



# Proteomics International

LABORATORIES LTD

ASX Release  
28 April 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 March 2022 and subsequent to the period end.

- **PromarkerD completes 'pre-assessment' for Medicare rebate:** Application lays the groundwork for test to be added to the Medicare Benefits Schedule
- **Key Opinion Leader (KOL) engagement - new Clinical Advisory Board appointed:** Board offers doctors' viewpoint in commercialisation of the PromarkerD blood test to assist its global rollout
- **PromarkerD patent granted in India:** Intellectual property portfolio now covers 63% of the world's population living with diabetes
- **PromarkerD Manufacturing Supply Chain and Regulatory update:** Proteomics International is pursuing multiple manufacturing and regulatory pathways simultaneously to maximise the opportunities for early product adoption across global markets
- **Partnering in the US and Europe:** Progress continues in licensing discussions to bring PromarkerD to diabetes patients worldwide
- **Novel biomarkers identified for asthma and COPD:** Proof-of-concept study identifies multiple novel protein biomarkers with potential to deliver a new diagnostic test
- **Unique panel of biomarkers identified for oesophageal cancer:** Successful completion of validation study targeting oesophageal adenocarcinoma, in collaboration with QIMR Berghofer
- **Endometriosis clinical validation study nearing completion:** The preliminary results from the clinical validation study are anticipated to be released in Q2 CY22.

### OPERATIONAL HIGHLIGHTS

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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

Proteomics International Laboratories Ltd

ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

T: +61 8 9389 1992 | E: [enquiries@proteomicsinternational.com](mailto:enquiries@proteomicsinternational.com) | W: [www.proteomicsinternational.com](http://www.proteomicsinternational.com)

## **i) Commercialisation of PromarkerD**

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### **PromarkerD completes ‘pre-assessment’ for Medicare rebate**

[ASX: 22 February 2022] Proteomics International completed the ‘pre-assessment’ phase of Australia’s medical reimbursement system for PromarkerD. The application lays the groundwork for the test to be added to the Medicare Benefits Schedule (MBS), an important step in bringing PromarkerD to the Australian market. Inclusion on the schedule would mean eligible patients receive a Medicare rebate for the test.

Proteomics International will now submit a full application for the ‘assessment’ stage of the process, which includes evaluation by a second sub-committee and consideration from the full Medical Services Advisory Committee. The committee is expected to meet in November 2022 to consider the proposal to include PromarkerD on the MBS, and may recommend, defer or reject the test for listing.

The Company is also pursuing Therapeutic Goods Administration (TGA) approval for PromarkerD, which is a parallel and independent process, as described below under the heading Manufacturing Supply Chain and Regulatory update.

### **Key Opinion Leader (KOL) engagement - new Clinical Advisory Board appointed**

[ASX: 12 April 2022] Proteomics International has assembled a team of world leading clinicians specialising in nephrology and endocrinology to advise the Company on its clinical and commercial initiatives towards a successful 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.

As part of its ongoing engagement with KOLs and industry representatives Proteomics International will host a booth and present its latest scientific findings on PromarkerD at the American Diabetes Association’s (ADA) 82<sup>nd</sup> Scientific Sessions in New Orleans, June 3-7, 2022. The ADA Scientific Sessions is one of the world’s largest preeminent diabetes conferences, with pre-pandemic attendance of over 15,000 professional attendees from 115 countries.

### **PromarkerD patent granted in India**

[ASX: 24 March 2022] Proteomics International was awarded a patent for PromarkerD in India. The country is home to more than 74 million people with diabetes, according to the International Diabetes Federation, and that number is expected to rise to almost 93 million by 2030. India has one of the highest number of adults living with diabetes in the world, second only to China.

Proteomics International already has a strong analytical services footprint in India, having operated in the country since 2004. The India patent complements those already granted in the USA, Europe, Australia, Brazil, Canada, China, Indonesia, Russia, Singapore and Japan.

Together, the Company’s PromarkerD intellectual property portfolio covers 63% of the world’s population living with diabetes. The India patent (no. 390245) is titled ‘Biomarkers associated with pre-diabetes, diabetes and diabetes related conditions’, and will extend until September 2031.

### **Manufacturing Supply Chain and Regulatory update**

To optimise its routes to market for PromarkerD, Proteomics International is pursuing multiple manufacturing and regulatory pathways simultaneously as described below. This strategy serves to de-risk these complex areas and maximises the opportunities for early product adoption across global markets.

Proteomics International is pleased to advise the transfer of its PromarkerD immunoassay manufacture to ISO 13485 certified manufacturer Biotem (France) [ASX: 12 August 2021] has

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progressed well despite global supply chain pressures [ASX: December Quarterly 2021]. The Company expects to update the market on several key developments in this area in the coming weeks. The completion of technology transfer and assay validation will represent a major milestone and enable large scale production of PromarkerD as Proteomics International targets sales globally. The PromarkerD assay is currently manufactured in Australia.

