Commercialising revolutionary diagnostic tests

Biotechnology

We initiate coverage on Proteomics International Laboratories Ltd. (ASX: PIQ) with a fair valuation of A$2.84, representing a 331% potential upside from the latest share price of A$0.66. We have taken a highly conservative approach in arriving at our valuation, using very cautious assumptions throughout the analysis. By estimating lower market penetration under the direct-to-customer/patient (DTC/DTP) model, compared to the potential impact of a licensing agreement with a major diagnostics or pathology company, we've ensured that our A$2.84 fair valuation is based on the most prudent expectations. This leaves significant room for upside if PIQ were to secure such partnerships or expand market reach beyond our conservative forecasts. PIQ develops accurate diagnostic tests using its proprietary Promarker™ platform. This technology leverages the science of proteomics to identify protein "fingerprints" in blood samples, enabling the detection of biomarkers that distinguish between individuals with and without disease. PIQ has a range of diagnostic tests at various stages of development, with PromarkerD, PromarkerEndo, and PromarkerEso in advanced phases. The commercial launch of PromarkerD in the US is targeted for H1 CY25 and PromarkerD and PromarkerEso in Australia for Q1 CY25, with PromarkerEndo commercialisation expected to follow shortly after.

There are huge market opportunities for PIQ's advanced diagnostic tests

PromarkerD can predict the onset of diabetic kidney disease up to 4 years in advance with a proven accuracy of 86% as demonstrated through multiple clinical studies on samples from over 5,000 patients. PromarkerEndo and PromarkerEso are novel blood tests that identify patients with endometriosis and esophageal cancer with approximately 90% accuracy, as demonstrated in clinical studies involving hundreds of patients. There are more than 500 million people with diabetes in the world, each a potential customer for PIQ's PromarkerD. It is estimated that approximately 190 million women and girls worldwide suffer from endometriosis, each a potential customer for PIQ's PromarkerEndo, and ~ 604,000 new cases of esophageal cancer were diagnosed globally in 2020. The current standard diagnosis procedures for endometriosis and esophageal cancer are invasive and costly.

PromarkerD commercialisation in the US is in sight

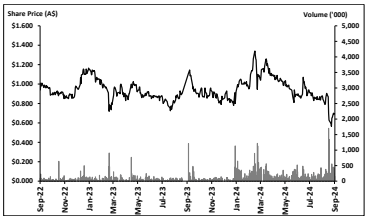
PIQ's Promarker™ tests, including PromarkerD, don't need FDA approval to sell in the US. Instead, PromarkerD sales in the US will be conducted through the Laboratory Developed Test (LDT) pathway via CLIA-certified laboratories. Pleasingly, US Medicare has confirmed a US$390.75 reimbursement rate for PromarkerD tests, which enhances our optimism about the product's future sales prospects in the large US market. PIQ is planning a US launch of PromarkerD in H1 CY25, utilising two Go-to-Market approaches: licensing to alternative pathology labs and service providers, and direct-to-consumer/patient (DTC/DTP) sales.

Valuation range of A$2.59–3.10 per share

We have used a DCF methodology to value PIQ at A$2.59 per share in a base-case scenario and A$3.10 per share in a bull-case scenario using conservative market penetration assumptions through a direct-to-patient (DTP) go-to-market strategy, which is expected to help PIQ retain a much larger share of revenues compared to traditional licencing models. Our valuation is only based on the commercialisation potential of PromarkerD, PromarkerEndo and PromarkerEso and does not include the value of PIQ's other tests in development. Key risks to our investment thesis include Commercialisation risk, market adoption risk, regulatory risk, and competition risk.

Date	08 Oct 2024
Share Price (A$)	0.66
Target Price (A$)	2.59-3.10
Price / NAV (x)	0.23x
Market Cap (A$m)	85.2
52-week L/H (A$)	0.55 / 1.40
Free Float (%)	70.7%
Bloomberg	PIQ.AU
Reuters	PIQ.AX

Price Performance (in A$)



Business description

Proteomics International Laboratories Ltd. (ASX: PIQ) is a medical technology company that focuses on proteomics. It provides PromarkerD, a protein-based diagnostic blood test to predict diabetic kidney disease (DKD). The company's products under development include PromarkerEndo, which is undergoing clinical validation for endometriosis diagnosis; PromarkerEso, which has completed clinical validation trials for esophageal cancer diagnosis; and OxiDx (2-tag), which is in late-stage development for oxidative stress diagnosis. PIQ also has a range of other novel diagnostic tests in earlier development stages.

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Disclosure - Readers should note that East Coast Research has been engaged and paid by the company featured in this report for ongoing research coverage.

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Investment Rationale

Proteomics International Laboratories Ltd. (ASX: PIQ) develops accurate diagnostic tests using its proprietary Promarker™ platform. This technology leverages the science of proteomics to identify protein "fingerprints" in blood samples, enabling the detection of biomarkers that distinguish between individuals with and without disease. PIQ has a range of diagnostic tests at various stages of development, with PromarkerD, PromarkerEndo, and PromarkerEso in advanced phases. The commercial launch of PromarkerD in the US in H1 CY25 and PromarkerD and PromarkerEso in Australia is targeted for Q1 CY25, with PromarkerEndo commercialisation expected to follow shortly after. PIQ is also currently generating revenue through its Analytical Services division.

PromarkerD can predict the onset of diabetic kidney disease up to 4 years in advance with a proven accuracy of 86% as demonstrated through multiple clinical studies on samples from over 5,000 patients.

PromarkerD – A novel and accurate diagnosis test for diabetic kidney disease

Diabetic Kidney Disease (DKD) is a serious complication of diabetes that affects the kidneys. PromarkerD can predict the onset of diabetic kidney disease up to 4 years in advance with a proven accuracy of 86%, as demonstrated through multiple clinical studies on samples from over 5,000 patients. It represents a major advancement in diabetes management by allowing for early detection and intervention, which are essential in preventing or delaying the progression of this serious complication to end-stage renal disease, such as the need for dialysis or a kidney transplant.

PromarkerEndo – A novel and accurate diagnosis test for Endometriosis

PromarkerEndo and PromarkerEso are simple blood tests that identify patients with endometriosis and esophageal cancer, respectively, with approximately 90% accuracy, as demonstrated in clinical studies involving hundreds of patients.

Endometriosis is a common and painful disease affecting about one in nine women and girls, often beginning in adolescence. It occurs when tissue similar to the lining of the uterus grows in other areas of the body where it doesn't belong. The current standard of care for Endometriosis diagnosis involves costly and complicated invasive surgery. PromarkerEndo utilises a novel blood test for the early diagnosis of endometriosis, achieving approximately 90% accuracy in an initial clinical study conducted on over 900 patients.

PromarkerEso – A novel and accurate diagnosis test for Esophageal Cancer

Esophageal cancer is a type of cancer that occurs in the esophagus, the long, hollow tube that connects the throat to the stomach. The esophagus helps move food from the mouth to the stomach for digestion. Esophageal adenocarcinoma (EAC) is the most common type of esophageal cancer and represents a significant unmet medical need. The five-year survival rate for this cancer is less than 20%, and esophageal cancer accounted for 1 in 20 cancer deaths worldwide in 2018. Screening for esophageal adenocarcinoma currently requires a costly and invasive endoscopy with a biopsy procedure. PromarkerEso utilises a novel blood test for the early diagnosis of esophageal cancer, achieving 94% accuracy in clinical studies conducted on over 500 patients.

Analytical services: PIQ's revenue-generating unit

PIQ's Analytical Services division generates revenue from providing specialised analytical services on a contract basis including for different drugs in development or undergoing clinical trials, providing an important income stream for the company. Over the last several years, revenue from PIQ's analytical services, combined with cash from grants and R&D tax incentives, has played a key role in offsetting the company's cash burn as it develops its extensive pipeline of diagnostic products.

There are more than 500 million diabetic people in the world, each a potential customer for PIQ's PromarkerD

There are huge market opportunities for PIQ's advanced diagnostic tests

Diabetes affects more than 537 million people globally and is a leading cause of chronic kidney disease. In both developed and developing countries, diabetes has become the primary cause of end-stage renal disease, often necessitating dialysis or kidney transplants, costing nations tens of billions of dollars. The growing population and increasing adoption of sedentary lifestyles are expected to provide a large target population for the industry.

There are similarly massive addressable markets for PromarkerEndo and PromarkerEso.

It is estimated that approximately 190 million women and girls worldwide suffer from endometriosis, each a potential customer for PIQ's PromarkerEndo

It is estimated that approximately 190 million women and girls worldwide suffer from endometriosis. This chronic condition affects about 10% of women of reproductive age globally, causing pain and potentially impacting fertility. The condition can be difficult to diagnose, often taking years for individuals to receive a proper diagnosis. the only available way for the diagnosis of endometriosis currently requires a laparoscopy with a biopsy (tissue sample). The annual economic impact of endometriosis is estimated at US$119 billion in the US, A$9.7 billion in Australia, and £8.2 billion in the UK, driven by healthcare expenses and lost productivity. PIQ's PromarkerEndo provides a non-invasive, cost-effective blood test for diagnosing endometriosis, offering a significant advantage over the current laparoscopy method.

~ 604,000 new cases of esophageal cancer were diagnosed globally in 2020, with the current diagnosis procedure being invasive and costing thousands of dollars

Approximately 604,000 new cases of esophageal cancer were diagnosed globally in 2020, according to estimates from the World Health Organization's International Agency for Research on Cancer (IARC). Esophageal cancer is relatively rare but has a high mortality rate, with about 544,000 deaths worldwide in the same year, making it the 6th leading cause of cancer-related deaths globally. The current diagnostic method for esophageal cancer involves an invasive and costly endoscopy-biopsy procedure, which in the United States costs approximately US$2,750. In 2018, total expenditure on esophageal cancer treatment in the U.S. reached US$2.9 billion. In the UK, the procedure costs between £1,000 and £2,000. This is while PIQ's PromarkerEso can accurately diagnose esophageal cancer through a novel blood test, which can be far more cost effective.

US Medicare has confirmed a US$390.75 reimbursement rate for PromarkerD

In November 2023, the Centers for Medicare & Medicaid Services (CMS) confirmed the payment rate of USD $390.75 for the PromarkerD predictive test for diabetic kidney disease in the United States. CMS, the federal agency responsible for providing health coverage to over 100 million Americans through Medicare and Medicaid, set this reimbursement rate for all patients accessing government-funded healthcare. If PIQ prices the test at this rate, patients with Medicare coverage would have no out-of-pocket costs. While there's further work required by PIQ to obtain agreed reimbursement coverage by CMS, CMS pricing is pivotal for PromarkerD's rollout, as many private insurers typically adopt CMS rates.

PromarkerD commercialisation in the US is in sight

PIQ's Promarker™ tests, including PromarkerD, don't need FDA approval to sell in the US. Instead PromarkerD sales in the United States will be conducted through the Laboratory Developed Test (LDT) pathway via CLIA-certified laboratories. ***The substantial Medicare rebate of USD $390.75 enhances our optimism about the product's future sales prospects in the US.***

Proteomics International is planning a US launch of PromarkerD in H1 CY25, utilising two Go-to-Market approaches: licensing to alternative pathology labs and service providers, and direct-to-consumer/patient (DTC/DTP) sales. Recently, the PromarkerD assay was set up in a third-party CLIA-certified reference lab in the US to explore additional clinical applications. Such facilities can also support the Go-to-Market strategies. The company is in talks with relevant service providers and partners to facilitate commercial sales. PromarkerD is also CE Mark registered, which means it's allowed to be sold in the European markets, where the company is in active engagement with regional distribution partners for future commercial sales of PromarkerD.

Valuation: DCF approach based on a Direct-to-Patient (DTP) go-to-market pathway indicates immense upside potential

We have used a DCF valuation method to value PIQ based on our forecasted sales of PromarkerD, PromarkerEndo and PromarkerEso diagnostic tests in the US and rest of the world (RoW), including EU, UK and Australia, based on a direct-to-consumer/patient (DTC/DTP) go-to-market strategy assumption. Compared to the traditional licencing model, PIQ's additional DTP go-to-

market strategy leverages advances in the field of digital health, allows for a faster market entry, and allows the company to retain a much larger share of profits.

We have conservatively assumed similar pricing for PromarkerEndo and PromarkerEso as PromarkerD in our model. Although there are no confirmed reimbursement rebates for PromarkerEndo and PromarkerEso in the US or elsewhere, we believe that due to the high cost and invasiveness of alternative diagnostic methods, patients will be willing to pay out of pocket for PIQ's tests for Endometriosis and Esophageal cancer diagnosis. For all three tests, we have assumed that product pricing in the rest of the world (RoW) will be 40% lower than in the US, which is typical for most pharmaceutical products.

Using these pricing assumptions, we have estimated the total addressable market for PromarkerD at US$29 billion, for PromarkerEndo at US$43 billion and for PromarkerEso at US$17 billion.

PIQ is targeting a US launch of PromarkerDin H1 CY25 and an Australian launch of PromarkerD and PromarkerEso in Q1 CY25, and expects the first commercial sales of PromarkerEndo in Q2 CY25.

We have assumed a soft launch of PromarkerD in FY25, with continuous growth over the next five years, reaching a market penetration of 0.50% by FY30. This projection is based on the assumption of a direct-to-customer/patient (DTC/DTP) model, which we've conservatively assumed to result in lower market penetration compared to a potential licensing agreement with a large, established diagnostics or pathology company. A faster and more extensive market penetration through complementary licensing agreements with external partners remains a potential upside to our valuation of PIQ. For conservatism, we have assumed commercial sales of PromarkerEndo and PromarkerEso to start no earlier than FY26. See Figure 15 on page 27 for our market penetration assumptions.

