



Proteomics International

LABORATORIES LTD

ASX Release
28 October 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 months to 30 September 2020 and subsequent to the period end:

- **First distribution agreement for easy-to-use, high volume immunoassay version of PromarkerD:** world's first predictive test for diabetic kidney disease to be made available in Italy through innovative distributor Medical Horizons SRL
- **Licence/Partnering discussions focused on PromarkerD immunoassay technology:** negotiations with prospective licensees/partners aim to bring simple, easy-to-use PromarkerD technology platform to patients around the world
- **PromarkerD international validation study:** results published in internationally peer-reviewed *Journal of Clinical Medicine* following joint clinical study with global pharma
- **Intellectual Property portfolio expands:** now includes trade-secrets, plus patents and trademarks covering 273 million (59%) of the world diabetes population
- **Partnership with QIMR Berghofer Institute to target oesophageal cancer:** new 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.

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 agreement for easy-to-use immunoassay version of PromarkerD test

[ASX: 16 October] Proteomics International signed a distribution licensing agreement for the immunoassay version of the PromarkerD predictive test for diabetic kidney disease. The agreement with innovative medical distributor Medical Horizons SRL will see the blood test made available to patients in Italy, where 3.7 million people, or one in 12 adults, have diabetes.

The distribution agreement with Medical Horizons is for two years, exclusive to Italy, and exclusive to PromarkerD (IA)[#]. Proteomics International will receive payment for each kit sold, which results in potential revenue to the Company in line with previously stated royalty models. As for any novel test, market penetration cannot be predicted accurately, hence for the new licence it is not possible to quantify the financial impact on Proteomics International in any given timeframe.

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

Licence/Partnering discussions focused on PromarkerD immunoassay technology

Proteomics International is continuing discussions with diagnostic and pharmaceutical companies in multiple countries to bring the immunoassay kit version of the PromarkerD test to patients. This simple technology platform is cost-effective and standard to clinical diagnostics laboratories around the world. The format allows hundreds of blood samples to be analysed quickly as part of a panel of routine blood tests. Proteomics International is also currently renegotiating deals with the Company's existing PromarkerD partners, allowing them to access the immunoassay version of the test.

PromarkerD international validation study results published in Journal of Clinical Medicine

[ASX: 12 October] The findings of a major multi-centre clinical study confirming the effectiveness of PromarkerD as a predictive test for diabetic kidney disease were published in the internationally peer-reviewed *Journal of Clinical Medicine*. The paper titled '*PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)*'¹ 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.

Peer-reviewed publications form an essential component of PromarkerD's adoption by Key Opinion Leaders and the wider diabetes community.

PromarkerD in the clinic

[ASX: 31 August] As presented in the Annual Report, the PromarkerD predictive test employs a "traffic light" scoring system for patient reports. The test results provide patients and their doctors with a risk score based on the likelihood they will develop diabetic kidney disease within the next four years. The score is based on a combination of a simple blood test that measures three plasma proteins combined with three commonly measured clinical factors (age, cholesterol and eGFR).

Patients with a moderate to high risk score now have new treatment options available to them via the gliflozin (SGLT2 Inhibitor) class of drugs. The first SGLT2 Inhibitor to be FDA approved as displaying renal protective properties was Canagliflozin (Invokana™) (see Proteomics International Investor Presentation August [ASX: 26 August]).

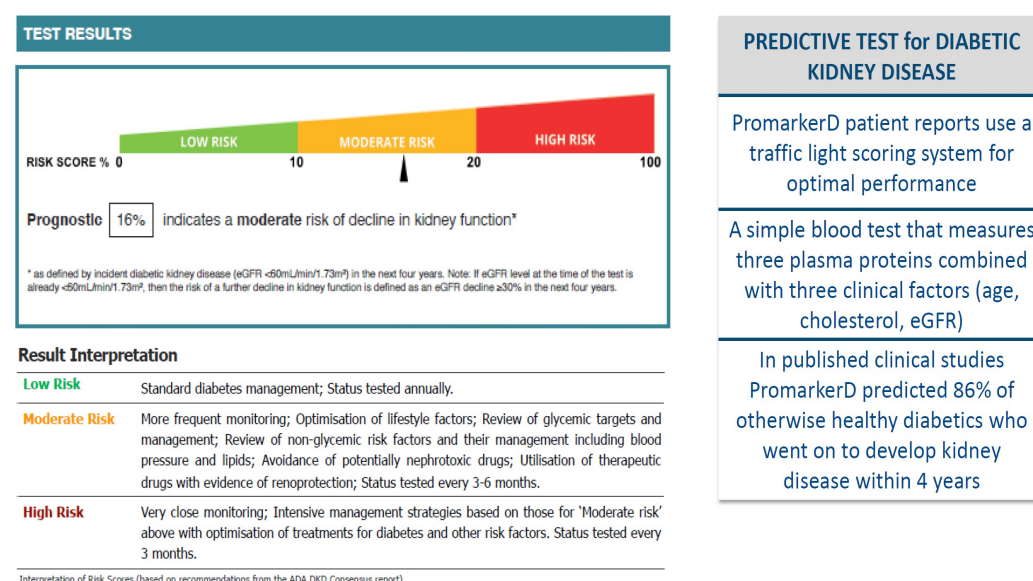
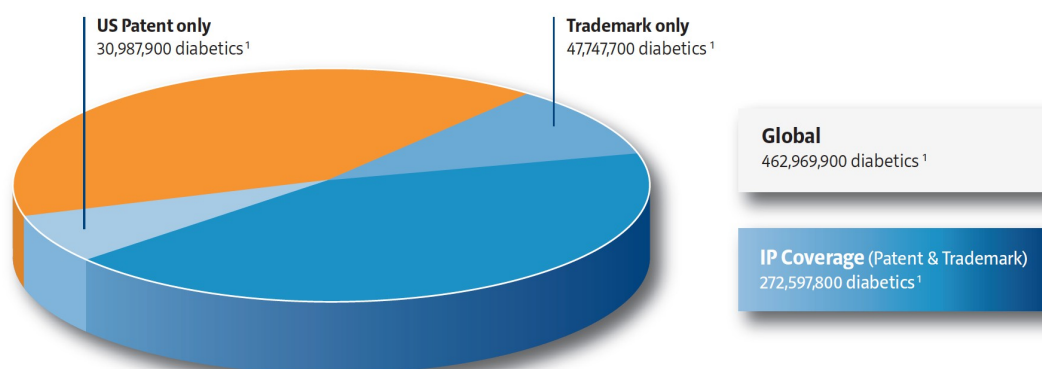


