EUROZ HARTLEYS

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PIQ: New Endometriosis Test Announced with Strong Diagnostic Performance

PIQ.ASX | PROTEOMICS INTERNATIONAL LABORATORIES LIMITED | HEALTHCARE | BIOTECHNOLOGY

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$0.79/sh	**A$1.80/sh** (UNCHANGED)	**SPECULATIVE BUY** (UNCHANGED)	**SETH LIZEE** SLIZEE@EUROZHARTLEYS.COM

Event

PIQ has announced the results of a novel world-first blood test for diagnosing endometriosis, it follows the company's breakthrough work from last year.

Impact

The new test was shown to **correctly identify up to 90% of patients with endometriosis** in a study of over 900 participants, a significant improvement from the initial version announced last August which was shown to correctly identify up to 78% of patients.

The simple test could provide an early screening tool for clinicians to rule in or rule out the need for invasive surgery - the current gold standard of diagnosis.

The company continues to believe a validated test will garner significant interest, both commercially and in the clinic.

Currently, it takes on average 7.5 years for women to get diagnosed, with no simple way to test for the condition. The gold standard for detection is an invasive surgical procedure (laparoscopy) followed by histopathology, which involves inserting a camera into the pelvis through a small cut in the abdominal wall and taking a biopsy for analysis.

Additionally, the study results indicate the current gold standard for diagnosis may actually be misdiagnosing some patients.

Endometriosis occurs when tissue lining the uterus spreads outside the uterine cavity, which often results in pain (sometimes severe) and infertility. **The debilitating condition affects 1 in 9 women, and costs Australia alone $9.7 billion each year.**

PIQ will now look to confirm the clinical performance and clinical utility of the test in an independent patient cohort, as well as accelerate pathways to commercialise the biomarker panel as a new diagnostic screening test for endometriosis.

These results, developed in collaboration with the Royal Women's Hospital and the University of Melbourne were presented at the 70th annual scientific meeting for the international Society for Reproductive Investigation.

Action

Speculative Buy, $1.80/sh Price Target

The successful development and commercialisation of a simple blood test for Endometriosis could provide further upside to our current Valuation and Price Target, which we continue to emphasize is exclusively based on PromarkerD.

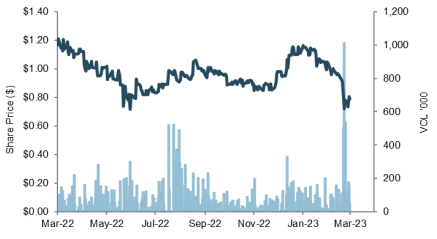
In the meantime, we continue to view the market's overreaction to last week's MSAC report on PromarkerD as a buying opportunity. The execution of a binding agreement with Sonic Healthcare USA provides a clear share price catalyst in the near term, with PIQ having recently stated in an update its in its closing stages.

Catalyst

- Binding Agreement with Sonic Healthcare USA
- US Reimbursement - Private /Public Payer Engagement
- US Sales

Share Price	0.79	A$/sh	
Price Target	**1.80**	**A$/sh**	
Valuation (DCF)	1.80	A$/sh	
WACC	12%		
Terminal Growth	3%		
Shares on issue	118.2	m	
Market Capitalisation	93.4	A$m	
Enterprise Value	84.8	A$m	
Cash (Pro-forma)	8.7	A$m	
Debt (inc. AASB16)	0.1	A$m	
Key Financial Metrics	**22A**	**23F**	**24F**
Revenue (A$m)	3.4	3.7	7.7
EBITDA (A$m)	-4.6	-4.4	-2.7
EBIT (A$m)	-5.0	-4.8	-3.2
Reported NPAT (A$m)	-5.0	-4.8	-3.2
Normalised NPAT (A$m)	-5.0	-4.8	-3.2
Gross Cashflow (A$m)	-4.1	-4.5	-2.8
Capex (A$m)	-0.1	-0.3	-0.8
Op. Free Cashflow (A$m)	-3.7	-4.8	-3.6
Revenue Growth (%)	15%	9%	106%
EBITDA Growth (%)	84%	-2%	-39%
Norm. NPAT Growth (%)	54%	-3%	-33%
Normalised EPS (Ac)	-4.6	-4.1	-2.7
Norm. EPS growth (%)	na	na	na
PER (x)	-17.3	-19.3	-29.0
EV:EBITDA (x)	-18.6	-19.1	-31.2
EV:EBIT (x)	-17.0	-17.5	-26.3