We have assumed a 30% revenue share for PIQ for all diagnostic tests sold through the DTC model, significantly higher than the 5-15% licensing fees PIQ might retain under a licensing agreement. We have then conservatively assumed a 75% gross margin as tests currently cost PIQ approximately US$10-20 each (produced under contract by an ISO 13485 manufacturer in France)—minimal compared to the assumed product pricing of US$390 per test.

Our other assumptions include a discount rate (WACC) of 14.2%, a fixed AUD/USD exchange rate of 0.67, and a terminal growth rate of 2% after FY30.

Our DCF model has yielded a valuation of A$2.59 in the base case scenario and A$3.10 in the bull case scenario for PIQ. Our mid-point fair valuation of A$2.84 represents a 331% upside potential to the latest share price of A$0.66.

While we have identified several key risks in investing in PIQ, we believe the most significant risk to our investment thesis is the commercialisation risk, given the inherent complexities of bringing a novel biopharmaceutical product to mass market.

Key catalysts for a re-rating of PIQ include the first commercial sales of PromarkerD in the US, targeted in H1 CY25, followed by global sales, particularly in Europe, the UK, and Australia. Additionally, PIQ is aiming to launch PromarkerEso in Australia under ISO 15189 accreditation in Q1 CY25, with a commercial launch of PromarkerEndo targeted for Q2 CY25.

While we think PIQ presents an attractive speculative opportunity due to its high reward/risk ratio, there are key risks to our investment thesis, including Commercialisation risk, market adoption risk, regulatory risk, and competition risk. Bringing a novel biopharmaceutical product to mass commercialisation presents inherent challenges. Manufacturing and supply chain complexities associated with producing and scaling novel diagnostic tests can lead to delays in revenue generation and profitability. Entering international markets requires navigating different regulatory, pricing, and healthcare systems, increasing complexity and risk.

Insights into the science of Proteomics

Proteomics is the large-scale study of proteins, which are vital molecules within living organisms that perform a wide array of functions necessary for life. Proteomics aims to identify, quantify, and analyse the structure, function, and interactions of proteins within a biological system, such as a cell, tissue, or organism.

Unlike our genes, the protein composition in our bodies varies from cell to cell and changes significantly over time. For instance, a cancerous cell will have a protein profile that is markedly different from that of a healthy cell, but almost an identical gene profile. Similarly, while a caterpillar and a butterfly share identical genes, differences in their proteins lead to the dramatic transformations observed throughout their lifecycle.

Key Aspects of Proteomics:

1. **Protein Identification**: Determining which proteins are present in a sample.
2. **Protein Quantification**: Measuring the abundance of specific proteins in a sample.
3. **Post-Translational Modifications (PTMs)**: Studying chemical changes that proteins undergo after they are synthesized, which can affect their function and activity.
4. **Protein-Protein Interactions**: Investigating how proteins interact with each other and with other molecules within a cell.
5. **Protein Function**: Understanding the roles that proteins play in biological processes.

Proteomics enables the customization of treatments based on an individual's unique protein profile, thereby improving the effectiveness of medical interventions.

Applications of Proteomics:

- **Disease Research**: Identifying protein biomarkers for diseases, which can lead to the development of diagnostic tests and new therapies.
- **Drug Development**: Discovering potential drug targets by understanding protein functions and interactions.
- **Personalized (Precision) Medicine**: Tailoring treatments based on an individual's protein profile.
- **Agriculture**: Enhancing crop yield and resistance by studying plant proteins.

Proteomics is essential in the field of Precision Medicine.

Most medical treatments follow a one-size-fits-all approach, which may not be effective for everyone—precision medicine offers a different strategy. According to the Federal Drug Administration (FDA), precision medicine is a healthcare approach that customises disease prevention and treatment by taking into account individual differences in genes, environments, and lifestyles. The goal of precision medicine is to personalise patient care, ensuring that the chosen treatment is the best fit for each patient's unique circumstances.

Proteomics is advancing precision medicine by enabling the discovery of protein biomarkers—distinctive "fingerprints" in the body that signal the presence of disease. Scientists can identify biomarkers with diagnostic potential and develop new, disease-specific tests. Additionally, proteomics allows researchers to monitor changes in protein biomarker levels during drug treatments. By understanding these biomarkers, researchers can assess drug effectiveness and create therapies tailored to individual patients, improving treatment outcomes and reducing adverse effects. This personalised approach, which aligns therapies with each patient's unique protein profile, marks a significant breakthrough in drug discovery and precision medicine.

Introducing Proteomics International

Proteomics International develops cutting-edge precision health and predictive diagnostic tests using its proprietary biomarker discovery platform, Promarker™. This innovative technology is based on the science of proteomics and identifies protein "fingerprints" in samples, enabling the detection of protein biomarkers that differentiate between individuals with and without a disease, all through a novel blood test. As a powerful alternative to genetic testing, this versatile technology can detect fingerprints from any biological source, ranging from wheat seeds to human plasma.

The Promarker™ platform has broad applications and is being utilised to create multiple new diagnostic tests to meet significant unmet medical and commercial needs. Proteomics now has a suite of diagnostic tests at the commercialisation and pre-commercialization stages, with PromarkerD, PromarkerEndo, PromarkerEso, and OxiDx each at crucial points in their development.

PIQ leverages the science of proteomics to develop innovative diagnostic tests that accurately distinguish individuals with a disease from healthy ones using a novel blood test.

Figure 1: Three key focus tests driven by PIQ's proprietary Promarker™ platform

Source: Company

Proteomics also generates revenue through its Analytical Services division, which offers fee-for-service contract research. This division specialises in biosimilars quality control, biomarker services, and pharmacokinetic testing for clinical trials. The revenue from Analytical Services helps financially support the company's commercialisation and research efforts until they become profitable. Additionally, this division provides synergies by expanding access to markets and clients.

PIQ's portfolio of advanced precision diagnostic products

Proteomics International has a range of diagnostic tests in both commercialisation and pre-commercialisation stages, including PromarkerD, PromarkerEndo, PromarkerEso, and OxiDx tests each at critical stages of development, with PromarkerD being the first in line for commercialisation.

PromarkerD - diabetic kidney disease diagnostic test

Diabetic Kidney Disease (DKD) is a serious complication of diabetes that affects the kidneys. It occurs when high blood sugar levels from diabetes damage the blood vessels in the kidneys, leading to impaired kidney function over time.

PromarkerD can predict the onset of diabetic kidney disease up to 4 years in advance with a proven accuracy of 86% as demonstrated through multiple clinical studies on samples from over 5,000 patients

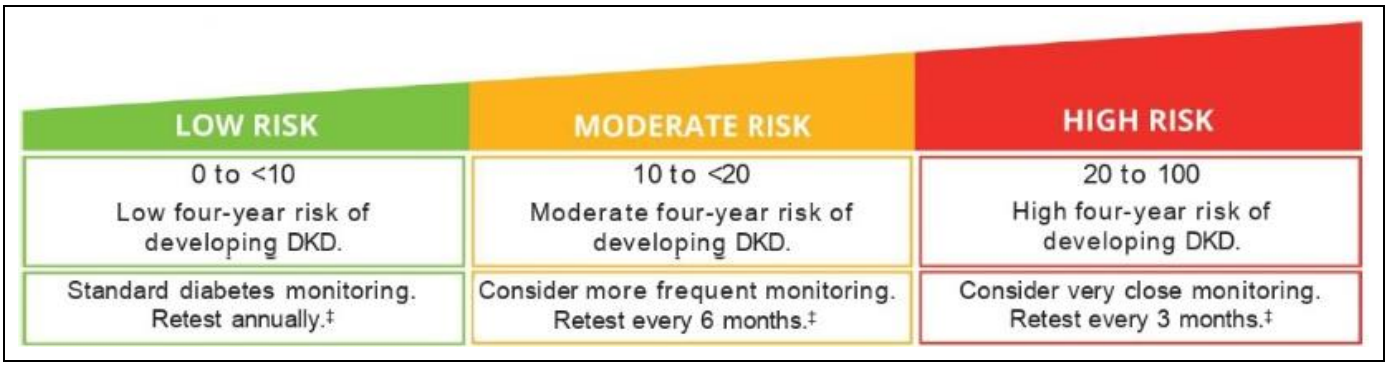
PromarkerD is a state-of-the-art diagnostic test developed to predict the risk of diabetic kidney disease (DKD) in people with diabetes. It represents a major advancement in diabetes management by allowing for early detection and intervention, which are essential in preventing or delaying the progression of this serious complication to end-stage renal disease, such as the need for dialysis or a kidney transplant.

How the PromarkerD Test System Functions

PromarkerD Test System is a novel blood test that measures a panel of three novel plasma biomarkers combined with 3 clinical factors at the time of the test. The combined raw data is then submitted to the PromarkerD Hub, and a test report is generated.

PromarkerD Hub is a software tool that contains a proprietary algorithm used to calculate a prognostic risk score of 0 to 100, using the PromarkerD protein biomarker panel with three clinical factors of age, HDL-cholesterol and eGFR. Patients in different risk categories will then be subject to different monitoring and intervention regimes (see **Figure 2**).

Figure 2: PromarkerD test results and intervention required for different risk groups



Source: Company

Multiple Clinical Studies validate PromarkerD

PromarkerD's ability to predict and diagnose diabetic kidney disease (DKD) has been validated through six clinical studies:

1. **Global Multi-Centre Prognostic Validation Study**: This global study involving 3,000 participants confirmed PromarkerD's effectiveness in predicting DKD risk. Retrospective analysis of blood samples from the CANVAS phase 3 trial showed that those identified as high-risk by PromarkerD were 13.5 times more likely to develop DKD. Results were presented at the American Diabetes Association (ADA) conferences and published in the Journal of Clinical Medicine[1].

   A stage 2 follow-up study demonstrated that PromarkerD could show the benefits of the SGLT2-inhibitor, canagliflozin, in over 2,000 participants. The test highlighted significant risk reductions for DKD in high-risk individuals taking the medication, underscoring

[1] PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS, Journal of Clinical Medicine.

PromarkerD's role in personalised treatment. Findings were published in the Journal of Clinical Medicine[2].

2. **Cross-Platform Assay Validation Study**: This study validated the reproducibility of PromarkerD across different technology platforms (IAMS and ELISA), showing over 90% correlation in risk scores. Results were presented at the Human Proteome Organization (HUPO) World Congress and published in Proteomes[3].
3. **Multi-Site Assay Validation Study**: This study confirmed the robustness and clinical applicability of the PromarkerD assay across multiple laboratories, marking a significant validation of a proteomics-based diagnostic test. Initial results were presented at HUPO and published in Clinical Proteomics[4].
4. **Prognostic Validation Study**: PromarkerD correctly predicted 86% of previously disease-free patients who developed DKD over four years in the validation cohort, and predicted 95% of cases in the development study. Results were presented at ADA and Australian Diabetes Society conferences and published in the Journal of Diabetes[5].
5. **Prognostic Development Study**: This study demonstrated that PromarkerD's biomarker panel improved predictions of rapid kidney function decline in type 2 diabetes patients beyond that of clinical factors alone, with results published in Diabetes Care[6].
6. **Diagnostic Study**: In a study of 572 patients, PromarkerD outperformed the gold-standard tests (ACR and eGFR) for diagnosing DKD. The study was published in EuPA Open Proteomics[7].

These studies confirm PromarkerD as an effective tool for early detection, risk prediction, and personalised treatment of diabetic kidney disease. ***The clinical trials demonstrated that the PromarkerD test accurately predicted 86% of disease-free patients who developed DKD within four years. Additionally, the PromarkerD test has a negative predictive value (NPV) of 98%, or "rule out" capability, that the patient will not develop DKD.***

PromarkerEndo - Endometriosis diagnostic test

Endometriosis is a common and painful disease affecting about one in nine women and girls, often beginning in adolescence. It occurs when tissue similar to the lining of the uterus grows in other areas of the body where it doesn't belong. Currently, there is no simple test for this condition, which can lead to pain and infertility and costs Australia $9.7 billion annually, according to Endometriosis Australia[8].

[2] Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Scores, Journal of Clinical Medicine.

[3] The New and the Old: Platform Cross-Validation of Immunoaffinity MASS Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease, Clinical Proteomics

[4] A robust multiplex immunoafnity mass spectrometry assay (PromarkerD) for clinical prediction of diabetic kidney disease, Clinical Proteomics.

[5] Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II, Journal of Diabetes.

[6] Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II, Diabetes Care.

[7] Comprehensive mass spectrometry based biomarker discovery and validation platform as applied to diabetic kidney disease, EuPA Open Proteomics.

[8] https://endometriosisaustralia.org/

Figure 3: An example of how Endometriosis affects the body

Source: Company and East Coast Research

PromarkerEndo is a novel blood test for early detection of endometriosis, powered by PIQ's proprietary Promarker™ platform. Similar to PromarkerD, PromarkerEndo also uses a traffic-light approach to diagnose people as low, moderate or high likelihood of moderate/severe endometriosis.

PromarkerEndo utilises a simple blood test for the early diagnosis of endometriosis, achieving approximately 90% accuracy in a clinical study conducted on over 900 patients.

Clinical studies in collaboration with the Royal Women's Hospital and University of Melbourne on over 900 patients have shown that the PromarkerEndo test can identify up to 90% of patients with the disease.

In February 2024, Proteomics International reached a significant milestone in developing its potential breakthrough blood test for endometriosis by confirming the clinical performance of the PromarkerEndo biomarkers in an independent patient cohort. This study was conducted in collaboration with the St John of God Subiaco Hospital Gynaecological Cancer Research Group and was presented at the 29th Annual Lorne Proteomics Symposium.

