ASX Release
8 February 2021

ASX code: PIQ

Proteomics International seeks FDA approval for PromarkerD

- **Pre-submission package for diabetic kidney disease (DKD) test lodged with the US Food and Drug Administration (FDA)**
- **Proteomics International expected to meet with the FDA to progress clearance within 10 weeks**
- **FDA pre-submission follows CE Mark regulatory approval for PromarkerD in Europe**
- **Globally there are 463 million adults living with diabetes, including 31 million in the US**
- **The Covid-19 pandemic has increased public awareness of the importance of diagnostic testing but caused a backlog in diagnostic services for other serious illnesses such as DKD - an issue that healthcare systems and diagnostic companies are now looking to address**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, is pleased to announce that it has filed a pre-submission package to the United States Food and Drug Administration (FDA) for the PromarkerD test for diabetic kidney disease.

The Company is seeking additional regulatory approval for the easy-to-use 'kit' version of PromarkerD, the world's first predictive diagnostic test for diabetic kidney disease. PromarkerD already has CE Mark in the European Union. FDA approval will enable broad-scale deployment of the simple, low-cost blood test in the US, where there are more than 30 million people with diabetes.

FDA pre-submission allows manufacturers of innovative diagnostics and medical devices to discuss specific aspects of the regulatory process and requirements with FDA experts. This consultative process will help Proteomics International determine the best regulatory path forward for PromarkerD, being either the De Novo Classification or 510(k) routes. Proteomics International is expected to meet with the FDA to progress clearance within 10 weeks.

PromarkerD uses a unique protein 'fingerprint' to predict the onset of diabetic kidney disease (DKD) up to four years before clinical symptoms appear. Accurately diagnosing at-risk type-2 diabetics allows physicians to provide treatment plans with the aim of slowing or even halting the kidney disease. Chronic kidney disease is one of the major complications arising from type-2 diabetes, which if left unchecked can lead to dialysis or kidney transplant, and costs the US healthcare system $130 billion per year in Medicare spending alone.[1]

Proteomics International will present the FDA with robust, peer-reviewed clinical performance data demonstrating the effectiveness of the test, including a 3,000-patient study undertaken in collaboration with a global top 20 pharmaceutical company.

[1] United States Renal Data System - https://adr.usrds.org/2020

Feedback from the pre-submission will provide valuable insights into what the Company will need to provide to make the approval process run as efficiently and timely as possible. FDA industry guidance suggests early interaction with the regulatory body may improve the quality of subsequent submissions, shorten total review times, and facilitate the development process for new devices.

Proteomics International managing director Dr Richard Lipscombe said FDA approval would be a significant commercialisation milestone for PromarkerD. *"FDA sign off would assure potential licensing partners and consumers that the test has been developed and manufactured to US safety, health and environmental protection standards. With CE Mark approval and FDA clearance we would have access to more than 70 per cent of the global IVD diagnostic market."*

Dr Lipscombe stated further, *"We are also seeing increased public awareness of the importance of diagnostic testing due to the Covid-19 pandemic, and diagnostic companies globally have received significant funding to enhance their testing capabilities. These companies are now looking to address the backlog in diagnosing other chronic diseases that has arisen due to the pandemic. We know that of these, diabetic kidney disease is one of the most prevalent and costly to deal with. Progression towards FDA approval for PromarkerD aligns well with US diagnostic companies looking to broaden the suite of tests they offer."*

In addition to the kit technology, PromarkerD can be made available to US patients as a laboratory developed test (LDT) ahead of FDA approval. Proteomics International is in advanced discussions with a number of diagnostic groups exploring this parallel route to market.

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

ENDS

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 protein biomarkers, combined with three routinely available conventional clinical variables (age, 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 virtual booth please see: www.PromarkerD.com/product

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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ASX Release
23 April 2021

ASX code: PIQ

Proteomics International achieves ISO 13485 certification: PromarkerD manufacturing update

- **ISO 13485 certification represents a stringent commitment to quality and safety standards required for manufacturing human diagnostic tests**
- **Manufacturing milestone expected to widen market opportunities for the PromarkerD test for diabetic kidney disease and underpin future regulatory approvals**
- **Certification paves the way for establishing Northern Hemisphere manufacturing of the PromarkerD diagnostic tests**
- **Manufacturing processes for PromarkerD reagents are being streamlined to facilitate scale-up of kit production**
- **Certification will also apply to Proteomics International's pipeline of other diagnostic tests under development**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to advise it has received ISO 13485 certification, the most widely-used international standard for quality management systems in the manufacture of medical devices.

