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**ASX Release**
**29 July 2020**

**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-month period to 30 June 2020.

- **International study with global pharma validates PromarkerD test for diabetic kidney disease:** predictive power of PromarkerD confirmed in 3,000-strong clinical trial
- **CE Mark registration for PromarkerD:** high-throughput immunoassay kit, PromarkerD (IA), achieves CE Mark status in Europe, allowing prospective laboratories to process much higher numbers of samples at a more cost-effective rate
- **Intellectual Property portfolio expands:** now includes trade-secrets, plus patents and trademarks covering 273 million (59%) of the world diabetes population
- **COVID-19 research grants awarded:** $200,000 in funding to support development of a rapid diagnostic test and isolate biomarkers that give insights into progression of the disease
- **Diagnostics pipeline expanded:** Promarker™ R&D expands to include endometriosis, *Giardia* parasite, chronic lung conditions, cancer, oxidative stress, plant dieback, diabetic retinopathy and COVID-19

## OPERATIONAL HIGHLIGHTS

Proteomics International's activities fall into three key areas:

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

### (i) Commercialisation of PromarkerD

**International study with global pharma validates PromarkerD predictive test**
[ASX: 14 June] A global, multi-centre study of 3,000 people confirmed the effectiveness of PromarkerD as a predictive test for diabetic kidney disease. The collaborative study with Janssen Research and Development applied the PromarkerD test system to patient samples from the CANVAS completed phase 3 clinical trial. Retrospective analysis of blood samples from the completed clinical trial showed that patients predicted by PromarkerD to be at high-risk of chronic kidney disease were 13.5 times more likely than the low-risk group to develop the disease. The study provides international validation of previous findings that PromarkerD is able to correctly predict a clinically significant decline in kidney function up to four years in advance, paving the way for future FDA approval of the test.

The results were presented at the world's leading diabetes conference, the 80th Scientific Sessions of the American Diabetes Association (ADA), in June. Proteomics International is now focused on partnering discussions with suitable organisations to bring PromarkerD to patients in the USA, and other major jurisdictions.

**CE Mark registration for PromarkerD**

[ASX: 16 April] As reported in the March Quarterly Business Update, Proteomics International achieved CE Mark registration for the PromarkerD immunoassay (IA)[#]. This high-throughput kit version of the PromarkerD test system will allow a greater number of prospective laboratories to process much higher numbers of samples at a more cost-effective rate.

It follows CE Mark registration for PromarkerD (MS), the mass spectrometry version of the test, and PromarkerD Hub, a software tool used to calculate the risk of kidney disease [ASX: 12 November 2019; 14 January]. The CE Mark provides a significant step for Proteomics International to license and sell PromarkerD throughout the European Union. PromarkerD is the only CE Mark approved predictive test for chronic kidney disease.

**Reimbursement Code and Further Regulatory Approvals**

The Company is working with specialist consultants towards further regulatory approvals in appropriate jurisdictions and to secure a US medical reimbursement code for PromarkerD. Proteomics International will provide details on these activities in the coming quarter. Whilst these initiatives will enhance the overall commercial value of PromarkerD it should be noted that the test could currently be sold and marketed in the US as a Laboratory Developed Test (LDT) via any CLIA approved laboratory.

**Intellectual Property portfolio expands**

Proteomics International continues to strengthen its intellectual property portfolio for PromarkerD. This IP, in the form of patents, trademarks and trade-secrets, provides the foundation for licensing discussions. New patents were recently secured for the potentially substantial markets of Brazil which has 16.8 million adults with diabetes, and Canada which has 2.8 million [ASX: 27 July]. Together the Company's granted patents and trademarks cover 273 million (59%) of the addressable diabetes patient population globally. As for any novel test, the level and timeframe of market penetration cannot be predicted accurately.

**Business Model for PromarkerD**

Due to the prevalence of diabetes and diabetic kidney disease the potential revenue from a test for diabetic kidney disease is considerable.

Proteomics International is actively pursuing identified global and regional licensing opportunities for PromarkerD across jurisdictions covered by its patents and trademarks and is currently in commercialisation discussions with several different parties.

The Company's business model is to out-license its intellectual property to diagnostics providers and to receive a royalty on each test sold. Proteomics International will also sell the specialist reagents required to perform each test, whilst the PromarkerD hub regulates use of the test by each provider. Under this model the licensee will cover the capital expenditure to distribute and promote PromarkerD within their network, thus removing a significant cost burden from Proteomics International.

