



# Proteomics International

LABORATORIES LTD

ASX Release

24 July 2023

ASX code: PIQ

## Quarterly Activities Report and Year Ahead

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 its business activities for the three months to 30 June 2023 and subsequent to the period end.

- **Exclusive licence agreement to take PromarkerD to the US market:** Proteomics International and Sonic Healthcare USA sign deal to bring test for diabetic kidney disease to the United States
- **New diagnostic blood test showcased at world's premier endometriosis conference:** Research indicating strong diagnostic performance of potential new blood test presented at 15<sup>th</sup> World Congress on Endometriosis
- **Drug treatment shown to lower PromarkerD diabetic kidney disease risk prediction scores:** Research published in international peer-reviewed *Journal of Clinical Medicine*
- **Clinical Advisory Board expanded to support PromarkerD USA and global rollout:** New members comprise highly respected healthcare professionals and key opinion leaders (KOLs) specialising in primary care diabetes education and management
- **Renewal of ISO 13485 certification and ISO 17025 accreditation:** Global laboratory accreditations to benefit launch of PromarkerD, analytical services and pipeline of novel diagnostics
- **PromarkerD continues to progress towards US reimbursement:** Substantial progress towards reimbursement pricing and approval

The Company is also pleased to provide guidance on its expected activities in key areas for FY24:

- **PromarkerD target markets**
- **New developments in the Promarker pipeline**
- **Target milestones FY24**

### 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

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## i) Commercialisation of PromarkerD

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### **Proteomics International and Sonic Healthcare USA sign exclusive licence agreement to take PromarkerD to the US market**

[ASX: 10 May] Proteomics International achieved a landmark milestone with the signing of an exclusive licence agreement with Sonic Healthcare USA to commercialise the PromarkerD test for diabetic kidney disease in the United States. Under the agreement, Sonic Healthcare USA will offer PromarkerD to physicians and healthcare systems through its client engagement teams across the US.

The agreement followed several months of work by both companies towards the roll-out of PromarkerD in the US. *“In signing with Sonic Healthcare USA, we believe we have an ideal partner to bring our PromarkerD technology to the world’s premier healthcare market, potentially benefiting millions of patients with diabetes,”* said Proteomics International managing director Dr Richard Lipscombe. *“The US is one of our key addressable markets and we expect this partnership to significantly increase the reach and adoption of PromarkerD”.*

Sonic Healthcare USA’s Chief Medical Officer Dr. Mohamed Salama said the PromarkerD test is an important prognostic tool that will substantially advance diagnostic offerings for the diabetic population, and he was looking forward to a fruitful partnership with Proteomics International.

The licence with Sonic Healthcare USA is initially for five years, extendable by mutual agreement, and exclusive to the United States (excluding Puerto Rico). In the United States, an estimated 32 million people, or 11 per cent of the population, live with diabetes. PromarkerD is currently a featured test on the Sonic Reference Laboratory website<sup>1</sup>, and the companies are working towards a soft launch of the test in Q4 CY23, followed by a full US market launch upon successful Centers for Medicare and Medicaid Services (CMS) coverage publication (outlined further below).

### **Drug treatment shown to lower PromarkerD diabetic kidney disease risk prediction scores**

[ASX: 3 May] Proteomics International announced research showing a significant reduction in the PromarkerD risk scores of patients with type 2 diabetes after taking the diabetes medicine canagliflozin, an SGLT2-inhibitor class drug (SGLT2-inhibitors are a widely used diabetes drug, now also indicated for the treatment of diabetic kidney disease). The results were published as a feature article in the international peer-reviewed *Journal of Clinical Medicine*.

The study was conducted as part of a long-running collaboration between Proteomics International and Janssen Research & Development, the pharmaceutical arm of Johnson & Johnson [ASX: 31 March 2020]. The research found the average PromarkerD risk score of patients taking canagliflozin dropped during the trial, while the average risk score of patients taking a placebo rose. The effect was greatest in participants who were identified by PromarkerD to be at high-risk of a decline in kidney function at the start of the study.

### **Clinical Advisory Board expanded to support PromarkerD USA and global rollout**

[ASX: 26 April] As reported in the March quarterly update, Proteomics International has appointed additional key opinion leaders (KOLs) to its world class PromarkerD Clinical Advisory Board. The new board members comprise highly respected healthcare professionals specialising in primary care diabetes education and management in the United States. These KOLs will be able to provide tailored advice from the 'voice of the customer' (patients and clinicians) perspective on the rollout of PromarkerD.