Performance



Source: Euroz Hartleys

Income Statement	22A	23F	24F
PromarkerD Royalties	0.0	0.2	2.3
Analysis Business	1.5	1.7	2.0
Consumables (Cost-through)	0.0	0.1	1.7
Other Income	1.9	1.7	1.7
Total Sales	**3.4**	**3.7**	**7.7**
(-) COGS	0.0	-0.2	-2.1
Gross Profit	3.4	3.5	5.5
(-) OPEX	-8.0	-8.0	-8.3
EBITDA	**-4.6**	**-4.4**	**-2.7**
(-) D&A	-0.4	-0.4	-0.5
EBIT	-5.0	-4.8	-3.2
(-) Net Finance	0.0	0.0	0.0
(-) Other Expenses	0.0	0.0	0.0
EBT	-5.0	-4.8	-3.2
(-) Tax	0.0	0.0	0.0
Reported NPAT	-5.0	-4.8	-3.2
(+/-) Abnormals	0.0	0.0	0.0
Norm NPAT	-5.0	-4.8	-3.2
Cash Flow Statement	**22A**	**23F**	**24F**
Profit Before Tax	**-5.0**	**-4.8**	**-3.2**
(+) D&A	0.4	0.4	0.5
(+) FX loss/(gain)	0.0	0.0	0.0
(+) Share base payments	0.5	0.0	0.0
(-) Tax Paid	0.0	0.0	0.0
(+/-)Other	-0.1	-0.1	-0.1
Gross Cashflow	**-4.1**	**-4.5**	**-2.8**
(-) Capital Expenditure	-0.1	-0.3	-0.8
(-) Change in NWC	0.5	0.0	-0.1
Operating Free Cashflow	**-3.7**	**-4.8**	**-3.6**
(-) acq of subs/other Invst.	0.0	0.0	0.0
(+) Proc. from disp of FA/subs	0.0	0.0	0.0
(-) Dividends Paid	0.0	0.0	0.0
(+) Equity issued	0.2	9.9	0.0
(+/-)Other	0.1	0.0	0.0
Net Cashflow	**-3.4**	**5.1**	**-3.6**
BoP Net Cash	**5.5**	**2.1**	**7.2**
(+/-) Net Cashflow	-3.4	5.1	-3.6
(+/-) AASB16	0.0	0.0	0.0
EoP Net Cash	**2.1**	**7.2**	**3.6**
Balance Sheet	**22A**	**23F**	**24F**
Cash	2.1	7.2	3.6
Receivables	0.4	0.5	1.0
Other Assets	1.8	1.8	1.8
Total Current Assets	**4.4**	**9.5**	**6.4**
PP&E	1.0	0.9	1.2
Other Assets	0.1	0.1	0.1
ROUA	0.0	0.0	0.0
Intangible Assets	0.0	0.0	0.0
Total Non-current Assets	**1.0**	**1.0**	**1.3**
Total Assets	**5.4**	**10.5**	**7.6**
Payables	1.5	1.5	2.0
Borrowing	0.0	0.0	0.0
Lease Liabilities	0.0	0.0	0.0
Provisions	0.2	0.2	0.2
Total Current Liabilities	**1.7**	**1.7**	**2.2**
Payables	0.1	0.1	0.1
Borrowing	0.0	0.0	0.0
Lease Liabilities	0.0	0.0	0.0
Provisions	0.2	0.2	0.2
Total Non-Current Liabilities	**0.3**	**0.3**	**0.3**
Total Liabilities	**2.0**	**2.0**	**2.5**
Net Assets	**3.4**	**8.4**	**5.2**
Issued Capital	19.3	29.2	29.2
Reserves	1.7	1.7	1.7
Accumulated Losses	-17.6	-22.5	-25.7
Total Equity	**3.4**	**8.4**	**5.2**

