

Proteomics International

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ASX Release

27 July 2020

ASX code: PIQ

Intellectual Property portfolio expands: PromarkerD secures patents for Brazil and Canada Business Model outlined

- **PromarkerD patent portfolio now covers USA, Europe, Australia, Brazil, Canada, China, Indonesia, Russia, Singapore and Japan**
- **Granted patent and trademark portfolio covers 59% of the 463 million adults living with diabetes - currently 1 in 3 develop diabetic kidney disease**
- **New patents secured for Brazil and Canada for the PromarkerD predictive test for diabetic kidney disease - Brazil has 16.8 million adults with diabetes and Canada has 2.8 million**
- **Intellectual property protection now afforded by patents, trademarks and trade-secrets providing the necessary foundation to accelerate commercial discussions**
- **PromarkerD software hub and proprietary reagents used in the test system provide additional levels of intellectual property security beyond the Company's comprehensive patent portfolio**
- **Early detection of diabetic kidney disease by PromarkerD can help prevent the need for renal replacement therapies, potentially saving global healthcare systems billions of dollars annually**
- **Significant commercial motivation for prospective partners – the addressable diabetes patient population in the USA alone who may benefit from an affordable test is in excess of 30 million**

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has secured patents for PromarkerD, the world's only low cost, high throughput predictive test for diabetic kidney disease, in Brazil and Canada.

The International Diabetes Federation estimates there are 463 million adults living with diabetes globally - currently 1 in 3 develop diabetic kidney disease (DKD). In results from a major international study recently presented at the 80th annual meeting of the American Diabetes Association, PromarkerD was able to predict those patients who went on to develop DKD during the four year study.

Proteomics International Managing Director Dr Richard Lipscombe said, *“being able to correctly predict an early decline in kidney function in these people means that doctors and patients can take action to prevent patients going on to costly dialysis and eventual kidney transplant.”* The annual cost of diabetic kidney disease is estimated at US\$50 billion per year in the USA alone.

The new patents complement those already granted in USA, Europe, Australia, China, Indonesia, Russia, Singapore and Japan (Table 1). Given the Company's ambitions to execute licensing transactions globally, the granting of the new patents secure other potentially lucrative jurisdictions.

Together the granted patents cover 225 million (49%) of the addressable diabetes patient population globally. The total protected market expands to 273 million (59%) when regions afforded patent or trademark protection are included.

The Company has received notification that Canada patent (no. 2811654) has been granted, and Brazil

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patent (no. BR1120130067640) has passed examination and is due to issue within the next two weeks. Both patents are titled “Biomarkers Associated with Pre-diabetes, Diabetes and Diabetes Related Conditions” and will extend until 20 September 2031.

Promarker™D

To strengthen the global IP position “Promarker” has been registered as a trademark in multiple target markets (Table 2). Promarker® trademark protection has the potential to extend the lifespan of future revenue streams beyond the expiry of the Company's patents.

Table 1: PromarkerD Patent coverage

The patents cover use of the test for diabetic kidney disease (DKD) unless otherwise stated.

Country	Patent/ Application No.	Status	Diabetes Prevalence ¹
Australia ²	2011305050	Granted	1,288,300
Brazil	BR1120130067640	Granting	16,780,800
Canada	2811654	Granted	2,793,500
China	ZL201180053583.9	Granted	116,446,900
Europe ^{2,3}	3151012	Granted	59,322,100
Hong Kong	18115912.3	Pending	723,400
India	3012/DELNP/2013	Pending	77,005,600
Indonesia	W00 2013 01585	Granted	10,681,400
Japan	2013-528474	Granted	7,390,500
Russia	2596486	Granted	8,288,500
Singapore	188527	Granted	640,400
USA ^{2,4}	US 9,146,243	Granted	30,987,900
Total			332,349,300

¹ International Diabetes Federation (IDF) Atlas 9th Edition 2019 [Age group 20-79 years; Total = Diagnosed (48.7%) + Undiagnosed (51.3%)].

² Australia, Europe, USA patent extended to cover use of the test for any form of kidney disease (NB Further studies are required to prove efficacy of PromarkerD for applications beyond DKD)

³ Covers France, Germany, Italy, Spain, Turkey, and the United Kingdom, which cumulatively have 29.6 million adults with diabetes.

⁴ USA patent further extended to cover method for identifying drugs for abnormal kidney function using one of the PromarkerD biomarkers (CDSL).

Table 2: Promarker® Trademark coverage

The Promarker® technology platform used to develop PromarkerD can be used to identify unique protein biomarkers “fingerprints” in any biological system.

