



Proteomics International

LABORATORIES LTD

ASX Release
29 January 2020

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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 December 2019.

- **CE Mark registration for PromarkerD predictive test for diabetic kidney disease test:** both PromarkerD (MS)[#] and PromarkerD Hub achieve CE Mark status in Europe
- **Janssen collaboration study advances:** in depth statistical analysis of the data is ongoing and an update will be provided in Q3 FY20
- **Cutting-edge protein biomarker analysis facility for Western Australia:** world-leading facility launched in partnership with Bioplatforms Australia and The University of Western Australia - new equipment is already providing an increased ability to identify biomarkers
- **\$3 million raised in heavily oversubscribed Placement:** successful capital raising providing funds for the commercialisation of PromarkerD, upgraded laboratory instruments and expanding the diagnostic products pipeline
- **More than \$1 million R&D tax incentive boost:** Balance sheet further boosted by \$1.1 million in research and development tax incentive

OPERATIONAL HIGHLIGHTS - PromarkerD CE MARK AND A WORLD-LEADING R&D CAPABILITY

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

CE Mark registration for PromarkerD

[ASX: 12 November; 14 January] Proteomics International secured CE Mark registration for its PromarkerD mass spectrometry (MS) test for diabetic kidney disease and, subsequent to the year end, for the PromarkerD Hub, both as IVD medical devices (in vitro diagnostic).

PromarkerD Hub is a software tool used to calculate the risk of kidney disease in patients with type 2 diabetes and operates in concert with both PromarkerD (MS)[#], or the recently-validated PromarkerD immunoassay (IA) [ASX: 17 September].

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 achieving future regulatory approvals of PromarkerD (IA)[#], which is a broader use technology platform readily accepted in pathology

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laboratories around the world. Proteomics International intends to lodge a CE Mark application for PromarkerD (IA) in the March quarter and a US FDA application by mid-year 2020.

Discussions with major diagnostics companies continue to develop as Proteomics International is focussed on executing agreements which will facilitate the roll-out and adoption of PromarkerD in additional geographic regions. The Company anticipates the full suite of CE Mark approvals for the PromarkerD test system to be a catalyst that will accelerate these partnering discussions.

Janssen collaboration study advances

As announced last year, Proteomics International entered into a collaborative study with Janssen, the pharmaceutical arm of Johnson & Johnson. The Janssen collaboration seeks to explore the performance of Proteomics International's PromarkerD predictive diagnostic test for diabetic kidney disease in samples from a completed clinical trial of Janssen's diabetes drug canagliflozin (Invokana™).

Of note, in late 2019 the US FDA approved canagliflozin to treat kidney disease in people with type 2 diabetes. In doing so canagliflozin became the only medicine in nearly 20 years, and the first diabetes medicine, to be approved to reduce risk of renal failure, dialysis or kidney transplantation.

Positive results from the collaborative study have the potential to fast-track the commercialisation of PromarkerD. If successful, PromarkerD may be designated as a Complementary Diagnostic (CDx) test for the treatment of diabetic kidney disease.

Both Proteomics International and Janssen are now performing in depth statistical analysis of the data and an update will be provided later in Q3 FY20.

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

ii) Diagnostics & iii) Analytical Services

Cutting-edge protein biomarker analysis facility for Western Australia

[ASX: 26 November] Proteomics International joined forces with Bioplatforms Australia and The University of Western Australia to launch a cutting-edge proteomics facility to explore biological markers affecting medicine, agriculture, the environment and marine world. The partners will co-invest A\$4.4m over the next four years in the expanded Western Australian Proteomics Facility.

Proteomics International's contribution will be \$1.25m in Capex and Opex over the four years, representing outstanding value for the enhanced capabilities the facility will offer. Equipment for the cutting-edge facility has now been installed and is already providing an increased ability to explore for and identify biological markers across a broad range of sectors. This enhanced capability could lead to the identification of new drug targets and the creation of diagnostic tests across medicine and agriculture, boosting both Proteomics International's analytical services and R&D activities.

Diagnostics R&D - the Promarker™ pipeline

With the installation of the new analytical instrumentation the Company is pressing on with its existing pipeline of diagnostics R&D. Current areas of focus are endometriosis, a gynaecological condition causing chronic pain and infertility, and parasite infection by *Giardia*, a leading cause of gastroenteritis worldwide. Proteomics International is also evaluating several new opportunities to seek novel biomarkers that could become innovative diagnostics tests for areas of significant unmet medical, veterinary and agricultural need. The Company will provide a comprehensive update on these activities at the end of Q3 FY20.

Biosimilars analytical service extended

Proteomics International has specialised in the analysis of biosimilars (generic protein drugs) since the Company received its world leading ISO 17025 laboratory accreditation in 2009. In November Proteomics International experienced a successful audit by NATA (National Association of Testing Authorities, Australia), which emphasised the high quality of analytical processes within the Company's facilities.

Proteomics International also took advantage of the downtime associated with its equipment upgrade to develop and launch a new specialist service for glycan analysis of biosimilars. This is an important addition to the Company's portfolio of services that are used to assess the quality of a biosimilar product, with the use of biosimilar drugs in the treatment of cancers continuing to expand.

FINANCIAL HIGHLIGHTS - SHARE PLACEMENT AND R&D TAX INCENTIVE BOLSTER BALANCE SHEET

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 December quarter was quiet for Analytical Services whilst the Company commissioned its new suite of instruments. Proteomics International achieved receipts from customers for the December quarter of \$74,000 (September quarter: \$373,000). With the expanded facility now operational the Company anticipates a boost to future analytical service activities.

