

MARCH 2020

WHOLESALE/INSTITUTIONAL INVESTOR EDUCATION REPORT

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This report has been factually prepared on generally available information.

This report has been written to provide qualified Wholesale, Sophisticated and Institutional Investors with detailed information about Proteomics International Laboratories Limited (ASX.PIQ).

This Report may provide information and our analyst insights, on Proteomics International Laboratories Limited to wholesale and institutional investors.

You should make your investment decision based on all available information.

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PromarkerD – A breakthrough in predicting diabetic kidney disease

RISK CATEGORY

RISK	HIGH / SPECULATIVE
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BRIEF COMPANY VIEW

Proteomics International ('Proteomics' or 'PIQ') is an Australian medical technology company operating 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. The Company uses its Promarker technology platform to develop diagnostic tests for diseases with unmet medical needs, and has successfully developed a diagnostic test named PromarkerD that can predict the onset of diabetic kidney disease up to four years in advance.

CORPORATE SNAPSHOT (03/03/2020)

ASX CODE	PIQ.ASX
SHARE PRICE	A\$0.28
12 MONTH HIGH/LOW	A\$0.44/A\$0.23
SHARES ON ISSUE	~92m
OPTIONS ON ISSUE	2.4m
AVERAGE DAILY VOLUME	~118,291
MARKET CAPITALISATION	~A\$26m
CASH – DEC 2019	~A\$2.5m + \$1.6m receivables, no debt

12 MONTH SHARE PRICE CHART



Proteomics International ('Proteomics', 'PIQ' or 'the Company') is an Australian medical technology company operating 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.

The Company's primary focus is to commercialise its PromarkerD test, the world-leading predictive diagnostic test for diabetic kidney disease; research and develop potential diagnostic tests for other chronic diseases including Endometriosis, Giardia, Asthma and Chronic Obstructive Pulmonary Disease, which can be commercialised after PromarkerD; and increase its analytical services revenue.

Investment Highlights

World-leading predictive diagnostic test: PromarkerD is the only commercialised, low-cost, high-speed, predictive test available for diabetic kidney disease that accurately predicts whether a person with diabetes will develop diabetic kidney disease, up to four years prior to typical diagnosis.

Huge target market: Diabetic kidney disease is one of the world's fastest growing causes of death. The World Health Organization (WHO) estimate that approximately 425m people had diabetes in 2017, and 1 in 3 diabetic adults go on to develop chronic kidney disease. Diabetic kidney disease can lead to kidney failure, requiring either a lifetime of dialysis (US\$89,000 p.a.) or kidney transplant, costing the global healthcare system billions of dollars annually.

Janssen (J&J) collaboration results expected in coming months: Janssen Research & Development, LLC ('Janssen') and PIQ are undertaking an ongoing joint study to explore the performance of PromarkerD predictive diagnostic test for diabetic kidney disease in samples from a completed ~3,600 patient Phase 3 clinical trial of Janssen's diabetes drug canagliflozin (Invokana™). The first phase of the study is nearing completion with positive results likely to have significant commercial appeal to Janssen and have the potential to fast-track the commercialisation of PromarkerD. If successful, PromarkerD may be designated as a Complementary Diagnostic (CDx) test for the treatment of diabetic kidney disease.

Deep pipeline: PromarkerD is the first commercial application of the Company's platform technology. The Company is working to leverage its Promarker platform to develop and commercialise a suite of diagnostic tests. The current development pipeline includes diagnostics tests for Endometriosis, Gastro and COPD, all of which represent major opportunities for the Company.

Increasing Analytical Services revenue: The Analytical Services unit, through which the Company provides specialist contract research services focusing on biosimilars quality control and pharmacokinetic testing, is presently the primary revenue generating area of the Company. The unit generated A\$1.5m revenues in FY2019, registering a 25% yoy growth over FY18. The division is expected to achieve continued growth on the back of a growing biosimilars (generic form of protein-based treatments) and pharmacokinetic services market.

Multiple licensing and revenue opportunities: PIQ has already executed regional licensing deals for its laboratory mass-spectrometer PromarkerD test (MS). The mass market immunoassay test (IA), which is expected to receive CE Mark approval in the coming months (with FDA approval to be sought thereafter) is expected to attract significant commercial interest from major pathology laboratories and global diagnostic equipment manufacturers.

Valuation: We have assigned PIQ a valuation of A\$78m (which equates to A\$0.85 per share on a fully diluted basis). We used a risk adjusted discounted cash flow methodology to arrive at our valuation. We have assigned values to the Company's analytical services revenue and the expected revenue from the PromarkerD test. The breakthrough PromarkerD test has the potential to provide the Company with significant upside value. This test has the potential to reduce the occurrence of kidney failure in diabetics and reduce the billions of dollars spent on the treatment of chronic kidney disease worldwide.

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Company Overview

PIQ listed on the ASX in April 2015 and is focused on developing predictive diagnostic tests for common diseases and providing bioanalytical services.

PIQ focuses on proteomics, which is the large-scale mapping of the structure and function of proteins. Understanding of proteomics can assist with improving the diagnosis of diseases and the identification of drugs that can be used to treat diseases. The Company's diagnostics development is made possible by its proprietary biomarker discovery platform called Promarker, which searches for protein 'fingerprints' in a sample.

Using this technology, the Company has already developed a revolutionary predictive diagnostic test named PromarkerD, which can accurately predict the onset of diabetic kidney disease up to 4 years in advance. PromarkerD has been rated the world's leading diagnostic test for diabetic kidney disease by the global research house Frost & Sullivan in its report titled Biomarkers Enabling Diabetes and Obesity Management.

PIQ operates from state-of-the-art facilities located on the QEII Medical Campus, Perth. Its laboratories were the first facility worldwide to gain ISO 17025 accreditation for proteomics services. It also holds Research and Development accreditation for ISO/IEC 17025, together with the OECD Principles of Good Laboratory Practice. The Company provides specialist contract research focusing on biosimilars quality control and pharmacokinetic testing for clinical trials. The analytical services revenue helps the Company to offset the expenditure on R&D and product development.

PIQ is headquartered in Harry Perkins Institute of Medical Research in Western Australia, has two representatives in USA and India, with agents/distributors also throughout Asia. In November 2019, the Company formed a partnership with Bioplatforms Australia and the University of Western Australia to launch a world leading facility in Western Australia.

The Company's current focus is to commercialise its PromarkerD test in major markets through royalty based licensing agreements, develop more diagnostic tests using its Promarker technology platform, and grow its analytical services revenue.

The Company works closely with the biotechnology and life sciences community across Australia and also has collaborations/partnerships to help achieve its objectives.

The Promarker Platform

Promarker is a ground-breaking platform technology that takes advantage of the ubiquity of proteins in the human body. Proteins are responsible for carrying out various functions in the body, with many diseases causing different proteins to be secreted into the blood, in varying concentrations.



The Promarker platform uses mass spectrometry-based technology to identify the proteins that can be used as biological markers of disease and other conditions. The technology can identify unique protein biomarkers 'fingerprints' and links the unique protein biomarkers to specific diseases, enabling Proteomics to formulate commercial diagnostic tests.

This disruptive technology can identify proteins that distinguish between people who have a disease and people who do not, using only a simple blood test. It is a powerful alternative to genetic testing. The technology can be used to identify fingerprints from any biological source, from wheat seeds to human serum.



Diagnostics Services

The Company uses its Promarker platform technology to identify the biomarkers of a disease to assist with the development of new diagnostic tests for chronic diseases with unmet medical needs. The Company does this by comparing the biomarkers obtained from the blood samples of both healthy and sick people. Biomarkers are a biological set of fingerprints that can be used to predict whether a person is at risk of developing a particular disease.

Proteomics is working towards developing and commercialising a suite of diagnostic tests using its Promarker platform. The current diagnostics pipeline is presented below:

Figure 1 – Biomarker research pipeline



The Promarker™ research pipeline and typical timeline is as follows:

Ethics & governance approval (3 months), Discovery (3-6 months), Proof of concept (3-6 months), Clinical studies (12 months)

The Company's protein biomarker discovery program is investigating protein 'fingerprints' associated with the following diseases:

Endometriosis

Endometriosis is a chronic gynaecological disorder characterised by the presence of endometrial-like tissue (glands and stroma) outside the uterus. Endometriosis affects one in ten women in their reproductive years (15-49) and costs \$12,000 per year for every person diagnosed.¹ This gynaecological condition causes chronic pain and infertility but is often difficult to diagnose. On average, it takes 8.5 years for women to be diagnosed from their first symptoms, and the current gold standard for detection is invasive surgery. The condition is estimated to cost Australia \$7.7 billion annually, two thirds of which is attributed to lost productivity.² The annual societal burden of endometriosis in the USA was estimated to be US\$69.4 billion.³ The same study reported that approximately two-thirds of the costs were due to lost productivity and one-third was due to direct healthcare costs.

The Discovery study for Endometriosis was initiated in April 2018. Results to date have identified several potential biomarkers for the disease, which now require verification using the next step in the pipeline. The Proof of Concept study is able to identify candidates with greater statistical confidence, and if successful, may lead to patentable IP.

Parasite infections: Giardia

Giardia is one of the most common parasitic human diseases globally. About 10% of those infected have no symptoms. In 2013, there were about 280 million people worldwide with symptomatic giardiasis. In some developing countries Giardia is present in 30% of the population⁴, and in the USA it is estimated that it is present in 3–7% of the population. The risk for human health is that some Giardia strains that affect pets can cross into humans (zoonotic), whilst others do not (host specific). Current tests cannot easily differentiate these host specific and zoonotic strains.

PIQ has identified strain specific Giardia targets using combination of its Promarker platform and bioinformatics techniques. Synthetic mimics of these targets have been manufactured using synthetic peptide chemistry, and these peptides have been used for antibody generation. The resulting antibodies are being assessed for performance in a paired immunoassay format. Prototype assays will then be tested against control samples in order to prove the technical viability of the assay.

Asthma and Chronic Obstructive Pulmonary Disease (COPD)

In December 2017, Proteomics collaborated with the Busselton Population Medical Research Institute to improve the diagnosis and treatment of lung conditions. The Company has received ethics approval for a

¹ PIQ/ASX source

² PIQ/ASX source

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5859693/>

⁴ PIQ/ASX source

discovery study to identify biomarkers for asthma and chronic obstructive pulmonary disease, which costs health care systems tens of billions of dollars a year. The agreement gives Proteomics International access to the globally recognised Busselton Health Study, one of the longest running epidemiological research programs in the world.

