ASX Release

30 July 2019

ASX code: PIQ

Quarterly Business Activities 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 30 June 2019.

- **PromarkerD featured by the American Diabetes Association:** PromarkerD interview featured at annual industry-leading diabetes conference. Proteomics International encouraged by interest from a range of global companies and tier 1 national diagnostic groups
- **Global rollout:** Proteomics International continues to develop existing regional PromarkerD licensing agreements, whilst actively pursuing newly identified global opportunities
- **Janssen collaboration on track:** analysis proceeding to explore gliflozin drug and PromarkerD predictive diagnostic test in the treatment of diabetic kidney disease
- **R&D for new diagnostic tests:** proof-of-concept study for *Giardia* moves towards prototype testing; Endometriosis study continues to be evaluated. Both *Giardia* and endometriosis present a significant opportunity due to high prevalence and ineffective diagnostic tools currently available
- **FY2019 Analytical Services revenue more than doubles:** Proteomics International's receipts from customers for the year to June were $1.7 million, more than doubling those of FY18

OPERATIONAL HIGHLIGHTS - PromarkerD ATTRACTS GLOBAL ATTENTION

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.

i) Commercialisation of PromarkerD

PromarkerD featured at American Diabetes Association 79th Scientific Sessions

[ASX: 7 June] Managing Director Dr Richard Lipscombe was invited to feature on the American Diabetes Association (ADA) TV News Network as a key opinion leader (KOL) on diabetic kidney

disease diagnostics. The interview, which included an update on PromarkerD, was broadcast at the industry's leading conference, the ADA 79th Scientific Sessions, in San Francisco from 7-11 June.

PromarkerD was also showcased in the ADA 79th Scientific Sessions Exhibit Hall, which provided further opportunities to meet with global companies and with tier 1 national diagnostic groups for the test's US roll-out.

Proteomics International at world's largest biotech conference

[ASX: 3 June] Proteomics International showcased PromarkerD at the BIO International Convention, the world's largest biotech conference, in Philadelphia from 3-6 June. This event offered unparalleled access to global biotech and pharma leaders with more than 17,000 attendees from 70 countries. The Company was part of Western Australia's 'Think Perth' delegation, led by WA Deputy Premier and Health Minister Roger Cook, and Chief Scientist Professor Peter Klinken.

PromarkerD international licensing, regulatory approval, and patents

Proteomics International continues to develop existing regional PromarkerD licensing agreements, whilst actively pursuing newly identified global opportunities, including from the ADA and BIO conferences.

Currently licence partners cover Mexico, Dominican Republic and Spain, and Proteomics International looks forward to providing significant updates on the roll-out of PromarkerD in these jurisdictions in the coming weeks.

[ASX: 29 July] To support the global roll-out of PromarkerD Proteomics International recently secured TGA regulatory approval for the PromarkerD software as an in vitro diagnostic (IVD) for export use. The PromarkerD software hub enables the delivery of results of the proprietary PromarkerD algorithm to Proteomics International's partners around the world.

Indonesian patent number W00 2013 01585 titled "Biomarkers Associated with Diabetic Nephropathy" was also granted [ASX: 29 July]. Indonesia has 10.3 million adults with diabetes, which ranks the nation sixth in the International Diabetes Federation estimates for diabetes burden.

The PromarkerD patent portfolio now covers Indonesia, Australia, China, Europe, Japan, Russia, Singapore and USA, with other major jurisdictions pending.

Collaboration study with Janssen on-going

The Janssen collaboration seeks to explore the behaviour of Janssen's gliflozin drug and Proteomics International's PromarkerD predictive diagnostic test in the treatment for diabetic kidney disease [ASX: 24 January]. The collaboration is proceeding as planned and the first phase of laboratory analyses is nearing completion. The data will then be unblinded and statistical analysis performed, with results expected later this calendar year.

The on-going collaborative study with Janssen was supported by positive data in Janssen's CREDENCE study (Canagliflozin and Renal Events in Diabetes), announced on 14 April, 2019. Janssen reported that canagliflozin cut the risk of renal failure or death by 30% in patients with type 2 diabetes (T2D) and chronic kidney disease (CKD). These results, unveiled at the International Society of Nephrology 2019 World Congress of Nephrology in Melbourne, Australia, were simultaneously reported in the *New England Journal of Medicine*.[1]

The new findings highlight the potential of the collaboration to establish PromarkerD as a Complementary Diagnostic (CDx) test for the treatment of diabetes complications. If successful, the PromarkerD test could potentially be used every time Janssen's diabetes drug, or several other drugs in the gliflozin class, are prescribed.

[1] Perkovic V, et al; Canagliflozin and renal outcomes in type 2 diabetes and nephropathy. N Engl J Med. 2019. DOI: 10.1056/NEJMoa1811744.

ii) Diagnostics

Proof of concept studies for endometriosis and *Giardia*

The proof of concept study for biomarkers that could be used to test endometriosis has been delayed. After positive results last year, a breakdown of the Company's high sensitivity mass spectrometry instrument used for discovery research has prevented the completion of confirmatory studies. This issue has now been addressed and the analysis remains on-going and is due to complete in the September quarter. If successful, the study may lead to patentable intellectual property for a disease that affects one in ten women in their reproductive years and does not have a diagnostic tool beyond invasive surgery. Given these factors, an effective, non-invasive test for endometriosis would be highly valuable to Proteomics International and a potential licensing partner.

