



Proteomics International

LABORATORIES LTD

ASX Release
24 April 2019

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Quarterly Business Update

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to provide the following update on its business activities for the three-month period to 31 March 2019.

- **Collaboration study commences with Janssen:** analysis of samples commences from global pharmaceutical company's completed clinical trial of gliflozin drug
- **Testing PromarkerD alongside the world's first drug for diabetic kidney disease:** Janssen recently reported that its gliflozin drug is the first diabetes medicine to demonstrate significant reduction in the risk of renal failure
- **US patent granted for abnormal kidney function drug development using PromarkerD biomarker:** the patent could provide significant commercial value to Proteomics International if a pharma company were to develop a drug treatment using this PromarkerD biomarker
- **International licensing deals:** first commercial use of PromarkerD immunoassay in Dominican Republic; roll-out of Laboratory Developed Test progressing in Mexico and Spain; discussions ongoing with several potential US partners
- **Key Opinion Leaders targeted:** engagement designed to drive demand for PromarkerD in the US
- **PromarkerD to be showcased at American Diabetes Association conference:** Proteomics International to exhibit at the 79th Scientific Sessions in San Francisco in June
- **R&D for new diagnostic tests:** proof of concept studies nearing completion for endometriosis and *Giardia*
- **Consecutive record quarters for Analytical Services revenue:** Proteomics International's receipts in the March quarter were another record, rising 18% to exceed \$0.6 million

OPERATIONAL HIGHLIGHTS - PromarkerD and new drugs for diabetic kidney disease

Proteomics International's principal activities fall into three key areas:

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

To implement this strategy, Proteomics International is continuing its global roll-out of the world-leading PromarkerD predictive diagnostic test for diabetic kidney disease. The company is also expanding the application of its Promarker™ technology platform for biomarker discovery to other chronic diseases with significant unmet medical need.

Proteomics International Laboratories Ltd

ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

T: +61 8 9389 1992 | E: enquiries@proteomicsinternational.com | W: www.proteomicsinternational.com

(i) Commercialisation of PromarkerD

Collaboration study commences with Janssen

[ASX: 24 January] Proteomics International has commenced analysis of samples from Janssen Research & Development (Janssen) in its Perth laboratory, under an agreement between the two companies to accelerate diabetic kidney disease and heart disease drug discovery using PromarkerD. The first stage of analysis of the samples, from a Janssen completed clinical trial of its gliflozin drug, will be completed mid-year.

On the 14 April 2019 it was widely reported that Janssen's canagliflozin drug significantly reduces the risk of renal failure in patients with type 2 diabetes and chronic kidney disease in a phase 3 clinical study. In announcing the results, Janssen stated that canagliflozin is the only medicine in nearly 20 years, and the first diabetes medicine, to demonstrate significant reduction in risk of renal failure, dialysis or kidney transplantation.

These new findings emphasise the potential of this collaboration to establish PromarkerD as a Complementary Diagnostic (CDx) test for the therapeutic treatment of diabetes complications. If successful, the PromarkerD test could be used every time Janssen diabetes drug, or the several other drugs in the gliflozin class, are prescribed. The collaboration also seeks to use PromarkerD to identify specific target populations that will respond to these diabetes therapies.

US patent granted for abnormal kidney function drug development using PromarkerD biomarker

[ASX: 22 February] Proteomics International has been granted a US patent for the use of one of the core PromarkerD biomarkers as a potential drug target. The PromarkerD test measures a panel of protein markers found in the blood, and the new patent is centred on one of these proteins known as CD5 antigen-like (CD5L). CD5L was previously considered to act as a regulator of lipid synthesis, and published research by Proteomics International and others suggests CD5L is a diagnostic marker for diabetic kidney disease and is involved in a patient's response to acute kidney injury.

CD5L could be a novel therapeutic target to treat kidney disease, and the new patent covers methods for identifying such drugs. Further research is required to confirm the role played by CD5L and confirm its viability as a drug target. The US patent number 10191067B2, titled "Method for Identifying an Agent for Treating Abnormal Kidney Function", is valid until 20 September 2031.

International licensing deals

Proteomics International has issued an invoice to Omics Global Solutions for a milestone payment upon first commercial use of PromarkerD as an immunoassay kit in the Dominican Republic [ASX: 18 Aug 2016]. This follows successful assay validation studies announced last quarter [ASX: 9 Nov 2018].

The company also continued to work closely with its partners towards the commercial roll-out of the PromarkerD Laboratory Developed Test in Mexico and Spain, both targeting first use in the June quarter.

[ASX: 24 January] Proteomics International rescinded its licensing deal with medical diagnostics company PrismHealthDx for the US due to ongoing rollout delays. Proteomics International is now in discussions with several US diagnostic and laboratory technology companies that offer larger markets and faster scale and deployment.

Key Opinion Leaders targeted

[ASX: 24 January] Following the publication of key PromarkerD clinical results, Proteomics International has been engaging with Key Opinion Leaders (KOLs) in the US. The company is collaborating to undertake selective studies with the KOLs to strengthen the association, and drive demand and uptake of PromarkerD.

