Proteomics International Laboratories Ltd

(PIQ $0.51) Speculative Buy - Initiation of Coverage

EUROZ HARTLEYS

Analyst	Date	Price Target
Seth Lizee	17th November 2020	$1.00/sh

Initiation of Coverage

Investment case

Proteomics International Laboratories Ltd (PIQ) is a Perth based medical technology company. Currently in the process of commercializing its novel diabetic kidney disease test, PromarkerD, the business has an additional pipeline of 10 other diagnostic tests in various stages of development and commercialization. This is in addition to a growing world class analytical services business; the income from which offsets PIQs overall cash burn.

Our investment case is predicated on the commercialization and rollout of PromarkerD. If PIQ can deliver on near term milestones and, in time, first sales, we believe the stock can trade up, perhaps substantially.

We initiate coverage on Proteomics International Laboratories Ltd with a Speculative Buy recommendation and 12-month Price Target of $1.00/sh, implying 96% upside from initiation.

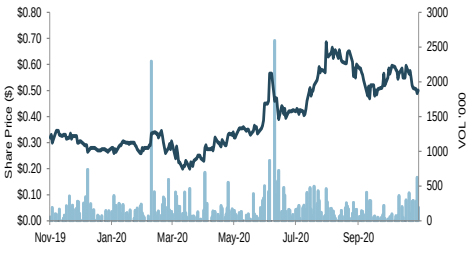
Investment Thesis

- **Massive Addressable Market** – There are an estimated 463m diabetics globally, this number is forecast to grow to 700m by 2045. 40% of these people will go onto eventually develop diabetic kidney disease ("DKD"). Sufferers develop serious co-morbidities before eventually going on (if they survive) to developed Kidney failure, requiring highly expensive dialysis or transplant.
- **Testing Limitation: Underdiagnosis** – DKD is asymptomatically present in most sufferers. Symptoms typically don't develop until later and more serious stages are reached, highlighting the need for testing. Current tests are limited to diagnosis, having essentially no predictive capacity, diagnostic ability is further burdened by limitations – overall leading to under-diagnosis.
- **Solution to Early Detection** – PromarkerD addresses a number of these current testing issues, specifically within early detection, providing physicians the ability to predict the onset of DKD up to 4 years in advance and with 86% accuracy.
- **Clinically Validated** - PromarkerD has been clinically validated in 4 peer-reviewed clinical studies on over 5,000 patients.
- **Game Changing Drugs: Early Treatment Possible** – A new class of drugs, gliflozins, are creating hope for early treatment, last year saw the first drug to be approved by the FDA for the treatment of DKD in 20yrs. This is significantly strengthening the value of early detection.
- **Big Pharma Partnership: Big Opportunities** – PIQ is currently collaborating with pharmaceutical giant Janssen, having already completed a successful stage 1 study, the results from the anticipated second stage are pending. These stage 2 results have the potential to open up significant commercial pathways.

Proteomics Int.Laboratories Ltd	Year End 30 June	
Share Price	$0.51	A$/sh
Price Target	**1.00**	**A$/sh**
Valuation (DCF)	1.00	A$/sh
WACC	20.0%	
Terminal Growth	2.5%	
Shares on issue	105	m
Market Capitalisation	53.0	A$m
Enterprise Value	44.3	A$m
Cash (Pro-forma)	8.8	A$m
Debt (inc. AASB16)	0.1	A$m

Key Financials	2020a	2021f	2022f
Revenue (A$m)	3.0	2.9	4.7
EBITDA (A$m)	-1.4	-2.0	-1.0
EBIT (A$m)	-1.7	-2.4	-1.3
Reported NPAT (A$m)	-1.8	-2.4	-1.4
Normalised NPAT (A$m)	-2.2	-2.4	-1.4
Gross Cashflow (A$m)	-1.2	-2.1	-1.1
Capex (A$m)	-1.4	-0.3	-0.3
Op. Free Cashflow (A$m)	-1.8	-2.3	-1.4
Revenue Growth (%)	11%	-2%	60%
EBITDA Growth (%)	-17%	47%	-52%
Norm. NPAT Growth (%)	14%	10%	-44%
Normalised EPS (Ac)	-2.26	-2.21	-1.25
Norm. EPS growth (%)	0.00	-0.02	-0.44
PER (x)	-22.3	-22.8	-40.5
EV:EBITDA (x)	-32.1	-21.9	-45.2
EV:EBIT (x)	-25.4	-18.5	-33.0
Net Debt (A$m)	-2.2	-6.0	-4.5
Net Debt:Equity (%)	-50%	-74%	-68%
Interest Cover (x)	na	na	na

Share Price Chart



Disclaimer

Euroz Hartleys Securities declares that it has acted as underwriter to and/or arranged an equity issue in and/or provided corporate advice to Proteomics International Laboratories Ltd during the last year. Euroz Hartleys Securities has received a fee for these services.

This analyst declares that he has a beneficial interest in Proteomics International Laboratories Ltd.

Proteomics International Laboratories Ltd

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- **Large Diagnostic Pipeline** – PIQ has leveraged its Promarker™ Platform to build a large pipeline of 10 novel diagnostic tests, all in various stages of research, development and commercialization. The tests target large addressable markets; individually they could each create numerous opportunities for PIQ.
- **Growing Analytical Services** – PIQ's growing and world leading analytical services business continues to offset the company's cash burn.
- **Experienced Board & Management** – PIQ boasts an experienced Management Team and Board of Directors displaying both commercial and technical backgrounds. Directors are well aligned owning ~24.7% (pre placement) of the business.
- **Attractive Valuation** – PIQ trades at a 49% discount to our $1.00/sh. Valuation. With an EV of $44.3m, we believe there is a highly attractive risk-to-reward balance with PIQ.
- **Upcoming Catalyst** – We note a number of short to medium term, catalyst lie ahead:

	CY'2020			CY'2021		
Key Catalyst	**Dec'Q**	**Mar'Q**	**Jun'Q**	**Sep'Q**	**Dec'Q**	**+CY'2022**
PromarkerD						
Further Licensing Deals						
Janssen Stg. 2 Results						
First Sales						
US Reimbursement Code						
Regulatory Approvals (FDA)						
Promarker™						
Endometriosis Update						
Giardia Update						
Analytical Services						
New contracts						

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Financial Statements	2019a	2020a	2021f	2022f
Income Statement				
PromarkerD Royalties	0.0	0.0	0.3	2.0
Analysis Business	1.5	1.4	1.6	1.7
Other Income	1.2	1.6	1.1	1.0
Total Sales	2.7	3.0	2.9	4.7
(-) COGS	0.0	0.0	-0.1	-0.4
Gross Profit	2.7	3.0	2.9	4.3
(-) OPEX	-4.3	-4.4	-4.9	-5.3
EBITDA	**-1.7**	**-1.4**	**-2.0**	**-1.0**
(-) D&A	-0.2	-0.4	-0.4	-0.4
EBIT	**-1.9**	**-1.7**	**-2.4**	**-1.3**
(-) Net Finance	0.0	0.0	0.0	0.0
(-) Other Expenses	-0.2	0.0	0.0	0.0
EBT	**-2.1**	**-1.8**	**-2.4**	**-1.4**
(-) Tax	0.0	0.0	0.0	0.0
Reported NPAT	**-2.1**	**-1.8**	**-2.4**	**-1.4**
(+/-) Abnormals	0.2	-0.4	0.0	0.0
Norm NPAT	**-1.9**	**-2.2**	**-2.4**	**-1.4**

Cash flow (A$m)	2019a	2020a	2021f	2022f
Profit Before Tax	**-2.1**	**-1.8**	**-2.4**	**-1.4**
(+) D&A	0.2	0.4	0.4	0.4
(+) FX loss/(gain)	0.0	0.0	0.0	0.0
(+) Share base payments	0.3	0.1	0.0	0.0
(-) Tax Paid	0.0	0.0	0.0	0.0
(+/-) Other	0.0	0.0	-0.1	-0.1
Gross Cashflow	**-1.6**	**-1.2**	**-2.1**	**-1.1**
(-) Capital Expenditure	0.0	-1.4	-0.3	-0.3
(-) Change in NWC	0.0	0.8	0.1	-0.1
Operating Free Cashflow	**-1.7**	**-1.8**	**-2.3**	**-1.4**
(-) acq of subs/other Invst.	0.0	0.0	0.0	0.0
(+) Proc. from disp of FA/subs	0.9	0.0	0.0	0.0
(-) Dividends Paid	0.0	0.0	0.0	0.0
(+) Equity issued	0.1	3.3	6.0	0.0
(+/-) Other	0.0	-0.4	0.0	0.0
Net Cashflow	**-0.7**	**1.0**	**3.7**	**-1.4**
BoP Net Cash	2.0	1.3	2.2	6.0
(+/-) Net Cashflow	-0.7	1.0	3.7	-1.4
(+/-) AASB16	0.0	-0.1	0.0	0.0
EoP Net Cash	**1.3**	**2.2**	**6.0**	**4.5**

Balance Sheet ($m)	2019a	2020a	2021f	2022f
Cash	1.5	2.4	6.1	4.6
Receivables	0.5	0.4	0.4	0.6
Other Assets	1.2	1.4	1.4	1.4
Total Current Assets	**3.2**	**4.1**	**7.8**	**6.6**
PP&E	0.2	1.3	1.2	1.2
Other Assets	0.2	0.0	0.0	0.0
ROUA	0.0	0.1	0.1	0.1
Intangible Assets	0.0	0.0	0.0	0.0
Total Non-current Assets	**0.4**	**1.4**	**1.4**	**1.3**
Total Assets	**3.6**	**5.6**	**9.2**	**7.9**
Payables	0.3	0.4	0.5	0.6
Borrowing	0.1	0.0	0.0	0.0
Lease Liabilities	0.0	0.1	0.1	0.1
Provisions	0.1	0.1	0.1	0.1
Total Current Liabilities	**0.5**	**0.6**	**0.7**	**0.8**
Payables	0.0	0.3	0.3	0.3
Borrowing	0.0	0.0	0.0	0.0
Lease Liabilities	0.0	0.1	0.1	0.1
Provisions	0.1	0.1	0.1	0.1
Total Non-Current Liabilities	**0.1**	**0.5**	**0.5**	**0.5**
Total Liabilities	**0.6**	**1.1**	**1.2**	**1.2**
Net Assets	**3.0**	**4.4**	**8.0**	**6.7**
Issued Capital	10.5	13.4	19.4	19.4
Reserves	0.7	1.1	1.1	1.1
Accumulated Losses	-8.3	-10.0	-12.4	-13.8
Total Equity	**3.0**	**4.4**	**8.0**	**6.7**

Performance Ratios	2019a	2020a	2021f	2022f
Growth & Margins				
Revenue Growth	na	11%	-2%	60%
EBITDA Growth	na	-17%	47%	-52%
EBIT Growth	na	-16%	37%	-44%
Normalized Net Profit Growth	na	14%	10%	-44%
EBITDA margin	-62%	-46%	-69%	-21%
EBIT margin	-69%	-58%	-82%	-29%
Normalized net profit margin	-71%	-73%	-82%	-29%
Effective tax rate	0%	0%	0%	0%
Liquidity				
Capex/depreciation	0.2	3.8	0.7	0.7
Current ratio	5.9	6.6	11.5	8.7
Quick ratio	6.6	6.1	12.7	9.0
Receivable days	68.1	44.4	44.4	44.4
Payable days	25.4	37.4	37.4	37.4
Risk Measures				
Dividend Cover	na	na	na	na
Payout ratio	0%	0%	0%	0%
Net interest cover	na	na	na	na
Net debt/equity	-45%	-50%	-74%	-68%
Returns				
ROIC	-59%	-39%	-30%	-20%
ROA	-53%	-39%	-26%	-17%
ROE	-64%	-49%	-30%	-20%

Share Data/Valuation	2019a	2020a	2021f	2022f
Share Data				
Issued shares	80.7	92.4	104.9	104.9
Weighted ave shares	80.4	86.5	98.7	104.9
Fully diluted shares	84.7	96.4	108.9	108.5
Basic EPS	-2.6	-1.9	-2.3	-1.3
YoY change	na	-0.3	0.2	-0.4
Fully diluted EPS	-2.5	-1.8	-2.2	-1.2
YoY change	na	-0.3	0.2	-0.4
Fully diluted normalised EPS	-2.3	-2.3	-2.2	-1.2
YoY change	na	0%	-2%	-44%
Dividend/share	0.0	0.0	0.0	0.0
Franking	na	na	na	na
Gross cashflow/share	-2.0	-1.3	-2.0	-1.0
NBV/share	3.7	4.8	7.7	6.4
NTA/Share	3.7	4.8	7.7	6.4
Valuation				
PER (Basic)	-19.6	-26.6	-22.0	-39.2
PER (Fully diluted)	-20.6	-27.8	-22.8	-40.5
PER (Fully diluted, normalized)	-22.4	-22.3	-22.8	-40.5
P/CFPS	-25.2	-37.7	-25.3	-50.3
Price/NBV	13.6	10.5	6.6	7.9
Price/NTA	13.6	10.5	6.6	7.9
Dividend Yield	0.0	0.0	0.0	0.0
EV/EBITDA	-26.6	-32.1	-21.9	-45.2
EV/EBIT	-23.9	-25.4	-18.5	-33.0
EV/Revenue	16.5	14.8	15.1	9.5

Other Information

Major shareholders:
Estimated free float:
12-mth High/Low (A$/sh)
Average daily volume (A$m)
ASX Code
Next result

Company Description

Proteomics International Laboratories Ltd (PIQ) is a Perth based medical technology company. Currently in the process of commercializing its novel diabetic kidney disease test, PromarkerD, the business has an additional pipeline of 10 other diagnostic tests in various stages of development and commercialization, in addition to a growing world class analytical services business.

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Executive Summary

In the following pages we provide detailed analysis in relation to the problem, solution and opportunity present. We have summarised this detailed analysis below.

Proteomics International Laboratories Ltd (PIQ) is a Perth based medical technology company.

Our investment case rests on the commercialisation of the company's novel predictive diagnostic test for Diabetic Kidney Disease, PromarkerD. Developed and validated in 4 clinical studies, including a 3rd party study with Janssen (subsidiary of Johnson & Johnson). The test can predict DKD with 86% accuracy up to 4 years out.

DKD is a chronic disease in which diabetes progressively damages the blood vessels in the kidneys. This irreversible damage gradually reduces kidney function, leading to numerous complications and in severe cases leading to kidney failure (end-stage renal disease) where the only treatments options are lifelong dialysis or kidney transplant. Both significantly reduce life expectancy and quality of life.

Dialysis costs an estimated US$72,000 per year per patient in the United States, with DKD costing Medicare US$39bn per year alone, roughly 14% of its annual budget. This not even including other massive costs arising from the complications of DKD.

The problem at hand is massive, with the International Diabetes Foundation estimating there are ~463m people (diagnosed and undiagnosed) with diabetes globally. This is expected to grow to 700m people by 2045, of these people ~40% will go onto developed DKD.

DKD progresses as a silent disease, most patients (9 out of 10) remain asymptomatic with kidney damage or reduced function. Symptoms do not typically appear until later and more severe stages are reached, and the damage has already occured.

We see the clear need for greater testing, especially early stage.

Despite this need, the current gold standard tests used have a number of limitations. Principally the near complete lack in predictive capacity. The current tests can only determine whether someone does or doesn't have DKD. This diagnostic aspect is even faced with limitations, especially in early stages of DKD, having the propensity to under-diagnose in certain circumstances.

A number of these issues are addressed by PromarkerD – primely the ability to predict the onset of DKD, solving a number of issues in early stage diagnosis.

The argument toward using PromarkerD has only become more compelling in the last 2 years, with the introduction of a new class of drugs, 'gliflozin's', for treating DKD. Janssen's Canagliflozin (Invokana™) drug approved September last year became the first drug in 20 years to be approved for the treatment of DKD – significantly increasing the value of early detection.

