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EUROZ HARTLEYS

PIQ: US Launch Tracking For Q4 CY23

PIQ.ASX | PROTEOMICS INTERNATIONAL LABORATORIES LIMITED | HEALTHCARE

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$0.87/sh	**A$1.80/sh** (FROM A$1.80/sh)	**SPECULATIVE BUY** (FROM SPECULATIVE BUY)	**SETH LIZEE** SLIZEE@EUROZHARTLEYS.COM

Event

PIQ has released its June quarterly results.

Impact

The company achieved a major milestone during the quarter by securing an exclusive agreement with Sonic Healthcare USA (SHUSA) to market PromarkerD in the United States. This agreement follows the initial binding letter of intent (LOI) signed last year.

Considering SHUSA's extensive US presence, years of experience, and vast resources, we believe PIQ is well positioned to commercialise PromarkerD in the United States – the world's largest healthcare market. The United States has an estimated +32 million people suffering from diabetes, each a potential user of PromarkerD.

SHUSA is progressing US reimbursement for the test. Earlier this year, the company successfully obtained a US reimbursement code (CPT PLA Code). In September, a proposed CMS pricing determination is expected to be published, with the final pricing to be published in the Clinical Lab Fee Schedule (CLFS) in January of next year. We note the establishment of CMS pricing is essential for the coverage and reimbursement of PromarkerD by public and private payers.

PIQ has indicated SHUSA is aiming for a soft launch in Q4 CY23, followed by a full US market launch upon the successful Medicare and Medicaid (CMS) coverage publication in early CY24.

In parallel, PIQ is now targeting licensing deals in key European markets, where PromarkerD is already CE Mark registered. Other countries of interest include Japan, Hong Kong and the Middle East, reflecting the importance of gateway markets or regions with high incidence of diabetes.

PIQ finished the Q with $6.0m of cash at bank, with a further $1.8m due to be received in the 2H of this CY.

Given the approaching US market launch, we have updated our forecasts.

Action

We maintain our Speculative Buy recommendation and $1.80 Price Target

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

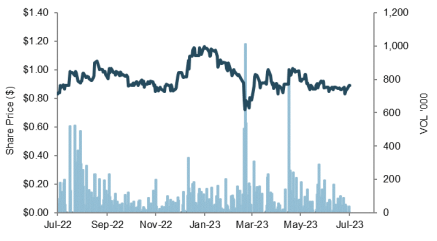
We note our valuation is exclusively based on PromarkerD, with no value ascribed for other programs in development (such as endometriosis).

Catalyst

- US Sales – Dec Q
- CMS Reimbursement Pricing – Dec/Mar Q
- Endometriosis Update – Dec Q
- Oesophageal Cancer Update – Sep Q

Share Price	0.87	A$/sh	
Price Target	**1.80**	**A$/sh**	
Valuation (DCF)	1.80	A$/sh	
WACC	11%		
Terminal Growth	3%		
Shares on issue	121.0	m	
Market Capitalisation	105.3	A$m	
Enterprise Value	97.5	A$m	
Cash (Inc R&D)	7.8	A$m	
Debt (inc. AASB16)	0.1	A$m	
Key Financial Metrics	**22A**	**23F**	**24F**
Revenue (A$m)	3.4	3.4	6.0
EBITDA (A$m)	-4.6	-4.9	-3.5
EBIT (A$m)	-5.0	-5.5	-4.2
Reported NPAT (A$m)	-5.0	-5.5	-4.2
Normalised NPAT (A$m)	-5.0	-5.5	-4.2
Gross Cashflow (A$m)	-4.1	-5.0	-3.6
Capex (A$m)	-0.1	-1.1	-0.8
Op. Free Cashflow (A$m)	-3.7	-7.1	-4.1
Revenue Growth (%)	15%	-1%	77%
EBITDA Growth (%)	84%	7%	-28%
Norm. NPAT Growth (%)	54%	10%	-24%
Normalised EPS (Ac)	-4.6	-4.5	-3.5
Norm. EPS growth (%)	na	na	na
PER (x)	-19.1	-19.1	-25.2
EV:EBITDA (x)	-21.4	-19.9	-27.7
EV:EBIT (x)	-19.6	-17.7	-23.3