Country	Also covered by Patent	Status	Diabetes Prevalence ¹
Australia	yes	Granted	1,288,300
China	yes	Pending	116,446,900
Dominican Republic	no	Granted	578,800
Europe ²	partial	Granted	59,322,100
Israel	no	Granted	644,300
Japan	yes	Granted	7,390,500
Mexico	no	Granted	12,805,200
New Zealand	no	Granted	259,800
Russia	yes	Granted	8,288,500
Singapore	yes	Granted	640,400
South Korea	no	Granted	3,689,400
USA	yes	Granted	30,987,900
Total			242,342,100

Class 44 – Medical diagnostics services (No. 1776917) & Class 5 – Diagnostic apparatus for medical purposes including diagnostics kits (No. 1806616)

¹ International Diabetes Federation (IDF) Atlas 9th Edition 2019 [Age group 20-79 years; Total = Diagnosed (48.7%) + Undiagnosed (51.3%)].

² Trademark covers all of European Union, representing an additional 29.8 million adults with diabetes beyond the European patents.

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The third component of the Company's intellectual property portfolio for the PromarkerD test system are Trade Secrets. These cover both the PromarkerD Hub (software algorithm) and the key antibody reagents used in the manufacture of the PromarkerD immunoassay (IA).

PromarkerD (IA) requires specialist reagents (antibodies used to detect the biomarkers) which the Company has produced and owns sole rights to their use. The PromarkerD Hub enables the delivery of results of the proprietary PromarkerD algorithm to Proteomics International's partners around the world. The algorithm operates via a remote server to provide an additional level of intellectual property security.

Table 3: Total Addressable Market

The total potential addressable markets for clinical pathology laboratories (it is expected the PromarkerD test may be performed once per year per patient on average (Standard of care: High-risk patients are tested every 3-6 months; Low-risk every 2 years)).

Addressable Market by Region	
	No. of diabetics ¹
USA Only	30,987,900
Patent Granted - Globally	224,850,100
Global	462,969,900

Assumptions:

¹ International Diabetes Federation (IDF) Atlas 9th Edition 2019 [Age group 20-79 years; Total = Diagnosed (48.7%) + Undiagnosed (51.3%)].

Business Model Outline

Proteomics International is actively pursuing identified global and regional licensing opportunities for PromarkerD across jurisdictions covered by its patents and trademarks and is currently in commercialisation discussions with several different parties.

The Company’s business model is to out-license its intellectual property to diagnostics providers and to receive a royalty on each test sold. Proteomics International will also sell the specialist reagents required to perform each test, whilst the PromarkerD hub monitors and counts use of the test by each provider.

Proteomics International is targeting a test price to the patient of between US\$55 and US\$150 (test price of US\$55 is based on use of existing American Medical Association CPT billing codes for similar analytes to the PromarkerD panel; test price of US\$150 is based on stakeholder engagement responses (Proteomics International market access study conducted by independent US consultant)). Standard industry royalty rates for out-licensing of intellectual property for diagnostics typically range from 5-15%.

PromarkerD has the potential to spare millions of people from future dialysis costs, and save healthcare systems billions of dollars. Consequently, the Directors of Proteomics International believe that ultimately the financial impact of each licence will be significant. However, as for any novel test, market penetration cannot be predicted accurately, hence for any new licences it is not possible to quantify the financial impact on Proteomics International in any given timeframe.

Authorised by Dr Richard Lipscombe (Managing Director) on behalf of the Board of PIQ.

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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. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each received CE Mark registration in the European Union.

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 high-speed, low cost predictive 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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ASX Release
9 October 2020

ASX code: PIQ

Proteomics International and QIMR Berghofer Institute partner to target oesophageal cancer

Highlights

- **Proteomics International partners with QIMR Berghofer Medical Research Institute (QIMR Berghofer) to improve detection of oesophageal adenocarcinoma, the most common oesophageal cancer.**
- **The Partnership will use the Promarker™ platform with QIMR Berghofer biomarkers to develop a simple blood test for a cancer whose incidence is rising rapidly.**
- **The test targets Barrett’s oesophagus, a pre-malignant condition associated with an increased risk of developing cancer of the oesophagus (food pipe) due to acid reflux.**
- **Significant unmet medical need with current diagnosis involving invasive endoscopy and biopsy which requires specialist medical expertise and costs US\$2,750 per patient¹.**
- **Across North America, Australia and Europe over 6 million patients suffer from the disease, with 850,000 of them having endoscopic screens each year in the USA alone.**
- **The collaboration is part of Proteomics International’s strategy to continually expand its diagnostics portfolio in areas of significant unmet medical need.**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a medical technology company specialising in novel clinical diagnostics, and QIMR Berghofer Medical Research Institute (QIMR Berghofer) have joined forces to improve detection of oesophageal adenocarcinoma, the most common form of oesophageal cancer in Australia.

