

Speculative

See key risks on Page 4 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

Analyst

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4D Medical (4DX)

Prospects for VA Contract Improving

Authorisation

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Recommendation

Buy (unchanged)

Price

\$0.825

Valuation

\$1.10 (previously \$1.05)

Risk

Speculative

GICS Sector

Healthcare Equipment and Services

Expected Return

Capital growth	33.3%
Dividend yield	0.0%
Total expected return	33.3%

Company Data & Ratios

Enterprise value	\$205.7m
Market cap	\$284.7m
Issued capital	345.1m
Free float	80%
Avg. daily val. (52wk)	\$533,000
12 month price range	\$0.29 - \$1.27

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	1.14	0.36	0.64
Absolute (%)	-27.31	129.17	28.91
Rel market (%)	-26.40	130.95	29.90

Absolute Price



SOURCE: IRESS

Commercialisation Momentum Continues To Build

The recently completed capital raise was well supported by institutions and retail shareholders following a spate of news flow regarding commercialisation activities for the XV LVAS in the United States. This included the first commercial contract with University of Miami and first scan completed at a Department of Veterans Affairs hospital. The VA is the largest hospital system in the US by some distance and its business could accelerate adoption of 4DX technology into mainstream by years.

Strong Cash Position

4DX raised \$45m in total, issuing ~50m new shares representing ~17% dilution. Following this round, pro-forma cash at 31 March is \$79.3m providing at last 2 years cash runway – assuming no abatement in the rate of cash burn.

While our financial model anticipates the company will have sufficient capital to achieve cash flow breakeven, there remains considerable uncertainty around the timing of key events including, in the main, large scale contracts with the VA. Notwithstanding, progress with VA negotiations accelerated from the moment of the appointment of Dr David Shulken (former Secretary to the Department of Veterans Affairs) as an advisor to the company in April. With 3.5m veterans within the VA system potentially eligible for screening to toxins from burn pit exposure, this opportunity continues to be the most lucrative. For the remainder of CY23 it is reasonable to expect the announcement of a pilot programme with at least one VA hospital. We also expect a second commercial contract in the private sector is likely as a pilot programs have been ongoing for months.

Investment View: Retain Buy (Spec) Valuation \$1.10

Changes to earnings are not material. As we had previously allowed for a capital raising in 2024, the dilution to shares on issue from our previous valuation assumption is modest, hence we maintain our speculative Buy rating. Valuation is increased by 4.7% to \$1.10 (from \$1.05) following model roll forward.

Earnings Forecast

June Year End	FY22	FY23e	FY24e	FY25e
Revenues	1.1	1.8	3.6	24.7
EBIT \$m	-24.5	-29.9	-28.8	-19.0
NPAT (underlying) \$m	-24.6	-29.9	-28.8	-19.0
NPAT (reported) \$m	-24.6	-29.9	-28.8	-19.0
EPS underlying (cps)	-8.4	-9.4	-8.4	-5.5
EPS growth %	nm	nm	nm	nm
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	-41%	-41%	-65%	-75%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Moving towards commercialisation

Overview of capital raise

8 May, institutional placement for \$20m @ \$0.91 – 20% discount to last price prior to the announcement.

24 May, Securities Purchase Plan (SPP) closes raising \$25m. Over-subscribed from the original \$15m limit. Directors chose not to scale back applications. Shares issued at \$0.89 representing lower of \$0.91 and 2.5% discount to the 5 day VWAP.

A total of 50 million shares were issued across both the placement and SPP representing ~17% of the shares on issue prior to these transactions.

New shares under the placement and SPP are entitled to 1 free attaching option for every two shares issued. The exercise price on the options of \$1.365 represents a 50% premium to the placement price.

Pro forma cash at 31 March 2023 becomes approximately \$79.6m inclusive of the cash raised in these transactions. Based on the most quarterly recent cash burn rate this represents 2 years of cash flow, however, we expect cash burn to begin to decline in FY24 as revenues from these early commercialisation initiatives grows.

Overview of recent commercialisation announcements

4DX is expanding its commercial footprint in Australia and the US. Commercialisation began in Australia in 2022 with the iMed contract which has now expanded to 27 sites. The following announcements relate to commercialisation activities in the United States.

