

ASX Release 17 April 2024

**ASX code: PIQ** 

# **Quarterly Activities Report**

Proteomics International Laboratories Ltd (Proteomics International; the Company; ASX: PIQ), a pioneer in predictive diagnostics is pleased to provide the following update on its business activities for the three months to 31 March 2024.

- **Institutional Placement raises A\$6.5m:** Placement to new and existing institutional investors added global reach to the share register and strengthened Company balance sheet
- **Update on commercialisation of PromarkerD in the USA:** Work is continuing toward a national launch of PromarkerD, the predictive blood test for diabetic kidney disease (DKD), in the USA
- Latest results validate biomarkers for PromarkerEndo blood test for endometriosis: Critical milestone achieved for PromarkerEndo with biomarker panel clinically validated in an independent patient group
- Agreement signed with University of Oxford to validate PromarkerEndo test for endometriosis:
   Proteomics International to acquire 600 patient plasma samples for further clinical validation of its diagnostic blood test
- Latest results validate biomarkers for PromarkerEso blood test for oesophageal adenocarcinoma: Critical milestone achieved for PromarkerEso, with biomarker panel clinically validated in second independent patient group
- Proteomics International retains its ISO 13485 certification: international standard recognises safety and quality management systems in the manufacture of medical devices, such as PromarkerD
- European patent granted for OxiDx technology: Proteomics International's subsidiary OxiDx Pty Ltd granted a patent in 19 major European countries for its platform technology to measure oxidative stress using a simple fingerprick blood test



**Proteomics International Laboratories Ltd** 

#### **OPERATIONAL HIGHLIGHTS**

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 PromarkerEndo, PromarkerEso, OxiDx and the Promarker™ pipeline
- (iii) Specialist accredited analytical services on a commercial basis

#### i) Commercialisation of PromarkerD

#### Update on launch of PromarkerD in the USA

[ASX: 18 March] Proteomics International advised that the USA launch of PromarkerD previously planned for Q2 2024, is now likely to be delayed. The Company continues to engage with its USA licensee, Sonic Healthcare USA [ASX: 10 May 2023] and will provide further updates to the market, as and when information becomes available.

#### PromarkerD - Outlook RoW

The Company remains focused on executing further licensing and distribution deals for the PromarkerD test in new jurisdictions and is currently in discussions with a number of parties. The Company's current focus for these activities is Europe, where PromarkerD is CE Mark registered and there are over 61 million adults with diabetes<sup>1</sup>.

#### Proteomics International retains its ISO 13485 certification

[ASX: 6 March] Proteomics International successfully retained its ISO 13485 certification, a globally recognised standard for safety and quality management systems in the manufacture of medical devices and diagnostic tests. The certification's primary purpose is to ensure patient safety is the priority. Recertification is valid for three years and will underpin future global sales of PromarkerD, and also benefit Proteomics International's pipeline of innovative diagnostic tests under development.

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) 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 plasma. The Promarker™ platform has broad applicability and the potential to produce multiple new diagnostic tests to address significant unmet medical and commercial needs.

During the quarter, Proteomics International's R&D focused on progressing clinical validation work for its tests for endometriosis (PromarkerEndo) and oesophageal cancer (PromarkerEso). In parallel, the Company is refining the technology platforms used for these tests in preparation for commercialisation, aiming to produce tests readily adaptable to clinical laboratory use.

For its potential new diagnostic tests, the Company is targeting early adoption routes that utilise the ISO 15189 international standard or the US Laboratory Developed Test (LDT) pathway for CLIA certified clinical laboratories. Experience gained from the commercialisation of PromarkerD has provided the Company with invaluable knowledge and experience to accelerate the

\_

<sup>&</sup>lt;sup>1</sup> International Diabetes Federation 2021

commercialisation of its tests in development.

#### Latest results validate biomarkers for PromarkerEndo blood test for endometriosis

[ASX: 1 February] Proteomics International achieved a critical milestone in the development of its potential breakthrough blood test for endometriosis, with the confirmation of the clinical performance of the PromarkerEndo biomarkers in an independent patient cohort. The study was performed in conjunction with the St John of God Subiaco Hospital Gynaecological Cancer Research Group [ASX: 30 June 2022], and presented at the 29<sup>th</sup> Annual Lorne Proteomics Symposium, the annual conference of the Australasian Proteomics Society.