### **PromarkerD continues to progress towards US reimbursement**

As announced previously, PromarkerD has been assigned a unique Current Procedural Terminology

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<sup>1</sup> [www.sonichealthcareusa.com](http://www.sonichealthcareusa.com)

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(CPT) Proprietary Laboratory Analyses (PLA) code that became effective in April [ASX: 3 January, 26 April]. Substantial progress towards reimbursement pricing and approval continues to be made:

Date	Activity	Status
Jan 2023	Unique CPT Proprietary Laboratory Analysis (PLA) code approved	Complete
Apr 2023	Centers for Medicare and Medicaid Services (CMS) posts updated code list. PLA code (0385U) for PromarkerD effective	Complete
May 2023	American Clinical Lab Association engaged by SHUSA to consider crosswalk or gapfill pricing	Complete
Jun 2023	CMS Clinical Lab Fee Schedule (CLFS) Annual Meeting to consider pricing	Complete
Sep 2023	CMS proposed pricing determinations published for comment	Pending
Jan 2024	CMS final pricing published	Pending

The establishment of CMS pricing is an essential component of coverage and reimbursement of PromarkerD by the US private payor market.

#### **Rest of World target markets for PromarkerD in FY24**

Building on the momentum of the licence for the United States, Proteomics International is now targeting licensing deals in the major European markets, where PromarkerD is already CE Mark registered. The Company is also pursuing Australian home market usage, noting the Promarker test was submitted to the TGA for approval in mid 2022 [ASX: 2 June 2022] and the Company anticipates receiving a decision in 1H FY24. TGA approval has already been secured for the PromarkerD software as an in vitro diagnostic (IVD) for export use [ASX: 29 July 2019]. Other countries of interest include Japan, Hong Kong and the Middle East, reflecting their importance as gateway markets or regions with high incidence of diabetes.

Proteomics International continues to develop its partnerships in the UK, Israel and Puerto Rico/Dominican Republic (See Annual Report 2022). Following publication of PromarkerD in a UK National Institute for Health & Care Excellence (NICE) Medtech Innovation Briefing “NICE Advice” [ASX: 14 Dec 2022], the Company is pursuing the test being included in the NICE Guidelines which will facilitate the countrywide roll out of PromarkerD in the UK.

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. Proteomics International believes its Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical and commercial needs.

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## DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



During the quarter, Proteomics International introduced new projects to its pipeline whilst continuing to progress its endometriosis, oesophageal cancer and oxidative stress diagnostics towards the commercialisation phase:

### New diagnostic blood test showcased at world's premier endometriosis conference

[ASX: 5 May] Proteomics International presented its potential new blood test for endometriosis at the 15<sup>th</sup> World Congress on Endometriosis, held in Edinburgh, Scotland. Endometriosis is a common and painful disease that affects one in ten women and girls, often starting in teenagers, and takes an average of 7.5 years to diagnose. At the moment, there is no simple way to test for the condition, which can cause pain and infertility, and in the UK alone, is estimated to cost the UK economy £8.2 billion a year in treatment, loss of work and healthcare related costs<sup>2</sup>.

The research presented at the conference indicates the strong diagnostic performance of the test, with the Company's preferred prototype correctly identifying up to 90% of patients when comparing moderate or severe endometriosis to symptomatic controls (no endometriosis) in a study of more than 901 participants [ASX: 24 March 2023]. The endometriosis test is being developed in collaboration with the Royal Women's Hospital and the University of Melbourne [ASX: 4 August 2021]. Proteomics International believes a validated endometriosis test will garner significant interest, both commercially and in the clinic.

### New developments in the Promarker pipeline

Proteomics International has been invited to present the latest results for its novel blood test for oesophageal adenocarcinoma at upcoming World Congress for Esophageal Diseases in Toronto, Canada. The Company has also signed an agreement to access additional patient samples from the Victorian Cancer Biobank, which will enable further external validation of the accuracy of the test [ASX: 20 July].

Proteomics International previously announced it was to become an industry partner to the Australian Centre for Accelerating Diabetes Innovations (ACADI) [ASX: 27 January 2022]. The Centre combines diabetes expertise from across Australia and aims at improving the lives of people living with diabetes. Following finalisation of contract terms and project plans Proteomics International is pleased to add a new R&D program to investigate predictive markers for diabetic neuropathy. The

<sup>2</sup> [www.endometriosis-uk.org/endometriosis-facts-and-figures](http://www.endometriosis-uk.org/endometriosis-facts-and-figures)

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Company will also explore the applicability of PromarkerD to patients with type 1 diabetes (in addition to its current use in type 2 diabetes).

OxiDx P/L, a majority owned subsidiary of Proteomics International, continues to develop commercial applications of its unique intellectual property to measure oxidative stress. OxiDx P/L was launched last year [ASX: 29 August 2022] to unlock the value from the 2-tag technology developed by Proteomics International in collaboration with the University of Western Australia. Proteomics International looks forward to providing detailed updates on OxiDx and its technology as the year progresses.

The other projects in the Promarker™ pipeline are at the proof of concept or early validation stage, whilst the Giardia project is currently on hold pending a review of its commercial and technical viability. The Company expects to make progress announcements about each diagnostic test in the year ahead.

