



# Proteomics International

LABORATORIES LTD

ASX Release  
23 January 2024

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 2023 and subsequent to the period end.

- **US Medicare confirms reimbursement price for PromarkerD:** Major milestone achieved with Proteomics International's predictive test for diabetic kidney disease assigned a payment rate of US\$390.75 which became effective 1 January 2024
- **PromarkerD to be available in Chile:** Expanded deal with established partner Omics Global Solutions extends reach in Central and South America
- **R&D tax incentive funding:** Company's cash reserves further strengthened by \$1.85 million government rebate
- **KOL engagement and PIQ in the media:** Proteomics International's team attended several important conferences, whilst the Company's diagnostic pipeline continues to attract media attention with new interviews on the importance of early screening for the chronic diseases of endometriosis and oesophageal cancer

### 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) Precision diagnostic tests in development - the Promarker™ pipeline
- (iii) Specialist accredited analytical services on a commercial basis

#### i) Commercialisation of PromarkerD

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##### **US Medicare confirms reimbursement price for PromarkerD**

[ASX: 22 November] The US Centers for Medicare & Medicaid Services (CMS) published its final determination of the national reimbursement price in the United States for the PromarkerD predictive test for diabetic kidney disease.

CMS is a federal agency that provides health coverage to more than 100 million Americans through Medicare and Medicaid. The reimbursement rate set by CMS applies to all patients accessing government-funded healthcare in the United States.

CMS is the single largest payer for health care in the United States, with Medicare and Medicaid collectively responsible for 42 per cent<sup>1</sup> of healthcare spending. Many private payers also follow CMS pricing. CMS assigned a payment rate of US\$390.75 for PromarkerD [ASX: 29 September], which is to

<sup>1</sup> <https://www.kff.org/mental-health/issue-brief/10-things-to-know-about-medicaid/>

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be delivered through Sonic Healthcare USA [ASX: 10 May]. The rate became effective on 1 January 2024.

### **PromarkerD to be available in Chile in expanded deal with Omics Global Solutions**

[ASX: 20 December] Proteomics International signed a licence agreement to expand PromarkerD's reach in Central and South America. The deal with established partner Omics Global Solutions will see the predictive test for diabetic kidney disease made available in the Republic of Chile, which is home to 1.7 million adults with diabetes. Almost one in eight adults in Chile have diabetes, where the number of people with the condition has risen almost 50 per cent in the past ten years<sup>2</sup>.

The licence with Omics is for five years, extendable by mutual agreement, and exclusive to Chile. The licence agreement also includes commercially agreed royalties based on sales of the test, which Omics manufactures under licence.

The test will initially be targeted at Chile's private payer market. Omics is also targeting expansion into other markets in Central and South America.

### **PromarkerD – Outlook 2024 (US and RoW)**

The US, as the world's largest healthcare market, remains Proteomics International's primary focus for sales of PromarkerD. Sonic Healthcare USA has an exclusive licence for the use and commercialisation of the test in the United States (ASX: 10 May 2023). Sonic Healthcare USA is primarily responsible for the marketing, promotion and sales of the test, and under the agreement there are timelines for key events to be achieved. Critical to this process is the recently announced milestone of reimbursement pricing. Both parties are continuing to work towards completing the technical and commercial requirements for a national launch of the test in Q2 2024. This can also be influenced by events outside of the control of the parties including challenges in global supply chains for equipment and materials, and of availability of suitably qualified staff. Proteomics International will receive a royalty on each test sold.

Proteomics International is also pleased to advise that it continues to advance its discussions with a range of potential partners to provide PromarkerD to patients with type 2 diabetes in new markets across the globe. The Company's current focus for these activities is Europe where PromarkerD is CE Mark registered and there are 61 million adults with diabetes.

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) Precision diagnostic tests in development – the Promarker™ pipeline and iii) Analytical services**

Proteomics International has a deep pipeline of novel precision health and predictive diagnostic tests in development. This R&D is enabled by the Company's proprietary biomarker discovery platform called Promarker, which searches for protein 'fingerprints' in a sample. This disruptive technology can identify proteins that distinguish between people who have a disease and people who do not, using only a simple blood test. It is a powerful alternative to genetic testing. The technology is so versatile it can be used to identify fingerprints from any biological source, from wheat seeds to human serum. The Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical and commercial needs.

### **Key Opinion Leader (KOL) engagement**

During the quarter Proteomics International was represented at several major industry, academic and professional conferences, including: the American Society of Nephrology Kidney Week (presentation on the economic health benefit of predictive testing for DKD); UK Diabetes Professional Care Annual Event (trade booth and KOL panel on DKD and clinical benefits of early detection); KDIGO (Kidney Disease: Improving Global Outcomes) Controversies Conference (invitation only

<sup>2</sup> International Diabetes Federation Diabetes Atlas 10th edition, 2021

forum on maintaining kidney health and preventing CKD); and AusBiotech Life Science Conference (focus on analytical services and pharmacokinetic testing). These events all serve to meet the Company's objective of engaging with potential users of its technology to drive awareness, adoption and uptake of its novel diagnostic tests.