Performance Ratios	22A	23F	24F
Growth & Margins			
Revenue Growth	15%	9%	106%
EBITDA Growth	84%	-2%	-39%
EBIT Growth	74%	-3%	-33%
Normalized Net Profit Growth	54%	-3%	-33%
EBITDA margin	-133%	-119%	-35%
EBIT margin	-145%	-130%	-42%
Normalized net profit margin	-145%	-130%	-42%
Effective tax rate	0%	0%	0%
Liquidity			
Capex/depreciation	0.3	0.6	1.5
Current ratio	2.6	5.5	3.0
Quick ratio	1.7	5.0	2.3
Receivable days	46.8	46.8	46.8
Payable days	68.7	68.7	68.7
Risk Measures			
Dividend Cover	na	na	na
Payout ratio	0%	0%	0%
Net interest cover	na	na	na
Net debt/equity	-62%	-86%	-69%
Returns			
ROIC	-147%	-57%	-62%
ROA	-92%	-46%	-42%
ROE	-147%	-57%	-62%
Share Data/Valuation	**22A**	**23F**	**24F**
Share Data			
Issued shares	105.8	118.2	118.2
Weighted ave shares	105.5	112.0	118.2
Fully diluted shares	109.3	118.2	118.2
Basic EPS	-4.7	-4.1	-2.7
YoY change	na	na	na
Fully diluted EPS	-4.6	-4.1	-2.7
YoY change	na	na	na
Fully diluted normalised EPS	-4.6	-4.1	-2.7
YoY change	na	na	na
Dividend/share	0.0	0.0	0.0
Franking	na	na	na
Gross cashflow/share	-3.9	-3.8	-2.4
NBV/share	3.2	7.1	4.4
NTA/Share	3.2	7.1	4.4
Valuation			
PER (Basic)	-16.8	-19.3	-29.0
PER (Fully diluted)	-17.3	-19.3	-29.0
PER (Fully diluted, normalized)	-17.3	-19.3	-29.0
P/CFPS	-20.3	-20.7	-33.5
Price/NBV	24.6	11.1	18.0
Price/NTA	24.6	11.1	18.0
Dividend Yield	0.0	0.0	0.0
EV/EBITDA	-18.6	-19.1	-31.2
EV/EBIT	-17.0	-17.5	-26.3
EV/Revenue	24.7	22.8	11.1

Analysis

Overview

PIQ has announced a new world-first blood test for diagnosing endometriosis, with results indicating strong diagnostic performance based on a study in over 900 participants.

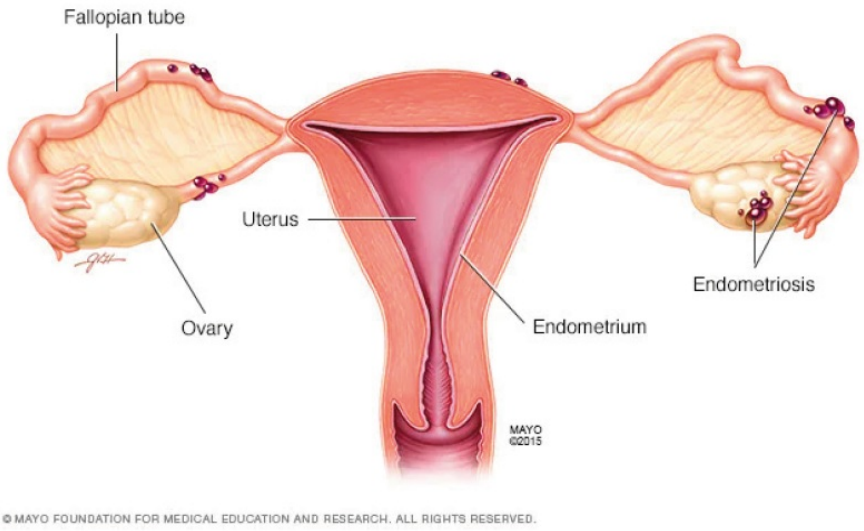
The test **correctly identifies up to 90% of patients with endometriosis**, and could potentially offer clinicians an early screening solution to rule in or rule out the need for invasive surgery - which is the current gold standard of diagnosis.