Early detection allowing early treatment has the potential to unlock significant financial savings globally, reducing a massive burden born by health care systems.

Every person who is stopped or even slowed from developing ESRD and needing dialysis is $72,000 saved per year – achieved across thousands of people, potentially billions in savings can be achieved.

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Additionally ,PromarkerD has the potential to support more personalised and targeted patient solutions – possibly reducing the need for expensive treatments.

Beyond the financial savings gained from private insurers and governments, there remains financial incentives to be had from major pharmaceutical companies through the deployment and use of PromarkerD.

These incentives manifest in the use of PromarkerD as a Complementary Diagnostic (CDx) test, providing physicians justification for early treatment solutions – such as Janssen's Canagliflozin drug. This could lead to PromarkerD being used upon prescription of drug treatments and/or throughout course of treatment (potentially lifetime).

This highlights the potentially significant opportunity which could come from PIQs collaboration with Janssen (a subsidiary of Johnson & Johnson), having already completed a clinical study (stage 1) independently validating PromarkerD. This collaboration was further expanded into a second stage to determine if PromarkerD can help assess the effectiveness of canagliflozin as a treatment for DKD, we would expect results by early CY'21. If the results demonstrate the ability to halt or reduce DKD risk then there would be solid grounds for the test to be used as a complementary diagnostic (CDx) test, possibly accelerating PromarkerD adoption.

PIQ is currently in the process of commercialising PromarkerD, having already signed licensing agreements in Mexico, Dominican Republic, Spain, Italy and Israel. Rollout has been delayed by COVID-19, we expect first PromarkerD sales in 1H'CY21 before scaling in parallel to achieving a number of commercial milestones – highlighted below as key catalyst.

Beyond this, PIQ has a further 10 novel diagnostic tests in its Research and development pipeline. These tests, in various stages of research, development and commercialisation, all of which have massive potential. All aim to address largely unmet medical needs currently faced, such as with Endometriosis – a debilitating condition affecting 1 in 9 women, whereby current diagnosis typically takes 9 to 12 years and is estimated to cost +A$10bn in Australia alone.

This leads onto PIQs growing Analytical Services business, broadly described as the most accredited protein testing laboratory in the world. The highly accredited business is exposed to a number of growing markets, overall having underwritten PIQs R&D work through slowing the consolidated businessed cash burn.

PIQ is well funded with $8.8m in cash (pro-forma) and no debt post it completing a $6m capital raising and receiving $1.1m in R&D grants.

Also, PIQ further features a highly experienced managment team and board of directors. Lead by founder and managing director Dr Richard Lipscombe, the team displays technical and commercial backgrounds. The board and management are highly aligned with shareholders – owning 24.7% (pre placement) of PIQ.

Our forecasts are driven by sales in regions with current agreements as well as the United States, our forecasts anticipate modest levels of penetration (10%) by 2030, with conservative royalty assumptions. We view the investment opportunity as highly attractive on valuation, we initiate coverage with a speculative buy recommendation and a $1.00/sh valuation and PT.

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We highlight material short to medium term catalyst:

	CY'2020			CY'2021		
Key Catalyst	**Dec'Q**	**Mar'Q**	**Jun'Q**	**Sep'Q**	**Dec'Q**	**+CY'2022**
PromarkerD						
Further Licensing Deals						
Janssen Stg. 2 Results						
First Sales						
US Reimbursement Code						
Regulatory Approvals (FDA)						
Promarker™						
Endometriosis Update						
Giardia Update						
Analytical Services						
New contracts						

Source: EHSL estimates

We anticipate PIQ to trade up upon achieving these catalyst, potentially substantially on some. Indicatively based on the response by the investment community to milestones achieved by other companies these share price trade ups could be in excess of 100% in some circumstances. This however, is only meant to provide guidance to positive share price response and the opportunity and is not a price target. We explore these comparable market responses further on.

Key Risks to Investment

We highlight risk factors relevant to our investment case:

Reimbursement/Coverage – Achieving reimbursement/coverage, within our forecasted operating regions, remains foundational to driving adoption and hence sales. Failure to receive payor coverage is likely to significantly hinder PIQs ability to generate any meaningful sales of PromarkerD, significantly impacting our investment thesis.

COVID-19 – No change or further deterioration in the pandemic remains a key risk to our forecast timelines. To date, commercialisation and planned rollouts have been put on hold as a result of COVID-19 per PIQs commentary in the annual report. Specifically, should no progress be made by mid next year then our timeline is likely to be delayed.

Regulatory – Changes to the current regulatory framework could impact operations, such as any changes to the LDT pathway in the United States. We note the updating to CE mark which shouldn't pose any issues, but investors should be made aware of.

Key relationships – PIQs commercial agreements and collaborations with various parties are important to the business's operations and future success. Loss or deterioration in any of these could impact the business.

Funding – Despite being well funded, funding will remain a risk until operating cashflow breakeven is achieved.

Dependence on Key personnel – A few key personnel, such as MD and founder Dr. Richard Lipscombe, have been critical in the company's development and progress to date. The loss of any of these key people could have material impacts on PIQ.

Competition – Although no direct competitors have been identified, the emergence of new technology always remains a possible risk.

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Valuation and Price Target

We Initiate coverage on PIQ with a $1.00/sh. Valuation and Price Target.

We have set our valuation based on a discounted cash flow (DCF) analysis of PIQ, we believe this method best accounts for the company's niche offering and its longer term potential.

However, in thinking about PIQs investment case we have further considered listed peers and recent industry peer transactions.

We have concluded there is a significant valuation (EV) difference between PIQ and both its listed peers and industry peer transactions. Although these peers are more commercially advanced with different product offerings, they are indicatively useful in showing PIQs potential. Specifically, if PIQ can demonstrate similar commercial progress we believe the stock can trade well and beyond our price target, potentially multiples of its current price.

We explore all of this in further detail below:

Discounted Cash Flow (DCF) Valuation

A summary of our discounted cash flow (DCF) valuation is presented below. We have forecasted free cashflows from 2021 through to 2031 with a terminal value that is grown at 2.5%. These cashflows have been heavily discounted using a WACC of 20%, we believe this captures the early stage nature of the company and its connected risks. Altogether we have calculated a $104.5m equity value for PIQ implying $1.00/sh.

FY		**2021**	**2022**	**2023**	**2024**	**2025**	//	**2031**
EBIT	A$m	-2.4	-1.3	1.4	7.7	19.8		64.1
(-) Tax	A$m	0.0	0.0	0.0	0.0	-4.5		-19.2
(+) D&A	A$m	0.3	0.3	0.5	0.4	0.4		0.5
(-) Capex	A$m	-0.3	-0.3	-1.3	-0.3	-0.3		-0.3
(-) Change in NWC	A$m	0.1	-0.1	-0.4	-0.8	-1.5		0.0
FCFF	**A$m**	**-2.3**	**-1.4**	**0.3**	**7.1**	**13.9**		**45.1**
Disc Factor	x	0.9	0.8	0.6	0.5	0.4		0.1
Disc FCFF	**A$m**	**-2.1**	**-1.1**	**0.2**	**3.8**	**6.1**		**6.7**
PV of Fcst's	A$m	56.5			WACC	20.0%		
PV of TV	A$m	39.3			TGR	2.5%		
EV	**A$m**	**95.9**						
(+) Cash	A$m	8.8						
(-) Debt	A$m	-0.1						
Equity Value	**A$m**	**104.6**						
(/) SOI, Fully Diluted	m	104.9						
Equity Value per Share	**A$/sh**	**1.00**						

We believe this model best captures the longer term value potential of PIQ. As PIQ begins to meet our milestones and de-risk itself we would anticipate this valuation to increase over time.

As a further analysis we have included sensitivities of some of the key assumptions which drive our valuation, these include:

- Average unit pricing
- Royalty Rate
- GP margin
- Discount rate and Terminal Growth Rate

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These sensitivities are shown below, we discuss the specific assumptions and inputs in addition to how we have set them further into this report.

Royalty Rate \ Average test Pricing (US$/test)	60	85	110	135	160	185	210	235
5.0%	0.24	0.38	0.51	0.64	0.77	0.90	1.03	1.16
7.5%	0.40	0.60	0.80	0.99	1.19	1.39	1.58	1.78
10.0%	0.56	0.82	1.09	1.35	1.61	1.87	2.13	2.39
12.5%	0.72	1.05	1.37	1.70	2.02	2.35	2.67	3.00
15.0%	0.88	1.27	1.66	2.05	2.44	2.83	3.22	3.61

Royalty Rate \ Market Penetration	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%	17.5%	20.0%
5.0%	0.10	0.29	0.46	0.64	0.82	1.00	1.17	1.35
7.5%	0.19	0.46	0.73	1.00	1.26	1.53	1.79	2.05
10.0%	0.29	0.64	1.00	1.35	1.70	2.05	2.41	2.76
12.5%	0.38	0.82	1.26	1.70	2.14	2.58	3.02	3.46
15.0%	0.46	1.00	1.53	2.05	2.58	3.11	3.64	4.16

GP Margin \ Average test Pricing (US$/test)	60	85	110	135	160	185	210	235
70%	0.34	0.52	0.69	0.86	1.03	1.20	1.37	1.54
75%	0.37	0.56	0.74	0.93	1.11	1.29	1.48	1.66
80%	0.40	0.60	0.80	0.99	1.19	1.39	1.58	1.78
85%	0.43	0.64	0.85	1.06	1.27	1.48	1.68	1.89
90%	0.46	0.69	0.91	1.13	1.35	1.57	1.79	2.01

TGR \ Discount Rate	9.5%	11.0%	12.5%	14.0%	15.5%	17.0%	18.5%	20.0%
0.0%	2.91	2.37	1.96	1.66	1.42	1.22	1.07	0.94
0.5%	3.02	2.44	2.01	1.69	1.44	1.24	1.08	0.95
1.0%	3.14	2.51	2.06	1.72	1.46	1.26	1.10	0.96
1.5%	3.27	2.59	2.12	1.76	1.49	1.28	1.11	0.97
2.0%	3.42	2.69	2.18	1.80	1.52	1.30	1.13	0.98
2.5%	3.59	2.79	2.24	1.85	1.55	1.32	1.14	1.00
3.0%	3.79	2.91	2.32	1.90	1.58	1.35	1.16	1.01

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Listed Peers

We have explored comparable listed peers below:

Listed Peers						EV/Revenue		
Company	**Code**	**Description**	**Adressable Market***	**Market Cap**	**Enterprise Value**	**FY'22**	**FY'23**	**FY'24**
RenalytixAI	LON: RENX	Commercialising test for CKD prorgression, based on 'AI', blood based biomarkers, and electronic health records, expensive (~US950/test), non-mass market	US$9.5bn	569.8	550.5	5.1	2.9	na
Volpara Health Tech.	ASX: VHT	SaaS diagnostic technology utilising AI to improve early detection of breast cancer	US$750m	342.4	277.0	8.7	6.0	na
Genetic Signatures	ASX: GSS	Specialist molecular diagnostic (MDx) for routine detection of infectious diseases	US$8.4bn	254.3	221.0	10.3	na	na
Atomo Diagnostics	ASX: AT1	Disposable rapid tests for COVID-19 and HIV	US$4.6Bn	136.4	110.0	2.6	1.8	na
Median				298.3	249.0	6.9	2.9	na
Average				325.7	289.6	6.7	3.6	na
PIQ	ASX: PIQ	Commercialising novel predictive DKD test	US$20.5bn**	53.0	44.3	9.5	5.0	2.6
All Figures in A$m unless otherwise stated								
*Sourced from PIQ investor presentation								
**ESHL assumption (discussed in TAM section)								

Source: EHSL estimates, Bloomberg LP

Peer comparisons are difficult in that PIQs offering is novel and niche in addition to its earlier commercial stage relative to listed peers. Never less, these peers are indicatively useful in showing the huge potential possible for PIQ.

UK based RenalytixAI is one of PIQs closest peers in our opinion. The companies chronic kidney disease (CKD) test KidneyIntelX is targeting a similar area to PIQ (discussed in detail further). RenalytixAI is similarly in the process of commercialisation, albeit more advanced than PIQ. However, the key discussion is its ~A$550m enterprise value which is +10x greater than PIQs. This is not saying PIQ should currently attract the same valuation, rather it outlines the potential pathway possible should it achieve the same level of commercialisation, such scenario would imply a ~5.25/sh. comparable price per share.

Overall, each of these listed companies are targeting similarly very large addressable markets to PIQ albeit in different areas. Individually attracting valuations between A$100m to upwards of A$600m they are indicative of the value proposition if PIQ can attain a modest level of commercialisation for its novel PromarkerD test. A successful outcome as such would see PIQ trade up significantly from its current levels.

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Diagnostic Kits & Equipment Company Transactions

In the past few years there have been a number of transactions in the sector. Whilst PIQs product offering is niche, we can still explore transactions of companies in the diagnostic kits and equipment industry as shown below:

Target	Target Description	Acquirer	Transaction Value (US$m)	Date	Status	Revenue* (US$m)	TV/Rev
ArcherDx Inc	ArcherDx Inc is offering sequencing technology for detecting variants associated with cancers and inherited diseases.	Invitae Corp	843	Jun-20	Pending	51	16.7
TearLab Corp	TearLab offers lab-on-a-chip technologies that can test for sensitive and specific biomarkers in tears at the point-of-care.	UM Accelmed LP	31	May-20	Completed	23	1.4
Exalenz Bioscience Ltd	Exalenz Bioscience is developing a tool that enables diagnoses and management of diseases and disorders of the digestive system.	Meridian Bioscience Inc	52	Feb-20	Pending	14	3.7
Expedeon Holdings Ltd	Expedeon Holdings Ltd offers products for protein discovery and analysis used for protein research and drug development.	Abcam PLC	132	Nov-19	Completed	14	9.2
Genomic Health Inc	Genomic Health offers genomic-based clinical diagnostic tests for cancer.	Exact Sciences Corp	3,121	Jul-19	Completed	394	7.9
Exosome Diagnostics Inc	Exosome Diagnostics develops biofluid based molecular diagnostic tests for use in personalized medicine.	Bio-Techne Corp	252	Jun-18	Completed	na	na
Foundation Medicine Inc	Foundation Medicine develops cancer diagnostic technology, offering tests enabling the personalization of cancer treatments.	Roche Holding AG	2,195	Jun-18	Completed	153	14.4
Astute Medical Inc	Astute Medicals offers solutions to improve the diagnosis of risk medical conditions and diseases such as abdominal pain, acute coronary syndromes, sepsis, congestive heart failure, kidney, and cerebrovascular injuries.	BioMerieux	90	Apr-18	Completed	na	na
LifeScan Inc	LifeScan offers products such as blood glucose meters, test strips, lancing devices, hospital meters, and linearity test kits.	Platinum Equity LLC	2,100	Mar-18	Completed	na	na
Multiplicom NV	Multiplicom offers cancer genetics, genetics and blood disorder, organ tumors, chromosome abnormalities, and kidney disorder diagnostic kits.	Agilent Technologies Inc	71	Dec-16	Completed	na	na
Affymetrix Inc	Affymetrix offers products, tools, and resources for plant and animal genomics and transcriptomics, basic research, and industrial application.	Thermo Fisher Scientific Inc	1,107	Jan-16	Completed	360	3.1
Median			**251.6**				**7.9**
Average			**908.5**				**8.0**

*Actual delivered revenue at transaction, US$m
Source: Bloomberg LP, EHSL Estimates

These peer transactions similarly to previously discussed listed peers indicatively demonstrate the significantly large potential upside possible for PIQ.

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Astute Medical Inc. is one of the closer peers in the table above. The company is focused on identifying biomarkers of acute medical conditions, its NephroCheck® test system uses novel biomarkers to identify risk of acute kidney injury. The company was purchased by BioMerieux for US$90m (A$125m) in April 2018, a comparable scenarios applied to PIQ would imply $1.28/sh., 151% higher than its last price.

