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COMPANY SNAPSHOT

Stock code:	PIQ AU
Price:	A$1.14
Market cap:	A$120.5m
Average daily turnover:	A$0.09m
Shares outstanding:	105.7m
Free float:	N/A

Iain Wilkie

+61 7 3334 4521

iain.wilkie@morgans.com.au

Scott Power

Analyst(s) own shares in the following stock(s) mentioned in this report:

– Proteomics International Laboratories

Proteomics International Laboratories

A predictive diagnostic test

- Proteomics International (ASX:PIQ) is a predictive diagnostics and bio-analytical medical technology company.
- The company operates in three segments: 1) Commercial (PromarkerD) – a predictive test for early detection of diabetic kidney disease (DKD); 2) R&D (Diagnostics) – development of novel tests using proteomics technology, Promarker™; and 3) Analytical services such as PK testing and biosimilars for clinical trials.
- Upcoming catalysts include: 1) US licensing deal for PromarkerD (1HCY22); 2) validation trial results in Endometriosis (1HCY22); 3) first sales PromarkerD in EU (1HCY22); 4) US reimbursement for PromarkerD (2HCY22); and 5) development of new tests from diagnostic pipeline (2HCY22).

Technology/ company overview

- PIQ has created a unique patented, cost effective and robust methodology for testing diseases with significant unmet need. The platform, Promarker™, analyses protein fingerprints at the molecular level from a blood sample and stratifies (or scores) patients based on the concentrations of biomarkers in healthy versus sick individuals, which may be in advance of symptom onset. These tests aim to address significant unmet need in diseases with poor early diagnosis, and thus implement preventative treatment that could improve patient outcomes.

PromarkerD

- PromarkerD is PIQ's first biomarker test predicting the onset of Diabetic Kidney Disease (DKD) and declining kidney function in patients with Type 2 diabetes, classifying patients into three risk classes (low, moderate, and high risk).
- Within the Diabetic population, 1 in 3 adults have chronic kidney disease, which leads to renal failure requiring dialysis or a kidney transplant (costing US$72,000 p.a. to treat). The current standard of care can only detect kidney disease once it is already present. This is problematic given the nature of DKD as a 'silent killer' and the irreversible damage done to the kidney prior to typical diagnosis.
- A key milestone for PromarkerD will be achieving a US distribution agreement for licensing of the test. Market analysis implies a per test rate of US$150, with industry average royalties ranging from 5% to 15%, which would imply US$15 per test received by PIQ. Management commentary suggests an initial agreement is expected to be signed within 1H22.

Diagnostics – other applications

- PIQ continues to invest in its research pipeline for further development of novel tests using its proprietary Promarker™ technology platform in different biomarkers to detect disease.
- Behind PromarkerD, Endometriosis presents an interesting opportunity for the company, given the significant unmet need and poor diagnosis methods.
- Additionally, PIQ has shown initial proof of concept for biosimilars in several other conditions such as Asthma and chronic obstructive pulmonary disease (COPD) and oesophageal cancer.

Analytics

- The analytics business provides an array of protein analysis services to corporate clients including pharmacokinetic testing, biosimilars/ biologics drug characterisation, proteome mapping, and others.
- Analytics business has been averaging 20% yoy growth over the last few years and provides a consistent revenue stream to fund R&D cash burn for novel test developments (in addition to R&D tax rebates).

Risks

- Key risks include inability to secure a US licensing deal for PromarkerD, technology, IP, and funding risks.

Background

Proteomics is a diagnostics and bio-analytical medical technology company. The company was founded in 2001 and listed on the ASX in 2015 (ASX:PIQ) and is based on QEII Medical Campus, Perth, Western Australia. The company continues to advance its commercialisation strategy of its lead test, PromarkerD, for diagnosis of diabetic kidney disease. Additionally, the company has a solid developmental pipeline of novel tests of biomarkers using the company's proprietary technology, Promarker™. PIQ also provides a range of analytical protein services that offset cash burn from R&D and product development.