In March 2024, Proteomics International announced the signing of a Material Transfer Agreement with the renowned University of Oxford to obtain approximately 600 patient plasma samples for its endometriosis study. The analysis of these samples is expected to be completed in 2024. A successful completion of this clinical study will support the commercialisation of the PromarkerEndo test system. At the same time, the company has begun streamlining PromarkerEndo to be suitable for clinical laboratory use. PIQ's ongoing activities related to PromarkerEndo development include:

- The diagnostic algorithm is being refined with the integration of a 'traffic light' scoring system.
- Analysis of samples from the University of Oxford is ongoing (results expected by the end of CY24).
- Development of the PromarkerEndo Hub for reporting patient results has begun.
- The analytical methodology is being refined for clinical use.
- Partnering discussions are progressing.

PromarkerEso – Esophageal Cancer diagnostic test

Esophageal cancer is a type of cancer that occurs in the esophagus, the long, hollow tube that connects the throat to the stomach. The esophagus helps move food from the mouth to the stomach for digestion. Esophageal adenocarcinoma (EAC) is the most common type of esophageal

cancer and represents a significant unmet medical need. The five-year survival rate for this cancer is less than 20%, and esophageal cancer accounted for 1 in 20 cancer deaths worldwide in 2018.

Figure 4: An example of how Esophageal Cancer affects the body

Source: Company and East Coast Research

PromarkerEso utilises a novel blood test for the early diagnosis of esophageal cancer, achieving approximately 90% accuracy in clinical studies conducted on over 500 patients.

Screening for esophageal adenocarcinoma currently requires a specialist endoscopy procedure that costs US $2,750 per patient in the United States[9], where the total expenditure on treating esophageal cancer was $2.9 billion in 2018.

In the US, 1.5 million endoscopies with biopsy are performed annually in individuals with chronic acid reflux symptoms, but despite this up to 90% of EAC cases continue to go undetected[10]. Given its aggressive nature and the low survival rate, research and new treatments are urgently needed to improve outcomes for patients with esophageal cancer.

It is estimated that 90% of EAC cases continue to remain undetected, while 25% of cases are misdiagnosed as negative by endoscopy. Proteomics International's novel blood test measures biomarkers—protein 'fingerprints' in the blood—to diagnose esophageal adenocarcinoma.

In clinical studies on over 500 patients, the PromarkerEso identified 94% of patients with the disease. In September 2024, PIQ reached a significant milestone when it announced positive results from the clinical validation study of 165 samples from the Victorian Cancer Biobank (VCB) (including of 66 samples from patients with EAC and 99 healthy controls). The samples were analysed to determine which individuals had EAC and which did not. The results demonstrated an accuracy of 94% in both determining patients as having EAC or not having EAC, confirming the diagnostic accuracy of PromarkerEso for distinguishing patients with EAC from healthy controls.

At the same time, PIQ refined the diagnostic algorithm to incorporate the "traffic light" scoring system into the PromarkerEso test system and is developing the PromarkerEso Hub for reporting patient results.

PIQ is preparing to launch PromarkerEso in Australia under ISO 15189 accreditation, targeting Q1 CY25, with other jurisdictions to follow in due course. In the US, the company will leverage its strong understanding of the Laboratory Developed Test (LDT) pathway and the Current

[9] www.newchoicehealth.com/endoscopy

[10] Endoscopic Screening Program for Control of Esophageal Adenocarcinoma in Varied Populations: A Comparative Cost-Effectiveness Analysis

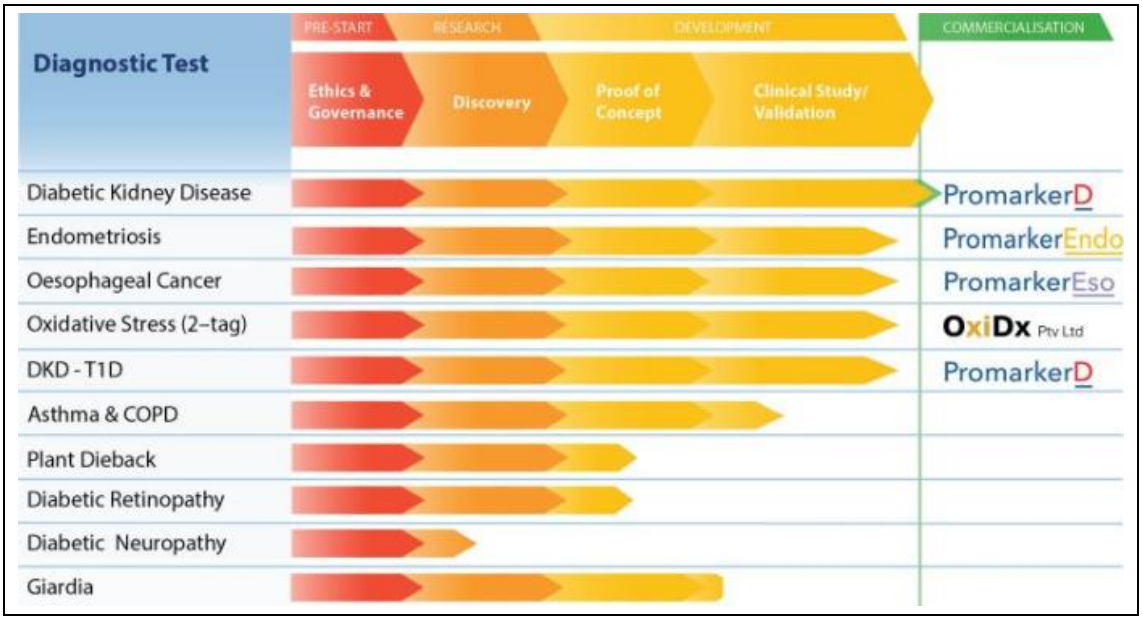
Procedural Terminology (CPT) code reimbursement process to accelerate commercialisation. PIQ is exploring both traditional out-licensing and direct-to-patient strategies as part of its refreshed go-to-market approach.

PIQ's other products in its R&D pipeline

PIQ has multiple other diagnostic tests in its development pipeline at earlier stages of clinical research and regulatory approval. These tests target a range of conditions, such as oxidative stress, diabetic kidney disease for type 1 diabetes and asthma. Figure 5 provides a comprehensive list of various products in PIQ's pipeline with their stages of development.

PIQ has a range of diagnostic tests targeting different conditions in earlier stages of development

Figure 5: The Promarker™ product portfolio targeting different conditions



Source: Company

OxiDx (2-tag) – Oxidative stress test

Oxidative stress is a condition that occurs when there is an imbalance between the production of free radicals and the body's ability to neutralise them with antioxidants. This imbalance leads to cell and tissue damage and is associated with various diseases and aging processes. Causes of Oxidative Stress can be excessive production of free radicals due to environmental factors, stress, unhealthy diet, or illness, and/or insufficient antioxidant defences due to poor diet, genetic factors, or certain medical conditions.

Early detection and management of oxidative stress due to the dangerous effects of Oxidative stress on the body over time, including:

- Cell and tissue damage: Free radicals can damage DNA, proteins, and lipids, leading to cell dysfunction and death.
- Chronic diseases: Linked to the development and progression of conditions such as cardiovascular disease, cancer, diabetes, neurodegenerative disorders (e.g., Alzheimer's and Parkinson's), and inflammatory diseases.
- Aging: Contributes to the aging process by damaging cells over time.

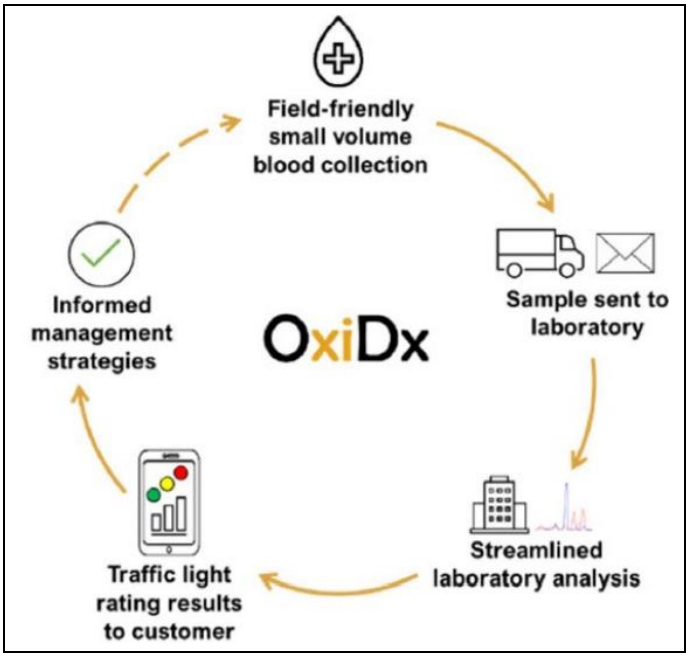
Once detected, maintaining a healthy lifestyle, including a diet rich in antioxidants, can help manage oxidative stress and reduce its impact on health.

Proteomics International has announced the creation of a spin-off company to commercialise its oxidative stress testing technology, developed in collaboration with The University of Western Australia. The newly established joint venture, OxiDx Pty Ltd, is 66% owned by PIQ and focused on developing cutting-edge medical diagnostic products using the patented '2-tag' method for measuring oxidative stress.

OxiDx utilises advanced diagnostic technology to detect subtle changes in protein structures, specifically the "decorations" on the surface of proteins known as post-translational modifications. The platform technology for systemic oxidative stress is designed for use as a monitoring tool in both the human and equine (horse) athletic industries.

OxiDx's patented technology enables comprehensive monitoring of oxidative stress levels, anytime and anywhere. It allows for results to be returned to customers within 24 hours using just a blood sample, providing a cost-effective solution for sequential sampling and large cohort collection.

Figure 6: OxiDx test system returns results in 24 hours



Source: Company

PIQ's OxiDx 2-tag diagnostic test can identify the presence of oxidative stress in the blood, helping athletes monitor their condition and potentially prevent injuries.

Diabetic Kidney Disease (DKD) in type 1 diabetes diagnostic test

Building on the success of the diabetic kidney disease project focused on type 2 diabetes, Proteomics International has expanded its collaboration with The University of Western Australia to identify early biomarkers for diabetic kidney disease (DKD) in type 1 diabetes.

In August 2024, PIQ announced the success of its PromarkerD test in predicting renal decline in patients with type 1 diabetes. Using the PromarkerD test, which was initially developed and validated for predicting renal decline in type 2 diabetes, researchers evaluated its effectiveness in a cohort of 92 individuals with type 1 diabetes from the Fremantle Diabetes Study Phase II. The results were positive, with PromarkerD demonstrating strong predictive accuracy.

Type 1 diabetes represents approximately 10% of all cases of diabetes and cannot be prevented[11]. Expanding the application of PromarkerD to patients with type 1 diabetes, who have unique clinical needs, opens up a new target market for the test.

Asthma and Chronic Obstructive Pulmonary Disease (COPD) diagnostic test

Proteomics International has completed a proof-of-concept study that identified several novel protein biomarkers for obstructive airway disease. Once validated, these biomarkers could lead to the development of a new diagnostic test for asthma and chronic obstructive pulmonary disease (COPD).

The initial study, conducted in collaboration with the Busselton Population Medical Research Institute, analysed plasma samples from 75 individuals with symptoms such as airway obstruction, atopy, bronchial hyper-responsiveness, and healthy controls. A patent application for methods of diagnosing airway disease has been filed. The next step is to validate the identified biomarkers in a larger clinical cohort, with the goal of refining them into a potential blood test for diagnosing obstructive airway disease.

Plant Dieback (Phytophthora cinnamomi) diagnostic test

In May 2024, Proteomics International announced a successful collaboration with Curtin University's Centre for Crop and Disease Management, resulting in a significant breakthrough in understanding how dieback affects plants. The findings were published in the Journal of Proteomics.

Phytophthora dieback, a plant disease that can rapidly spread, poses a serious threat to native vegetation and premium crops such as avocados. Phytophthora cinnamomi, the most impactful dieback species, greatly affects biodiversity and causes tens of millions of dollars in crop losses annually in Australia.

This deeper understanding of dieback's mode of action enables Proteomics International to develop diagnostic tools for accurate soil detection, offering valuable benefits to the agricultural and related industries.

Diabetic Retinopathy and Diabetic neuropathy diagnostic tests

Following the success of its diabetic kidney disease project, Proteomics International has expanded its collaboration with The University of Western Australia to search for early markers of diabetic retinopathy, the leading cause of blindness in the U.S.

This collaboration leverages the Promarker™ platform to identify prognostic markers in the blood that can predict the risk of developing retinopathy, particularly sight-threatening cases. The program draws on the Fremantle Diabetes Study, which previously provided the valuable samples that led to PromarkerD.

Discovery experiments have already identified potential biomarkers for early detection of retinopathy, and the next step is to validate these markers in a larger cohort.

In addition, the company has partnered with the Australian Centre for Accelerating Diabetes Innovations (ACADI) to further assess PromarkerD in type 1 diabetes diagnostic test, and has launched a new R&D program focused on identifying predictive biomarkers for diabetic neuropathy.

[11] International Diabetes Federation 2021

Analytical services: PIQ's revenue generating unit

Proteomics International provides specialist contract research, focusing on biosimilars quality control, biomarker discovery and pharmacokinetic testing for clinical trials. Australia is a global leader in clinical trials due to its efficient regulatory framework and high-quality trial sites, and all samples from each trial require specialist analytical testing. Proteomics International is now registered as a Research Services Provider (RSP) with the Australian Government, enabling eligible clients to claim tax incentives.