Broadly speaking there is clearly interest in the sector, the transactions listed above only date back ~4 years however amount to billions of dollars in M&A activity. Although targeting different markets and in different stages of commercialisation, the transaction peer set demonstrates a potential pathway for PIQ whereby a takeover by large medical diagnostic companies is possible, furthermore the list indicatively shows potentially significantly large upside possible if PIQ can attain similar levels of commercialisation.

Price Target and Recommendation

Our $1.00/sh. Price Target per our analysis requires PIQ achieving the level of commercial adoption outlined. Broadly stated as achieving modest levels of market penetration (~10%) within our forecasts regions within 10 years' time under certain commercial structures and terms. Following our math this describes rapid levels of earnings growth, per our analysis and discussion we believe this to be achievable for a novel diagnostic test, only implying a modest ~1% global market penetration by our final forecast year (2031). Furthermore, as shown in our sensitivities we see potential for PIQ to trade well beyond our Price Target should it expand beyond the constrains our assumptions. The factors and risks surrounding these assumptions further drive our Speculative Buy recommendation.

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Company Background

Proteomics International Laboratories Ltd ("PIQ") is a Perth based medical technology company. The company operates at the forefront of predictive diagnostics and bio-analytical services, specializing in proteomics the large-scale study of proteins.

Founded in 2001 and listed in April 2015, the business is centred around commercialization of its pioneering diabetic kidney disease test, PromarkerD, whilst also using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests. These undertakings are partially offset by PIQs growing analytical services business.

Key Business Segments:

- PromarkerD
- Promarker™ Platform & Pipeline
- Analytical Business

We discuss each segment in detail in this report.

PromarkerD

How it works:

PromarkerD is a blood test that assesses the risk of Diabetic Kidney Disease (DKD) in patients with type 2 diabetes.

The test uses a simple blood test to measure a panel of three novel biomarkers in combination with 3 clinical factors, these data points are fed into a proprietary algorithm to produce a report. The IP of the test is contained in the three biomarkers used, with trade secrets in the algorithm.

The three biomarkers are:

- ApoA4 (Apolipoprotein A-IV, plasma protein)
- CD5L (CD5 antigen-like)
- IBP3 (Insulin-like growth factor-binding protein 3)

These are combined with the 3 clinical factors (age, HDL-cholesterol and eGFR).

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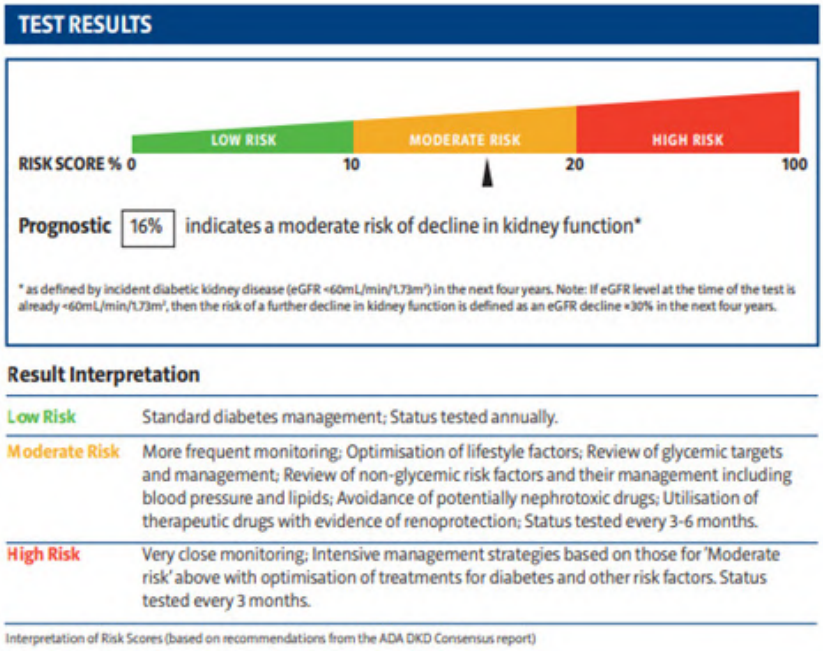
The patient report generated uses a traffic light scoring system as shown below:



Source: PIQ website

The results are presented as 'low, moderate, or high' risk based on cut-off points selected to optimize test performance.

More simply:

- Moderate risk – Provides optimal sensitivity to increase true positives
- High risk – Provides optimal specificity to reduce false positive

The test has significant power with patients who are placed on either ends (low or high risk). This was highlighted in the recent Janssen clinical study, which showed high risk patients were 13.5x more likely to develop DKD than low risk patients.

Clinical Studies

4 clinical studies, including 1 third party (Janssen) have been completed on PromarkerD. These studies demonstrate and validate PromarkerDs' prognostic utility in accurately predicting future renal decline (incident Diabetic Kidney Disease) in people with type 2 diabetes. Specifically, PromarkerD has been shown to accurately predict 86% of otherwise healthy people who went on to develop DKD.

A total of 5,277 patients took part across all studies, including 3,568 in the 4th study (Janssen Stage 1).

The first 3 studies were conducted using large Australian community-based cohorts (from the Fremantle Diabetes Study, 'FDS'), these geographically constraint cohorts (all residents situated in WA) created high quality clinical data given the high patient return.

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The second prognostic validation study, Janssen Stage 1, was conducted using data from a very large and completely independent (of FDS) multi-centre clinical trial cohort, called CANagliflozin cardioVascular Assessment Study (CANVAS). This study provided PIQ with a third-party evaluation and validation of PromarkerD, strengthening the portfolio of growing evidence.

In March 2020, Janssen expanded the collaboration into a second stage study. The second stage study (Janssen Stage 2) will determine if PromarkerD can assess the effectiveness of canagliflozin as a treatment for DKD. Results from this study are expected early CY'21.

This study could lay the foundation for the use of PromarkerD as a Complementary Diagnostic (CDx) test, whereby it would be used:

- Upon prescription of drug treatments for diabetes; or
- Throughout a patient's course of treatment (potentially lifetime) to monitor the ongoing risk of developing DKD

A successful study outcome would show either, reduced risk of developing DKD (lowering PromarkerD risk stratification), or stable risk of developing DKD (unchanged PromarkerD risk stratification). One of these outcomes seems logically likely, since if the drug currently works for 'sicker' individuals, one would expect it to be somewhat effective with 'less sick' individuals. However, regardless of outcome, these study results have no bearing on PromarkerDs effectiveness.

Current Studies published include:

- *2016 - Diagnostic Study, titled: Comprehensive mass spectrometry-based biomarker discovery and validation platform as applied to diabetic kidney disease*
- *2017 – Prognostic Development Study, titled: Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II*
- *2019 – Prognostic Validation Study, titled: Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II*
- *2020 – 2nd Prognostic Validation Study (Janssen stg. 1), titled: PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)*

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These studies and their results are discussed in further detail within Appendix A.

Statistical highlights of each of the four studies are shown in the table below:

Study	The Diagnostic Study	Prognostic Development Study	Prognostic Validation Study	Prognostic Validation Study (3rd Party)
Study Count	1	2	3	4 (Janssen Stg 1)
Publish Year	2016	2017	2019	2020
Study Cohort	Fremantle Diabetes Study (FDS)	Fremantle Diabetes Study (FDS)	Fremantle Diabetes Study (FDS)	CANVAS
Total Cohort Size	572	345	792	3568
Clinical Characteristics (Total Cohort)*				
Age (Years)	66.6±10.6	67.0±9.4	64.4±10.9	62.7±7.9
BMI (Kg/m2)	30.9±5.6	31.0±5.5	31.7±6.2	32.7±6.1
Diabetes Duration (Years)	10.0 (3.0-16.0)	9.0 (3.0-15.2)	6.0 (1.3-14.0)	12.4 (8.0-18.0)
Gender, %Male	53.1	51.9	56.2	67
eGFR	79.7±21.2	80.6±18.8	82.7±16.9	77.0±18.8
eGFR<60ml/min/1.73m2 (%)	16.1	13.1	10.5	16.5
Urine ACR (mg/mmol)	4.1 (0.9-18.3)	2.9 (0.9-8.7)	2.5 (0.9-7.1)	1.32 (0.7-4.0)
Outcome Cohort/Sub-Cohort	'Test'	'Clinical + Biomarkers Model 2'	'Validation'	'Placebo+Canagliflozin'
Performance Measure**	Incident CKD	Incident CKD	Incident CKD	Incident CKD
AUC	0.81	0.92	0.88	0.81
95%CI	n/a	0.88-0.95	0.84-0.93	0.80-0.83
Sensitivity	88.0	94.3	86.1	73.2
Specitivity	68.0	78.0	78.2	76.8
PPV	n/a	38.4	30.4	58.8
NPV	n/a	98.9	98.1	86.4
H-L Test (X2, P)	n/a	5.70, 0.68	5.6, 0.78	n/a
**Validation Cohort shown for 'clinical characteristics' in Prognostic Validation Cohort*				
***Incident CDK defined as eGFR<60ml/min/1.73m^2*				

Source: Comprehensive mass spectrometry based biomarker discovery and validation platform as applied to diabetic kidney disease, Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II, Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II, PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS), ESHL Estimates.

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Competitors

There is limited competition with PromarkerD. Beyond existing tests (eGFR and ACR), which have no predictive capacity (discussed further), there is essentially only UK based RenalytixAI KidneyIntelX test.

Although KidneyIntelX may appear to address the same issue as PromarkerD, the two tests address different areas of the DKD testing issue.

Compared to PromarkerD, KidneyIntelX appears to target later stages of CKD, specifically around predicting the progression of early CKD, whereas PromarkerD is developped to predict incident DKD. As a result of these different clinical end-points, there is no utility in comparing the statistical results.

The two tests may even be viewed as complementary to each other. PromarkerD may be used early on, across a wider group, whereas KidneyIntelX would be for sicker more targeted testing in later stages.

Nonetheless, even when compared head to head, PromarkerD exhibits certain benefits. On cost, KidneyintelX at US$950/test is significantly more expensive than PIQs targeted US$50-150/test for PromarkerD. Furthermore, PromarkerD does not require integrated electronic health records like the KidneyintelX test. As a result we can see greater mass market potential for PromarkerD.

Patents

PromarkerD is patented across a majority of key global regions, covering 49% of the global diabetics population (IDF figures).

Patents cover use of PromarkerD for diabetic kidney disease (DKD), with extended version in certain regions including:

- Australia, Europe, United States – Patents are extended to cover use for any form of kidney disease.
- United States – Patents further extended to cover methods for identifying drugs for abnormal kidney function using the CD5l biomarker (one of three PromarkerD biomarkers).

All patents are valid until September 2031.

Specific coverage and status is shown in the table below:

PromarkerD Patent Coverage		
Country	**Patent / Application No.**	**Status**
Australia*	2011305050	Granted
Brazil	BR1120130067640	Granting
Canada	2811654	Granted
China	ZL201180053583.9	Granted
Europe* **	3151012	Granted
Hong Kong	18115912.3	Pending
India	3012/DELNP/2013	Pending
Indonesia	W00 2013 01585	Granted
Japan	2013-528474	Granted
Russia	2596486	Granted
Singapore	188527	Granted
USA* ***	US 9,146,243	Granted

** Patent extended to cover use of the test for any form of Kidney Disease (NB Further Studies required to prove efficay of PromarkerD for Applications beyond DKD)*

*** Covers France, Germany, Italy, Spain, Turkey, and the United Kingdom*

**** Patent further extended to cover method for identifying drugs for abnormal kidney functions using one of the PromarkerD biomarkers (CD5L)*

Source: PIQ Annual Report

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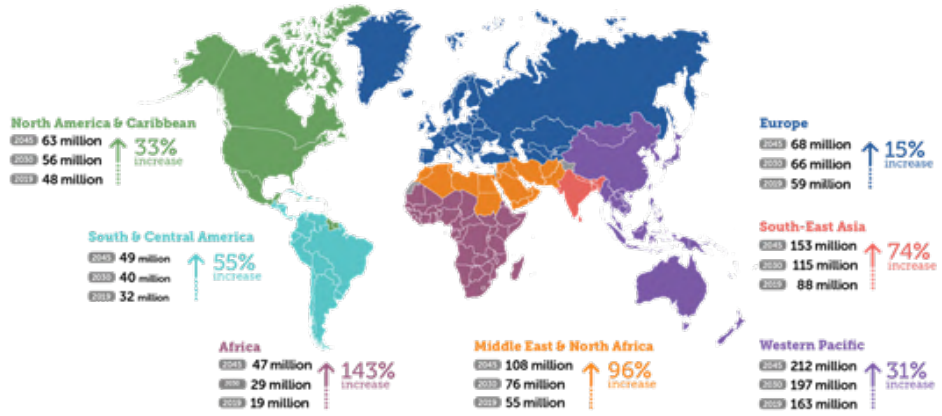
The Situation: An Under-Recognized Health Crisis

Diabetic Kidney Disease (DKD) is a chronic disease caused by poorly controlled diabetes, progressively causing kidney damage and reducing overall kidney function. DKD develops in ~40% of patients with diabetes, sufferers typically develop serious complications or if they live long enough, eventual develop Kidney failure requiring expensive kidney dialysis or transplant.

The International Diabetes Foundation (IDF) estimate there is currently 463 million people living with diabetes globally, (both diagnosed and undiagnosed). This figure is estimated to grow to 700 million people by 2045.



Source: International Diabetes Foundation

The IDF estimates that 50% of people with diabetes are undiagnosed sufferers.

Overtime, poorly controlled diabetes can cause damage to blood vessel clusters in your kidneys that filter waste from your blood. This can lead to kidney damage and cause high blood pressure. High blood pressure can cause further kidney damage by increasing the pressure in the filtering system of the kidneys.

Slowly progressing over a number of years, DKD sufferers remain mostly asymptomatic until reaching the later and more serious stages. It is estimated 9 out of 10 patients are unaware they have kidney damage or reduced kidney function at all.

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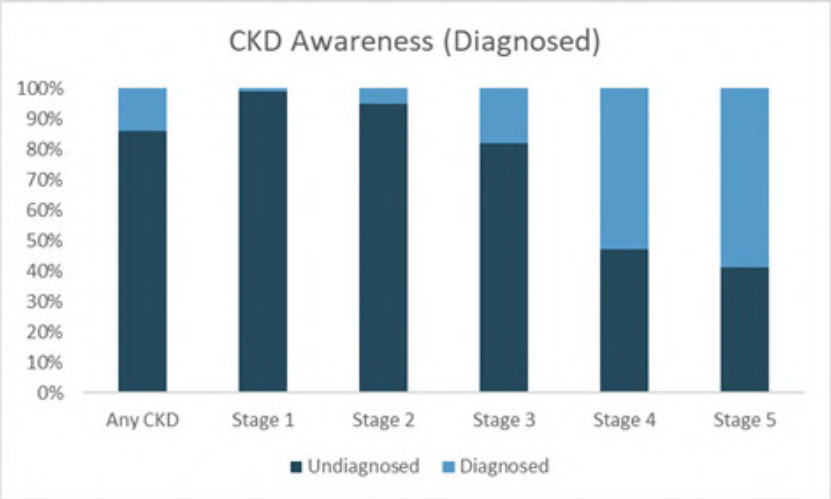
This underdiagnosis is extremely prevalent in the early stages of the disease, and still very high even in its final stages as shown below:



Source: Canagliflozin for the Treatment of Diabetic Kidney Disease and Implications for Clinical Practice: A Narrative Review

This lack of awareness is concerning when considering the serious impact DKD has on mortality, with the disease causing a 20% increase in 10-year cumulative all-cause mortality.