The partnership will see Proteomics International use its Promarker™ platform to analytically and then clinically validate a panel of biomarkers—protein ‘fingerprints’ in the blood—that QIMR Berghofer researchers found are associated with early stages of the cancer. The aim is to develop a simple blood test for oesophageal adenocarcinoma.

Upon development, the test could be offered to patients with Barrett’s oesophagus, a pre-malignant condition associated with an increased risk of developing oesophageal cancer. Barrett’s oesophagus is a condition that affects approximately 2% of the population² and occurs when the oesophagus is damaged by acid reflux.

The American Gastroenterological Association recommends people with Barrett’s oesophagus are regularly screened to check for pre-cancerous cells, with surveillance ranging from every three months to triennially. If discovered early, the pre-cancerous cells can be treated to prevent oesophageal cancer.

QIMR Berghofer medical researcher Associate Professor Michelle Hill, who led the team that discovered the biomarkers, said the blood test under development could fundamentally change oesophageal cancer screening.

¹ www.newchoicehealth.com/endoscopy

² Barrett’s oesophagus: epidemiology, diagnosis and clinical management (2016); doi.org/10.5694/mja16.00796

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“At the moment, patients have to undergo an invasive endoscopy, with a camera passed down their throat to look for changes in the oesophagus tissue, and a biopsy taken. It’s uncomfortable for patients, requires specialist expertise, and comes with some risk of perforation and bleeding,” she said. Endoscopies are also expensive, costing an average of US\$2,750 in the USA.

Proteomics International managing director Dr Richard Lipscombe said the new technology aimed to identify the 5% of people most at risk of oesophageal adenocarcinoma, and prioritise treatment for those patients. “It has huge potential to bring down the overall number of endoscopy procedures, limit unnecessary patient discomfort and reduce the burden on the health system,” he said.

If the oesophageal adenocarcinoma collaboration is successful, Proteomics International will have first rights to license the IP and commercialise the test worldwide. The collaboration will be for one year and both parties will bear their own costs. QIMR Berghofer has patents pending for the biomarker panel in Australia, Canada, China, Europe and the United States.

The collaboration is part of Proteomics International’s strategy to continually expand its diagnostics portfolio, including in-licensing IP to strengthen the Company’s Promarker™ R&D pipeline. Proteomics International’s proprietary Promarker™ platform has already been used to develop PromarkerD, the world’s first commercially-available test for diabetic kidney disease.

Oesophageal adenocarcinoma has been highlighted as a major global health concern, and the incidence is rising rapidly having increased five-fold in Australia in the last 40 years. Across North America, Australia and Europe it is estimated there are over 6 million patients suffering from the disease, with 850,000 of them having endoscopic screens each year in the USA alone.

Authorised by Dr Richard Lipscombe (Managing Director) on behalf of the Board of PIQ.

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About QIMR Berghofer (www.qimrberghofer.edu.au)

QIMR Berghofer Medical Research Institute was established by the Queensland Government 75 years ago and has a rich history of scientific discoveries and translational medical research. QIMR Berghofer is focused on improving health by developing new diagnostics and better treatments and prevention strategies, specifically in the areas of cancer, infectious diseases, mental health and chronic disorders. The Institute works in close collaboration with clinicians and other research institutes and is home to approximately 1000 scientists, students and support staff. QIMR Berghofer has an active program for the commercialisation of technologies, including those developed in conjunction with academic or commercial collaborators.

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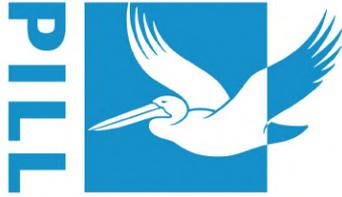
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ASX Release
12 October 2020
ASX code: PIQ

PromarkerD international validation study results published in Journal of Clinical Medicine

Medical Technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce the publication of the successful validation results from a major multi-centre clinical study confirming the effectiveness of PromarkerD as a predictive test for diabetic kidney disease.

The findings have been published online as an early version of the internationally peer-reviewed Journal of Clinical Medicine in a paper titled '*PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)*'¹. These results were first presented at the world's leading diabetes conference, the 80th Scientific Sessions of the American Diabetes Association (ADA) [ASX: 15 June].

The joint publication between Proteomics International, The University of Western Australia Medical School and Janssen Research and Development is the first external validation study of PromarkerD which confirms the prognostic utility of the test for incident chronic kidney disease (CKD).

PromarkerD scores were measured at baseline ('Year 0') in 3,568 patients with type 2 diabetes with pre-existing high-risk of cardiovascular disease from the completed four-year phase 3 CANVAS clinical trial. The primary finding of the publication is that PromarkerD accurately predicted which patients in the trial would develop clinically significant CKD during the four-year period.