The discovery program remains pending whilst the Company focuses its resources on PromarkerD clinical studies and its existing diagnostics programs.

PromarkerD

The Company has successfully achieved the identification of biomarkers with respect to kidney disease in people with Type 2 diabetes. With this information the Company has developed a diagnostic test, PromarkerD, that accurately predicts whether a diabetic is at risk of developing kidney disease. This can be determined through a simple blood test.

The Company has successfully completed development and validation studies (four years each) for PromarkerD. In clinical studies involving 792 patients, the PromarkerD test predicted 86% of previously disease-free patients who went on to develop diabetic kidney disease within four years.⁵ The test can also diagnose diabetic patients already suffering from diabetic kidney disease with higher accuracy than the current gold standard tests.

As per results presented at the 18th Annual Diabetes Technology Meeting, the PromarkerD protein biomarkers vastly outperform both existing diagnostic tests (albumin creatinine ratio “ACR” urine test, and estimated glomerular filtration rate “eGFR” blood test) in predicting future diabetic kidney disease, with adjusted odds ratio (OR)=1.98 (95%CI 1.31-3.01) versus OR=1.16 (0.94-1.42) and OR=0.87 (0.85-0.90).⁶

The PromarkerD technology has also been validated by the peer-reviewed scientific journal EuPA Open Proteomics, the official journal of the European Proteomics Association. It has also been rated the world’s leading diagnostic test for diabetic kidney disease by the global research house Frost & Sullivan in its report titled Biomarkers Enabling Diabetes and Obesity Management.

Huge Addressable Market

Diabetic Kidney Disease (DKD) is a chronic disease in which the kidneys get damaged and cannot filter blood the way they should.

Diabetes is among the leading causes of kidney disease. Diabetes results in high blood sugar levels and over time, these high glucose levels can damage various areas of the body, including the cardiovascular system and kidneys. The kidney damage that results is known as diabetic nephropathy. Diabetic nephropathy is a major cause of long-term kidney disease and end-stage renal disease (ESRD). In ESRD, the kidneys no longer work well enough to meet the needs of daily life. ESRD can lead to kidney failure with potentially life-threatening consequences. The longer a person has diabetes the more likely they are to develop kidney disease. About 1 in 3 adults with diabetes currently develop chronic kidney disease. The International Diabetes Federation (IDF) estimated 463 million adults had diabetes in 2019, which is almost four times the 108m adults with diabetes in 1980.⁷

Kidney disease is associated with a tremendous economic burden. In 2010, 2.62 million people received dialysis worldwide and it is expected that the need for dialysis will double by 2030. In 2015, the total Medicare spending for beneficiaries with kidney disease was nearly USD100 billion in US alone.⁸

There are no early symptoms of diabetic kidney disease. A person can lose up to 90% of their kidney functions before experiencing any symptoms. According to Kidney Health Australia, less than 10% of people with chronic kidney disease are aware they have the condition.⁹ If kidney disease is detected early and managed appropriately, the deterioration in kidney function can be significantly reduced and may also be reversed.

There is currently no affordable, mass market test available for predicting the onset of diabetic kidney disease. PromarkerD, the world’s first predictive diagnostic test for diabetic kidney disease can predict the onset of

⁵ Diabetes Care 2017; Diabetes and its Complications 2019

⁶ <http://128.242.110.24/API/MCP-7843.pdf>

⁷ PIQ/ASX source

⁸ <https://www.who.int/bulletin/volumes/96/6/17-206441/en/>

⁹ <https://kidney.org.au/health-professionals/prevent/statistics>

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disease before clinical symptoms appear. Doctors can then prescribe an early therapeutic treatment to stop the onset of disease.

Figure 2 – Global prevalence of diabetes

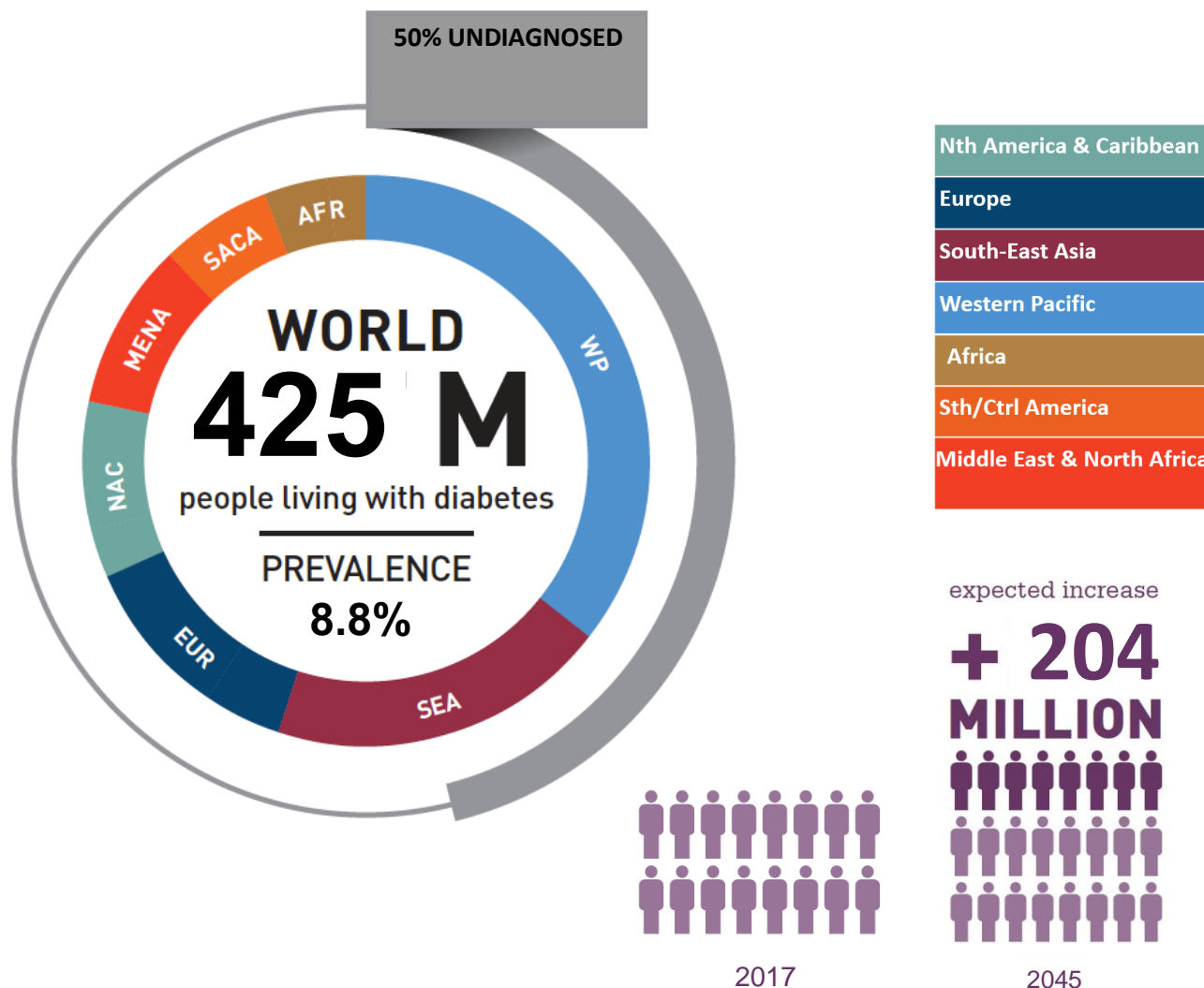


Table 1 – Estimated diabetic population in the geographies where PromarkerD has been patented:

Country	Diabetic population (millions) ¹⁰
USA	30
Europe	56.8
Australia	1.1
China	114
Japan	7.2
Russia	9.2
Singapore	0.6
Dominican Republic	1.1
Mexico	12

¹⁰ International Diabetes Federation

Major cost/benefit factor to drive uptake

Currently there is no, affordable, mass market test to predict the onset of diabetic kidney disease. Early treatment can slow down the disease progression and prevent or delay the onset of kidney failure. The main aim of treatment is to maintain and control blood glucose levels and blood pressure. This may involve the use of medication.

If diabetic kidney disease is not treated timely, the patient is at a high risk of kidney failure. The only treatment options for kidney failure are either dialysis or kidney transplant.

Kidney dialysis: This treatment is a way to remove waste products and extra fluid from the blood. The two main types of dialysis are haemodialysis and peritoneal dialysis. The first method is more common and requires the patient to visit a dialysis centre and be connected to an artificial kidney machine about three times a week. Each session takes three to five hours. The second method may be done at home. The annual cost for haemodialysis is approximately US\$89,000 per year.¹¹ A year of peritoneal dialysis costs around US\$53,000.

Transplant: In some situations, the best option is a kidney transplant or a kidney-pancreas transplant. For patients not covered by health insurance, a kidney transplant typically costs up to US\$260,000 or more once pre-transplant screening, donor matching, surgery, post-surgical care and the first six months of drugs are accounted for. Additionally, it costs about US\$17,000 a year for anti-rejection drugs post-transplant.¹²

Kidney disease is associated with a huge economic burden. High-income countries typically spend more than 2–3% of their annual health-care budget on the treatment of end-stage kidney disease, even though those receiving such treatment represent under 0.03% of the total population.¹³

PromarkerD can predict the onset of disease before clinical symptoms appear, enabling the doctors to prescribe an early therapeutic treatment to stop or delay the onset of disease, resulting in significant benefits to the patients and healthcare system.

Table 2 - highlights the benefits that PromarkerD can bring to the patients and the healthcare system:

With PromarkerD	Without PromarkerD
Unequivocal Cost Benefit	
Test Price US\$50 Predicts kidney disease with 86% accuracy up to four years out	Dialysis cost US\$89,000 per year ongoing for the patient's life
Unequivocal Patient Benefit	
Non-invasive blood test Patients can alter habits / receive treatment to stop onset of the disease	Dialysis machine for term of life

Existing diagnostics tests for kidney disease

There are currently two standard tests for diagnosing kidney disease:

Blood test for eGFR (estimated glomerula filtration rate)

A blood test to check kidney function. GFR results show whether your kidneys are filtering at a normal level

- a eGFR of 60 or more is in the normal range.