The Analytical Services component of Proteomics International is built around its proprietary technology platform. This centres upon the Company's ISO 17025 laboratory accreditation for analytical services, which recognises its ability to consistently achieve technically valid results and is the most widely used laboratory standard for US Federal testing laboratories.

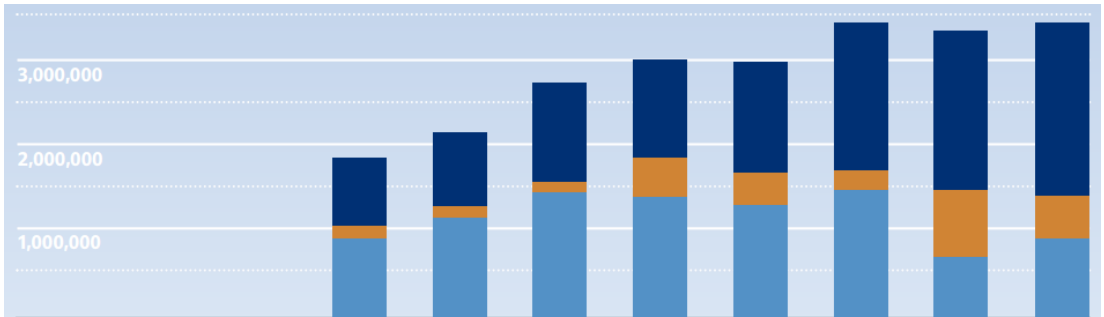
PIQ's Analytical Services division generates revenue from providing specialised analytical services including for different drugs in development or undergoing clinical trials, providing a key income stream for the company

Notably, biologics and biosimilars are the fastest-growing class of drugs entering clinical trials. According to Grand View Research, the global clinical trials market size was valued at USD 80.7 billion in 2023 and is projected to grow at a compound annual growth rate (CAGR) of 6.49% from 2024 to 2030 to reach USD 123.5 billion by 2030[12]. At the same time, the global biosimilars market, valued at USD 35.4 billion in 2024, is expected to grow to USD 82.2 billion by 2029[13]. Additionally, the global proteomics market, valued at USD 32.8 billion in 2023, is forecasted to reach USD 161.9 billion by 2035[14].

Revenue from Analytical Services remains a key income stream for Proteomics International, and the company continues to seek opportunities for growth. This includes targeting the clinical trials sector for pharmacokinetic testing and developing companion/complementary diagnostics (CDx) through biomarker analysis.

Over the last several years, revenue from PIQ's analytical services, combined with cash from grants and R&D tax incentives, has played a key role in offsetting the company's cash burn as it develops its extensive pipeline of diagnostic products. While this revenue may not be large, it is important as it helps reduce the need for dilutive capital raisings, providing financial support until revenues from the commercialisation of PromarkerD, PromarkerEndo and PromarkerEso begin to materialise.

Figure 7: Historical revenues from Analytical Services division, grants and government incentives



		2017	2018	2019	2020	2021	2022	2023	2024
Analytical Services	$	925,537	1,176,457	1,468,076	1,423,070	1,310,824	1,489,323	730,340	892,143
Grants and other Income	$	144,484	130,343	128,833	454,389	386,770	235,232	741,690	517,498
Research & Development Tax Incentive	$	790,751	844,123	1,139,403	1,138,815	1,290,899	1,711,903	1,848,832	2,156,377

Source: Company

[12] Grand View Research, Clinical Trials Market Size & Trends, 2024

[13] Mordor Intelligence, Biosimilars Market Size, 2024

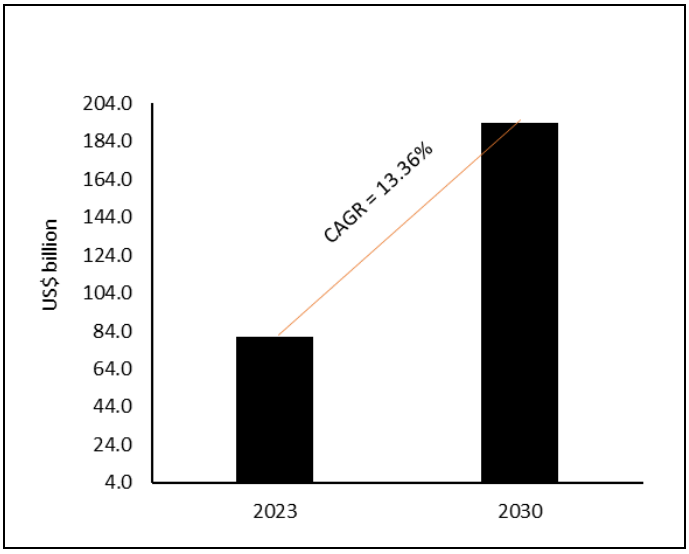
[14] Allied market research, proteomics market by component, 2024

There are huge market opportunities for Promarker™ products

The global biomarkers market was valued at USD 81.04 billion in 2023 and is projected to grow at a compound annual growth rate (CAGR) of 13.36% from 2024 to 2030. Market growth is expected to be driven by the increasing prevalence of cancer, the importance of companion diagnostics, rising investments in research, and significant innovations resulting from ongoing studies[15].

Government grants and research funding for the discovery and development of novel biomarkers are further driving market growth. Additionally, the introduction of biomarker-based diagnostic kits for screening high-risk populations, along with the rising prevalence of genetic disorders, is anticipated to expand the market's customer base.

Figure 8: Global market size for biomarkers



Source: Grand View Research, East Coast Research

The addressable market for PromarkerD is massive

There are more than 500 million diabetic people in the world, each a potential customer for PIQ's PromarkerD

Diabetes affects more than 537 million people globally and is a leading cause of chronic kidney disease, which can result in severe health complications and increased mortality. In both developed and developing countries, diabetes has become the primary cause of end-stage renal disease[16], often necessitating dialysis or kidney transplants. The growing population and increasing adoption of sedentary lifestyles are expected to provide a large target population for the industry.

According to Diabetes Australia[17], diabetes-related kidney disease is one of the most prevalent and potentially debilitating complications of diabetes. Approximately 330,000 Australians with diabetes also have chronic kidney disease, and around 10,000 of these individuals will develop kidney failure, requiring dialysis or a kidney transplant—representing about 37% of all kidney

[15] Biomarkers Market Size, Share & Trends Analysis, Grand View Research, 2024

[16] Diabetic kidney diseases revisited: A new perspective for a new era, National Library of Medicine.

[17] Diabetes-Related Kidney Disease Report, Diabetes Australia, 2023

failure cases. Every year in Australia 324 people living with diabetes are undergoing kidney transplant.

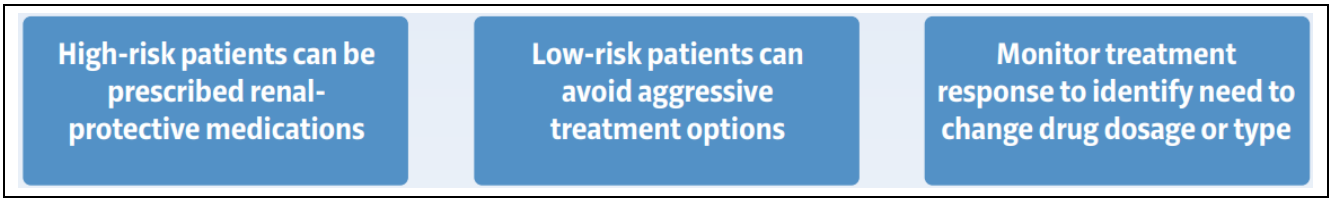
The economic impact of diabetes-related kidney disease on Australia is estimated at $2.68 billion annually, with kidney failure alone accounting for $1.9 billion. This significantly strains hospital capacity, as people with diabetes undergoing dialysis make up around 5% of all hospital admissions.

However, Diabetes Australia mentions that much of this is preventable. Early detection can help slow or prevent most kidney disease. Unfortunately, less than one in four Australians living with diabetes are getting their kidneys checked within recommended timeframes, with the lack of sensitivity of the currently available checks being one of the major contributing factors – PromarkerD can solve this.

The biomarker segment is witnessing rapid technological advancements due to the high demand for personalised medicine. Importantly, existing standard-of-care tests cannot predict diabetic kidney disease (DKD) onset until it is already present, resulting in less effective therapeutic treatments and additional complications. This is while PIQ's PromarkerD diagnostic blood test can predict DKD onset up to 4 years before clinical symptoms appear.

PromarkerD was employed in a clinical study titled "*Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Prediction Scores*" to assess the impact of the SGLT2-inhibitor drug on PromarkerD risk scores as a treatment for diabetic kidney disease (DKD). The study revealed that early intervention with Canagliflozin led to a reduction in PromarkerD scores among high-risk patients, demonstrating the drug's effectiveness in lowering the risk of kidney function decline in those at high risk of developing chronic kidney disease. With PromarkerD's prognostic test and effective treatments, doctors can now better improve outcomes and tailor treatment strategies to meet each diabetes patient's needs.

Figure 9: PromarkerD helps with the prevention and effective treatment of diabetic kidney disease (DKD)



Source: Company

To ensure patient access to these new technologies, a reimbursement framework needs to be developed to meet the changing market scenario. This will potentially encourage manufacturers to invest in new products, as reimbursement policies have a direct impact on the development and growth of diagnostic and prognostic tools.

Given the significant impact of diabetes-related kidney disease on the Australian economy, even a modest reduction in kidney failure cases through early detection of the kidney disease could result in over half a billion dollars in cost savings. For this reason, we are hopeful that Australia's Medicare is likely to follow US Medicare in reimbursing the cost of PromarkerD predictive test for DKD.

If PIQ prices the PromarkerD test in line with the US Medicare reimbursement rate of US$390.75, there could potentially be no out-of-pocket cost for over 100 million Americans covered by CMS.

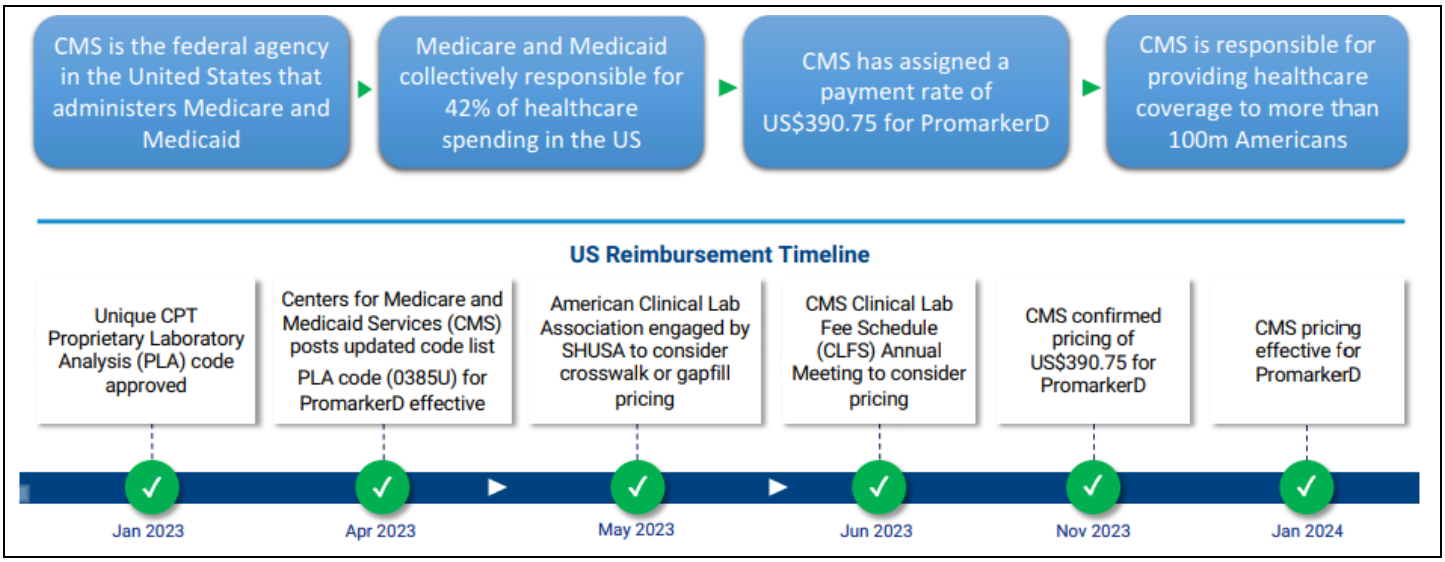
US Medicare has confirmed a US$390.75 reimbursement rate for PromarkerD

In November 2023, the Centers for Medicare & Medicaid Services (CMS) confirmed the payment rate of USD $390.75 for the PromarkerD predictive test for diabetic kidney disease in the United States. CMS, the federal agency responsible for providing health coverage to over 100 million Americans through Medicare and Medicaid, set this reimbursement rate for all patients accessing

government-funded healthcare. Medicare covers healthcare costs for individuals over 65, while Medicaid supports eligible low-income Americans. As the largest payer for healthcare in the U.S., CMS oversees 42% of healthcare spending through these programs.

If PIQ prices the test at this rate, patients would have no out-of-pocket costs. Additionally, CMS pricing is favourable for PromarkerD's rollout, as many private insurers typically adopt CMS rates.

