Proteomics International Laboratories

Better diagnostic tests

Share Price: A$0.63

ASX: PIQ

Sector: Healthcare

12 December 2024

Proteomics International Laboratories (ASX: PIQ) is a biotech company that is developing precision diagnostic medical tests that identify protein biomarkers via blood samples and consequently, medical indications. The company is poised to commercialise 3 of them in the first half of CY25 (1H25) – PromarkerD for Diabetic Kidney Disease (DKD), PromarkerEndo for Endometriosis and PromarkerEso and Esophageal cancer – all named after the Promarker platform these tests were developed from.

PIQ's tests can make a significant difference

All 3 tests offer a simpler and more cost-effective diagnosis potentially enabling earlier intervention and a more effective treatment. Moreover, there is an extensive pipeline of indications the company could develop tests for in the future, based on the work it has done to date.

The company is in better shape than before, even if investors do not realise it

The next 12 months are set to be pivotal for PIQ. In 1H25, the company intends to launch PromarkerD in the USA, Australia and Europe. Investors appear to be sceptical about PIQ's ambitions because the company had an exclusive licensing agreement with Sonic Healthcare USA to commercialise PromarkerD in the USA for DKD, but PIQ severed the deal in September 2024 after it was clear that the deal would not deliver the outcomes the company desired. The company now intends to use multiple Go-to-Market strategies, rather than license to any one company. This could result in the company making higher revenues than would otherwise be the case.

Valuation of $2.19-$3.31 per share

Using an SOTP/NPV methodology, we value PIQ at $295.3m in a base case and $446.6m in an optimistic (or bull) case, equating to $2.19 per share and $3.31 per share respectively. The key catalyst for creating shareholder value will be the successful commercialisation of the suite of Promarker diagnostic tests. Please see p.21 for more details on our valuation rationale. Key risks to our thesis, outlined in further detail on p.23, include commercial, regulatory and key personnel risks.

Market cap. (A$ m)	82.5
# shares outstanding (m)	130.9
# shares fully diluted (m)	134.8
Market cap ful. dil. (A$ m)	84.9
Free float	100%
52-week high/low (A$)	1.34 / 0.565
Avg. 12M daily volume ('1000)	221.4
Website	proteomics.com.au

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)

Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$)	2.19-3.31
WACC	13%

Source: Pitt Street Research

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Introducing Proteomics International Laboratories

Proteomics is named after the term for the science of large-scale mapping of the structure and function of proteins.

Proteomics was born in 2001, founded by a pair of scientists working on protein analysis at the University of Western Australia - Dr Richard Lipscombe and the late Dr Bill Parker. The pair believed that the science of proteomics would be a major opportunity for drug discovery and development. Proteomics is the large-scale mapping of the structure and function of proteins. Unlike genes, the protein make-up in individual bodies differs from cell to cell and can change considerably over time. To make a long story short, understanding proteomics can help speed up diagnosis and the identification of drugs that can be used to treat diseases, specifically by noting the differences in the concentration of proteins between the sick and the healthy, then identifying a set of biomarkers that are different in the healthy as opposed to the sick. Tests look for these biomarkers and tell a doctor if patients have these diseases.

Over the following 14 years until its 2015 ASX listing, the company invested $6.5m to develop its capabilities – funded through contract work, industry grants and R&D tax rebates. When the company listed, it was focused on developing simple diagnostic tests and providing protein analysis and had a market capitalisation of $10.1m – paling in comparison to its ~$81m market capitalisation today. Indeed, within days of listing, it secured a 12-month contract with A2 Milk to provide protein analysis.

Within a month of listing, the company unveiled PromarkerD as the world's first predictive test for the diagnosis of DKD. This followed a $2m clinical study of 576 diabetic patients between 2010 and 2014 which found PromarkerD predicted 84% of individuals vulnerable to the disease. Since then, the company has continued to refine the test, seek and obtain commercial agreements, and expand the use of the Promarker platform into new indications. And now, the first Promarker tests are on the cusp of commercialisation in the USA, Europe and Australia.

The Key reasons to look at Proteomics

Proteomics, with its multiple diagnostic tests, presents an opportunity for the following reasons:

1) **PromarkerD has efficacy and is backed by extensive clinical evidence**. PromarkerD has been tested on 5,000 patients just for DKD, with an accuracy of 86% - in other words, it can detect 86 out of every 100 patients with DKD. In relation to endometriosis and esophageal cancer, prototype versions of the tests are >90% accurate.
2) **Proteomics will commercialise multiple tests during CY25.**
   - PromarkerD is set to be launched the US, Europe and Australia during the first half of CY25.
   - PromarkerEso and PromarkerEndo are scheduled for launch in Australia in CY25 followed by the EU and USA likely in CY26.

   This means there will be revenues reflected in the current financial year and multiple share price catalysts that could result in shares being re-rated. **Promarker can ease major burdens to healthcare systems and society more broadly**. All of the diseases Promarker is initially targeting (DKD, endometriosis and esophageal cancer) are rapidly growing health problems and are difficult to diagnose until later stages, by which point it may be too late for effective treatment. The ability to accurately predict the onset of these conditions via a novel blood test at a step earlier enough to prevent worsening of the disease (or even the development of

the disease in the first place by identifying those at risk) could save health care systems globally hundreds of millions of dollars.

3) **PIQ has frameworks in place for commercialisation.** Extensive patent protection in all major jurisdictions, significant support in the medical community, necessary manufacturing certification. It has CE Mark approval for PromarkerD Immunoassay IVD and although it is not formally FDA approved, it will enter the US market utilising the Lab Developed Test (LDT) pathway via CLIA certified laboratories.
4) **Proteomics has a revenue generating bioanalytical service business**. This helps offset cash burn reducing the need for capital raisings before commercialisation of its tests. As at 30 June, the cash balance was A$6.6m, which does not include an R&D Tax Incentive of $2m to be received post-FY24.
5) **There may be future upside from further indications** which are currently at a proof-of-concept stage. Some of these include Asthma, COPD, Diabetic retinopathy and giardia. Moreover, the OxiDX against Oxidative Stress offers upside too (see Appendix I).
6) **Proteomics has an ideal Go-to-Market Pathway** pursuing a hybrid strategy of traditional licensing and a Direct to consumer/patient (DTC/DTP) model. Investors were disappointed that PIQ's exclusive licensing deal with Sonic Healthcare USA for the USA did not proceed, but the company is better positioned now. Beyond the obvious benefit of the company retaining a higher proportion of revenues, it will mean the time and cost of patient acquisition will be lower too.
7) **PIQ has a quality leadership team with skin in the game** – owning 13% of the company**.** The company is led by Managing Director Richard Lipscombe who has led the company since its foundation, when he was managing the Protein Analysis Facility at the University of Western Australia and has taken it to the cusp of commercialisation. Recent appointees Dr James Williams and Aaron Brinkworth bring significant sector experience to the table as well.
8) **We believe Proteomics is undervalued** at its current market capitalisation. Using an SOTP/NPV methodology, we have valued PIQ at $295.3m in a base case and $446.6m in an optimistic (or bull) case, equating to $2.19 per share and $3.31 per share respectively, based on the current number of shares on issue.

An overview of Promarker

Promarker is Proteomics' platform that is used to create diagnostic tests based on the differences in the protein make-up of people with and without a disease.

