



Proteomics International

LABORATORIES LTD

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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.

ENDS

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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