¹¹ PIQ/ASX source

¹² <https://investors.dimerix.com/DownloadFile.axd?file=/Report/ComNews/20190926/02151329.pdf>; <https://health.costhelper.com/kidney-transplant.html>

¹³ <https://www.who.int/bulletin/volumes/96/6/17-206441/en/>

- a eGFR of less than 60 may mean you have kidney disease.
- a GFR of 15 or less is called kidney failure. Most people below this level need dialysis or a kidney transplant.

Urine Test for Albumin

Albumin is a protein found in blood. A healthy kidney does not let albumin pass into the urine. A damaged kidney lets some albumin pass into the urine. The less albumin in urine, the better. Having albumin in the urine is called albuminuria. A urinary albumin-to-creatinine ratio (ACR) result of:

- 30 mg/g or less is normal
- more than 30 mg/g may be a sign of kidney disease

However, the accuracy of both these tests is poor and neither test can predict if the patient will develop kidney disease in the future, which is what the PromarkerD test does. Also, a published review study in a peer-reviewed journal has shown that for diabetic patients already suffering from chronic kidney disease, PromarkerD can diagnose the presence of disease that was missed by the current gold standard tests: ACR and eGFR tests.

PromarkerD – two tests to capture mass market

The Company has developed two types of tests to capture mass market:

1. **Mass Spectrometry - Laboratory Developed Test (LDT):** The LDT version of the test utilises 'mass spectrometry' to identify specific biomarkers of proteins. Mass spectrometers are common in laboratories throughout most developed nations. The LDT permits fast adoption of a new test in advanced markets and faster regulatory pathway.
In September 2019, the Company successfully completed the transfer of PromarkerD technology to its clinical diagnostics partner Atturo, enabling the roll out of PromarkerD as a mass-spectrometry laboratory developed test (MS-LDT) to license partners in the European market.
2. **Immunoassay – Delivered either as a Kit Version or a Laboratory Developed Test**
 - a. **Immunoassay Kit:** The kit version is a complete package provided to laboratories. It uses an immunoassay format (also known as in vitro diagnostic or IVD) that utilises 'key antibody reagents' to identify the specific biomarker proteins. It does not require a mass spectrometer and can be used by most pathology labs around the world, especially India, China, and Japan. Unlike a LDT, the kit version requires regulatory approval in each region.
 - b. **Immunoassay LDT:** If provided the 'key antibody reagents' separately (i.e not in a complete packaged kit) CLIA certified laboratories can utilise the reagents to undertake their own LDT tests. Given the nuances of the regulatory framework, CLIA certified laboratories do not require FDA approval to run the immunoassay version of PromarkerD if conducted as a LDT.

In November 2018, PIQ announced the completion of production of the prototype immunoassay kit version of the PromarkerD test under licence and presented positive performance verification results at the 18th Annual Diabetic Technology Meeting in North Bethesda, USA.

In 2019 the Company has also developed and successfully validated its own version of the PromarkerD immunoassay. This immunoassay has been designed using advanced CaptSure technology (TGR Biosciences, Australia) and complements the initial PromarkerD immunoassay developed by Omics Global Solutions. The Company's PromarkerD immunoassay has been developed to be delivered via an enzyme-linked immunosorbent-assay (ELISA) format. The testing laboratory can use the PromarkerD immunoassay to measure separately the concentration of the novel panel of three protein biomarkers: Apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L) and Insulin growth factor binding protein 3 (IGFBP3). **Please see figure 4 & 5 below.**

The PromarkerD immunoassay uses the CaptSure technology platform whereby chemically tagged antibodies bind to the target biomarker in solution and are then immobilised on the surface through the peptide tag. This translates to a more efficient, faster, and simpler assay protocol than standard sandwich immunoassays. This technology can also be readily converted to automated immunoassay platforms.

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PromarkerD Hub - The results from all platforms are sent to the PromarkerD Hub, a proprietary piece of software that uses a complex algorithm to determine the patient's risk of developing diabetic kidney disease. The PromarkerD Hub provides another level of IP protection on top of the Company's granted biomarker patents.

Figure 3 – Antibody targeting

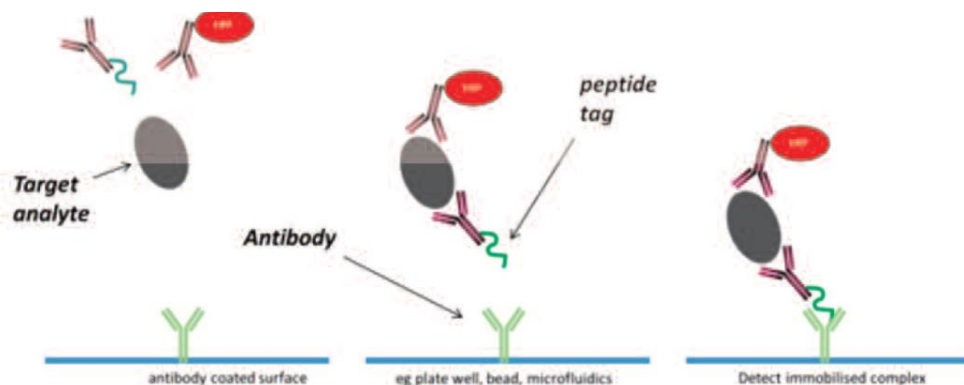
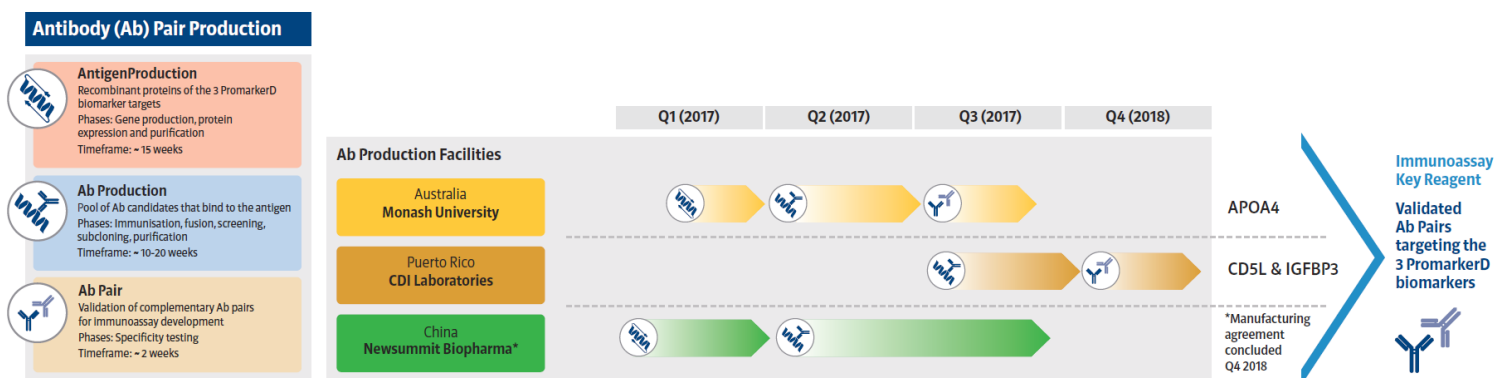
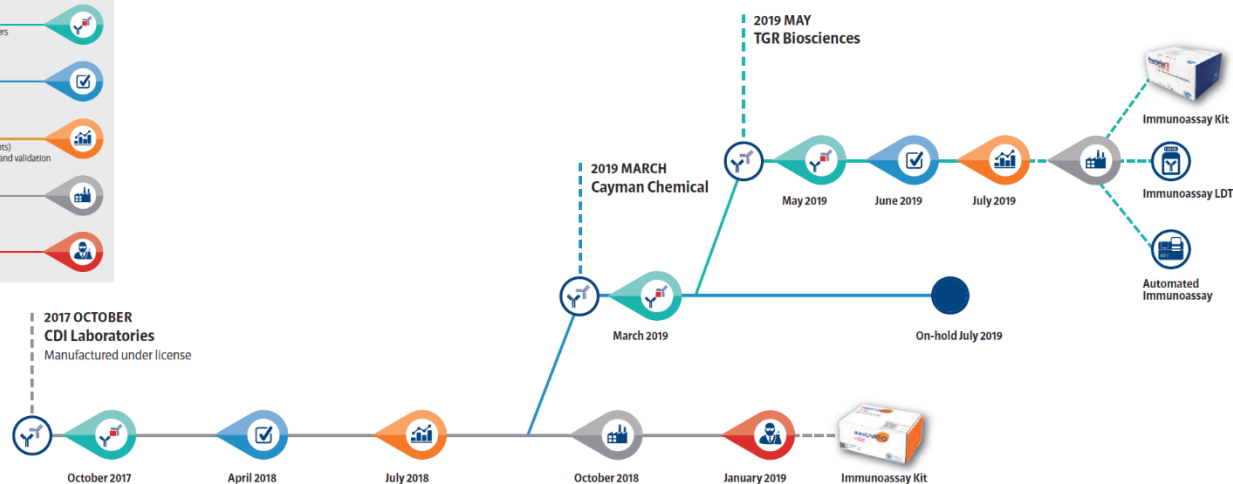
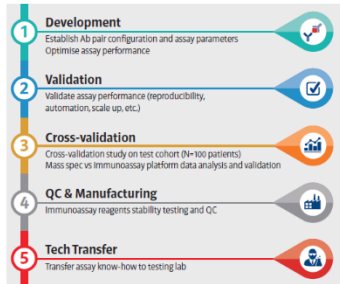


Figure 4 & 5 - Immunoassay Development



Proteomics International has engaged multiple Ab production facilities as contingencies.

Immunoassay Production



Immunoassay Developers - CDI Laboratories (Puerto Rico), Cayman Chemical (USA), TGR Biosciences (Australia). Proteomics International has engaged multiple facilities as contingencies.
Immunoassay Kit (CDI Laboratories) - Manufactured under licence for partner Omics Global Solutions. Product marketed in Dominican Republic as INNOVATIO RD.