Proteomics International is targeting a test price to the patient of between US$55 and US$150 (test price of US$55 is based on use of existing American Medical Association CPT billing codes for similar analytes to the PromarkerD panel; test price of US$150 is based on stakeholder engagement responses (Proteomics International market access study conducted by independent US consultant)). Standard industry royalty rates for out-licensing of intellectual property for diagnostics typically range from 5-15%.

As part of the global launch for PromarkerD, the Company elected to first license in several smaller geographic jurisdictions, being Mexico (PromarkerD (MS)[#]), Dominican Republic (licence to develop own PromarkerD (IA)[#]) and most recently in Spain (PromarkerD (MS)[#]), however, sales of the test in these jurisdictions are on-hold with clinics and hospitals unable to offer the test due to the COVID-19 pandemic.

The launch into these initial jurisdictions has allowed Proteomics International to create brand awareness and prove PromarkerD in real-life clinical settings, both of which are important for future licensing opportunities in larger geographic areas.

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Importantly, on the back of recent key milestones of immunoassay development, CE Mark registration, and the successful international study with Janssen, Proteomics International is receiving strong interest for PromarkerD from more advanced markets and will update the ASX accordingly as and when events occur.

# 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

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

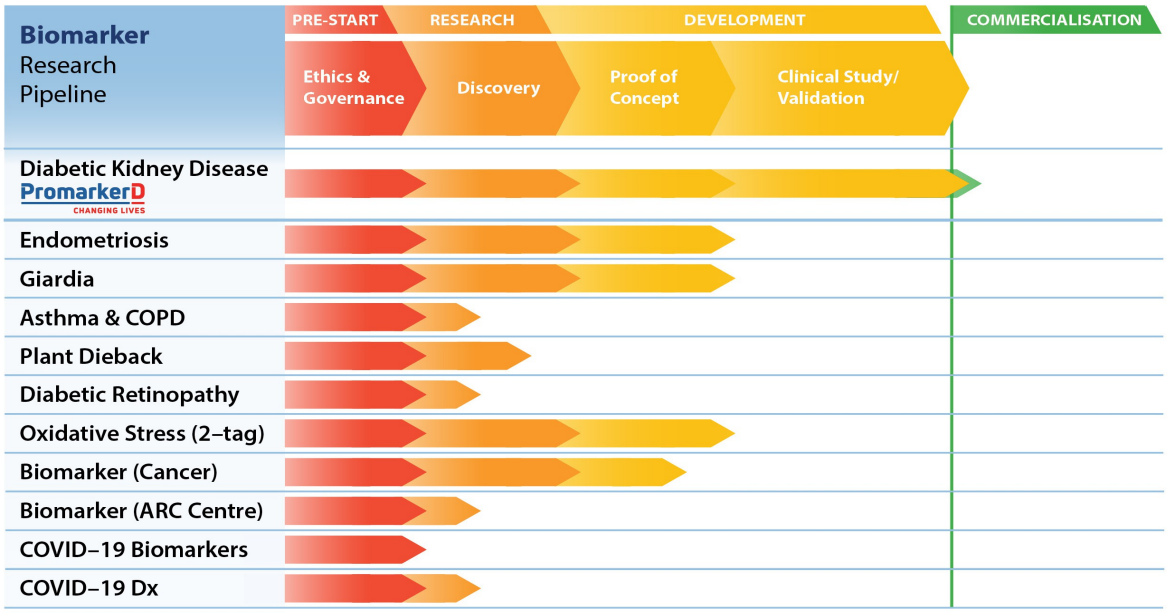
### Diagnostics pipeline expanded

[ASX: 7 April] As reported in the March Quarterly Activities Report, Proteomics International expanded its diagnostics R&D pipeline using the Promarker™ platform. The Company is targeting new diagnostic tests for chronic diseases with significant unmet need and market opportunity across medicine, veterinary health and agriculture. Fully-funded research programs are now in place for endometriosis, the *Giardia* parasite (the leading cause of infectious gastroenteritis worldwide), chronic lung conditions, cancer, oxidative stress, diabetic retinopathy, plant dieback disease and COVID-19.

### COVID-19 research grants awarded

[ASX: 25 May] Proteomics International was awarded two grants worth a combined $200,000 under the Western Australian COVID-19 Research Grants Program. The grants will support the Company's recently announced COVID-19 research programs to develop a rapid diagnostic test for the identification of the SARS-CoV-2 virus, and to isolate biomarkers that give insights into the progression of the COVID-19 disease. Both areas of research are aimed at improved medical treatment of patients to assist in the re-opening of Australian and global borders. The research is ongoing and expected to be completed over the next 8-12 months.

**DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE**




The Promarker™ R&D pipeline and typical timeline is as follows: Ethics & governance approval (3 months), Discovery (6 months), Proof of concept (6 months), Clinical studies/Validation (12 months). Updated 30th June 2020.

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## 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's receipts from customers for the year to 30 June of $1.75 million showed good resilience despite difficult market conditions at the end of the financial year (FY19: $1.73 million). June quarter receipts were $375,000 (March quarter: $930,000), and included a sharp drop in turnover in April which made the group eligible for State and Federal COVID-19 stimulus packages. Receipts continue to be driven by revenue from Analytical Services and Proteomics International has observed a strong rebound in demand across all sectors in the last two months.

The net operating cash outflow from operating activities for the year to 30 June was $783,000 (FY19: $1.74 million). June quarter cash outflow was $926,000 (March inflow: $657,000). Expenditure remained 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
  - Seeking regulatory approvals to support PromarkerD commercialisation
- Development and manufacturing of test batches of the immunoassay (kit) version of PromarkerD
- Expansion of the Promarker™ diagnostics R&D pipeline

**ASX Listing Rule 4.7C**
Payments at item 6.1 of the Appendix 4C of $121,000 relate to normal remuneration of Executive and Non-Executive Directors.

**Cash position**
At 30 June 2020 the Company had cash reserves of $2.37 million (March $3.12 million). These reserves will be strengthened by an estimated R&D tax incentive rebate of $1.2 million expected to be received in the first half of the new financial year, and based on average quarterly net spend provides the Company greater than 12 months cash runway.

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 high-speed, low cost predictive 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** | **30 June 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 | 375 | 1,752 |
| 1.2 | Payments for | | |
| | (a) research & development | (962) | (2,808) |
| | (b) product manufacturing & operating costs | (85) | (276) |
| | (c) advertising & marketing | (14) | (114) |
| | (d) leased assets | 0 | 0 |
| | (e) staff costs | (262) | (762) |
| | (f) administration & corporate costs | (167) | (450) |
| 1.3 | Dividends received (see note 3) | 0 | 0 |
| 1.4 | Interest received | 8 | 21 |
| 1.5 | Interest & other costs of finance paid | (6) | (14) |
| 1.6 | Income taxes paid | 0 | 0 |
| 1.7 | Government grants & tax incentives | 100 | 1,251 |
| 1.8 | Other (Deferred Grant Income) | 87 | 617 |
| **1.9** | **Net cash from / (used in) operating activities** | **(926)** | **(783)** |
| **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 | (35) | (1,444) |
| | (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** | **(35)** | **(1,444)** |



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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) | (2) | 3,076 |
| 3.2 | Proceeds from issue of convertible debt securities | 0 | 0 |
| 3.3 | Proceeds from exercise of options | 155 | 223 |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | 4<br>0 | (217)<br>0 |
| 3.5 | Proceeds from borrowings | 0 | 0 |
| 3.6 | Repayment of borrowings | (18) | (165) |
| 3.7 | Transaction costs related to loans & borrowings | 0 | 0 |
| 3.8 | Dividends paid | 0 | 0 |
| 3.9 | Other (provide details if material) | 0 | 164 |
| **3.10** | **Net cash from / (used in) financing activities** | **139** | **3,081** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash & cash equivalents at beginning of period | 3,187 | 1,511 |
| 4.2 | Net cash from / (used in) operating activities (see 1.9 above) | (926) | (783) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (35) | (1,444) |
| 4.4 | Net cash from / (used in financing activities (item 3.10 above) | 139 | 3,081 |
| 4.5 | Effect of movement in exchange rates on cash held | 0 | 0 |
| **4.6** | **Cash & cash equivalents at end of quarter** | **2,365** | **2,365** |

| **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 | 910 | 1,087 |
| 5.2 | Cash deposits | 1,455 | 2,100 |
| 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)** | **2,365** | **3,187** |

| **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 | 121 |
| 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) | 926 |
| 8.2 | Cash & cash equivalents at quarter end (Item 4.6) | 2,365 |
| 8.3 | Unused financing facilities available at quarter end (item 7.5) | 0 |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 2,365 |
| **8.5** | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | **3** |

*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: These cash reserves will be strengthened by an estimated R&D rebate of $1.2 million in the first half of the new financial year.

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: 29th July 2020

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.

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