

ASX Release 30 January 2019

ASX code: PIQ

LABORATORIES LTD

# **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 December 2018.

- Collaboration agreement signed with US big pharma: deal with Janssen Research &
   Development, LLC to accelerate diabetic kidney disease and heart disease drug discovery
   using PromarkerD
- **Production of PromarkerD kit version completed:** new PromarkerD immunoassay results presented at 18th Diabetes Technology Meeting in USA
- **Record quarterly revenue:** continued strength from Analytical Services contracts resulted in quarterly revenue increasing 42% to exceed \$0.5 million
- **PromarkerD test to enter Europe:** licence deal with Patia Europe to see PromarkerD test available in Spain
- Dual technology platform provides more licensing opportunities for PromarkerD
- **R&D** for new diagnostic tests: proof of concept studies on-going for endometriosis and *Giardia*

#### **OPERATIONAL HIGHLIGHTS** - PromarkerD attracts interest from big pharma

Proteomics International's principal activities fall into three key areas: (i) commercialisation of PromarkerD, (ii) R&D for new diagnostic tests, and (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 also continues to apply its Promarker<sup>TM</sup> technology platform for biomarker discovery to other chronic diseases with significant unmet medical need.

# (i) Commercialisation of PromarkerD

# Proteomics signs collaboration agreement with US big pharma

[ASX: 26 November] Proteomics International signed a collaborative agreement with Janssen Research & Development, LLC. The study will see PromarkerD predictive technology used to accelerate drug discovery for diabetic kidney disease. The collaboration will also evaluate how PromarkerD performs in predicting heart disease, another major complication caused by diabetes and a new application for PromarkerD.

The collaboration has the potential to establish PromarkerD as a Complementary Diagnostic (CDx) test for the therapeutic treatment of diabetes complications. If successful the PromarkerD test could be expected to be used every time Janssen diabetes drugs are prescribed (becoming a gold standard test). Potentially of even greater value, PromarkerD could be used to identify specific target

populations that will respond to certain diabetes treatments, thus becoming valuable to numerous pharma companies serving the diabetes sector.

#### PromarkerD immunoassay (kit) version completed for commercial release

[ASX: 9 November] Manufacture of the PromarkerD immunoassay kit was completed following production of the key antibody reagents in Puerto Rico, and manufacture of the kit in certified facilities in California (in partnership with licence partner Omics Global Solutions).

To ensure the highest quality of product stringent Quality Control targets have been set for the immunoassay. Initial release batches were prepared in January following a rescheduling due to the end of year holiday shutdown. Minor productions issues were experienced with this batch which meant it was not certified for release. Another production run is scheduled for the beginning of February and commercial sales in the Dominican Republic remain imminent.

Results verifying the performance of the new PromarkerD immunoassay were presented at the 18th Annual Diabetes Technology Meeting in North Bethesda, Maryland, USA on 9 November.

## **PromarkerD Laboratory Developed Test licensing**

[ASX: 24 October] Proteomics International announced a licence deal that will see the PromarkerD test enter the Spanish market with Patia Europe. Currently there are 3.6 million adults with diabetes in Spain, where, like the rest of Europe, the incidence of diabetes is increasing rapidly. The licence permits Patia Europe to commercialise the PromarkerD mass spectrometry "Laboratory Developed Test" (LDT), which permits fast adoption of a new test in advanced markets.

The exclusive licence agreement for Spain is for two years and Proteomics International will receive a royalty on each test sold. Patia Europe is on track to launch PromarkerD within the next 3 months. In Mexico, sister company Patia Biopharma is tracking slightly behind the original rollout schedule but now following the lead of Patia Europe and targeting a similar launch date.

[ASX: 24 January] Proteomics International rescinded its exclusive licensing deal for the US with medical diagnostics company PrismHealthDx (Prism) due to ongoing rollout delays. Proteomics International is now negotiating with a number of US diagnostic and laboratory technology companies that offer larger markets and faster scale and deployment, including tier 1 national diagnostic groups.

### **Dual technology platforms to accelerate PromarkerD rollout**

The successful development of the PromarkerD immunoassay platform [ASX: 9 November 2018] has created new opportunities for the licensing of PromarkerD. The immunoassay reagents can be configured into a Laboratory Developed Test (LDT) for use by certified laboratories, which parallels the LDT using the existing mass spectrometry platform. The dual technology platforms offer greater choice to the large market of certified clinical laboratories that conduct these types of test.

In parallel with the fast roll-out of PromarkerD using the Laboratory Developed Test route, Proteomics International is also pursuing registration of the kit version of the test for larger scale adoption as market demand increases. The PromarkerD kit is being used to target new commercialisation deals in Japan, India and China, and opens the door to further commercialisation discussions around the world.

#### (ii) Diagnostics

## Proof of concept studies underway for endometriosis and Giardia

A proof of concept study is continuing 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 and costs \$12,000 per year for every person diagnosed. Results are due this quarter and, if successful, the proof of concept study may lead to patentable intellectual property.

