary diagnostics - empagliflozin and semaglutide offer new drug treatments for DKD; Kidney Research UK declare a public health emergency

OPERATIONAL HIGHLIGHTS

Proteomics International's activities fall into three key areas:

(i) commercialisation of PromarkerD, the predictive test for diabetic kidney disease (DKD)
(ii) Precision diagnostic tests in development - the Promarker™ pipeline
(iii) Specialist accredited analytical services on a commercial basis

i) Commercialisation of PromarkerD

US Medicare sets reimbursement price for PromarkerD and Australian regulatory decision

[ASX: 29 September] The US Centers for Medicare & Medicaid Services (CMS) set a national reimbursement price for the PromarkerD predictive test for diabetic kidney disease. In a major commercial milestone for Proteomics International, CMS assigned a payment rate of US$390.75 for PromarkerD in the United States. The test will be delivered through Sonic Healthcare USA [ASX: 10 May 2023].

CMS is the single largest payer for health care in the United States, with Medicare and Medicaid collectively responsible for 42 per cent of healthcare spending and providing health coverage to more than 100 million Americans. The rate, set by the Medicare Advisory Panel on Clinical Diagnostic

Laboratory Tests, is expected to become final after a 30-day public comment period, and become effective from 1 January 2024.

Separately, Proteomics International was advised by the Australian Therapeutic Goods Administration (TGA) of its decision not to include the PromarkerD test in the Australian Register of Therapeutic Goods (ARTG), due primarily to a change of manufacturer [ASX: 29 September].

The TGA decision temporarily impacts the ability of the Company to sell its test in Australia but does not affect the Company's activities in the United States, where the test is using the CLIA Laboratory Developed Test (LDT) framework, or Europe, where PromarkerD is CE Mark registered. Approximately 32 million adults live with diabetes in the United States and 61 million in Europe, compared to 1.5 million in Australia.

Sector related developments for PromarkerD, Key Opinion Leader (KOL) engagement and advocacy

A growing number of existing therapeutics for diabetes are now demonstrating utility as novel treatment options for chronic kidney disease:

- In September, the sodium glucose co-transporter protein 2 (SGLT2) inhibitor, **empagliflozin** (Jardiance® [Boeheringer Ingelhiem/Eli Lilly]), joined canagliflozin and dapagliflozin, in receiving approval from both the European Medical Authority (EMA) and US Federal Drug Administration (FDA) for use in the treatment of diabetic kidney disease[1].
- In October, the kidney outcomes trial for the glucagon-like peptide-1 (GLP-1) agonist **semaglutide** (Ozempic [Novo Nordisk]) was stopped early for efficacy reasons[2]. Read out of the results is expected in 2024, which will indicate the efficiency of this class of drug in the management of DKD.

These are important and positive developments for PromarkerD because they amplify the use case for the test. These drugs could be offered early to selected patients stratified as at high-risk of developing DKD by PromarkerD, to potentially stop the onset of kidney function decline. Using PromarkerD and these drugs together in this way is an area of precision medicine referred to as **complementary or companion diagnostics (CDx).**

This type of utility for PromarkerD was confirmed in the recently published peer reviewed study by Proteomics International and Jansen Research & Development which showed a significant reduction in the PromarkerD risk scores for developing DKD of patients with type 2 diabetes after taking canagliflozin [ASX: 3 May].

A test like PromarkerD could also be used to monitor the kidney health of a patient when they are prescribed these drugs to determine if the treatment and dosage is effective.

The health and economics burden of kidney disease to western medical systems was recently highlighted by **Kidney Research UK**'s launch of its report "Kidney disease: A UK public health emergency"[3]. The importance of the report was emphasised by its formal launch at the British Houses of Parliament on 11 September, which noted (amongst other things) that cases of kidney disease are growing so rapidly they risk costing the UK economy £13.9 billion annually by 2033 without significant government intervention. Proteomics International co-funded the report and was represented at the formal launch event by members of the Company's Clinical Advisory Board and its UK distributor, Apacor.