Table 3 - the key difference between the two tests:

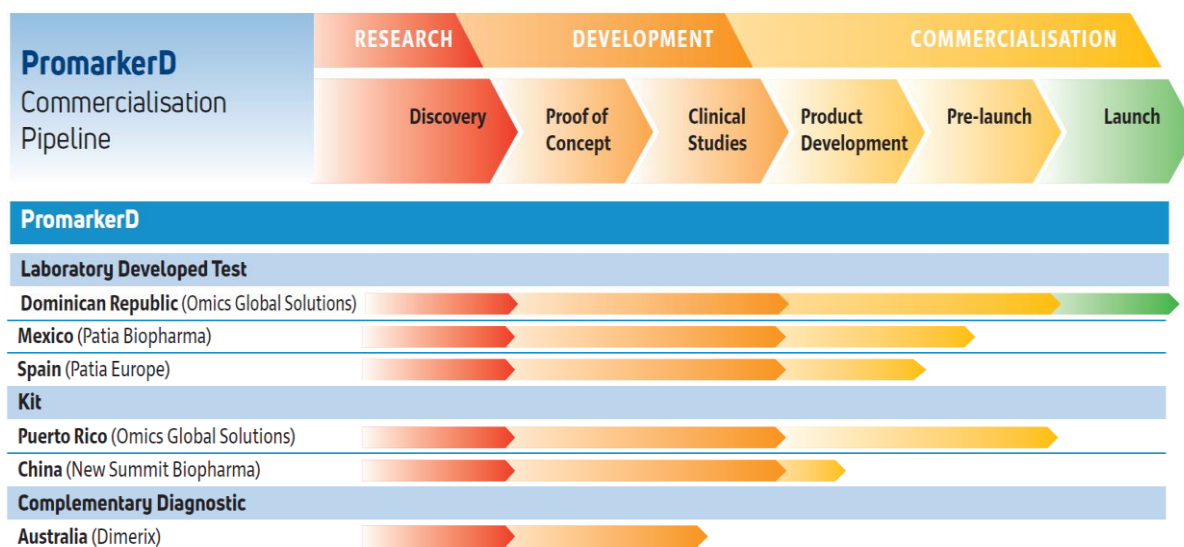
	Laboratory Developed Test (LTD)	In Vitro Diagnostic Test (IVD)
Type of technology	Either immunoassay or mass spectrometry	Immunoassay
How it works	The PromarkerD LTD analyses the protein fingerprint of a patient's blood to help diagnose and prognose kidney function. Utilising either mass spectrometry or immunoassay technology for analysis. Proteomics International's partners can run the LTD within their own specialist laboratories. Blood results from these analyses are then sent to the PromarkerD Hub to determine the patient's risk of developing diabetic kidney disease in the next 4 years.	The PromarkerD IVD uses immunoassay technology to diagnose and prognose kidney function. It can be manufactured as either an immunoassay kit or can be configured to run on an automated machine platform, allowing the analysis of hundreds of blood samples at a time.
Pros	<ul style="list-style-type: none"> - Permits fast adoption of a new test in advanced markets - Does not require regulatory preapproval - Can be used to build market demand prior to wider release of a kit format 	<ul style="list-style-type: none"> - Can be used in pathology laboratories around the world, subject to regulatory approval - Easier for laboratories to implement - Can be supplied through existing distribution channels of diagnostic companies - Has the potential to open up new markets, including those in China, India and Japan
Cons	<ul style="list-style-type: none"> - Test must be performed in a certified laboratory - Every laboratory must set up their own version of the test 	<ul style="list-style-type: none"> - Takes longer to reach the market because of manufacture and regulatory approval process

Commercialisation Progress of PromarkerD

The Company is seeking to commercialise PromarkerD through sourcing partners to distribute the diagnostic test. The Company is currently in discussions with a number of diagnostic and pharmaceutical companies across multiple regions.

The Company has entered into various agreements, detailed below, involving the licencing of LTD tests as well as production and licencing of IVD (In Vitro Diagnostic) test kits. PIQ will receive a royalty on all tests sold. These licencing deals will serve as an important stepping stone for accelerating rollout of PromarkerD in other major jurisdictions around the world.

Figure 6 – PromarkerD commercialisation pipeline



Dominican Republic: In March 2018, the Company launched the PromarkerD test (LDT version) in Dominican Republic. The Company has provided an exclusive licence to Omics Global Solution and its sister Company Macrotech Farmaceutica to distribute PromarkerD in the Dominican Republic. The kits are manufactured by Omics in Puerto Rico, which is a US territory and therefore will fall under the umbrella of the US FDA guidelines providing a pathway into the US market.

Mexico: Mexico has one of the highest rates of diabetes in the world, with 13 million adults suffering from the condition. In June 2018, Proteomics International signed a licence agreement with Patia BioPharma to launch MS-LDT version of PromarkerD in Mexico, with biomarker analysis to be provided by an authorised laboratory. However, biomarker analysis could not be initiated by the specified laboratory due to commercial restructure. In July 2019, the licence was extended to immunoassay LDT version of PromarkerD, with biomarker analysis to be provided by an authorised laboratory. The roll out of the test is pending for the PromarkerD validation by authorised laboratory.

Spain: Spain has been witnessing an increase in the incidence of diabetes, with the current diabetic population estimated at 3.6 million.¹⁴ In November 2018, the Company signed a licence agreement with Patia Europe to launch PromarkerD MS-LDT version in Spain. The licence is for the MS LDT version of PromarkerD and is exclusive for two years.

In September 2019, the Company launched PromarkerD MS LDT version of the test in Spain. The test is being commercialized by Patia Europe, with the LDT being offered through an expansion of the partnership with specialist mass spectrometry diagnostics firm Atturos, as described earlier.

US/Europe/Japan/India: The Company is negotiating with a number of diagnostic and laboratory technology companies that offer large markets and fast scale and deployment, including tier 1 national diagnostics groups. The Company has received European CE mark registration for its PromarkerD mass spectrometry (MS) test for diabetic kidney disease as well as for the PromarkerD hub, both as IVD medical devices. PIQ intends to lodge a CE mark application for PromarkerD (Immunoassay version) in March 2020 quarter and a US FDA application by mid-2020.

PromarkerD as Complementary Diagnostics (CDx)

When a diagnostic test is used alongside a drug therapy, it is known as a companion or complementary diagnostic (CDx). There are 21 drugs in clinical trials for DKD. This highlights that the need for new therapeutic treatments for complications of diabetes has been recognised by the pharmaceutical industry. A companion diagnostic test can identify patients for whom the drug will work or not work. This is a powerful tool for pharmaceutical companies that are:

- conducting clinical trials, given patient populations can be targeted to enhance overall efficacy; and/or
- commercialising/promoting an approved treatment, given a CDx test can determine whether a patient should be treated, guiding a patient to their treatment.

¹⁴ <https://idf.org/our-network/regions-members/europe/members/159-spain.html>

PIQ is collaborating with Janssen Research & Development, LLC ('Janssen') and to a lesser extent Dimerix Limited (DXB.ASX) to assist with the development of Diabetic Kidney Disease treatments. If successful PromarkerD may be assigned as a Complementary Diagnostic (CDx) test, utilised by physicians to prescribe a suitable treatment.

The Proteomics-Janssen Collaboration

Before going into more detail about the Proteomics-Janssen Collaboration it is important to note that Janssen sought out Proteomics International for this joint study, not the other way around, as is often the case for junior ASX listed healthcare/biotech companies engaging with large pharma.

Janssen Research & Development, LLC and Proteomics International have been in discussions for several years but it was not until November 2018 that the relationship was formalised via a collaboration agreement. Under the agreement there is a joint study to explore the performance of PromarkerD predictive diagnostic test for diabetic kidney disease in samples from a completed Phase 3 clinical trial of Janssen's diabetes drug canagliflozin (Invokana™).

Invokana™/canagliflozin is an oral diabetes medicine that helps control blood sugar levels. Invokana™ is also used to reduce the risk of cardiovascular events (including heart attack, stroke or death) in adults with type 2 diabetes and established cardiovascular disease.

Late last year, post Janssen's successful Phase 3 'Credence' clinical trial, the FDA approved Invokana™ to treat kidney disease in people with type 2 diabetes. In doing so canagliflozin became the only medicine in nearly 20 years, and the first diabetes medicine, to be approved to reduce risk of renal failure, dialysis or kidney transplantation.

Under the collaboration agreement Janssen has provided Proteomics International samples from its completed 2017 CANVAS Phase 3 clinical trial of ~3,600 diabetes sufferers with cardiovascular issues and Proteomics is performing the sample testing, with joint analysis of the study results.

Positive results from the collaborative study have the potential to fast-track the commercialisation of PromarkerD. If successful, PromarkerD may be designated as a Complementary Diagnostic (CDx) test for the treatment of diabetic kidney disease.

Both Proteomics International and Janssen are now performing in depth statistical analysis of the data and an update will be provided later in Q3 FY20.

Why Janssen would find PromarkerD commercially valuable

As reported by Fierce Pharma in April 2019, Janssen would be actively looking for a way to reverse the sinking Invokana™ sales, which have been falling since the FDA gave the drug a boxed warning of lower-limb amputations. Invokana™ suffered a 21% sales drop in 2018 on top of a similar decline in 2017, when the FDA added the label warning. Invokana™ revenue fell to US\$881 million in 2018 from US\$1.4 billion in 2016, the Company reported.¹⁵

Despite the side-effect warnings Invokana™ is obviously a very effective drug and in April 2019 Janssen reported the results from the phase 3 Credence study of Type 2 diabetes patients with chronic kidney disease. Invokana™ plus standard of care topped standard of care alone at delaying the disease's progress by a difference of ~30%. The drug also hit its end-points on several cardiovascular outcomes, including cutting the risk of cardiovascular (CV) death and heart failure-related hospitalisations by 31%.¹⁶

Importantly for Janssen, the study also showed no imbalance in amputation or bone fracture and no new safety concerns were identified in this study of high-risk patients.

¹⁵ <https://www.fiercepharma.com/pharma/invokana-win-kidney-patients-could-help-j-j-right-sglit2-ship>

¹⁶ <https://www.prnewswire.com/news-releases/invokana-canagliflozin-significantly-reduces-the-risk-of-renal-failure-in-patients-with-type-2-diabetes-and-chronic-kidney-disease-in-the-landmark-phase-3-credence-study-300831777.html>

Kidney disease is a common complication of Type 2 diabetes, and poor kidney function can trigger heart failure and other serious cardiovascular problems. Holding kidney disease at bay represents a “huge advance” for patients, Janssen executive James List said ahead of the data release.