Endometriosis is a common and painful disease that affects approximately one in seven women and girls<sup>1</sup>, often starting in teenagers (see PIQ Annual Report 2023). It occurs when tissue similar to the lining of the uterus grows in other parts of the body where it does not belong. At the moment, there is no simple way to test for the condition, which can cause pain and infertility, and costs Australia \$9.7 billion each year<sup>2</sup>.

The next step in bringing PromarkerEndo to the clinic is a larger clinical validation study to confirm the accuracy of the test (see below; ASX: 25 March).

### Agreement signed with University of Oxford to validate PromarkerEndo test for endometriosis

[ASX: 25 March] Proteomics International and the globally respected University of Oxford signed a Material Transfer Agreement to allow the Company to acquire approximately 600 patient plasma samples for further clinical validation of the PromarkerEndo diagnostic blood test. The analysis of the University of Oxford samples is expected to be completed over the next 4 months.

Proteomics International's believes an early screening test to help rule in or rule out the need for invasive surgery would be a substantial step forward to assist in the identification and subsequent management of women and girls with endometriosis.

# Latest results validate biomarkers for PromarkerEso blood test for oesophageal adenocarcinoma

[ASX: 1 February] Proteomics International also achieved a critical milestone in the development of its potential breakthrough blood test for oesophageal adenocarcinoma, with the confirmation of the clinical performance of the PromarkerEso biomarkers in a second independent patient cohort. The study was performed in conjunction with the Victorian Cancer Biobank [ASX: 23 July 2023], and presented at the 29<sup>th</sup> Annual Lorne Proteomics Symposium, the annual conference of the Australasian Proteomics Society.

Oesophageal adenocarcinoma is the most common form of oesophageal cancer and is an area of significant unmet medical need. The overall five-year survival rate for this cancer is less than 20 per cent, and 1 in 20 cancer deaths worldwide in 2018 were attributed to oesophageal cancer<sup>3</sup>. An estimated 10-15% of patients with chronic acid reflux develop Barrett's oesophagus, a condition which is asymptomatic and affects 1-2% of Western populations<sup>4</sup>.

The next step in bringing PromarkerEso to the clinic is further clinical validation studies to confirm the accuracy of the test, and the Company is in discussion with potential groups to access the required samples.

# **European patent granted for OxiDx technology**

[ASX: 28 February] Proteomics International's subsidiary OxiDx Pty Ltd was granted a European patent across 19 countries for its platform technology to measure oxidative stress, significantly expanding the intellectual property protection coverage of the unique fingerprick blood test.

Oxidative stress is implicated in over 70 health conditions, with a person's levels often reflective of health and fitness. The ability to measure oxidative stress has broad application across multiple

**Proteomics International Laboratories Ltd** 

<sup>&</sup>lt;sup>2</sup> endometriosisaustralia.org

<sup>&</sup>lt;sup>3</sup> Nature Reviews Gastroenterology & Hepatology, 2021, doi.org/10.1038/s41575-021-00419-3

<sup>&</sup>lt;sup>4</sup> American Society for Gastrointestinal Endoscopy, www.asge.org

markets including professional sports, horse racing industries and stock production, and can also serve as a complementary diagnostic (CDx) test for assessing treatment efficacy and precision medicine.

#### **Analytical Services**

The demand for analytical services remains steady, although currently at a lower level than in 2023. The Company continues to look for opportunities to grow these revenues, targeting the clinical trials sector for both pharmacokinetic testing and the development of companion/complementary diagnostics through biomarker analysis.

### **Events and Marketing**

During the quarter Proteomics International was represented at the BioAsia 2024 Summit (26-28 February), the Lorne Proteomics Symposium (31 January - 3 February), and the Pathology Technology Australia Congress (11-13 March). The Company's Head of Clinical Studies, Dr Kirsten Peters, also spoke with Phoenix Sound<sup>5</sup> (a podcast, which can be accessed via the Company's website), to discuss the future of endometriosis care and the positive impact of a diagnostic blood test for the condition.