The net operating cash inflow for the December quarter was \$70,000 supported by the R&D tax rebate (see below) (September outflow: \$584,000). Expenditure was in line with budget and centred on the following areas:

- R&D spending relating to the completion of the immunoassay (kit) version of PromarkerD
- Installation of new equipment to expand the Company's R&D capability for biomarker discovery and analysis (Proteomics International will receive co-investment funds in the March quarter)
- Costs for seeking regulatory approvals to support PromarkerD commercialisation
- Business development and commercialisation costs for the roll-out of PromarkerD

\$3 million raised in heavily oversubscribed Placement

[ASX: 15 November] Proteomics International raised A\$3.0 million through the issue of 10.8 million shares in the Company. The heavily-oversubscribed Placement received strong demand from new and existing institutional, family office, sophisticated and professional investors. Funds raised significantly strengthened the Company's balance sheet, providing capital for the commercialisation of PromarkerD, upgraded laboratory instruments and generation of early stage IP for the diagnostic products pipeline.

More than \$1 million R&D tax incentive boost

[ASX: 29 October] Proteomics International's balance sheet was further boosted by the receipt of A\$1.1 million in research and development tax incentive for FY19. The Company spent \$2.62 million on R&D during the previous financial year, making it eligible for an Australian Government rebate of \$1,134,662.

Cash position

At 31 December 2019 the company had cash reserves of \$2.45 million and current receivables of \$1.54 million.

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ENDS

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. PromarkerD recently launched in Spain through Proteomics International's partnership with Patia Europe.

Further information is available through the PromarkerD web portal.

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.

For further information please contact:

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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")

31 December 2019

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	74	447
1.2 Payments for		
(a) research & development	(703)	(1,285)
(b) product manufacturing & operating costs	(86)	(137)
(c) advertising & marketing	(33)	(73)
(d) leased assets	0	0
(e) staff costs	(210)	(374)
(f) administration & corporate costs	(106)	(227)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	2	8
1.5 Interest & other costs of finance paid	(3)	(8)
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	1,135	1,135
1.8 Other (provide details if material)	0	0
1.9 Net cash from / (used in) operating activities	70	(514)
2. Cash flows related to investing activities		
2.1 Payments to acquire:		
(a) property, plant & equipment	(1,322)	(1,324)
(b) businesses (see item 10)	0	0
(c) investments	0	0
(d) intellectual property	0	0
(e) other non-current assets	0	0
2.2 Proceeds from disposal of:	0	0
(a) property, plant & equipment	0	0
(b) businesses (see item 10)	0	0
(c) investments	0	0
(d) intellectual property	0	0
(e) 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	(1,322)	(1,324)

Quarterly report for entities subject to Listing Rule 4.7B

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 shares	3,076	3,076
3.2 Proceeds from issue of convertible notes	0	0
3.3 Proceeds from exercise of share options	68	68
3.4 Transaction costs related to issues of shares, convertible notes or options	(209)	(209)
3.5 Proceeds from borrowings	0	0
3.6 Repayment of borrowings	(126)	(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	2,809	2,934

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash & cash equivalents at beginning of quarter / year to date	1,050	1,511
4.2 Net cash from / (used in) operating activities (see 1.9 above)	70	(514)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(1,322)	(1,324)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	2,809	2,934
4.5 Effect of movement in exchange rates on cash held	0	0
4.6 Cash & cash equivalents at end of quarter	2,607	2,607

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	2,557	836
5.2 Cash deposits	50	214
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)	2,607	1,050

6. Payments to directors of the entity & their associates	Current Quarter \$A,000
6.1 Aggregate amount of payments to these parties included in item 1.2	96
6.1 Aggregate amount of cash flow from loans to these parties included in item 2.3	0
6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	
Executive director remuneration	51
Non-Executive directors' remuneration	45

7. Payments to related entities of the entity & their associates	Current Quarter \$A,000
7.1 Aggregate amount of payments to these parties included in item 1.2	2
7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3	0
7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	
N/A	

8. Financing facilities available <i>Add notes as necessary for an understanding of position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities	0	0
8.2 Credit standby arrangements	0	0
8.3 Other (please specify)	0	0
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		
N/A		

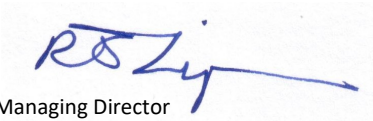
9. Estimated cash outflows for next quarter	\$A'000
9.1 Research & development	650
9.2 Product manufacturing & operating costs	100
9.3 Advertising & marketing	50
9.4 Leased assets	0
9.5 Staff costs	200
9.6 Administration & corporate costs	100
9.7 Other (provide details if material)	0
9.8 Total estimated cash outflows	1,100

10. Acquisitions & disposals of business entities (items 2.1(b) & 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity	N/A	N/A
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		

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.

Sign here:



Managing Director

Date: 29th January 2020

Print Name: Dr Richard Lipscombe

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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. The quarterly report is unaudited.
4. The following items are additional items in AASB 107 but have not been included in this report:
 - 20.1 reconciliation of cash flows arising from operating activities to operating profit or loss.
 - 51 itemised disclosure relating to maintaining operating capacity.
 - 52 itemised disclosure relating to segment reporting.