Figure 1: The PromarkerD test employs a "traffic light" scoring system

¹ J. Clin. Med. (2020) 9, 3212; doi.org/10.3390/jcm9103212



Assumptions: ¹ International Diabetes Federation (IDF) Atlas 9th Edition 2019 [Age group 20-79 years; Total = Diagnosed (48.7%) + Undiagnosed (51.3%)].

Figure 2: Number of adults with Type-2 diabetes covered by PromarkerD patents and Promarker trademark

Intellectual Property portfolio expands

[ASX: 27 July] New patents were secured for the potentially substantial markets of Brazil which has 16.8 million adults with diabetes, and Canada which has 2.8 million. As reported in the Company's Annual Report, Proteomics International has established a strong intellectual property portfolio for PromarkerD. This IP, in the form of patents, trademarks and trade-secrets, provides the foundation for on-going licensing discussions. Together the Company's granted patents and trademarks cover 273 million (59%) of the addressable diabetes patient population globally.

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

Partnership with QIMR Berghofer Institute to target oesophageal cancer

[ASX: 9 October] 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.

Further details on the Company's Promarker™ R&D pipeline will be provided in the December quarter.

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.

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Proteomics International achieved receipts from customers for the September quarter of \$543,000 (June quarter: \$375,000). Receipts continue to be driven by revenue from Analytical Services and Proteomics International is observing strong demand across all sectors.

The net operating cash outflow for the September quarter was \$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
- Expansion of the Promarker™ diagnostics R&D pipeline

Heavily-oversubscribed Placement raises \$6 million

[ASX: 23 October] A successful placement brought new UK and Australia-based institutions onto the Company's share register. The Placement raised \$6 million (before costs) through the issue of 12.5 million shares at \$0.48 per share, a discount of 14.9% to the 20-day VWAP. The heavily-oversubscribed Placement was supported by institutions and sophisticated professional investors, and closed early due to overwhelming investor response.

Funds from the Placement will drive the delivery of the ground-breaking PromarkerD test in major global markets, following the recent achievement of a number of milestones for the test. The funds received will also strengthen Proteomics International's balance sheet for future licensing negotiations, and assist in accelerating the diagnostic pipeline.

ASX Listing Rule 4.7C

Payments at item 6.1 of the Appendix 4C of \$103,000 relate to normal remuneration of Executive and Non-Executive Directors.

Cash position

At 30 September 2020 the Company had cash reserves of \$1.74 million (June \$2.37 million), which excludes \$6 million (before costs) to be received from the Placement. These reserves will be further strengthened by an estimated R&D tax incentive rebate of \$1.1 million expected to be received in the December quarter.

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

78 169 979 971

Quarter ending ("current quarter")

30 September 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	543	543
1.2 Payments for		
(a) research & development	(717)	(717)
(b) product manufacturing & operating costs	(62)	(62)
(c) advertising & marketing	(29)	(29)
(d) leased assets	0	0
(e) staff costs	(224)	(224)
(f) administration & corporate costs	(158)	(158)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	3	3
1.5 Interest & other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	20	20
1.8 Other (Deferred Grant Income)	0	0
1.9 Net cash from / (used in) operating activities	(624)	(624)
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	(2)	(2)
(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	(2)	(2)

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)	0	0
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	0	0
3.4	Transaction costs related to issues of equity securities or convertible debt securities	0	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	0	0
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash & cash equivalents at beginning of period	2,365	2,365
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(624)	(624)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(2)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	0	0
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	Cash & cash equivalents at end of quarter	1,739	1,739
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	785	910
5.2	Cash deposits	954	1,455
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)	1,739	2,365
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		103
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.		
	N/A		

8. Estimated cash outflows for next quarter	\$A'000
8.1 Net cash from / (used in) operating activities (see 1.9 above)	(624)
8.2 Cash & cash equivalents at quarter end (Item 4.6)	1,739
8.3 Unused financing facilities available at quarter end (item 7.5)	0
8.4 Total available funding (Item 8.2 + Item 8.3)	1,739
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	3*
<i>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.</i>	
8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer:	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: * Excludes funds of \$6 million (before costs) to be received from Placement [ASX 23 October] and estimated R&D tax incentive rebate of \$1.1 million expected to be received in the December quarter.	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer:	
<i>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.</i>	

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 October 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.