The participants in the study had a median PromarkerD score of 2.9%, with 70.5% categorised as low-risk, 13.6% as moderate-risk and 15.9% as high-risk for developing CKD. Patients predicted by PromarkerD to be at high-risk of CKD were 13.5 times more likely than the low-risk group to develop the disease, with the results showing high statistical significance ($P = 1.3 \times 10^{-104}$).

In addition, the Authors observed that the results from this group of diabetes patient at high-risk of cardiovascular disease showed differences from previous publications in community-based diabetes patients². This highlights pathways that can be explored to refine the renal decline algorithm for such patients and forms part of the Company's on-going collaboration with Janssen [ASX: 31 March].

Proteomics International managing director Dr Richard Lipscombe, also senior author on the paper, said this was a pivotal study for the Company. "*Peer-reviewed publications form an essential component of PromarkerD's adoption by Key Opinion Leaders and the wider diabetes community. The clinical data will now form an important part of the evidence in an application for FDA regulatory approval of the PromarkerD test system,*" he said.

Authorised by Terry Sweet (Chair) on behalf of the Board of PIQ.

ENDS

¹ J. Clin. Med. (2020) 9, 3212; doi.org/10.3390/jcm9103212

² J. Diabetes Complic. (2019) 33, 107406; doi.org/10.1016/j.jdiacomp.2019.07.003

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About PromarkerD (www.PromarkerD.com)

PromarkerD is a predictive test for the early detection of chronic kidney disease (CKD) in patients with type-2 diabetes. CKD is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant.

The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of disease by measuring three serum proteins (ApoA4, CD5L and IGFBP3), combined with three routinely available conventional clinical variables (age, high-density lipoprotein (HDL)-cholesterol and estimated glomerular filtration rate (eGFR)).

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. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each achieved CE Mark registration in the European Union.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD ADA virtual booth please see: www.PromarkerD.com/product

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ASX Release
16 October 2020

ASX code: PIQ

First distribution agreement for easy-to-use immunoassay version of PromarkerD test

- **World's first predictive test for diabetic kidney disease to be made available in Italy in partnership with innovative Italian distributor Medical Horizons SRL**
- **Licence marks the first distribution agreement for the easy-to-use, high volume immunoassay version of the PromarkerD test**
- **Agreement is for two years, and will see Medical Horizons become the exclusive distributors for PromarkerD in Italy**
- **Italian Key Opinion Leaders already engaged to help drive early adoption of the test by major hospitals**
- **Italy is home to 3.7 million people with diabetes, with 60 million diabetics across the EU**
- **The launch of PromarkerD immunoassay in Italy to drive demand for the test in other jurisdictions - licensing discussions ongoing in multiple countries**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has signed a distribution licensing agreement for the immunoassay version of the PromarkerD predictive test for diabetic kidney disease. The agreement with leading medical distributor Medical Horizons SRL will see the blood test made available to patients in Italy, where 1 in 12 adults has diabetes.

Proteomics International managing director Dr Richard Lipscombe said the partnership marked the first distribution licensing deal for the immunoassay version of the PromarkerD test, PromarkerD (IA). *"Previously we focused on the more sophisticated mass spectrometry test, but the release of this easy-to-use, higher throughput immunoassay platform opens up many more market opportunities,"* he said.

"The availability of the CE Marked PromarkerD immunoassay kit allows new licensing models for this ground-breaking test. We can enter into more traditional distribution agreements with proven companies like Medical Horizons."

The immunoassay (ELISA) technology is cost-effective and standard to clinical diagnostics laboratories around the world. The format allows hundreds of blood samples to be analysed quickly as part of a panel of routine blood tests.

The distribution agreement with Medical Horizons is for two years, exclusive to Italy, and exclusive to PromarkerD (IA). Proteomics International will receive payment for each kit sold. Further details of the licence agreement are commercially sensitive and remain confidential. As for any novel test, market penetration cannot be predicted accurately, hence for the new licence it is not possible to quantify the financial impact on Proteomics International in any given timeframe.

Italy is home to 3.7 million people with diabetes according to the International Diabetes Federation. Across Europe, there are 60 million people with diabetes, and the number is expected to rise to 68 million by 2045 without immediate action. Currently one-in-three people with diabetes develop

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chronic kidney disease and PromarkerD is the only test available in the European Union for predicting the onset of the condition.

Medical Horizons CEO Guido Osto said bringing PromarkerD to patients in Italy will support clinical decision-making. *“With this technology used as an annual test, doctors will be able to identify at-risk patients for early intervention,”* he said. *“It will help minimise the effects of diabetic kidney disease, and potentially save the healthcare system billions of Euros.”*

Medical Horizons will now complete registration of PromarkerD with the Italian Ministry of Health (one month) at which point the test can start being sold. Medical Horizons are already engaged with a number of Italian Key Opinion Leaders for the promotion and early adoption of the test by major hospitals. The engagement with these KOLs will also help drive awareness and understanding of PromarkerD’s benefits in additional markets [ASX: 12 Oct].

