



Proteomics International

LABORATORIES LTD

ASX Release
28 April 2020

ASX code: PIQ

Quarterly Business Update

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 31 March 2020.

- **Janssen study progresses and expands:** findings from first stage of collaboration with US big pharma to be presented at world's leading diabetes conference in June
- **CE Mark registration for PromarkerD:** high-throughput immunoassay kit, PromarkerD (IA), and PromarkerD Hub achieve CE Mark status in Europe allowing new prospective laboratories to process much higher numbers of samples at a more cost effective rate
- **Patent filed for diagnostic test for endometriosis:** newly identified biomarkers provide breakthrough for Proteomics International in the effort to create a world-first test for endometriosis
- **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
- **Strong cash balance:** all programs fully funded by existing cash reserves

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

Janssen study progresses and expands

Proteomics International is collaborating with Janssen Research & Development to target treatment of diabetic kidney disease (DKD) [ASX: 26 November 2018]. The studies involve Proteomics International's scientific team working with Janssen scientists firstly to validate the effectiveness of PromarkerD as a DKD predictive diagnostic test across a completed Janssen clinical trial, and then to ascertain the relationship of PromarkerD to treatment.

[ASX: 31 March] The results of the first stage have been accepted for presentation at the world's leading diabetes conference, the 80th Scientific Sessions of the American Diabetes Association (ADA) in June 2020, and will be delivered jointly by the two teams. Janssen and Proteomics International have now agreed to extend the collaboration to examine the PromarkerD score in patient samples after treatment, to assess if patients display an improved prognosis .

Positive results from the collaborative study have the potential to fast-track the commercialisation of PromarkerD.

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CE Mark registration for PromarkerD

[ASX: 14 January; 16 April] Proteomics International achieved CE Mark registration for the PromarkerD immunoassay (IA)[#], the high-throughput kit version of the PromarkerD test system.

PromarkerD is the only test available in the Europe Union (EU) for predicting the onset of diabetic kidney disease, and PromarkerD (IA) will allow a greater number of prospective laboratories to process much higher numbers of samples at a more cost effective rate.

The Company also secured CE Mark registration for the PromarkerD Hub, a software tool used to calculate the risk of kidney disease. It follows CE Mark registration for PromarkerD (MS), the mass spectrometry version of the test, in the previous quarter [ASX: 12 November 2019].

The CE Mark provides a significant step for Proteomics International to license and sell PromarkerD throughout the European Union. It provides assurance to European consumers and potential licensing partners that the product has been developed and manufactured to meet EU safety, health and environmental protection requirements. Importantly, these registrations lay the groundwork for future regulatory approvals, including an application to the US FDA which Proteomics International intends to lodge mid-year 2020.

(ii) Diagnostics & (iii) Analytical Services

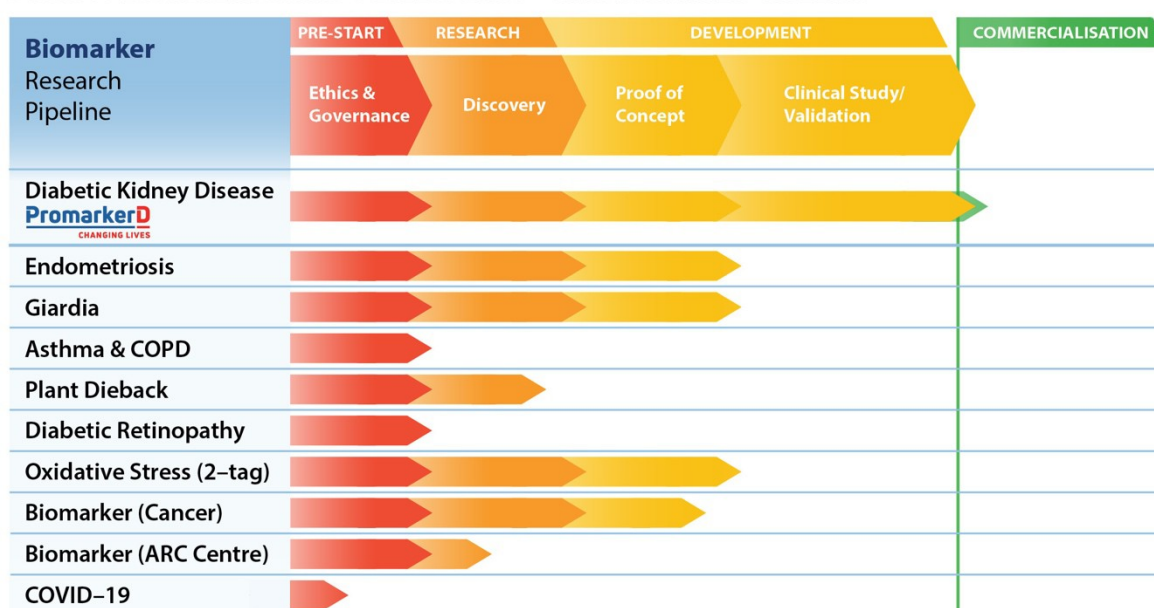
Patent filed for diagnostic test for endometriosis

[ASX: 23 March] Proteomics International identified protein ‘fingerprints’ in the blood that could be used to test for endometriosis. The ‘fingerprints’—known as biomarkers—have potential to be developed into a simple blood test for the painful condition that occurs when the tissues that line the uterus spread outside of the uterine cavity.

