



Proteomics International

LABORATORIES LTD

ASX Release
31 October 2022

ASX code: PIQ

Quarterly Activities Report

Proteomics International Laboratories Ltd (Proteomics International, the Company; ASX: PIQ), a medical technology company at the forefront of precision medicine and predictive diagnostics, is pleased to provide the following update on a quarter that the Board believes represented a major inflexion point in its corporate development.

The business activities for the three months to 30 September 2022 have included the achievement of several significant de-risking events across commercial partnering for PromarkerD, maturing of the Promarker™ diagnostics pipeline, alongside substantial inward funding, which collectively provide an excellent foundation for Proteomics International's future commercial success:

- **Binding letter of intent signed with Sonic Healthcare USA:** Exclusive letter of intent to take PromarkerD into the US market
- **Potential breakthrough blood test able to detect people with endometriosis:** Early version of test successfully detected up to 78% of people with the painful condition
- **New Promarker test for oesophageal cancer demonstrated strong diagnostic performance:** Prototype diagnostic test for oesophageal adenocarcinoma detected up to 90% of people with the frequently-fatal condition
- **OxiDx launched to maximise oxidative stress technology:** Independent spin-off business to commercialise technology for measuring oxidative stress
- **Clinical utility study showed PromarkerD test offers improved treatment options for doctors in the fight against diabetic kidney disease:** Results published in peer-reviewed journal *PLOS ONE*
- **European PromarkerD patents expanded beyond diabetes:** New patent potentially doubles target audience by providing protection for using PromarkerD in Europeans with prediabetes
- **\$8m raised in Heavily Oversubscribed Placement:** Successful Placement supported by Australian institutions, and sophisticated and professional investors
- **R&D tax incentive:** Cash reserves further strengthened by \$1.7m in research and development tax incentive in October 2022.

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

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Potential milestones, impacts and share price catalysts for FY23

Milestone	Dec Qtr '22	1H CY23	Impact
PromarkerD			
Licensing Deals			Execution of Sonic Healthcare USA licence. Drive global uptake and future revenue
First Sales			Drive revenue
Reimbursement - US			CPT PLA code outcome & Payor coverage
Regulatory Submissions, Approvals & Reimbursement RoW			Build user confidence in product & assist in global roll-out
Promarker™			
Endometriosis Dx			New first-in-class diagnostic test
Oesophageal Cancer Dx			New first-in-class diagnostic test
Diagnostics Pipeline Updates			New IP (validation & proof of concept results)
Analytical Services			
New Contracts			Off-set cash burn & engages potential future partners

In addition to the achievements detailed below, Proteomics International continues to engage potential partners for further licensing deals for PromarkerD (focussed on Europe), and regulatory and reimbursement approvals in previously stated jurisdictions. The Company will provide further updates on these developments in the coming quarters.

i) Commercialisation of PromarkerD

Proteomics International signed binding letter of intent with Sonic Healthcare USA to take PromarkerD into the US market

[ASX: 9 August] Proteomics International signed a binding and exclusive letter of intent with Sonic Healthcare USA, Inc. (a division of Sonic Healthcare Limited; ASX: SHL) regarding entering into an exclusive licence for use of the Company's PromarkerD test for diabetic kidney disease in the United States.

The binding and exclusive letter of intent documents the preliminary terms and expectations for how Proteomics International and Sonic Healthcare USA will work together to bring the PromarkerD test to patients in the US (excluding Puerto Rico), and for finalising an Exclusive Licence Agreement by 31 December 2022 (which may be extended), subject to the parties formalising milestone events and timelines in relation to the commercialisation process.

Key milestones include optimising the test for a high-throughput environment within Sonic Reference Laboratories to enable commercial sale of PromarkerD, preparing for a submission to secure a Proprietary Laboratory Analysis (PLA) reimbursement code for the PromarkerD test [ASX: 28 October 2021], and forecasting sales targets for PromarkerD in the US marketplace.

All activities are proceeding as planned and the PromarkerD test for diabetic kidney disease risk assessment is now a featured test on the Sonic Reference Laboratory (USA) test menu¹ whilst the Company expects to know the outcome of the PLA code registration in Q1 CY23.