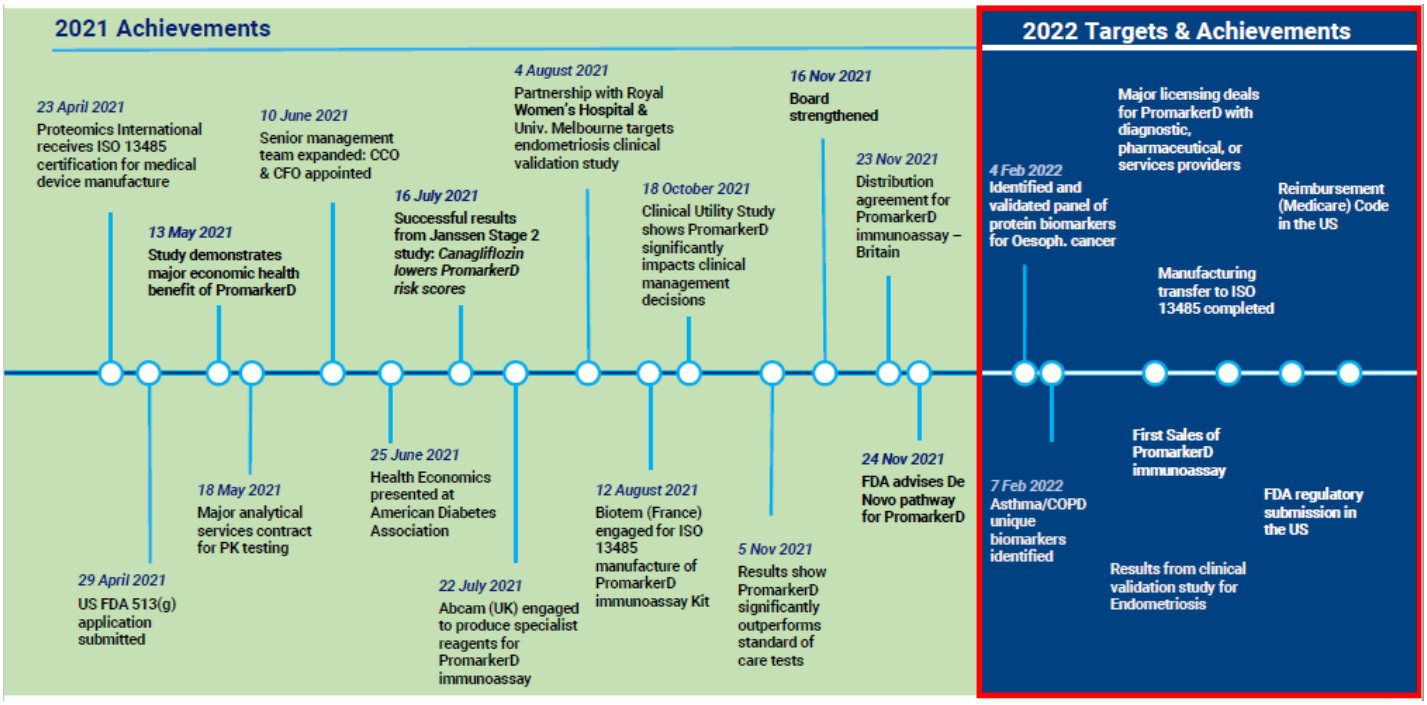
Key value drivers

The key value drivers for the business are the following:

- Potential US licensing deal for PromarkerD and first sales in EU.
- Further IP development with novel tests, particularly the opportunity for Endometriosis with trial results expected 1HCY22.
- Continued revenue growth from the Analytical Services.
- PIQ has a tightly held register with directors owning ~22% of the company.
- Cash burn through diagnostics is offset by revenue from the analytical business and R&D tax rebate.
- Strong board of directors with extensive industry experience (including 14+ PhDs within the company).
- Well-funded to complete current pipeline with A$4.5m in cash as at 31 December 2021 post a A$6.0m placement (October 2020).