Proteomics International managing director Dr Richard Lipscombe said achieving this ISO certification was a key milestone underpinning production and future global sales of the PromarkerD test for diabetic kidney disease. "*The ISO 13485 manufacturing standard provides the foundation to regulatory requirements for medical diagnostics and has been adopted by markets including the European Union, Australia, Japan, Canada and, most recently, the United States,*" he said.

The certification is awarded to only those companies that can demonstrate an ability to produce safe, effective products that consistently meet the expectations of customers and regulators. It represents a stringent commitment to quality and safety standards in the production of diagnostic tests.

Additionally, the certification will bolster the Company's ongoing commercial discussions with global diagnostic companies and manufacturing partners.

Manufacture of the PromarkerD immunoassay kits currently occurs under licence in Australia. In order to meet Proteomics International's anticipated worldwide demand for PromarkerD, the Company has commenced discussions with selected Northern Hemisphere diagnostics manufacturers with the objective of streamlining the future production of the assay.

Production of the PromarkerD immunoassay requires specialist reagents, including synthetic protein standards and antibodies (used to detect the target protein biomarkers). As part of securing its supply chain, Proteomics International is now constructing recombinant versions of the antibodies which are more stable than those from normal antibody cell lines, and hence will provide a more consistent product over the long term. Importantly, this manufacturing process will facilitate the

scale-up in production of the PromarkerD immunoassay reagents and kits, without impacting current regulatory approvals.

The ISO 13845 certification will also apply to Proteomics International's pipeline of other diagnostics currently under development, including tests for endometriosis and asthma. "*With the engagement of global manufacturing partners, we are building a robust framework that will help accelerate both the commercialisation of subsequent novel tests, alongside the worldwide roll-out of PromarkerD,*" Dr Lipscombe said.

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

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ASX Release
29 April 2021

ASX code: PIQ

Proteomics International files US FDA 513(g) regulatory submission

- **513(g) application will allow Proteomics International to determine the best product classification and FDA regulatory path for PromarkerD**
- **Application replaces pre-submission package filed in February, after the FDA limited this pathway to urgent applications only due to the COVID-19 pandemic**
- **FDA is expected to provide feedback within 60 days**
- **Projected timelines to a full FDA application and subsequent commercialisation remain unaffected**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has filed a 513(g) submission to the United States Food and Drug Administration (FDA) for its PromarkerD test for diabetic kidney disease.

The application replaces the pre-submission package lodged with the FDA in February [ASX: 8 February], after the regulatory body took the unprecedented step of limiting the pre-submission route to urgent applications only due to the COVID-19 pandemic.

The FDA advised the Company that it is unable to conduct an in-depth review of the pre-submission due to its current COVID-19 related resource limitations. However, other review pathways remain open, and consequently Proteomics International has closed its pre-submission and replaced it with the 513(g) request.

As with pre-submission, the 513(g) application will allow Proteomics International to determine the best regulatory path for PromarkerD - either the De Novo Classification or 510(k) route. The main difference from the pre-submission is that clinical data is not required in 513(g) requests.

The FDA is expected to assess the application and provide feedback on the applicable regulatory pathway within 60 days. The Company is preparing to file a full application under either pathway in Q3 CY21, in line with previously stated timeframes.

Proteomics International managing director Dr Richard Lipscombe said, *"The suspension of the detailed pre-submission pathway was understandable, and FDA's response to a 513(g) request will provide the information we need for the next steps in obtaining market clearance for PromarkerD in the US. We look forward to working closely with the FDA despite the ongoing pandemic, and we continue to expand our marketing activities in the US and beyond as we address this next regulatory step."*

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

ENDS

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ASX Release
13 May 2021

ASX code: PIQ

Study demonstrates major economic health benefit of PromarkerD - PromarkerD reimbursement update