Although end stage renal disease (ESRD, or kidney failure) is the most recognizable outcome of DKD, the majority of patients go onto die from cardiovascular diseases and infections – complications of the underlying DKD.

Should ESRD be reached, patients are left with little options. Sufferers are either required to have a kidney transplant or undertake dialysis. Both of these options shorten life expectancy and reduce quality of life for patients, these procedures further come with significant medical costs.

The financial costs of DKD and CKD in general are just as significant.

In the United States alone Medicare spending on CKD and ESRD amounted to US$120 billion in 2017, ESRD accounted for US$36 billion of that. Concurrent CKD and diabetes cost US$39 billion in the same period, which is almost 14% of all Medicare spending despite accounting for only 6.7% of Medicare beneficiaries.

The Problem – Existing Diagnostic Options

DKD's health burden is evident, furthermore its asymptomatic progression highlights the clear need for testing options.

Despite this, there are few options which themselves come with numerous limitations

The clinical diagnosis of DKD is based on estimating kidney function and kidney damage, the current gold standard tests used to determine this are:

- estimated Globular Filtration Rate (eGFR)
- Urinary Albumin-to-Creatine Ratio (ACR)

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We discuss the limitations of these tests in detail in Appendix B. However, they are broadly simplified as:

- **No Predictive capacity:** eGFR and ACR have essentially no predictive ability, essentially limited in being able to determine whether someone 'does' or 'doesn't' have DKD
- **Diagnostic limitations:** Each tests come with respective limitations, under-diagnosis in certain situations as well as reduced accuracy (especially in early stages).

The key result of this problem is underdiagnosis of DKD.

The solution – PromarkerD

The PromarkerD test is well placed to solve the issues faced by existing diagnostic tests, specifically the gold standard eGFR and ACR tests. We have outlined these limitations in broad terms as being missed diagnosis and very limited predictive capacity, these are solved by using PromarkerD, as validated in 4 clinical studies.

The low hanging fruit that the test best addresses in our view is the ambiguous pre-DKD/early DKD stages (highlighted in the table below).

Prognosis of CKD by GFR and albuminuria categories: KDIGO 2012

GFR categories (ml/min per 1.73 m²) Description and range				Persistent albuminuria categories Description and range: A1 Normal to mildly increased <30 mg/g <3 mg/mmol	A2 Moderately increased 30–300 mg/g 3–30 mg/mmol	A3 Severely increased >300 mg/g >30 mg/mmol
	G1	Normal or high	≥90			
	G2	Mildly decreased	60–89			
	G3a	Mildly to moderately decreased	45–59			
	G3b	Moderately to severely decreased	30–44			
	G4	Severely decreased	15–29			
	G5	Kidney failure	<15			

Green, low risk (if no other markers of kidney disease, no CKD); yellow, moderately increased risk; orange, high risk; red, very high risk.

Source: KDIGO, EHSL

As we discuss, this region is where the greatest limitations in current testing are faced. It is also where the greatest impact can be had on stopping or slowing the progression of DKD, and with it its complications.

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Gamechanger: New Treatment Options

Historically, treatment of DKD has been around managing the underlying risk factors. This can and does work, however, it is not revolutionary as should already be done.

However, approach to treatment has changed in the last few years with the development of new drugs for treating DKD. SGLT2 inhibitors, also known as Gliflozin, appear to exhibit renal-protective properties able to reduce the risk of renal failure, dialysis, or kidney transplant in DKD patients.

These developments were highlighted last year with Janssens' Canagliflozin (Invokana™) drug being the first drug in 20 years to be approved for the treatment of DKD.

However, the drug can only be effectively used when an early diagnosis is made, it is not for use in later stages of DKD, such as severe renal impairement (eGFR< 30ml/min/1.73m2) or ESRD.

This significantly increases the importance and value of early detection for respective treatment and management of DKD, creating a very compelling argument for PromarkerD.

Consider the high cost of ESRD, patients who develop kidney failure as discussed are left with either lifelong dialysis or kidney transplant, both very expensive.

Dialysis alone costs ~$US72,000 per year per patient in the United States, even a minor reduction in final ESRD incidence through early detection and treatment/management would likely have a net cost savings.

This concept does not even consider the financial savings possible with reducing complications of DKD (possible intermediate costs), or even possibly future use of PromarkerD for optimising treatment plans (i.e. reducing use of expensive drugs for people who don't require it).

Altogether, we can see PromarkerDs' strong clinical utility and broader economics.

Commercial Strategy and Outlook

PIQ is in the initial stages of commercialising it's novel PromarkerD test.

Commercial Pathway

The PromarkerD test can be done through two primary ways, either via a Immunoassay (IA) or Mass Spectrometer (MS).

We consider the immunoassay (IA) process as being the best method. IA uses a procedure for detecting or measuring specific proteins or other substances through the use of antibodies.

We see the process as being superior due to the high throughput, ease of use, and standardization (as long as singular platform is used). No specialised equipment is required either, this means a greater number of tests at a lower cost can be completed, it also means diagnostic providers are more likely to use them.

PIQ has designed its immunoassay version using TGR Biosciences' advanced CaptSure™ technology platform.

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The Mass Spectrometer (MS) process on the other hand operates through measuring the mass to charge ratio of a molecule to determine its chemical structure. This process can be rolled out very quickly in certain labs, hence early agreements signed by PIQ with it. However, we don't see it as a suitable method due to its requirements for expensive and difficult to operate Mass Spectrometers, making quick and widespread adoption more difficult.

We would expect these early agreements still in progress to be re-built around the immunoassay (IA) version, specifically using TGRs' IA platform.

Further to this, there are three potential commercial pathways PIQ can undertake, which are:

- **In-Vitro Diagnostic (IVD) Test** – An IVD test uses the immunoassay (IA) method, either through a kit or on an automated machine platform. Subject to the regulatory approvals required, this pathway would allow the test to be used in any pathology laboratory. This process allows for faster adoption and usage of the test, with input kits or reagents supplied by a manufacturer. We see this as the target pathway, although this hasn't been available until recently (certain regions) due to regulatory requirements.
- **Laboratory Developed Test (LDT)** – The LDT pathway can use either immunoassay or mass spectrometer version of PromarkerD. The pathway doesn't come with the same regulatory hurdles allowing rapid rollout in certain markets. This has been the current pathway used as PIQ progresses its regulatory certifications. PIQ will initially sell PromarkerD as LDTs in the United States through CLIA (clinical laboratory improvements amendments) certified laboratories. There are approximately 260,000 approved laboratories in the United States, this allowing PIQ to circumnavigate the FDA as it continues with its applications.
- **Complementary Diagnostic (CDx) Test** – A third possible commercial pathway is through using PromarkerD as a complementary diagnostic (CDx) test. A CDx pathway would see PromarkerD used to help determine and optimise clinical decision making.

We expect IVD and CDx to be the main pathways going forward, with LDTs used in certain regions as PIQ progresses regulatory approval (eg. United States).

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(PIQ $0.51) Speculative Buy - Initiation of Coverage

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Commercial Agreements

Part of PIQs launch pathway has involved first licensing in several smaller jurisdictions. Some of these deals have included earlier mass-spectrometer versions of PromarkerD, originated before the development of the immunoassay version. Although PIQ was likely previously near first sale, the onset of COVID-19 has put sales of these tests on hold across all jurisdictions. Further to this unexpected delay, we would in time expect these agreements to be re-organised to use the immunoassay versions of PromarkerD, if not already in that version, either as a kit or LDT test.

These agreements include:

- **Dominican Republic,** Immunoassay (in-house dev.) – This was one of PIQs first international licensing deals. The agreement with Omnics Global Solutions (Omnics) would see it develop and market its own immunoassay test through its sister company Macortech Farmaceutica. Macortech Farmaceutica is the exclusive provider of dialysis services, instruments, and reagents in the Dominican Republic.
- **Mexico,** Mass Spectrometer (MS) – PIQ signed an agreement with Patia Biopharma to commercialise PromarkerD in Mexico. The deal brokered by the Carlos Slim Foundation, would see Patia develop and commercialise a mass spectrometer (MS) LDT version of the PromarkerD test. Targeted to be initially introduced to private hospitals and clinics before expanding into government hospitals. We would expect this to be re-organised into an immunoassay version test.
- **Spain,** Mass spectrometer (MS) – PIQ signed a deal with Patia Europe, in similar fashion to the one in Mexico, the deal would see Patia develop and commercialise a mass spectrometer (MS) LDT version of the PromarkerD test. We would expect this to re-organise into an immunoassay version as well.
- **Italy,** Immunoassay (IA), kit version – PIQ last month signed its first immunoassay kit version agreement with Italian medical distributor Medical Horizons SRL. The exclusive agreement will see Medical Horizons distribute the kit within Italy. Medical Horizons are set to complete a medical registration of PromarkerD with the Italian Ministry of Health (1 month), after which tests can be sold.
- **Israel**, Immunoassay (IA), kit version – PIQ last week signed its second distribution agreement for the immunoassay kit with medical distributor Zotal Ltd for two years exclusivity in Israel. Zotal is set to complete product registration and reimbursement applications with the Israeli Department of Medical Devices and Ministry of Health, this is expected to take ~6 months. Parallel to this, in preparation of sales Zotal will engage with key Israel opinion leaders for the promotion and early adoption of PromarkerD.

These early agreements demonstrate the commercial interest in PromarkerD, going forward we expect further agreements to be signed. Each one expanding PIQs global reach in parallel to growing awareness of the novel test.

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Janssen Collaboration

PIQs collaboration with Janssen Research & Development (Janssen, owned by Johnson&Johnson) highlights the interest of major global pharmaceutical companies in PromarkerD. We see significant potential in the collaboration, possibly opening new doors for the company.

PIQ initially signed the agreement in 2018, this agreement saw a successful joint study (Janssen stage 1) undertaken (previously discussed). In march of this year, the collaboration was further expanded to determine if PromarkerD can help assess the effectiveness of canagliflozin as a treatment for DKD.

As we previously discussed, there are a number of positive outcomes which could emerge from this stage 2 study, specifically the potential for it to lead into the use of PromarkerD as a complementary Diagnostic (CDx).

We see further externalities emerging from this collaboration around providing PIQ greater credibility on the basis its actively working with a major multinational pharmaceutical company.

Regulatory Approvals

PromarkerD is in various stages of regulatory approvals globally. We have highlighted on CE Marking and FDA approval, which contain the bulk of our outlook regions.

CE Mark

CE Mark is a requirement to sell medical devices in the EU.

PIQ has secured CE mark registration for its PromarkerD Immunoassay kit (April 2020), PromarkerD Hub (January 2020), and PromarkerD Mass spectrometer (MS) version (November 2019), all as IVD medical devices (in-vitro diagnostic). The marking demonstrates the product has been developed and manufactured to meet EU safety, health, and environmental standards. The CE marking provides comfort to potential licensing partners and consumers alike. Furthermore, the CE mark provides additional foundation towards securing future FDA Approval.

FDA

The regulatory requirements for sale of diagnostic tests in the United States isn't as straight forward as in the EU. Sale of 'kits' such as PIQs immunoassay kit would require FDA approval, however there are ways to circumnavigate this requirement and fast track sales ahead of securing approval.

Diagnostic tests developers can go down the pathway of using the Laboratory Developed Test (LDT) in CLIA (Clinical Laboratory Improvement Amendments) certified labs, this process does not require FDA approval.

It is our understanding that in the short term, PIQ will use this pathway to market while it progresses on securing FDA approval. However, in reality there won't likely be much difference, PIQ is still able to sell testing reagents to the labs (to make the tests) just not fully constructed kits.

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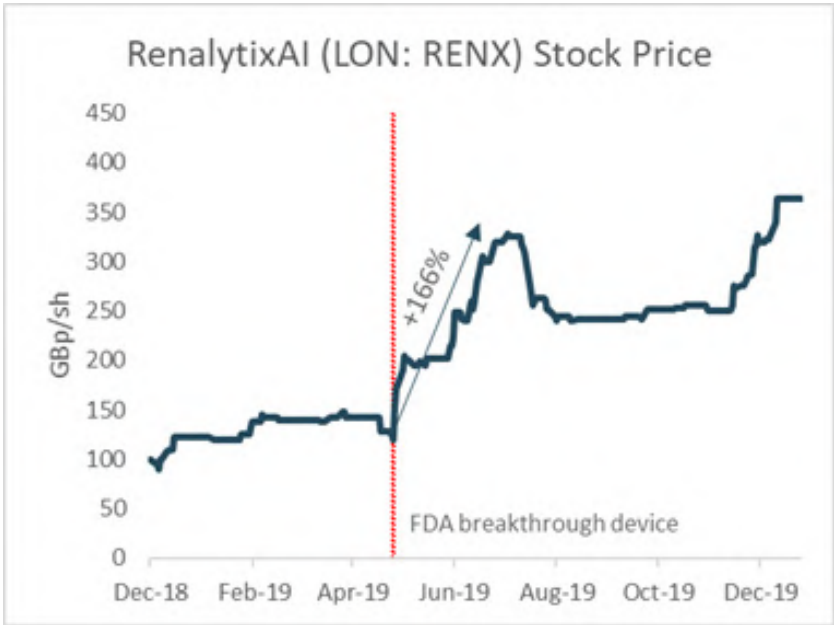
We understand in the medium term that PIQ is seeking FDA approval for PromarkerD under the 'De Novo' or 510(k) pathways. Prior to approval, the FDA requires companies to comply with FDA 21 CFR 820, essentially quality management.

We see FDA approval as being more medium term as a result of FDA 21 CFR 820 compliance. In short, PIQ could seek approval for its test (currently manufactured by TGR biosciences), however, should it begin producing it in the United States then a new FDA approval would be required. As a result, we would expect PIQ to wait until it secures a domestic (United States) manufacturing partner before attempting to secure FDA approval. We would expect this to occur between late CY'21 and mid CY'22.

Although we don't see FDA approval stopping or being critical towards commercialisation, rather aiding it, we do however believe receiving it will be very favourably viewed by the market.

Looking at RenalytixAI (close PIQ peer) share price movement post receiving "breakthrough device recognition" from the FDA gives us an example of the trade up possible. Although this situation does not constitute regulatory approval, it is indicatively useful in this analysis as a broad reference point. We highlight the chart below illustrating the price change post announcement.



Source: Bloomberg LP

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Medical Costs Reimbursement – Reimbursement Codes & Coverage

Achieving large scale adoption and commercialisation of PromarkerD is reliant on PIQ securing cost reimbursement and coverage of the test. Failing to receive, achieve, or meet whatever required in different countries will result in PromarkerD test costs falling directly on to patients.

Policies that cover reimbursement of medical costs vary by different countries and regions. We are mainly focused on the United States and Europe at this time, the specific process for both are discussed in detail within Appendix C.

We specifically see attainment of a US reimbursement code (CPT® Proprietary Laboratory Analyses [PLA] code) as being a major milestone and catalyst.

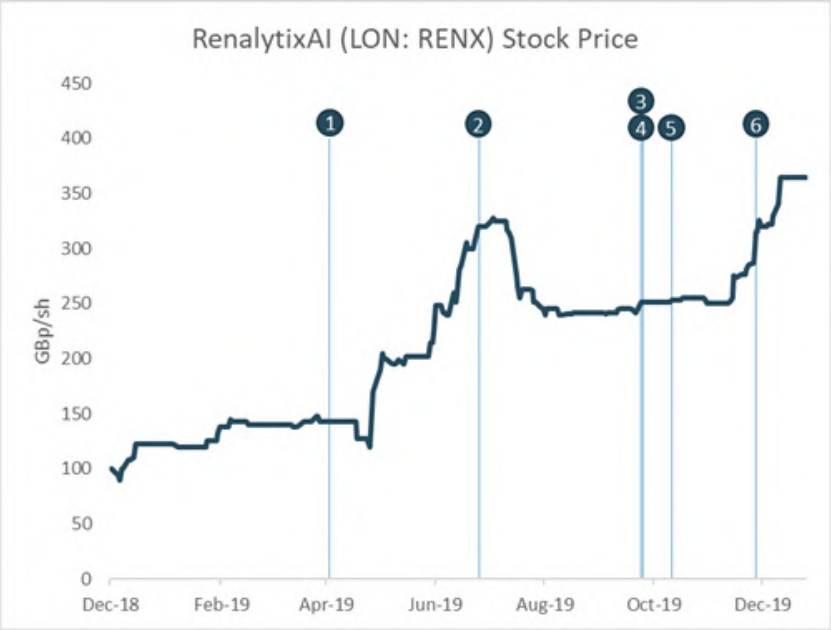
We anticipate PIQ will received a CPT PLA code around the 1H'CY2021.