As part of Endometriosis Awareness Month in March, Proteomics International hosted a panel discussion featuring key experts in the endometriosis sector. The discussion brought together clinicians, researchers, patients and community members to shed light on the challenges, successes, strategies, and future developments in diagnosing endometriosis. These events align with the Company's objective of actively engaging with potential users of its technology to foster awareness, adoption and uptake of its novel diagnostic tests.

#### **FORTHCOMING EVENTS**

During the next quarter, Proteomics International will be represented at the following conferences:

- Diabetes UK Professional Conference; 17-19 April, London, UK
- 15<sup>th</sup> Annual Clinical Trials Summit 2024; 29-30 May, Mumbai, India
- Bio 2024 (Biotechnology Industry Organization) International Convention; 3-6 June, San Diego, USA

#### 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.

# **Institutional Placement raises \$6.5M**

[ASX: 23 January] Proteomics International raised \$A6.5m via an institutional placement to leading institutional investors in Asia and Australia. As part of the placement Fidelity Investment Management became a substantial shareholder of PIQ [ASX: 30 January]. Funds raised from the placement are being used to commercialise the PromarkerD predictive test for DKD and fund further development of the Promarker™ diagnostics pipeline, and general working capital.

#### **Operations**

The additional resources described above, coupled with Proteomics International's increasingly broad pipeline, provide exciting new avenues for company growth. To take advantage of these

<sup>&</sup>lt;sup>5</sup> Phoenix Sound - The future of Endometriosis care

opportunities, the Company is reviewing the additional Board and Management skills and experience necessary to support acceleration of its commercialisation initiatives.

Managing Director, Dr Richard Lipscombe presented an investor update to delegates at the Euroz Hartleys 2024 Healthcare Forum [ASX: 6 February] and to Jefferies institutional clients [ASX: 28 March].

#### **Revenue & Expenditure**

Proteomics International achieved cash receipts from customers for the March quarter of \$173,000 (December quarter: \$209,000). The net operating cash outflow for the March quarter was \$1.97 million (cash inflow in December quarter: \$0.4 million). Expenditure centred on the following areas:

- R&D for projects in the Promarker<sup>™</sup> diagnostics pipeline, led by PromarkerEndo and PromarkerEso
- Acceleration of the commercialisation of PromarkerEndo and PromarkerEso
- 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

# **ASX Listing Rule 4.7C**

Payments at item 6.1 of Appendix 4C of \$160,000 relate to normal remuneration of Executive and Non-Executive Directors.

# **Cash Position**

At 31 March, the Company had cash reserves of \$9.04 million (31 December: \$4.97 million).