- **Independent modelling estimates instigating PromarkerD testing could produce net savings for US payors of US$862 million over four years per million type 2 diabetes patients tested**
- **The study provides validation of the potential economic health benefit of PromarkerD in diabetic kidney disease management, which improves the likelihood that the test will be reimbursed by payors**
- **Results will be released online ahead of presentation at Virtual ISPOR 2021, the world's leading conference for health economics and outcomes research, from 17-20 May 2021**
- **Proteomics International to seek a CPT Proprietary Laboratory Analyses (PLA) code to facilitate the reimbursement of the innovative PromarkerD test by payors in the US**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce the results of an economic health benefit study for PromarkerD following comprehensive economic modelling and consultation with key industry stakeholders. The Company is set to seek a CPT Proprietary Laboratory Analyses (PLA) reimbursement code for its innovative PromarkerD test for diabetic kidney disease.

Independent consultant Boston Healthcare Associates modelled the budget impact of a proactive testing regime using PromarkerD for assessing diabetic kidney disease in patients with type 2 diabetes, compared to the current standard of care. The study found that, at US$150 a test, and over four years, PromarkerD produced estimated savings of up to US$2.4 billion against costs of US$1.5 billion for every million type 2 diabetes patients tested.

The modelling showed instigating PromarkerD testing produced estimated net savings for payors of US$862 million over four years per million patients tested. The savings primarily arise from slowing the progression of diabetic kidney disease against costs from increased testing and the use of preventative medications.

Proteomics International managing director Dr Richard Lipscombe said, "*With PromarkerD testing, patients may delay or avoid costly end outcomes such as dialysis and kidney transplants. Given there are approximately 31 million diabetics in the United States alone, the economic benefit of PromarkerD is clearly evident*."

Boston Healthcare Associates and Proteomics International will present the modelling at the annual conference of the Professional Society for Health Economics and Outcomes Research, Virtual ISPOR 2021, the world's leading conference for health economics, from 17-20 May 2021. The event is typically attended by global healthcare leaders, including policy makers, payors and health economists.

Proteomics International will now pursue a reimbursement code for PromarkerD based on its extensive engagement with expert panels representing physicians, laboratories and payors, including national and regional entities. Securing a reimbursement code will facilitate the reimbursement of the PromarkerD test by insurance companies and other payors in the US.

A CPT Proprietary Laboratory Analyses (PLA) code uniquely identifies a test for the laboratory and the payors. Reimbursement codes and payer coverage in the US are initiated through the American Medical Association (AMA) and its Current Procedural Terminology (CPT) Editorial Panel. The approval and acceptance of a PLA code follows assessment of the economic health benefit and clinical utility of a new test.

Dr Lipscombe said although securing a code is relatively straightforward, it is imperative that the code is covered and reimbursed by insurers. "*Our surveys indicate that a price between US$100 and US$300 per test would be considered reasonable, while US$550 or higher would be considered prohibitively expensive. The Company looks forward to updating shareholders when the final details have been determined for the reimbursement code.*"

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

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ASX Release
18 May 2021

ASX code: PIQ

Proteomics International secures major analytical services contract in pharmacokinetic testing

- **New pharmacokinetic testing contract signed with Avance Clinical**
- **Study will examine a novel lysosomal storage disorder drug as part of clinical trials**
- **The analytical services contract is Proteomics International's largest to date, valued at $243,000**
- **The Company is actively pursuing similar high value contracts in the analytical services markets**
- **Contract links to Proteomics International's integrated business model and wider strategic vision to exploit its specialised biomarker discovery and analytical services capabilities**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has secured a major pharmacokinetic testing contract with Australia's largest clinical trial contract research organisation Avance Clinical.

The contract will see Proteomics International perform advanced pharmacokinetic testing of a novel drug for lysosomal storage disorder. It is the Company's largest single analytical services contract to date, with a value of $243,000.

Pharmacokinetics is the study of what happens to drugs once they are inside the body, including the rate at which they are absorbed, distributed, metabolised and excreted. Australia is a leading destination for clinical trials[1] and Proteomics International offers specialist accredited testing services in this fast-growing area.

The contract with Avance Clinical is part of a Phase I clinical trial, which will examine the safety, tolerability and pharmacokinetics of the lysosomal storage drug on behalf of a US pharmaceutical company. The work will be undertaken over the next three months.