### **Proteomics International renews its ISO 13485 certification and ISO 17025 accreditation**

Proteomics International proudly received the world's first ISO 17025 accreditation for proteomics services in 2009, and today operates one of the world's most accredited protein testing laboratories. [ASX: 17 April] The National Association of Testing Authorities (NATA) approved the continuation of Proteomics International's ISO 17025 accreditation, a global standard that ensures a laboratory is technically competent and produces accurate, valid and reliable results.

The British Standards Institution (BSI) also renewed Proteomics International's ISO 13485 certification, which ensures safety and quality management in the design, development, manufacture and sale of medical devices.

Both renewals continue to benefit the global product launch of PromarkerD, and underpin the Company's analytical services and pipeline of innovative diagnostic tests under development.

### **FORTHCOMING EVENTS**

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

1. General Practice Conference & Exhibition; 22-23 July, Perth, Western Australia
2. 17<sup>th</sup> Bioshares Biotech Summit, 24-25 July, Hobart, Tasmania
3. Australian Diabetes Congress; 23-25 August, Adelaide, South Australia
4. 19<sup>th</sup> ISDE World Congress (International Society for Diseases of the Esophagus); 8-10 September, Toronto, Canada

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

#### **Revenue & Expenditure**

Proteomics International achieved cash receipts from customers for the June quarter of \$198,000 (March \$187,000). The net operating cash outflow for the June quarter was \$2.2 million (March quarter outflow \$1.7m). Expenditure centred on the following areas:

- Business development and commercialisation costs for the rollout 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

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### Exercise of options

[ASX: 1 May] Additional funds were received following the exercise of employee options raising \$112,000 before costs.

### ASX Listing Rule 4.7C

Payments at item 6.1 of Appendix 4C of \$146,000 relate to normal remuneration of Executive and Non-Executive Directors.

### Cash position

At 30 June 2023 the Company had cash reserves of \$6.03 million (March \$8.08 million). These reserves will be strengthened by a forecast R&D tax incentive rebate of circa \$1.8 million to be received in the 1H FY24.

### TARGET MILESTONES FY24

Proteomics International is anticipating multiple potential share price catalysts for FY24. The timing for announcement of the next milestones across multiple target areas are shown below:

Milestone	Qtr	Sep	Dec	Mar	Jun	Impact
<b>PromarkerD</b>						
First Sales in USA						Initiate pathway to significant revenues
CMS Reimbursement Pricing Set						Supports broad adoption of test
Regulatory Submissions, Approvals & Reimbursement RoW						Build user confidence in product & assist in global roll-out
Licensing Deals in RoW						Drive global uptake and future revenue
<b>Promarker™</b>						
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)
<b>Analytical Services</b>						
New Contracts						Engages potential future partners & enhances revenue profile

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>30 June 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	198	1,748
1.2 Payments for		
(a) research & development	(1,170)	(4,519)
(b) product manufacturing & operating costs	(192)	(710)
(c) advertising & marketing	(129)	(290)
(d) leased assets	0	0
(e) staff costs	(731)	(2,708)
(f) administration & corporate costs	(367)	(1,362)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	57	110
1.5 Interest & other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	140	2,005
1.8 Other (provide details if material)	0	0
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,194)</b>	<b>(5,726)</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	(4)	(1,218)
(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	53	53
(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	(20)	(32)
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>29</b>	<b>(1,197)</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)	112	11,513
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	(674)
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>112</b>	<b>10,839</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash & cash equivalents at beginning of period	8,080	2,111
4.2 Net cash from / (used in) operating activities (see 1.9 above)	(2,194)	(5,726)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	29	(1,197)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	112	10,839
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>6,027</b>	<b>6,027</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	235	1,868
5.2 Cash deposits	5,792	6,212
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>6,027</b>	<b>8,080</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		146
6.2 Aggregate amount of payments to related parties and their associates included in item 2		20
<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 Non-Executive and Executive Directors</p> <p>Payments at 6.2 relate to payments to OxiDx Pty Ltd of which Proteomics International Laboratories Limited owns 67%</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)		\$A'000 (2,194)
8.2 Cash and cash equivalents at quarter end (Item 4.6)		6,027
8.3 Unused financing facilities available at quarter end (Item 7.5)		0
8.4 Total available funding (Item 8.2 + Item 8.3)		6,027
<b>8.5 Estimated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)</b>		<b>2.7*</b>
<i>*Excludes R&amp;D tax incentive rebate of circa \$1.8 million expected to be received in the December quarter.</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: 24 July 2023

Authorised by: The Board  
(Name the body or officer authorising release - see note 4)

### Notes

1. The quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entities activities for the past quarter, how they have been financed and the effect this has had on the cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of AASB 107: Statement of Cash Flows apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee-eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.