Authorised by the Board of 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

Lisa Barnes

Public Relations

Profile Media

T: +61 8 9389 1992 T: +61 416 583 672

E: enquiries@proteomicsinternational.com E: lisab@profilemedia.com.au

Dirk van Dissel Kyle Moss
Investor Relations & Corporate Advisor
Condour Advisor

Funda Markey

Candour Advisory Euroz Hartleys
T: +61 408 326 367 T: +61 8 9488 1400

E: dirk@candouradvisory.com.au E: kmoss@eurozhartleys.com

# **Appendix 4C**

# Quarterly report for entities subject to Listing Rule 4.7B

# Name of entity

| Prot     | eomics International Laboratories Ltd          |                                    |                         |
|----------|--|------------------------------------|-------------------------|
| ABN      |  | Quarter ending ("current quarter") |                         |
| 78 1     | 69 979 971                                     | 31 March 2024                      |                         |
| Cor      | nsolidated statement of cash flows             | Current Quarter<br>\$A'000         | Year to date<br>\$A'000 |
| 1.       | Cash flows related to operating activities     |                                    |                         |
| 1        | Receipts from Customers                        | 173                                | 583                     |
| 2        | Payments for                                   |                                    |                         |
|          | (a) research & development                     | (1,127)                            | (2,458)                 |
|          | (b) product manufacturing & operating costs    | (165)                              | (468)                   |
|          | (c) advertising & marketing                    | (51)                               | (246)                   |
|          | (d) leased assets                              | 0                                  | 0                       |
|          | (e) staff costs                                | (561)                              | (2,003)                 |
|          | (f) administration & corporate costs           | (315)                              | (857)                   |
| .3       | Dividends received (see note 3)                | 0                                  | 0                       |
| .4       | Interest received                              | 45                                 | 167                     |
| .5       | Interest & other costs of finance paid         | 0                                  | 0                       |
| .6       | Income taxes paid                              | 0                                  | 0                       |
| .7       | Government grants & tax incentives             | 0                                  | 1,849                   |
| .8       | Other (provide details if material)            | 26                                 | 104                     |
| .9       | Net cash from / (used in) operating activities | (1,975)                            | (3,329)                 |
| <u>.</u> | Cash flows related to investing activities     |                                    |                         |
| 2.1      | Payments to acquire:                           |                                    |                         |
|          | (a) entities                                   | 0                                  | 0                       |
|          | (b) businesses (see item 10)                   | 0                                  | 0                       |
|          | (c) property, plant & equipment                | 0                                  | (378)                   |
|          | (d) investments                                | 0                                  | 0                       |
|          | (e) intellectual property                      | 0                                  | 0                       |
|          | (f) other non-current assets                   | 0                                  | 0                       |
| .2       | Proceeds from disposal of:                     | 0                                  | 0                       |
|          | (a) entities                                   | 0                                  | 0                       |
|          | (b) businessess (see item 10)                  | 0                                  | 0                       |
|          | (c) property, plant & equipment                | 0                                  | 15                      |
|          | (d) investments                                | 0                                  | 0                       |
|          | (e) intellectual property                      | 0                                  | 0                       |
|          | (f) other non-current assets                   | 0                                  | 0                       |
| .3       | Cash flows from loans to other entities        | 0                                  | 0                       |
| .4       | Dividends received (see note 3)                | 0                                  | 0                       |
| .5       | Other (provide details if material)            | 0                                  | 0                       |
| .6       | Net cash from / (used in) investing activities | 0                                  | (363)                   |

ASX Listing Rules Appendix 4C (17/07/20) + See chapter 19 of the ASX Listing Rules for defined terms

| Con        | solidated statement of cash flows   | <b>Current Quarter</b> | Year to date    |
|------------|---|------------------------|-----------------|
|            |   | \$A'000                | \$A'000         |
| 3.         | Cash flows from financing activities  |                        |                 |
| 3.1        | Proceeds from issues of equity securities (excluding convertible debt securities)                               | 6,504                  | 6,504           |
| .2         | Proceeds from issue of convertible debt securities  | 0                      | 0               |
| 3.3        | Proceeds from exercise of options   | 0                      | 625             |
| .4         | Transaction costs related to issues of equity securities or   | (445)                  | (451)           |
|            | convertible debt securities   | 0                      | 0               |
| 3.5        | Proceeds from borrowings  | 0                      | 0               |
| .6         | Repayment of borrowings   | 0                      | 0               |
| .7         | Transaction costs related to loans & borrowings   | 0                      | 0               |
| 8.8        | Dividends paid  | 0                      | 0               |
| .9         | Other (provide details if material)   | (10)                   | 31              |
| 3.10       | Net cash from / (used in) financing activities  | 6,049                  | 6,709           |
|            |   |                        |                 |
| •          | Net increase / (decrease) in cash and cash  |                        |                 |
|            | equivalents for the period  |                        |                 |
| .1         | Cash & cash equivalents at beginning of period  | 4,970                  | 6,027           |
| .2         | Net cash from / (used in) operating activities (see 1.9 above)  | (1,975)                | (3,329)         |
| .3         | Net cash from / (used in) investing activities (item 2.6 above)   | 0                      | (363)           |
| .4         | Net cash from / (used in financing activities (item 3.10 above)   | 6,049                  | 6,709           |
| 1.5        | Effect of movement in exchange rates on cash held   | 0                      | 0               |
| .6         | Cash & cash equivalents at end of quarter   | 9,044                  | 9,044           |
|            | Describition of each 9 and arrivalents  |                        |                 |
| 5.         | Reconciliation of cash & cash equivalents   | Comment Occasion       | Previous Quarte |
|            | at the end of the quarter (as shown in the  | Current Quarter        |                 |
|            | consolidated statement of cash flows) to the  | \$A'000                | \$A'000         |
|            | related items in the accounts   | 706                    | 1 212           |
| 5.1        | Bank balance  | 706                    | 1,213           |
| .2         | Cash deposits   | 8,338                  | 3,757           |
| 5.3        | Bank overdrafts   | 0                      | 0               |
| 5.4<br>5.5 | Other (provide details)  Cash & cash equivalents at end of quarter  | 0                      | 0               |
|            | (should equal item 4.6 above)   | 9,044                  | 4,970           |
|            |   |                        |                 |
| <b>.</b>   | Payments to related parties of the entity & their associates  |                        | Current Quarter |
|            |   |                        | \$A,000         |
| .1         | Aggregate amount of payments to related parties and their associates included in item 1                         |                        | 160             |
| 5.2        | Aggregate amount of payments to related parties and their associates included in item 2                         |                        | 0               |
|            |   |                        |                 |
|            | any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an |                        |                 |