Proteomics International managing director Dr Richard Lipscombe said the Company is seeing its analytical services activity return to pre-Covid-19 levels of growth. *"Proteomics International's pharmacokinetic testing business continues to strengthen, boosting our analytical services revenue, which in turn helps offset our diagnostic R&D and commercialisation expenditure,"* he said.

Proteomics International's mission statement is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease. *"Our strategy is to exploit our extensive biomarker discovery and analytical services capabilities to target new opportunities in Companion and Complementary Diagnostics (CDx), with the goal of generating valuable intellectual property,"* Dr Lipscombe said.

1 Australian Clinical Trials Capability 2018 (Austrade)

Underpinning this ambition, the US Food & Drug Administration (FDA) is encouraging the integration of biomarkers in medical product development and approval, to support product monitoring and use in clinical practices.[2] Dr Lipscombe said, *"Drug developers were starting to ask for innovative biomarker-based diagnostic tests to help ensure treatments are safe and effective for patients - there was the potential for Proteomics International to create both new revenue streams and IP related to clinical trials."*

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

ENDS

About Avance Clinical (www.avancecro.com)
Avance Clinical is an Australian owned Contract Research Organisation that has been providing high-quality clinical research services fit for global regulatory standards to the local and international drug development industry for 20 years. Avance specialises in supporting biotech companies with their early phase clinical trials leveraging the world-class early phase clinical trials ecosystem in Australia.

Avance Clinical is able to deliver great value to biotech clients through deep experience with the ethics and regulatory process, established relationships with all of the early phase trial sites and adoption of new technologies including integrated eClinical solutions.

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[2] www.fda.gov/science-research/about-science-research-fda/biomarkers-fda

ASX Release
10 June 2021

ASX code: PIQ

CCO and CFO appointed to bolster executive team

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) today announced the expansion of its executive team with the appointments of Vik Malik as its new Chief Commercialisation Officer (CCO) and Jacqueline Gray as its new Chief Financial Officer (CFO).

A worldwide executive search was undertaken in preparation for what is set to be a transformative period for Proteomics International.

Medical Technologies commercialisation veteran Vik Malik will lead Proteomics International's commercial roll-out of the Company's innovative diagnostic products centred on the PromarkerD predictive test for diabetic kidney disease. Starting 1st June, he will initially be based in the USA. Mr Malik has an extensive network of clinical (KOL) and business professionals in the healthcare, medical device and diagnostics sectors, which will prove invaluable as Proteomics International ramps up the commercialisation of PromarkerD in the US and Europe.

Jacqueline Gray is a well-credentialed finance professional with experience across global brands including in the technology, healthcare and media sectors. Effective 12th July 2021, Ms Gray will have responsibility for Proteomics International's finance, accounting and financial strategy development.

Proteomics International Managing Director Dr Richard Lipscombe said he was very pleased to welcome Mr Malik and Ms Gray to the newly-created roles.

"With the assistance of renowned global recruitment companies, we conducted an exhaustive search for the ideal executives to bring in for our next stage of growth. Vik and Jacqueline have a wealth of expertise in their respective specialities, and have extensive experience in fast-growing companies similar to Proteomics International. We are delighted to appoint them to these new positions. Their knowledge and experience will further bolster our executive team and will help drive our Company's growth globally."

Mr Malik said he is excited to have the opportunity to bring the ground-breaking PromarkerD test to global markets and change the standard of care for patients worldwide. Ms Gray said that this is an exciting time to join Proteomics International as the Company accelerates its next phase of expansion.

Chief Commercialisation Officer: Vik Malik

Mr Malik has more than 20 years' experience in the life sciences and healthcare industries as a commercialisation expert and business strategy advisor for several multinational, growth-stage and startup medical device and diagnostics companies.

Mr Malik has been involved in the launch of numerous disruptive medical technologies, cutting-edge biotherapies, innovative healthcare IT solutions and customised business process outsourcing services to penetrate new and emerging markets.

Most recently, Mr Malik served as Chief Executive Officer and board director for surgical software startup ClaraSim Systems (USA), and has previously held senior leadership positions with IQVIA (IMS Health + Quintiles), BioFuse Medical, Deloitte Consulting - Healthcare & Life Sciences, and Ascension Orthopedics, as well as sales, marketing and business development roles at TissueLink Surgical, Serono Laboratories and Wyeth Pharmaceuticals.