Timeline and upcoming milestones

Figure 1: Timeline and upcoming milestones



Source: Morgans estimates, company data

Key risks

Key risks include:

- **Commercialisation risk** – there is risk that PIQ is unable to successfully commercialise its products, or secure favourable licensing deals in the US and globally.
- **Technology risks** – Inherent risks in the process of developing technology and in the process of discovering, developing, and commercialising a diagnostic test.
- **Funding risks** – While currently the company's analytic services business is funding R&D cash burn, there is risk if any material changes in existing contracts or future contracts could impact revenue and thus funding the commercialisation and research pipeline.

Mechanism of Action

Proteomics is the large-scale mapping of the structure and function of proteins. Proteins differ from genes in that their make-up changes over time. The analysis of proteins is particularly useful in developing personalised medicine and can assist in the diagnosis of disease. The diagnostic tests developed by PIQ analyses blood samples using a rapid immunoassay to identify proteins that can be used as a biological marker for a particular disease. The identification and concentration of these proteins along with clinical factors provides a "fingerprint" that can be analysed through proprietary algorithms that PIQ develops.

Applications

Diabetic Kidney Disease (DKD)

Diabetic Kidney Disease (DKD) is chronic kidney disease caused by diabetes and is the gradual irreversible loss of kidney function caused by high blood sugar levels.

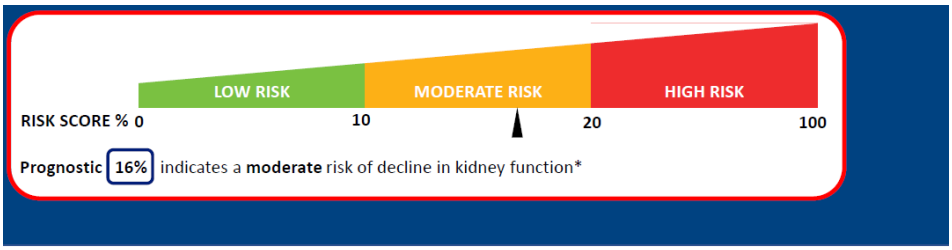
Globally, there are more than 463 million diabetics, and it is estimated that 1 in 3 diabetic adults currently suffer from chronic kidney disease. Declining kidney function can often go unnoticed, it can fall below 15-20% before the onset of any symptoms. The damage to the kidney is irreversible and thus early diagnosis and treatment is key to effective patient outcomes. If left untreated DKD leads to renal failure requiring dialysis or a kidney transplant. This is a costly process, which ultimately can be avoided if diagnosed early before kidney damage.

The current standard of care uses traditional tests such as eGFR and ACR, which are outdated and can only detect disease once it is already present (i.e. the damage has already been done). Many of these patients ultimately require dialysis or a kidney transplant.

PIQ has developed a unique patented test, PromarkerD, which can predict the onset of DKD prior to any symptoms (up to four years).

The test is revenue ready and can scale and roll out globally. The test is based on a simple technology platform that can easily be integrated into any pathology lab. A blood sample is drawn and then analysed using a rapid immunoassay to measure the plasma proteins combined with three clinical factors (age, cholesterol, eGFR). The data is then analysed by the PromakerD software via the cloud, which then calculates the patient's kidney disease risk score. As shown below, the platform employs a risk categorisation (low, moderate, and high risk), which indicates a treatment intervention and testing regimen.

