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PIQ Signs Licensing Agreement with Sonic Healthcare USA

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

PRICE
A\$1.01/sh

TARGET PRICE
A\$1.80/sh
(UNCHANGED)

RECOMMENDATION
SPECULATIVE BUY
(UNCHANGED)

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Event

PIQ has signed an exclusive licensing agreement with Sonic Healthcare USA (SHUSA, a division of Sonic Healthcare) to take PromarkerD to market in the United States; this follows the initial binding Letter of Intent (LOI) signed last year.

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. Furthermore, under the agreement SHUSA will be primarily responsible for the marketing and promotion of the test.

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.

Impact

This is a major de-risking event for the company, and importantly should put to rest any concerns which may have emerged amongst investors in recent months following the extension of the initial LOI, or subsequent MSAC decision earlier this year.

Partnering with SHUSA, a company which has a broad US presence, years of experience, and extensive resources, places PIQ in a prime position to commercialise PromarkerD in the US, the largest healthcare market in the world. The United States has 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.

While specific commercial terms are confidential, our analysis suggests even modest market adoption can translate into very lucrative royalties, which would fall mostly to the bottom line. PIQ has previously pointed towards a minimum test price of US\$150 (based on stakeholder engagement), with standard industry royalty rates ranging from 5-15%.

Looking towards initial sales, SHUSA has already made considerable commercial progress in lead up to now, having secured a US reimbursement code (CPT PLA code), optimised the PromarkerD test for a high throughput environment, and marketed the test (as evident by its listing as a 'featured test' on its website, link [here](#)).

Next steps are around securing payer coverage, which PIQ recently stated is ongoing.

We have also made some tweaks to our forecasts.

Action

We maintain our Speculative Buy recommendation and \$1.80 Price Target.

Our investment case is predicated on the commercialization 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.

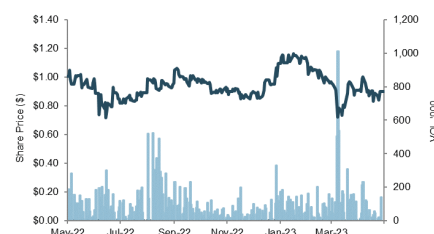
We note our valuation is exclusively based on PromarkerD, with no value ascribed for other programs in development (such as endometriosis).

Catalyst

- US Reimbursement - Private /Public Payer Engagement
- US Sales - 2HCY23

Share Price	1.01	A\$/sh	
Price Target	1.80	A\$/sh	
Valuation (DCF)	1.80	A\$/sh	
WACC	12%		
Terminal Growth	3%		
Shares on issue	120.8	m	
Market Capitalisation	122.0	A\$m	
Enterprise Value	113.8	A\$m	
Cash (Pro-forma)	8.2	A\$m	
Debt (inc. AASB16)	0.1	A\$m	
Key Financial Metrics	22A	23F	24F
Revenue (A\$m)	3.4	3.4	7.7
EBITDA (A\$m)	-4.6	-4.6	-2.7
EBIT (A\$m)	-5.0	-5.0	-3.2
Reported NPAT (A\$m)	-5.0	-5.0	-3.2
Normalised NPAT (A\$m)	-5.0	-5.0	-3.2
Gross Cashflow (A\$m)	-4.1	-4.6	-2.8
Capex (A\$m)	-0.1	-0.3	-0.8
Op. Free Cashflow (A\$m)	-3.7	-4.9	-3.6
Revenue Growth (%)	15%	0%	124%
EBITDA Growth (%)	84%	0%	-41%
Norm. NPAT Growth (%)	54%	0%	-35%
Normalised EPS (Ac)	-4.6	-4.1	-2.7
Norm. EPS growth (%)	na	na	na
PER (x)	-22.2	-24.6	-37.8
EV:EBITDA (x)	-25.0	-24.9	-41.9
EV:EBIT (x)	-22.9	-22.9	-35.4

Performance



Source: Euroz Hartleys

Income Statement	22A	23F	24F
PromarkerD Royalties	0.0	0.0	2.3
Analysis Business	1.5	1.7	2.0
Consumables (Cost-through)	0.0	0.0	1.7
Other Income	1.9	1.7	1.7
Total Sales	3.4	3.4	7.7
(-) COGS	0.0	0.0	-2.1
Gross Profit	3.4	3.4	5.5
(-) OPEX	-8.0	-8.0	-8.3
EBITDA	-4.6	-4.6	-2.7
(-) D&A	-0.4	-0.4	-0.5
EBIT	-5.0	-5.0	-3.2
(-) Net Finance	0.0	0.0	0.0
(-) Other Expenses	0.0	0.0	0.0
EBT	-5.0	-5.0	-3.2
(-) Tax	0.0	0.0	0.0
Reported NPAT	-5.0	-5.0	-3.2
(+/-) Abnormals	0.0	0.0	0.0
Norm NPAT	-5.0	-5.0	-3.2
Cash Flow Statement	22A	23F	24F
Profit Before Tax	-5.0	-5.0	-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	-4.6	-2.8
(-) Capital Expenditure	-0.1	-0.3	-0.8
(-) Change in NWC	0.5	0.0	-0.1
Operating Free Cashflow	-3.7	-4.9	-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	11.0	0.0
(+/-)Other	0.1	0.0	0.0
Net Cashflow	-3.4	6.1	-3.6
BoP Net Cash	5.5	2.1	8.3
(+/-) Net Cashflow	-3.4	6.1	-3.6
(+/-) AASB16	0.0	0.0	0.0
EoP Net Cash	2.1	8.3	4.6
Balance Sheet	22A	23F	24F
Cash	2.1	8.3	4.6
Receivables	0.4	0.4	1.0
Other Assets	1.8	1.8	1.8
Total Current Assets	4.4	10.5	7.4
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	11.5	8.7
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	9.5	6.2
Issued Capital	19.3	30.4	30.4
Reserves	1.7	1.7	1.7
Accumulated Losses	-17.6	-22.6	-25.8
Total Equity	3.4	9.5	6.2

