ASX Release
28 July 2022

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 2022.

- **PromarkerD partnering:** US licensing negotiations advance towards execution; discussions ongoing with new potential distribution and laboratory partners in several European countries
- **Endometriosis clinical validation study - diagnostic readout positive:** Results to be presented at Fertility Society ANZ conference following significant milestones achieved in the development of what could become the world's first non-invasive test for endometriosis.
- **PromarkerD manufacturing tech-transfer completed:** Successful production of components for more than 50,000 tests
- **PromarkerD registration submitted to the Australian TGA:** Submission is an important step for the national and global rollout
- **Clinical Advisory Board for PromarkerD global rollout:** Key Opinion Leaders to assist the rollout of the PromarkerD test
- **Proteomics International awarded $400,000 to support manufacturing capability in Australia:** Funding to support future manufacture of the PromarkerD test for Australia and South-East Asia
- **Study showed PromarkerD ability to also predict late-stage kidney decline in type-2 diabetes patients:** Research extends the potential use of PromarkerD to predict a further decline in renal function among people who already have kidney disease
- **Exclusive licence to oesophageal cancer biomarkers:** Proteomics International granted a worldwide licence to commercialise biomarkers that can test for oesophageal adenocarcinoma

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

PromarkerD manufacturing tech-transfer completed – Successful production of components for more than 50,000 tests

[ASX: 16 June 2022] Proteomics International successfully produced a pilot batch of PromarkerD test components with specialist ISO 13485-certified immunoassay manufacturer Biotem. Working closely with the Company, Biotem has completed the transfer of the manufacturing process and produced key components to assemble more than 50,000 tests for predicting the onset of diabetic kidney disease.

The pilot production run was a significant step in demonstrating the technology transfer required for large-scale global distribution. While the 50,000 tests have been manufactured for quality control and regulatory testing, they will also form part of inventory for initial sales.

PromarkerD registration submitted to the Australian TGA

[ASX: 2 June 2022] Proteomics International filed a submission to the Australian Therapeutic Goods Administration (TGA) for inclusion of PromarkerD in the Australian Register of Therapeutic Goods (ARTG). The submission is an important step for the national and global rollout of PromarkerD because Australia is one of the major reference countries, in addition to the US Food & Drug Administration (FDA), European Union CE Mark, Health Canada and Japan.

The TGA will now review the submission, a process which is expected to take six to nine months. If approval for registration is successful, then PromarkerD can be sold in Australia.

Clinical Advisory Board for PromarkerD global rollout

[ASX: 12 April 2022] As reported in the March quarterly update, Proteomics International has assembled a team of world leading clinicians specialising in nephrology and endocrinology. The team is advising the Company on its clinical and commercial initiatives towards a successful market launch of the PromarkerD test for diabetic kidney disease to physicians globally.

The Key Opinion Leaders (KOLs) will serve as global brand ambassadors and provide validation towards the Company's clinical and commercial initiatives, providing specific and tailored advice from the voice of the customer perspective to assist the rollout of the PromarkerD test.

Proteomics International awarded $400,000 to support manufacturing capability in Australia

[ASX: 12 May 2022] Proteomics International was awarded $413,516 in funding to support the PromarkerD manufacture in Australia. The funding was awarded by MTPConnect as part of the Australian Government's $45 million BioMedTech Horizons program, an initiative of the Medical Research Future Fund. The program aims to support innovative health technologies, drive discoveries towards proof-of-concept and commercialisation that address key health challenges, and maximise entrepreneurship and idea potential.

The funding will supplement the Company's existing manufacturing strategy and budget, supporting future manufacture of the PromarkerD test for Australia and South-East Asia by building upon Proteomics International's specialised ISO 13485 certification. The funding will also help obtain TGA approval [ASX: 28 April 2022] and registration of PromarkerD under the Medical Benefits Scheme [ASX: 22 February 2022]. The funding must be spent over 12 months and Proteomics International will match the funds dollar-for-dollar, plus additional in-kind contributions.

Study showed PromarkerD can also predict late-stage kidney decline in type-2 diabetes patients

[ASX: 6 June 2022] The Company presented a study at the American Diabetes Association's 82nd Scientific Sessions, 3-7 June in New Orleans, United States, demonstrating the potential ability of the PromarkerD test to predict late-stage renal decline. PromarkerD is already a proven diagnostic test for diabetic kidney disease, predicting the onset of the condition up to four years in advance. This

study extended the potential use of PromarkerD to predict a further decline in renal function among people who already have kidney disease.