The real commercial opportunity, as we see it, is that Janssen could use PromarkerD to identify which Type 2 diabetic patients were at risk of developing chronic kidney disease and therefore could be prescribed Invokana™. There is a logical view that if these high-risk patients commenced Invokana™ treatment earlier than usual then the health of the kidneys could be better preserved, with obvious flow on benefits. The big positive for Janssen is that they would capture a patient group up to four years earlier than they would normally, and importantly before their competitors. In addition, there is potential for these would-be patients to receive a lower dose of Invokana™ thereby reducing any potential side-effects of the drug, thus improving the drug’s safety profile.

In summary, the collaboration has the potential to establish PromarkerD as a Complementary Diagnostic (CDx) test for the therapeutic treatment of diabetes complications. Becoming a Complementary Diagnostic means a PromarkerD test could be used:

- every time drugs in the gliflozin class are prescribed; and
- throughout a patient’s course of treatment (potentially lifetime) to monitor the risk of developing chronic kidney disease.

Should this be the case it would mean PromarkerD would be incredibly valuable to Janssen via attaining more patients and restricting competition.

One Competitor – RenalytixAI

RenalytixAI is a developer of artificial intelligence (AI) enabled clinical diagnostic solutions for kidney disease. The Company’s product is designed to create significant improvements in kidney disease risk assessment, clinical care and patient stratification for drug clinical trials. The AI platform the Company utilises considers distinct sources of patient data, including large electronic health records, predictive blood-based biomarkers and other genomic information for analysis by learning computer algorithms. Overtime, RenalytixAI intends to construct a unique pool of kidney disease-related data for different AI-enabled applications designed to improve predictive capability and clinical utility.

Table 4 – Renalytix AI vs Proteomics International

	RENALYTIX AI	PROTEOMICS INT.
CODE	RENX.LSE	PIQ.ASX
SHARE PRICE	£3.45	A\$0.335
12 MONTH HIGH/LOW	£3.70/£1.15	A\$0.44/A\$0.23
SHARES ON ISSUE	~59m	~92m
MARKET CAPITALISATION	£208m (A\$405m)	~A\$31m
FY19 REVENUE	N/A	A\$1.5m
FY19 NET LOSS	£6.9m (A\$13.5m)	A\$2.1m

RenalytixAI Plc (LON: RENX, Mkt Cap: A\$405m) – KidneyIntelX™

KidneyIntelX™ is designed to diagnose and improve clinical management of patients with Type 2 diabetes with progressing kidney disease. The diagnostic uses machine learning algorithms and the combination of predictive blood-based biomarkers, genetic factors and electronic health records to derive a KidneyIntelX™ ‘score’. The ‘score’ highlights the patient’s level of risk of kidney disease, driving data acquisition for care pathway development and deployment.

We see this as being fundamentally different to the PromarkerD™ blood test which identifies and measures the concentration levels of a panel of novel protein markers (biomarkers) that are highly effective in diagnosing and predicting diabetic kidney disease. The process of this test includes (1) obtaining a patient’s blood via a routine blood test, (2) laboratory analysis of the blood sample using the PromarkerD™ laboratory developed test or PromarkerD diagnostic test kit, (3) processing the results of the blood analysis at the PromarkerD hub, and (4) analysing the results to determine the patient’s risk level of developing diabetic kidney disease in the next four years.

We understand RenalytixAI's KidneyIntelX™ test costs ~US\$1,000 per patient and involves a number of various tests and measures. Compared to PromarkerD's ~US\$50 per test cost and ease of use, we do not see how RenalytixAI will ever be able to compete on price or ease of use. Thus, we see PromarkerD being a true gold standard mass market predictive diabetic kidney disease test.

Furthermore, we note RenalytixAI's market capitalisation is ~A\$405m which we believe is testament to the value northern hemisphere stock markets place on such predictive diagnostic technologies as KidneyIntelX™ but also shows how undervalued Proteomics is at a market capitalisation of ~A\$31m.

Regulatory Pathway and Approvals

Components of PromarkerD

There are three distinct components of PromarkerD, which require approval across each major jurisdiction (European CE Mark, US FDA, Australian TGA), namely:

1. **PromarkerD mass spectrometry (MS) version** – Test designed for sophisticated laboratories. In the US, CLIA Certified laboratories can run the MS version of the test without FDA approval.
2. **PromarkerD immunoassay (IA) kit version** – Traditional platform technology, which virtually all competent laboratories globally can run. Proteomics required to get approval in all jurisdictions for the IA Kit version to be used. IA Kit version enables fast throughput and easy adoption globally.
3. **PromarkerD Hub** - an integral component of the PromarkerD test system and processes data obtained from the PromarkerD mass spectrometry (MS) or immunoassay (IA) technology platforms.

CE Mark – Europe

1. **PromarkerD MS version** – CE Mark registration granted 12 November 2019.
2. **PromarkerD IA kit version** – It is expected that Proteomics will apply for CE Mark Approval in Q1 CY2020. Approval should be granted shortly after submission, given the prior approval of the MS version and comprehensive data pack.
3. **PromarkerD Hub** – CE Mark registration granted on 14 January 2020

CE Mark provides assurance to potential licensing partners and consumers in the EU that the product has been developed and manufactured to meet EU safety, health and environmental protection requirements. The successful registration of the IA kit version of PromarkerD, will provide complete CE Mark approval. This is a major milestone for Proteomics as it:

- facilitates the widespread sale and distribution of both versions of PromarkerD across Europe;
- significantly de-risks PromarkerD in the eyes of tier-1 diagnostic companies that Proteomics are endeavouring to execute a significant, European licensing transaction with; and
- will build a solid case for PromarkerD to receive US FDA approval.

FDA Approval

- **PromarkerD MS version** – Does not initially require FDA approval as CLIA certified laboratories may run the test. In total, CLIA covers approximately 260,000 laboratory entities.¹⁷ For non-certified laboratories to run the MS version, FDA approval will be necessary (most laboratories with a mass spectrometer are CLIA certified).
- **PromarkerD IA kit version** – Proteomics intends to lodge the US FDA application by mid-year 2020.
- **PromarkerD Hub** - Proteomics intends to lodge the US FDA application by mid-year 2020.

CE Mark approval and potentially the inclusion of data from the Janssen collaboration is expected to support and expedite the FDA approval process. Based on similar submissions the Company anticipates receiving FDA approval 6 – 9 months post lodgement, assuming there are no requests for additional data.

¹⁷ <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>

FDA approval is a significant catalyst for Proteomics. Similar to CE Mark approval, FDA approval will likely facilitate an attractive licensing transaction with a tier-1 diagnostic company. It must be noted that the Company is currently actively pursuing a US licensing transaction, which may be achieved prior to FDA approval.

TGA Approval – Australia

- **PromarkerD MS version** – For non-certified laboratories to run the MS version, TGA approval will be necessary.
- **PromarkerD IA kit version** – Proteomics intends to lodge the TGA application by mid-year post FDA submission.
- **PromarkerD Hub** – TGA approval received for export use on 29 July 2019

TGA approval for PromarkerD will be a focus for Proteomics post CE Mark and FDA approval, as these applications can effectively be replicated and submitted.

Analytical Services

The Analytical services unit offers specialist protein analysis services to a range of pharmaceutical, biotechnology and academic clients around the world on a fee-for-service basis. It is currently the primary revenue generating division of the Company, with revenue increasing 25% in FY19 to A\$1.5m.

PIQ's Analytical Services provides two primary services:

Biosimilars & biologics development: The Company assists pharmaceutical companies develop biosimilars drug “generics”. Biosimilars are the generic version of an approved biologic (protein-based treatment). Unlike the generic version of drugs in which the active ingredient is identical to the approved product, biosimilars are highly similar in terms of quality, safety and efficacy to an approved drug.

Additionally, the Company also offers Proteome mapping, Protein Qualification (iTRAQ), Targeted Mass Spectrometry (MRM/SRM), Protein ID by Mass Spectrometry and Post-translation Modifications (PTMs) services.

PIQ's services deliver immediate, independent and affordable assistance in demonstrating biosimilarity, (i.e. that the compound is the same as the original).

Biosimilars are complex generic protein drugs

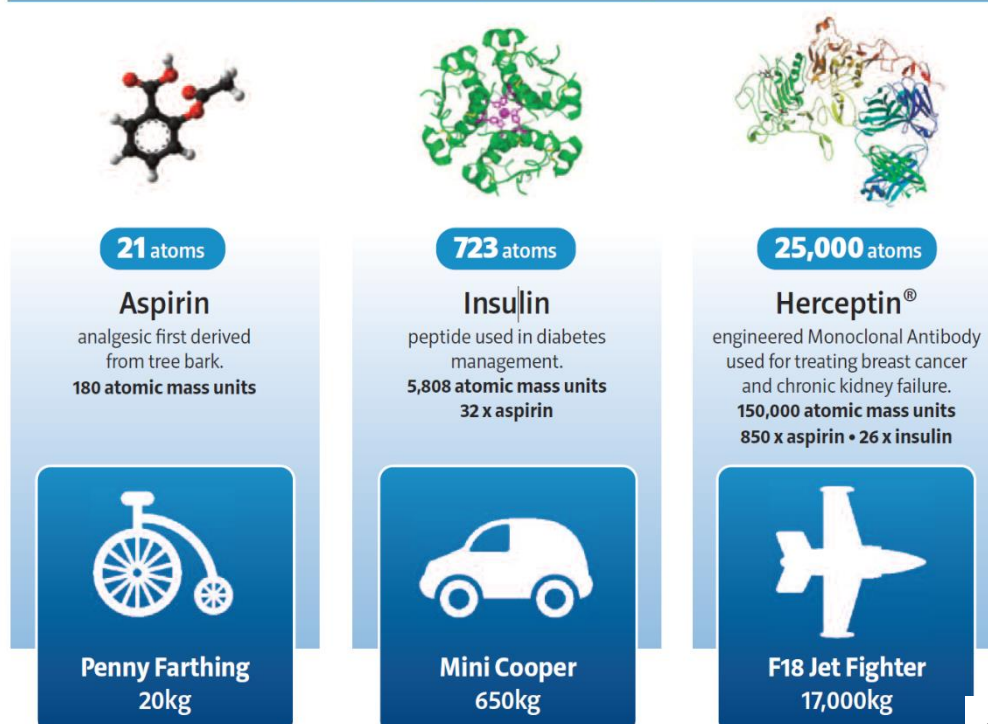


Figure 7 – Biosimilars

Biosimilars copy existing biological medicines coming off patent (for example Herceptin), and are required to show robust chemical comparability to the original product at every stage of development, and consequently require precise quality control testing. Biosimilars are not required to be identical because of the highly complex nature of biologics.