Performance Ratios	22A	23F	24F
Growth & Margins			
Revenue Growth	15%	0%	124%
EBITDA Growth	84%	0%	-41%
EBIT Growth	74%	0%	-35%
Normalized Net Profit Growth	54%	0%	-35%
EBITDA margin	-133%	-134%	-35%
EBIT margin	-145%	-145%	-42%
Normalized net profit margin	-145%	-145%	-42%
Effective tax rate	0%	0%	0%
Liquidity			
Capex/depreciation	0.3	0.6	1.5
Current ratio	2.6	6.2	3.5
Quick ratio	1.7	5.8	2.9
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%	-87%	-74%
Returns			
ROIC	-147%	-52%	-52%
ROA	-92%	-43%	-37%
ROE	-147%	-52%	-52%
Share Data/Valuation	22A	23F	24F
Share Data			
Issued shares	105.8	120.8	120.8
Weighted ave shares	105.5	113.3	120.8
Fully diluted shares	109.3	120.8	120.8
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	-2.3
NBV/share	3.2	7.8	5.2
NTA/Share	3.2	7.8	5.2
Valuation			
PER (Basic)	-19.1	-21.9	-33.7
PER (Fully diluted)	-19.8	-21.9	-33.7
PER (Fully diluted, normalized)	-19.8	-21.9	-33.7
P/CFPS	-23.1	-23.4	-39.0
Price/NBV	28.0	11.5	17.4
Price/NTA	28.1	11.5	17.4
Dividend Yield	0.0	0.0	0.0
EV/EBITDA	-22.1	-22.0	-37.0
EV/EBIT	-20.2	-20.3	-31.2
EV/Revenue	29.3	29.4	13.1

Analysis

PIQ has announced it's signed 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 follows 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 Locations



Source: Company website

The license is for a term of 5-years, extendable by mutual agreement, and is exclusive to the United States (excluding Puerto Rico).

Whilst specific commercial terms are confidential, PIQ have stated the license includes commercially agreed royalties on sales of the test (at a price which is subject to PIQ's reasonable verification and determination), with terms provided for the payment for PromarkerD test reagents.

The license also outlines timelines for milestone events to be achieved in relation to the commercialization process, which include without limitation:

- Mutually agreed arrangements for PLA Code submission and validation
- Information technology sharing and security
- Operations and procurement; and
- Commercial efficacy validation based on relevant market analysis

Finally, under the agreement, Sonic Healthcare USA will be primarily responsible for the marketing and promotion of the test. We note the company has already listed PromarkerD as a featured test on its front webpage, link [here](#).

Essentially:

- This means PIQ will received 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.

Reimbursement - Next Steps

Earlier this year, a new dedicated CPT PLA Reimbursement code was approved for PIQ's lead diagnostic test 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.

In the US, reimbursement codes are managed by the American Medical Association (AMA), and are known as a Current Procedural Terminology (CPT) codes. PLA codes are one of the four groups of CPT codes.

The code for PromarkerD (0385U) has 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).

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

Establishing a test price in the CLFS is a share price catalyst.

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

- Public – Medicare and Medicaid (administered by CMS) are the two main public payers, these organisation 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.

Securing Medicare and Private insurance coverage designation(s) is a share price catalyst.

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 2). These royalties should fall mostly to the bottom line.

Figure 2: US PromarkerD Royalties Sensitivity Table

Royalties (A\$m)	Market Penetration (%)					
	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

Forecasts

We have made some slight tweaks to our forecasts.

We now anticipate first sales will occur out of the US in 2H CY23.

Our consolidated forecasts are shown below:

Figure 3: Consolidated Forecasts

FY	Units	2022	2023e	2024e	2025e	2026e
PromarkerD Forecasts						
Unit Sales	'000s	0	0	148	426	988
Market Penetration (Forecasted Regions)	%	0.0%	0.0%	0.4%	1.1%	2.5%
Market Penetration (Global)	%	0.0%	0.0%	0.0%	0.1%	0.2%
Group Revenue Forecasts						
PromarkerD Royalties	A\$m	0.0	0.0	2.3	6.7	15.6
Analysis Business	A\$m	1.5	1.7	2.0	2.3	2.6
PromarkerD consumables (Costs-through)	A\$m	0.0	0.0	1.7	4.2	7.0
Other Income	A\$m	1.9	1.7	1.7	1.7	1.7
Total Sales	A\$m	3.4	3.4	7.7	14.9	26.8
% Growth	%	15%	0%	124%	94%	80%

Source: EH estimates

We continue to stress that forecasts remain fluid in these early days of commercialisation. We note there is ample opportunity for PIQ to exceed these figures should it attain greater market share than we forecast – especially now with Sonic Healthcare USA as a partner.

We currently only forecast sales of PromarkerD, however note other Promarker™ pipeline programs could yield commercial outcomes in the future.

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Company disclosures

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Proteomics International Laboratories Limited (PIQ.ASX) | Price A\$1.01 | Target price A\$1.80 | Recommendation Speculative Buy;

Price, target price and rating as at 10 May 2023 (not covered)*

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