Figure 10:The path to achieving reimbursement pricing for PromarkerD in the US



Source: Company

Demand for PIQ's Analytical Services to consistently grow

The increasing focus on personalised and precision medicine has heightened the demand for biomarkers to identify specific disease markers and customise treatment plans. The services segment is expected to experience strong growth over the forecast period. Biomarkers play a key role in clinical trials by enabling patient stratification, monitoring treatment responses, and assessing safety. Biomarker services support the design, execution, and analysis of clinical trials, ensuring biomarkers are effectively used in drug development decisions. Additionally, clinical laboratories and diagnostic service providers offer biomarker-based diagnostic testing for various diseases, aiding in accurate early diagnosis and monitoring.

Biomarkers play a crucial role in speeding up drug development by predicting drug efficacy more effectively than traditional clinical endpoints. This allows for the early identification of candidates likely to fail, reducing overall drug development costs. As a result, major players in this segment are increasingly focusing on integrating biomarkers into the drug development process.

With the rising demand for biomarker services in drug developments, PIQ's Analytical Services division is expected to see sustained revenue growth over the long term, in our view.

Large addressable markets for other Promarker™ diagnostic tests

In addition to PromarkerD, there are also large markets for PIQ's other diagnostic tests in advanced development stages, namely PromarkerEndo, PromarkerEso and OxiDx (2-tag). All of PIQ's diagnostic tests in advanced development stages are protected by granted or pending patents in key developed and high-population markets.

PromarkerEndo - *Endometriosis*

It is estimated that approximately 190 million women and girls worldwide suffer from endometriosis[18]. This chronic condition affects about 10% of women of reproductive age globally, causing pain and potentially impacting fertility. The condition can be difficult to diagnose, often taking years for individuals to receive a proper diagnosis.

Endometriosis remains under-researched and is often misdiagnosed, contributing to a large number of undiagnosed cases.

According to endometriosis Australia, the only available way for the diagnosis of endometriosis currently requires a laparoscopy with a biopsy (tissue sample). A laparoscopy is a surgical procedure performed under general anesthesia, where a small telescope is inserted through the belly button to allow the doctor to examine the organs in the pelvis and abdomen. This procedure magnifies the tissues, enabling the detection of even small amounts of endometriosis. Suspected tissue is removed during the laparoscopy and sent to a pathologist for confirmation through microscopic examination.

Endometriosis affects 1 in 9 women and girls, presenting a massive addressable market for PromarkerEndo. The current standard of care for endometriosis diagnosis involves invasive surgery, costing thousands of dollars.

In some cases, a diagnosis may be suggested without a laparoscopy, such as when the doctor feels abnormal tissue in the pelvis, detects an endometriosis cyst on the ovary or another pelvic organ, or occasionally sees endometriosis that has grown through the vagina. However, the only way to confirm the diagnosis with certainty is through laparoscopy and/or biopsy.

Endometriosis imposes a significant burden on society, largely due to the frequent delays in diagnosis, as surgical intervention is necessary for histological confirmation. This delay exacerbates symptoms, increases the risk of central and peripheral sensitisation, and drives up costs for both patients and their nations. The annual economic impact of endometriosis is estimated at US$119 billion in the US[19], A$9.7 billion in Australia[20], and £8.2 billion in the UK[21], driven by healthcare expenses and lost productivity.

PIQ's PromarkerEndo provides a non-invasive, cost-effective blood test for diagnosing endometriosis, offering a significant advantage over the current laparoscopy method. The prototype test has demonstrated 90% accuracy in clinical studies, and we believe that, following successful commercialisation, its multiple benefits will drive strong sales growth.

PromarkerEso - *Esophageal cancer*

Approximately 604,000 new cases of esophageal cancer were diagnosed globally in 2020, according to estimates from the World Health Organization's International Agency for Research on Cancer (IARC). Esophageal cancer is relatively rare but has a high mortality rate, with about 544,000 deaths worldwide in the same year, making it the 6th leading cause of cancer-related deaths globally.

Esophageal cancer, while less common than other cancers, remains one of the deadliest forms of cancer due to late-stage diagnosis and limited treatment options.

There are two main types of esophageal cancer:

Squamous cell carcinoma: More common in developing countries, associated with smoking, alcohol consumption, and poor nutrition.

[18] Endometriosis, The World Health Organization

[19] Endometriosis Is Undervalued: A Call to Action, 2022

[20] Armour et al. 2019; Ernst & Young 2019

[21] Endometriosis Facts and Figures, Endometriosis UK, 2012

Adenocarcinoma: More common in developed countries, linked to obesity, acid reflux, and Barrett's esophagus.

Risk factors include smoking, heavy alcohol consumption, obesity, gastroesophageal reflux disease (GERD), Barrett's esophagus, poor diet (low in fruits and vegetables), and chronic esophageal irritation.

esophageal cancer is the 6th leading cause of cancer-related deaths globally, with current standard of care diagnosis involving time consuming and costly endoscopy with biopsy.

Esophageal cancer ranks as the 7th most common cancer worldwide. The 5-year survival rate for esophageal cancer is low, often less than 20%, primarily due to late diagnosis. Early-stage detection offers a better prognosis, but esophageal cancer is often asymptomatic until advanced stages.

The current diagnostic method for esophageal cancer involves an invasive and costly endoscopy-biopsy procedure, which in the United States costs approximately US$2,750[22]. In 2018, total expenditure on esophageal cancer treatment in the U.S. reached US$2.9 billion. In the UK, the procedure costs between £1,000 and £2,000.

In addition, it is estimated that 90% of esophageal cancer cases continue to remain undetected, while 25% of cases are misdiagnosed as negative by endoscopy. Therefore, there is a strong need for a more accurate, affordable and non-invasive diagnostic test for screening and monitoring high-risk populations. PromarkerEso addresses this need with a novel blood test for early detection of esophageal cancer. Its efficacy has been demonstrated in clinical trials, and we believe it has strong market potential upon successful commercialisation.

OxiDx (2-tag) – *Oxidative stress*

Oxidative stress and muscle injury are closely linked. Oxidative stress occurs when there is an imbalance between the production of reactive oxygen species (ROS) and the body's ability to neutralise them with antioxidants. In muscles, oxidative stress can play both damaging and signalling roles.

Muscle Damage: High levels of ROS can directly damage muscle cells, leading to muscle injury. ROS attacks cell membranes, proteins, and DNA, impairing muscle function and causing inflammation. This damage is often seen in conditions of intense exercise, trauma, or chronic diseases.

Inflammation: Oxidative stress promotes inflammation by activating signalling pathways and immune responses, which can exacerbate muscle damage. Inflammatory cells can further produce ROS, creating a cycle of damage.

Delayed Muscle Recovery: Elevated oxidative stress can hinder the repair and recovery process of injured muscle tissue by disrupting cellular repair mechanisms and increasing the degradation of proteins needed for muscle regeneration.

As such, managing oxidative stress through antioxidants and proper recovery is essential to prevent muscle injury. Muscle injuries are frequent in athletes. Despite their high incidence, advances in clinical diagnostic criteria and imaging, their optimal management and rehabilitation strategies are still debated in literature. Muscle injuries account for up to 55% of all sports injuries and cost the Australian economy over $2 billion annually[23].

[22] newchoicehealth.com/endoscopy/cost

[23] Muscle Injuries: A Brief Guide to Classification and Management

PIQ's OxiDx (2-tag) diagnostic test utilizes a simple fingerstick blood sample to detect subtle changes in protein structures caused by oxidative stress in both humans and racehorses. It has proven to be an effective tool for monitoring athletic performance, potentially saving significant costs by preventing muscle injuries in both athletes and racehorses.

PromarkerD commercialisation in the US is in sight

PIQ's Promarker™ tests, including PromarkerD, don't need FDA approval to sell in the US. Instead, they can proceed down the Laboratory Developed Test (LDT) pathway, which makes things easier for PIQ to commercialise its diagnostic tests in the US.

The LDT pathway in the U.S. allows clinical laboratories to develop, validate, and offer their own diagnostic tests without seeking premarket approval from the U.S. Food and Drug Administration (FDA). LDTs are primarily regulated under the Clinical Laboratory Improvement Amendments (CLIA), which focus on lab quality and accuracy. However, the FDA has historically exercised enforcement discretion, meaning it has not required premarket approval or clearance for most LDTs. The LDT pathway provides a flexible framework for labs to rapidly innovate and respond to emerging medical needs.

PromarkerD sales in the United States will be conducted through the Laboratory Developed Test (LDT) pathway via CLIA-certified laboratories. ***The substantial Medicare rebate of USD $390.75 enhances our optimism about the product's future sales prospects in the US.***

Proteomics International is planning a US launch of PromarkerD in H1 CY25 through a hybrid approach of traditional licensing and direct-to-consumer/patient (DTC/DTP) go-to-market approach.

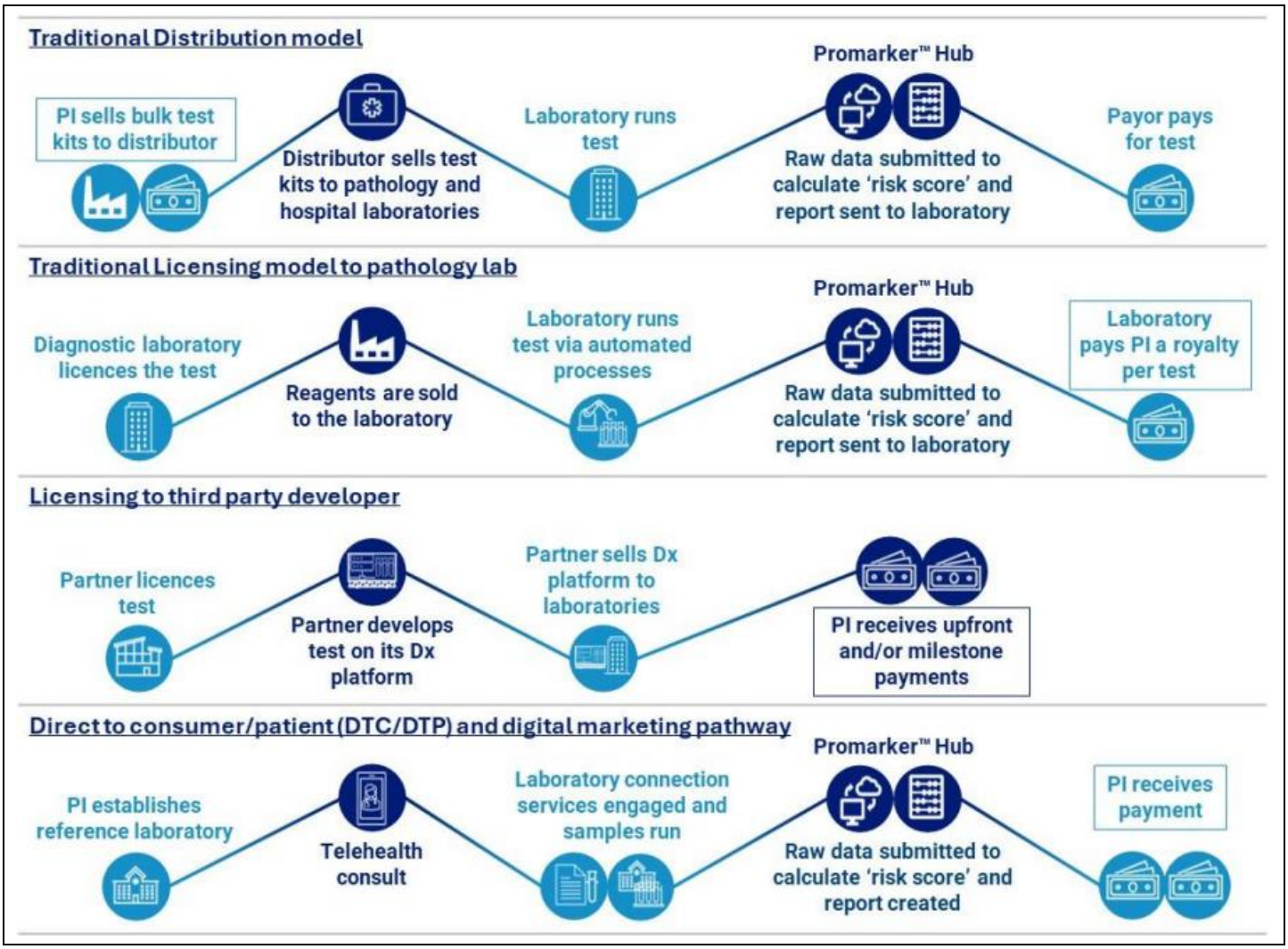
Proteomics International is planning a US launch of PromarkerD in H1 CY25, utilising two Go-to-Market approaches: licensing to alternative pathology labs and service providers, and direct-to-consumer/patient (DTC/DTP) sales.

Advances in digital health and direct-to-consumer healthcare, spurred by key shifts in medical practice following the global pandemic and the rise of social and digital media, are revolutionising once costly and low-volume market channels for diagnostic testing. These changes are turning them into more affordable and attractive opportunities. With digital platforms and established e-commerce practices, consumers can now opt to bypass traditional healthcare pathways.

> *Virtual or digital health refers to the use of technology to deliver healthcare services and manage health outcomes remotely. It leverages digital tools, such as mobile apps, wearable devices, telemedicine, and electronic health records, to enhance the efficiency, accessibility, and personalisation of healthcare.*

To generate early revenue, the Company is focusing on specialist adoption channels through laboratories that follow the ISO 15189 international standard or the US Laboratory Developed Test (LDT) pathway for CLIA-certified clinical labs. These pathways are well-suited to the Promarker test platform and align with Proteomics International's expertise, while also providing a foundation for implementing hybrid Go-to-Market models, such as combining traditional and digital approaches.