These results follows an early version of the test PIQ announced last year, which was shown to correctly identify up to 78% of patients with endometriosis.

Endometriosis Overview

Endometriosis is a debilitating condition, occurring when the tissue that lines the uterus spreads outside of the uterine cavity (Figure 1). The condition often results in pain (sometimes severe) and infertility.

Figure 1: Endometriosis diagram



Source: Mayo clinic

Key statistics of the condition:

- Affects 1 in 9 women.
- There are ~830,000 women living with endometriosis in Australia, with an estimated +200 million worldwide.
- It is estimated to cost Australia alone $9.7 billion every year in direct healthcare costs and lost productivity.

Currently there is no simple way to diagnose the disease, with the gold for detection being an invasive laparoscopy followed by histopathology. This is a medical procedure where a camera is inserted into the pelvis through a small cut in the abdominal wall, and then a biopsy taken for analysis.

Currently, due to a lack of testing options, **it takes on average 7.5yrs to be diagnosed.**

Study Results

In this new study, PIQ in collaboration with the Royal Women's Hospital and the University of Melbourne, has further developed and refined its diagnostic modelling to improve sensitivity and specificity, which includes the addition of a 'traffic light' scoring system to optimise test performance. Through this follow up study, PIQ has developed a far more accurate test for endometriosis, which could provide even greater clinical utility.

The test works by measuring the concentration of biomarkers in the blood which are thought to be associated with endometriosis. PIQ has identified a panel of 14 biomarkers, with analysis showing these biomarkers all relate to biological pathways that could be linked to the unwanted tissue growth that occurs in endometriosis.

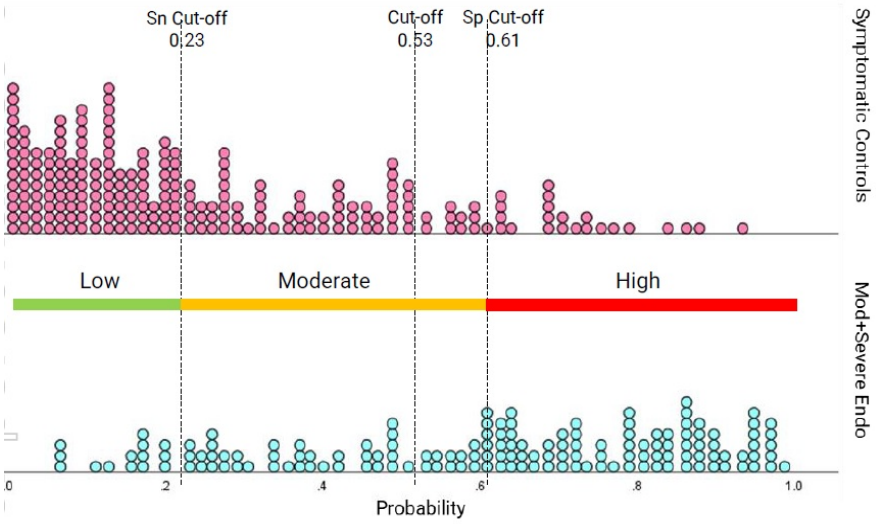
Following on from earlier work, PIQ has used these biomarkers, in combination with clinical factors, to build a series of statistical models which use different combinations of biomarkers to diagnose the disease.

