ASX Release
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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 30 September 2019.

- **Janssen collaboration study progresses:** first phase of laboratory analyses completed with global pharmaceutical drug developer, Janssen; statistical analysis now underway, with results due in Q3 of FY20
- **PromarkerD launched in Spain:** diabetic kidney disease test available under exclusive licence agreement with Patia Europe
- **Technology transfer opens door to new markets in Europe:** PromarkerD mass spectrometry technology successfully transferred to clinical diagnostics partner Atturos in Ireland
- **Advanced immunoassay In Vitro Diagnostic Test (IVD) validated:** PromarkerD test now offered in two technology platforms
- **PromarkerD clinical results published in peer-reviewed journal:** latest results show PromarkerD has excellent negative predictive value ("rule-out" capability)
- **PromarkerD secures TGA approval for software IVD and Indonesian patent:** the software web portal enables the secure delivery of test results to partners around the world
- **New pharmacokinetic analysis contracts secured:** continued analytical services revenue supports development of pioneering diagnostics
- **R&D tax offset strengthens balance sheet:** receipt (post quarter) of $1.1 million from R&D Tax offset gives cash reserves exceeding $2 million

OPERATIONAL HIGHLIGHTS - PromarkerD - PIVOTAL MILESTONES ACHIEVED

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

1. Commercialisation of PromarkerD
2. R&D for new diagnostic tests
3. Analytical services on a commercial basis

(i) Commercialisation of PromarkerD

Proteomics International achieved three pivotal milestones in the commercialisation of PromarkerD in the quarter: validation of the immunoassay version of the PromarkerD technology, successful technology transfer of the PromarkerD mass spectrometry assay to specialist molecular diagnostics company Atturos in Europe, and launch of PromarkerD in Spain. Further results on the performance

of PromarkerD in clinical studies were also published in the *Journal of Diabetes and its Complications*.

These milestones significantly improve the commercial utility of PromarkerD and as a result the Company has advanced on-going, and entered into new, discussions with tier-1 diagnostics and pharmaceutical companies, targeting global markets to expand the global reach of PromarkerD.

Janssen collaboration study progresses

As announced on 24 January, Proteomics International entered into a collaborative study with Janssen, the pharmaceutical arm of Johnson & Johnson. The Janssen collaboration seeks to explore the behaviour of Janssen's gliflozin drug (Invokana™) and Proteomics International's PromarkerD predictive diagnostic test in the treatment for diabetic kidney disease. Invokana™ is already registered for the treatment of type-2 diabetes and is expected shortly to have its label broadened as a preventative medicine for diabetic kidney disease after positive phase 3 clinical trials results earlier this year.

Proteomics International is pleased to report that the first phase of laboratory analyses was completed in October. The data will now be unblinded and statistical analysis performed simultaneously by Janssen and Proteomics International. The Company is excited by the potential transformative outcome of these results, which are expected in Q3 FY20.

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. Being established as a CDx means the PromarkerD test could potentially be used every time Janssen's diabetes drug, or several other drugs in the gliflozin class, are prescribed.

PromarkerD launched in Spain

[ASX: 13 September] Proteomics International launched PromarkerD in Spain, where diabetes affects 10 per cent of the adult population or 3.6 million people. The launch coincided with PromarkerD being showcased at the 55th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Barcelona from September 16-20.

Being live in Spain signifies a pivotal milestone in the commercialisation of PromarkerD, providing a valuable reference point, which is anticipated to expedite commercial discussions in additional jurisdictions.

The launch is the culmination of an exclusive licence agreement with Patia Europe and Proteomics International will receive a royalty on each test sold. This licence is for two years and covers the mass spectrometry laboratory developed test (MS-LDT) version for PromarkerD (see Annual Report 2019 and below).

Technology transfer opens door to new markets in Europe

[ASX: 12 September] Proteomics International and clinical diagnostics firm Atturos successfully transferred the PromarkerD test system to Atturos' laboratories in Ireland. The achievement means PromarkerD is available as a MS-LDT to licence partners in Europe.

Proteomics International and Atturos scientists undertook a stringent validation process of the PromarkerD method, and demonstrated data equivalence in 100 patient samples analysed in both laboratories. The results of this successful "cross-over" study were presented at the 18th Human Proteome Organization World Congress in Adelaide in September.

Advanced immunoassay In Vitro Diagnostic Test (IVD) validated

[ASX: 17 September] Proteomics International validated the company's new advanced PromarkerD immunoassay In Vitro Diagnostic Test (IVD) platform. The successful validation means the PromarkerD test for diabetic kidney disease is now available in two technology platforms (mass spectrometry and immunoassay), servicing the Laboratory Developed Test and IVD markets.

The new PromarkerD IVD technology can be manufactured as either a kit or configured to run on automated immunoassay platforms to meet the diverse needs of clinical diagnostics laboratories around the world. The additional technology platform increases the attractiveness of PromarkerD to the diagnostics community, and is expected to accelerate commercialisation of the ground-breaking test.

PromarkerD clinical results published in peer-reviewed journal

[ASX: 10 September] The latest clinical validation results for PromarkerD have been published in the peer-reviewed *Journal of Diabetes and its Complications*. PromarkerD is the first test in the world capable of predicting the onset of diabetic kidney disease, with a study of 447 patients confirming PromarkerD correctly predicted 86 per cent of people who went on to develop chronic kidney disease within four years.