Figure 11: Go-to-market pathways for PIQ's suite of novel diagnostic tests



Source: Company

Recently, the PromarkerD assay was set up in a third-party CLIA-certified reference lab in the US to explore additional clinical applications. Such facilities can also support the Go-to-Market strategies. The company is in talks with relevant service providers and partners to facilitate commercial sales.

With the significant market opportunity and generous Medicare rebate, we think there will be plenty of interest from large pharma companies to partner with PIQ for the sale of PromarkerD in the US market. If they price the test in line with CMS's reimbursement rate, there will be no out-of-pocket costs for the 40% of Americans covered by Medicare and Medicaid.

Additionally, PromarkerD has the potential to save medical insurance companies considerable amounts by preventing the onset of diabetic kidney disease (DKD) in patients with diabetes. Treatments for DKD, such as dialysis and kidney transplants, are both intensive and expensive, often costing hundreds of thousands of US dollars.

PIQ entered a licencing agreement with Sonic Healthcare USA to commercialise PromarkerD in the US in May 2023. The company, however, ended the agreement with Sonic Healthcare USA in September 2024, noting certain milestones and KPIs were not met to commercialise the product. Given the lessons learned from this experience, PIQ is now targeting the direct-to-customer/patient (DTC/DTP) approach to achieve first sales and build brand awareness. The

company has also noted the potential for greater profit margins from the sales of the product by this route as well as a much faster market entry compared to the traditional licencing model.

PIQ has also indicated that it's actively engaged in negotiations with other licencing partners for the sales of PromarkerD in the US as well as in the EU. Given the promising economic potential of PromarkerD, we are optimistic that there will be significant interest from third parties to partner with PIQ for the sale of PromarkerD.

Patents for PromarkerD have been granted in all major jurisdictions, including the US. The PromarkerD patent family and trademark cover 72% of the global diabetic population.

International rollout of PromarkerD

While the highly attractive US market remains a major focus, it's not the only near-term revenue opportunity. Internationally, the rollout of PromarkerD is gaining momentum, with new markets targeted and distribution agreements secured.

PromarkerD is CE Mark registered, meaning that it's allowed for sale to the European markets.

In Europe, Growth Medics BV has been engaged to attract and manage regional distribution partners in Belgium, the Netherlands, Spain, and Italy, while Eurobio Scientific will handle distribution in France.

In France, an estimated 3.9 million people, or 8.6% of the adult population, are living with type 2 diabetes[24]. The direct costs associated with the disease are estimated to exceed EUR 8.5 billion annually[25]. Additionally, France has one of the highest rates of end-stage renal disease in Europe[26].

PromarkerD is already CE Mark registered, which means it's allowed to be sold in the European markets. **Figure 12** highlights key commercialisation partnerships established to date.

[24] diabetesatlas.org/idfawp/resource-files/2021/11/IDF-Atlas-Factsheet-2021_EUR.pdf

[25] link.springer.com/article/10.1007/s41669-017-0050-3

[26] globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-10-6

Figure 12: PIQ's commercialisation partners for PromarkerD's international rollout

Territory	Partner	Agreement Type	Technology	Status	Term	Notes
Partners 30 Jun 2024						
France *3.9m Type 2 diabetics*	EuroBio Scientific	Distribution [Exclusive]	Immunoassay Kit	Pre-launch	2024 - 2029	Exclusive distributor in France under a sub-distribution agreement with Apacor (UK). Proteomics International to receive payment for each PromarkerD kit sold. [ASX: 24 June 2024]
Belgium, Netherlands, Spain & Italy *61m Type 2 diabetics (in Europe)*	Growth Medics	Sales partner [Exclusive]	Immunoassay Kit	Active	2024 - 2026	Sales agency engaged to find, develop and manage distribution partners and customers. [ASX: 17 June 2024]
Chile *1.7m Type 2 diabetics*	Omics Global Solutions	Technology Licence [Exclusive]	Innovatio ND2 (developed own Immuno-assay)	Pre-launch	2023 -2031*	Test registered with Ministry of Health. [ASX: 20 December 2023]
United States *32m Type 2 diabetics*	Sonic Healthcare USA	Licence [Exclusive]	Immunoassay LDT	Pre-launch	2023 - 2028	For use and commercialisation of PromarkerD test in the US (excluding Puerto Rico). Secured unique CPT Proprietary Laboratory Analysis (PLA) code and CMS reimbursement of US $390.75 per test. [ASX: 10 May 2023]
United Kingdom *4.8m Type 2 diabetics*	Apacor Limited	Distribution [Exclusive]	Immunoassay Kit	Pre-launch	2021 - 2028	Test registered with UK Medicines & Healthcare products Regulatory Agency. NICE MedTech Innovation Briefing "NICE Advice" published. [ASX: 15 February 2023]
Dominican Republic & Puerto Rico *1.3m Type 2 diabetics*	Omics Global Solutions	Technology Licence [Exclusive]	Innovatio ND2 (developed own Immuno-assay)	Launched	2016 - 2031*	Test registered with Ministry of Health. First sales commenced. Securing public reimbursement (Puerto Rico linked to CMS pricing). [ASX: 18 August 2016]

Source: Company

Valuation: DCF approach based on a Direct-to-Patient (DTP) go-to-market pathway indicates immense upside potential

We have used a DCF valuation method to value PIQ based on our forecasted sales of PromarkerD, PromarkerEndo and PromarkerEso diagnostic tests in the US and rest of the world (RoW), including EU, UK and Australia.

Proteomics International (PIQ) has several diagnostic tests in advanced development stages, with PromarkerD already being commercialised and PromarkerEndo and PromarkerEso set to follow.

Given the lack of significant competition for PIQ's diagnostic tests, we have chosen a DCF valuation method to estimate the company's fair value under two different market penetration scenarios.

After the unsuccessful partnership with Sonic Healthcare USA to commercialise PromarkerD in the US, the company is now targeting a hybrid approach of traditional licensing and a direct-to-patient strategy for its novel diagnostics.

We think this approach seems sensible, as large distribution companies are often slow to launch new pharmaceutical products due to the extensive bureaucracy and internal politics involved.

A direct-to-patient (DTP) strategy for commercialising diagnostic tests presents several key advantages.

First, it leverages advancements in digital health and direct-to-consumer healthcare, driven by shifts in medical practice following the global pandemic and the rise of social and digital media. These developments have transformed traditionally expensive and low-volume diagnostic testing channels into more cost-effective and scalable opportunities. With the use of digital platforms and established e-commerce models, patients can now bypass conventional healthcare pathways.

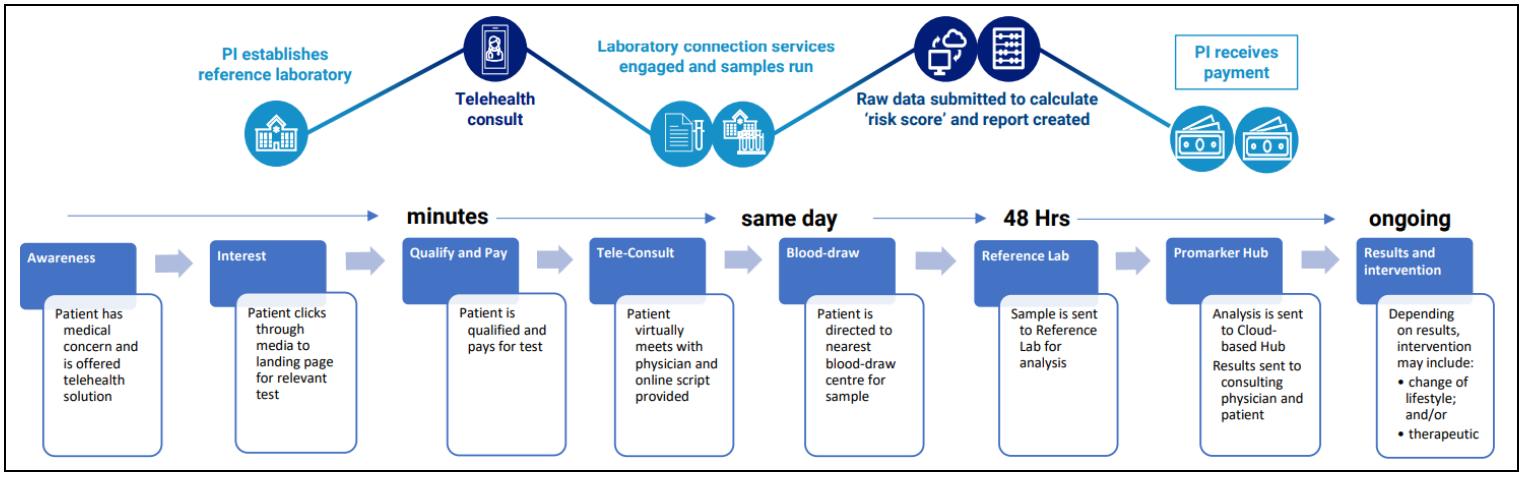
Compared to traditional licencing model, PIQ's revised hybrid traditional licencing and direct-to-consumer/patient (DTC/DTP) go-to-market strategy leverages advances in the field of digital health, allows for a faster market entry, and allows the company to retain a much larger share of profits.

Second, the DTP model enables faster market entry. The company anticipates receiving its first revenues from PromarkerD commercialisation in H1 CY25. Additionally, it expects to launch PromarkerEndo and PromarkerEso in Australia as early as Q2 and Q1 CY25, respectively, using the same DTP model.

Third, a DTP approach allows PIQ to potentially retain a significantly larger portion of revenues compared to traditional licensing fees of 5-15% of revenues, especially given the Medicare rebate of US$390 available in the US. As a result, we've used a 30% revenue share assumption in our DCF model—still conservative but much higher than the typical 5-15% licensing fees.

In addition, PIQ has indicated that it's actively engaged in negotiations with other licencing partners for the sales of PromarkerD in the US as well. Given the promising economic potential of PromarkerD and the healthy Medicare rebate in place, we are optimistic that there will be significant interest from third parties to partner with PIQ for the sale of PromarkerD.

Figure 13: A direct to consumer/patient (DTC/DTP) and digital pathway significantly speeds up time to diagnoses, treatment and intervention. It also helps PIQ bring forward revenues from its novel diagnostic tests as opposed to traditional licencing approaches



Source: Company

Our DCF (discounted cash flow) valuation methodology has the following key assumptions:

Total Addressable Market (TAM) assumptions: Our DCF model is based on the commercialisation assumptions for PromarkerD, PromarkerEndo, and PromarkerEso in the US and key international markets (specifically the EU, UK, and Australia). The potential to enter additional markets, as well as the commercial prospects of PIQ's other diagnostic tests, still in earlier stages of development, represent a potential upside to our valuation of the company.

In the US alone, over 32 million individuals are living with diabetes—each a potential PromarkerD user, 65 million women aged 15-44 as potential PromarkerEndo users, and 20-120 million adults eligible for esophageal cancer screening

Figure 14 summarises our TAM assumptions for PromarkerD, PromarkerEndo, and PromarkerEso. We have conservatively assumed similar pricing for PromarkerEndo and PromarkerEso as PromarkerD. Although there are no confirmed reimbursement rebates for PromarkerEndo and PromarkerEso in the US or elsewhere, we believe that due to the high cost and invasiveness of alternative diagnostic methods, patients will be willing to pay out of pocket for PIQ's tests for Endometriosis and Esophageal cancer diagnosis.

For all three tests, we have assumed that product pricing in the rest of the world (RoW) will be 40% lower than in the US, which is typical for most pharmaceutical products.

The United States presents a substantial market opportunity, with over 32 million individuals living with diabetes—each a potential PromarkerD user, 65 million women aged 15-44 as potential PromarkerEndo users, and 20-120 million adults eligible for esophageal cancer screening. For our TAM estimation, we have conservatively based our calculations on the lower end of the 20-120 million range. We have estimated the total addressable market for PromarkerD at US$29 billion, for PromarkerEndo at US$43 billion and for PromarkerEso at US$17 billion.

Figure 14: Promaker™ Total addressable market (TAM) assumptions

Key assumptions	Units	Value
PromarkerD TAM (US)	People 'M	32
PromarkerD test price in the US (US$)	US$	390
PromarkerD TAM (RoW)	People 'M	70
PromarkerD test price in RoW (US$)	US$	234
PromarkerD total addressable market	**US$'bn**	**29**
PromarkerEndo TAM (US)	People 'M	65
PromarkerEndo test price in the US	US$	390
PromarkerEndo TAM (RoW)	People 'M	74
PromarkerEndo test price in RoW	US$	234
PromarkerEndo total addressable market	**US$'bn**	**43**
PromarkerEso TAM (US)	People 'M	20
PromarkerEso test price in the US	US$	390
PromarkerEso TAM (RoW)	People 'M	40
PromarkerEso test price in RoW	US$	234
PromarkerEso total addressable market	**US$'bn**	**17**

Source: Various resources and East Coast Research

With a total addressable market for PromarkerD, PromarkerEndo, and PromarkerEso exceeding US$89 billion (based on our estimates), even a small market penetration could generate substantial revenues for PIQ.

Revenue and cost assumptions: We have assumed a soft launch of PromarkerD in FY25, with continuous growth over the next five years, reaching a market penetration of 0.50% by FY30. This projection is based on the assumption of a direct-to-customer/patient (DTC/DTP) model, which we've conservatively estimated to result in lower market penetration compared to a potential licensing agreement with a large, established diagnostics or pathology company.

PIQ has indicated that it is pursuing a hybrid approach and is actively engaged in negotiations with other licensing partners for PromarkerD sales in the US and EU. Given the strong economic potential of PromarkerD, we are optimistic that third parties will show significant interest in partnering with PIQ for its distribution. As a result, faster and more extensive market penetration through complementary licensing agreements with external partners remains a potential upside to our valuation of PIQ. For conservatism, we have assumed commercial sales of PromarkerEndo and PromarkerEso to start no earlier than FY26.