A second proof of concept study is also underway 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

## **Proteomics wins Export Award**

[ASX: 24 October] Proteomics International took out the Health and Biotechnology category of the WA Industry and Export Awards on October 18. The export award reflected the company's doubling of export-derived revenue to \$795,000 for the 2018 financial year, coupled with growth in long-term markets such as India, and expansion into new markets with the first sales to China and the Netherlands.

#### FINANCIAL HIGHLIGHTS - Record receipts following continued strong revenue growth

Proteomics International's business model is to continue the commercialisation of PromarkerD whilst using its Promarker<sup>TM</sup> 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.

Receipts from customers for the quarter were a record for Proteomics International. Operating cash inflow from customers again showed a quarterly increase rising 42% to \$515,000 for the December quarter (previous \$363,000). Current and future orders from analytical services are strong, and royalty payments that Proteomics International receives from licences for PromarkerD will further enhance future cash flows.

There was a net operating cash inflow for the quarter from operating activities of \$321,000. In light of its strong cash position (see below) the company has continued its elevated expenditure (cf 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 31st December 2018 the company had cash reserves of \$2.93 million.

#### Cash boost to support company growth

[ASX: 5 October, 17 October] Proteomics International bolstered its balance sheet with \$928,399 received (in the September Quarter) from the sale of its shareholding in CPR Pharma Services. Proteomics International incurred a \$249,000 accounting loss on the transaction; an MOU with CPR remains in place targeting diagnostics and analytical services for clinical trials [ASX: 2 February 2018]. Proteomics International also received \$834,403 in R&D Tax Incentive, following a \$1.94 million R&D spend in 2017-18 [ASX: 17 October].

# Adelaide Equity Partners and Scintilla Capital appointed as Corporate Advisors

[ASX 14 November] Proteomics International has appointed new advisors to help unlock investor value and establish the foundation for further corporate growth. Adelaide Equity is an independent

investment bank, specialising in the provision of corporate advisory services for small-mid ASX listed companies in the healthcare, natural resource, industrial and technology sectors. Scintilla Capital is a specialist fund manager focused on high growth microcap ASX listed companies that target the disruptive technologies of tomorrow.

**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 bioanalytical 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<sup>™</sup> 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	Quarter ending ("current quarter")	
78 169 979 971	31 December 2018	

Coı	nsolidated 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	515	878
1.2	Payments for		
	(a) research & development	(654)	(1,248)
	(b) product manufacturing & operating costs	(70)	(134)
	(c) advertising & marketing	(21)	(77)
	(d) leased assets	0	0
	(e) staff costs	(185)	(344)
	(f) administration & corporate costs	(96)	(178)
3	Dividends received (see note 3)	0	0
4	Interest received	13	19
5	Interest & other costs of finance paid	(15)	(30)
l.6	Income taxes paid	0	0
7	Government grants & tax incentives	834	834
8	Other (provide details if material)	0	0
9	Net cash from / (used in) operating activities	321	(280)

2.	Cash flows related to investing activities		
2.1	Payments to acquire:		
	(a) property, plant & equipment	(15)	(25)
	(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) businessess (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)		
2.6	Net cash from / (used in) investing activities	(15)	903

<sup>+</sup> See chapter 19 for defined terms

1 September 2016

Cor	nsolidated statement of cash flows	Current Quarter	Year to date
		\$A'000	\$A'000
3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	38	38
3.2	Proceeds from issue of convertible notes	0	0
3.3	Proceeds from exercise of share options	25	25
3.4	Transaction costs related to issues of shares,	0	0
	convertible notes or options	0	0
3.5	Proceeds from borrowings	0	0
3.6	Repayment of borrowings	(39)	(78)
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	24	(15)

4.	Net increase / (decrease) in cash and cash		
	equivalents for the period		
4.1	Cash & cash equivalents at beginning of quarter / year to date	2,595	2,317
4.2	Net cash from / (used in) operating activities (see 1.9 above)	321	(280)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(15)	903
4.4	Net cash from / (used in financing activities (item 3.10 above)	24	(15)
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	Cash & cash equivalents at end of quarter	2,925	2,925

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	375	1,245
5.2	Cash deposits	2,550	1,350
5.3	Bank overdrafts	0	0
5.4	Other (provide details)	0	0
5.5	Cash & cash equivalents at end of quarter	2.025	2 505
	(should equal item 4.6 above)	2,925	2,595

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	95
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	44

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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	1
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	Total facility amount	Amount drawn
	Add notes as necessary for an	at quarter end	at quarter end
	understanding of position	\$A'000	\$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 len	der, 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	500
9.2	Product manufacturing & operating costs	60
9.3	Advertising & marketing	35
9.4	Leased assets	50
9.5	Staff costs	175
9.6	Administration & corporate costs	80
9.7	Other (provide details if material)	0
9.8	Total estimated cash outflows	900

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		

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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.
- This statement gives a true and fair view of the matters disclosed.

Date: Sign here: 30th January 2019

**Managing Director** 

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 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. 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.

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<sup>+</sup> See chapter 19 for defined terms