The Company's laboratory was the first laboratory in the world to receive ISO 17025 accreditation for proteomics services and also holds Research and Development accreditation to ISO/IEC 17025, together with the OECD Principles of Good Laboratory Practice. The Company is one of only a few laboratories worldwide that has the accreditation to provide protein-based drug analysis. This recognises the Company's ability to consistently achieve technically valid, traceable and reproducible results.

Pharmacokinetic testing (PK) for clinical trials: Pharmacokinetics is the science of what happens to a drug when it enters the body. It studies how the chemical changes from the moment it is administered to the point it is ultimately eliminated from the body. The fate of any drug can change depending on how it is administered, the form it is in and the size of the dose. Pharmacokinetic testing is a critical step in the development and commercialisation of a new drug. It helps to ensure drugs are safe and effective, and also examines how the chemical changes in individual patients.

Proteomics International launched new pharmacokinetic (PK) testing services for clinical trials in 2017. These services are now an integral part of the Company's Analytical Services. Proteomics International can undertake pre-clinical and clinical PK quantitative assays for any investigational drug product.

Partnership with Linear Clinical Research Ltd

In November 2016, the Company announced it had entered into a partnership with Linear Clinical Research Ltd (Linear) to provide advanced analytical services for clinical trials performed at Linear.

PIQ utilises their Promarker technology to test the patient response to drugs during clinical trials. PIQ can analyse blood samples taken from patients to determine how long a drug stays in a patients' system. The service allows drug developers to bring drugs to market more efficiently.

Linear conducts research on around 30 drug and medical therapies a year. The increasing number of clinical trials being conducted in Australia will result in the continued stream of projects for Linear.

In July 2019, the Company secured two new contracts to conduct pharmacokinetic (PK) analyses, with a combined value of A\$418,000. The phase I clinical studies will examine the safety performance of novel autoimmune disease drugs for two China based pharmaceutical companies, with the studies to be undertaken over 3-10 months.

Cutting-edge protein biomarker analysis facility for Western Australia

In November 2019, Proteomics International joined forces with Bioplatforms Australia and The University of Western Australia to launch a cutting-edge proteomics facility to explore biological markers affecting medicine, agriculture, the environment and marine world. The partners will co-invest A\$4.4m over the next four years in the expanded Western Australian Proteomics Facility.

Proteomics International's contribution will be A\$1.25m in Capex and Opex over the four years, representing outstanding value for the enhanced capabilities the facility will offer. The new facility will provide increased ability to explore for and identify biological markers across a broad range of sectors. This enhanced capability could lead to the identification of new drug targets and the creation of diagnostic tests across medicine and agriculture, boosting both Proteomics International's analytical services and R&D activities.

Industry Overview

Biosimilars Market: The global biosimilars market size is expected to reach a value of USD 61.47 billion by 2025, according to a new report by Grand View Research, Inc. It is expected to expand at a CAGR of 34.2% over the forecast period.¹⁸ Several of the existing biological drugs would be reaching patent expiry in the coming decade, which would provide an opportunity for many innovator companies as well as generic manufacturers to offer services, specially tailored toward biosimilars. The biosimilar market growth would be further fuelled by factors such as cost effectiveness of biosimilars and growing prevalence of chronic diseases.

¹⁸ <https://www.grandviewresearch.com/press-release/global-biosimilars-market>

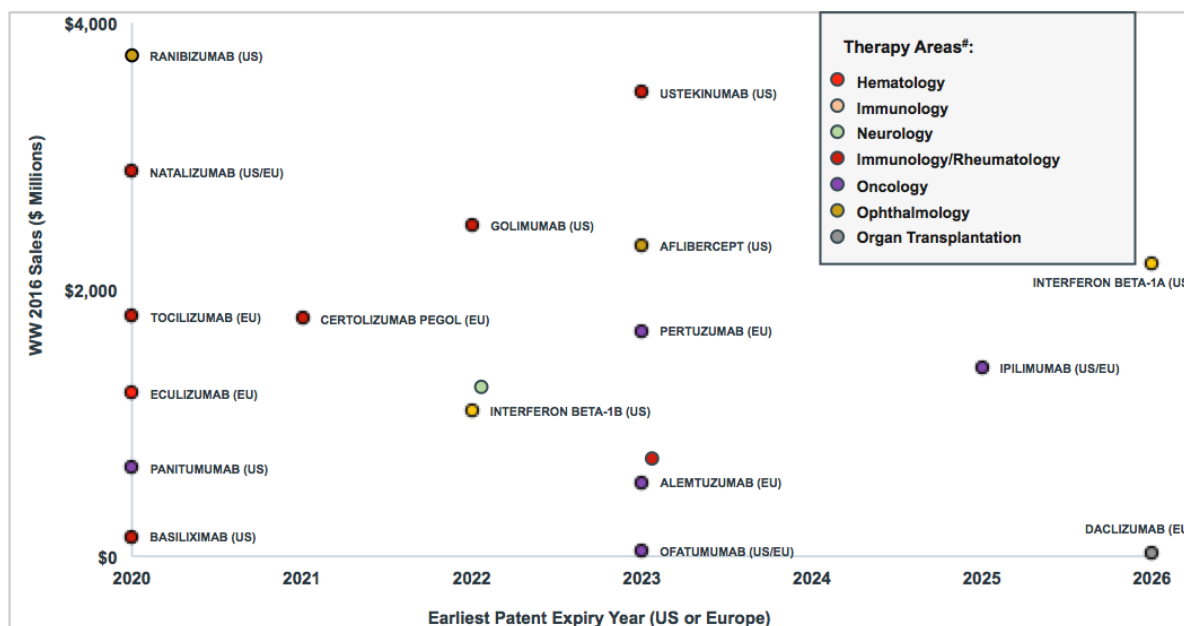
Table 4 - The biosimilars currently approved

Biologic	Australia	Canada	China	EU	Japan	S. Korea	US
Adalimumab				4			2
Bevacizumab				1			1
Calcitonin							1*
Declizumab			1				
Enoxaparin sodium				2			
Epoetin alpha			3	3	1		
Epoetin lambda	3						
Epoetin zeta				2			
Etanercept	1	2	1	2	1	2	1
Filgrastim (G-CSF)	3	1	2	9 (two later withdrawn)	3		11
Follitropin alpha (FSH)	1			2			
Glucagon							1*
Hyaluronidase							1*
Infiximab	2	2		3	2	2	3
Insulin glargine	1	1	1	2	2	2	1*
Insulin lispro				1			1*
Peg-Filgratim			1			1	
Peg-Interferon			1				
Rituximab				6		1	
Retepase			1				
Somatropin	2	1		2 (one later withdrawn)	1	2	1*
Teriparatide				2			
Trastuzumab				2		2	1
Total	13	7	11	40	10	12	15

* Approved via 505(b)(2) pathway before the dedicated biosimilars 351(k) pathway was established.

Source: <https://www.raps.org/news-and-articles/news-articles/2018/6/trends-in-biosimilars-innovative-approaches-to-ex>

Figure 8 - The biologics targeted for biosimilar development in long term (patent expiry 2020-2030).



Source: <https://www.raps.org/news-and-articles/news-articles/2018/6/trends-in-biosimilars-innovative-approaches-to-ex>

A biosimilar product application must include data demonstrating biosimilarity to the reference product. This usually includes data from analytical studies demonstrating that the biological product is highly similar to the reference product, notwithstanding minor differences in clinically inactive components; animal studies, including an assessment of toxicity; and a clinical study or studies sufficient to demonstrate safety, purity, and potency of the proposed biosimilar product in one or more of the indications for which the reference product is licensed. This typically includes assessing immunogenicity, pharmacokinetics (PK) and, in some cases, pharmacodynamics (PD) and may also include a comparative clinical study.

Biosimilar development begins with extensive structural and functional characterisation which underpins all further product development activities. Proteomics International operates a world leading ISO/IEC 17025:2017 accredited protein analysis laboratory, with a proven track record in characterising biosimilars.

Pharmacokinetic Testing Services:

As per a report by ResearchandMarkets, the global pharmacokinetics services market is expected to reach USD1.2 billion by 2025, registering an 8.3% CAGR during the forecast period.¹⁹ Rising adoption of pharmacokinetic and toxicology studies for determination of several parameters such as no-observed-effect levels (NOEL), human equivalent doses (HED) levels, and pharmacokinetic/pharmacodynamic (PK/PD) drivers are expected to fuel market growth.

Based on drug type, PK services for small molecules dominated the market in 2017 and is expected to maintain its lead during the forecast period fuelled by high service penetration and the growing popularity of generics. PK services for large molecules are expected to grow significantly during the forecast period, driven by the presence of a significant number of biologics and biosimilars in the clinical development phase.

Proteomics International can undertake pre-clinical and clinical PK quantitative assays for any investigational drug product.

A research report released by Frost & Sullivan in September 2016, highlighted that Australia is a popular destination for clinical trials as a result of its superior clinical research and healthcare infrastructure, world class research capabilities and highly skilled research personnel. Cost and regulatory speed and flexibility are also contributing to Australia being a preferred destination to conduct clinical trials and has resulted in an increasing number of trials being conducted in Australia.

¹⁹ <https://www.researchandmarkets.com/reports/4582051/pharmacokinetics-services-market-size-share-and>

Each year, around 1000 new clinical trials are commenced in Australia from phase 1 (first human trials) through to phase IV (post-market trials) for medicines and medical devices.

Table 5 - The clinical trial activity growth in Australia, by intervention type and phase:

	Drug						Device	Drug & Device	Other	Total
	Phase I	Phase II	Phase III	Phase IV	Other	Drug Total				
Growth (p.a. 2010-2015)	6.6%	3.2%	2.7%	(1.2%)	(2.3%)	2.7%	12.6%	13.4%	5.0%	4.7%

Source: ANZCTR; L.E.K. analysis

PIQ offers a comprehensive suite of new pre-clinical and clinical testing capabilities including pharmacokinetic (PK), pharmacodynamic (PD), and companion diagnostic (CDx) services. We believe that PIQ is well placed to capitalise on the increasing number of clinical trials being conducted in Australia, and anticipate a double-digit growth in the Analytical services revenue going forward.