Dr Lipscombe said Proteomics International was currently renegotiating deals with the Company’s existing PromarkerD partners, allowing them to access the immunoassay version of the test. *“We also expect that bringing PromarkerD to Italy will drive demand for the test in other jurisdictions, and we’re continuing discussions with diagnostic and pharmaceutical companies in multiple countries.”*

Authorised by the Board Proteomics International Laboratories Ltd (ASX:PIQ).

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About PromarkerD (www.PromarkerD.com)

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Further information is available through the PromarkerD web portal.

To visit the PromarkerD ADA virtual booth please see: www.PromarkerD.com/product

About Medical Horizons (www.medicalhorizons.it)

Medical Horizons was created to identify medical innovation worldwide that has the potential to become innovative new products, and then develop their commercialisation through a selected Italian sales network. The Company's existing products cover a number of cancers, women's health and new-born screening. Medical Horizons is one of the most trusted players in the medical import field in Italy, and its expertise includes understanding the commercial interest that innovative devices will have for the Italian market to ensure products will meet the needs of prospective users .

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ASX Release
23 October 2020

ASX code: PIQ

Proteomics International raises \$6m in heavily oversubscribed Placement

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, is pleased to advise that it has received firm commitments for a share placement to raise \$6 million (before costs) through the issue of 12.5 million shares in the Company (the "Placement").

The Placement was at an issue price of \$0.48 per share, a discount of 14.9% to the 20 day VWAP and was heavily oversubscribed, supported by UK and Australian-based institutions, and sophisticated and professional investors.

Funds from the Placement will be used for:

- Manufacture & up-scaling of reagent inventory for the PromarkerD predictive test
- Marketing of, and accelerating regulatory approvals for PromarkerD
- Accelerating the development and commercialisation of the Company's Promarker™ pipeline
- Strengthening the Company's balance sheet for future licensing negotiations
- General working capital

Euroz Hartleys Securities Limited acted as Sole Lead Manager and Bookrunner to the Placement, and Candour Advisory acted as Corporate Advisor to the Placement.

Proteomics International managing director Dr Richard Lipscombe said, *"We are delighted with the enormous level of support received both from new and existing investors, including UK and Australian institutions. Following the recent achievements for PromarkerD, these funds will drive the delivery of the test into major global markets. I take this opportunity to thank existing shareholders for their continued support and to welcome new investors to the Proteomics International register."*

The shares under the Placement are expected to be issued on or around 2 November 2020 pursuant to the Company's 15% placement capacity under Listing Rule 7.1.

The Company has also agreed to issue:

- 1,100,000 options in consideration for advisory services to be provided by Euroz Hartleys for a six-month period following completion of the Placement; and
- 1,100,000 options in consideration for services provided by Candour Advisory as Corporate Advisor to the Placement.

The options will have an exercise price of \$0.75 per option and an expiry date that is two years after the date of issue (Options). The Options will not be quoted.

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The issue of Options will be put to shareholder approval at an extraordinary general meeting to be held in the 2021 calendar year at which time the Company will also refresh its placement capacity.

Authorised by the Board Proteomics International Laboratories Ltd (ASX:PIQ).

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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.

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For further information please contact:

Dr Richard Lipscombe

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Proteomics International

LABORATORIES LTD

Terms and Conditions of Lead Manager and Corporate Advisor Options

The Options entitle the holder to subscribe for Shares on the following terms and conditions:

a) *Exercise Price*

The exercise price per Option is \$0.75.

b) *Entitlement*

Each Option shall entitle the holder the right to subscribe (in cash) for one Share in the capital of the Company.

c) *Option Period*

The Options will expire at 5:00pm WST on the date that is two years after the date of grant of the Options (**Expiry Date**). Subject to clause (g), Options may be exercised at any time prior to the expiry date and Options not so exercised shall automatically lapse on the Expiry Date.

d) *Ranking of Share Allotted on Exercise of Option*

Each Share allotted as a result of the exercise of any Option will, subject to the Constitution of the Company, rank in all respects pari passu with the existing Shares in the capital of the Company on issue at the date of issue.

e) *Voting*

A registered owner of an Option (**Option Holder**) will not be entitled to attend or vote at any meeting of the members of the Company unless they are, in addition to being an Option Holder, a member of the Company.

f) *Transfer of an Option*

Options are transferrable at any time prior to the Expiry Date. This right is subject to any restrictions on the transfer of Options that may be imposed by the ASX.

g) *Method of Exercise of an Option*

(i) The Company will provide to each Option Holder a notice that is to be completed when exercising the Options (**Notice of Exercise of Options**). Options may be exercised by the Option Holder by completing the Notice of Exercise of Options and forwarding the same to the Company Secretary to be received prior to the expiry date. The Notice of Exercise of Options must state the number of Options exercised and the consequent number of ordinary shares in the capital of the Company to be allotted; which number of Options must be a multiple of 2,500 if only part of the Option Holder's total Options are exercised, or if the total number of Options held by an Option Holder is less than 2,500, then the total of all Options held by that Option Holder must be exercised.

