ASX Release
27 January 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 31 December 2021.

- **PromarkerD significantly outperforms standard of care tests in predicting future kidney function decline:** Clinical study shows PromarkerD identifies 84% of patients who declined - all of whom were missed by current gold standard tests
- **Clinical utility study demonstrates appeal of PromarkerD testing to clinicians:** Survey finds PromarkerD significantly impacts physicians' prescribing and monitoring decisions, helping to inform treatment decisions to improve clinical outcomes for patients
- **PromarkerD distribution network expands to Britain:** Distribution agreement with Apacor Limited (UK) to bring PromarkerD test to patients in England, Scotland and Wales
- **FDA advises regulatory pathway for PromarkerD in US:** PromarkerD test system to follow a De Novo classification pathway for regulatory approval
- **Engagement with Key Opinion Leaders (KOLs):** Proteomics International is finalising appointments to a clinical advisory board amid ongoing engagements with national and international professional bodies and clinical experts in diabetes and nephrology
- **Proteomics International secures major analytical services contract for pharmacokinetic testing:** circa $400,000 contract will see the Company test a novel drug for degenerative and inflammatory diseases
- **R&D tax incentive and manufacturing funding:** Cash reserves further strengthened by $1.2 million in research and development tax incentive and a $100,000 manufacturing voucher
- **Director appointments:** Dr Robyn Elliott and Neville Gardiner welcomed to the Board as independent, non-executive Directors

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

PromarkerD significantly outperforms standard of care tests in predicting future kidney function decline

[ASX: 5 November] A study demonstrated that the PromarkerD test for diabetic kidney disease outperforms current standard of care tests in predicting the onset of diabetic kidney disease. The research compared the PromarkerD test to standard of care tests, the estimated glomerular filtration rate (eGFR) and urinary albumin:creatinine ratio (ACR) during a four-year follow-up period.

The clinical study involved retrospective analysis of more than 850 community-based patients with type 2 diabetes from the Fremantle Diabetes Study Phase II. Results showed PromarkerD correctly identified 84% of patients with normal kidney function who went on to experience kidney function decline in the next four years. Critically, all of these patients would have been missed by the eGFR and ACR tests which constitute the current gold standard of care under the global KDIGO (Kidney Disease Improving Global Outcomes) guidelines for risk classification. PromarkerD also identified 89% of patients with abnormal kidney function who declined further over the course of the study.

The study found patients classified by PromarkerD as high risk were 21 times more likely to develop diabetic kidney disease within four years than those classified as low risk. Patients classified as moderate risk by PromarkerD were eight times more likely than low-risk patients to develop the disease. The study was presented at Kidney Week 2021, the annual meeting of the American Society of Nephrology (ASN), in November.

Clinical utility study demonstrates appeal of PromarkerD testing to clinicians

[ASX: 18 October] As reported in the September quarterly update, a clinical utility study demonstrated that PromarkerD can help inform doctors' treatment decisions to improve clinical outcomes for patients with type 2 diabetes. The US-based web survey of 400 primary care physicians and endocrinologists found the PromarkerD test significantly impacted physicians' prescribing and monitoring decisions.

The analysis showed that PromarkerD tests were more important to physicians than the current standard-of-care tests — eGFR and ACR. More than three-quarters of physicians reported they were very or extremely likely to use PromarkerD in the future.

Senior author of the study Dr Alexander Turchin, an endocrinologist at Boston's Brigham and Women's Hospital, said "*When presented with moderate or high-risk PromarkerD results, physicians were more likely to implement renoprotective changes—such as increasing monitoring frequency, prescribing SGLT2 inhibitor drugs ('gliflozins') or replacing ibuprofen—than if they did not have the PromarkerD test results. These changes can help avoid end-stage interventions such as dialysis and kidney transplant. In contrast, when presented with low-risk PromarkerD results, the likelihood of aggressive treatment and health care resource utilisation reduced.*"

The results were presented at AMCP Nexus, a managed-care pharmacy conference in Denver, USA, in association with Boston Healthcare Associates and specialist US endocrinologists, in October.

PromarkerD distribution network expands to Britain

[ASX: 23 November] Proteomics International signed a distribution agreement with Apacor Limited (UK) to bring its PromarkerD test for diabetic kidney disease to patients in England, Scotland and Wales. The distribution agreement provides medical diagnostics company Apacor Limited with the right to sell the immunoassay version of the PromarkerD test.

Apacor have 25 years of experience in medical and analytical diagnostics and specialise in bringing ground-breaking technologies to their customers. Importantly, Apacor have strong relationships with government and professional healthcare bodies across the UK; dialogue with these bodies to introduce PromarkerD to the UK is now ongoing.