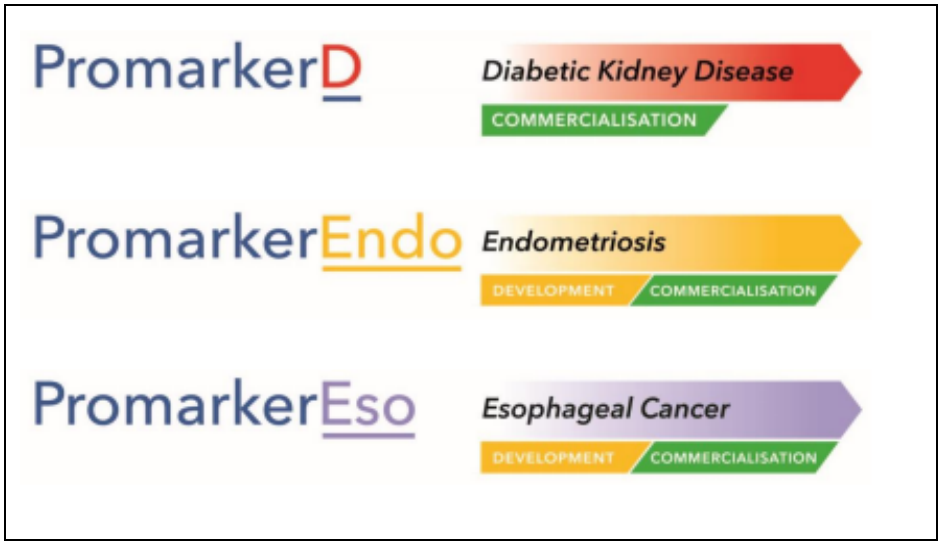
Promarker is Proteomics' platform that is used to create diagnostic tests based on the differences in the protein make-up of people with and without a disease. By comparing blood or other samples taken from both sick and healthy people, PIQ can produce a set of 'biomarkers' – biological signatures that can be used to test for particular conditions.

The 3 tests set being commercialised in CY25 are (Figure 1):

- **PromarkerD** for DKD,
- **PromarkerEndo** for Endometriosis and,
- **PromarkerEso** for Esophageal cancer.

PromarkerEndo and PromarkerEso are purely diagnostic tests, while PromarkerD is a predictive test.

Figure 1: PIQ's diagnostic tests



Source: Company

Proteomics has a Licensing agreement with Omics Global Solution in Puerto Rico, the Dominican Republic and Chile, where PromarkerD is being commercialised although not reimbursed in all of them. It has a distribution license in the UK with Apacor and in France with Eurobio as well as CE Mark approval for Europe. The company is looking to enter the USA and Europe in CY25, starting with PromarkerD. We will cover the company's US and European commercialisation plans in a later section of this report.

What PIQ's tests could do and why they are needed

PIQ's tests could significantly shake up the diagnostic processes of the diseases it targets by enabling diseases to be identified at an earlier stage and in a more cost-efficient way.

PIQ's tests could significantly shake up the diagnosis of the diseases it targets by enabling diseases to be identified at an earlier stage and in a more cost-efficient way. DKD, Endometriosis and Esophageal Cancer are all conditions that have had little to no diagnostics innovation for decades and that can take significant time to detect – by which time it may be too late to treat effectively – and may only be detectable by invasive means. Endometriosis for instance can normally only be diagnosed by invasive surgery. DKD is currently identified with a urine test or a simple blood test, but these tests are not very sensitive or accurate and the disease is often not diagnosed until it is chronic.

But if these diseases can be detected earlier, it may be possible to detect it at a stage where it is easier to treat. For instance, it may be treated with lower drug doses with lower side-effects. And there is extensive evidence to suggest that Promarker can. In respect of DKD, it can detect the condition up to four years before any clinical symptoms appear.

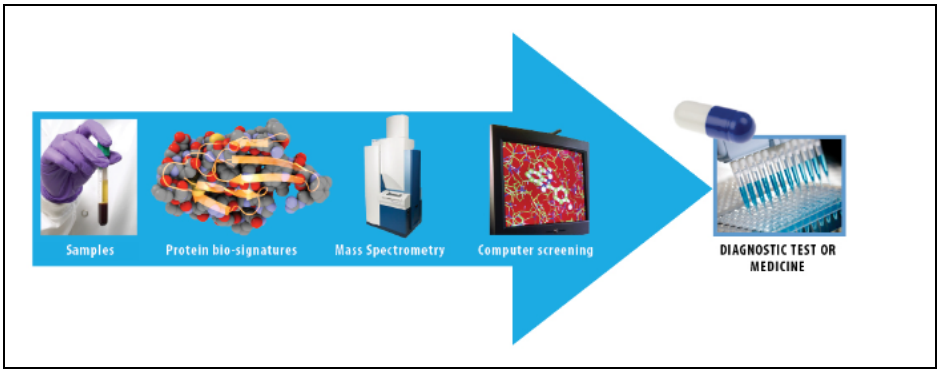
Looking specifically at PromarkerD, it detects the likelihood of getting the disease. It could therefore prevent people from developing kidney disease by enabling them to make necessary changes to their lives that could reduce the risk of developing these conditions. In so doing, it could save the healthcare systems billions of dollars and improve the quality of life for patients through remaining healthier for longer.

How PIQ's tests were developed and how they work

PIQ's tests were based off PIQ's Promarker platform which uses mass spectrometry-based technology to identify the proteins that can be used as biological markers of diseases. PromarkerD was reengineered onto an immunoassay while PromarkerEso and PromarkerEndo use mass spectrometry.

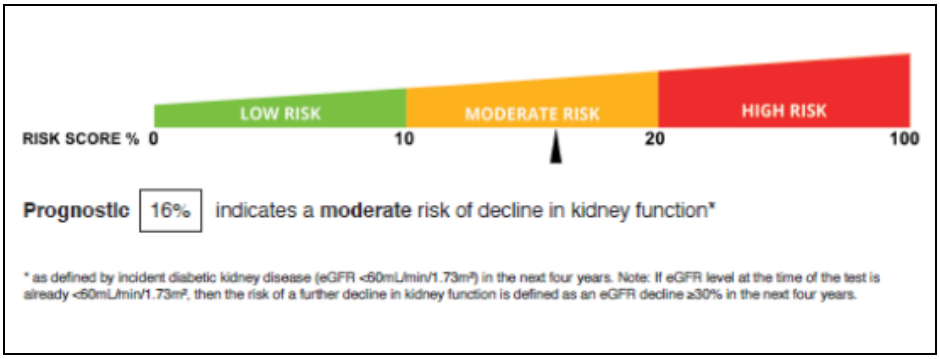
Blood samples are examined for these biomarkers and their presence can be used to identify the presence of diseases or the risk of developing diseases (Figure 2). The result is returned as a traffic light system, with patients graded as 'Low', 'Moderate' or 'High' risk (Figure 3). A management plan is developed accordingly. The specific biomarkers depend on the indication but the biomarkers for DKD are: apolipoprotein A-IV (ApoA4), CD5 antigen-like (CD5L) and insulin-like growth factor-binding protein (IGFBP3/IBP3), in addition to three clinical factors measured at time of the test: age, high-density lipoprotein (HDL) cholesterol and eGFR.

