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**ASX Release**
**28 January 2021**

**ASX code: PIQ**

# Quarterly Activities Report

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, is pleased to provide the following update on its business activities for the three months to 31 December 2020:

- **First and second distribution agreements for PromarkerD immunoassay test:** Italy and Israel become first markets for easy-to-use, high volume technology platform
- **Licence/Distribution discussions for PromarkerD Immunoassay continue:** Proteomics International is in discussions with various prospective partners and continues to receive significant inbound interest for PromarkerD
- **PromarkerD validation and clinical performance results published:** Key Opinion Leader (KOL) engagement has continued with the publication of three studies in internationally peer-reviewed journals *Clinical Proteomics*, *Proteomes* and the *Journal of Clinical Medicine*
- **Regulatory and reimbursement pathways pursued:** the Company is actively engaged with a number of regulatory/reimbursement bodies in a number of jurisdictions
- **Partnership with QIMR Berghofer Institute to target oesophageal cancer:** collaboration to develop a simple blood test to expand the Promarker™ diagnostics pipeline
- **Heavily-oversubscribed Placement raises $6 million:** new UK and Australia-based institutions join the Company's share register
- **Proteomics receives $1.1 million in R&D tax incentive:** cash reserves boosted by Australian Government rebate

## OPERATIONAL HIGHLIGHTS

Proteomics International's activities fall into three key areas:

(i) commercialisation of PromarkerD
(ii) R&D for new diagnostic tests using the Promarker™ pipeline
(iii) analytical services on a commercial basis

### (i) Commercialisation of PromarkerD

**First distribution agreements for PromarkerD immunoassay test**

[ASX: 16 October, 12 November] Italy and Israel became the first markets for the easy-to-use immunoassay version of the PromarkerD test for diabetic kidney disease. As reported in the September quarterly update, Proteomics International signed a distribution licensing agreement with innovative medical distributor Medical Horizons SRL in October to bring PromarkerD (IA) to patients in Italy. The country is home to 3.7 million people with diabetes, or one in 12 adults.

Medical Horizons have completed registration of PromarkerD with the Italian Ministry of Health and are now engaged with a number of Italian Key Opinion Leaders for early adoption of the test by major hospitals.

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In November, Proteomics International appointed Zotal Ltd as the exclusive distributor for PromarkerD in Israel, a country recognised as a global leader in the life-science industry and renowned for its early adoption of cutting-edge medical technologies. One in eight adults in Israel has diabetes, and the disease is the country's fifth leading cause of death.

Zotal will now complete product registration and reimbursement applications for PromarkerD with the Israeli Department of Medical Devices, Ministry of Health and engage with Israeli Key Opinion Leaders for the promotion and early adoption of the test by major hospitals.

Both distribution agreements are for two years, exclusive to their respective countries and exclusive to PromarkerD (IA). Proteomics International will receive payment for each kit sold. As for any novel test, market penetration cannot be predicted accurately, hence for the new licences it is not possible to quantify the financial impact on Proteomics International in any given timeframe.

**PromarkerD validation and clinical performance results published**

[ASX: 12 October, 5 November] An international validation study and additional clinical assay performance results for the PromarkerD test were published in three peer-reviewed scientific journals. As advised in the previous quarterly update, the findings of a global multi-centre clinical study confirming the effectiveness of PromarkerD as a predictive test for diabetic kidney disease were published in the *Journal of Clinical Medicine.* The paper was the first external validation study of PromarkerD, and was jointly authored by Proteomics International, The University of Western Australia Medical School and Janssen Research and Development.

The publication of PromarkerD clinical results in major scientific journals is a key component of the Company's strategy to engage with Key Opinion Leaders (KOLs). Clinical practitioners and industry partners rely on the peer-reviewed system to prove the utility of novel tests such as PromarkerD.

Two further studies demonstrating the robust technical performance of the test were published in the journals *Clinical Proteomics* and *Proteomes*. The results form an essential basis for further regulatory approvals of the PromarkerD test system and its adoption by pathology laboratories worldwide.

**Roll-out of a novel chronic disease diagnostic test during a global pandemic**

The necessity for clinical pathology laboratories to focus testing on the SARS-CoV-2 virus has naturally restricted testing for other diseases. This has presented limitations for the immediate roll-out of the novel PromarkerD test, and there have been impacts in each country (Spain, Mexico, Dominican Republic, Italy, Israel) where Proteomics International has a licence or distribution agreement.

Proteomics International believes that there is strong, pent-up demand for screening for major diseases neglected during the pandemic, including diabetes and its complications such as chronic kidney disease. Diagnostics companies will also be strongly positioned with additional testing capacity, alongside a community now more aware of the importance of early testing for disease.

Taken together, this has provided the opportunity for Proteomics International to prepare PromarkerD so that it is market ready as the pandemic comes under control. To this end Proteomics International is in discussions for the manufacture of PromarkerD to be relocated to the northern hemisphere, and is pursuing regulatory and reimbursement pathways in a number of jurisdictions. The Company will adjust timelines and provide details where they are material to achieving roll-outs in a specified time period.