The finding came from analysis of the completed CANagliflozin cardioVascular Assessment Study (CANVAS), as part of the ongoing collaboration between Proteomics International and Janssen Research & Development, LLC [ASX: 31 March 2020; 15 June 2020].

PromarkerD partnering

The Company's primary target market remains the US, where negotiations to license PromarkerD to a major diagnostics laboratory partner continue to advance towards execution. For Europe, activities to bring PromarkerD to the UK market with National Health Service (NHS) product reimbursement continue positively, however, the distribution agreement for the Italy market has been terminated and Proteomics International is in discussions with multiple new parties who are interested in representing the Italy territory, in addition to several other new EU sales territories. The Italian distribution agreement was executed as the Company's first immunoassay partner immediately prior to the Covid-19 pandemic and Proteomics International has now adopted an improved assessment system to qualify potential new distribution and laboratory partners based on key capabilities required to successfully launch, promote and run the PromarkerD test.

Proteomics International's partnering activities across multiple jurisdictions are shown below.

Territory	Partner	Agreement Type	Technology	Status	Start/Term	Commentary
Targets 30 Jun 2022						
USA		License	Immunoassay-LDT	In negotiation		Negotiations advance towards execution with potential laboratory partners.
Europe		Distribution	Immunoassay Kit	In discussion		Discussions ongoing with new potential distributors for France, Ireland, Italy, Poland, Spain.
RoW		License /Distribution	Immunoassay	Market/partner assessment		Country market assessments have been completed for all sales territories covered by the Company's patent portfolio. Potential strategic partners are being identified.
Partners 30 Jun 2022						
UK	Apacor	Distribution [Exclusive]	Immunoassay Kit	Live [Pre-launch]	Nov 2021-23	Preparing documentation for reimbursement assessment by UK National Health Service (NHS).
Israel	Zotal	Distribution [Exclusive]	Immunoassay Kit	Live [Inactive]	Nov 2020-22	Registration of PromarkerD in Israel on hold since Feb 21 pending: (1) kit manufacturer to ISO 13485; (2) PromarkerD sales in another region. In negotiation about future steps.
Puerto Rico & Dominican Republic	Omics Global Solutions	Technology License [Exclusive]	Innovatio ND2 (developed own Immunoassay)	Live	Aug 2016-31*	Test launched in Puerto Rico via Immuno Reference Lab June 2022. Currently focused on KOL awareness initiatives.
Ireland	Atturos	Technology License [Non-exclusive]	MS-LDT	Live [Inactive]	Feb 2020-23	Technology transfer completed for PromarkerD MS-LDT.
Italy	Medical Horizons	Distribution [Exclusive]	Immunoassay Kit	Terminated [Dormant]	Oct 2020-22	Agreement terminated 27 July 2022.
Spain	Patia Europe	License [Exclusive]	MS-LDT	Expired [Dormant]	Nov 2018-20	Agreement expired.
Mexico	Patia BioPharma	License [Exclusive]	MS-LDT extended to Immunoassay	Expired [In negotiation]	Jun 2018-21	Registration of PromarkerD in Mexico on hold since Jun 21 pending: (1) kit manufacturer to ISO 13485; (2) Free sale certificate following TGA or FDA registration. In negotiation about future steps.

MS - mass spectrometry LDT - Laboratory developed test * Life of Patents (20 Sep 2031)

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) R&D for new diagnostic tests using the Promarker™ pipeline and iii) Analytical services

During the quarter, Proteomics International made significant advances in two of its diagnostic research and development projects using the Company's Promarker™ technology platform [See Annual Report 2021]. Proteomics International believes its Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical needs.

Endometriosis clinical validation study - diagnostic readout positive

[ASX: 30 June 2022] Proteomics International announced preliminary results from its clinical validation study which showed several plasma proteins are statistically significant biomarkers for endometriosis. The study analysed 857 samples in collaboration with the Royal Women's Hospital and the University of Melbourne.

The next phase of analysis will use the validated biomarkers to build a diagnostic model, as was performed for PromarkerD. This process of statistical modelling will determine the accuracy (sensitivity and specificity) of the potential new blood test, that could become the world's first non-invasive test for endometriosis.

The results of the validation study will be presented at the Fertility Society of Australia and New Zealand Annual Conference (FSANZ 2022), being held 30 July - 2 August in Sydney, NSW.