Figure 2: How Promarker works



Source: Company

Figure 3: Example of Promarker test results for DKD



Source: Company

The Clinical evidence backing up Promarker-based tests

Promarker-based tests have been tested on thousands of patients - >5,000 alone in respect of PromarkerD.

Promarker-based tests has been tested on thousands of patients – >5,000 alone in respect of PromarkerD. In this section, we outline the evidence of the utility of PIQ's tests.

The Fremantle Study/Prognostic Development Study (PromarkerD)

Having developed the Promarker proteomics discovery platform, the company undertook a $2m study in 576 patients between 2010 and 2014. It formed a part of the famous Fremantle Diabetes Study (FDS) conducted by the University of Western Australia, so-called because it was a postcode-defined population around the port of Fremantle. The FDS first began in 1993, and its aim was to examine clinically relevant aspects of diabetes including usual care, metabolic control, complications and cost.

PIQ's objective of the study was to look for new biomarkers in the blood of patients with diabetes that predicted the likelihood of those patients developing DKD. Then and now, conventional assessment and monitoring of kidney disease is by measurement of albuminuria (analysing urine for signs of kidney dysfunction) or the estimated glomerular filtration rate (eGFR) (a simple blood test). The trouble with these is that they may not detect kidney

disease until an advanced stage, and that these metrics can alter for other reasons including hydration status and medication changes[1].

The result was the development of PromarkerD, a panel of biomarkers that could predict:

- Which patients with diabetes will progress to have a significant decline in kidney function better than any other current known measure.
- Which people with apparently healthy kidney function as measured by conventional tests are at risk of kidney problems.

PromarkerD correctly predicted 86% of otherwise healthy diabetics who would go on to develop chronic kidney disease (CKD).

This study was subsequently validated twice. In one study (the Prognostic Validation Study), the robustness of the study was assessed in an independent group of 500 patients over a four-year prior. In this study, PromarkerD correctly predicted 86% of previously disease-free patients who went on to develop chronic kidney disease. A further study (the Multi-Site Assay Validation Study) refined the original assay to enable higher throughput and clinical application. Independent analysis of those samples proved the robustness between different test sites.

The CANVAS Study (PromarkerD)

In late 2018, Proteomics signed a research collaboration agreement with Johnson & Johnson Innovative Medicine (formerly Janssen Research & Development). The parties agreed to undertake a study using PromarkerD to analyse samples from previously completed kidney disease trials done by Janssen.

The CANVAS study, which enrolled 3,000 people worldwide, was called the Cardiovascular Assessment Study (CANVAS) and aimed to assess how the PromarkerD score correlated with drug response in patients with DKD.

Patients predicted by PromarkerD to be at high-risk of chronic kidney disease were 13.5 times more likely than the low-risk group to develop the disease.

Stage 1 was completed in early 2020 and it shows that patients predicted by PromarkerD to be at high-risk of chronic kidney disease were 13.5 times more likely than the low-risk group to develop the disease. This validated previous findings that PromarkerD could predict a clinically significant decline in kidney function up to four years in advance.

Stage 2 was entered into after Stage 1 and its aim was to assess the effectiveness of canagliflozin (a sodium-glucose cotransporter-2 (SGLT2) inhibitor class drug) as pre-emptive treatment for DKD. This study shows that diabetes patients without DKD who took the medication experienced significant reduction in their risk scores for developing DKD compared to placebo. The effect was the greatest in participants predicted by PromarkerD to be at high-risk of a decline in kidney function at the start of the study.

Separately, J&J's CREDENCE trial that found canagliflozin (a diabetes treatment for blood glucose control sold as Invokana) reduced the risk of renal failure in patients with type 2 diabetes and chronic kidney disease. It was the first drug in 20 years to significantly reduce the risk of renal failure, dialysis or kidney transplantation.

[1] https://promarkerd.com/wp-content/uploads/2019/04/Identification-of-Novel-Circulating-Biomarkers-Predicting-Rapid-Decline-in-Renal-Function-in-Type-2-Diabetes-The-Fremantle-Diabetes-Study-Phase-II.pdf

PIQ's Endometriosis Study (PromarkerEndo)

Proteomics entered a collaboration with the Royal Women's Hospital and the University of Melbourne in August 2021, utilising the latter's endometriosis database and tissue bank. The University of Melbourne and the Women's Hospital were to provide blood samples, PIQ to perform the analysis and the parties would assess the clinical significance. The study was to validate existing biomarkers discovered by Proteomics.

PromarkerEndo had a specificity of 90% in a study of over 900 participants.

In August 2022, initial results were unveiled and PromarkerEndo had a specificity of 78% - in other words 78 every 100 women with the disease were successfully identified. By the end of the study, at which point there had been more than 900 participants, the specificity had improved to 90% for identifying severe endometriosis from healthy controls.

A further study was conducted in 2023, using samples from patients obtained from the St John of God Subiaco Hospital Gynaecological Cancer Research Group. These results demonstrated excellent statistical significance of multiple biomarkers in diagnosing endometriosis.

The Esophageal Cancer Study (PromarkerEso)

Proteomics built up this test (PromarkerEso) from a collaboration with the QIMR Berghofer Medical Research Institute which validated a select panel of biomarkers in a study of more than 300 patients across two independent clinical cohorts. PIQ owns the exclusive worldwide rights to commercialise those biomarkers.

The company conducted a Diagnostic Model Development Study. A series of statistical models were developed to assess the accuracy of the biomarker panel in diagnosing different levels of disease severity, from oesophageal adenocarcinoma to a comparison with the pre-malignant condition of Barrett's oesophagus as well as a comparison to healthy controls. These novel diagnostic tools demonstrated that the biomarkers added statistically significant performance to the clinical models, with the validated performance for sensitivity of 76-90% across the key categories, with specificity of 64-89%.

In 2023, the research was expanded to include a further 350 cancer samples from the Victorian Cancer Biobank. The results demonstrated excellent statistical significance of multiple biomarkers in diagnosing oesophageal cancer. In September 2024, a further independent clinical validation study in 165 samples, the most recent clinical validation study for PromarkerEso, showed 94% accuracy in diagnosing oesophageal adenocarcinoma from healthy controls.

The most recent clinical validation study for PromarkerEso showed 94% accuracy.

The Indications Proteomics is Targeting with its tests and the Markets for Them

Diabetic Kidney Disease (DKD)

There are two types of diabetes. Type 1, where the pancreas does not make insulin because the body's immune system attacks the cells that make insulin. In Type 2, the pancreas slows down making insulin and one's body becomes resistant to it. The latter is more common, accounting for roughly 90% of all cases.

537m people have diabetes globally, 62m of which in the EU and 32m in the USA.

537m people have diabetes globally, 62m of which in the EU and 32m in the USA[2]. All up 3 in 4 global diabetics live in low- and middle-income countries[3]. Diabetes is responsible for 6.7m deaths per year – equating to 1 every 5 seconds. Diabetes causes at least US$966bn in health expenditure – a 316% increase in 15 years and 11.5% of global health expenditure[4]. The population with diabetes is expected to reach 643m by 2030 and 783m by 2045, while diabetes-related health expenditure is expected to exceed US$1,028bn by 2030 and US$1,054bn by 2045.