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

1 investor.lilly.com/news-releases

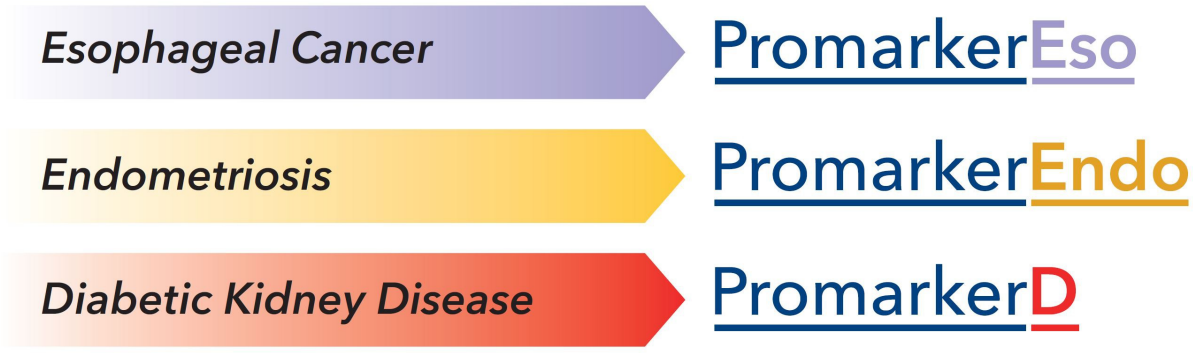
2 www.novonordisk.com/news-and-media

3 Kidney Research UK. Kidney disease: A UK public health emergency

ii) Precision diagnostic tests in development – the Promarker™ pipeline and iii) Analytical services

Proteomics International has a deep pipeline of novel precision health and predictive diagnostic tests in development. This R&D is enabled by the Company's proprietary biomarker discovery platform called Promarker, which searches for protein 'fingerprints' in a sample. This disruptive technology can identify proteins that distinguish between people who have a disease and people who do not, using only a simple blood test. It is a powerful alternative to genetic testing. The technology is so versatile it can be used to identify fingerprints from any biological source, from wheat seeds to human serum. The Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical and commercial needs.

During the quarter, Proteomics International's R&D focused on progressing clinical validation work for its tests for endometriosis and oesophageal adenocarcinoma.



Oesophageal cancer test presented at World Congress for Esophageal Diseases

[ASX: 20 July, 8 September] Proteomics International presented the latest results for its novel blood test for oesophageal adenocarcinoma, named Promarker*Eso*, at the 19th ISDE World Congress for Esophageal Diseases in Toronto, Canada. The prototype test now shows strong discrimination at early and late stages of the disease, correctly identifying 89% of patients with oesophageal adenocarcinoma and 92% of patients without the condition.

The conference presentation built on earlier work which identified and validated a panel of glycoprotein biomarkers using 300 samples from two independent clinical cohorts [ASX: 27 September 2022]. The commercial development of Promarker*Eso* is ongoing, with the current step being to confirm the clinical performance of the test in additional independent patient cohorts [ASX: 20 July]. The World Congress also enabled engagement with several global KOLs in the field, which is critical to the future broad adoption of the test.

Oesophageal adenocarcinoma is the most common form of oesophageal cancer with a five-year survival rate of approximately 20%. It is evident that there is a significant unmet medical need to better determine who would benefit from an endoscopy, and the Company believes there is large market potential for a simple diagnostic test.

OxiDx technology secures patent in Japan

[ASX: 4 September] Proteomics International subsidiary OxiDx Pty Ltd was granted a landmark patent in Japan for its platform technology to measure oxidative stress. The patent marks the first of a new family of patents pending in all major jurisdictions for OxiDx's next generation diagnostics technology, and is another illustration of Proteomics International's specialist platform technologies.

Oxidative stress is implicated in more than 70 health conditions[4], with levels often reflective of a person's health and fitness. Measuring oxidative stress has broad application across multiple

[4] doi: 10.1373/clinchem.2005.061408

markets, including as a complementary diagnostic (CDx) test for assessing treatment efficacy and for enabling personalised dosing in clinical trials. It can also be used to monitor competition preparedness and reduce injuries among professional athletes and in the horse racing industry.