Endometriosis affects one in nine Australian women and is currently diagnosed with a surgical procedure. Direct medical costs (outpatient and hospitalisation) associated with endometriosis in the United States surpass US\$17.3 (A\$27) billion annually. If successful, it would be the world’s first non-invasive test for endometriosis.

The biomarkers were identified via the Promarker™ platform, and Proteomics International has filed a patent application for the invention. The Company is looking to partner with organisations with access to patient samples ahead of a large clinical study, which is anticipated to provide the basis for commercialisation.

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).

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Diagnostics pipeline expanded

Alongside the recent significant upgrade in analytical capability [ASX 26 November 2019], Proteomics International proactively vetted biomarker discovery and diagnostics development opportunities. The Company targeted new diagnostic tests for chronic diseases with significant unmet need and market opportunity across medicine, veterinary and agriculture [ASX: 7 April].

This led to the expansion of diagnostics R&D pipeline using the Promarker™ platform. Alongside endometriosis, advances included achievement of proof-of-concept for a diagnostic to detect harmful strains of the *Giardia* parasite, the leading cause of infectious gastroenteritis worldwide. The Company will commence analysis into chronic lung conditions, and finalise advanced in-licensing and commercialisation opportunities in cancer and oxidative stress.

New biomarker discovery programs have been established in diabetic retinopathy and plant dieback disease. COVID-19 research programs have also been initiated 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. All programs are fully-funded.

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 rebate. This model continues to make optimum use of the Company's resources. The Company also completed an over-subscribed share placement in the December quarter.

Proteomics International achieved receipts from customers for the March quarter of \$930,000 (December quarter: \$74,000). They comprised receipts from Analytical Services, which were not materially affected by COVID-19, and an extraordinary payment of operating and co-investment funds for the expanded WA Proteomics Facility [ASX: 26 November 2019].

The net operating cash inflow for the March quarter was \$657,000 driven by the co-investment funds (December inflow: \$70,000). Expenditure was in line with budget and centred on the following areas:

- Development and manufacturing of test batches of the immunoassay (kit) version of PromarkerD
- Installation of new equipment to expand the Company's R&D capability for biomarker discovery and analysis
- Costs for seeking regulatory approvals to support PromarkerD commercialisation
- Business development and commercialisation costs for the roll-out 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 31 March 2020 the company had cash reserves of \$3.12 million (December \$2.45 million).

Authorised by the Board of Proteomics International Laboratories Ltd.

ENDS

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About PromarkerD (www.PromarkerD.com)

The PromarkerD test system assesses the risk of diabetic kidney disease (DKD) in patients with type 2 diabetes. Chronic kidney disease is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant. PromarkerD is a simple blood test that uses a unique protein 'fingerprint' to provide an early detection of the onset of disease. In clinical studies published in leading journals PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years.

Further information is available through the PromarkerD web portal.

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

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 cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Proteomics International Laboratories Ltd

ABN

78 169 979 971

Quarter ending ("current quarter")

31 March 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	930	1,377
1.2 Payments for		
(a) research & development	(561)	(1,846)
(b) product manufacturing & operating costs	(54)	(191)
(c) advertising & marketing	(27)	(100)
(d) leased assets	0	0
(e) staff costs	(126)	(500)
(f) administration & corporate costs	(56)	(283)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	5	13
1.5 Interest & other costs of finance paid	0	(8)
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	16	1,151
1.8 Other (Deferred Grant Income)	530	530
1.9 Net cash from / (used in) operating activities	657	143
2. Cash flows related to investing activities		
2.1 Payments to acquire:		
(a) entities	0	
(b) businesses (see item 10)	0	0
(c) property, plant & equipment	(85)	(1,409)
(d) investments	0	0
(e) intellectual property	0	0
(f) other non-current assets	0	0
2.2 Proceeds from disposal of:	0	0
(a) entities		
(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	(85)	(1,409)

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	3,078
3.2 Proceeds from issue of convertible debt securities	0	0
3.3 Proceeds from exercise of options	0	68
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(12)	(221)
3.5 Proceeds from borrowings	0	0
3.6 Repayment of borrowings	18	(147)
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	8	2,942

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash & cash equivalents at beginning of period	2,607	1,511
4.2 Net cash from / (used in) operating activities (see 1.9 above)	657	143
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(85)	(1,409)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	8	2,942
4.5 Effect of movement in exchange rates on cash held	0	0
4.6 Cash & cash equivalents at end of quarter	3,187	3,187

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	1,087	2,557
5.2 Cash deposits	2,100	50
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)	3,187	2,607

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	

7. Financing facilities available	Total facility amount	Amount drawn
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>	at quarter end	at quarter end
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	\$A'000	\$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.	<div style="border: 1px solid black; padding: 5px; min-height: 40px;"> N/A </div>	

8. Estimated cash outflows for next quarter	\$A'000
8.1 Net cash from / (used in) operating activities (see 1.9 above)	657
8.2 Cash & cash equivalents at end of quarter (Item 4.6)	3,187
8.3 Unused financing facilities available at quarter end (item 7.5)	0
8.4 Total available funding (Item 8.2 + Item 8.3)	3,187
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	>4*
* Given the positive net cash flows from operating activities for the quarter, there are more than four Estimated quarters of funding available	
8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:	
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:	
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:	
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:	

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: 28th April 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 activities 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 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 - 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.