Turning to DKD, this is a broad term applied to any kidney damage caused by diabetes. Of all types of kidney damage, diabetes the leading cause[5]. High blood glucose, or blood sugar, damages the blood vessels in a patient's kidneys and thus impedes kidney function. It estimated that 1 in 3 of diabetics have DKD, 90% of whom are Type 2 diabetes. This would equate to 10.66m patients in the USA, 20.66m in the EU and 500k people in Australia based on the IDF's above estimate for the entire population of diabetics. But PIQ believes it can instead serve those who ***don't*** have DKD, predicting whether or not they will develop DKD.

Kidney function can fall below 15-20% with no symptoms. By the point when DKD is detected by symptoms, it is typically at a more advanced stage where the condition is chronic and more difficult to treat. But if DKD is detected earlier, doctors may be able to prescribe an early therapeutic treatment to slow or stop the disease that they wouldn't be able to at a later stage.

Endometriosis

Endometriosis is a condition in which tissue that normally lines the uterus grows on tissues/organs outside the uterus, such as the ovaries, fallopian tubes or the intestines. This results in chronic pain and menstrual irregularities.

It affects 1 in 9 women in Australia and costs nearly A$10bn per year[6]. It can occur as early as the teenage years. Diagnosis typically takes 7-12 years because it can only be diagnosed with invasive surgery – specifically a process that involves inserting a camera into the pelvis through an incision in the abdominal wall, to obtain a biopsy for histopathology analysis. Even when it occurs, it can misdiagnose some patients, particularly in the early stages.

There are varying estimates for endometriosis in the UK and USA. In our modelling, we assumed 7.28m in the USA and 10.5m in the EU.

There are varying estimates for the USA and EU patient population (Figure 4) but we have first modelled official census data for the female population 15-44 (where the vast majority of patients are) then modelled one-ninth

[2] IDF Diabetes Atlas 10th edition.
[3] This includes certain EU countries but also China and Indonesia (with 160m between them) as well as Africa and India.
[4] IDF data
[5] National Institute of Diabetes and Digestive and Kidney Diseases.
[6] According to Endometriosis Australia

(11.11%) of that. These equate to 7.39m in the USA, 14.8m in the EU and 609k in Australia

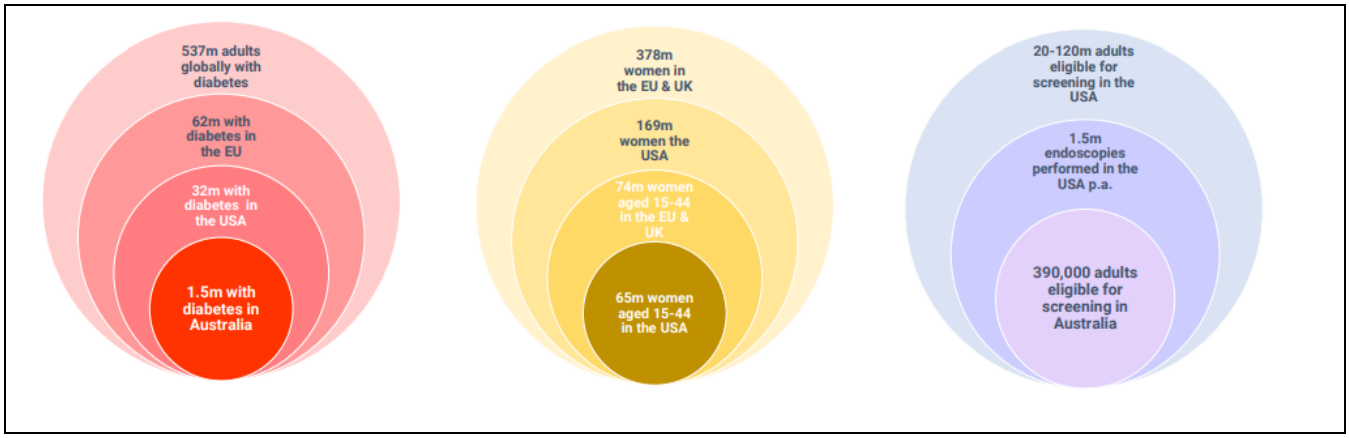
Esophageal cancer

Esophageal cancer can only be detected via a specialist endoscopy procedure that costs nearly US$3,000 per patient in the USA. Although it is not the most common cancer, the prevalence is increasing dramatically worldwide, with a six-fold increase of Esophageal adenocarcinoma (EAC) – the most common type of esophageal cancer - over the last 40 years. The overall five-year survival rate for this cancer is less than 20%[7], because it is frequently diagnosed too late for effective treatment.

Although the patient population of esophageal cancer is low, PIQ hopes to provide an easy testing alternative to the hundreds of thousands of endoscopic screens that are performed.

The diagnosed population for esophageal cancer is low with 20,000 per annum in the USA[8] and 53,000 in the EU[9]. Nonetheless, PromarkerEso's objective is to provide an easy testing alternative to the hundreds of thousands of endoscopic screens that are performed. It is estimated that there are 1.5m endoscopies performed in the USA alone – albeit for patients with a variety of cancers and other indications. Although there are no indications of the number of endoscopic screening procedures in the EU, we have assumed 2m to account for the ~30% higher population in the EU. PIQ estimates there are 390,000 Australians eligible for screening (Figure 4).

Figure 4: Target Populations for Promarker's Initial Indications (Left to Right: DKD, Endometriosis, Esophageal cancer)



Source: Company

[7] Nature Reviews Gastroenterology & Hepatology, 2021, doi.org/10.1038/s41575-021-00419-3
[8] City of Hope Cancer Centre data
[9] World Health Organisation Global Cancer Observatory

Next steps

Proteomics is planning to launch its tests with the following timeframes (Figure 5):

- PromarkerD in Australia and the EU Q1 CY25, with the US to follow during H1 of CY25
- PromarkerEso in Australia during Q1 CY25
- PromarkerEndo in Australia during Q2 CY25

PIQ intends for US and EU launches for PromarkerEso and Promarker Endo to follow although the exact timeframe is unknown at this stage.

Figure 5: Timeframe for the commercialisation of the suite of Promarker tests

Source: Company

PromarkerD is CE Mark registered in the EU, while in the USA it is provided via the Lab Developed Test (LDT) pathway.

PromarkerD is CE Mark registered in the EU, while in the USA it is provided via the Lab Developed Test (LDT) pathway as an alternative to FDA registration to start with. This enables the company to sell via CLIA (Clinical Laboratory Improvement Amendments) certified labs prior to FDA approval. There are 320,000 CLIA labs in the USA[10], although any one lab has the ability to serve the whole US market.

The LDT pathway may not appear a conventional path for US market entry for many investors, but it is worth considering that LDT is conventional for diagnostics whilst the FDA is conventional for drugs. PIQ intends to subsequently seek 510(k) approval but will commence with the LDT route.

The Centers for Medicare & Medicaid Services (CMS) have set a US$390.75 reimbursement rate for PromarkerD. This rate applies to all patients accessing government-funded healthcare through Medicare and Medicaid which account for over 40% of healthcare spending. It was well ahead of management expectations, which had prepared for US$150-200.

PIQ will launch PromarkerD using the ISO 15189 pathway in Australia.