FORTHCOMING EVENTS

During the next quarter Proteomics International is attending the following conferences:

1. Australian Biospecimen Network Association (ABNA) Conference; 18-20 October, Gold Coast
2. AusBiotech Life Science Conference; 1-3 November, Brisbane
3. The American Society of Nephrology Kidney Week; 2-5 November, Philadelphia, USA
4. The Australian Diabetes Educators Association WA Branch Conference; 3 November, Perth
5. Royal Australian College of Surgeons Academic Conference (focus on oesophageal cancer); 16-17 November, Melbourne
6. Diabetes Professional Care Annual Event; 15-16 November, London, United Kingdom
7. KDIGO (Kidney Disease: Improving Global Outcomes) Controversies Conference on Maintaining Kidney Health and Preventing CKD; 30 November - 2 December, Rome, Italy

Proteomics International Laboratories Ltd is holding its Annual General Meeting on 23 November, at the Harry Perkins Institute for Medical Research, Perth.

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 make optimum use of its resources.

Proteomics International in the media

There is growing awareness in Australia of the enormous challenges being posed by chronic kidney disease[5] in light of the kidney health emergency being faced in the UK and USA. The Company's Managing Director Dr Richard Lipscombe was interviewed on the subject on both 6PR Perth and Channel 9 News[6].

Revenue & Expenditure

Proteomics International achieved cash receipts from customers for the September quarter of $201,000 (June quarter: $198,000). The net operating cash outflow for the September quarter was $1.7 million (June quarter: $2.2 million). Expenditure centred on the following areas:

- Business development and commercialisation costs for the rollout of PromarkerD.
- Manufacturing costs for the PromarkerD immunoassay kit, successfully producing reagents to meet supply needs for the next six months.
- Regulatory and reimbursement activities to support PromarkerD commercialisation, successfully achieving an assigned payment rate of US$390 from CMS.
- R&D for projects in the Promarker™ diagnostics pipeline.

Exercise of options

[ASX: 14 August] Additional funds were received following the exercise of 1,250,000 options raising $625,000 before costs.

5 Kidney Health Australia. Deloitte Access Economics report: Changing the chronic kidney disease landscape

6 www.proteomics.com.au/newsroom/inthemedia/media-coverage/

ASX Listing Rule 4.7C
Payments at item 6.1 of Appendix 4C of $166,000 relate to normal remuneration of Executive and Non-Executive Directors.

Cash position
At 30 September, the Company had cash reserves of $4.91 million (30 June: $6.03 million). These reserves will be strengthened by a forecast R&D tax incentive rebate of $1.85 million to be received in this December quarter.

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. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

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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 September 2023**

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	201	201
1.2	Payments for		
	(a) research & development	(685)	(685)
	(b) product manufacturing & operating costs	(172)	(172)
	(c) advertising & marketing	(155)	(155)
	(d) leased assets	0	0
	(e) staff costs	(734)	(734)
	(f) administration & corporate costs	(289)	(289)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	62	62
1.5	Interest & other costs of finance paid	0	0
1.6	Income taxes paid	0	0
1.7	Government grants & tax incentives	0	0
1.8	Other (provide details if material)	46	46
1.9	**Net cash from / (used in) operating activities**	**(1,726)**	**(1,726)**
2.	**Cash flows related to investing activities**		
2.1	Payments to acquire:		
	(a) entities	0	0
	(b) businesses (see item 10)	0	0
	(c) property, plant & equipment	(3)	(3)
	(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	0	0
	(b) businessess (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)	0	0
2.6	**Net cash from / (used in) investing activities**	**(3)**	**(3)**

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)	625	625
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	(6)	(6)
	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
3.10	**Net cash from / (used in) financing activities**	**619**	**619**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	6,027	6,027
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(1,726)	(1,726)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(3)
4.4	Net cash from / (used in financing activities (item 3.10 above)	619	619
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	**Cash & cash equivalents at end of quarter**	**4,917**	**4,917**

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	373	235
5.2	Cash deposits	4,544	5,792
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)**	**4,917**	**6,027**

6.	**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	153
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 Executive and Non-Executive Directors

7.	**Financing facilities available**	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
	Note: the term "facility" includes all forms of financing arrangements available to the entity.		
	Add notes as necessary for an understanding of the sources of finance available to the entity.		
7.1	Loan facilities	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 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)	(1,726)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	4,917
8.3	Unused financing facilities available at quarter end (Item 7.5)	0
8.4	Total available funding (Item 8.2 + Item 8.3)	4,917
8.5	**Estimated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)**	**3***

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: *Excludes estimated R&D tax incentive rebate of $1.8m expected to be received in the December quarter.

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 the questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance Statement

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

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

Date: 26 October 2023

Authorised by: The Board

(Name the 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 the 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-eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee,you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.