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PIQ: US Pricing Exceeds Expectations; TGA Update

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

PRICE **A$1.00/sh**

TARGET PRICE **A$2.00/sh** (FROM A$1.80/sh)

RECOMMENDATION **SPECULATIVE BUY** (UNCHANGED)

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Event

PIQ's lead predictive diagnostic test, PromarkerD, has secured a reimbursement rate of US$390.75 from the Centers for Medicare & Medicaid Services (CMS) in the United States.

The test is being commercialised in the US through Sonic Healthcare USA, a division of Sonic Healthcare (ASX: SHL), one of the largest diagnostic companies in the world.

In parallel, the TGA advised PromarkerD will not be included into the Australian Register of Therapeutic Goods (ARTG) at this stage, primarily due to a change in manufacturer.

Impact

The establishment of CMS pricing is essential for the coverage and reimbursement of PromarkerD by public and private payers within the United States.

The CMS-determined price applies to all individuals accessing government-funded healthcare in the United States, encompassing more than 100 million Americans. This notably constitutes the largest payer group, incorporating both Medicare for Americans over 65 and Medicaid for low-income individuals. Moreover, we note private payers will typically reimburse around the rate set by the CMS.

The US$390/test price is substantially higher than the US$150/test we had modelled. While we acknowledge pricing is likely to reduce with time and scale (CMS typically reviews every 3-years), the higher starting price sets a good foundation for long-term pricing of PromarkerD.

The price is expected to be finalised after a 30-day period of public comment, and then become effective and published in the Clinical Lab Fee Schedule from 1 January 2024. We do not expect the price to change, as such we have pushed it through our model. Our forecasts also incorporate a gradual price reduction over time.

Having secured a US reimbursement code (CPT PLA Code) early this year, and now with an established price, the last item remains around securing payor coverage. There are numerous payer organisations in the United States, both public and private.

In parallel, PIQ announced a decision by the TGA to not include PromarkerD into the ARTG at this stage. The primary reason related to a request that the clinical and analytical data needed to be predominately collected on the currently manufactured version of the test (ie immunoassay version in Europe), noting PIQ had filed the registration for the immunoassay version of the test originally manufactured in Australia. Consequently, PIQ will now consider its alternatives to address the items that the TGA has raised.

However, it's important to recognise **this decision does NOT affect the activities in the United States where the test is using the CLIA Laboratory Developed Test (LDT) framework (ie. Does NOT need FDA approval), or in Europe, where PromarkerD is CE Mark registered**.

Action

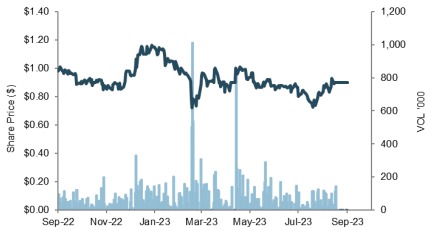
We maintain our Speculative Buy recommendation with an upgraded $2.00/sh Price Target, which reflects the better than expected pricing.

Catalysts

- US Sales – Dec'Q (soft launch) / Early CY24 (Full launch)
- Endometriosis Update – Dec'Q

Share Price	1.00	A$/sh	
Price Target	**2.00**	**A$/sh**	
Valuation (DCF)	2.00	A$/sh	
WACC	11%		
Terminal Growth	3%		
Shares on issue	122.3	m	
Market Capitalisation	122.3	A$m	
Enterprise Value	114.6	A$m	
Cash (Inc R&D)	7.8	A$m	
Debt (inc. AASB16)	0.1	A$m	
Key Financial Metrics	**23A**	**24F**	**25F**
Revenue (A$m)	3.3	6.0	12.4
EBITDA (A$m)	-5.7	-4.7	-0.9
EBIT (A$m)	-6.2	-5.2	-1.5
Reported NPAT (A$m)	-6.2	-5.2	-1.5
Normalised NPAT (A...	-6.2	-5.2	-1.5
Gross Cashflow (A$m)	-5.3	-4.7	-0.9
Capex (A$m)	-1.2	-0.8	-0.8
Op. Free Cashflow (A...	-6.9	-5.9	-2.2
Revenue Growth (%)	-3%	80%	107%
EBITDA Growth (%)	25%	-18%	-80%
Norm. NPAT Growth ...	25%	-16%	-71%
Normalised EPS (Ac)	-5.1	-4.3	-1.3
Norm. EPS growth (%)	na	na	na
PER (x)	-19.4	-23.4	-79.6
EV:EBITDA (x)	-20.1	-24.6	-125.9
EV:EBIT (x)	-18.4	-21.9	-74.7