Investment Case

Disruptive technology platform with global potential

The Company's proprietary Promarker platform has the ability to identify protein biomarkers for diseases, using a simple blood test. These biomarkers can then be used to create diagnostic tests for those diseases. The Company has successfully developed a test for diagnosis of diabetic kidney disease using its platform, and is working towards applying its Promarker technology platform to create new diagnostic tests for chronic diseases with unmet medical need.

Scalable licensing model with high margins and negligible rollout cost

The Company's revenue model includes creating new diagnostic tests using the Promarker platform, which can be commercialised through an out-licensing model. PIQ aims to receive upfront licence fee and royalty-based revenue on each test sold. The licensing model allows the Company to leverage the sales and marketing expertise of its distribution partners, resulting in better penetration and quick scalability of its diagnostic tests at minimal rollout costs.

Janssen collaboration offers independent big pharma validation for PromarkerD and a potential high value commercialisation pathway

The results from the Janssen study are expected in the coming months and assuming success it will provide independent validation of the PromarkerD test by a global pharma Company over a large and diverse patient group (~3,600 patients across the US). A successful study outcome will likely involve co-authoring of publications/presentations with Janssen scientists and a potential expansion of the relationship. Ultimately, we see Janssen/J&J as a potential commercial partner for PIQ in some form as the commercial drivers for Janssen to grow and protect market share for its CKD drug Invokana™ are incredibly strong.

Strong cash position with minimal burn rate ensures rollout is funded

The Company's recent successful capital raise leaves the Company with a very strong cash position of ~\$4.1m including receivables. The Placement saw a number of new Institutional and Family Office investors join the register, which shows broadening awareness of PIQ as a stock on the ASX. Overall burn is minimal, despite an increase this CY due to capital spend on regulatory and reimbursement items – which are significant value add factors for the Company.

Upgraded 'Western Australian Proteomics Facility' provides engine room for new protein market identification

Proteomics has launched a World-leading facility in partnership with Bioplatforms Australia and The University of Western Australia. The new equipment is already providing an increased ability to identify biomarkers and

provides the basis for increased future revenue growth from its Analytical Services division, both from biosimilars testing as well as pharmacokinetic testing for clinical trials. The Analytical services revenue helps to offset the cash burn from R&D and product development, reducing the out of pocket expenses. The Analytical services revenue increased 25% yoy in FY2019.

Strong, multi-layered IP position

The Company owns patents for PromarkerD in major jurisdictions including US, Europe, China, Russia, Singapore, Australia, Indonesia and Japan, which collectively have a diabetic population of approximately 235m and also have patent application pending in other jurisdictions including India, and Brazil. The Company has also been granted trademark for the Promarker brand in multiple jurisdictions. Promarker trademark protection has the potential to extend the lifespan of future revenue streams beyond the expiry of Proteomics International's patents. The PromarkerD Hub, which is a proprietary software algorithm, provides another level of IP protection on top of the Company's biomarker patents and also provides certainty in ensuring Proteomics receives its royalties on all tests undertaken.

Proven technology platform - pipeline of potential globally significant tests

The Company has already developed PromarkerD as a Proof of Concept of its Promarker technology platform and is working to leverage its Promarker platform to develop and commercialise a suite of diagnostic tests. The current development pipeline includes diagnostics tests for Endometriosis, Gastro and COPD, all of which represent major opportunities for the Company.

PromarkerD - world leading technology in an area of unmet medical need

The Company's PromarkerD test is the only low-cost, high-speed, predictive commercialised test available for diabetic kidney disease that accurately predicts whether a person with diabetes will develop diabetic kidney disease, up to four years prior to typical diagnosis. Diabetic kidney disease is one of the major complications of diabetes, affecting 1 in 3 diabetics. There are no early symptoms for diabetic kidney disease, and a person can lose up to 90% of kidney function without experiencing any symptoms. Diabetic kidney disease often leads to kidney failure, which can only be treated by dialysis or kidney transplant, costing the global healthcare system billions of dollars. PromarkerD can predict the onset of disease up to four years prior to clinical symptoms appear, and the deterioration in kidney function can be significantly reduced or possibly reversed through medication and lifestyle changes, saving billions of dollars for the healthcare system.

Table 6 - PIQ vs Typical Biotechs: all the upside without the clinical risks, costs & extended timelines

In our opinion, PIQ represents an attractive investment opportunity in the healthcare sector with all the upside associated with a typical biotech and minimal risk. The table below presents a comparative analysis of PIQ vs a typical biotech:

Features	PIQ	Typical Biotechs
Enormous markets	✓	✓
Minimal clinical risk	✓	X
No waiting for results	✓	X
Short clinical development (for new products)	✓	X
No binary outcome	✓	X
Licensing deals executed	✓	X
Commercially ready product(s) – already launched in some markets	✓	X
Existing revenues and low cash burn	✓	X
Strong financial position – no need for additional capital	✓	X
Proprietary Platform technology	✓	Potentially
Peer reviewed	✓	Potentially
Tight capital structure	✓	Potentially

Intellectual Property

The Company owns three families of patents in a number of jurisdictions for the biomarkers identified with pre-diabetes, diabetes and diabetes related conditions. All the patents are valid till 2031.

Table 7 - The patents granted and pending for PromarkerD in various jurisdictions.

Family One patents relate to use of PromarkerD as a diagnostic test for diabetic kidney disease

Countries with granted IP	Patents
USA	✓
Europe	✓
Australia	✓
China	✓
Japan	✓
Russia	✓
Singapore	✓
Indonesia	✓
Brazil	Pending
Canada	Pending
Hong Kong	Pending
India	Pending

In addition to the above patents, the Company has secured exclusive licensing to a family of allied patents for the diagnosis of kidney damage. This provides additional protection for the PromarkerD test in Europe. PromarkerD's patent protection in the US has also been extended to include other forms of kidney disease.

This patent family has the potential to extend PromarkerD's clinical utility to include the prediction of any form of kidney disease. Additionally, the Company has also been granted US patent for method for identifying drugs for abnormal kidney function. This has the potential to enable PromarkerD to be used as an endpoint marker in clinical trials for any new kidney disease drug. To avoid patent infringement, any pharma company using a method covered by the claims in the patent in the USA to develop a treatment using CD5L as a target will need to reach commercial agreement with Proteomics International Laboratories Ltd. Furthermore, there is the opportunity for the PromarkerD test to be used as a companion diagnostic (CDx) test alongside any therapeutic treatment concerning the CD5L target, both as a pre and post treatment diagnostic tool.

The PromarkerD Hub – PIQ proprietary algorithm

The PromarkerD Hub is proprietary software algorithm that provides another level of IP protection on top of the Company's biomarker patents already granted in multiple jurisdictions (including the EU, USA, Japan and China).

The PromarkerD Hub is an integral component of the PromarkerD test system and processes data obtained from the PromarkerD mass spectrometry (MS) or immunoassay (IA) technology platforms. All data read-outs from any lab around the world using the PromarkerD test are sent to PIQ's Perth IT system where the data is converted into a score which is then returned to the lab that undertook the test. This last level of IP also provides certainty around what royalties PIQ should receive.

The PromarkerD Hub was recently granted CE Mark approval and was granted TGA regulatory approval for export use last year.

Top 20 Shareholders

Rank	Name	Units	% of Units
1.	Richard John Lipscombe	10,074,614	12.49
2.	Richard John Lipscombe <Luk A/C>	8,186,590	10.15
3.	Xylo Pty Ltd <Parker Family A/C>	4,208,784	5.22
4.	John Sutherland Richardson Dunlop	3,855,188	4.78
5.	Sparrow Holdings Pty Ltd <Super Sweet Fund A/C>	2,335,500	2.89
6.	Scintilla Strategic Investments Limited	2,250,000	2.79
7.	HSBC Custody Nominees (Australia) Limited	2,087,054	2.59
8.	Randolph Resources Pty Ltd	1,949,000	2.42
9.	Littlejohn Embrey Engineering Pty Ltd	1,635,500	2.03
10.	Ocean Mist Pty Ltd <Waterford Super Fund A/C>	1,400,000	1.74
11.	Slade Technologies Pty Ltd <Embrey Family Superfund A/C>	1,364,500	1.69
12.	Darlene Valerie Gould	877,904	1.09
13.	BFM Superannuation Fund Pty Ltd	800,000	0.99
14.	Bjouxz Pty Ltd <The Loz Super Fund A/C>	750,000	0.93
15.	Patricia Marton	714,694	0.89
16.	Camberwell Gynaecology Clinic Pty Ltd <Skinner Super Fund A/C>	649,400	0.80
17.	Marie Joyce Bohringer	635,393	0.79
18.	Moore & Sotomi Investments Pty Ltd <Roger Moore Family A/C>	627,000	0.78
19.	Bowtrust Pty Ltd	578,848	0.72
20.	J A Botha Pty Ltd	578,847	0.72
Total ORDINARY FULLY PAID shares held by Top 20 holders		45,558,816	56.50
Total Remaining Holders Balance		35,128,149	43.50

** As per PIQ 2019 Annual Report*

Board & Management

Mr. Terry Sweet, FAICD
Chairman

Mr. Terry Sweet has been a Director of several listed companies over the past 30 years in both executive and non-executive capacities. These companies include XRF Scientific Ltd, where he was Managing Director for 4 years, Western Biotechnology Ltd, Heartlink Ltd, and Scientific Services Ltd. Originally trained as a chemist, his interests and expertise now lie in the area of development and supervision of a culture of Board integrity, commensurate with technology commercialisation. Terry is a Fellow of the Australian Institute of Company Directors and has been involved with the Company for 5 years.