ASX Listing Rules Appendix 4C (17/07/20) + See chapter 19 of the ASX Listing Rules for defined terms

| Finai   | ncing facilities available  | Total facility amount | Amount draw   |  |  |
|---------|---|-----------------------|---------------|--|--|
| Note:   | the term "facility" includes all forms of financing arrangements available to the entity.   | at quarter end        | at quarter en |  |  |
| Add no  | otes as necessary for an understanding of the sources of finance available to the entity.   | \$A'000               | \$A'000       |  |  |
| 1 Loan  | facilities  | 0                     | 0             |  |  |
| 2 Credi | it standby arrangements   | 0                     | 0             |  |  |
| 3 Othe  | r(please specify)   | 0                     | 0             |  |  |
| 1 Total | financing facilities  | 0                     | 0             |  |  |
|         |   | _                     |               |  |  |
| Unus    | ed financing facilities available at quarter end  |                       | 0             |  |  |
| i Inclu | Include in the box below a description of each facility above, including the lender, interest rate, maturity  |                       |               |  |  |
| date    | date and whether it is secured or unsecured. If any additional facilities have been entered into or are   |                       |               |  |  |
| prop    | osed to be entered into after quarter end, include a note providing details of those f  | acilities as well.    |               |  |  |
| N/A     |   |                       |               |  |  |
|         |   |                       |               |  |  |
| Estin   | nated cash outflows for next quarter  |                       | \$A'000       |  |  |
| Net c   | ash from / (used in) operating activities (see 1.9 above)   |                       | (1,975)       |  |  |
| 2 Cash  | and cash equivalents at quarter end (Item 4.6)  |                       | 9,044         |  |  |
| 3 Unus  | ed financing facilities available at quarter end (Item 7.5)   |                       | 0             |  |  |
| 1 Total | available funding (Item 8.2 + Item 8.3)   |                       | 9,044         |  |  |
| 5 Estim | nated quarters of funding available at quarter end (Item 8.4 divided by Item 8.1)   |                       | 4.6           |  |  |
| 8.6.1   | 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? |                       |               |  |  |
| Answ    | Answer:   |                       |               |  |  |
| 8.6.2   | 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, where the steps and how likely does it believe that they will be successful?                         |                       |               |  |  |
| Answ    | Answer:   |                       |               |  |  |
| 8.6.3   | 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?   |                       |               |  |  |
| Answ    | 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 answer  | ed.                   |               |  |  |

# **Compliance Statement**

| 1              | This statement has been prepared in accordance with                 | n 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:          |   |  |  |
| Authorised by: |   | The Board (Name the body or officer authorising release - see note 4)      |  |

#### **Notes**

- 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".
- 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.