PIQ's prefered diagnostic model targets a potential early screening test to rule in or rule out the need for invasive surgery. The model works by distinguishing symptomatic controls (ie. no endometriosis) from moderate and severe endometriosis, and employs the same 'traffic light' scoring system (Figure 2) used by PIQ's lead test, PromarkerD, which is currently being rolled out in the United States.

The results of this model indicate strong diagnostic performance, with:

- Optimised sensitivity: 90%
- Optimised specificity: 90%
- Area Under the Curve (AUC) of 0.84 (implying excellent discrimination).

Figure 2: Symptomatic Controls vs Moderate/Severe Endo Dot Plot



Source: Company announcement

For comparison, the Prostate-Specific Antigen (PSA) diagnostic test for prostate cancer (blood test measuring the concentration of the PSA protein), has a statistical performance of:

- Prostate cancer vs no cancer: 0.68 AUC (P=<0.001, this does not even qualify as acceptable discrimination, which requires an AUC of >0.70);
- PSA cut-of threshold (3ng/ml): 32% sensitivity, 87% specificity

We also highlight a second version of the test: the healthy controls (no endometriosis) vs severe endometriosis diagnostic model.

This model showed an 'outstanding' level of discrimination with an AUC of 0.97, and an optimised sensitivity of 89% and specificity of 95%. It should also be noted, the very high sensitivity and specificity meant no traffic-light approach was used for this model.

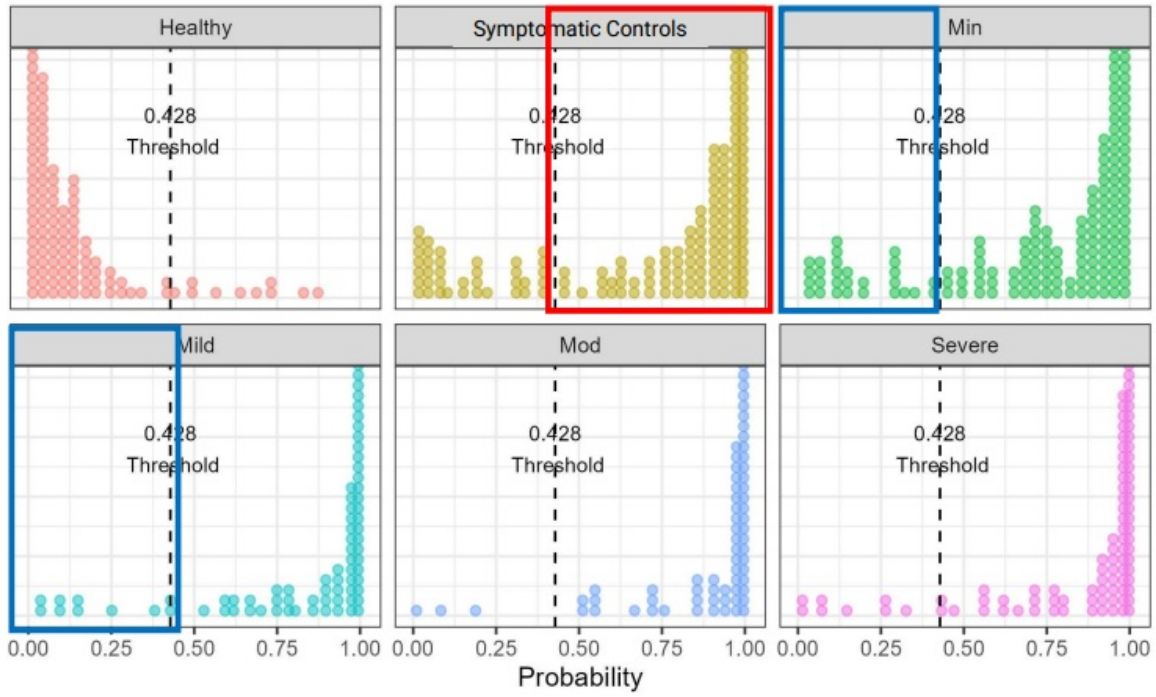
There are two particular takeaways from this:

1. Indicates the biomarkers are discriminating between endometriosis and non-endometriosis (ie. correct biomarkers selected); and
2. The biomarker scores also suggest many of the "symptomatic controls" may actually have endometriosis, and that some patients classified as "minimal endometriosis" may not have endometriosis

This data suggest the current gold standard for diagnosis (invasive surgery) may be misdiagnosing some patients in the early stages of Endometriosis.