Figure 2: PromarkerD



Risk Score	Intervention	Testing Regimen
Low Risk	• Standard diabetes management	Test every 12-24 months
Moderate Risk	• More frequent monitoring • Optimisation of lifestyle • Review of glycemic targets and management • Review non-glycemic risk factors • Avoidance of potentially nephrotoxic drugs • Utilisation of therapeutic drugs	Test every 6 months
High Risk	• Very close monitoring • Intensive management strategies based on those for 'Moderate risk' above with optimisation of treatments for diabetes and other risk factors	Test every 3 months

*as defined by incident diabetic kidney disease (eGFR <60ml/min/1.73m²) in the next four years. Note: if eGFR level at the time of the test is already <60ml/min/1.73m², then the risk of a further decline in kidney function is defined as an eGFR decline >30% in the next four years

Source: Proteomics

PromarkerD in the clinic

The technology is backed by extensive research, which has proven its ability to predict the onset of chronic kidney disease within 4 years. In total, PromarkerD has been tested in over 5,000 patients including in a 4-year longitudinal clinical study in Western Australia. The peer reviewed article showed the test was able to predict 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within 4 years.

Furthermore, in collaboration with Janssen (J&J), PIQ conducted an international study that predicted the incident DKD in the completed CANVAS trial, showing that high-risk patients were 13.5 times more likely to develop DKD than counterparty low-risk patients. Extending this, it continued the collaboration with Janssen of a completed clinical trial that assessed the drug treatment canagliflozin vs placebo on PromarkerD risk scores in over 2,000 patients with no incident of DKD at baseline. The study found the average PromarkerD risk score of patients taking canagliflozin dropped during the trial, while the average risk score of patients taking a placebo rose. The most significant reductions were seen in the patients classified by PromarkerD at the start of the trial as at high risk of developing DKD. Each of these results was statistically significant.

Market opportunity and regulatory approvals

There is a large opportunity for PromarkerD, given the size of the diabetic patient population. The average test price is US$150, with standard industry royalty rates ranging from 5% to 15%, which would imply ~US$15 per test at the mid-point. Given the minimal costs to maintain the test and produce the result, the royalties are expected to be close to 100% gross margin.

In the US, PIQ plans to follow the Laboratory Developed Test (LDT) pathway, which enables the test to be used in CLIA laboratories (over 2,000) prior to De Novo classification for FDA approval.

PIQ is working with consultants in the US on a strategy for reimbursement. It has identified a unique reimbursement code and payment coverage in the US and has published several papers on the Economic Health Benefit and Clinical utility.

In Australia, PIQ plans to submit an application to the Medical Services Advisory Committee (MSAC) (meeting in November 2022) to consider including the

PromarkerD on the Medicare Benefits Schedule (MBS), which, if approved, will likely result in Medicare rebates for patients. Additionally, the company is seeking Therapeutic Goods Administration (TGA) approval.

In Europe, PromarkerD has received CE Mark registration, and secured ISO 13485 certification for the manufacture of medical devices.

Current licensing transactions include:

- **Great Britain** – Apacor Ltd for immunoassay (product registration expected 1HCY22).
- **Italy** – Medical Horizons SRL for immunoassay test, registered for use with Italian Ministry of Health (sales expected 1HCY22).
- **Israel** – Zotal Ltd for immunoassay test, product registration on hold pending ISO 13485 manufacturing.

Endometriosis

PIQ is also in the process of creating a novel test for endometriosis. Endometriosis is a debilitating condition in which tissue that normally lines the inside of the uterus grows outside the uterus – most commonly involving ovaries, fallopian tubes and the tissue lining the pelvis. The main symptoms include chronic pain and menstrual irregularities. It is estimated that 1 in 9 women suffer from endometriosis globally. Often diagnosis is prolonged, typically taking 7-12 years due to the current diagnosis, which requires an invasive surgical procedure. This represents a significant unmet need for a diagnostic test, such as a blood test that can identify the biomarkers associated with the condition, without the need for invasive surgery. Endometriosis is also an expensive disease to manage largely due to lost productivity due to poor prognosis as well as treatment costs (estimated costs of $9.7bn a year in Australia alone).