What about Australia? PIQ will launch PromarkerD using the ISO 15189 clinical certification pathway in Australia (equivalent to the LDT route in the USA). PIQ has previously applied for PromarkerD to be included on the Australian Register of Therapeutic Goods (ARTG) but was knocked back. The TGA indicated that the submitted information did not contain adequate detail to enable the registration of the product that is intended for sale, given that it was on the Company's original immunoassay version, made in Australia,

[10] CMS data

rather than its current manufacturer. The Company had earlier moved to an ISO 13485 accredited manufacturer in Europe to prepare for launch and intends to reapply to the TGA in due course.

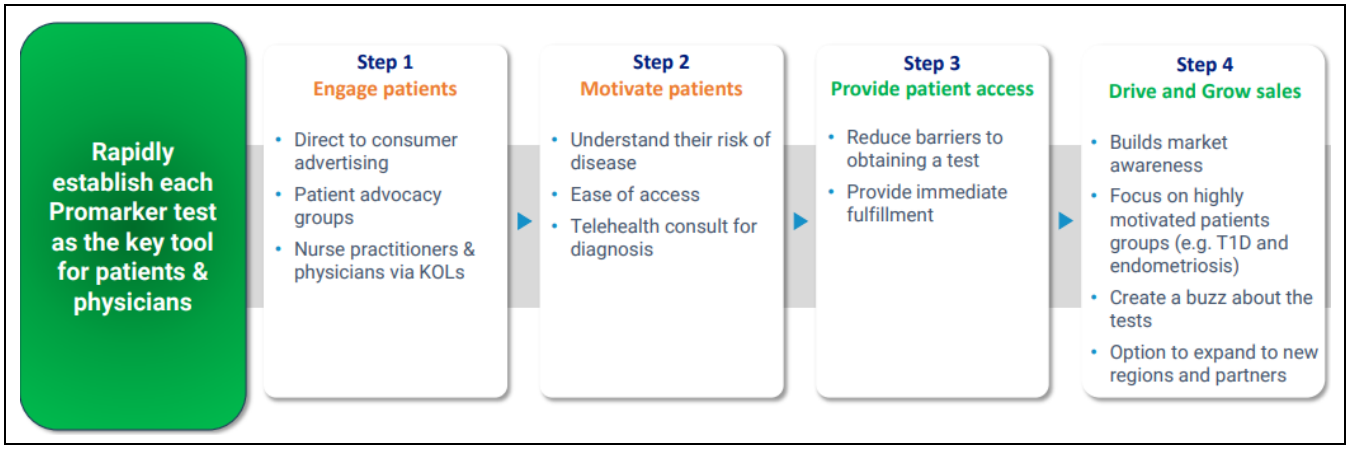
What about Latin America? PIQ has already commercialised PromarkerD through its partner Omics Global Solutions in Puerto Rico and the Dominican Republic, with Chile pending. The company intends to explore expanding sales to neighbouring countries, with the key to expanding sales being securing public reimbursement, and this is something its licensee is working on.

PIQ's business model

Proteomics is pursuing a hybrid go-to-market strategy comprising a new Direct to Customer/Patient (DTC/DTP) model alongside the traditional licensing model which had been anticipated by investors whilst the agreement with Sonic USA existed. This may mean Promarker may not reach as high a proportion of the market – at least not as fast – as it would have with a licensing deal, but it will mean the company keeps a higher share of revenue than it otherwise would (Figure 6).

To this end, the company has over the past several years built awareness among Key Opinion Leaders and primary care physicians. A survey of nearly 400 Endocrinologists and Primary Care Physicians found that 96% of them were likely to use PromarkerD test scores to inform clinical decision-making[11].

Figure 6: DTP Strategy



Source: Company

What will Ozempic mean for PromarkerD? There has been a perception by many investors that Ozempic could hurt other health companies by reducing their markets. By reducing the incidence of obesity, and perhaps diabetes (the original intent of the drug), you could reduce the health problems that come with these indications. However, what investors are forgetting is that drugs like Ozempic do not cure indications once they are already present, and they do not identify people who are at risk of diabetes. This being said, the latter limitation is something PromarkerD could help with. It could identify patients for better management of diabetes, adherence to medications and focus on diet and exercise and prevent conditions from getting worse.

[11] https://pmc.ncbi.nlm.nih.gov/articles/PMC9342737/

Proteomics' pipeline

OxiDx

OxiDx is a diagnostic product for measuring oxidative stress.

OxiDx is a diagnostic product for measuring oxidative stress. It is based upon the principals of detecting subtle changes in protein structures – 'decorations' that sit on the surface of a protein and are known as post-translational modifications. OxiDx measures systemic oxidative stress in a fingerpick blood sample Proteomics owns 66% of a stand-alone entity attempting to unlock the value of OxiDx, with the UWA owning 33%.

Oxidative stress is implicated in over 70 health conditions with levels often reflective of a person's health and fitness. It has broad application across multiple markets including as a complementary diagnostic test for assessing treatment efficacy and precision medicine by enabling personalised dosing in clinical trials, or as an athletic monitoring tool for competition preparedness and to reduce injuries in Professional Sports, as well as in horse racing.

Proteomics is at the pre-commercialisation stage with OxiDx. Notwithstanding that considerable progress has been made – in the form of multiple peer-reviewed publications on the technology and obtaining second generation patents in Japan and Europe in September 2023 and February 2024 respectively, complementing existing patents in the USA and Australia – the commercialisation of the suite of Promarker tests will be the key focus of the company, and driver of shareholder value in the short to medium term.

Future Indications with Promarker

Proteomics aspires to commercialise new tests against other conditions too including:

- **Asthma and Chronic Obstructive Pulmonary Disease (COPD):** PIQ previously completed a proof-of-concept study that identified multiple novel protein biomarkers for obstructive airway disease. These biomarkers, once validated, have the potential to deliver a new diagnostic test for asthma and chronic obstructive pulmonary disease (COPD). An initial proof-of-concept study, performed in collaboration with the Busselton Population Medical Research Institute, analysed plasma samples from 75 individuals with a range of symptoms including airway obstruction, atopy, bronchial hyper-responsiveness and healthy controls. A patent application on methods for diagnosing airway disease has been filed. Potential biomarkers from this study are to be validated in a larger clinical cohort. The results of this validation will refine the panel of biomarkers into a potential new blood test for diagnosing obstructive airway disease.
- **Plant Dieback (*Phythophthora cinnamomi*):** In May 2024, Proteomics International announced it had collaborated successfully with the Curtin University's Centre for Crop and Disease Management to make an important breakthrough in understanding how dieback impacts plants, with the findings published in the Journal of Proteomics. Phytophthora dieback is a plant disease that can spread rapidly and have a significant impact on native vegetation and premium crops such as avocados. Phytophthora cinnamomi is considered the species of dieback that has the greatest impact on biodiversity, and also causes tens of millions of dollars of crop losses annually in Australia alone.

  A greater understanding of dieback and its mode of actions means Proteomics International is better equipped to develop diagnostic tools

to accurately detect dieback in the soil, which would be of significant benefit to the agricultural industry, and others.

