ASX Release
31 January 2023

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 31 December 2022 and subsequent to the period end.

- **Major milestone achieved as CPT PLA reimbursement code approved for PromarkerD in the United States:** Code is key to PromarkerD being covered by both Medicare and private health insurers in the US
- **UK's National Institute for Health and Care Excellence (NICE) published Medtech Innovation Briefing on PromarkerD:** Advice for clinicians reported that PromarkerD is effective at predicting renal function decline in people with type 2 diabetes
- **Letter of intent with Sonic Healthcare USA extended:** Discussions to finalise an Exclusive Licence Agreement for PromarkerD progress following achievement of major milestones
- **PromarkerD patent granted in Hong Kong:** Region acts as an important gateway for the much larger China market
- **Precision diagnostics facility received $2 million funding boost:** Expansion of the WA Proteomics Facility to accelerate the development of precision diagnostic tests
- **R&D tax incentive funding:** The Company's cash reserves further strengthened by $1.7 million government rebate
- **Exercise of Director options and Completion of Placement by Directors:** a further $518,000 was raised from directors after exercise of options and a shareholder approved placement

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™ pipeline
(iii) analytical services on a commercial basis

i) Commercialisation of PromarkerD

CPT PLA reimbursement code approved in the United States

[ASX: 3 January] Proteomics International achieved a major milestone in the commercialisation of PromarkerD with the approval of a new dedicated CPT® Proprietary Laboratory Analyses (PLA) code for the test in the United States. The CPT PLA code—issued by the American Medical Association—is key to PromarkerD reimbursement being covered by both Medicare and private health insurers in the US, and hugely important for enabling affordable access and broad adoption of the test.

In the United States, an estimated 32 million people, or 11 per cent of the population, live with diabetes. The newly-approved code for PromarkerD (0385U) has been published and will be effective from 1 April 2023. The next step is engaging with both private payers and the Centers for Medicare & Medicaid Services (CMS) to establish payment and include PromarkerD in their Clinical Lab Fee Schedule.

UK's National Institute for Health and Care Excellence (NICE) published Medtech Innovation Briefing on PromarkerD

[ASX: 14 December] The National Institute for Health and Care Excellence (NICE), an independent organisation established by the UK Government to provide guidance and advice on medical treatments, published a Medtech Innovation Briefing on PromarkerD.

Medtech Innovation Briefings are commissioned by the National Health Service (NHS) in the UK. Known as NICE advice, they are designed to increase awareness of new technologies for planning and commissioning new innovation in the UK healthcare industry. The briefing, aimed at clinicians, managers and procurement professionals in the UK, reported that PromarkerD is effective at predicting renal function decline in people with type 2 diabetes.

There is a rigorous selection process for inclusion in the NICE advice process, taking into account the potential benefits of a technology, its regulatory status, clinical evidence and more. There were only 28 Medtech Innovation Briefings published in 2022.

The NICE advice supports the reimbursement process and broader adoption of PromarkerD in the UK, and its publication enables Proteomics International to pursue inclusion of PromarkerD in the NICE Guidelines and to engage with the NHS Supply Chain Tender process. The Company will provide timelines for these processes when known.

Letter of intent with Sonic Healthcare USA extended

[ASX: 31 and 5 January] Proteomics International has extended the term of its letter of intent with Sonic Healthcare USA until 28 February 2023. The binding and exclusive LOI provides for entering into an Exclusive Licence Agreement for use of the PromarkerD predictive test for diabetic kidney disease in the United States by Sonic Healthcare USA [ASX: 9 August 2022]. The terms of the Exclusive Licence Agreement continue to be progressed and the extension provides both parties the further necessary time to finalise the agreement.

A number of major milestones have already been achieved under the LOI, including the key granting of a new dedicated CPT PLA reimbursement code which was approved at the beginning of January (see above). The test has also been optimised for a high-throughput environment and PromarkerD became a featured test on the Sonic Reference Laboratory (USA) test menu in October 2022. Both parties continue to work diligently toward achieving a successful roll-out of PromarkerD across the USA and to formalise milestone events and timelines in relation to the commercialisation process.

PromarkerD patent granted in Hong Kong

[ASX: 11 November] Patent protection for PromarkerD was expanded to Hong Kong, where 11.6% of the population—or 686,000 adults—have diabetes. Hong Kong is also an important gateway market, with potential for the test to be introduced there prior to entering the much larger China market.

The Hong Kong patent complements those already granted in the USA, Europe, Australia, Brazil, Canada, China, Indonesia, Russia, Singapore, India and Japan. Together, the Company's PromarkerD intellectual property portfolio covers 64% of the world’s population living with diabetes.

Update: PromarkerD first sales; Immunoassay kit manufacture; Australian regulatory and Medical Benefit Schedule submissions

[ASX: 24 November] First sales for the PromarkerD test were achieved in Central America through licence partner Omics Global Solutions, and discussions continue with potential new licensing

partners in target jurisdictions.