A second proof of concept study developing an improved diagnostic test for the parasite *Giardia* has made substantial progress and moved towards prototype testing. The study is being undertaken 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.

Strain specific *Giardia* targets have been identified using a combination of proteomics and bioinformatics techniques. Synthetic mimics of these targets have been manufactured using synthetic peptide chemistry, and these peptides have been used for antibody generation. The resulting antibodies are being assessed for performance in a paired immunoassay format. Prototype assays will then be tested against control samples in order to prove the technical viability of the assay. The commercial viability of the immunoassay will not be known until completion of this last phase, which is expected to take another four months.

Giardia is one of the most common parasitic human diseases globally. About 10% of those infected have no symptoms. In 2013, there were about 280 million people worldwide with symptomatic giardiasis. In some developing countries *Giardia* is present in 30% of the population, and in the USA it is estimated that it is present in about 5% of the population. Existing diagnostic tests have low accuracy presenting a large market opportunity for Proteomics International.

iii) Analytical Services

Revenue from analytical services continued to be driven by volume in biosimilars and pharmacokinetic (PK) 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).

Subsequent to the quarter, Proteomics International announced it was expanding its partnership with Linear Clinical Research, securing two new contracts to conduct pharmacokinetic testing [ASX: 26 July]. The contracts have a combined value of $418,000, with the studies to be undertaken over the next 3-10 months. The contracts further validate Proteomics International's PK testing capabilities and highlight the growth potential of the analytical services business.

FINANCIAL HIGHLIGHTS - REVENUE GROWTH 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 achieved record receipts from customers for the year to 30 June of $1.73 million, more than doubling those of the previous year (FY18: $818,000). June quarter receipts of $245,000 were lower than recent quarters but the Company continues to maintain a strong order book as exemplified by the recently announced analytical services contracts for pharmacokinetics

testing described above. Royalty and milestone payments that Proteomics International receives from licences for PromarkerD will further enhance future cash flows.

There was a larger than usual net operating cash outflow for the June quarter of $1.06 million, against $1.70 million for the year as a whole. This increased net outflow was as a result of the lower quarterly receipts, and several one-off expenditures in relation to PromarkerD commercialisation and elevated expenditure (as compared to FY18) in the following areas:

- R&D spending relating to the completion of the immunoassay (kit) version of PromarkerD [the immunoassay version is critical to PromarkerD's future product development because the format is easier to deploy to all potential markets]
- Development spending relating to the roll-out of the Laboratory Developed Test (mass spectrometry) version of PromarkerD
- Costs for seeking regulatory approvals
- Business development and commercialisation costs for the roll-out of PromarkerD

These necessary expenditures will be reduced in future quarters but have enabled Proteomics International to make significant advances in a number of areas, and for which the Company will provide updates in the coming weeks.

At 30th June 2019, Proteomics International had cash reserves of $1.51 million (30th March $2.58million) and these reserves will be strengthened by an estimated R&D rebate of $1.1 million in the first half of the new financial year. Additionally, the Company has $150,000 on long term deposit and trade debtors of approximately $450,000.

Proteomics International at top Hong Kong investment summit

Managing Director Dr Richard Lipscombe presented Proteomics International to Asian investors at 121 Tech Investment in Hong Kong on June 12-13. The 121 Tech Investment summit was an opportunity to deliver in-depth presentations and host private one-on-one meetings with institutional and sophisticated investors.

Proteomics International will undertake further investor engagement events through September.

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	**Quarter ending ("current quarter")**
78 169 979 971	**30 June 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	245	1,729
1.2	Payments for		
	(a) research & development	(727)	(2,584)
	(b) product manufacturing & operating costs	(81)	(286)
	(c) advertising & marketing	(160)	(324)
	(d) leased assets	(76)	(76)
	(e) staff costs	(200)	(733)
	(f) administration & corporate costs	(68)	(307)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	9	45
1.5	Interest & other costs of finance paid	(5)	(26)
1.6	Income taxes paid	0	0
1.7	Government grants & tax incentives	0	858
1.8	Other (provide details if material)	0	0
1.9	**Net cash from / (used in) operating activities**	**(1,063)**	**(1,704)**

2.	**Cash flows related to investing activities**		
2.1	Payments to acquire:		
	(a) property, plant & equipment	(7)	(38)
	(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**	**(7)**	**890**

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	44	119
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)	(149)
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**	**5**	**8**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of quarter / year to date	2,576	2,317
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(1,063)	(1,704)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	890
4.4	Net cash from / (used in financing activities (item 3.10 above)	5	8
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	**Cash & cash equivalents at end of quarter**	**1,511**	**1,511**

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	461	526
5.2	Cash deposits	1,050	2,050
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)**	**1,511**	**2,576**

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	82
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	48
	Non-Executive directors' remuneration	34

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	10
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 *Add notes as necessary for an understanding of position*	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	600
9.2	Product manufacturing & operating costs	75
9.3	Advertising & marketing	50
9.4	Leased assets	20
9.5	Staff costs	180
9.6	Administration & corporate costs	70
9.7	Other (provide details if material)	0
9.8	**Total estimated cash outflows**	**995**

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:  Date: 30th July 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.