- **Diabetic Retinopathy**: Following the success of the diabetic kidney disease project, Proteomics International extended its collaboration agreement with The University of Western Australia to seek early markers for diabetic retinopathy, the major cause of blindness in the US. This collaboration is applying the Promarker™ platform to look for prognostic markers in the blood that can identify patients at risk of retinopathy, especially sight-threatening retinopathy. The program is again utilising the Fremantle Diabetes Study which provided the rich sample repository that led to PromarkerD. Discovery experiments have yielded potential biomarkers for the early diagnosis of retinopathy. The next stage is to verify these biomarkers in a larger cohort set.
- **Diabetic neuropathy:** Following the partnership with the Australian Centre for Accelerating Diabetes Innovation (ACADI) Proteomics International has added a new R&D program to investigate predictive biomarkers for diabetic neuropathy.
- **Giardia (causing gastroenteritis):** Giardia is a leading cause of infectious gastroenteritis worldwide and one of the most common parasitic human diseases. Proteomics International has identified strain specific Giardia targets however further work is required to develop an assay for clinical use. The project is currently on hold pending a review of its commercial and technical viability.

Proteomics' leadership

The company's current board and leadership composition is as follows (Figure 7 and Figure 8):

Figure 7: Proteomics' leadership composition

Board of Directors	
Name and Designation	**Profile**
James Williams Non-Executive Chairman	Dr Williams is an accomplished manager, director, scientist, entrepreneur and investor with experience covering all aspects of technology translation. Over the past 25 years he has been involved from concept to commercialisation, including as CEO, CTO, Director and Chair, of numerous public and private biotech companies which have resulted in five FDA approved drugs, devices and diagnostics. He conceived the technology behind iCeutica Inc (acquired in 2011) and co-discovered the lead therapy for ASX-listed Dimerix Limited (ASX: DXB), currently in Phase 3 trials for Chronic Kidney Disease. Dr Williams is currently CEO of the Health Translation Group, a not-for-profit company focusing on translation of medical research outcomes, a Director of the Perron Institute for Neurological and Translational Science and agriculture start-up Demagtech, and a member of the WA State Government's Health and Medical Life Sciences Industry Advisory Group. He was previously co-founder and Investment Director of early-stage VC firm Yuuwa Capital LP, and appointed director on several portfolio companies, a Director of early-stage clinical trial facility Linear Clinical Research and a member of the Australian Federal Government's Entrepreneurs' Program Committee.
Richard Lipscombe Managing Director	Dr Lipscombe is a co-founder of the Company, is a highly practiced 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. Dr Lipscombe has international experience in both business and science 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 co-founded Proteomics International Pty Ltd in 2001. Richard is well published in peer reviewed journals, and holder of several patents.
Paul House Non-Executive Director	Mr House is the current Chief Executive Officer of Imdex Limited, a leading global Mining-Tech company. He 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. Mr House has previously held Chief Financial Officer and COO roles, and was Senior Manager for several years at a leading global management consultancy firm. Mr House has a track record for delivery of business performance targets, revenue growth, margin improvement, market share and productivity, across multiple services, markets and borders.

Neville Gardiner Non-Executive Director	Mr Gardiner is a seasoned finance professional with over 30 years' experience advising Boards of public and private companies on mergers and acquisitions, project development, equity and debt capital markets, transaction structuring, capital allocation and complex commercial problem solving. Mr Gardiner was recently a Partner of Deloitte in its M&A Advisory team. Prior to Deloitte Mr Gardiner was Co-Founder and Managing Director of Torridon Partners, an independent corporate advisory firm. Torridon Partners was acquired by Deloitte in 2016. He has held leadership positions at Macquarie Bank, Bank of America Merrill Lynch and Arthur Andersen, and has broad industry sector exposure including health-tech, fin-tech, mining and mining services, infrastructure, energy, and fabrication and construction.
Aaron Brinkworth Non-Executive Director	Mr Brinkworth is a former biopharmaceutical executive with 25 years industry experience. Over a 22-year career are Gilead Sciences (NDQ:GILD), he held senior commercial, patient access and strategic licensing roles. Mr Brinkworth has led Gilead's Asia Pacific commercial and access operations where he was responsible for developing high performing sales, marketing and distribution networks across the region. He managed geographically dispersed teams and business partners across 31 countries and is experienced in building strategic partnerships with industry leaders, government officials and non-government organisations. Mr Brinkworth currently serves on the board of Resonance Health (ASX:RHT) as a non-executive Director. He is a graduate of the AICD Company Directors course and maintains active membership of the AICD.
Karen Logan Company Secretary	Ms Logan has extensive compliance, capital raising, merger and acquisition, IPO and backdoor listing experience in a diverse range of industries including technology, media, resources, health care and life science. She has assisted a substantial number of private start-up and established businesses transition to being publicly-listed companies for over 13 years. Ms Logan is presently the principal of a consulting firm and secretary of a number of ASX-listed companies, providing corporate and accounting services to those clients.
Jacqueline Gray CFO and Head of Corporate Development	Ms Gray has over 25 years of experience as Senior Finance Executive for multiple global companies, based in London, and several emerging, high growth companies in the medical technology, SaaS, digital marketing, e-commerce, retail and renewables sectors, based in Perth. She has a successful track record with developing & implementing strategy, building high performance teams, M&A and post-merger integration. Her previous roles include Finance Director of the Economist Intelligence Unit, senior roles with BBC Worldwide, and Financial Controller of several hospitals and medical facilities for Healthcare of Australia. Ms Gray also leads the Company's Corporate Development, with a focus on PromarkerEndo.

Source: Company

Figure 8: PIQ clinical advisory board for PromarkerD

Source: Company

Proteomics' peers

We have compiled a list of Proteomics' peers, companies seeking to commercialise diagnostic tests. We have considered both ASX and foreign-listed companies.

Local peers

Atomo Diagnostics (ASX: AT1) was founded in 2010 and has been focused on developing rapid tests. Its flagship FebriDx test is able to diagnose HIV/AIDs and is in pharmacies in Australia, the UK and Europe.

Genetic Signatures (ASX: GSS) has a technology that converts a typical 4 base DNA and RNA sequence into a 3-base sequence, hence its name '3 base'. It doubles the genome size and makes it easier to look for unique genetic signatures of target organisms. The company had its EasyScreen Gastrointestinal Parasite Detection Kit (which uses the 3base technology) approved by the FDA earlier in CY24.

Rhythm Biosciences (ASX: RHY) is developing rapid detection kits for Colorectal cancer (ColoStat). The technology, which uses a finger prick blood sample was pioneered by the CSIRO and exclusively licensed to Rhythm in 2017. Despite the company showing clinical evidence, it has had difficulty in obtaining medical approval.

BCal Diagnostics (ASX:BDX) is developing a non-invasive diagnostic technology to detect breast cancer. It uses Liquid Chromatography Mass Spectrometry (LCMS) to detect changes in a patient's blood which may be indicative of breast cancer.

Cleo Diagnostics (ASX:COV) is developing a blood test (CleoDx) for the accurate and early diagnosis of ovarian cancer. Similar to the tests of Proteomics, it detects the indication in a non-invasive, low-cost way potentially enabling more efficacious treatment by virtue of detecting the disease earlier.