Figure 15 outlines our market penetration assumptions in the base case scenario. In the bull case scenario, we've assumed a slightly faster and broader market penetration for all three tests.

Figure 15: Market penetration assumptions for different tests

(Year end June)	2025e	2026e	2027e	2028e	2029e	2030e
PromarkerD market penetration (%)	0.01%	0.05%	0.20%	0.30%	0.40%	0.50%
PromarkerEndo market penetration (%)	0.00%	0.05%	0.12%	0.25%	0.40%	0.50%
PromarkerEso market penetration (%)	0.00%	0.05%	0.12%	0.25%	0.40%	0.50%

Source: East Coast Research

We have assumed a 30% revenue share for PIQ for all diagnostic tests sold through the DTC model, significantly higher than the 5-15% licensing fees PIQ might retain under a licensing agreement. We have then conservatively assumed a 75% gross margin as tests currently cost PIQ approximately US$10-20 each (produced under contract by an ISO 13485 manufacturer in France)—minimal compared to the assumed product pricing of US$390 per test.

WACC, capital costs and exchange rate assumptions: PIQ's proposed direct-to-consumer (DTC) approach is designed to be capital-efficient, but the company will still need to allocate a significant portion of its cash flow from product sales in the first 2-3 years to marketing, awareness campaigns, and scaling efforts. Therefore, we've assumed the company will need to raise A$8 million in FY25 and an additional A$4 million in FY26 to cover commercialization costs and provide working capital, supplementing revenue from Analytical Services and R&D tax incentives. After this, we expect accelerated sales from various tests to generate free cash flow, allowing the company to fund its growth internally.

We have also assumed PIQ will remain debt-free and have applied a discount rate (WACC) of 14.2% to project free cash flows in our DCF model.

We have projected free cash flows through FY30 and then calculated a terminal value based on a terminal growth rate assumption of 2%. This rate reflects the expectations for global population growth as well as the anticipated increase in diabetes and esophageal cancer cases, driven primarily by sedentary lifestyles, widespread obesity, and rising consumption of processed foods in developed nations. Additionally, we have used a fixed AUD/USD exchange rate of 0.67 in our calculations.

Our DCF model has yielded a valuation of A$2.59 in the base case scenario and A$3.10 in the bull case scenario for PIQ. Our did-point fair valuation of A$2.84 represents a 331% upside potential to the latest share price of A$0.66. Below is the summary of our final valuation range (**Figure 16**).

Our DCF valuation indicates a substantial upside potential to PIQ's current share price

Figure 16: DCF valuation for PIQ (post financing)

PIQ Valuation (A$m)	Base case	Bull case
Present value of FCF	91	125
PV of Terminal FCF	296	339
Firm Value	**387**	**464**
Net debt (cash)*	(6.2)	(6.2)
Total Equity Value (A$)	**393**	**470**
Minority interest	7	8
Equity attributable to PIQ shareholders	**386**	**462**
Diluted shares no. (post-financing)^	149	149
Implied price (A$ cents)	**2.59**	**3.10**
Current price (A$)	0.660	0.660
Upside (%)	*292.5%*	*369.5%*
Mid-point fair valuation (A$)	**2.84**	
Upside (%)	*331.0%*	
Price / NAV (X)	0.23x	

**As of 30 June 2024*

^We have assumed 14.4m new shares will be issued across FY25 and FY26. The figure includes 3.6m of options and performance rights as well.

Source: East Coast Research

Our valuation of PIQ is highly sensitive to changes in WACC and terminal growth rate assumptions, as depicted in (**Figure 17**).

Figure 17: Sensitivity of intrinsic value to the discount rate and terminal growth rate (base case)

		WACC						
	2.59	11.2%	12.2%	13.2%	14.2%	15.2%	16.2%	17.2%
Terminal Growth Rate	0.5%	3.36	2.96	2.63	2.35	2.12	1.91	1.74
	1.0%	3.50	3.07	2.72	2.43	2.18	1.97	1.78
	1.5%	3.65	3.19	2.82	2.50	2.24	2.02	1.83
	2.0%	3.83	3.33	2.92	**2.59**	2.31	2.08	1.88
	2.5%	4.02	3.48	3.04	2.68	2.39	2.14	1.93
	3.0%	4.24	3.64	3.17	2.79	2.47	2.21	1.98
	3.5%	4.48	3.83	3.31	2.90	2.56	2.28	2.04

Source: East Coast Research

PIQ presents an attractive speculative opportunity

While there are still commercialisation risks, PIQ's Promarker™ diagnostic tests have demonstrated excellent accuracy across multiple clinical studies. In Addition, these tests can potentially save nations billions of dollars in cost savings through the early detection of various deadly diseases. Therefore, the question is not if, but when, they will be commercialised, in our opinion.

While speculative, we believe PIQ's risk-to-reward ratio makes it an appealing investment opportunity.

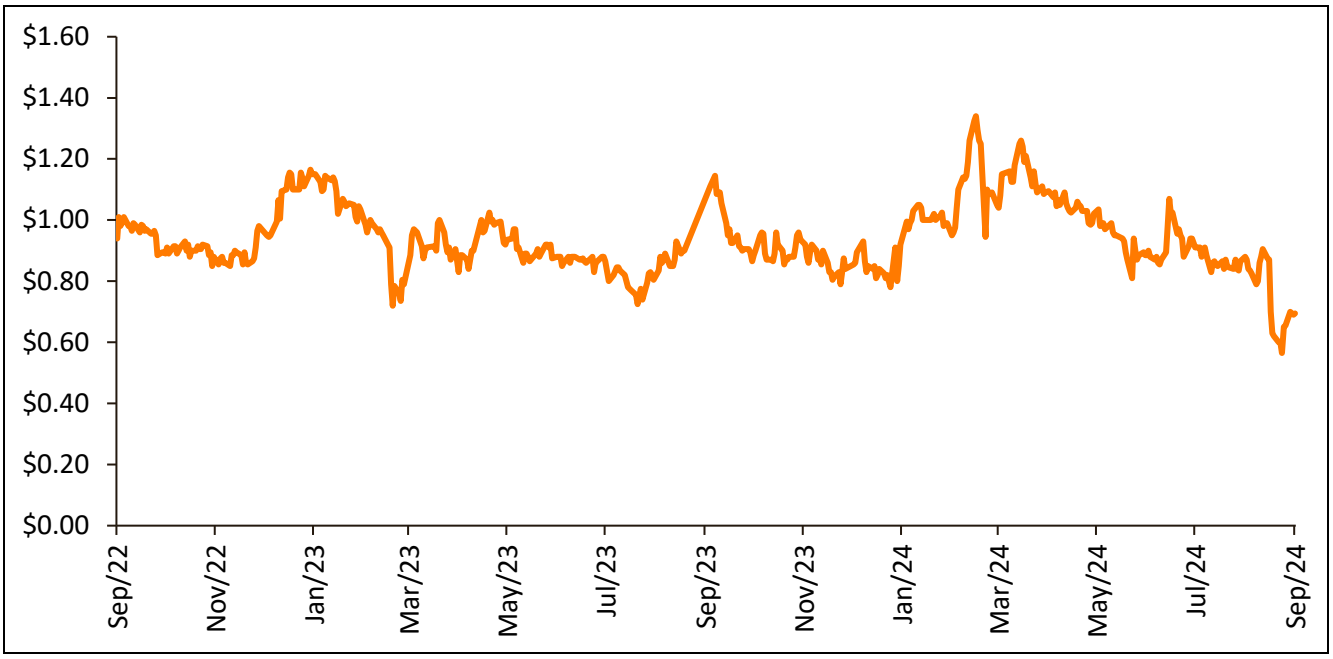
We view the US Medicare rebate approval for PromarkerD as further validation of its efficacy, which should accelerate market penetration in the US, as many patients may face no out-of-pocket costs. For PromarkerEndo and PromarkerEso, the high cost and invasive nature of current diagnostic methods make these tests appealing alternatives, with patients likely willing to pay out-of-pocket to avoid costly procedures like surgery or endoscopic biopsy.

With over 300 million potential users across key developed markets for PromarkerD, Endo, and Eso combined, even a modest uptake, such as the one assumed in our model, could lead to a stock valuation in multiples of the company's current market capitalisation.

Although commercialising these novel tests presents challenges, as seen with the unsuccessful Sonic Healthcare USA partnership in the US, we see this as a positive. PIQ has now opted for a more potentially profitable route by also selling directly to patients, leveraging recent advances in digital health to reach the market more effectively.

Additionally, the company has gained valuable insights from the commercialisation of PromarkerD, which it will leverage to achieve faster market entry for PromarkerEndo and PromarkerEso.

Figure 18: PIQ's share price has been a laggard in waiting for the commercialisation of PromarkerD. A successful commercialisation of any of Promarker™ diagnostic tests is expected to see a significant jump in PIQ's stock price



Source: Metastock and East Coast Research

Catalysts for re-rating of PIQ

We believe the following factors could drive a re-rating of PIQ, narrowing the gap to our valuation range:

PIQ is targeting a US launch of PromarkerD in H1 CY25 and an Australian launch of PromarkerD and PromarkerEso in Q1 CY25, and expects the first commercial sales of PromarkerEndo in Q2 CY25.

- **Commercial sales of PromarkerD in the US:** PIQ's share price declined following the termination of its licensing agreement with Sonic Healthcare USA. However, the company is now in discussions with several other potential licensing partners and, more importantly, is focused on a direct-to-customer/patient (DTC/DTP) strategy to accelerate PromarkerD sales in the US. PIQ has indicated that it is targeting a US launch in H1 CY25. We believe the commercial launch of PromarkerD will be a key catalyst for a re-rating of PIQ's share price, as it will demonstrate the commercial viability of the Promarker™ tests and address market concerns.

- **Commercial sales of PromarkerD in the rest of the world, in particular Europe, the UK and Australia:** PromarkerD is CE Mark registered, which means it can be sold in Europe. Growth Medics BV has been engaged to attract and manage regional distribution partners in Belgium, the Netherlands, Spain, and Italy, while Eurobio Scientific will handle distribution in France. These are key markets for PromarkerD where tens of millions of people are suffering from diabetes and its complications.

- **Commercial launch of PromarkerEso in Australia:** PIQ is preparing to launch PromarkerEso in Australia under ISO 15189 accreditation, targeting Q1 CY25, with other jurisdictions to follow in due course. In the US, the company will leverage its strong understanding of the Laboratory Developed Test (LDT) pathway and the Current Procedural Terminology (CPT) code reimbursement process to accelerate

commercialisation. PIQ is exploring both traditional out-licensing and direct-to-patient strategies as part of its refreshed go-to-market approach.

- **Commercial launch of PromarkerEndo:** PIQ has indicated it is targeting a launch of PromarkerEndo in Q2 CY25, building upon the strong diagnostic performance of its test in already completed clinical studies. In March 2024, Proteomics International also announced the signing of a Material Transfer Agreement with the renowned University of Oxford to obtain approximately 600 patient plasma samples for its endometriosis study. The analysis of these samples is expected to be completed in 2024. A successful completion of this clinical validation study will support the commercialisation of the PromarkerEndo test system.

- **Successful Clinical Study Results:** PIQ has a portfolio of diagnostic products at various stages of development. Positive outcomes from ongoing and future clinical studies for these tests are likely to boost investor sentiment and positively influence PIQ's stock market performance.

Key Risks

Although we think PIQ presents an attractive speculative opportunity, we see the following risks to our investment thesis:

- **Commercialisation risk:** While Promarker™ diagnostic tests, in particular PromarkerD, PromarkerEndo, and PromarkerEso, have demonstrated clinical validity and, in some cases, received regulatory approval for sale, they have not yet been commercially launched in any major market. Bringing a novel biopharmaceutical product to mass commercialisation presents inherent challenges. Manufacturing and supply chain complexities associated with producing and scaling novel diagnostic tests can lead to delays in revenue generation and profitability.

- **Market adoption risk:** Physicians and healthcare providers may be slow to adopt new treatments and diagnostic tests, especially if they are unfamiliar with the technology or if there are established alternatives.

While we have identified several key risks in investing in PIQ, we believe the most significant risk to our investment thesis is the commercialisation risk, given the inherent complexities of bringing a novel biopharmaceutical product to mass market.

- **Regulatory risk:** There is a risk that approval for PromarkerEndo and PromarkerEso in highly regulated markets, such as the US and Europe, takes longer than expected, resulting in a delay in achieving expected commercial success. At some point, PIQ may also need to secure FDA approval for the sale of PromarkerD in the US. Obtaining FDA approval could be significantly more challenging compared to the current Laboratory Developed Test (LDT) pathway.

- **Intellectual Property Concerns:** The pharma, biotech, and healthcare industries are rapidly evolving due to technological advancements, making the protection of intellectual property (IP), such as unique formulations and product designs, increasingly challenging. As the industry expands, IP disputes and patent challenges may emerge, particularly concerning innovative formulations and delivery methods.

- **Timing risk:** There is a risk that PIQ's clinical programmes and commercialisation of products may take longer to execute than expected, negatively affecting investor sentiment towards the company.

- **Competition risk:** There is a 'what if' scenario in which new and/or existing competitors develop a superior and more affordable product targeting the same market opportunity as PIQ. If this risk materialises, it could hinder the company's market share growth and margins.

- **Forex risk:** As management commercialises the products across different geographies, PIQ's earnings will be in the local currency of applicable markets. Currency fluctuations can impact the company's total earnings in A$.