Clinical data

To date, PIQ has developed what it believes will become the world's first blood test for endometriosis. The first proof of concept study was performed on 54 women, which returned statistically significant results, showing the replicability of the biomarker panel.

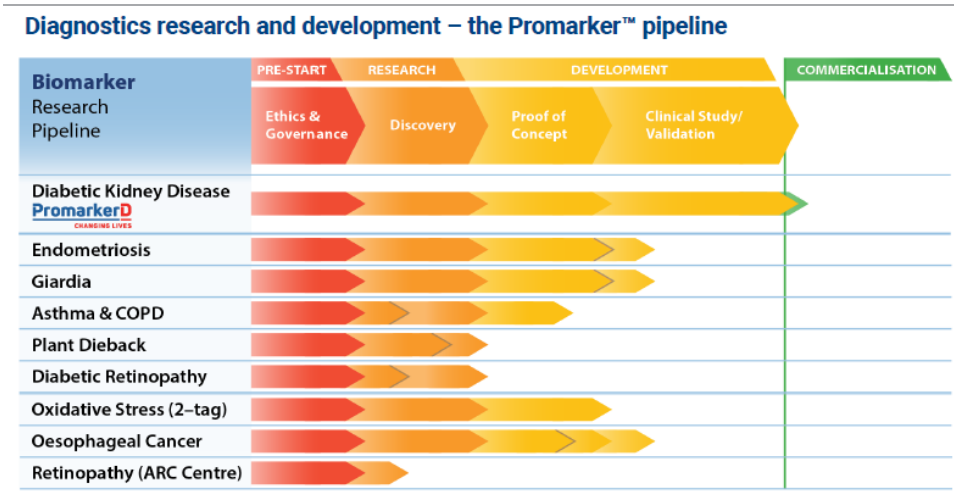
PIQ signed an agreement with the University of Melbourne and the Royal Women's Hospital to collaborate on development of a novel test for endometriosis. The collaboration will give PIQ access to a large database and patient cohort. The clinical validation study comprises 900 patients with results expected 1HCY22.

Other diagnostics

PIQ has a strong focus on research and development for novel tests using its proprietary Promarker™ technology platform. Each identified biomarker and disease is aimed at addressing an area with significant unmet need, with a large addressable market and thus significant revenue potential. There has been progression in proof-of-concept studies for multiple protein biomarkers to test diseases including Asthma and COPD, and oesophageal cancer.

An overview of the research and development pipeline as well as stages of progression is summarised in the below figure.

Figure 3: Diagnostics pipeline



Source: Proteomics

Analytical services

PIQ also offers protein analysis services with broad applications in proteomics, biosimilars, and biomarker discovery and validation. The company has a track record of delivering technically valid, traceable, and reproducible results (ISO 17025 and ISO 13485 accreditations). PIQ has secured major analytical services contracts for blue chip pharmaceutical, biotechnology and academics worldwide. The analytic services provide clients with a range of different services based around pharmacokinetic testing and proteomic-based testing including biosimilars / biologics drug characterisation, proteome mapping, protein quantitation (iTRAQ), targeted mass spectrometry (MRM/SRM), protein ID by mass spectrometry, post-translational modifications, and other additional services.

The analytical services division provides a consistent revenue stream, alongside the R&D tax rebates to fund the research and development pipeline in the diagnostics division.

Some recent analytical services contracts include:

- Linear Clinical Research/ Sironax Ltd - A$409,000 over the next 12 months as part of the Phase 1 trial for novel drug for degenerative and inflammatory disease.
- Avance Clinical - $243,000 to performance pharmacokinetic testing of novel drug for lysosomal storage disorder.

Queensland

Brisbane	+61 7 3334 4888
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Brisbane: Edward St	+61 7 3121 5677
Brisbane: Tynan Partners	+61 7 3152 0600
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Northern Territory

Darwin	+61 8 8981 9555

New South Wales

Sydney	+61 2 9043 7900
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South Australia

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