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PromarkerD to be showcased at BIO and American Diabetes Association conferences

Proteomics International will present PromarkerD at the American Diabetes Association's 79th Scientific Sessions in San Francisco from June 7-11. The team will be based at booth #1738. Proteomics International will also be part of the Australian delegation to BIO, the world's largest biotechnology conference, to be held in Philadelphia from June 3-6.

(ii) Diagnostics

Proof of concept studies being finalised for endometriosis and *Giardia*

A proof of concept study is nearing completion for biomarkers that could be used to test endometriosis, after Proteomics International discovered the potential biomarkers in 2018 [ASX: 23 August]. Endometriosis affects one in ten women in their reproductive years. If successful, the proof of concept study may lead to patentable intellectual property.

A second proof of concept study is also progressing for an improved diagnostic test for the parasite *Giardia*, in collaboration with Murdoch University Veterinary School and a leading US veterinary company. The test under development is strain specific and could be used to test if pets infected with *Giardia* present a risk to their owners.

(iii) Analytical Services

Revenue from analytical services continued to be strong (see Financial Highlights) driven by continued volume in biosimilars and pharmacokinetic testing. Additional revenue is derived from specialist analytical work (e.g. food product quality control) and provision of external biomarker analysis services, including companion diagnostics (CDx).

FINANCIAL HIGHLIGHTS - Strong revenue continues

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.

Proteomics International's receipts from customers for the March quarter were another record with operating cash inflow from customers of \$606,000 (18% ahead the December quarter's previous record figure of \$515,000).

The year to date operating cash inflow of \$1.48 million is a 151% increase on the equivalent period last year (\$0.59 million). Royalty and milestone payments that Proteomics International receives from licences for PromarkerD will further enhance future cash flows.

There was a net operating cash outflow for the quarter from operating activities of \$361,000. In light of its strong cash position the company has continued with elevated expenditure (as compared to FY 2018) in the following areas:

- R&D spending relating to the completion of the immunoassay (kit) version of PromarkerD
- Development spending relating to the roll-out of the Laboratory Developed Test (mass spectrometry) version of PromarkerD
- Business development and commercialisation costs for the roll-out of PromarkerD

At 30th March 2019 the company had cash reserves of \$2.58 million (31st December \$2.93 million).

ENDS

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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:

Dr Richard Lipscombe
Managing Director
Proteomics International Laboratories Ltd
T: +61 8 9389 1992
E: enquiries@proteomicsinternational.com

Susan Fitzpatrick-Napier
[Public Relations & Media Contact]
Digital Mantra Group
T: +61 2 8218 2144 or +1 415-951-3228
E: team@dmgpr.com

Dirk van Dissel
[Corporate Advisor & Investor Relations]
Adelaide Equity Partners
T: +61 8 8232 8800
E: dvandissel@adelaideequity.com.au

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 March 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	606	1,484
1.2 Payments for		
(a) research & development	(609)	(1,857)
(b) product manufacturing & operating costs	(71)	(205)
(c) advertising & marketing	(87)	(164)
(d) leased assets	0	0
(e) staff costs	(189)	(533)
(f) administration & corporate costs	(61)	(239)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	17	36
1.5 Interest & other costs of finance paid	9	(21)
1.6 Income taxes paid	0	0
1.7 Government grants & tax incentives	24	858
1.8 Other (provide details if material)	0	0
1.9 Net cash from / (used in) operating activities	(361)	(641)
2. Cash flows related to investing activities		
2.1 Payments to acquire:		
(a) property, plant & equipment	(6)	(31)
(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	928
(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)	0	0
2.6 Net cash from / (used in) investing activities	(6)	897

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	0	38
3.2 Proceeds from issue of convertible notes	0	0
3.3 Proceeds from exercise of share options	50	75
3.4 Transaction costs related to issues of shares, convertible notes or options	0	0
3.5 Proceeds from borrowings	0	0
3.6 Repayment of borrowings	(32)	(110)
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	18	3

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash & cash equivalents at beginning of quarter / year to date	2,925	2,317
4.2 Net cash from / (used in) operating activities (see 1.9 above)	(361)	(641)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(6)	897
4.4 Net cash from / (used in) financing activities (item 3.10 above)	18	3
4.5 Effect of movement in exchange rates on cash held	0	0
4.6 Cash & cash equivalents at end of quarter	2,576	2,576

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	526	375
5.2 Cash deposits	2,050	2,550
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)	2,576	2,925

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	85
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	54
Non-Executive directors' remuneration	31

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	0
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	550
9.2 Product manufacturing & operating costs	90
9.3 Advertising & marketing	90
9.4 Leased assets	0
9.5 Staff costs	180
9.6 Administration & corporate costs	80
9.7 Other (provide details if material)	0
9.8 Total estimated cash outflows	990

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:

24th April 2019

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.