Performance



Source: IRESS

Income Statement	23A	24F	25F
PromarkerD Royalties	0.0	2.3	7.1
Analysis Business	0.7	1.0	1.1
Consumables (Cost-through)	0.0	0.8	2.2
Other Income	2.6	1.9	1.9
Total Sales	**3.3**	**6.0**	**12.4**
(-) COGS	0.0	-1.1	-3.3
Gross Profit	3.3	4.8	9.1
(-) OPEX	-9.0	-9.5	-10.0
EBITDA	**-5.7**	**-4.7**	**-0.9**
(-) D&A	-0.5	-0.6	-0.6
EBIT	-6.2	-5.2	-1.5
(-) Net Finance	0.0	0.0	0.0
(-) Other Expenses	0.0	0.0	0.0
EBT	-6.2	-5.2	-1.5
(-) Tax	0.0	0.0	0.0
Reported NPAT	-6.2	-5.2	-1.5
(+/-) Abnormals	0.0	0.0	0.0
Norm NPAT	-6.2	-5.2	-1.5

Cash Flow Statement	23A	24F	25F
Profit Before Tax	**-6.2**	**-5.2**	**-1.5**
(+) D&A	0.5	0.6	0.6
(+) FX loss/(gain)	0.0	0.0	0.0
(+) Share base payments	0.4	0.0	0.0
(-) Tax Paid	0.0	0.0	0.0
(+/-)Other	0.0	0.0	0.0
Gross Cashflow	**-5.3**	**-4.7**	**-0.9**
(-) Capital Expenditure	-1.2	-0.8	-0.8
(-) Change in NWC	-0.4	-0.5	-0.6
Operating Free Cashflow	**-6.9**	**-5.9**	**-2.2**
(-) acq of subs/other Invst.	0.0	0.0	0.0
(+) Proc. from disp of FA/subs	0.1	0.0	0.0
(-) Dividends Paid	0.0	0.0	0.0
(+) Equity issued	10.8	10.0	0.0
(+/-)Other	-0.1	0.0	0.0
Net Cashflow	**3.9**	**4.1**	**-2.2**
BoP Net Cash	**2.1**	**6.0**	**10.1**
(+/-) Net Cashflow	3.9	4.1	-2.2
(+/-) AASB16	0.0	0.0	0.0
EoP Net Cash	**6.0**	**10.1**	**7.9**

Balance Sheet	23A	24F	25F
Cash	6.0	10.2	7.9
Receivables	0.1	0.8	1.6
Other Assets	2.2	2.2	2.2
Total Current Assets	**8.3**	**13.1**	**11.7**
PP&E	1.6	1.8	1.9
Other Assets	0.1	0.1	0.1
ROUA	0.1	0.1	0.1
Intangible Assets	0.0	0.0	0.0
Total Non-current Assets	**1.7**	**1.9**	**2.0**
Total Assets	**10.1**	**15.0**	**13.8**
Payables	0.9	1.1	1.3
Borrowing	0.0	0.0	0.0
Lease Liabilities	0.0	0.0	0.0
Provisions	0.1	0.1	0.1
Total Current Liabilities	**1.1**	**1.2**	**1.5**
Payables	0.6	0.6	0.6
Borrowing	0.0	0.0	0.0
Lease Liabilities	0.0	0.0	0.0
Provisions	0.0	0.0	0.0
Total Non-Current Liabilities	**0.6**	**0.6**	**0.6**
Total Liabilities	**1.8**	**1.9**	**2.1**
Net Assets	**8.3**	**13.2**	**11.6**
Issued Capital	30.2	40.2	40.2
Reserves	1.8	1.8	1.8
Accumulated Losses	-23.6	-28.9	-30.4
Total Equity	**8.3**	**13.1**	**11.6**

Performance Ratios	23A	24F	25F
Growth & Margins			
Revenue Growth	-3%	80%	107%
EBITDA Growth	25%	-18%	-80%
EBIT Growth	25%	-16%	-71%
Normalized Net Profit Growth	25%	-16%	-71%
EBITDA margin	-172%	-78%	-7%
EBIT margin	-187%	-87%	-12%
Normalized net profit margin	-188%	-88%	-12%
Effective tax rate	0%	0%	0%
Liquidity			
Capex/depreciation	2.3	1.3	1.2
Current ratio	7.6	10.8	7.9
Quick ratio	6.5	10.3	7.2
Receivable days	16.0	47.5	47.5
Payable days	38.4	36.5	36.5
Risk Measures			
Dividend Cover	na	na	na
Payout ratio	0%	0%	0%
Net interest cover	na	na	na
Net debt/equity	-72%	-77%	-68%
Returns			
ROIC	-75%	-40%	-13%
ROA	-62%	-35%	-11%
ROE	-75%	-40%	-13%