Apacor managing director Anthony Bellm said he was excited about PromarkerD and being able to partner with Proteomics International to bring the test to the UK. "*This world-first test offers huge benefits for the growing number of people living with diabetes in Great Britain, as well as significant savings to the NHS,*" he said. The term of the agreement with Apacor is for two years, extendable for additional periods of one year by mutual agreement, exclusive to England, Scotland and Wales, and exclusive to the PromarkerD immunoassay (IA) version of the test.

FDA advises regulatory pathway for PromarkerD in US

[ASX: 24 November] Proteomics International received notification from the United States Food and Drug Administration (FDA) that the PromarkerD test system should follow a De Novo classification pathway for regulatory approval. This guidance follows the Company's 513(g) application to the FDA in April 2021 [ASX: 29 April], with the response delayed due to COVID-19 related resource limitations. The De Novo pathway for medical device marketing in the US was added by the FDA to address novel devices of low to moderate risk, such as blood tests, that do not have a valid predicate device, i.e. there is no similar device already approved.

Proteomics International is now preparing for a full product application to the FDA proposing the PromarkerD test system as a Class IIa IVD (In Vitro Diagnostic). It is expected the Company will submit this application in Q1 CY22, with the FDA timeline for review of such applications being approximately 12 months. Whilst the Company is pursuing FDA approval, the primary route to market for PromarkerD in the US remains the LDT (Laboratory Developed Test) path through CLIA (Clinical Laboratory Improvement Amendments) certified labs, which allows sales to commence prior to any FDA approval.

Engagement with Key Opinion Leaders (KOLs)

Proteomics International is pursuing multiple avenues to drive the global uptake of PromarkerD through engagement with key professional bodies and clinical experts in diabetes and nephrology. In addition to conference presentations described above, the Company is finalising discussions with several KOLs to form a clinical advisory board and will provide further information on this subject in due course.

Proteomics International was also an industry partner on the recently announced successful grant application to establish an Australian Centre for Accelerating Diabetes Innovations (ACADI), which has been awarded $10 million over four years from the Australian Government's Medical Research Future Fund. Proteomics International's involvement in ACADI is subject to contract with terms and roles to be determined. The centre combines diabetes expertise from across Australia and aims at improving the lives of people living with diabetes, including addressing diabetic kidney disease.

PromarkerD – Outlook 2022

The Company is pleased to advise that it continues to advance its discussions with potential US/Global laboratory partners to provide PromarkerD to diabetes patients. Entry into the US market would mark a major milestone for the Company as it executes its global commercialisation strategy for PromarkerD.

Nonetheless, Proteomics International has been experiencing delays to its supply lines due to the variant waves of the Covid-19 pandemic. Whilst these issues are not currently material for the Company, they have delayed the ISO 13485 manufacture of the PromarkerD assay [ASX: September Quarterly] and have the potential to affect engagement with diagnostics facilities and subsequent roll-out of PromarkerD.

The Company was expecting to achieve first sales of PromarkerD in Italy during the quarter under its agreement with Medical Horizons [ASX: 16 October 2020], however, this has been delayed and the Company is now targeting first sales in Italy during the first half of CY22.

Sales arising from the second distribution agreement for the PromarkerD immunoassay kit, which is

with Zotal Ltd for Israel [ASX: 12 November 2020], remain dependent on the completion of the transfer to ISO 13485 kit manufacturing [ASX: September Quarterly].

Proteomics International will continue to pursue national/international regulatory and reimbursement approvals for PromarkerD and the Company will provide further guidance as material milestones are achieved.

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

During the quarter, Proteomics International continued to advance several of its diagnostic research and development projects using the Company's Promarker™ technology platform [See Annual Report 2021]. Over the coming months the Company expects to update the market on a number of key developments. Proteomics International believes its Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical needs.

Diagnostics – Endometriosis

The Company notes the previously announced research agreement with the University of Melbourne and the Royal Women's Hospital [ASX: 4 August 2021] to develop a world-first test for endometriosis has also been affected due to Covid-19. Proteomics International is pleased to confirm the laboratory analysis is continuing to progress, however, this clinical validation study has been affected by supply and critical equipment availability issues. Preliminary results are still expected in Q1 CY22 and if successful, the Company is confident this program will receive significant commercial interest.

Diagnostics – Outlook 2022

The Company looks forward to announcing further results from its other diagnostic tests in development during the course of 2022.

iii) Analytical services

Proteomics International secures major analytical services contract for pharmacokinetic testing

[ASX: 16 December] Proteomics International was awarded a major pharmacokinetic testing contract as part of its growing partnership with Linear Clinical Research. The circa $400,000 contract will see Proteomics International test a novel drug for degenerative and inflammatory diseases on behalf of the Australian arm of pharmaceutical company Sironax Ltd.

The study is part of a Phase I clinical trial examining the safety, tolerability and pharmacokinetics of the drug, and will be undertaken over the next 12 months. It comes amid strong global demand for pharmacokinetic testing, the study of what happens to drugs once they are inside the body, including the rate at which they are absorbed, distributed, metabolised and excreted.