(ii) The Notice of Exercise of Options by an Option Holder must be accompanied by payment in full for the relevant number of shares being subscribed, being an amount of \$0.75 per Share.

(iii) Subject to paragraph (g)(i) above, the exercise of less than all of an Option Holder's Options will not prevent the Option Holder from exercising the whole or any part of the balance of the Option Holder's entitlement under the Option Holder's remaining Options.

(iv) Within 14 business days from the date the Option Holder properly exercises Options held by the Option Holder, the Company shall issue and allot to the Option Holder that number of Shares in the capital of the Company so subscribed for by the Option Holder.

(v) If the Company is listed on the ASX, the Company will within 3 business days from the date of issue and allotment of Shares pursuant to the exercise of an Option, apply to the ASX for, and use its best endeavours to obtain, Official Quotation of all such Shares, in accordance with the Corporations Act and the Listing Rules of the ASX.

(vi) The Company will generally comply with the requirements of the Listing Rules in relation to the timetables imposed when quoted Options are due to expire. Where there shall be any inconsistency between the timetables outlined herein regarding the expiry of the Options and the timetable outlined in the Listing Rules, the timetable outlined in the Listing Rules shall apply.

h) *Reconstruction*

In the event of a reconstruction (including consolidation, sub-division, reduction or return) of the issued capital of the Company, all rights of the Option Holder will be changed to the extent necessary to comply with the Corporations Act and ASX Listing Rules applying to the reconstruction of capital, at the time of the reconstruction.

i) *Participation in New Share Issues*

There are no participating rights or entitlements inherent in the Options to participate in any new issues of capital which may be made or offered by the Company to its shareholders from time to time prior to the expiry date unless and until the Options are exercised. The Company will ensure that during the exercise period, the record date for the purposes of determining entitlements to any new such issue, will be such date required under the Listing Rules in order to afford the Option Holder an opportunity to exercise the Options held by the Option Holder.

j) *No Change of Options' Exercise Price or Number of Underlying Shares*

The Options do not confer the right to a change in exercise price or change to the number of underlying securities except in the circumstances outlined in Listing Rule 6.22. There are no rights to change the exercise price of the Options or the number of underlying Shares if there is a bonus issue to the holders of ordinary shares. If the Company makes a pro rata issue of securities (except a bonus issue) to the holders of ordinary shares (other than an issue in lieu or in satisfaction of dividends or by way of dividend investment) the Option exercise price shall be reduced according to the formula specified in the Listing Rules.

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Proteomics International

LABORATORIES LTD

ASX Release
3 November 2020

ASX code: PIQ

Proteomics International receives \$1.1 million in R&D tax incentive

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, is pleased to announce that its cash reserves have been further strengthened by the receipt of \$1.1 million in research and development tax incentive for the 2019-20 financial year. This follows the recent successful placement of \$6m [ASX: 23 October; 2 November].

Proteomics International's business model sees the Company pursue ground-breaking R&D with blue-sky potential in next generation diagnostic tests underpinned by revenue generated from providing sophisticated analytical services.

As commercialisation proceeds for PromarkerD, the world-leading predictive test for diabetic kidney disease, Proteomics International continues to invest in its biomarker discovery program centred on the Promarker™ technology platform and developing new fee-for-service analytical methods.

In 2019-20, Proteomics International spent \$2.62 million on R&D, making the company eligible for an Australian Government rebate of \$1,138,815.

The Federal R&D tax incentive encourages companies engaging in beneficial research to Australia by providing a cash rebate of 43.5% for qualifying activities.

Authorised by Dr Richard Lipscombe (Managing Director) on behalf of the Board of PIQ.

ENDS

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Proteomics International

LABORATORIES LTD

ASX Release
5 November 2020
ASX code: PIQ

PromarkerD clinical assay performance results published in peer-reviewed journals

Highlights

- **PromarkerD clinical assay platforms successfully validated for reproducibility, robustness and stability**
- **High correlation between PromarkerD (MS)[#] and PromarkerD (IA)[#] technology platforms proves reliability of PromarkerD test system**
- **Multiple peer-reviewed publications demonstrate clinical and analytical validity of PromarkerD predictive test for diabetic kidney disease**
- **Publications drive engagement with Key Opinion Leaders and adoption of PromarkerD by the wider diabetes community**
- **Proteomics International continues to pioneer clinical diagnostic test development using Promarker™ technology**

Medical Technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, announces the publication of two successful studies demonstrating the robust technical performance of the PromarkerD predictive test for diabetic kidney disease.