Global

Cellivery Therapeutics (KOSDAQ: A268600) researches and develops therapeutic drugs for life-threatening diseases comprising cancer, inflammation, metabolic, and neurodegenerative diseases. It develops small molecule, antibody, and vaccine drugs based on its therapeutic molecule systemic delivery technology. The company is based and listed in South Korea.

LigaChem Biosciences (KOSDAQ: A141080) researches and develops products for various therapeutic areas, including antibiotics, anti-fibrotics, immuno-oncology, oncology; and antibody-drug conjugate (ADC) platform technology and small molecule drugs. It also sells medical devices and supplies. It has a research collaboration and license agreement with AMGEN for the development and commercialisation of ADCs. LigaChem is also listed and headquartered in South Korea.

Carna Biosciences (TSE:4572) a clinical-stage biopharmaceutical company, discovers and develops drug therapies to treat unmet medical needs in Japan.The company also offers profiling, NanoBRET TE intracellular kinase cell-based assay, protein detection and interaction, live-cell kinase assay, and tyrosine kinase cell-based assay services. It also focuses on developing products for the treatment of various diseases.

Samsrita Labs (BSE:539267) operates as a bio-pharmaceutical company in India. The company offers DNA, RNA, and chromosomal based tests for oncology, pharmacogenomics, infectious diseases, genetic disorders, transplantation typing, and pre-natal and pre-implantation genetic diagnostic; and karyotype and fluorescence in-situ hybridisation analysis. The company is listed in India and is based in southern city of Hyderabad.

Renalytix (AIM:RENX) develops artificial intelligence-enabled in vitro diagnostic solutions for clinical management of kidney diseases in the United States. The company offers KidneyIntelX, a diagnostic platform that employs an artificial intelligence-enabled algorithm that combines various data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record systems to generate a unique patient risk score. Its products are used in kidney disease diagnosis and prognosis, clinical care, patient stratification for drug clinical trials, and drug target discovery.

Valuation and catalysts

We value Proteomics at $295.3m in our base case and $446.6m in our optimistic (or bull) case. These figures amount to $2.19 per share and $3.31 per share respectively.

We value Proteomics at $295.3m in our base case and $446.6m in our optimistic (or bull) case. These figures amount to $2.19 per share and $3.31 per share respectively (Figure 9). We have only accounted for the opportunities in DKD, endometriosis and Esophageal screenings in the USA, EU and Australia. We have not accounted for further markets and further indications for Promarker at this stage but may in future reports if the company makes further progress in those regards.

The key assumptions driving our DCF valuation are as follows below and summarised in Figures 10 and 11:

- **Commercial launch**. We assume PromarkerD is commericialised in CY25, starting in Australia in Q1 followed by the EU and USA later in CY25. For PromarkerEndo and PromarkerEso, we assume launch in Australia in mid-CY25 with the EU and USA gradually over the following 2 years. In all instances, we assume a slower ramp up in the EU due to the fragmented nature of the markets.
- **Revenue model.** We have assumed the company signs a partnership short of a full licensing deal that enables it to keep 40% of all revenues. We assume a US reimbursement rate of US$390.75 as the company confirmed to shareholders in September 2023[12], with an EU reimbursement of US$262, being 33% below the US price. We have assumed the same price is achieved for each of the three tests, however, PromarkerEndo could attract a higher price, which presents additional upside.
- **Market sizes.** We assumed total markets of:
  - **i)** 21.1m, 40.9m and 1m for patients eligible for DKD screening in the USA, EU and Australia respectively,
  - **ii)** 14.8m, 7.4m and 609k for endometriosis in the USA, EU and Australia respectively, and
  - **iii)** 1.5m, 2m and 390k for esophageal screenings in the USA and EU respectively.

  Our rationale of these populations was outlined on p.10-11. Moreover, we assume patient growth of 2% per annum.

[12] See ASX release 29 September 2023

- **Market penetration**. In Australia and the USA, our base case assumes a 1.5% penetration for PromarkerD, 2% for PromarkerEndo and 4% for PromarkerEso. In our bull case, these figures are 2%, 2.5% and 6% respectively. In the EU, we assume a smaller market share given the fragmented nature of the market.
- **Costs and margins.** We assume a 45% FCF margin on revenues retained by the company in our base case and 50% in our bull case.
- **Funding.** With $6.6m in cash, an existing analytics business and a matter of months before commercialisation, we have not assumed the company needs further debt or equity financing.
- **Tax.** We assume a 30% corporate tax rate. Even though corporate taxes are lower in the USA and EU, we have kept the Australian rate to compensate for state taxes in certain US states as well as for the potential repatriation of foreign profits to Australia.
- **Exchange rate.** We modelled entirely in US dollars and used an exchange rate of A$1=US$0.66.
- **Cost inflation.** We assumed 2% growth per annum.
- **Discount rate.** We arrive at a WACC of 13%, reflecting no debt financing and a 13% cost of equity. This is derived from a 4% risk-free rate of return, a 6% equity premium and a 1.5x beta.
- **Time frame and Terminal growth.** Our model lasts for 10 calendar years, beginning on 1 January 2025 and ending on 31 December 2034. We have not assumed terminal growth beyond this.

Figure 9: Our valuation of Proteomics

Sum of the Parts Valuation	Base Case		Bull Case	
	A$m	A$ps	A$m	A$ps
PromarkerD	173.10	1.28	266.56	1.98
PromarkerEndo	88.87	0.66	126.61	0.94
PromarkerEso	26.71	0.20	46.77	0.35
rNPV	**288.68**	**2.14**	**439.93**	**3.26**
Cash (FY24 close)	6.64	0.05	6.64	0.05
Debt (FY24 close)	-	-	-	-
Equity Value	**295.32**	**2.19**	**446.57**	**3.31**
Current Valuation	84.94	0.63	84.94	0.63
Upside		248%		426%

Estimates: Pitt Street Research

Figure 10: The assumptions underpinning our valuation of Proteomics (base case)

Assumptions (base case)	PromerkerD	PromarkerEndo	Promarker Eso
Estimated market size (mn patients)			
EU	*40.92*	*14.85*	*2.00*
USA	*21.12*	*7.39*	*1.50*
Australia	*0.99*	*0.61*	*0.39*
CAGR market growth	2.0%	2.0%	2.0%
Estimated market penetration (%)			
EU	1.5%	2.0%	4.0%
USA	2.0%	3.0%	6.0%
Australia	2.0%	3.0%	6.0%
Realised price (US$) - USA	390.75	390.75	390.75
Realised price (US$) - EU & Aus	262	262	262
Peak sales (US$m) - Global	470.80	236.62	85.97
Revenue share to PIQ	40%	40%	40%
Discount rate	13%	13%	13%
Tax rate	30%	30%	30%
NPV (US$m) per share - base case	114.25	58.65	17.63
NPV (A$m) per share - base case	173.10	88.87	26.71

Estimates: Pitt Street Research

Figure 11: The assumptions underpinning our valuation of Proteomics (bull case)

Assumptions (bull case)	PromerkerD	PromarkerEndo	Promarker Eso
Estimated market size (mn patients)			
EU	*40.92*	*14.85*	*2.00*
USA	*21.12*	*7.39*	*1.50*
Australia	*0.99*	*0.61*	*0.39*
CAGR market growth	2.0%	2.0%	2.0%
Estimated market penetration (%)			
EU	2.0%	2.5%	6.0%
USA	2.5%	3.5%	8.0%
Australia	2.5%	3.5%	8.0%
Realised price (US$) - USA	390.8	390.8	390.8
Realised price (US$) - EU & Aus	261.8	261.8	261.8
Peak sales (US$m) - Global	608.09	268.05	120.59
Revenue share to PIQ	40%	40%	40%
Discount rate	13%	13%	13%
Tax rate	30%	30%	30%
NPV (US$m) per share - bull case	175.93	83.56	30.87
NPV (A$m) per share - bull case	266.56	126.61	46.77

Estimates: Pitt Street Research

Catalysts for a re-rating of Proteomics

We foresee the stock being re-rated to our valuation range driven by the following factors:

– The company commercialising PromarkerD, PromarkerEndo and PromarkerEso on schedule and without the need for further capital raisings.