# Definitions:

"Promarker" - the proprietary technology used to discover and evaluate proteins for use as diagnostics
"PromarkerD/PromarkerD test system" - the patented predictive diagnostic test for Diabetic Kidney Disease
"PromarkerD (MS)" - the predictive diagnostic test for Diabetic Kidney Disease using Mass Spectrometry
"PromarkerD (IA)" - the predictive diagnostic test for Diabetic Kidney Disease using ImmunoAssay
"PromarkerD Hub" - the proprietary software tool used to calculate the risk of Diabetic Kidney Disease in diabetes patients

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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) Diagnostics & (iii) Analytical Services

**Partnership with QIMR Berghofer Institute to target oesophageal cancer**

[ASX: 9 October] As reported in the September quarterly update, Proteomics International has joined forces with QIMR Berghofer Medical Research Institute (QIMR Berghofer) to improve detection of oesophageal adenocarcinoma, the most common form of oesophageal cancer in Australia. The collaboration is part of Proteomics International's strategy to continually expand its diagnostics portfolio to target commercial opportunities in areas of significant unmet need.

**Promarker™ pipeline advances**

Important for the future commercial application of potential new Promarker™ derived biomarkers, the above PromarkerD assay performance studies also illustrate the potential for adoption of Proteomics International's Promarker™ mass spectrometry diagnostics platform in future clinical practice. The Company has positioned its R&D arm at the forefront of this technological approach, which has the potential to overtake current immunoassay technology and assume mainstream use in clinical pathology laboratories. Exemplifying this, the *Clinical Proteomics* publication [ASX: 5 November] is one of the first validations of a proteomics derived multi-biomarker diagnostic test in a clinical setting.

Several diagnostics projects in the Promarker™ pipeline are at pivotal stages in their development. Proteomics International is engaged with a number of global partners and collaborators who have been affected by the Covid-19 pandemic, and this has slowed progress on some fronts. Nonetheless, the Company does not consider any delays to be material and it will continue to provide updates on its diagnostics pipeline as milestones are achieved, with a number of significant milestones expected to occur in the current and subsequent quarters.

## FINANCIAL HIGHLIGHTS

Proteomics International's business model is to continue the commercialisation of PromarkerD whilst using its Promarker™ technology platform to create a pipeline of novel diagnostic tests, and offset the cash burn from R&D and product development through its analytical services revenue, coupled with the R&D tax incentive rebate. This diversified model has shown its strength in the current economic climate and enables the group to continue to make optimum use of its resources.

Proteomics International achieved receipts from customers for the December quarter of $186,000 (September quarter: $543,000). Receipts continue to be driven by revenue from analytical services.

The net operating cash inflow for the December quarter was $205,000 (September outflow $624,000). Expenditure was in line with budget and centred on the following areas:

- Business development and commercialisation costs for the roll-out of PromarkerD
- Seeking a reimbursement code in the USA to support PromarkerD commercialisation, specifically, market engagement studies through specialised consultants addressing:
  - Economic Health Benefit (Payer Budget Impact study) for insurers/payers
  - Clinical Utility (Decision Impact study) for test adoption by health professionals
- Expansion of the Promarker™ diagnostics R&D pipeline

**Heavily-oversubscribed Placement raises $6 million**

[ASX: 23 October, 2 November] A successful placement brought new UK and Australia-based institutions onto the Company's share register. The heavily-oversubscribed Placement raised $6 million (before costs) and closed early due to overwhelming investor response. Funds from the

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Placement will drive the delivery of the PromarkerD test in major global markets, strengthen Proteomics International's balance sheet for future licensing negotiations, and assist in accelerating the diagnostic pipeline.

**Proteomics receives $1.1 million in R&D tax incentive**

[ASX: 3 November] The Company's cash reserves were further strengthened by the receipt of $1.1 million in research and development tax incentive. In 2019-20, Proteomics International spent $2.62 million on R&D, which enabled the company to receive an Australian Government rebate of $1,138,815 for the 2020 financial year.

**ASX Listing Rule 4.7C**

Payments at item 6.1 of the Appendix 4C of $110,000 relate to normal remuneration of Executive and Non-Executive Directors.

**Cash position**

At 31 December 2020 the Company had cash reserves of $7.54 million (September $1.74 million).

Authorised by the Board Proteomics International Laboratories Ltd (ASX.PIQ).