We would expect PIQ to significantly trade up upon receiving this code.

Indicatively, we refer to share price movement of RenalytixAI (LON: RENX), closest comparable to PIQ, when:

1. CPT PLA public agenda likely posted (estimated)
2. US CPT code Granted
3. Preliminary Medicare Pricing issued by CMS
4. CPT Code Effective
5. US insurer, CDPHP to provide coverage
6. Medicare national price set

These events annotated in the chart below:



Source: Bloomberg LP, EHSL estimates

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Sales, Marketing & Key Opinion Leaders

Regulatory approval, reimbursement codes and establishment of pricing are key towards achieving commercialisation, however, there still remains the final uptake by the end user and hence sales.

We have previously discussed PIQs target to out-license to partners, which could include:

- Diagnostic Companies (e.g. Siemens, who could add it to automated immunoassay panel)
- Medical Distributors (who sell it on)
- Laboratories and/or Laboratory Networks (Sell & do test)

There are numerous pathways these partners can then undertake to sell PromarkerD. Customers could include:

- Hospitals and/or hospital networks
- Laboratories and/or laboratory networks
- Individual physicians

Although we believe PIQ is unlikely to take on direct marketing, there is nothing stopping it should they choose to do so. We would expect PIQ to get more involved with establishing direct partners and broadly spreading awareness through various means including key opinion leaders, conferences, additional studies, etc.

Key Assumptions

There are a handful of key assumptions which form the foundation of our outlook and quantifying the opportunity at hand.

Business Structure – PIQ's business model is to out-license its intellectual property to diagnostics providers (laboratories) or broader medical distributors and to receive a royalty on each test sold. PIQ will also sell the specialist reagents required to perform each test, however we expect this to be sold at cost. The PromarkerD hub further regulates the use of the test by each provider.

This pathway removes significant cost burden normally required, this model will see the licenses cover the costs to both distribute and market PromarkerD.

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Market Penetration – There are a number of underlying variables which will determine the ultimate penetration and respective rate of adoption. As we discuss further on, we maintain the view of simplicity in our forecasts of these figures. Nevertheless, we see the key variables affecting them include:

- **Market Sophistication** – The level of sophistication in broad healthcare systems can affect how PromarkerD or novel tests in general are adopted. Economies with developed and formal "sophisticated" healthcare systems such as the United states can give pathway to wide levels of adoption which could easily reach 30, 40, or 50%. We broadly assume this to follow a countries level of wealth in absence of other factors.
- **Market Fragmentation** – A fragmented diagnostic market, split amongst many players, can make adoption more difficult and slower than a more consolidated market (e.g. United states) vs a more fragmented one (e.g. Spain).
- **Government/Organisation Initiatives** – The presence of top-level initiatives/mandates can overrule all the above and allow fast tracking and broad adoption of new tests, such as PromarkerD. Examples of this include:
  - United States – The U.S. Department of Health and Human Services (HHS) launched the 'Advancing American Kidney Health' Initiative in July 2019. Laying out three goals:
    - Reducing risk of Kidney Failure;
    - Improve access to a quality of person-centred treatments for kidney failure; and
    - Increase access to kidney transplants

    A foundation of this is "Improved identification of populations at risk and in early stages of Kidney disease". The initiative is through proposed changes in payment models, which will incentivise preventative care amongst other things.
  - China – The state council, issued a blueprint release of the Healthy China Action Plan in 2016. The plan covered all urgent challenges facing the sector, including prevention and control of major disease such as diabetes. The nationwide health campaign started in 2019 following the issuance of a guidance document.

These initiatives potentially open up massive avenues for fast tracking tests such as PromarkerD. Even more significant would be the inclusion into standards of care mandates, making it the de-facto gold standard.

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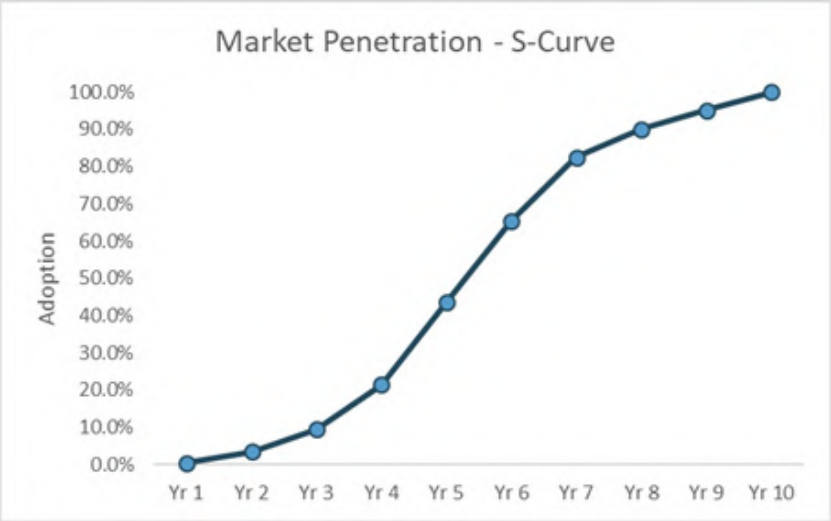
Overall, we have maintained a simple outlook as a result of PromarkerD being in its early stages. We have forecasted a rollout of the test in countries with current partners in addition to the United States.

We are broadly targeting a 10% final market penetration within 10 years of first sales. We have modelled adoption via a typical s-curve (shown below).



Source: EHSL estimate

Pricing – PIQ has previously outlined a potential pricing range for the PromarkerD test, stated as being US$50-155/test. We would expect this range to vary by country, with "poorer" countries unlikely to pay the same level as "richer" countries.

Using this guiding range, we have applied a simple four-tiered assumption across penetrated regions. Shown below:

Broad Level Economic Tiers	Pricing (US$/test)
High	150
Moderate	100
Low	50
Very Low	25

Source: EHSL estimates

These tiers are respectively applied to our forecasted countries as shown below:

Country	Pricing (US$/test)
Spain	150
Mexico	100
Dominican Republic	50
Italy	150
Israel	100
United States	150

Source: EHSL estimates

We see this as a conservative starting point, however, in reality these are likely to vary.

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Royalty Rate – PIQ in past announcements have articulated a potential 5-15% royalty rate range achievable on PromarkerD sales. These rates can vary between countries and agreements due to a number of factors. The main one affecting this is 'bargaining power' of the partner.

In efficient and consolidated markets such as the United States, a single provider could have wide market breadth allowing a faster and deeper rate of adoption, such agreement is likely to come with a royalty rate on the lower end. Whereas a fragmented market such as the wider European union would require multiple individual agreements, likely achievable at higher royalty rates, hence as a whole a higher royalty rate could be possible in the EU.

As a whole we have maintained a simple and conservative 7.5% royalty rate assumption across the board, we see this a realistic and achievable.

Margins

PIQs' out-licensing royalty model means no marketing or distribution expenses are required, further kits and reagents are to be manufactured by third parties reducing capital outlay needed to the bare minimum. This lack of operating costs should allow royalties received on PromarkerD sales to follow almost straight to the bottom line. We have conservatively assumed an 80% gross profit margin is achieved on royalties received.

Total Addressable Market

We have outlined the potential annual revenues achievable within countries which PIQ currently holds (or pending) patents on PromarkerD, shown below:

Country	IDF Region	Patent Status	Diabetic Pop. (2021e)	% of Global	Test price**	Total Adressable Market (US$m/pa)†	PIQ Royalty Potential (US$m/pa)††
Australia	W. Pacific	Granted	1.3	0%	$150.0	200	15
Brazil	S. & C. America	Granting	17.5	4%	$25.0	437	33
Canada	N. America & C.	Granted	2.9	1%	$150.0	431	32
China	W. Pacific	Granted	120.5	25%	$50.0	6,026	452
Europe*	Europe	Granted	30.2	6%	$150.0	4,524	339
Hong Kong	W. Pacific	Pending	0.7	0%	$150.0	112	8
India	SE. Asia	Pending	80.8	17%	$25.0	2,021	152
Indonesia	W. Pacific	Granted	11.1	2%	$25.0	276	21
Japan	W. Pacific	Granted	7.6	2%	$150.0	1,147	86
Russia	Europe	Granted	8.5	2%	$50.0	423	32
Singapore	W. Pacific	Granted	0.7	0%	$150.0	99	7
United States	N. America & C.	Granted	31.9	7%	$150.0	4,780	359
Total			**313.7**	**65%**	**$65.3**	**20,478**	**1,536**

†Assumes 1 test per person per year

††Using 7.5% Royalty Rate

*Covers: France, Germany, Italy, Spain, Turkey, and the UK

**ESHL estimates, broadly grouped by economic categories (GDP/Capita)

Source: PIQ Annual Report, IDF, EHSL estimates

We can begin to see the immense size of the opportunity present – this is not even accounting for the forecasted growth in diabetes prevalence going forward.

Beyond this there also remains countries where PIQ currently doesn't hold patents on PromarkerD, these countries amount to ~51% of the global diabetic population.

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It is further worth to mentioning that PromarkerD could potentially expand to be applicable beyond just people with diabetes, but include pre-diabetics or high-risk groups (e.g. Over 45yrs old).

Outlook & Forecasts

We have forecasted sales of PromarkerD within countries where PIQ currently has a partner, in addition to the United States, which we view as a key market and likely to form part of their near-term sales.

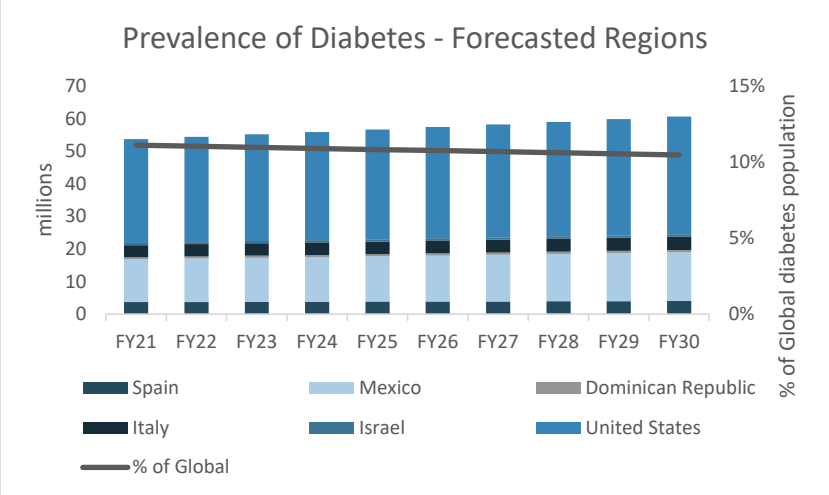
Beyond that, we highlight there is potential for PIQ to sign additional agreements in Europe in the near term, as well as larger markets like China in the medium term.

Our forecasting has been kept simple in this early stage of commercialisation, the key inputs which form our forecast are shown in the table below:

Key Inputs		Diabetes Est.			2030 Target		
Country	IDF Region	2019	2030	First Sales	Penetration	Pricing	Royalty
Spain	Europe	3.6	4.0	3Q'FY21	10%	150	7.5%
Israel	Europe	0.6	0.7	4Q'FY21-1Q'FY22	10%	100	7.5%
Italy	Europe	3.7	4.1	3Q'FY21	10%	150	7.5%
Mexico	N. America	12.8	14.9	3Q'FY21	10%	100	7.5%
United States	N. America	31.0	36.2	4Q'FY21-1Q'FY22	10%	150	7.5%
Dominican Republic	S. America	0.6	0.7	3Q'FY21	10%	50	7.5%
Total/Blended		52.3	60.7		10%	135.9	7.5%

Source: IDF, EHSL Estimates

We have first quantified the number of diabetics within each forecasted country using the IDFs starting (2019) estimate and then growing these figures with their respective region forecast growth rates. The results of this shown below.



Source: EHSL Estimates

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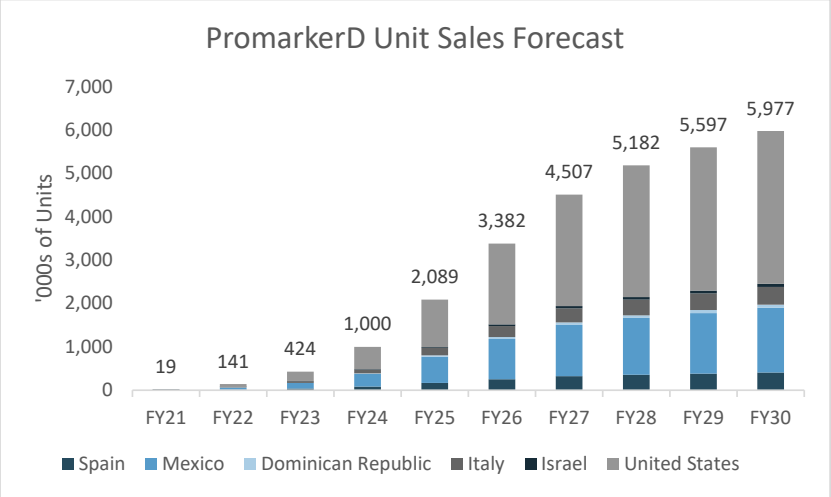
Applying the target market penetration and modelling adoption via the 'S-Curve' we estimate unit sales, as shown below:



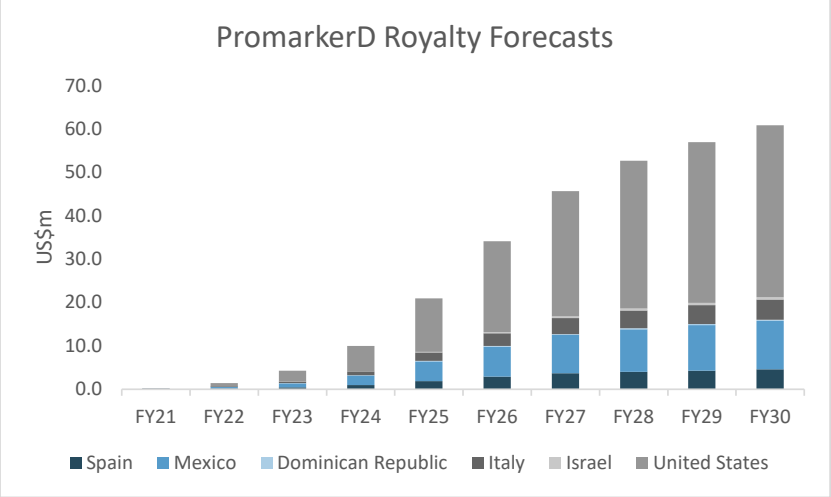
Source: EHSL Estimates

Sales begin modestly, we forecast a conservative 19,000 test sold in FY'21. This begins to quickly grow into sizable numbers, achieving 1 million annual tests shortly after FY'24.

Although these volumes appear sizeable, we see these figures as achievable and possibly conservative when considering the relative market penetration.

These base forecasts would still, by 2030, only amount to ~1% of all people with diabetes (diagnosed and undiagnosed) using the test once per year. We can begin to see the sizable blue sky possible should PIQ gain modest levels of market penetration beyond our forecasts.