– Further R&D work proving the efficacy and utility of PromarkerD, PromarkerEndo and PromarkerEso as well as the use of Promarker against further indications.

– Proteomics entering other markets with its Promarker range, particularly Australia.

– Proteomics making progress with OxiDx.

– The broader market for small cap health stocks recovering as interest rates start to decline in Australia, which is anticipated to be in the first half of CY25.

Key Risks facing Proteomics

We see the following key risks facing Proteomics as a company, and thus the key risks to our investment thesis:

- **Regulatory risk.** The company's ability to commercialise its product is contingent on regulators maintaining approval where it already exists (including meeting ongoing regulatory compliance requirements) and giving approval to new products. A failure to give new products approval, or even a withdrawal of approval, could be catastrophic.
- **Commercial risk**. There is the risk that the company may fail to execute its commercial objectives for a variety of reasons including
  - i) the failure to find commercial partners,
  - ii) supply chain issues,
  - iii) lack of acceptance by the market, and
  - iv) competition.
- **Key personnel risk**. There is the risk that the company may lose key personnel and be unable to replace them and/or their contribution to the business.
- **Capital risk**. There is the risk that the company may need future capital raisings. There is no guarantee that the company will be able to raise such capital, let alone on favourable terms. Even if successful, this would be dilutive to existing shareholders.

Glossary

Biomarkers – A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease.

Biosimilars – A biological produce that is highly similar to and has no clinically meaningful differences from existing products.

Diabetes – A disease where either the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces.

Diabetic Kidney Disease (DKD) – A type of kidney disease caused by diabetes.

Endometriosis – A disease where tissue similar to the lining of the uterus grows outside the uterus.

Endoscopy – A procedure where doctors pass cameras into the body to look at organs or tissue to diagnose conditions.

In vitro – In a tube.

In Vitro Diagnostic Test (IVD) – Tests that can detect diseases, conditions and infections, typically conducted in test tubes or similar conditions as opposed to in vivo tests which are conducted in the body itself.

Laboratory Developed Test (LDT) – A type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.

Oxidative Stress – An imbalance of free radicals and antioxidants in the body.

Plant Dieback (*Phythophthora cinnamomi*) - Phytophthora dieback is a plant disease that can spread rapidly and have a significant impact on native vegetation and premium crops such as avocados.

Proteomics – The large-scale study of proteins.

Sensitivity – The ability of a medical test to correctly identify those with a disease or medical indication.

Specificity – The ability of a medical test to correctly identify those without the disease.

Appendix I – Capital Structure

Class	Number (m)	% of share capital
Ordinary Shares	130,892,616	97.1%
Options	3,940,000	2.9%
Total Diluted shares	**134,832,616**	

Source: Company

Appendix II – Director Ownership of Shares

Director	Number	% of share capital
Richard Lipscombe	16,417,125	12.2%
Neville Gardiner	117,647	0.1%
Paul House	1,036,511	0.8%
Total Director Shares	**17,571,283**	**13.0%**

Source: Company

Appendix III – Patents for PromarkerD

Country	Patent/Application No	Status	Granting date (d/m/year)	Expiry date (d/m/year)
Australia	2011305050	Granted	20/9/2011	20/9/2031
USA	14/277,371	Granted	15/08/2017[13]	20/9/2031
China	201180053583.9	Granted	14/06/2016	20/9/2031
Singapore	188527	Granted	Pre-2016	20/9/2031
Russia	2596486	Granted	10/08/2016	20/9/2031
European Community	3151012	Granted	21/03/2018	20/9/2031
Brazil	BR112013006740	Granted	27/07/2020	20/9/2031
Canada	2811654	Granted	27/07/2020	20/9/2031
India	3012/DELNP/2013	Granted	24/03/2022	20/9/2031
Japan	2013-528474	Granted	29/01/2018	20/9/2031
Hong Kong	1256827B	Granted	11/11/2022	20/9/2031
Indonesia	W00 2013 01585	Granted	29/07/2019	20/9/2031

Source: Company Annual Reports

[13] The date marks the most recent expansion of the patent. It originally only included DKD, but now covers all kidney disease.

Appendix IV – Publications relevant to PromarkerD

Bringans SD, et al. A robust multiplex immunoaffinity mass spectrometry assay (PromarkerD) for clinical prediction of diabetic kidney disease. Clin Proteomics. 2020.

Bringans SD, et al. Comprehensive mass spectrometry based biomarker discovery and validation platform as applied to diabetic kidney disease. EuPA Open Proteomics. 2017.

Bringans SD, et al. The New and the Old Platform Cross-Validation of Immunoaffinity Mass Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease. Proteomes. 2020

Bringans SD, et al. PromarkerD as an immunoaffinity mass spectrometry assay for diabetic kidney disease. Poster presented at the 18th Human Proteome Organisation World Congress. 2019.

Bringans et al, Using AB SCIEX TOF/TOF™ and QTRAP® Systems (2011). Protein Biomarker Research Pipeline for Developing Protein Biomarkers for Diabetic Kidney Disease.

Burchenal W, et al. Demonstrating the Economic Health Benefit of using the PromarkerD In Vitro Diagnostic Test in the Prediction of Diabetic Kidney Disease. Poster presented at the American Diabetes Association's 81st Scientific Sessions, 2021.

Davis TME, et al. Apoptosis inhibitor of macrophage and diabetic kidney disease. Cell Mol Immunol. 2019.

Fusfeld L, et al. Evaluation of the clinical utility of the PromarkerD in-vitro test in predicting diabetic kidney disease and rapid renal decline through a conjoint analysis. PLOS ONE, 2021.

Peters KE, et al. A Comparison of PromarkerD to Standard of Care Tests for Predicting Renal Decline in Type 2 Diabetes. Poster presented at ASN Kidney Week, 2021.

Peters KE, et al. Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Scores. Journal of Clinical Medicine, 2023.

Peters KE, et al. Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. Diabetes Care. 2017.

Peters KE, et al. PromarkerD: A Novel Test for Predicting Rapid Decline in Renal Function in Type 2 Diabetes. Poster presented at the 18th Human Proteome Organisation World Congress. 2019.

Peters KE, et al. PromarkerD Predicts Late-Stage Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). Poster presented at the American Diabetes Association's 82nd Scientific Sessions, 2022.

Peters KE, et al. PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS) J Clin Med. 2020.

Peters KE, et al. Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II. J Diab Comp. 2019.

Appendix V – Analysts' Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms

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