Analytical Services – Outlook 2022

The Company currently anticipates growing demand for its analytical services during the course of 2022 and is looking forward to updating the market as and when agreements are entered into.

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 December quarter of $354,000 (September quarter: $373,000).

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 December quarter was $0.1 million (September quarter: $1.16 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

Proteomics receives $1.2 million in R&D tax incentive
[ASX: 14 December] Proteomics International's cash reserves were strengthened by the receipt of $1.2 million in research and development tax incentive. In 2020-21, Proteomics International spent $2.85 million on R&D, enabling the Company to receive an Australian Government rebate of $1,240,156.

Company awarded $100,000 manufacturing funding
[ASX: 3 November] Proteomics International was awarded a $100,000 voucher to support the manufacture of clinical diagnostic tests in Western Australia. This will allow the Company to establish local manufacturing quality control capabilities for PromarkerD, supporting the future large-scale manufacture of the test for Australia and the South-East Asia region.

The funding is made possible through the MTPConnect WA Life Sciences Innovation Hub MTP Manufacturing Voucher Program, and was announced by WA State Development, Jobs and Trade Minister Roger Cook. The $100,000 voucher will be matched dollar for dollar by Proteomics International, with the project to be completed over nine months.

ASX Listing Rule 4.7C
Payments at item 6.1 of the Appendix 4C of $119,000 relate to normal remuneration of Executive and Non-Executive Directors.

Cash position
At 31 December 2021 the Company had cash reserves of $4.5 million (September $4.4 million). These reserves were strengthened by an R&D tax incentive rebate of $1.2 million received in the December quarter. The Company is confident that its diversified business model places it in a strong financial position to fund its objectives for CY22.

Director appointments
[ASX: 16 November; 26 October] Proteomics International welcomed Dr Robyn Elliott and Neville Gardiner to its Board as independent, non-executive Directors.

Mr Gardiner is a seasoned finance professional with over 30 years' experience advising Boards of public and private companies, most recently as a partner of Deloitte. Dr Elliott is an Executive Director at CSL Behring, a subsidiary of CSL Limited [ASX: CSL], with a proven track record in product development, clinical trials, regulatory affairs, audits, quality management, project management and operational strategy.

Mr Gardiner has assumed the role of Chair, following the retirement of Proteomics International Laboratories Ltd Chairman Terry Sweet at the 2021 AGM. Mr Sweet was instrumental in taking the

Company from its initial public listing as an R&D-focused $10 million dollar enterprise to the commercially-driven $100 million (circa) business it is today.

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.

For further information please contact:

Dr Richard Lipscombe
Managing Director
Proteomics International Laboratories Ltd
T: +61 8 9389 1992
E: enquiries@proteomicsinternational.com

Dirk van Dissel
Investor Relations & Corporate Advisor
Candour Advisory
T: +61 408 326 367
E: dirk@candouradvisory.com.au

Kyle Moss
Corporate Advisor
Euroz Hartleys
T: +61 8 9488 1400
E: kmoss@eurozhartleys.com

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 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	354	727
1.2	Payments for		
	(a) research & development	(806)	(1,689)
	(b) product manufacturing & operating costs	(87)	(145)
	(c) advertising & marketing	(44)	(86)
	(d) leased assets	0	0
	(e) staff costs	(304)	(578)
	(f) administration & corporate costs	(411)	(689)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	2	4
1.5	Interest & other costs of finance paid	(2)	(2)
1.6	Income taxes paid	0	0
1.7	Government grants & tax incentives	1,240	1,240
1.8	Other (Deferred Grant Income)	0	0
1.9	**Net cash from / (used in) operating activities**	**(58)**	**(1,218)**
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	(12)	(60)
	(d) investments	0	0
	(e) intellectual property	0	0
	(f) other non-current assets	0	0
2.2	Proceeds from disposal of:		
	(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)		
2.6	**Net cash from / (used in) investing activities**	**(12)**	**(60)**

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	0
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	198	222
3.4	Transaction costs related to issues of equity securities or convertible debt securities	0 0	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**	**198**	**222**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of period	4,420	5,604
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(58)	(1,218)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(12)	(60)
4.4	Net cash from / (used in financing activities (item 3.10 above)	198	222
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	**Cash & cash equivalents at end of quarter**	**4,548**	**4,548**

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	998	870
5.2	Cash deposits	3,550	3,550
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)**	**4,548**	**4,420**

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	119
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)	(58)
8.2	Cash & cash equivalents at quarter end (Item 4.6)	4,548
8.3	Unused financing facilities available at quarter end (item 7.5)	0
8.4	Total available funding (Item 8.2 + Item 8.3)	4,548
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**N/A***

** Based on the Company's average quarterly cash outflows the Company has approximately 4 quarters of funding available; this assumes no increase in revenue from analytical services or sales of its diagnostic tests.*

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: 27th January 2022

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.