¹ www.sonicreferencelab.com/featured-testing/

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Clinical utility study demonstrated PromarkerD test offers improved treatment options for doctors in the fight against diabetic kidney disease

[ASX: 2 August] A study demonstrating the clinical utility of the PromarkerD test in predicting diabetic kidney disease was published in the scientific journal *PLOS ONE*. The publication provided important peer-reviewed validation of initial results that were previously presented at major industry conferences [ASX: 18 October 2021].

The survey of 400 primary care physicians and endocrinologists showed that doctors ranked PromarkerD results as more important than current standard-of-care tests eGFR (estimated glomerular filtration rate) and ACR (urinary albumin - creatinine ratio), and found PromarkerD risk scores would significantly impact physician decision-making. In the study 78% of physicians said they were very or extremely likely to order the PromarkerD test for their type 2 diabetes patients, with only 2% indicating they would not order the test.

European PromarkerD patents expanded beyond diabetes

[ASX: 25 July] European patent protection for Proteomics International's PromarkerD predictive test was expanded to include diagnosing all individuals who are prediabetic and asymptomatic for kidney disease. Globally 537 million adults have diabetes, and an additional 541 million (10.6% of the world's adult population) have prediabetes, an at-risk category for kidney disease. Further clinical studies are needed to demonstrate that PromarkerD can be used to diagnose kidney disease beyond those with diabetes.

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 several of its diagnostic research and development projects using the Company's Promarker™ technology platform [See Annual Report 2022]. Proteomics International believes its Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical needs.

Potential breakthrough blood test able to detect people with endometriosis

[ASX: 1 August] An early version of the Company's potential world-first blood test for endometriosis successfully detected up to 78% of people with the painful condition. The results were presented at the Fertility Society of Australia and New Zealand Annual Conference (FSANZ 2022) in Sydney, 30 July - 2 August 2022.

Endometriosis is a common and painful disease that affects one in nine women and girls, often starting in teenagers. At the moment, there is no simple way to test for the condition beyond invasive surgery. The Company is currently undertaking additional data analysis to enhance the accuracy and clinical utility of its test, which is due to complete 1H CY23.

The study was a collaboration between Proteomics International, the Royal Women's Hospital and the University of Melbourne [ASX: 4 August 2021].

New Promarker test for oesophageal cancer demonstrated strong diagnostic performance

[ASX: 27 September] Proteomics International's prototype diagnostic test for oesophageal adenocarcinoma showed strong diagnostic performance, detecting up to 90% of people with the frequently-fatal condition. The results were presented at the 18th World Congress for Esophageal Diseases, held virtually and in Tokyo, Japan, 26-28 September 2022.

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Oesophageal adenocarcinoma is the most common form of oesophageal cancer and is an area of significant unmet medical need, with current screening requiring a specialist endoscopy procedure that costs US\$2,750 per patient in the United States. The results represent an exciting milestone in the development of a potential new accurate, easy to use test for oesophageal adenocarcinoma. To enhance the accuracy and clinical utility of its test the Company is currently undertaking additional data analysis, which is due to complete 1H CY23.

Proteomics International believes that successfully validated blood tests for either endometriosis or oesophageal cancer will each garner significant interest, both commercially and in the clinic.

OxiDx Pty Ltd launched to maximise oxidative stress technology

[ASX: 29 August] Proteomics International announced the spin-off of an independent business to commercialise technology for measuring oxidative stress testing technology developed by Proteomics International and The University of Western Australia. The new incorporated joint venture—OxiDx Pty Ltd—will focus on developing innovative medical diagnostic products using the patented ‘2-tag’ measure for oxidative stress.

Oxidative stress has been implicated in many chronic diseases, and the ‘2-tag’ method could be part of the next generation of medical diagnostic tests. The technology has several target applications, including chronic fatigue, muscular dystrophy, high-performance athletes and the horse racing industry.

OxiDx now operates as a stand-alone entity focused on unlocking value from the oxidative stress measure through disruptive medical diagnostic products. OxiDx bears its own costs. Proteomics International and its shareholders own 66 per cent of OxiDx, and The University of Western Australia own 33 per cent.

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.

Revenue & Expenditure

Proteomics International achieved receipts from customers for the September quarter of \$260,000 (June quarter: \$292,000). Receipts continue to be driven by revenue from analytical services, which has been slow to recover following the Covid-19 pandemic, however, the Company anticipates a return to long term growth trends in the coming quarters.