Performance



Source: Euroz Hartleys

Income Statement	22A	23F	24F
PromarkerD Royalties	0.0	0.0	1.2
Analysis Business	1.5	1.7	2.0
Consumables (Cost-through)	0.0	0.0	1.1
Other Income	1.9	1.7	1.8
Total Sales	**3.4**	**3.4**	**6.0**
(-) COGS	0.0	0.0	-1.2
Gross Profit	3.4	3.4	4.8
(-) OPEX	-8.0	-8.3	-8.3
EBITDA	**-4.6**	**-4.9**	**-3.5**
(-) D&A	-0.4	-0.6	-0.7
EBIT	-5.0	-5.5	-4.2
(-) Net Finance	0.0	0.0	0.0
(-) Other Expenses	0.0	0.0	0.0
EBT	-5.0	-5.5	-4.2
(-) Tax	0.0	0.0	0.0
Reported NPAT	-5.0	-5.5	-4.2
(+/-) Abnormals	0.0	0.0	0.0
Norm NPAT	-5.0	-5.5	-4.2
Cash Flow Statement	**22A**	**23F**	**24F**
Profit Before Tax	**-5.0**	**-5.5**	**-4.2**
(+) D&A	0.4	0.6	0.7
(+) 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**	**-5.0**	**-3.6**
(-) Capital Expenditure	-0.1	-1.1	-0.8
(-) Change in NWC	0.5	-1.1	0.2
Operating Free Cashflow	**-3.7**	**-7.1**	**-4.1**
(-) 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	11.0	5.0
(+/-)Other	0.1	0.0	0.0
Net Cashflow	**-3.4**	**3.9**	**0.9**
BoP Net Cash	**5.5**	**2.1**	**6.0**
(+/-) Net Cashflow	-3.4	3.9	0.9
(+/-) AASB16	0.0	0.0	0.0
EoP Net Cash	**2.1**	**6.0**	**6.9**
Balance Sheet	**22A**	**23F**	**24F**
Cash	2.1	6.0	6.9
Receivables	0.4	0.4	0.8
Other Assets	1.8	1.8	1.8
Total Current Assets	**4.4**	**8.3**	**9.5**
PP&E	1.0	1.5	1.6
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**	**1.6**	**1.7**
Total Assets	**5.4**	**9.8**	**11.2**
Payables	1.5	0.4	1.0
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**	**0.6**	**1.2**
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**	**0.9**	**1.5**
Net Assets	**3.4**	**8.9**	**9.8**
Issued Capital	19.3	30.4	35.4
Reserves	1.7	1.7	1.7
Accumulated Losses	-17.6	-23.1	-27.3
Total Equity	**3.4**	**8.9**	**9.8**

Performance Ratios	22A	23F	24F
Growth & Margins			
Revenue Growth	15%	-1%	77%
EBITDA Growth	84%	7%	-28%
EBIT Growth	74%	10%	-24%
Normalized Net Profit Growth	54%	10%	-24%
EBITDA margin	-133%	-143%	-58%
EBIT margin	-145%	-161%	-69%
Normalized net profit margin	-145%	-161%	-69%
Effective tax rate	0%	0%	0%
Liquidity			
Capex/depreciation	0.3	1.8	1.1
Current ratio	2.6	13.5	8.3
Quick ratio	1.7	15.6	8.1
Receivable days	46.8	46.8	46.8
Payable days	68.7	18.3	36.5
Risk Measures			
Dividend Cover	na	na	na
Payout ratio	0%	0%	0%
Net interest cover	na	na	na
Net debt/equity	-62%	-68%	-71%
Returns			
ROIC	-147%	-61%	-43%
ROA	-92%	-56%	-37%
ROE	-147%	-62%	-43%
Share Data/Valuation	**22A**	**23F**	**24F**
Share Data			
Issued shares	105.8	121.0	121.1
Weighted ave shares	105.5	113.4	121.0
Fully diluted shares	109.3	121.0	121.1
Basic EPS	-4.7	-4.5	-3.5
YoY change	na	na	na
Fully diluted EPS	-4.6	-4.5	-3.5
YoY change	na	na	na
Fully diluted normalised EPS	-4.6	-4.5	-3.5
YoY change	na	na	na
Dividend/share	0.0	0.0	0.0
Franking	na	na	na
Gross cashflow/share	-3.9	-4.1	-3.0
NBV/share	3.2	7.4	8.1
NTA/Share	3.2	7.4	8.1
Valuation			
PER (Basic)	-18.5	-19.1	-25.2
PER (Fully diluted)	-19.1	-19.1	-25.2
PER (Fully diluted, normalized)	-19.1	-19.1	-25.2
P/CFPS	-22.4	-21.2	-29.4
Price/NBV	27.1	11.8	10.8
Price/NTA	27.1	11.8	10.8
Dividend Yield	0.0	0.0	0.0
EV/EBITDA	-21.4	-19.9	-27.7
EV/EBIT	-19.6	-17.7	-23.3
EV/Revenue	28.4	28.6	16.2