The primary route to market for PromarkerD in the US is the LDT (Laboratory Developed Test) path through CLIA (Clinical Laboratory Improvement Amendments) certified labs, with product produced and sold using Proteomics International's existing manufacturing supply chains. The Company has also identified it can seek FDA approval for PromarkerD via the De Novo classification pathway [ASX: 24 November 2021]. Following a gap analysis based on the FDA advised classification path, Proteomics International has reset its expectations for FDA submission and will apply when ISO 13485 certified assay production and validation has been completed. Over the coming months the Company will provide further updates on these developments.

Proteomics International is also pursuing Therapeutic Goods Administration (TGA) approval for PromarkerD because Australia is one of the major reference countries in addition to US FDA, EU CE Mark, Health Canada and Japan. Approval from reference countries can expedite the registration processes in other countries (e.g. Israel, South-East Asia). The Company has identified it is eligible for an "abridged" registration path, which provides a 6-9 month review timeframe. As part of the two-stage application process for inclusion of PromarkerD in the Australian Register of Therapeutic Goods (ARTG), Proteomics International submitted its ISO 13485 certificate as evidence of its Quality Management System to the TGA, and this has been accepted as qualifying manufacturer evidence. The second stage Product Assessment dossier is now being prepared.

#### **Partnering in the US, Europe and Rest-of-World markets**

Proteomics International is pleased to advise that its discussions with potential US/EU/Global laboratory partners to provide PromarkerD to diabetes patients worldwide have advanced. Entry into the US market remains a key milestone for the Company for CY22 as it executes its global commercialisation strategy for PromarkerD. The EU also remains a key market for PromarkerD, with the test having already completed CE Mark registration, and Proteomics International is continuing to evaluate strategies for early adoption of PromarkerD there.

Working with its distribution partner Apacor, Proteomics International is making significant progress in the UK. PromarkerD has been successfully registered with the Medicines and Healthcare products Regulatory Agency (MHRA), and the Company has engaged with the National Institute of Clinical Excellence (NICE) regarding the adoption of PromarkerD by the UK's National Health Service. Over the coming months the Company will provide details on these developments.

Further information about PromarkerD is available through the web portal ([www.PromarkerD.com](http://www.PromarkerD.com)).

*To visit the PromarkerD virtual product display please see: [www.PromarkerD.com/product](http://www.PromarkerD.com/product)*

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

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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], exemplified by the achievements below. Proteomics International believes its Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical needs.

#### **Novel biomarkers identified for asthma and COPD**

[ASX: 7 February 2022] Proteomics International's proof-of-concept study identified multiple novel protein biomarkers for obstructive airway disease. These biomarkers, once validated, have the

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potential to deliver a new diagnostic test for asthma and chronic obstructive pulmonary disease (COPD).

The proof-of-concept study, performed in collaboration with the Busselton Population Medical Research Institute, analysed plasma samples from 75 individuals with a range of symptoms including airway obstruction, atopy, bronchial hyper-responsiveness and healthy controls. The results were presented at the 27th Lorne Proteomics Symposium, Victoria.

Proteomics International will now work with its collaborators to validate the biomarkers in larger clinical cohorts and refine the panel of biomarkers into an effective diagnostic test for obstructive airway disease. This additional analysis is expected to be performed over the next 12-18 months.

Proteomics International also filed a patent application covering screening, diagnostic and prognostic methods of using these airway disease biomarkers.

### **Unique panel of biomarkers identified for oesophageal cancer**

[ASX: 4 February 2022] Proteomics International and QIMR Berghofer Medical Research Institute successfully completed a validation study targeting oesophageal adenocarcinoma, the most common form of oesophageal cancer in Australia.

The research studied multiple proteins in the blood associated with early-stage oesophageal adenocarcinoma. From these, Proteomics International and QIMR Berghofer were able to identify a panel of biomarkers with the potential to be used as a diagnostic test. They also validated the panel using blood samples from more than 300 patients.

The results of the study were presented at the 27th Lorne Proteomics Symposium, the annual conference of the Australasian Proteomics Society. Proteomics International and QIMR Berghofer are currently finalising arrangements for the future development of the biomarkers into a diagnostic test for oesophageal cancer.

### **R&D for new diagnostic tests - Endometriosis**

The Company has continued to make progress in the development of its novel test for endometriosis, despite initial delays due to Covid-19 [ASX: December Quarterly 2021]. The main goal of the endometriosis program is to validate the previously identified biomarker panel in a large validation study (n=900) involving the University of Melbourne and the Royal Womens Hospital [ASX: 4 August 2021].

The preliminary results are expected to be released in Q2 CY22 and, if successful, the Company is confident this program will garner significant commercial interest, because endometriosis is a debilitating disease that affects 1 in 9 women and costs Australia \$9.7 billion a year (the global opportunity is significantly higher). Diagnosis typically takes 7-12 years due to the lack of a simple diagnostic test beyond invasive surgery.