Applying respective country unit pricing assumption and royalty rates (flat 7.5%) we generate our forecasts of PromarkerD royalties, as shown below:



Source: EHSL Estimates

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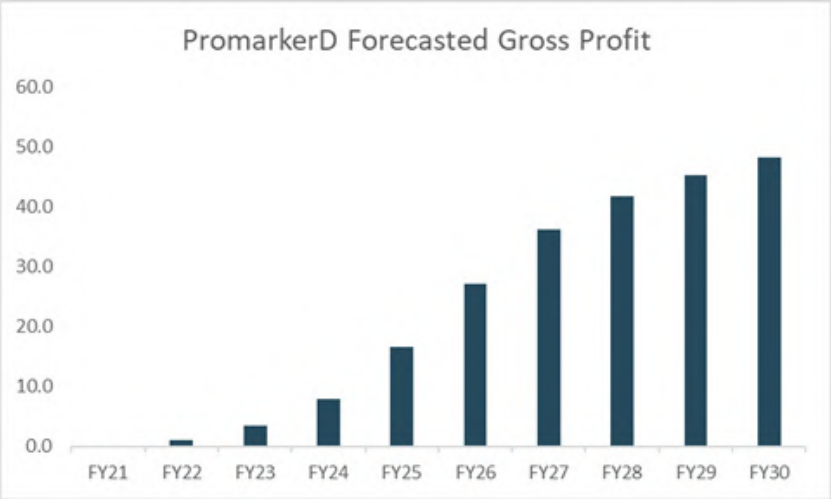
Applying our forecasted GP margin, we see segment gross profit below:



Source: EHSL Estimates

Our forecast shows the generation of sizeable relative revenues as moderate PromarkerD uptake occurs in our forecasted regions. In order to be achieved, our forecasts rely on PIQ achieving a number of key commercial milestones. These milestones discussed in detail previously, include but are not limited to: signing commercial agreements, achieving reimbursement and payor coverage, etc.

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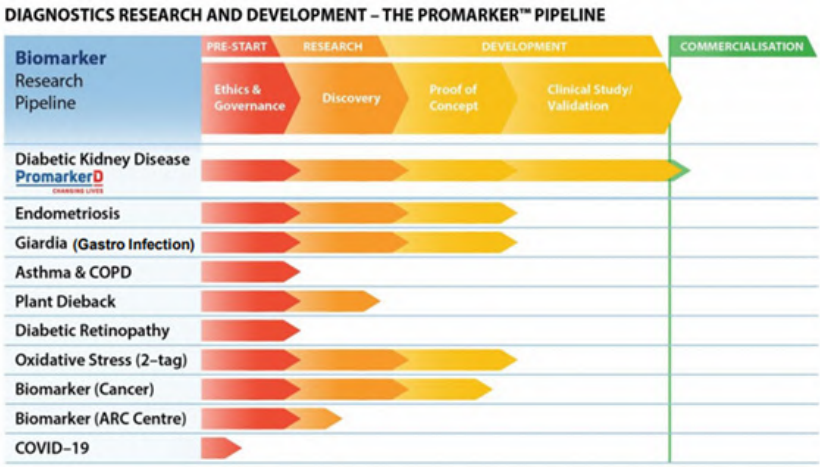
Promarker™ Platform

The Promarker™ platform is a propietary technology-based workflow platform developed by PIQ. The platform was used to discover, verify, and analytically validate the panel of protein biomarkers used to build the headline PromarkerD test.

Source: PIQ Annual Report

PIQ aims to continue leveraging this platform to develop and commercialise a suite of diagnostic tests. The various near-term biomarkers (highlighted in the pipeline below) individually could create significant opportunities down the line for PIQ – some tests having enormous addressable markets.



Source: PIQ Investor Presentation

We view these potential opportunities as free options in our investment thesis, not currently ascribing any value.

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The pipeline opportunities include:

Endometriosis

Status: Proof of concept study completed, Validation study pending

Endometriosis is a chronic gynaecological disorder; the deliberating condition occurs when the tissues that line the uterus spread outside of the uterine cavity and surround other organs.

Endometriosis affects 1 in 9 women, its estimated ~200 million women will experience it.

PIQ released an update in March 2020 on its proof of concept study for endometriosis biomarkers. The study performed on 54 women returned statistically significant results.

Diagnosis of endometriosis currently takes 7 to 12 years, with testing mostly limited to invasive procedures. The gold standard test involves an invasive laparoscopy, a procedure requiring a small cut in the abdominal wall to insert a camera.

PIQ's proof of concept study presents a significantly safer and easy alternative, using a simple blood test to test for endometriosis using protein biomarkers.

On the back of this, PIQ has submitted an extensive patent application. The patent describe a panel of novel biomarkers potentially capable of diagnosing endometriosis.

PIQ is currently seeking a partner in order to source patient samples and undertake a larger clinical study.

We anticipate clinical studies to be fast and broadly straight forward. Conceptually thinking, such studies would only require a cohort of people who are known to have and not have endometriosis, then validating the biomarkers panel to distinguish the two.

If successful it would be the first non-invasive test for endometriosis.

Given the large prevalence, cost, and lack of diagnostics, PIQ believes there would be significant commercial interest.

Oxidate Stress Markers – '2-tag' Technology

Status: Commercialisation Discussion, Proof of concept study completed, clinical validation pending

Pre-dating the companies listing, PIQ has been in collaboration with the University of Western Australia (UWA), this ongoing partnership is developing a process which could become the next generation of medical diagnostic tests.

The system called '2-tag' technology measures oxidative stress. The process works using two labels ("2-tag") that attach to proteins in the sample and wherein the ratio of the signals from the labels can be used for clinical and analytical purposes.

Oxidative stress refers to an imbalance of free radicals and antioxidants in the body. The human body produces reactive oxygen species (e.g. free radicals) during normal metabolic processes, while at the same time the body's cells produce antioxidants that neutralise these 'free radicals. Typically, the body is able to maintain this balance, however, if uncontrolled, free radicals can cause damage to DNA and proteins.

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This damage, a result of high oxidative stress levels, have been linked to wide range of diseases which include:

- Stroke
- Heart Attack
- Parkinson's disease, and
- Muscular dystrophy and muscle damage

The methodology being developed by PIQ can be applied to asses a wide range of reactive oxygen species. The process goes further to possibly include adapted versions which could assist in the characterisation of the structure of biosimilars (protein-based drugs).

PIQ currently aims to commercialise a novel test with UWA that measures the effect of these free radicals on the body's antioxidant defence, the kit developed has the potential to identify oxidative stress in its early stages before non-reversable damage has occurred – allowing the introduction of early treatment.

This process builds on PIQs existing Promarker™ platform, going beyond simply identifying the number and types of protein to further understand the subtle 'decorations' on the actual proteins.

PIQ has gone further to demonstrate proof on concept in several published studies, specifically targeting Duchenne muscular dystrophy in addition to exploratory works in aquaculture and sports management

PIQ holds patents on "method to determine the redox [oxidation] state of proteins ('2-Tag')", currently holding patents in the United States and Australia, per below:

- United States - US 8,043,824 B2
- Australia - AU2006/001757

Although in its nascent stages and targeting novel areas of research, further progress has the potential to open up a new and potentially significant vertical.

Giardia (Causing Gastroenteritis)

Status: Proof of concept study completed, Validation study pending

PIQ is developing an improved giardia diagnostic test, currently collaborating with Murdoch University Veterinary School and a leading US veterinary company.

Giardia is heavily prevalent being one of the most common parasitic human diseases globally, surveillance data has suggested there are ~ 280m case each year.

The CDC estimates there are 1.2m cases each year in the united states, other estimates have this as high a 3-7% of the US population, with estimated prevalence rates as high as 30% in certain developing countries.

Although Giardia is not typically fatal, it does have complications which include:

- Dehydration – Result of severe diarrhoea
- Malnutrition - Result of severe diarrhoea
- Lactose Intolerance – May last long after infection is gone

The main issue highlighted with PIQ is the risk of certain zoonotic strains (strains which can cross from pets to humans) and the limitation of current tests to differentiate between the two.

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To date PIQ has identified strain specific Giardia targets and with this developed a prototype immunoassay. This prototype is pending validation using field samples, however as a result of COVID-19 it has been delayed. We expect further updates sometime between the end of this calendar year and into the new year.

If successful there could be large commercial opportunities as a consequence of the high levels of prevalence.

Oesophageal Cancer Biomarkers

Status: Proof of concept study completed. Clinical validation pending

PIQ announced last month it had entered into a partnership with QIMR Berghofer Medical Research Institute (QIMR Berghofer). The two aim to improve the detection of oesophageal adenocarcinoma cancer, the most common type of oesophageal cancer.

Under the partnership, PIQ will use its Promarker™ platform to analytically and then clinically validate a panel of biomarkers identified by QIMR berghofer, the novel biomarkers have been found to be associated with the early stages of oesophageal adenocarcinoma cancer.

The biomarkers target Barrett's Oesophagus, a pre-malignant condition associated with an increased risk of developing cancer of the oesophagus (food pipe) due to acid reflux.

Current standard of testing involves an endoscopy and biopsy, this procedure is invasive and costly, requiring specialist medical expertise and costing ~US$2,750 per patient in the United States.

There is an estimated +6m individuals who suffer from Barrett's oesophagus across North America, Australia, and Europe. In the United States alone, over 850,000 people undergo endoscopic screens every year – costing US$2.4bn (at a avg. rate of $US2,750/patient).

PIQ and QIMR Berghofer aim to use these results, if successful, to make a simple blood test for the cancer. This revolutionary feat would fundamentally change the screening of oesophageal adenocarcinoma cancer.

PIQ has further outlined the technology would be targeted at identifying the top 5% of people most at risk of oesophageal adenocarcinoma cancer, allowing physicians to prioritise these patients.

QIMR Berghofer currently has patents pending in:

- Australia
- Canada
- China
- Europe, and
- United States

If everything is successful, the agreement would see PIQ having first rights to license the IP and commercialise the test globally.

The current collaboration is outlined to last 1 year with each party bearing their own costs.

Overall there is significant opportunity through the potential reductions in costly endoscopy procedures.

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Plant Dieback (Phytophthora Cinnamomi)

Status: Discovery study ongoing.

PIQ is in an ongoing collaboration with the Centre for Crop and Disease Management and Curtin University investigating proteomic analysis (determining the protein maps) of the plant pathogen Phytophthora cinnamomic.

Plant Dieback poses a major threat to the Australian environment, it currently infects +1m hectares of WA bushland, including premium crops. The pathogen inhibits roots from absorbing water and nutrients, resulting in death, hence its name. Plant Dieback is estimated to cost the economy $160m per year in damage.

Research being undertaken by PIQ has the potential to identify weakness which could be used to help eradicate the disease.

Novel Disease Biomarkers – ARC Centre for Personalised Therapeutics Technologies

Status: In-licensing discussion (Ethics approved. Discovery study pending).

PIQ is in an ongoing collaboration with the Australian Research Council Centre for Personalised Therapeutics Technologies to apply the Promarker™ platform to complementary diagnostics. The two are targeting a discovery project in areas of significant unmet medical needs, currently in advanced discussions with other consortium members.

Asthma & COPD

Status: Ethics approval received, discovery study underway

PIQ announced in its recent annual report of having received ethics approval for a discovery study. The study in collaboration with Busselton Population Medical Research Institute aims to identify biomarkers for asthma and chronic obstructive pulmonary disease (COPD).

PIQs collaboration on the study gives it access to the globally recognised Busselton Health study, established in 1966 it is one of the longest running epidemiological research programs in the World.

Diabetic Retinopathy

Status: Ethics approval received, discovery study underway

PIQ has an ongoing collaboration agreement with the University of Western Australia (UWA) to identify early markers for diabetic retinopathy.

Diabetic retinopathy is vision impairment caused by diabetes and is a common complication of the underlying disease, developing in 1 of 3 diabetics. Caused by damage to the blood vessel at the back of the eye, diabetic retinopathy is a leading cause of blindness in the united states, contributing to ~20,000 new cases every year.

Early diagnosis has potential to reduce incidence, with early intervention and treatment reducing the risk of blindness by 95%.

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PIQ's collaboration is making use of the Fremantle Diabetes Study (FDS) sample repository to look for prognostic biomarkers in the blood that can potentially identify patients at risk of diabetic retinopathy. This same study provided the data used in developing PromarkerD.

Successful results have the potential to create huge impacts on quality of life and generate substantial economic benefits.

COVID-19 Biomarkers

Status: Ethics approval pending, method development underway prior to discovery study

PIQ currently working with respiratory physicians on a program to identify potential biomarkers for COVID-19 susceptibility and response.

Analysing blood samples taken from patients at diagnosis, the goal is to:

A. Identify whether there are biomarkers in mild COVID-19 patients, specifically markers that are protective in that individual, and

B. Determine if there are biomarkers which predict severe or critical COVID-19 infections.

Successful identification of such biomarkers would be immensely valuable to clinicians, allowing triage of patients upon diagnosis, ultimately helping hospitals allocate there, in some cases, limited resources.

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Analytical Business

The Analytical Business, based in Perth, operates out of a world class facility at the QEII medical centre. PIQ was the first company in the world to receive ISO 17025 laboratory accreditation for proteomics services (protein testing), and can be broadly described as the most accredited protein testing laboratory in the world.

Key services offered are:

- Specialist analytical work (e.g. food product quality control)
- Consulting services
- External biomarker analysis services
- Biosimilars testing, and
- Pharmacokinetic (PK) testing

The business has been important in underwriting the broader groups R&D spending – slowing the cash burn as the company moves to commercialize PromarkerD, as well as continuing to grow its pipeline of novel tests within the Promarker tech platform pipeline.

Accreditation

PIQ analytical business possesses significant accreditation, per above in 2009 the business was the first laboratory in the world to received ISO/IEC accreditation for proteomics services (Accreditation number: 16838).

PIQs internationally recognised accreditations include:

- ISO 17025: 2015 – R&D with Good Laboratory Practice (GLP) overlay
- ISO 17025: 2015 – Chemical Testing

These achievements define PIQ's consistent ability to provide technically valid, traceable, and reproducible results. Valuable in providing clients and regulatory authorities confidence in test results received.

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Key markets

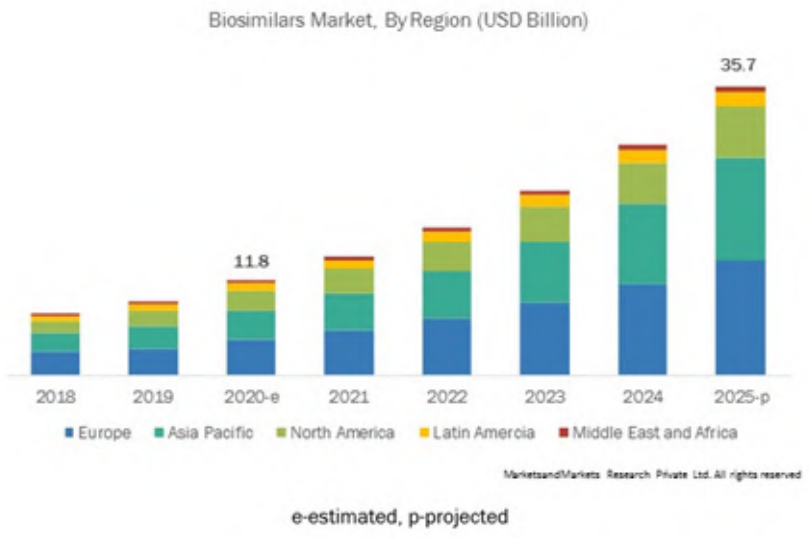
Biosimilars & Biologics

Biosimilars and Biologics are a type of medicine which are highly similar to a 'reference' biological medicine. They are not exact copies, but have the same effect.

PIQ is well placed to help pharmaceutical companies develop their own biosimilars once the patent on the original reference medicine ends.