The results form an essential basis for regulatory approvals related to the PromarkerD test system and its adoption by pathology laboratories worldwide. Importantly, they also illustrate the potential for adoption of the Promarker™ diagnostics platform in future clinical practice.

The findings have been published online as early versions of internationally peer-reviewed academic journals, and also as an industry application note:

1. The journal *Clinical Proteomics*, article titled “A robust multiplex immunoaffinity mass spectrometry assay (PromarkerD) for clinical prediction of diabetic kidney disease”¹, and *Agilent Technologies Clinical Research Application Note*, titled “From Nanoflow to Standard Flow LC/MS for Routine Quantitative Plasma Proteomics in Diabetic Kidney Disease Research”².

Article summary: The PromarkerD assay has already demonstrated clinical validity. This study refined the original research grade mass spectrometry assay to enable higher throughput and clinical application.

Independent analysis of the same set of samples across multiple laboratories proved the robustness of the protocol between different test sites (Proteomics International, the

¹ Clin Proteom (2020) 17:37; doi.org/10.1186/s12014-020-09302-w

² Agilent Technologies Publication Part Number: 5994-2381EN

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University of Sydney, and Atturos Ltd (Ireland)). The joint publication is one of the first validations of a proteomics derived multi-biomarker diagnostic test in a clinical setting.

2. The journal *Proteomes*, article titled “*The New and the Old: Platform Cross-Validation of Immunoaffinity Mass Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease*”³.

Article summary: Reproducible protein measurement across technology platforms is an essential component of determining a specific disease state, such as diabetic kidney disease. This publication proved there was high correlation between the advanced mass spectrometry (IAMS) platform and the traditional immunoassay (ELISA - enzyme linked immunosorbant assay) platform, with >90% of the samples achieving PromarkerD risk scores within 5% of the other platform's score.

Both technology platforms were successfully validated for assay reproducibility, robustness and stability for the PromarkerD test system.

Preliminary results of both studies were first presented at the 18th Human Proteome Organization (HUPO) World Congress [ASX: 12 September 2019; 17 September 2019].

Proteomics International managing director Dr Richard Lipscombe said, “*This type of robust performance data is essential in achieving regulatory approvals for the PromarkerD test system. Not only do the results prove the test can be used reliably in today's clinical laboratories, but they also offer an insight into the use of the Promarker platform in clinical practice in the decades to come.*”

Peer-reviewed publications form an essential component of engaging with Key Opinion Leaders to drive PromarkerD's adoption by the wider diabetes community. PromarkerD scientific publications now include:

- 1. Cross-Platform Assay Validation Study**
(2020) The New and the Old: Platform Cross-Validation of Immunoaffinity Mass Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease. *Proteomes* 8(4), 31
- 2. Multi-site Assay Validation Study**
(2020) A robust multiplex immunoaffinity mass spectrometry assay (PromarkerD) for clinical prediction of diabetic kidney disease. *Clin Proteomics* 17:37
- 3. Global Multi-Centre Prognostic Validation Study**
(2020) PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). *Journal of Clinical Medicine* 9, 3212
- 4. Prognostic Validation Study**
(2019) Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II. *Journal of Diabetes and its Complications* 33 (12), 107406
- 5. Biomarker Clinical Utility**
(2019) Apoptosis inhibitor of macrophage (AIM/CD5L) and diabetic kidney disease. *Cellular & molecular immunology* 16(5):521.
- 6. Prognostic Development Study**
(2017) Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. *Diabetes Care* 40, 1548-1555.
- 7. Prognostic Development Study**
(2017) Novel circulating biomarkers predict rapidly declining renal function in type 2 diabetes: The Fremantle Diabetes Study. *Diabetes* 66 (Supplement 1).
- 8. Diagnostic Study**
(2017) Comprehensive mass spectrometry based biomarker discovery and validation platform as applied to diabetic kidney disease. *EuPA Open Proteomics* 14, 1-10.

Authorised by Terry Sweet (Chair) on behalf of the Board of PIQ.

ENDS

³ *Proteomes* (2020) 8(4), 31; doi.org/10.3390/proteomes8040031

About PromarkerD (www.PromarkerD.com)

PromarkerD is a predictive test for the early detection of chronic kidney disease (CKD) in patients with type-2 diabetes. CKD is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant.