## **FINANCIAL AND CORPORATE HIGHLIGHTS**

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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 March quarter of \$335,000 (December quarter: \$354,000).

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

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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 March quarter was \$1.28 million (December quarter: \$0.1 million). Expenditure centred on the following areas:

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

#### **ASX Listing Rule 4.7C**

Payments at item 6.1 of the Appendix 4C of \$141,000 relate to normal remuneration of Executive and Non-Executive Directors.

#### **Cash position**

At 31 March 2022 the Company had cash reserves of \$3.3 million (December \$4.5 million). These reserves will be strengthened by a forecast R&D tax incentive rebate of circa \$1.5 million to be received in the December quarter. 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](http://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](mailto:enquiries@proteomicsinternational.com)

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

Kyle Moss  
Corporate Advisor  
Euroz Hartleys  
T: +61 8 9488 1400  
E: [kmoss@eurozhartleys.com](mailto:kmoss@eurozhartleys.com)

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## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

**Name of entity**

<b>Proteomics International Laboratories Ltd</b>	
<b>ABN</b>	<b>Quarter ending ("current quarter")</b>
<b>78 169 979 971</b>	<b>31 March 2022</b>

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date ( months) \$A'000</b>
<b>1. Cash flows related to operating activities</b>		
1.1 Receipts from Customers	335	1,062
1.2 Payments for		
(a) research & development	(915)	(2,604)
(b) product manufacturing & operating costs	(63)	(208)
(c) advertising & marketing	(29)	(115)
(d) leased assets	(46)	(46)
(e) staff costs	(302)	(880)
(f) administration & corporate costs	(258)	(947)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	1	5
1.5 Interest & other costs of finance paid	0	(2)
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	0	1,240
1.8 Other (provide details if material)	0	0
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,277)</b>	<b>(2,495)</b>
<b>2. Cash flows related to investing activities</b>		
2.1 Payments to acquire:		
(a) entities	0	0
(b) businesses (see item 10)	0	0
(c) property, plant & equipment	(8)	(68)
(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
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(8)</b>	<b>(68)</b>

<b>Consolidated statement of cash flows</b>	<b>Current Quarter</b>	<b>Year to date</b>
	<b>(\$A'000)</b>	<b>( months)</b>
	<b>(\$A'000)</b>	<b>(\$A'000)</b>
<b>3. Cash flows from financing activities</b>		
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	24	246
3.4 Transaction costs related to issues of equity securities or 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
<b>3.10 Net cash from / (used in) financing activities</b>	<b>24</b>	<b>246</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash & cash equivalents at beginning of period	4,548	5,604
4.2 Net cash from / (used in) operating activities (see 1.9 above)	(1,277)	(2,495)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(8)	(68)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	24	246
4.5 Effect of movement in exchange rates on cash held	0	0
<b>4.6 Cash &amp; cash equivalents at end of quarter</b>	<b>3,287</b>	<b>3,287</b>
<b>5. Reconciliation of cash &amp; cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts</b>	<b>Current Quarter</b>	<b>Previous Quarter</b>
	<b>(\$A'000)</b>	<b>(\$A'000)</b>
5.1 Bank balance	787	998
5.2 Cash deposits	2,500	3,550
5.3 Bank overdrafts	0	0
5.4 Other (provide details)	0	0
<b>5.5 Cash &amp; cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>3,287</b>	<b>4,548</b>
<b>6. Payments to related parties of the entity &amp; their associates</b>		<b>Current Quarter</b>
		<b>(\$A,000)</b>
6.1 Aggregate amount of payments to related parties and their associates included in item 1		141
6.2 Aggregate amount of payments to related parties and their associates included in item 2		0
<p>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</p> <p style="padding-left: 40px;">Payments at 6.1 relate to normal remuneration of Non-Executive and Executive Directors</p>		

<b>7. Financing facilities available</b>	<b>Total facility amount at quarter end</b>	<b>Amount drawn at quarter end</b>
<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>	<b>\$A'000</b>	<b>\$A'000</b>
7.1 Loan facilities	0	0
7.2 Credit standby arrangements	0	0
7.3 Other (please specify)	0	0
<b>7.4 Total financing facilities</b>	<b>0</b>	<b>0</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>0</b>
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		
<b>8. Estimated cash outflows for next quarter</b>		
		<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (see 1.9 above)		(1,277)
8.2 Cash and cash equivalents at quarter end (Item 4.6)		3,287
8.3 Unused financing facilities available at quarter end (Item 7.5)		0
8.4 Total available funding (Item 8.2 + Item 8.3)		3,287
<b>8.5 Estimated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)</b>		<b>2.6</b>
<p>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise a figure for the estimated quarters of funding available must be included in item 8.5.</p> <p>8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:</p> <p>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?</p> <p>Answer:</p>		
<p>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?</p> <p>Answer:</p>		
<p>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?</p> <p>Answer:</p>		
<p>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.</p>		



## 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 April 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.