US Commercialisation

In May, PIQ executed an exclusive licensing agreement with Sonic Healthcare USA (a division of Sonic Healthcare) for the use and commercialisation of the PromarkerD predictive test for diabetic kidney disease in the United States.

This followed the initial binding Letter of Intent (LOI) signed last year.

Sonic Healthcare (ASX: SHL, $17bn Mkt cap) is one of the largest diagnostic companies in the world, providing care to over 100 million patients per year. Its US division is the third largest laboratory medicine company in the United States.

Figure 1: Sonic Healthcare USA Overview

Source: Company presentation

Figure 2: Sonic Healthcare USA Locations

Source: Company website

The 5-year agreement includes commercially agreed royalties on sales of the test, timelines for milestone events to be achieved in relation to the commercialisation process, and provides terms for payment for the test's reagents.

Under the agreement, SHUSA will offer PromarkerD to physicians and healthcare systems through its client engagement teams across the United States.

In summary:

- This means PIQ will receive a royalty on every PromarkerD test sold.
- Standard industry royalty rates range from 5-15% (we conservatively use 7.5% in our modelling).
- This translates to between US$7.50 and US$22.50 in royalties received on every test sold (assuming US$150/test, indicated based on stakeholder engagement).

Given these are royalties, these revenues should fall mostly to the bottom line.

PIQ has indicated SHUSA is aiming for a soft launch in Q4 CY23, followed by a full US market launch upon the successful Medicare and Medicaid (CMS) coverage publication in early CY24.

US Reimbursement

Considerable progress has been made on establishing US reimbursement, with some key activities approaching (Figure 3).

Figure 3: US Reimbursement Activities

Date	Activity	Status
Jan 2023	Unique CPT Proprietary Laboratory Analysis (PLA) code approved	Complete
Apr 2023	Centers for Medicare and Medicaid Services (CMS) posts updated code list. PLA code (0385U) for PromarkerD effective	Complete
May 2023	American Clinical Lab Association engaged by SHUSA to consider crosswalk or gapfill pricing	Complete
Jun 2023	CMS Clinical Lab Fee Schedule (CLFS) Annual Meeting to consider pricing	Complete
Sep 2023	CMS proposed pricing determinations published for comment	Pending
Jan 2024	CMS final pricing published	Pending

Source: Quarterly report

In January, a new dedicated CPT PLA reimbursement code was approved for PromarkerD in diabetic kidney disease (DKD).

This was a major milestone for the company; securing a new dedicated CPT PLA code is key to reimbursement coverage of the test by both Medicare and private health insurers in the United States.

All diagnostic tests must have relevant reimbursement coding in order to bill and receive payments for performing tests, amongst other things.

The code for PromarkerD (0385U) has since been published and became effective on 1 April 2023. The PLA code was issued to Sonic Reference Laboratory which is part of Sonic Healthcare USA (a division of Sonic Healthcare Ltd, ASX: SHL).

As we outlined in previous research, coding is among the various moving parts involved in US reimbursement, which include:

- Coding - How will payers identify the test (CPT code secured).
- Coverage - Will payers pay for the test, and under what conditions; and
- Pricing - What will payers pay for the test.