The Company also announced an additional collaboration with St John of God Health Care which will provide an independent patient cohort that can be used to confirm the clinical performance of any new test.

Exclusive licence to oesophageal cancer biomarkers

[ASX: 21 June 2022] Proteomics International secured an exclusive worldwide licence to commercialise biomarkers that can test for the most common form of oesophageal cancer, oesophageal adenocarcinoma, a condition that is commonly caused by acid reflux. The licence agreement between Proteomics International and the QIMR Berghofer Medical Research Institute follows a partnership between the two organisations, which included a joint study of more than 300 patients [ASX: 9 October 2020].

The QIMR Berghofer intellectual property includes granted patents in multiple jurisdictions and will allow the Company to use the biomarkers to develop and commercialise a simple blood test for oesophageal adenocarcinoma. Current screening requires a specialist endoscopy which can cost US$2,750 per patient.

Promarker™ pipeline update

Whilst significant advances in the Promarker diagnostics pipeline were achieved for the endometriosis diagnostic test in this quarter, and with the oesophageal cancer and asthma/COPD diagnostics in the previous quarter, several projects have been delayed or are on-hold. This reflects instrument capacity constraints, in part caused by maintenance issues arising from border closures, and has also meant some datasets have not achieved levels of sensitivity that the Company desires for its development of novel diagnostics tests. Proteomics International has instigated a number of initiatives to overcome these obstacles, which will yield improved results going forward, and looks forward to providing updates on the outcomes of these steps in due course.

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.

Revenue & Expenditure

Proteomics International achieved receipts from customers for the June quarter of $292,000 (March quarter: $335,000) and an additional $340,000 in grants.

Receipts continue to be driven by revenue from analytical services. In particular, the Company has observed a significant increase in demand for its pharmacokinetic testing services (related to clinical

trials), and renewed interest in biosimilars testing - an area that was negatively affected in FY21 by the Covid-19 shutdowns in markets such as India.

The net operating cash outflow for the June quarter was $1.04 million (March quarter: $1.28 million). Expenditure centred on the following areas:

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

ASX Listing Rule 4.7C
Payments at item 6.1 of the Appendix 4C of $139,000 relate to normal remuneration of Executive and Non-Executive Directors.

Cash position
At 30 June 2022 the Company had cash reserves of $2.1 million (March $3.3 million). These reserves will be strengthened by a forecast R&D tax incentive rebate of circa $1.5 million to be received in the 1H FY23. The Company is confident that its diversified business model places it in a sound financial position to fund its current objectives.

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 June 2022**

Consolidated statement of cash flows		**Current Quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows related to operating activities**		
1.1	Receipts from Customers	292	1,354
1.2	Payments for		
	(a) research & development	(828)	(3,432)
	(b) product manufacturing & operating costs	(86)	(294)
	(c) advertising & marketing	(60)	(175)
	(d) leased assets	46	0
	(e) staff costs	(296)	(1,176)
	(f) administration & corporate costs	(453)	(1,400)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	0	5
1.5	Interest & other costs of finance paid	0	(2)
1.6	Income taxes paid	0	0
1.7	Government grants & tax incentives	340	1,580
1.8	Other (provide details if material)	0	0
1.9	**Net cash from / (used in) operating activities**	**(1,045)**	**(3,540)**
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	(61)	(129)
	(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**	**(61)**	**(129)**

Consolidated statement of cash flows		Current Quarter $A'000	Year to date (12 months) $A'000
3.	**Cash flows from financing activities**		
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	246
3.4	Transaction costs related to issues of equity securities or	0	0
	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 (leased assets)	(70)	(70)
3.10	**Net cash from / (used in) financing activities**	**(70)**	**176**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	3,287	5,604
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(1,045)	(3,540)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(61)	(129)
4.4	Net cash from / (used in financing activities (item 3.10 above)	(70)	176
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	**Cash & cash equivalents at end of quarter**	**2,111**	**2,111**
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	1,111	787
5.2	Cash deposits	1,000	2,500
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)**	**2,111**	**3,287**
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		139
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**	**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)	(1,045)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	2,111
8.3	Unused financing facilities available at quarter end (Item 7.5)	0
8.4	Total available funding (Item 8.2 + Item 8.3)	2,111
8.5	**Estimated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)**	**2.0***

*The Company expects to receive an R&D tax incentive rebate of circa $1.5m in 1H FY23.

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 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: 28 July 2022

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.