Dr. Richard Lipscombe, PhD (London), MA (Oxford)
Founder & Managing Director

Dr. Richard Lipscombe, a co-founder of the Company, is a highly practised business manager and protein chemist expert in analysing biomolecules using proteomics techniques. He has an extensive expertise in chemistry, immunology, mass spectrometry, peptide synthesis, high performance computing and robotics. Richard has international experience in both science and business gained over a 30-year period in Australia, USA and the UK,

including work in hospital and academic laboratories and commercial organisations. He completed his chemistry degree (MA) at Oxford University, his PhD in immunology at London University and was a Post-Doctoral scientist (molecular immunology) in a large research institution in Australia (Telethon Kids Institute). After managing the Protein Analysis Facility at the University of Western Australia, he cofounded Proteomics International Pty Ltd in 2001. Richard is well published in peer review journals, and holder of several patents. Richard has been with the Company for over 17 years.

Dr. Roger Moore, R (Denmark), BPharm (U.Syd)
Non-Executive Director

Dr. Roger Moore has 40 years' experience in the international pharmaceutical industry, including almost 30 years as President of Novo Nordisk Japan (Novo Nordisk is the world's largest manufacturer of insulin and a global leader in diabetes care). Roger established Novo's organisation in Japan as the first employee in 1977, and worked for the company until his retirement as Chairman at the end of 2007. From 2000, Roger was appointed Senior Vice President, Japan and Oceania Region, responsible for Novo Nordisk's business in Japan, Australia, New Zealand and the Pacific. He was also appointed a member of the Senior Management Board, Novo Nordisk A/S. In 2007 Mr Moore was awarded the Knight's Cross of the Order of the Dannebrog (R) by Queen Margrethe II of Denmark. Roger joined the Board in October 2016.

Mr. Paul House, GAICD, BCom (UWA)
Non-Executive Director

Mr. Paul House previously served eight years as the Managing Director of SGS India, where he was responsible for a workforce of approximately 4,500 personnel across 65 locations in India, including 38 laboratories. SGS is the world's leading Testing, Inspection and Certification (TIC) company, and operates a network of offices and laboratories in more than 140 countries. Paul has previously held Chief Financial Officer and Chief Operating Officer roles, and was Senior Manager for several years at a leading global management consultancy firm. Paul has a track record for delivery of business performance targets, revenue growth, margin improvement, market share and productivity, across multiple services, markets and borders. Paul joined the Board in November 2017.

Mr. Chuck Morrison, BSc (Boston), MBA (Boston)
Head of Business Development

Mr. Chuck Morrison has 36 years' experience in life sciences, biotechnology, and diagnostic industries. John has a degree in chemistry and an MBA from Boston University. He has held several management positions while at NEN Life Sciences and DuPont before focusing his last 15 years in Business Development at Perkin Elmer. John successfully executed many licensing deals and several global acquisitions while in that role. John is based in Massachusetts, USA and joined the Company in May 2014.

Dr. Pearl Tan, PhD (Australia)
PromarkerD Business Manager

Dr. Pearl Tan joined Proteomics International in 2013 to lead the commercialisation of its patented 2-tag technology (used for the measurement of oxidative stress). Pearl has a background in research and completed her PhD in Biochemistry and Molecular Biology at The University of Western Australia. Pearl is now working with the business development team to commercialise the PromarkerD test.

Financial Overview

FY19 - The Company generated A\$1.5m in revenue from Analytical services in FY19, registering a 25% yoy growth over FY18. Additionally, the Company reported a R&D tax incentive of A\$1.1m, grant income of A\$78,458, interest income of A\$48,248, and other income of A\$2,127, taking the total revenue to A\$2.74m.

1H FY20 Revenue

Consolidated revenue from continuing operations and grants & other income for the six months to 31 December 2019 was \$925,060 and \$24,269 respectively (31 December 2018: \$864,198) an increase of 9%.

Expenditure

Consolidated expenses for the six months to 31 December 2019 totalled \$2,150,879 (31 December 2018: \$2,662,985) a decrease of 19% and remained in-line with budget. Expenditure has decreased yoy as a result of the finalisation of PromarkerD assays and the preparation for regulatory filing.

Net position

The Company reported a loss from continuing operations for the six months to 31 December 2019 of \$1,201,550 (31 December 2018 loss: \$1,780,108).

Net cash flow

Net cash outflow from operating activities over the period was \$435,596 (2018 net cash outflow \$284,971). Net cash outflow from investing activities was \$1,346,074 (2018: net cash inflow \$902,735), with \$1,346,074 spent on capital equipment during the period (2018: \$nil).

There was a net cash inflow for the half year of \$943,852 (2018: net cash inflow \$608,678).

As of 30th December 2019, the Company had cash reserves of A\$2.5m, and trade and other receivables of A\$1.6m. We believe that the cash reserves, coupled with the Analytical Services revenue and tax incentive is sufficient to cover the Company's R&D and operating expenses and that there is no requirement to raise additional capital in the foreseeable future.

Valuation & Assumptions

We have valued PIQ using a risk adjusted valuation methodology. We have had to make a series of assumptions which are given below.

- Market size and sales are predicted in US\$ but revenues to PIQ are converted to A\$ using a AUD:USD exchange rate of 0.66.
- We have only assigned value to PromarkerD and the Company's Analytical Services division. For PromarkerD, we have only considered US and Europe.
- Market size. We have estimated the target market size as patients with Type 2 diabetes in each region.
- Penetration rate. Given that PromarkerD is the only affordable mass market test in the world that can predict the onset of diabetic kidney disease, we believe that the test can achieve a penetration as high as 40% within 5 years of launch in major jurisdictions. However, the actual penetration achieved depends on the Company's distribution partners and since the Company has yet to secure distribution partners in the major markets of US and Europe, we have assumed the peak market penetration of 20% in all the regions.
- Ramp-up Rate: We note that the Company has developed two types of tests to capture mass market. However, since the Company has yet to obtain regulatory approval for the kit version of the test, and the LDT version of the tests can only be conducted by certified laboratories, we have assumed a slow ramp-up in the initial years of launch and an accelerated roll-out once the Company launches the kit version in the respective markets. We believe the test would reach peak penetration in the 9th year and enjoy full penetration till patent expiry.

PromarkerD ramp-up rate to peak penetration post market launch

Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
3%	8%	15%	24%	48%	68%	80%	91%	100%	100%

Source: AEP Estimate

- Price per test. We have adopted Proteomics' estimated test price of EUR100 in Europe and Dominican Republic. We have assumed a US\$50 test price in the US which is 20% higher than the test price in the Europe, noting this price point is yet to be tested commercially.
- Royalty rate. We have assumed a 10% royalty rate on all PromarkerD tests revenue to PIQ.
- Revenue assumptions for PromarkerD are probability weighted. We are confident that the Company will secure regulatory approval for the tests in the US and the Europe and hence have attributed a 80% probability of success of the PromarkerD test getting to market.
- Manufacturing Costs: We assume 4% of gross sales as the cost of manufacturing and other allied costs.
- Discounted cash flow. The resulting probability weighted royalties, analytical services revenue and costs

are then discounted by a further 15% and taxed at a 30% corporate tax rate to arrive at a probability weighted DCF.

- Summary. After all the assumptions above, we arrive at a valuation of **A\$78m (A\$0.85 per share)**, with significant flex on both the upside and downside.
- Sensitivities. There are a multitude of sensitivities in this valuation, with some key sensitivities listed below:

Royalty to PIQ		Price per test (USD)				
		40	45	50	55	60
	5%	0.35	0.38	0.42	0.46	0.50
	7.5%	0.52	0.58	0.63	0.69	0.75
	10%	0.69	0.77	0.85	0.92	1.00
	12.5%	0.86	0.96	1.06	1.15	1.25
	15%	1.04	1.15	1.27	1.38	1.50

Key Risks

Commercialisation risk: A failure to successfully develop and commercialise its products and services could lead to a loss of opportunities and adversely impact the Company's operating results and financial position. Further, even if the Company does achieve market commercialisation of any of its products and services, it may not be able to sustain it or otherwise achieve commercialisation to a degree that would support the ongoing viability of its operations.

Drug Market Risk: The research and development process typically takes 10 to 15 years from discovery to commercial product launch. This process is conducted in various stages to test, along with other features, the effectiveness and safety of a product. There is a risk at each stage of development that the Company may not achieve the goals of safety and/or effectiveness and that the Company may have to abandon a product.

Timing Risk: Delays in timelines may inhibit optimal partnerships, milestone payments and long-term revenues. Timeline delays can be caused by but not limited to:

- Trial requirements and recruitment rates
- The regulatory approval process
- Ability to find distribution partners

Given our valuation has a probability weighting and a WACC discount rate applied to it, delays in expected licencing deals and royalty rates have a negative impact on valuation.

Regulatory Risk: The introduction of new legislation or amendments to existing legislation by governments, developments in existing common law, or the respective interpretation of the legal requirements in any of the legal jurisdictions that govern the Company's operations or contractual obligations, could impact adversely on the assets, operations and, ultimately, the financial performance of the Company.

Funding Risk: The Company may not be able to raise additional finance when needed or, if available, the terms of the financing might not be favourable to the Company and might involve substantial dilution to Shareholders. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations and scale back development & research programmes.

Dependence on Key Personnel: The Company's performance is substantially dependent on Dr Lipscombe and the other members of its senior management and key technical staff to continue to develop and manage the Company's operations. The loss of any of these Directors, employees, consultants or scientific advisers could have an adverse effect on the business and its prospects.

Dependence on Key Relationships: The Company currently has strategic business relationships with other organisations that it relies upon for key parts of its business, such as obtaining the use of the mass spectrometers, chromatography systems and other equipment important to the Company's activities. The loss or impairment of any of these relationships could have a material adverse effect on the Company's operations, at least until alternative arrangements can be implemented.

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DISCLOSURE: Adelaide Equity Partners is retained as Investor Relations and Corporate Advisor to PIQ and receives fees for these services. Adelaide Equity Partners was engaged as corporate advisor for the November 2019 Placement and received capital raising fees for its services. In addition, Adelaide Equity received out-of-the money options for advisory services (options are still subject to issue).

Researching and completing this report has been carried out as a separate assignment by an independent contract research organisation to further AEP wholesale client understanding of PIQ. Costs incurred as part of completing this report, namely the contracted research, have been reimbursed by the Company.

ANALYST CERTIFICATION

Each research analyst primarily responsible for the content of this research report, in whole or in part, certifies that with respect to each security or issuer that the analyst covered in this report: all of the views expressed accurately reflect his or her personal views about those securities or issuers and were prepared in an independent manner.