Next steps from here will involve working with private payers and engaging with the Centers for Medicare & Medicaid Services (CMS) to establish payment and include PromarkerD in their Clinical Lab Fee Schedule.

Pricing

Once a new CPT code is established, the next step involves engaging with the Centres for Medicare & Medicaid Services (CMS) to establish a national Medicare price in the Clinical Laboratory Fee Schedule (CLFS).

There are two ways to establish a price:

- Cross Walking – Establishing a price using an existing test in market if suitably comparable; generally easier to do; or
- Gap Filling – Empirically calculating a price based on various inputs when there is no suitable comparable in market.

SHUSA engaged the America Clinical Lab Association last month to consider which of these pathways was most appropriate. The company has further indicated the proposed CMS pricing determination will be published for comment this September, with the final pricing to be published in January of next year.

PIQ is anticipating a US$150/test price point in the US based on stakeholder engagement responses from a market access study.

Whilst securing a code and connected price is key, it does NOT mean the test is covered or will be paid for by payers – this is a separate exercise (see below).

Payer Coverage

There are numerous payer organisations in the United States, both public and private, who cover and pay for medical services under varying conditions. Securing coverage from these payers is key to having a PromarkerD test paid for when used. Without coverage, patients will have to pay for PromarkerD out of pocket – which would limit large scale adoption.

The US payer base is highly fragmented among public and private insurers, where:

- Public – Medicare and Medicaid (administered by CMS) are the two main public payers, these organisations cover approximately ~35% of the population
- Private – Hundreds of insurers in the US, however, the top 5 cover nearly half the population

Medicare coverage decisions can be disseminated on a national or local level, where:

- Local Coverage Designation (LCD) – Coverage and pricing can be established in one of the 12 Medicare Administrative Contractor (MAC) jurisdictions. Nearly all CMS coverage decisions for molecular tests are LCDs; or
- National Coverage Designation (NCD) – Binding across every Medicare geography, Supersedes LCDs, and are issued directly by the CMS.

Securing coverage by Private insurance is more opaque than public, varying considerably by organisation and underlying plans. However, private payers will often use Medicare coverage policies as a benchmark for their own.

US Market Opportunity

The United States represents a massive market opportunity with an estimated +32 million people suffering from diabetes – each a potential user of PromarkerD. On average each person with diabetes should be tested once per year with PromarkerD.

Even modest market adoption of PromarkerD in the US can translate into very lucrative royalties for PIQ (Figure 4). These royalties should fall mostly to the bottom line.

Figure 4: US PromarkerD Royalties Sensitivity Table

Royalties (A$m)	Market Penetration (%)					
Royalty Rate (%)	1.0%	2.5%	5.0%	10.0%	15.0%	25.0%
5.0%	3.5	8.6	17.3	34.5	51.8	86.3
7.5%	5.2	12.9	25.9	51.8	77.7	129.4
10.0%	6.9	17.3	34.5	69.0	103.5	172.6
12.5%	8.6	21.6	43.1	86.3	129.4	215.7
15.0%	10.4	25.9	51.8	103.5	155.3	258.9