- **Partnership and Distribution Challenges:** If the product is licensed to or distributed by another company, poor performance from that partner could negatively affect commercialisation. Entering international markets requires navigating different regulatory, pricing, and healthcare systems, increasing complexity and risk.

Appendix I: PIQ's SWOT Analysis

Figure 19: SWOT analysis

Strengths	Weakness
(1) PIQ's PromarkerD can predict the onset of chronic kidney disease up to four years in advance with an 86% accuracy. (2) PromakerD has achieved a US Medicare reimbursement price of US$390 per test with the commercial launch in the US targeted for H1 CY25. (3) PIQ's PromarkerEndo has demonstrated approximately 90% accuracy in clinical studies for diagnosing endometriosis through a novel blood test, in contrast to the current standard of care, which requires invasive surgery for diagnosis. (4) PIQ's PromarkerEso has demonstrated 94% accuracy in clinical studies for diagnosing esophageal cancer through a novel blood test, compared to the current standard of care, which requires costly and time-consuming endoscopy with biopsy. (5) Mass addressable markets for PromakerD, Endo and Eso diagnostic tests, estimated at over US$110 billion. (6) revenue from Analytical Services is partially offsetting the cash burn from R&D activities. (7) PIQ has a highly experienced leadership team in place with deep experience in medical technology and a large skin in the game.	(1) None of PIQ's diagnostic tests have yet been commercially launched in any major market. The commercialisation of a novel biopharmaceutical product poses significant challenges, including manufacturing and supply chain complexities. These issues, particularly in scaling up the production of diagnostic tests, can result in delays in revenue generation and profitability. (2) PromarkerEndo and PromarkerEso do not have regulatory approvals for sales in highly regulated markets, such as the US and Europe. (3) Currently, PIQ does not generate free cash flows and is reliant on capital raisings to fund its operations.
Opportunities	**Threats**
(1) PIQ's Promarker™ technology allows for the development of innovative diagnostic tests that are superior to the existing methods and the company has a range of novel diagnostic tests in its pipeline. (2) PromarkerD is permitted for sale in the EU market, which presents a massive sales growth opportunity independent of successful commercialisation in the US. (3) The sales potential for PromarkerEndo and PromarkerEso is enormous. PIQ is planning to launch PromarkerEso in Q1 CY25, with the PromarkerEndo launch scheduled for later in the same year.	(1) At some point, PIQ may need to secure FDA approval for the sale of PromarkerD in the US. Obtaining FDA approval could be significantly more challenging compared to the current Laboratory Developed Test (LDT) pathway. (2) Superior products may be developed by other researchers. (3) The revised hybrid traditional and direct-to-consumer/patient (DTC/DTP) go-to-market strategy could potentially be more capital-intensive than initially anticipated.

Source: East Coast Research

Appendix II: Highly experienced leadership team in place

Proteomics International's leadership team brings extensive and varied experience from the life sciences, healthcare, and finance sectors (Figure 20).

Figure 20: Proteomics International's management and board

Name and Designation	Profile
Mr Neville Gardiner **Chairman & Independent Non-Executive Director**	• Neville is an experienced finance professional with over 30 years of expertise in advising public and private company boards on mergers and acquisitions, project development, capital markets, and complex transactions. He was a Partner at Deloitte in Mergers & Acquisitions after co-founding and leading Torridon Partners, which was later acquired by Deloitte in 2016. • Neville has also held senior roles at Macquarie Bank, Bank of America Merrill Lynch, and Arthur Andersen, with experience across various sectors including health tech, mining, infrastructure, and energy. He joined PIQ's Board in November 2021.
Dr Richard Lipscombe **Managing Director**	• Richard, a co-founder of the company, is an accomplished business manager and expert in protein chemistry with over 30 years of international experience in Australia, the USA, and the UK. His expertise spans chemistry, immunology, mass spectrometry, peptide synthesis, high-performance computing, and robotics. • Richard holds a chemistry degree from Oxford University, a PhD in immunology from London University, and has worked as a post-doctoral scientist in molecular immunology. After managing the Protein Analysis Facility at the University of Western Australia, he co-founded Proteomics International in 2001. Richard is also well-published and holds several patents.
Dr James Williams **Non-Executive Director**	• Dr. Williams is a seasoned manager, director, scientist, and investor with over 25 years of experience in the life sciences industry. He has held leadership roles in numerous biotech companies, contributing to the commercialisation of five FDA-approved drugs and medical devices. Notably, he developed the technology behind iCeutica Inc. (acquired in 2011) and co-discovered a lead therapy for Dimerix Limited (ASX: DXB), now in Phase 3 trials for Chronic Kidney Disease. • Currently, Dr. Williams serves as CEO of Health Translation Group Ltd, a Director of the Perron Institute for Neurological and Translational Science, and agriculture start-up Demagtech. He is also part of the WA State Government's Health and Medical Life Sciences Industry Advisory Group. His previous roles include co-founder and Investment Director of Yuuwa Capital, Director of Linear Clinical Research.
Mr Paul House **Non-Executive Director**	• Paul has over 30 years of experience with multinational corporations and is currently the CEO and Managing Director of Imdex (ASX: IMD). He previously served as Managing Director of SGS India, overseeing 4,500 staff and 38 laboratories. Paul has held CFO and COO roles, delivering business performance targets, revenue growth, and market share across various sectors. • Paul is a Fellow of the Australian Institute of Management and a Graduate Member of the Australian Institute of Company Directors. Paul joined the Board in November 2017.

Mr Roger Moore **Non-Executive Director**	• Roger has 40 years of experience in the international pharmaceutical industry, including nearly 30 years as President of Novo Nordisk Japan, a global leader in diabetes care and obesity therapies. He was the first employee of Novo Nordisk in Japan, establishing the company's presence there in 1977, and served until his retirement as Chairman in 2007. • Roger also served as Senior Vice President overseeing Japan, Australia, New Zealand, and the Pacific, and was a member of Novo Nordisk's Senior Management Board. Roger was awarded the Knight's Cross of the Order of the Dannebrog in 2007. He joined the Board in October 2016.
Ms Jacqueline Gray **Chief Financial Officer and Head of Corporate Development**	• Jacqueline brings over 25 years of experience as a Senior Finance Executive, having worked with several global companies in London and high-growth, emerging businesses across the medical technology, SaaS, digital marketing, e-commerce, retail, and renewables sectors in Perth. • Jacqueline has a strong track record in developing and implementing strategy, building high-performing teams, and managing M&A and post-merger integration. Her past roles include Finance Director at the Economist Intelligence Unit, senior positions at BBC Worldwide, and Financial Controller for multiple hospitals and medical facilities with Healthcare of Australia. Jacqueline also oversees the Company's Corporate Development, with a particular focus on PromarkerEndo.

Source: East Coast Research

Appendix III: Patents

PIQ's diagnostic tests in advanced development stages are protected by granted or pending patents in key developed and high-population markets.

PIQ owns three families of patents for PromarkerD in key markets for Diabetic Kidney Disease, biomarkers associated with pre-diabetics, diabetes and diabetes-related conditions (International patent application PCT/AU2011/001212), and kidney disease. PromarkerD intellectual property portfolio covers 72% of the world's population living with diabetes. All patents are valid until 2031.

You can find the company's patent coverage details for PromarkerEndo and PromarkerEso in the following figures:

Endometriosis		
Title: "Endometriosis biomarkers"		
Derived from International Patent Application PCT/AU2021/050227		
If granted, patent projected to be valid until March 2041		
Country/Region	**Application/ Patent No.**	**Status**
Australia	AU2021237128	Pending
Brazil	BR112022018339	Pending
Canada	CA3169082	Pending
China	CN115349091	Pending
Europe	EP4121776	Pending
India	202217049212	Pending
Japan	JP2023520132	Pending
Singapore	11202252510K	Pending
US	US2023089507	Pending
Indonesia	P00202211148	Pending
Republic of Korea	KR20220154725	Pending
Mexico	MX/a/2022/011397	Pending

Oesophageal Cancer		
Title: "Glycoprotein biomarkers for esophageal adenocarcinoma and Barett's esophagus and uses thereof"		
Derived from International Patent Application PCT/AU2015/050723		
All patents valid until November 2035		
Country/Region	**Application/ Patent No.**	**Status**
Australia[4]	AU2015349613	Granted
Canada[4]	CA2967869	Pending
China[4]	CN107430126	Granted
Europe[4,5]	EP3221701	Granted/ Validated
Hong Kong[4]	HK1244877	Granted
United States[4]	US2022018843	Pending

Oxidative Stress (2-Tag)		
Proteomics International owns two families of patents for Two-Tag in key markets with others pending		
1) Title: "Methods for determining the redox status of proteins"		
Derived from International Patent Application PCT/AU2006/001757		
All patents valid until November 2026		
Country/Region	**Patent No.**	**Status**
Australia	AU2006317506	Granted
USA	US8043824	Granted
2) Title: "Methods for measuring relative oxidation levels of a protein"		
Derived from International Patent Application PCT/AU2019/050267		
If granted, all patents projected to be valid until March 2039		
Country/Region	**Application/ Patent No.**	**Status**
Australia	AU2019240758	Pending
Canada	CA3094249	Pending
China	CN112020650	Pending
Europe[6]	EP3775927	Granted
India	IN202017044154	Pending
Indonesia	P00202007798	Pending
Japan	JP7325436	Granted
Singapore	SQ11202008979Q	Pending
USA	US2021041449	Pending

Appendix IV: Financial Statement

Profit & Loss (A$'M)	2023	2024	2025e	2026e	2027e	2028e	2029e	2030e
Revenue	**3.2**	**3.3**	**4.7**	**23.7**	**62.9**	**113.3**	**169.4**	**213.3**
Operating expenses	(9.0)	(9.3)	(14.2)	(22.5)	(35.4)	(50.0)	(64.0)	(75.0)
EBITDA	**(5.8)**	**(6.0)**	**(9.5)**	**1.2**	**27.5**	**63.3**	**105.3**	**138.3**
Depn & Amort	0.0	(0.7)	(0.1)	(0.1)	(0.2)	(0.3)	(0.5)	(0.8)
EBIT	**(5.8)**	**(6.7)**	**(9.6)**	**1.1**	**27.4**	**63.0**	**104.9**	**137.6**
Finance Cost	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0
Profit/(Loss) before tax	**(5.7)**	**(6.5)**	**(9.6)**	**1.1**	**27.4**	**63.0**	**104.9**	**137.6**
Tax expense	0.0	0.0	0.0	(0.3)	(8.2)	(18.9)	(31.5)	(41.3)
NPAT	**(5.7)**	**(6.5)**	**(9.6)**	**0.8**	**19.1**	**44.1**	**73.4**	**96.3**

Cash Flow (A$'M)	2023	2024	2025e	2026e	2027e	2028e	2029e	2030e
Profit after tax	(5.7)	(6.5)	(9.6)	0.8	19.1	44.1	73.4	96.3
Depn & Amort	0.0	0.7	0.1	0.1	0.2	0.3	0.5	0.8
Changes in working capital	(0.3)	(0.7)	(0.6)	(1.0)	(2.1)	(2.8)	(3.1)	(2.4)
Other operating activities	0.3	0.8	0.0	0.0	0.0	0.0	0.0	0.0
Operating cashflow	**(5.7)**	**(5.6)**	**(10.1)**	**(0.2)**	**17.2**	**41.6**	**70.8**	**94.6**
Purchase of plant and equipment	(1.2)	(0.4)	(0.1)	(0.5)	(1.3)	(2.3)	(3.4)	(4.3)
Other investing activities	0.0	0.0	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)
Investing cashflow	**(1.2)**	**(0.4)**	**(3.1)**	**(3.5)**	**(4.3)**	**(5.3)**	**(6.4)**	**(7.3)**
Equity raised (repurchased)	10.8	6.6	8.0	4.0	0.0	0.0	0.0	0.0
Net proceeds from borrowings	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Finanncing activities	(0.1)	(0.0)	0.0	0.0	0.0	(0.0)	(0.0)	0.0
Net change in cash	3.9	0.6	(5.2)	0.4	12.9	36.4	64.4	87.4
Cash at End Period	6.0	6.6	1.5	1.9	14.8	51.1	115.6	202.9

Balance Sheet (A$'M)	2023	2024	2025e	2026e	2027e	2028e	2029e	2030e
Cash	6.0	6.6	1.5	1.9	14.8	51.1	115.6	202.9
Total Assets	10.1	10.9	5.7	7.7	24.4	66.2	137.4	231.3
Total Liabilities	1.8	1.6	1.2	1.4	2.0	2.7	3.4	4.0
Shareholders' Funds	8.3	9.2	4.5	6.3	22.5	63.6	134.0	227.3

Ratios	2023	2024	2025e	2026e	2027e	2028e	2029e	2030e
Net debt (cash)/Equity	-	-67.1%	-23.0%	-22.4%	-63.8%	-79.7%	-85.9%	-89.1%
Total Cash / Total Assets	-	61.1%	25.9%	23.9%	60.4%	77.2%	84.1%	87.7%
Return on Equity (%)	-	NM	NM	14.1%	133.2%	102.6%	74.3%	53.3%

Source: East Coast Research Estimates

Appendix V: Analyst's Qualifications

Behzad Golmohammadi, the lead analyst on this report, is an equity research analyst at Shares in Value (East Coast Research).

- Behzad has a bachelor's degree in Engineering (Industrial) and a master's degree in Applied Finance (Investing) from Sydney Business School, where he was the top performer in his cohort. He has also passed the first two levels of the CFA Program.
- Behzad has several years of experience working as an Equity Research Analyst and Technical Analyst in Australia and overseas and has a broad knowledge of ASX-listed companies.

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