#### **Diagnostics – Outlook 2024**

Proteomics International's R&D pipeline is focused on progressing clinical validation work for its tests for endometriosis and oesophageal adenocarcinoma. The primary next step towards commercialisation for both tests is confirming their clinical performance in additional independent patient cohorts [Endometriosis - ASX: 5 May 2023; Oesophageal cancer - ASX: 20 July 2023]. Results from new studies are expected in early-mid CY24.

*Esophageal Cancer*

PromarkerEso

*Endometriosis*

PromarkerEndo

*Diabetic Kidney Disease*

PromarkerD

Additional diagnostic tests in development include diabetic retinopathy, asthma & COPD, oxidative stress, and plant dieback. Proteomics International looks forward to providing updates on these tests as new results are achieved through CY24.

#### **Analytical Services – Outlook 2024**

The Company anticipates steady demand for its analytical services during the course of 2024 and is looking forward to updating the market as and when agreements are entered into.

#### **FORTHCOMING EVENTS**

During the next quarter, Proteomics International will attend the following conferences:

1. Lorne Proteomics Conference; 31 January-3 February, Lorne, Victoria
2. Euroz Hartleys Healthcare Forum; 6 February, Perth
3. BioAsia 2024; 26-28 February, Hyderabad, India

#### **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 make optimum use of its resources.

#### **Proteomics International in the media**

There is growing awareness in Australia of the enormous challenges being posed by chronic diseases and the importance of early screening to detect them. Both the PromarkerEndo and PromarkerEso diagnostics tests have received media coverage with interviews on Channel 7 News, and ABC and 2GB Radio<sup>3</sup>.

<sup>3</sup> [www.proteomics.com.au/newsroom/inthemedial/media-coverage/](http://www.proteomics.com.au/newsroom/inthemedial/media-coverage/)

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### **Proteomics International receives \$1.85 million in R&D tax incentive**

[ASX: 9 November] Proteomics International's cash reserves were further strengthened by the receipt of \$1.85 million in research and development tax incentive for the 2022-23 financial year. Proteomics International spent \$4.25 million on R&D during the year, enabling the company to receive an Australian Government rebate of \$1,848,832. The tax incentive encourages companies engaging in beneficial research to Australia by providing a cash rebate of 43.5% for qualifying activities.

### **Revenue & Expenditure**

Proteomics International achieved cash receipts from customers for the December quarter of \$209,000 (September quarter: \$201,000). The net operating cash inflow for the December quarter was \$0.4 million (cash outflow in September quarter: \$1.7 million) following the receipt of the R&D tax incentive rebate of \$1.85m. Expenditure centred on the following areas:

- Business development and commercialisation costs for the rollout of PromarkerD.
- Manufacturing costs for the PromarkerD immunoassay, successfully producing reagents to meet supply needs for the next six months.
- Regulatory and reimbursement activities to support PromarkerD commercialisation, successfully achieving an assigned payment rate of US\$390 from CMS.
- R&D for projects in the Promarker™ diagnostics pipeline.

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

Payments at item 6.1 of Appendix 4C of \$158,000 relate to normal remuneration of Executive and Non-Executive Directors.

### **Cash position**

At 31 December, the Company had cash reserves of \$4.97 million (30 September: \$4.91 million).

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.

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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 December 2023</b>

<b>Consolidated statement of cash flows</b>	<b>Current Quarter \$A'000</b>	<b>Year to date \$A'000</b>
<b>1. Cash flows related to operating activities</b>		
1.1 Receipts from Customers	209	410
1.2 Payments for		
(a) research & development	(646)	(1,331)
(b) product manufacturing & operating costs	(131)	(303)
(c) advertising & marketing	(40)	(195)
(d) leased assets	0	0
(e) staff costs	(708)	(1,442)
(f) administration & corporate costs	(253)	(542)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	60	122
1.5 Interest & other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	1,849	1,849
1.8 Other (provide details if material)	32	78
<b>1.9 Net cash from / (used in) operating activities</b>	<b>372</b>	<b>(1,354)</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	(375)	(378)
(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	15	15
(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>(360)</b>	<b>(363)</b>

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<b>Consolidated statement of cash flows</b>	<b>Current Quarter</b>	<b>Year to date</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	625
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	0	(6)
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)	41	41
<b>3.10 Net cash from / (used in) financing activities</b>	<b>41</b>	<b>660</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash & cash equivalents at beginning of period	4,917	6,027
4.2 Net cash from / (used in) operating activities (see 1.9 above)	372	(1,354)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(360)	(363)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	41	660
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>4,970</b>	<b>4,970</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	1,213	235
5.2 Cash deposits	3,757	5,792
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>4,970</b>	<b>6,027</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		158
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>Payments at 6.1 relate to normal remuneration of Executive and Non-Executive Directors.</p>		

<b>7. Financing facilities available</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</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>		
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>		
8.1 Net cash from / (used in) operating activities (see 1.9 above)		372
8.2 Cash and cash equivalents at quarter end (Item 4.6)		4,970
8.3 Unused financing facilities available at quarter end (Item 7.5)		0
8.4 Total available funding (Item 8.2 + Item 8.3)		4,970
<b>8.5 Estimated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)</b>		<b>N/A</b>
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.		

## 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: 23 January 2024

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.