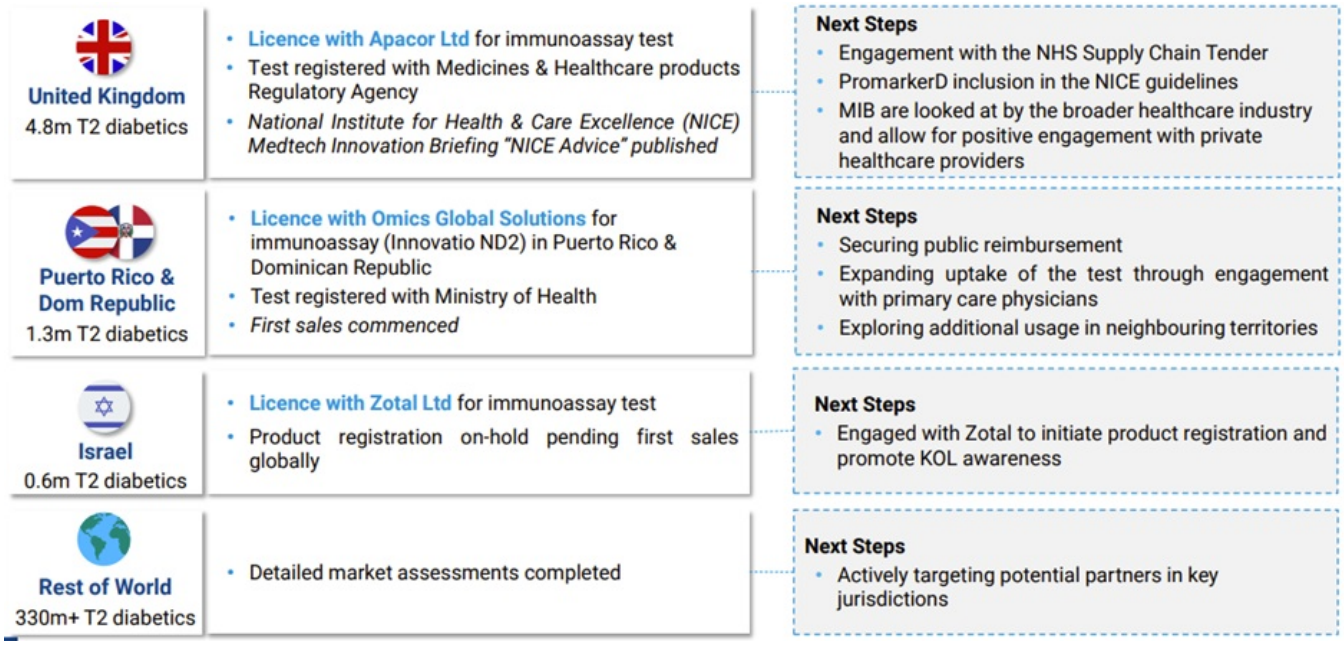
**Assuming US$150/test, 0.7 A$/US$ fx, ~32m patient TAM*

Source: EH Analysis

RoW Market Opportunity

PIQ is now targeting licensing deals in the key European Markets, where PromarkerD is already CE Mark registered. Other countries of interest include Japan, Hong Kong and the middle East, reflecting the importance of gateway markets or regions with high incidence of diabetes.

Figure 5: RoW Target Markets



Source: Company presentation

Forecasts

We have updated our forecasts to incorporate a soft launch in Q4 CY23; these forecasts reflect a conservative uptake profile.

We continue to note these forecasts are fluid in nature. As a mass market test, with theoretically +32 million potential users in the United States alone, there is significant potential for these figures to be exceeded – as highlighted in Figure 4 .

We have broken down our forecasts into US and Rest of World (RoW) figures.

We continue to model sales using a conservative US$150/test, with a 7.5% royalty rate, noting industry royalties typically range between 5 and 15%

We will look to further refine these forecasts as sales begin.

Figure 6: Sales Forecasts

FY	Units	2022	2023e	2024e	2025e	2026e
PromarkerD Forecasts						
US Unit Sales	'000s	0	0	69	152	266
RoW Unit Sales	'000s	0	0	3	12	27
Total Unit Sales	'000s	0	0	72	164	293
Market Penetration (Forecasted Regions)	%	0.0%	0.0%	0.2%	0.4%	0.7%
Market Penetration (Global)	%	0.0%	0.0%	0.0%	0.0%	0.1%
Group Revenue Forecasts						
PromarkerD Royalties	A$m	0.0	0.0	1.2	2.7	4.8
Analysis Business	A$m	1.5	1.7	2.0	2.3	2.6
PromarkerD consumables	A$m	0.0	0.0	1.1	2.4	4.3
Other Income	A$m	1.9	1.7	1.8	1.8	1.8
Total Sales	**A$m**	**3.4**	**3.4**	**6.0**	**9.2**	**13.5**
% Growth	%	15%	-1%	77%	53%	47%

Source: EH analysis

We continue to note our revenue forecasts are purely based on PromarkerD, we don't include any potential sales from other later stage tests in development – such as endometriosis.