Share Data/Valuation	23A	24F	25F
Share Data			
Issued shares	121.0	122.3	122.3
Weighted ave shares	113.4	121.7	122.3
Fully diluted shares	121.0	122.3	122.3
Basic EPS	-5.1	-4.3	-1.3
YoY change	na	na	na
Fully diluted EPS	-5.1	-4.3	-1.3
YoY change	na	na	na
Fully diluted normalised EPS	-5.1	-4.3	-1.3
YoY change	na	na	na
Dividend/share	0.0	0.0	0.0
Franking	na	na	na
Gross cashflow/share	-4.4	-3.8	-0.7
NBV/share	6.9	10.8	9.5
NTA/Share	6.9	10.7	9.5
Valuation			
PER (Basic)	-19.4	-23.4	-79.6
PER (Fully diluted)	-19.4	-23.4	-79.6
PER (Fully diluted, normalized)	-19.4	-23.4	-79.6
P/CFPS	-22.7	-26.3	-134.0
Price/NBV	14.5	9.3	10.5
Price/NTA	14.5	9.3	10.5
Dividend Yield	0.0	0.0	0.0
EV/EBITDA	-20.1	-24.6	-125.9
EV/EBIT	-18.4	-21.9	-74.7
EV/Revenue	34.5	19.1	9.3

Analysis

The Centers for Medicare & Medicaid Services (CMS) have set a national reimbursement price for PromarkerD in the United States.

The agency set a price of US$390.75 per test, which is substantially higher than the US$150 we had used in our modelling.

The CMS-determined price applies to all individuals accessing government-funded healthcare in the United States, encompassing more than 100 million Americans. This notably constitutes the largest payer group, incorporating both Medicare for Americans over 65 and Medicaid for low-income individuals.

Moreover, we note private payers will typically reimburse around the rate set by the CMS.

The price is expected to be finalised after a 30-day period of public comment, and then become effective and published in the Clinical Lab Fee Schedule from 1 January 2024.

The finalisation of this pricing will form an important step in the process of securing US reimbursement, noting considerable progress has been made to date (Figure 1).

Figure 1: 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	Complete
Jan 2024	CMS final pricing published	Pending

Source: Company announcement, EHL analysis

As we have outlined in past research, there are various moving parts involved in US reimbursement, they include:

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

Coding

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).

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 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.

Sonic Healthcare (ASX: SHL, $14bn 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 2: Sonic Healthcare USA Overview

Source: Company presentation

Figure 3: 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$19.50 and US$58.50 in royalties received on every test sold (Based on the CMS pricing of ~US$390 per test).**

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 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 and 5).These royalties should fall mostly to the bottom line.

Figure 4: US PromarkerD Royalty Revenue Sensitivity Table

Royalty Rate (%) \ Royalties (A$m)	Market Penetration (%) 1.0%	2.5%	5.0%	10.0%	15.0%	25.0%
5.0%	9.8	24.5	49.1	98.2	147.2	245.4
7.5%	14.7	36.8	73.6	147.2	220.9	368.1
10.0%	19.6	49.1	98.2	196.3	294.5	490.8
12.5%	24.5	61.3	122.7	245.4	368.1	613.5
15.0%	29.4	73.6	147.2	294.5	441.7	736.2

Source: EHL analysis
**assumes US$390/test, 0.64 Fx, ~32m patient TAM*

Figure 5: US PromarkerD Royalty Revenue Sensitivity Table

Royalty Rate (%) \ Royalties (A$m)	Tests Sold Per Annum ('000s) 25.0	100.0	500.0	1,000.0	2,500.0	5,000.0
5.0%	0.8	3.0	15.2	30.5	76.2	152.3
7.5%	1.1	4.6	22.9	45.7	114.3	228.5
10.0%	1.5	6.1	30.5	60.9	152.3	304.7
12.5%	1.9	7.6	38.1	76.2	190.4	380.9
15.0%	2.3	9.1	45.7	91.4	228.5	457.0

Source: EHL analysis
**assumes US$390/test, 0.64 Fx*

Forecasts

We have updated our forecasts to incorporate the US$390 CMS pricing, among other changes.

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 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	2023	2024e	2025e	2026e
PromarkerD Forecasts						
US Unit Sales	'000s	0	0	50	152	266
RoW Unit Sales	'000s	0	0	0	8	24
Total Unit Sales	'000s	0	0	50	160	290
Market Penetration (Forecasted Regions)	%	0.0%	0.0%	0.1%	0.4%	0.7%
Market Penetration (Global)	%	0.0%	0.0%	0.0%	0.0%	0.1%
Group Revenue Forecasts						
PromarkerD Royalties	A$m	0.0	0.0	2.3	7.1	12.6
Analysis Business	A$m	1.5	0.7	1.0	1.1	1.3
PromarkerD consumables	A$m	0.0	0.0	0.8	2.2	3.6
Other Income	A$m	1.9	2.6	1.9	1.9	1.9
Total Sales	**A$m**	**3.4**	**3.3**	**6.0**	**12.4**	**19.4**
% Growth	%	15%	-3%	80%	107%	57%

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.

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Proteomics International Laboratories Limited (PIQ.ASX) | Price A$1.00 | Target price A$2.00 | Recommendation Speculative Buy;

Price, target price and rating as at 29 September 2023 (not covered)*

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