ENDS

**About Proteomics International Laboratories (PILL)** (www.proteomicsinternational.com)

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on Perth's QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the Company's world-leading test for diabetic kidney disease, PromarkerD. The Company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

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# Appendix 4C

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

**Name of entity**

**Proteomics International Laboratories Ltd**

| **ABN** | **Quarter ending ("current quarter")** |
|---|---|
| **78 169 979 971** | **31 December 2020** |

| **Consolidated statement of cash flows** | | **Current Quarter $A'000** | **Year to date $A'000** |
|---|---|---|---|
| **1.** | **Cash flows related to operating activities** | | |
| 1.1 | Receipts from Customers | 186 | 729 |
| 1.2 | Payments for | | |
| | (a) research & development | (689) | (1,406) |
| | (b) product manufacturing & operating costs | (65) | (127) |
| | (c) advertising & marketing | (12) | (41) |
| | (d) leased assets | 0 | 0 |
| | (e) staff costs | (216) | (440) |
| | (f) administration & corporate costs | (139) | (297) |
| 1.3 | Dividends received (see note 3) | 0 | 0 |
| 1.4 | Interest received | 1 | 4 |
| 1.5 | Interest & other costs of finance paid | 0 | 0 |
| 1.6 | Income taxes paid | 0 | 0 |
| 1.7 | Government grants & tax incentives | 1,139 | 1,159 |
| 1.8 | Other (Deferred Grant Income) | 0 | 0 |
| **1.9** | **Net cash from / (used in) operating activities** | **205** | **(419)** |
| **2.** | **Cash flows related to investing activities** | | |
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | 0 | 0 |
| | (b) businesses (see item 10) | 0 | 0 |
| | (c) property, plant & equipment | (15) | (17) |
| | (d) investments | 0 | 0 |
| | (e) intellectual property | 0 | 0 |
| | (f) other non-current assets | 0 | 0 |
| 2.2 | Proceeds from disposal of: | | |
| | (a) entities | 0 | 0 |
| | (b) businesses (see item 10) | 0 | 0 |
| | (c) property, plant & equipment | 0 | 0 |
| | (d) investments | 0 | 0 |
| | (e) intellectual property | 0 | 0 |
| | (f) other non-current assets | 0 | 0 |
| 2.3 | Cash flows from loans to other entities | 0 | 0 |
| 2.4 | Dividends received (see note 3) | 0 | 0 |
| 2.5 | Other (provide details if material) | | |
| **2.6** | **Net cash from / (used in) investing activities** | **(15)** | **(17)** |

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| Consolidated statement of cash flows | | Current Quarter $A'000 | Year to date $A'000 |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | 6,000 | 6,000 |
| 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 | (387)<br>0 | (387)<br>0 |
| 3.5 | Proceeds from borrowings | 0 | 0 |
| 3.6 | Repayment of borrowings | 0 | 0 |
| 3.7 | Transaction costs related to loans & borrowings | 0 | 0 |
| 3.8 | Dividends paid | 0 | 0 |
| 3.9 | Other (provide details if material) | 0 | 0 |
| **3.10** | **Net cash from / (used in) financing activities** | **5,613** | **5,613** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash & cash equivalents at beginning of period | 1,739 | 2,365 |
| 4.2 | Net cash from / (used in) operating activities (see 1.9 above) | 205 | (419) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (15) | (17) |
| 4.4 | Net cash from / (used in financing activities (item 3.10 above) | 5,613 | 5,613 |
| 4.5 | Effect of movement in exchange rates on cash held | 0 | 0 |
| **4.6** | **Cash & cash equivalents at end of quarter** | **7,542** | **7,542** |

| **5.** | **Reconciliation of cash & cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | **Current Quarter $A'000** | **Previous Quarter $A'000** |
|---|---|---|---|
| 5.1 | Bank balance | 587 | 785 |
| 5.2 | Cash deposits | 6,955 | 954 |
| 5.3 | Bank overdrafts | 0 | 0 |
| 5.4 | Other (provide details) | 0 | 0 |
| **5.5** | **Cash & cash equivalents at end of quarter (should equal item 4.6 above)** | **7,542** | **1,739** |

| **6.0** | **Payments to related parties of the entity & their associates** | **Current Quarter $A,000** |
|---|---|---|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 110 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | 0 |

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments*

Payments at 6.1 relate to normal remuneration of Non-Executive and Executive Directors

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| 7. | **Financing facilities available**<br>*Note: the term "facility" includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **Total facility amount at quarter end**<br>**$A'000** | **Amount drawn at quarter end**<br>**$A'000** |
|---|---|---|---|
| 7.1 | Loan facilities | 0 | 0 |
| 7.2 | Credit standby arrangements | 0 | 0 |
| 7.3 | Other(please specify) | 0 | 0 |
| **7.4** | **Total financing facilities** | **0** | **0** |

| | | |
|---|---|---|
| **7.5** | **Unused financing facilities available at quarter end** | **0** |

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

N/A

| 8. | **Estimated cash outflows for next quarter** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (see 1.9 above) | 205 |
| 8.2 | Cash & cash equivalents at quarter end (Item 4.6) | 7,542 |
| 8.3 | Unused financing facilities available at quarter end (item 7.5) | 0 |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 7,542 |
| **8.5** | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | **N/A** |

*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.*

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

8.6.3 Does the entity expect to be able to continue its operations and to meet it's business objectives and, if so, on what basis?

Answer:

*Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 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: 28 January 2021

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

**Notes**

1. The quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entities acitivities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and proisions of. AASB 107: Statement of Cash Flows apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee - e.g. Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.