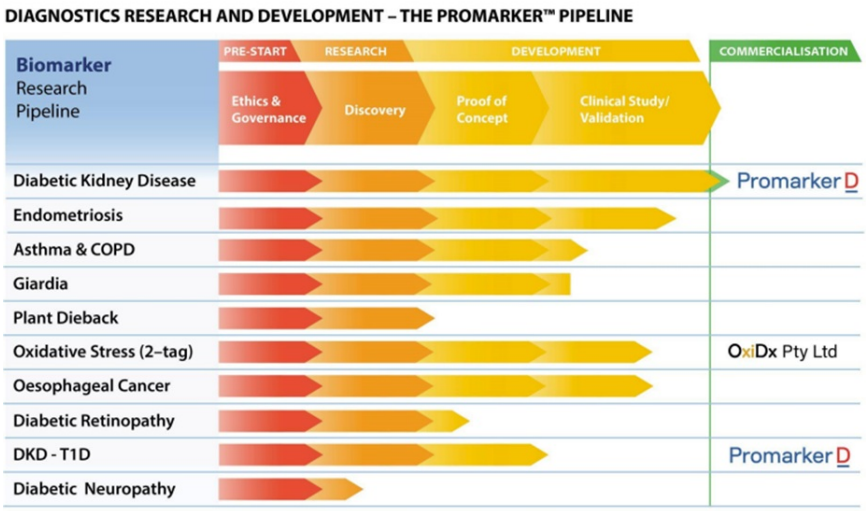
Development Pipeline

PIQ maintains a pipeline (Figure 7) of various other tests in development.

We can anticipate near term updates on:

- Endometriosis – December Quarter
- Oesophageal Cancer – September Quarter

Figure 7: Development Pipeline



Source: Company presentation

Endometriosis

Earlier this year PIQ announced results of a novel world-first blood test for diagnosing endometriosis. The new test was shown to correctly identify up to 90% of patients with endometriosis in a study of over 900 participants,

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.

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.

Next steps looked 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.

Oesophageal Cancer

Last year, PIQ announced the results of its prototype oesophageal cancer diagnostic test. The test was shown to detect up to 90% of people with Oesophageal cancer.

Oesophageal cancer is an area of significant unmet medical need, accounting for 1 in 20 cancer deaths worldwide and costing the US healthcare system $2.9 billion per annum alone (as of 2018)

Current screening requires patients undergo an endoscopy – an invasive, uncomfortable, and potentially risky procedure that costs on average US$2,750 in the United States

Next steps involved refining and validating the test, including:

- Further develop the statistical modelling to improve the test sensitivity and specificity, including the use of the 'traffic light' system developed for PromarkerD
- Refine the reproducibility of the biomarker measurements to produce a test suitable for the US Laboratory Developed Test (LDT) pathway via CLIA certified labs
- Confirm the clinical performance in an additional independent cohort; and
- Conduct formal economic health benefits and clinical utility studies

Personal disclosures

We hereby certify that all of the views expressed in this report accurately reflect our personal views about the subject company or companies and its or their securities, and we are not in possession of, nor does this Research contain any inside information.

No part of our compensation was, is or will be directly or indirectly, related to the specific recommendations or views expressed by the authoring analyst in this research, nor has any attempt been made to influence this Research.

Company disclosures

The companies and securities mentioned in this report, include:

Proteomics International Laboratories Limited (PIQ.ASX) | Price A$0.87 | Target price A$1.80 | Recommendation Speculative Buy;

Price, target price and rating as at 28 July 2023 (not covered)*

Additional disclosures

The analyst declares that they have a beneficial interest in: Proteomics International Laboratories Limited (PIQ.ASX)

Euroz Hartleys declares that it has provided corporate advice during the last year and has received a fee for these services from: Proteomics International Laboratories Limited (PIQ.ASX)

Euroz Hartleys declares that it has acted as underwriter to, and/or arranged an equity issue in, and/or been engaged in a capital raising during the last year. Euroz Hartleys has received a fee for these services from: Proteomics International Laboratories Limited (PIQ.ASX)

Euroz Hartleys has received an allocation of shares and/or options as part of our fee for the provision of Corporate services. These holdings are maintained in our Nominee company, and may present a potential benefit to Euroz Hartleys when sold for: Proteomics International Laboratories Limited (PIQ.ASX)

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