The biosimilar market is expected to grow at a 24.7% CAGR over the next 5 years from US$11.8bn in 2020 to US$35.7bn in 2025.

The year by year market growth and composition shown below:



Source: Markets and Markets

The bulk of this market is contained within Europe, Asia-Pac, and North America.

We can further examine the market by looking at the pipeline of potential future biosimilars based on forecasted patent expiries of the existing drugs.

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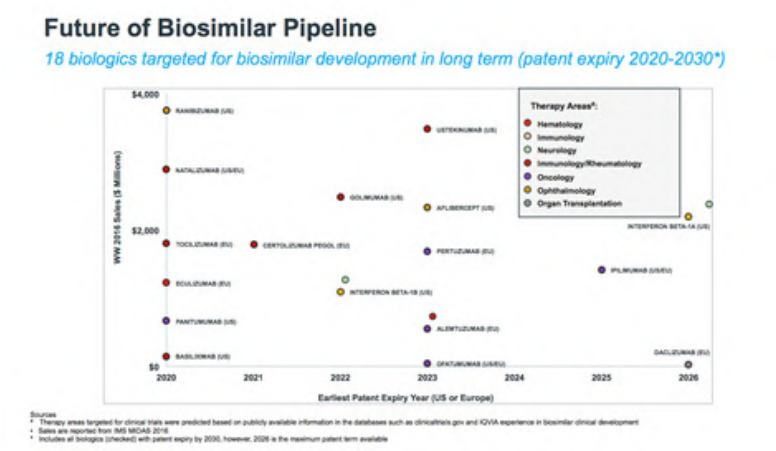
Patent expiry date and respective annual drug sales are shown in the chart below:



Source: RAPS

We can begin to see the massive size of the biosimilars and biologics market in addition to its rapid growth outlook, both of these factors creating increasing opportunities for PIQ.

Pharmacokinetic (PK) Testing

PIQ works with pharmaceutical companies proving pre-clinical and clinical quantitative testing of any new investigational drugs.

Using its expertise and experience in target mass spectrometry, PIQ provides a suite of testing capabilities which include:

- Pharmacokinetic (PK)
- Pharmacodynamic (PD), and
- Companion Diagnostic (CDx) services

The scale of opportunity present for PIQ is demonstrated by the scale of the broader clinical trial market. The global clinical trial market is expected to grow at a CAGR of 5.1% between 2020 and 2027, worth an estimated US$46.8bn in 2019.

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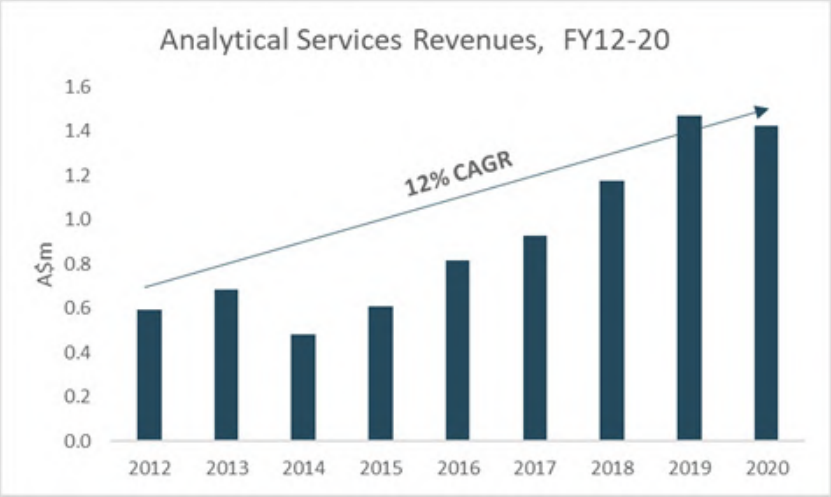
Outlook & Forecasts

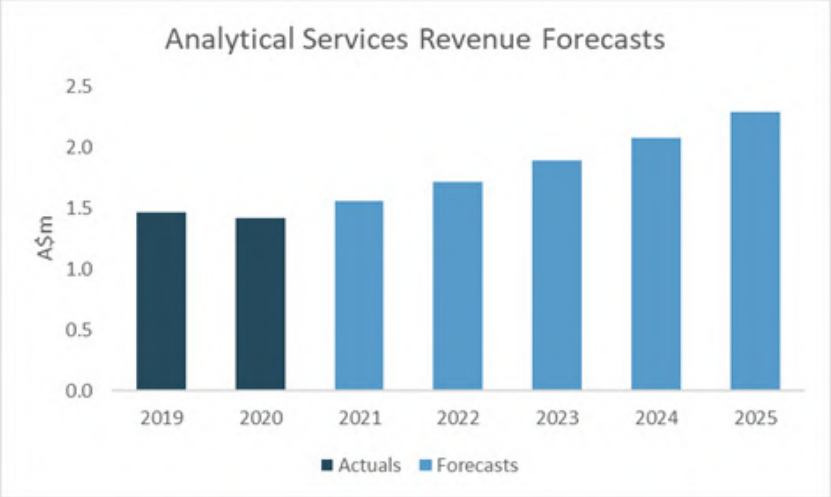
The analytical business has grown revenues in 6 of the last 8 years, growing at a CAGR of 12% over this period to $1.4m in 2020.



Source: PIQ Annual Reports, EHSL estimates

Although sales were slightly down in 2020, the result of COVID-19, we see sufficient room for further growth going forward. This demonstrated by our previous discussion of large and growing addressable markets.

We have conservatively forecasted revenues growing at 10% per year over the next 5 years, to $2.3m in 2025, well achievable in our opinion.



Source: PIQ Annual Reports, EHSL estimates

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Financials

P&L

Our summary P&L forecasts out to 2025 are shown below:

FY	Units	2019	2020	2021	2022	2023	2024	2025
PromarkerD Royalties	A$m	0.0	0.0	0.3	2.0	6.0	14.1	29.5
Analysis Business	A$m	1.5	1.4	1.6	1.7	1.9	2.1	2.3
Other Income	A$m	1.2	1.6	1.1	1.0	1.0	1.0	1.0
Total Sales	A$m	2.7	3.0	2.9	4.7	8.8	17.2	32.8
(-) COGS	A$m	0.0	0.0	-0.1	-0.4	-1.2	-2.8	-5.9
(-) OPEX	A$m	-4.3	-4.4	-4.9	-5.3	-5.7	-6.1	-6.6
EBITDA	A$m	-1.7	-1.4	-2.0	-1.0	2.0	8.2	20.3
(-) D&A	A$m	-0.2	-0.4	-0.4	-0.4	-0.6	-0.5	-0.5
EBIT	A$m	-1.9	-1.7	-2.4	-1.3	1.4	7.7	19.8
(-) Net Finance	A$m	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(-) Other Expenses	A$m	-0.2	0.0	0.0	0.0	0.0	0.0	0.0
(-) Tax	A$m	0.0	0.0	0.0	0.0	0.0	0.0	-4.5
NPAT	A$m	-2.1	-1.8	-2.4	-1.4	1.4	7.7	15.2
(+/-) Abnormals	A$m	0.2	-0.4	0.0	0.0	0.0	0.0	0.0
Norm NPAT	A$m	-1.9	-2.2	-2.4	-1.4	1.4	7.7	15.2

Source: PIQ Annual Reports, EHSL estimates

Key Takeaways:

- We anticipate first sales for PromarkerD occurring in FY'21, baring COVID-19 does not deteriorate between then
- We are forecasting PromarkerD achieves a 3.7% market penetration within our regions of forecasts by 2025, translating to ~2m units sold within that FY
- We forecast a continuance in PIQs Analytical Services businesses growth
- Base on all of this we anticipate profitability being achieved in 2023

Further areas of discussion:

Operating Expenses

Although forecasting cost structure at this early stage is difficult, we anticipate PIQs overhead will remain relatively light as a result of their targeted out-license business model. We anticipate modest levels of operating costs growth, growing at a CAGR of ~9% between 2020 and 2025, to $6.6m.

Taxes

PIQ as of FY20 retains ~$10m in accumulated losses, we expect this to grow over the next 2 years before being consumed against future earnings. This situation has the effect of temporarily reducing PIQs effective tax rate in early years of profitability.

Other Income

Foundational to PIQs success has been its continual R&D spending, having spent ~$2.6m in FY'20 on R&D PIQ was eligible for a ~$1.1m tax rebate. We do not expect PIQ to stop investing in R&D and have consequently forecasted tax rebates inline with historical levels (~$1m/pa) going forward.

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Balance Sheet

Our consolidated balance sheet forecasts out to 2025 are shown below:

FY	Units	2019	2020	2021	2022	2023	2024	2025
Cash	A$m	1.5	2.4	6.1	4.6	4.9	12.0	25.9
Receivables	A$m	0.5	0.4	0.4	0.6	1.1	2.1	4.0
Other	A$m	1.2	1.4	1.4	1.4	1.4	1.4	1.4
Total Current Assets	A$m	3.2	4.1	7.8	6.6	7.4	15.5	31.3
PP&E	A$m	0.2	1.3	1.2	1.2	2.0	1.8	1.6
Other Assets	A$m	0.2	0.1	0.1	0.1	0.1	0.1	0.1
Total Assets	A$m	3.6	5.6	9.2	7.9	9.5	17.4	33.0
Payables	A$m	0.3	0.4	0.5	0.6	0.7	0.9	1.3
Borrowing	A$m	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Lease Liabilities	A$m	0.0	0.1	0.1	0.1	0.1	0.1	0.1
Provisions	A$m	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total Current Liabilities	A$m	0.5	0.6	0.7	0.8	0.9	1.1	1.5
Non-current Liabilities	A$m	0.1	0.5	0.5	0.5	0.5	0.5	0.5
Total Liabilities	A$m	0.6	1.1	1.2	1.2	1.4	1.6	1.9
Net Assets	A$m	3.0	4.4	8.0	6.7	8.1	15.8	31.1

Source: PIQ Annual Reports, EHSL estimates

Key areas of discussion:

Cash, Debt, & liquidity

We forecast PIQ maintains ~$8.8M in pro-forma cash, post its successful $6m capital raising, and $1.1m R&D tax incentive.

PIQ has no debt other than minor lease liabilities.

Property, Plant and Equipment

PIQ operates a capital light business model, specifically in respect to PromarkerD per our previous commentary we do not expect this to change as a result of the out-licensing model.

We have forecasted modest levels of capital expenditure broadly in line with the business's historical levels, mostly around the analytical business, we further expect this capital expenditure to be clustered into larger chunks which occur every couple year – relating to new equipment purchased (e.g. Mass Spectrometers).

Dividend

We have not forecasted any dividends occurring at this early stage.

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Board of Directors and Management

Board of Directors:

Mr Terry Sweet

Title: Chairman

Education/Accreditations: FAICD

Shares Owned: 2,348,00

Options Owned: 400,000

Background: Terry has been a director of several listed companies over the past 30 years in both executive and non-executive capacities. These companies include XRF Scientific Ltd, Heartlink Ltd, and scientific Services Ltd. Originally trained as a chemist, his interests and expertise now lie in the area of development and supervision of a culture of board integrity, commensurate with technology commercialisation. Terry is a fellow of the Australian Institute of Company Directors and joined the board in June 2014.

Dr Richard Lipscombe

Title: Managing Director

Education/Accreditations: PhD (London), MA (Oxford)

Shares Owned: 19,048,705

Options Owned: 0

Background: Richard, a co-founder of the company, is a highly practised business manager and protein chemist expert in analysing biomolecules using proteomic techniques. He has an extensive expertise in chemistry, immunology, mass spectrometry, peptide synthesis, high performance computing robotics. Richard has international experience in both science and business gained over a 30-year period in Australia, USA, and the UK, including work in hospital and academic laboratories and commercial organisations. He completed his chemistry degrees (MA) at Oxford University, his PhD in immunology at London University and was a Post-Doctoral scientist (molecular immunology) in a large research institution in Australia (Telethon Kids Institute). After managing the protein analysis facility at the university of Western Australia, he co-founded Proteomics International Ltd in 2001, Richard is well published in peer previewed journals, and holder of serval patents.

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Mr Roger Moore

Title: Director

Education/Accreditations: R (Denmark), B Pharm (U. Syd)

Shares Owned: 717,000

Options Owned: 200,000

Background: Roger has 40 years' experience in the international pharmaceutical industry, including almost 30 years as President of Novo Nordisk Japan (Novo Nordisk is the world's largest manufacture of insulin and a global leader in diabetes care). Roger established Novo's organisation in Japan as the first employee in 1977, and worked for the company until his retirement as chairman at the end of 2007. From 2000, Roger was appointed senior vice president, Japan, Australia, New Zealand and the pacific. He was also appointed a member of the senior management board, Novo Nordisk A/S. in 2007 Mr Moore was awarded the Knight's Cross of the order of the Dannebrog (R) by Queen Margrethe II of Denmark. Roger joined the board in October 2016.

Mr Paul House

Title: Director

Education/Accreditations: GAICD, BCom (UWA)

Shares Owned: 718,864

Options Owned: 200,000

Background: Paul has over 25 years' experience with multi-national corporations and is currently CEO of Imdex (ASX: IMD). He recently served eight years as Managing Director of SGS India, where he was responsible for a workforce of 4,500 personnel and 38 laboratories; SGS is the world's leading testing, inspection and Certification (TIC) company. Previously held CFO and COO roles and has a track record for delivery of business performance targets, revenue growth, margin improvement, market share and productivity, across multiple services, markets and border. A Fellow of the Australian Institute of Management and a Graduate Member of Australian Institute of Company Directors, Paul joined the Board in November 2017.

Management Team:

John C. Morrison

Title: Head of Business Development

Background: John has over 35 year' experience in life sciences, biotechnology, and diagnostic industries. John has a degree in Chemistry and an MBA from Boston University. He has held several management positions while at NEN Life Sciences and DuPont before focusing his last 15 years in business development at Perkin Elmer. John successfully executed many licensing deals and several global acquisitions while in that role. John is based in Massachusetts (United States) and joined the company in 2014.

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Dr Kerryn Garrett

Title: General Manager

Background: Kerryn is responsible for overseeing the day-to-day operations of the company as well as ensuring that operations are in line with the strategic direction of the company. Kerryn joined Proteomics International in 2019, and previously held the role of Laboratory Manager. Kerryn has over 30 years of research experience, and brings a key set of expert skills from her extensive experience in the diagnostic pathology industry and the regulatory elements of accreditation agency NATA.

Dr Scott Bringans

Title: Research Manager

Background: Scott has over 20 years' experience in protein chemistry and mass spectrometry, and leads the diagnostic program encompassing PromarkerD. Alongside this is the development of novel methodology to add to Proteomics International's technology platform and continually expanding the fee-for-service and quality testing portfolio. Scott has been with the company for 14 years.

Dr Pearl Tan

Title: Business Manager - PromarkerD

Background: Pearl is focused on leading the team commercialising PromarkerD. She has been with Proteomics International since 2013, and her previous roles include Chief Operating Officer of Proteomics International and leading the commercialisation of the patented 2-tag technology (used to measure oxidative stress). Pearl has background in research and completed her PhD in Biochemistry and Molecular Biology at the University of Western Australia.

Dr Javed Khan

Title: Business Manager – Analytical Services

Background: Javed has international commercial experience gained over 10 years in the life science industry. With a PhD in chemistry and Biomolecular Science from Macquarie University, Javed joined Proteomics International as a computational proteomics specialist in 2013, before transitioning into project management/business development and was recently appointed manager of the company's extensive analytical services business portfolio.