Mr Malik has a Bachelor of Science (Marketing) from Southern Illinois University, USA.

Chief Financial Officer: Jacqueline Gray

Ms Gray is a chartered accountant and has more than 20 years' executive experience in both Perth and London, driving the implementation of strategy, meaningful business reporting and a sound governance framework.

She has served as the Chief Financial Officer for a range of ASX-listed and privately-owned businesses, managing revenues in excess of $100 million.

Ms Gray joins Proteomics International from digital marketing and ecommerce agency RooLife Group, having previously held senior leadership positions at Velpic, City Farmers, Morrison, Sungrid and the West Australian Community Foundation. She has also worked for global companies including the Economist Group, BBC Worldwide, HealthCare of Australia and Arthur Andersen.

Ms Gray holds a Bachelor of Business (Accounting) from Edith Cowan University and a Graduate Diploma in Applied Corporate Governance from the Governance Institute of Australia.

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Media / ASX Release

ASX code: PIQ

World-first predictive test for Diabetic Kidney Disease could save $384 billion over 10 years

- **Independent modelling estimates the PromarkerD predictive test for diabetic kidney disease (DKD) would increase the quality of care and could save US payers almost USD400 billion over 10 years**
- **The US is home to 31 million adults with diabetes who are at risk of DKD - cost savings stem from slowed disease progression, delayed or prevented dialysis and kidney transplants, and fewer dialysis crashes**
- **Results to be presented at the American Diabetes Association's 81st Scientific Sessions, 25-29 June 2021**

25 June 2021, Boston, USA and Perth, Australia: Proteomics International Laboratories Ltd (ASX: PIQ) announces testing for diabetic kidney disease with the PromarkerD prognostic blood test could save US payers almost USD400 billion over 10 years, research suggests. The ground-breaking PromarkerD test is the only test capable of predicting the onset of diabetic kidney disease in patients with type 2 diabetes.

Independent consultant Boston Healthcare Associates modelled the budget impact of using PromarkerD compared to the current standard of care, to proactively test for diabetic kidney disease in patients with type 2 diabetes but who otherwise have no sign of kidney disease.

It found the test—developed by Proteomics International—could result in net savings to Medicare and commercial insurers of USD384 billion over 10 years.

There are 31 million adults with diabetes in the US. Instigating the simple test, set at USD150 for an annual testing regime, would cost $8.9 billion annually, however, could produce savings of USD473 billion over ten years. Savings stem primarily from slowing the progression of diabetic kidney disease, followed by benefits from delaying or preventing dialysis and kidney transplants, and a reduction in dialysis crashes.

The findings will be presented at the virtual American Diabetes Association's 81st Scientific Sessions at 11:30am ET on Friday 25 June 2021 *(presentation details below).*

Proteomics International managing director Dr Richard Lipscombe said the research extends the initial modelling [ASX: 13 May] to emphasise the benefits of an early, accurate and cost-effective prognosis. "*Testing patients with type 2 diabetes every 6-12 months with PromarkerD would enable early intervention for those at high-risk of developing diabetic kidney disease*," he says.

"*This would decrease the need for expensive late-stage interventions, such as dialysis and kidney transplants. It would also assist in stratifying which patients would receive new DKD preventative therapeutic treatments. The potential benefits to the patient and the healthcare system are enormous.*"

The PromarkerD test has received CE Mark registration and is currently available in Europe, with Proteomics International in advanced discussions to bring the test to the clinic in the US.

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

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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 protein biomarkers, combined with three routinely available conventional clinical variables (age, 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.

ADA 81st Scientific Sessions poster presentation (#813-P; 13-A Health Care Delivery - Economics), titled: *Demonstrating the Economic Health Benefit of using the PromarkerD In Vitro Diagnostic Test in the Prediction of Diabetic Kidney Disease*
Burchenal W[1], Datar M[1], Peters KE[2], Fernandez GC[2], Morrison JC[2], Lipscombe RJ[2]
[1]Boston Healthcare Associates, Boston, MA, USA, [2]Proteomics International, Perth, WA, Australia

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

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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