Importantly the latest results show PromarkerD also has an excellent negative predictive value or "rule-out" capability, with the test correctly predicting 98 per cent of people who did not go on to develop diabetic kidney disease within four years. The research was conducted in collaboration with The University of Western Australia Medical School.

PromarkerD secures TGA approval for software IVD and Indonesian patent

[ASX: 29 July] Proteomics International secured TGA regulatory approval for PromarkerD software as an in vitro diagnostic (IVD) for export use. The software was included on the Australian Register of Therapeutic Goods on the 24 July 2019. The remote software hub enables the secure delivery of test results to Proteomics International's partners around the world, and provides an additional level of intellectual property security beyond the company's comprehensive patent portfolio.

Proteomics International also added to its extensive patent portfolio, securing a patent for PromarkerD in Indonesia, which is home to more than 10 million people with diabetes - the sixth highest in the world. The PromarkerD patents are now in place in Indonesia, Australia, China, Europe, Japan, Russia, Singapore and USA, with other major jurisdictions pending.

(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 placed on hold whilst the Company focuses on the advancement of PromarkerD.

A second proof of concept study developing an improved diagnostic test for the parasite *Giardia* has continued with prototype testing of an immunoassay version of the test. 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.

Giardia is one of the most common parasitic human diseases globally and existing diagnostic tests have low accuracy presenting a large market opportunity for Proteomics International. Results of the prototype testing are expected in Q2/Q3 of FY20.

(iii) Analytical Services

Revenue from analytical services was driven by 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).

New pharmacokinetic analysis contracts secured

[ASX: 26 July] Proteomics International expanded its partnership with Linear Clinical Research, securing two new analytical services contracts with a combined value of $418,000. The contracts are

to perform pharmacokinetic analysis of novel autoimmune disease drugs, further validating Proteomics International's pharmacokinetic testing capabilities. The revenue from Proteomics International's specialist analytical services continues to support the development and commercialisation of the Company's pioneering diagnostic tests.

FINANCIAL HIGHLIGHTS - ANALYTICAL SERVICES REVENUE CONTINUES TO OFFSET CASH BURN

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 receipts from customers for the September quarter of $373,000 (June quarter FY19: $245,000). The Company continues to maintain a strong order book as exemplified by the analytical services contracts for pharmacokinetics testing described above.

Royalty payments that Proteomics International receives from the launch of PromarkerD are expected to be modest initially but will enhance future cash flows. Future licences for PromarkerD are also anticipated to add to Proteomics International's revenue in the form of upfront and milestone payments.

The net operating cash outflow for the September quarter of $584,000 was in line with budget, and significantly reduced from the previous quarter (June $1.06 million). This expenditure was centred on PromarkerD commercialisation in the following areas:

- R&D spending relating to the analysis of clinical trial samples from the Janssen collaboration
- R&D spending relating to the completion of the immunoassay (kit) version of PromarkerD
- Costs for seeking regulatory approvals
- Business development and commercialisation costs for the roll-out of PromarkerD

At 30 September 2019, Proteomics International had cash reserves of $1.05 million (30th June $1.51million) and trade receivables of approximately $320,000, and these reserves were strengthened by an R&D rebate of $1.1 million post the quarter [ASX: 29 October].

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 September 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	373	373
1.2	Payments for		
	(a) research & development	(582)	(582)
	(b) product manufacturing & operating costs	(51)	(51)
	(c) advertising & marketing	(40)	(40)
	(d) leased assets	0	0
	(e) staff costs	(164)	(164)
	(f) administration & corporate costs	(121)	(121)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	6	6
1.5	Interest & other costs of finance paid	(5)	(5)
1.6	Income taxes paid	0	0
1.7	Government grants & tax incentives	0	0
1.8	Other (provide details if material)	0	0
1.9	**Net cash from / (used in) operating activities**	**(584)**	**(584)**

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

Consolidated statement of cash flows		Current Quarter $A'000	Year to date Year to date $A'000
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	0	0
3.2	Proceeds from issue of convertible notes	0	0
3.3	Proceeds from exercise of share options	0	0
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)	(39)
3.7	Transaction costs related to loans & borrowings	0	0
3.8	Dividends paid	0	0
3.9	Other (deposit released from escrow)	164	164
3.10	**Net cash from / (used in) financing activities**	**125**	**125**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash & cash equivalents at beginning of quarter / year to date	1,511	1,511
4.2	Net cash from / (used in) operating activities (see 1.9 above)	(584)	(584)
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)	125	125
4.5	Effect of movement in exchange rates on cash held	0	0
4.6	**Cash & cash equivalents at end of quarter**	**1,050**	**1,050**

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	836	461
5.2	Cash deposits	214	1,050
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)**	**1,050**	**1,511**

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	74
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
	No-Executive directors' remuneration	23

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 *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		

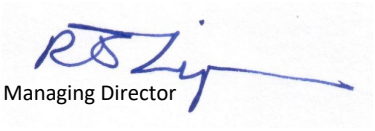
9.	Estimated cash outflows for next quarter	$A'000
9.1	Research & development	450
9.2	Product manufacturing & operating costs	40
9.3	Advertising & marketing	50
9.4	Leased assets	0
9.5	Staff costs	150
9.6	Administration & corporate costs	60
9.7	Other (provide details if material)	0
9.8	**Total estimated cash outflows**	**750**

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: 31st October 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.