The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of disease by measuring three serum proteins (ApoA4, CD5L and IGFBP3), combined with three routinely available conventional clinical variables (age, high-density lipoprotein (HDL)-cholesterol and estimated glomerular filtration rate (eGFR)).

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. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each achieved CE Mark registration in the European Union.

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

Further information is available through the PromarkerD web portal.

To visit the PromarkerD ADA virtual booth please see: www.PromarkerD.com/product

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Proteomics International

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ASX Release
12 November 2020

ASX code: PIQ

Israel becomes the first Middle Eastern market for PromarkerD immunoassay test

- **Proteomics International appoints Zotal Ltd as the exclusive distributor for PromarkerD in Israel**
- **The Licence Agreement is the first Middle Eastern market for PromarkerD, the world's first predictive test for diabetic kidney disease**
- **Israel is recognised as a global leader in the life-science industry and renowned for its early adoption of cutting-edge medical technologies**
- **One in eight adults in Israel has diabetes, and the disease is the country's fifth leading cause of death**
- **Partnership marks the second distribution agreement for the easy-to-use, high volume immunoassay version of the test and comes just weeks after agreement to distribute PromarkerD in Italy**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has signed a distribution agreement to bring PromarkerD, the world's first predictive test for diabetic kidney disease, to the Middle East.

The licensing agreement provides leading medical distributor Zotal Ltd with the right to sell the immunoassay version of PromarkerD (PromarkerD (IA)) to clinical laboratories where it will be used for patient monitoring and to assist in diabetes disease management. Israel has a growing elderly population with a real demand for easy, accessible, affordable diagnostics.

The partnership is the second distribution agreement for the immunoassay version of the test, and comes just weeks after the announcement of a licence to bring PromarkerD (IA) to Italy [ASX: 16 October].

Israel has one of the highest diabetes mortality rates among OECD countries, with diabetes the fifth leading cause of death in Israel¹. Based on data from the Israeli Diabetes Registry, there are currently 550,000 people in Israel with diabetes, and the same number at the stage defined as pre-diabetes. Globally a third of people with diabetes currently have chronic kidney disease and PromarkerD will become the only test available in the Middle East for predicting the onset of the condition.

Zotal Head of Personalized and Predictive Medicine, Dana Cohen said *"The Israeli Ministry of Health attaches great importance to the prevention of diabetes by improving the monitoring of the disease. The PromarkerD test could be a win-win for patients and the healthcare system and meaningful cost saving tool."*

Israel is recognised as a global leader in the life-science industry and renowned for its early adoption of cutting-edge medical technologies - its healthcare and biotech industry employs 83,000 people across 1,600 life sciences companies. The country's R&D spending, as a proportion of GDP, is the

¹ www.healthdata.org/israel

highest in the OECD and Israel's healthcare technology market is estimated at US\$6.2 billion (7.5% of GDP).

The agreement with Zotal is for two years, exclusive to Israel, and exclusive to PromarkerD (IA). Proteomics International will receive payment for each kit sold. Further details of the licence agreement are commercially sensitive and remain confidential. As for any novel test, market penetration cannot be predicted accurately, hence for the new licence it is not possible to quantify the financial impact on Proteomics International in any given timeframe.

Zotal will now complete product registration and reimbursement applications for PromarkerD with the Israeli Department of Medical Devices, Ministry of Health, which is expected to take approximately six months. As part of preparing for PromarkerD sales, Zotal will engage with Israeli Key Opinion Leaders for the promotion and early adoption of the test by major hospitals. The engagement with these KOLs will complement recent scientific publications [ASX: 12 October; 5 November] to help drive awareness and understanding of PromarkerD's benefits in new markets.

Proteomics International managing director Dr Richard Lipscombe said the immunoassay technology was cost-effective and standard to clinical diagnostics laboratories around the world. *"The recently-released PromarkerD immunoassay kit allows hundreds of blood samples to be analysed quickly as part of a panel of routine blood tests,"* he said. *"The platform opens up a host of new market opportunities, including more traditional distribution agreements with proven companies like Zotal."*

Dr Lipscombe said Proteomics International was continuing discussions with diagnostic and pharmaceutical companies to bring PromarkerD to more regions around the world. *"We believe entering both the European and Middle Eastern markets in recent weeks will drive demand for PromarkerD in 2021 and beyond."*

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About Zotal Ltd (www.zotal.co.il)

For more than three decades, Zotal has been a leading provider of high-quality, state-of-the-art products for the medical and life sciences market in Israel, selling and supporting products in varying environments including life science research laboratories, fertility clinics and clinical diagnostic laboratories. Zotal is focusing its efforts in broadening the personalised medicine and predictive diagnostic products intended for selecting appropriate and optimal therapies.

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