The manufacture and scale-up of production and validation batches of the PromarkerD immunoassay kit is continuing through the Company's ISO 13485 certified manufacturer in Europe. This follows the successful tech-transfer and pilot batch production [ASX: 16 June 2022].

The assessments of PromarkerD by the Australian Therapeutic Goods Administration (TGA) [ASX: 2 June 2022] and by the Medical Services Advisory Committee (MSAC) for the test to be included in the Australian Medicare Benefits Schedule are also ongoing. The Company expects to advise of outcomes from these submissions in Q2 of CY23.

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 continued to advance several of its diagnostic research and development projects using the Company's Promarker™ technology platform. Proteomics International believes its Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical needs.

Precision diagnostics facility received $2 million funding boost

[ASX: 20 October] Proteomics International, The University of Western Australia (UWA) and Bioplatforms Australia announced a $2 million expansion of the WA Proteomics Facility to accelerate the development of precision diagnostic tests. The WA Proteomics Facility is a Public Private Partnership between the three organisations. It is jointly managed by Proteomics International and UWA, and combines their respective expertise to explore biological protein markers that affect medicine, agriculture, and the environment [ASX: 26 November 2019].

Over the next three years, the partners will co-invest $2 million to increase capacity and throughput at the cutting-edge facility with new equipment for automated sample handling and analytical quantitation, coupled with the development of advanced data processing tools. Under the management agreement, Bioplatforms Australia (through the Commonwealth Government National Collaborative Research Infrastructure Strategy (NCRIS)) will contribute $1.7m to the facility for capital and operational purposes, of which half the funds will be paid to Proteomics International to expand its laboratory capacity. Proteomics International and UWA will each invest a further $150,000 in cash.

The expanded facility is expected to be fully operational in 2023.

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 enables the group to continue to make optimum use of its resources.

Revenue & Expenditure

Proteomics International achieved cash receipts from customers for the December quarter of $1.1 million (September $260,000). Receipts from customers continue to be driven by revenue from analytical services, with this quarter supplemented with exceptional revenue of $850,000 from the BioPlatforms-UWA partnership (see above).

The net operating cash inflow for the December quarter was $597,000 (September quarter outflow $2.4 million). Expenditure 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, including the one-off purchase of new sophisticated analytical instruments for biomarker analysis (see above)

Proteomics International receives $1.7 million in R&D tax incentive
[ASX: 17 October] Proteomics International's cash reserves were further strengthened by the receipt of $1.7 million in research and development tax incentive for the 2021-22 financial year. Proteomics International spent $3.94 million on R&D during the year, enabling the company to receive an Australian Government rebate of $1,711,904. The tax incentive encourages companies engaging in beneficial research to Australia by providing a cash rebate of 43.5% for qualifying activities.

Exercise of Director options and Completion of Placement by Directors
[ASX: 24 October] Additional funds were received following the exercise of director options raising $268,000 before costs. [ASX 24 November] Following shareholder approval a further $250,000 was raised from three directors upon completion of Tranche 2 of the $8 million placement [ASX: 15 and 22 August].

ASX Listing Rule 4.7C
Payments at item 6.1 of Appendix 4C of $223,000 relate to normal remuneration of Executive and Non-Executive Directors.

Cash position
At 31 December 2022 the Company had cash reserves of $6.8 million (September $6.4 million). These reserves have been further strengthened subsequent to the quarter end by the exercise of corporate advisory and employee options raising $1.86 million before costs [ASX: 11, 19 and 27 January].

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	**31 December 2022**

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	1,103	1,363
1.2	Payments for		
	(a) research & development	(1,197)	(2,391)
	(b) product manufacturing & operating costs	(203)	(407)
	(c) advertising & marketing	(28)	(84)
	(d) leased assets	0	0
	(e) staff costs	(776)	(1,420)
	(f) administration & corporate costs	(21)	(768)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	7	8
1.5	Interest & other costs of finance paid	0	0
1.6	Income taxes paid	0	0
1.7	Government grants & tax incentives	1,712	1,865
1.8	Other (provide details if material)	0	0
1.9	**Net cash from / (used in) operating activities**	**597**	**(1,834)**
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	(689)	(1,068)
	(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**	**(689)**	**(1,068)**

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)	518	8,268
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	(30)	(654)
	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**	**488**	**7,614**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	6,427	2,111
4.2	Net cash from / (used in) operating activities (see 1.9 above)	597	(1,834)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(689)	(1,068)
4.4	Net cash from / (used in financing activities (item 3.10 above)	488	7,614
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	**Cash & cash equivalents at end of quarter**	**6,823**	**6,823**

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	611	5,427
5.2	Cash deposits	6,212	1,000
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)**	**6,823**	**6,427**

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	223
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 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)		597
8.2	Cash and cash equivalents at quarter end (Item 4.6)		6,823
8.3	Unused financing facilities available at quarter end (Item 7.5)		0
8.4	Total available funding (Item 8.2 + Item 8.3)		6,823
8.5	**Estimated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)**		**N/A**

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: 31 January 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.