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Top Shareholders

The top 17 PIQ shareholders are shown below:

Top PIQ Shareholders*		Shareholding		
Rank	Shareholders	m	%	Director
1	Richard Lipscombe	19.05	20.6%	X
2	John Dunlop	3.86	4.2%	
3	Estate of William Parker	3.00	3.3%	
4	Terry Sweet	2.35	2.5%	X
5	Randolph Resources Pty. Ltd.	1.95	2.1%	
6	Littlejohn Embrey Engineering Pty Ltd	1.54	1.7%	
7	Slade Technologies Proprietary Limited	1.36	1.5%	
8	Slade Techonologies Pty Ltd	1.36	1.5%	
9	Scintilla Capital Pty Ltd	1.12	1.2%	
10	Lisa Floan	1.10	1.2%	
11	Konrad Floan	0.89	1.0%	
12	Harley Dalton	0.81	0.9%	
13	The Himstedt Family Trust	0.77	0.8%	
14	Paul House	0.72	0.8%	X
15	Ian Moore	0.72	0.8%	X
16	Patricia Marton	0.69	0.7%	
17	Darlene Gould	0.65	0.7%	
	Total	**41.93**	**45.4%**	**24.7%**
Source; IRESS, as of 30-sept-20				

**Shareholding figures have not been updated post the most recent capital raising.*

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Appendices

Appendix A: PromarkerD Clinical Studies

Study Discussions as follows:

Study: Diagnostic Study (2016)

Title: Comprehensive mass spectrometry-based biomarker discovery and validation platform as applied to diabetic kidney disease

Journal published: EuPA Open Proteomics

This first study formed the foundation for the PromarkerD Test. The study discussed the use of the Promarker™ platform workflow to discover a panel of significant plasma biomarkers. The final biomarker MRM assay proteins were:

- Adiponectin
- Apolipoprotein A-IV
- Apolipoprotein C-III
- Complement C1q subcomponent subunit B
- Complement factor H-related protein 2
- Hemoglobin subunit beta
- Insulin-like growth factor-binding protein 3
- Protein AMBP

These proteins were then deployed across a 572 patient, independent cohort with type 2 diabetes. The multivariate analysis within a 572-patient cohort provided a panel of markers that performed well when either ACR or eGFR was the gold standard. This early stage study demonstrated strong discrimination (AUC=0.81) within the biomarker eGFR model (BM eGFR Model), which made use of:

- APOA4_Pep 2
- APOC3_Pep 1
- CFHR2_Pep 1
- IBP3_Pep 2

This early study demonstrated adding the protein panel significantly increased the prognostic benefit to known clinical risk factors in predicting renal decline in patients with T2DM.

Study: Prognostic Development Study (2017)

Title: Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II

Journal published: American Diabetes Association (ADA) conference proceedings

The study followed on from the 2016 diagnostic study; assessing a selection of biomarkers ability to predict rapid decline in eGFR in type 2 diabetes on a cohort of 345 community-based patients from the Fremantle Diabetes Study Phase II (FDS2).

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Biomarkers assessed (part of study objective) were:

- Plasma Apolipoprotein (apo) A-IV (apoA4)
- Apo C-III
- CD5 Antigen-like (CD5L)
- Complement C1q subcomponent subunit B (C1QB)
- Complement factor H-related protein 2
- Insulin-like growth factor binding protein 3 (IBP3)

The primary outcome of the trial was 'eGFR trajectory', similar analysis was also performed on:

- ≥30% eGFR fall
- Incident CKD (eGFR <60ml/min/1.73m2), and
- eGFR decline of ≥5 ml/min/1.73m2/year

As discussed, there is continued debate on the consensus definition of DKD. Likely the reason the study undertook analysis on these different definitions. We however view incident CKD as being the best definition, and hence the most relevant clinical end point in our view.

When looking at the Incident CKD (eGFR <60ml/min/1.73m2) end-point, the 'Clinical + Biomarker Model 2' showed strong discrimination (AUC=0.92) and reasonable calibration (Calibration slope=083). Excellent negative predictive value was further achieved (NPV=98.9%).

Study: Prognostic Validation Study (2019)

Title: Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II

Journal published: Journal of Diabetes and Its Complications

The 2019 study aimed to validate PromarkerD's ability to predict renal decline in an independent cohort of people with type 2 diabetes.

Data on 792 participants (patients who attended three biennial assessments in the original study) from the Fremantle Diabetes Study Phase II (FDS2) were used to validate PromarkerD's prognostic utility for predicting rapid renal decline over a four year follow up period.

Similarly, to previous studies different definitions of rapid eGFR decline were assessed, which were:

- incident DKD (eGFR <60 mL/min/1.73m2 at Year 4 in individuals above this threshold at baseline)
- ≥30% eGFR decline between study entry (baseline) and Year 4 (7.5%/year)
- annual decline in eGFR ≥5 mL/min/1.73m2 calculated as (baseline eGFR - Year 4 eGFR)/(follow-up time between baseline and Year 4)

The PromarkerD test had been further refined, now using a panel of plasma biomarkers (apoA4, CD5L and IGFBP3) with clinical variables (age, HDL-cholesterol and eGFR).

The consensus model demonstrated strong discrimination (AUC=0.88, 95%CI=0.84-0.93) and sensitivity (86.1%) and an excellent negative predictive value (98.1%). Overall having acceptable calibration.

The study overall proved PromarkerD to be an accurate prognostic test for future renal decline in an independent validation cohort of people with type 2 diabetes.

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Study: Third Party Prognostic Validation Study (2020)

Title: PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)

Journal published: Journal of Clinical Medicine

Also known as the 'Janssen Stage 1' study done with PIQ, it was the first 3rd party study done, and the second prognostic validation study.

The study provided external validation of the PromarkerD test, continuing to demonstrate that PromarkerD can predict clinically significant incident CDK in people with type 2 diabetes.

The study was also on the largest cohort to date, the large sample size was from the CANagliflozin CardioVascular Assessment Study (CANVAS), a large multi-center clinical trial independent of Australian population-based cohort which was used to develop the test. The participants were well characterized with clinical data available from bi-annual CANVAS trial visits

Although results were slightly less robust than previous Prognostic validation study (2019), we interpret this as a result of the "sicker" population. Highlighted by:

- Patients with longer diabetes duration, 12.4 yrs [8.0-18.0] (vs Median 9.0 [3.0-16.0] seen in previous studies)
- Lower overall eGFR of 77±18.8 (vs 80.6±18.8 seen in previous studies)
- Higher % of incident DKD, 16.5% (vs Median 13.1% seen in previous studies)
- Greater % male population, 67% (vs Median 53.1% in previous studies)

Despite all of this the study still assessed and validated the prognostic utility of PromarkerD in accurately predicting future renal decline (incident DKD) in people with type 2 diabetes

Additionally, and not to be missed, this study provides a huge and high-quality data set, which PIQ can use to refine and build upon PromarkerD with.

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Appendix B - Current Standards of Diagnosis

The clinical diagnosis of Diabetic Kidney Disease (DKD) is based on estimating kidney function (GFR) and kidney damage.

The KDGIO defines criteria for chronic kidney disease as [either of the following for >3 months]:	
Kidney Damage Markers	Albuminuria (AER ≥30 mg/24hrs; ACR ≥30 mg/g)
	Urine sediment abnormalities
	Electrolyte and other abnormalities due to tubular disorders
	Abnormalities detected by histology
	Structural abnormalities detected by imaging
	History of kidney transplantation
Decreased GFR	eGFR < 60 ml/min per 1.73 m2

Source: KDGIO 2012

The gold standard, and most widely used tests are the measurement of estimated Globular Filtration Rate (eGFR) and urinary albumin-to-creatine ratio (ACR, albuminuria). (highlighted in red)

The KDIGO further combines these two tests into a 'prognosis' matrix (shown below), however as we discuss, we see major limitations in its capabilities and hence utility.

Prognosis of CKD by GFR and Albuminuria Categories: KDIGO 2012

GFR categories (ml/min/ 1.73 m²) Description and range				Persistent albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-300 mg/g 3-30 mg/mmol	>300 mg/g >30 mg/mmol
	G1	Normal or high	≥90			
	G2	Mildly decreased	60-89			
	G3a	Mildly to moderately decreased	45-59			
	G3b	Moderately to severely decreased	30-44			
	G4	Severely decreased	15-29			
	G5	Kidney failure	<15			

Green: low risk (if no other markers of kidney disease, no CKD); Yellow: moderately increased risk; Orange: high risk; Red, very high risk.

Source: KDIGO 2012, clinical practice guidelines

These two tests are used to identify DKD, which is identified clinically by persistently high urinary albumin-to-creatinine ratio ≥30 mg/g and/or sustained reduction in eGFR below 60 ml/min per 1.73 m2

This "and/or" statement is where all the issues and limitation of current DKD diagnosis arise. The standard tests used have their own limitations, especially in the early stages of DKD. The result of this 'grey' criteria is that under-diagnosis can occur and does occur.

An example of a possible missed DKD is when an eGFR >60 ml/min per 1.73 m2 and no present albuminuria is registered. The patient in this situation would not be defined as having DKD (considered low risk), this is a very real outcome with a UKPD study showing 51% of patients who go onto develop DKD do not show preceding albuminuria.

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Although there are other 'hall markers' of kidney damage which could have resolved this example issue (as shown in the table) their widespread use in this early stage, and in consensus, is unlikely. Some practitioners may even consider the absence of an elevated ACR and a normal to moderate eGFR as fine and not proceed further. This issue doesn't even begin to bring up the limitations in eGFR testing which could add a further layer of complexity to this problem.

We can begin to see how under diagnosis of DKD has occurred – specifically within early stages.

This above discussion is only centred on 'diagnosis', whether a person has DKD or doesn't. The concept of a predictive test, which would allow early intervention before DKD develops is not available with current standard tests, a form of this is discussed (using heat map for risk), however this is very limited in any utility due to the same limitation discussed around diagnosis.

Glomerular Filtration Rate - Estimated Globular Filtration Rate (eGFR)

The estimated Glomerular Filtration Rate is the best way to measure how well a person's kidneys filter waste from their blood, overall it is the best measure of kidney function. Simply stated, if a person's filtration rate is low, then the kidney is not working properly.

In reality, it is difficult to calculate the actual rate at which a person's kidneys are functioning. Hence the use of an 'estimated' GFR, this estimated figure is calculated using a formula which incorporates:

- Age
- Gender
- Blood Creatine Level

Creatine is a waste product produced by the muscles, it is usually removed from the blood by the kidneys before passing out in the urine. When the kidneys aren't working properly creatine will remain in a person's blood.

The test is not measured in children aged less than 18 or if you are pregnant.

Incident DKD is defined by sustained reduction in eGFR below 60 ml/min per 1.73 m^2.

The different GFR categories are shown below:

GFR Category	eGFR (ml/min/1.73m2)	Interpretation
G1	≥90	Normal to High
G2	60-89	Mildly decreased
G3a	45-59	Mildly to moderately decreased
G3b	30-44	Moderately to severely decreased
G4	15-29	Severely decreased
G5	>15	Kidney Failure

Source: KDIGO

eGFRs above 60 (G1 and G2) are not indicative of DKD unless other markers of kidney damage are present. Urinary albumin-to-creatinine ratio (ACR) is typically used as the marker of kidney damage. Hence why these two tests in conjunction are what's used as the basis for staging DKD.

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Despite wide implementation of the test – many clinicians and patients remain unaware of the uncertainty associated with the GFR estimating equation.

This is demonstrated in the statistical accuracy of the test, specifically its P30, which is the statistical likelihood of eGFR being within ±30% of GFR. The eGFR test is at best 90% accurate in estimating GFR within ±30% (common estimating equations sit between 80-90%)

Potentially more significant, the eGFR equation is significantly less precise at higher GFRs test, the result of the equations characteristics. This is very troubling on the basis of early detection of DKD, which may be associated with an elevated GFRs (hyperfiltration).

Kidney Damage - Urinary Albumin-to-Creatinine Ratio (ACR)

Kidney damage is typically determined using urinary albumin-to-creatinine ratio (ACR), ACR works by detecting elevated levels of protein (albuminuria) in the urine; a marker of kidney damage.

Other markers of kidney damage according to the KDIGO include:

- Urine sediment abnormalities
- Electrolyte and other abnormalities due to tubular disorders
- Abnormalities detected by histology
- Structural abnormalities detected by imaging
- History of kidney transplantation

Albuminuria is the increased excretion of urinary albumin. Albumin is the most common type of protein in the urine, most individuals excrete trace amounts. The persistent increase in quantities of albumin is a marker of kidney damage.

The preferred test for albuminuria is a urinary albumin-to-creatinine ratio performed on a spot urine sample, preferably in the morning.

The presence of Albuminuria ACR ≥30 mg/g (≥3 mg/mmol) for >3 months is criteria for kidney damage.

ACR is categorized as:

Category	Albumin-to-Creatinine Ratio (ACR)		Interpretation
	(mg/mmol)	(mg/g)	
A1	<3	<30	Normal to Mildly increased
A2	3-30	30-300	Moderately increased
A3	>30	>300	Severely Increased

Source: KDIGO

Despite Albuminuria (determined through ACR) strength as a risk biomarker for DKD there remains significant limitations in its usage.

Most significantly is the fact that not all persons with DKD and reduced eGFR have Albuminuria – the result being under diagnosing of DKD.

A 2006 study (UKPD) showed 51% of people who developed an eGFR<60 ml/min per 1.73 m2 (incident DKD) did not have any preceding albuminuria.

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In addition to this, how albuminuria is measure is not always a standardized process. The measurement and common usage of the ACR test is considered a gold standard mostly as a result of patient convenience. Whereas there are other methods such as multiple collections over a specified time.

On top of this, daily variation in albuminuria is considerably high, further varying between individuals.

Albuminuria may also be increased by:

- Episodic hyperglycemia
- High blood pressure (BP)
- High-protein diet
- Exercise
- Fever
- Urinary tract infection (UTI), and
- Congestive heart failure

All these issues highlight the considerable limitations which come with using the ACR test.

Appendix C - Reimbursement Codes & Coverage

United States

In the United States, the process involves first applying for a relevant reimbursement code. In the case of PromarkerD, this would fall under the CPT® Proprietary Laboratory Analyses (PLA) code set. CPT PLA codes are managed by the American Medical Association (AMA) through the CPT Editorial Panel.

Codes can be applied for and granted quarterly (fall, winter, spring, summer)

The process takes a ~3 months from application deadline to code publication date, consider the "Fall 2020" quarter timeline as an example:

- Oct. 7 – Application submission deadline
- Oct. 14 – Public agenda posted to website
- Oct. 23 – Interest party comment request deadline
- Oct. 28 – PLA-TAG consideration completed
- Nov. 5 – Panel vote (at panel meeting)
- Jan. 1 – New and deleted codes, publication date
- Apr. 1 – New and deleted codes, effective date

Codes then become effective the following quarter, whereby test can be sold and reimbursed using the code.

Although securing the physical code itself is broadly straight forward, the greater challenge and more complex component is making sure that connected code will be covered by insurers. This means engaging with these key stakeholders and outlining an acceptable price point for PromarkerD, as PIQ has articulated it has done and is continuing to do (i.e. $50-150/test price points).

This next step towards establishing broad adoption of the code involves engaging with the Centres for Medicare & Medicaid Services (CMS) to establish of a national Medicare price in the Clinical Laboratory Fee Schedule (CFLS).

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Following this, the CMS determines whether and to what extent a new product will be covered and reimbursed under Medicare, this decision is typically followed closely by private payors.

This final process is one of the most important, it involves seeking a National Coverage Determination (NCD). This can be requested by either external parties (e.g. PIQ) or by CMS under different circumstances.

The process takes 6-9 months from application to final decision.

In the absence of a NCD, coverage is at the discretion of Medicare contracted based on a local determination.

Europe

Reimbursement codes follow a broadly similar process to the United States, although codes are done on a country by country basis (there isn't a centralised EU system as with regulation). However, the process is broadly stated as being less intensive than the United States as there are fewer stakeholders involved, typically just a government agency (managing universal healthcare).

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