PIQ has arrived at this conclusion, noting there are symptomatic controls who map similarly to the endometriosis cases across all stages (Figure 3 , red box), and that there are also minimal/mild endometriosis cases who map like healthy controls, and that this is also seen in the moderate/severe cases (Figure 3 , blue boxes).

Figure 3: Dot Plots Across Condition (rASRM) Stages



Source: Company announcement

This potential misdiagnosis could be the result of confounders (extraneous variables), such as: batch effect (variations between measurements of different groups of samples), age of samples, collection of samples, pain markets, and/or even micro-lesions.

In the case of micro-lesions, this could be possible as it can be difficult for surgeons to definitively detect and confirm the small lesions that begin to occur in the early stages of endometriosis.

All together, this highlights the fact that endometriosis is a complex condition with a broad spectrum of clinical indications, and that it will not be defined by a simple positive versus negative test - hence PIQ's 'traffic light' system approach.

Next Steps

The next steps from here and our respective commentary include:

- **Confirm the clinical performance and clinical utility of the test in independent cohorts;**

Timing on this will depend on PIQ's ability to secure samples from an independent cohort. We note PIQ announced an additional collaboration agreement last year with St John of God Health care, where the company signed a material transfer agreement to access ~250 clinical samples. These samples are from the St John of God Subiaco Hospital Gynaecological Cancer Research Group, and were obtained from patients with either clinically-confirmed endometriosis or other bening (non-cancerous) conditions.

The key risk here is that diagnostic results are weaker in a follow up validation study, however given the size of the study discussed in this research (n=901) we feel this risk has been reduced. Furthermore in our view, the test's impressive diagnostic performance, coupled with the lack thereof any other simple diagnostic alternatives, provides PIQ ample maneuvering space on this front.

- **Accelerate pathways to commercialise the biomarker panel as a new diagnostic screening test for endometriosis; and**

We believe these results, combined with the growing interest in the condition, place PIQ in a solid position to begin commercial discussions. The only caveat in our view will be the number of biomarkers required in the final diagnostic model, where the greater number may limit this to certain parties.

We note PIQ has filed patents in all major jurisdictions for a method to measure a panel of protein biomarkers to determine whether a subject has endometriosis. As stated in prior announcements, the company retains ownership of its background IP, with newly created IP to be jointly owned by each party that contributes to its creation.

PIQ believes a validated diagnostic screening test for endometriosis will garner significant interest, both commercially and in the clinic

There is precedent of PIQ commercialising its technology, with the company currently in the closing stages of finalising an exclusive licensing agreement with Sonic Healthcare USA for its lead predictive diagnostic test, PromarkerD. This test is currently in the process of being rolled out in the United States.

- **Undertake further work on early stages of endometriosis**

As illustrated previously, this research highlights the current gold standard for diagnosis (invasive surgery) may be misdiagnosing some patients in the early stages of Endometriosis. PIQ has stated this will require further work on patients with early stages of the condition or with symptoms, and to look more closely at their existing diagnosis. This kind of work has the potential to change the way we think of endometriosis. That said, we don't think this will limit PIQ's ability to commercialise a screening test in the meantime, and will likely happen in parallel to this.

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Company disclosures

The companies and securities mentioned in this report, include:

Proteomics International Laboratories Limited (PIQ.ASX) | Price A$0.79 | Target price A$1.80 | Recommendation Speculative Buy;

Price, target price and rating as at 27 March 2023 (not covered)*

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