The September quarter included a number of strategic one-off payments which led to an unusually large net operating cash outflow of \$2.4 million (June quarter: \$1.05 million) and centred on the following areas:

- Business development and commercialisation costs for the roll-out of PromarkerD - including engagement of the Company's new Clinical Advisory Board [ASX: 12 April]
- Manufacturing costs for the PromarkerD immunoassay kit - achievement of milestones in the supply chain validation [ASX: 16 June]
- Regulatory and reimbursement activities to support PromarkerD commercialisation - in particular, submissions for the Australian Medical Services Advisory Committee (MSAC) [ASX: 22 February] and Therapeutic Good Administration (TGA) [ASX: 2 June]
- R&D for projects in the Promarker™ diagnostics pipeline - including in-licensing fees for the oesophageal cancer biomarker project [ASX: 21 June]

The Company anticipates future cash outflows will normalise at circa \$1.5m per quarter (before any future PromarkerD sales are taken into consideration).

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\$8m raised in highly-successful Placement

[ASX: 15 August] Proteomics International raised \$8 million (before costs) through the issue of 9.41 million shares in the Company. The Placement was at an issue price of \$0.85 per share, a discount of 11.1% to the 5-day VWAP. It was heavily oversubscribed, supported by Australian-based institutions, and sophisticated and professional investors.

Directors Neville Gardiner, Paul House and Roger Moore will participate in Tranche 2 of the Placement (total \$0.25m), subject to shareholder approval at the upcoming AGM.

Funds from the Placement (after costs) are being used to build inventory of the PromarkerD predictive test for diabetic kidney disease, support US sales and marketing for PromarkerD, develop the Promarker™ diagnostics pipeline and for general working capital.

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 September 2022 the Company had cash reserves of \$6.4 million (June \$2.1 million). These reserves have been further strengthened by receipt of an R&D tax incentive rebate of \$1.7 million [ASX: 17 October] and \$268,000 from the exercise of Director Options [ASX: 24 October], plus award of infrastructure funding of \$850,000 via the Public Private Partnership with The University of Western Australia (UWA) and Bioplatforms Australia [ASX: 20 October].

Annual General Meeting

The 2022 AGM will be held on 24 November and the Company looks forward to providing a further update on its activities at that time.

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 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	260	260
1.2 Payments for		
(a) research & development	(1,194)	(1,194)
(b) product manufacturing & operating costs	(204)	(204)
(c) advertising & marketing	(56)	(56)
(d) leased assets	0	0
(e) staff costs	(644)	(644)
(f) administration & corporate costs	(747)	(747)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	1	1
1.5 Interest & other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	153	153
1.8 Other (provide details if material)	0	0
1.9 Net cash from / (used in) operating activities	(2,431)	(2,431)
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	(379)	(379)
(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) 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)	0	0
2.6 Net cash from / (used in) investing activities	(379)	(379)

Consolidated statement of cash flows	Current Quarter	Year to date
	\$A'000	\$A'000
3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	7,750	7,750
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	(624)	(624)
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	7,126	7,126
4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash & cash equivalents at beginning of period	2,111	2,111
4.2 Net cash from / (used in) operating activities (see 1.9 above)	(2,431)	(2,431)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(379)	(379)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	7,126	7,126
4.5 Effect of movement in exchange rates on cash held	0	0
4.6 Cash & cash equivalents at end of quarter	6,427	6,427
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	Previous Quarter
	\$A'000	\$A'000
5.1 Bank balance	5,427	1,111
5.2 Cash deposits	1,000	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)	6,427	2,111
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
<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
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		
8.1 Net cash from / (used in) operating activities (see 1.9 above)		\$A'000 (2,431)
8.2 Cash and cash equivalents at quarter end (Item 4.6)		6,427
8.3 Unused financing facilities available at quarter end (Item 7.5)		0
8.4 Total available funding (Item 8.2 + Item 8.3)		6,427
8.5 Estimated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)		2.6*
<i>*In October the Company received an additional \$1.7 million in R&D tax incentive rebate plus \$268,000 from the exercise of Director Options.</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:		
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.		

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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 October 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.