- **5 April** – first commercial contract in the US (University of Miami). Minimum of \$1m - \$1.5m over 5 years.
- **13 April** – Dr David Shulken appointed as advisor to 4DX. Dr Shulken is a previous Secretary of the US Department of Veterans Affairs. He was recently named by industry publication *Modern Healthcare* as one of the “50 Most Influential Physician Executives in the Country” and as among the “One Hundred Most Influential People in American Healthcare”. Dr Shulken’s key value add is his network of contacts within the VA as 4DX looks to deploy XV Technology as part of the VA’s implementation of PACT Act-enabled care for Veterans.
- **1 May** – First commercial XV LVAS scan within the VA at Harry S. Truman VA hospital Columbia, Missouri;
- **5 May** – First pilot programme with the Military Health System (MHS) within the US Department of Defence. Fixed volume of scans to be performed at commercial rates but no revenue guidance included;
- **18 May** – Announces granting of first “Authority To Operate” at Harry S. Truman memorial VA Hospital;
- **23 May** – company unveils CT based ventilation perfusion product (CT:VQ) at the American Thoracic Society Annual Meeting. The technology is a potential market disruptor to conventional imaging for diagnosis of pulmonary embolism.
- The 4DX technology does not require a contrast media for the perfusion piece, hence it is a potential market disruptor for the nuclear medicine VQ scan initially and later for CTPA based assessment¹. The logistics of a nuclear medicine scan

¹ CT Pulmonary Angiography

make it a cumbersome and costly examination, hence why 4DX will target the VQ scan initially.

Summary

The company has made pleasing progress with the commercialisation of the XV LVAS technology in 1H CY23. Collectively revenues expectations remain fairly modest, however, for FY23 we expect \$1.2m in commercial (SaaS) revenues.

The appointment of Dr David Shulken as an advisor is likely to be pivotal for gaining penetration to the very large Veterans Affairs (VA) market. Given his previous office at the VA, Dr Shulken's network of contacts is likely to include key decision makers and in our view these are essential to accelerating adoption. The VA is well funded to pay for the XV LVAS scan via PACT Act funding which was made in to law in 2022.

The awarding of the Authority To Operate (ATO) at Harry S. Truman is another important milestone. Once a second hospital within the VA grants a second ATO the company will be eligible to apply for a National ATO, providing it with authorisation to operation at all 171 major clinical centres within the VA network.

For the moment, the nature of the relationship with Harry S. Truman VA hospital remains loosely defined and this is likely based on commercial sensitivities. We expect the company to announce a formal pilot study with the VA as the next step in the process. The pilot program with MHS is exactly the style of engagement we would expect with the VA.

REIMBURSEMENT PROGRESS

Before the end of CY 2023 we expect at least one of the peer reviewed clinical trial papers will be published.

From 1 July the class III CPT code comes into effect, allowing hospitals to bill the XV LVAS scan. Patients will be required to self pay for this test.

As each of these pieces falls into place the company will gradually move toward the ultimate goals of commercial agreements with the VA healthcare system, reimbursement from medicare, and additional commercial contracts with healthcare systems outside of the VA.

While our financial model anticipates the company will have sufficient capital to achieve breakeven cash flow, there remains considerable uncertainty around the timing of key events. Nevertheless, the progress with the VA accelerated following the appointment of Dr Shulken as an advisor. With up to 3.5m veterans within the VA potentially eligible for screening to toxins from burn pit exposure, this opportunity continues to be the most lucrative.

Changes to earnings are not material. As we had previously allowed for a capital raising in 2024 the dilution to shares on issue from our previous valuation assumption is modest, hence we maintain our speculative buy rating. Valuation is increased to \$1.10 following a roll forward of the model.

4DX Medical

4DX Medical Limited (4DX) is a Melbourne-based software technology company commercialising its patented imaging platform, 'XV Technology'. This four-dimensional lung imaging technology utilises proven, patented mathematic models and algorithms to convert X-ray scans into quantitative data to enhance the capacity of physicians to manage patients with respiratory diseases and diseases of the lung.

- The XV (Ventilation) system received FDA approval in May 2020 and TGA approval shortly after. The US market alone is estimated at up to 73m lung assessments annually. The technology has the potential to replace each of the existing modalities for the assessment of lung function. The initial target markets are luminary hospital sites in the US and specifically in-patient CT Scans of which there are ~10.9m performed in the US each year.
- 4DX will deliver the service via a Software as a Service (SaaS) model whereby images are processed in the cloud by a range of third party providers utilising the 4DX proprietary technology. The company intends to charge US\$175 per scan which should provide it with better than 90% gross profit margin, however, first commercialisation agreements are yet to be signed.
- 4DX is a new imaging technology that is somewhat disruptive to well established clinical practice. It has broad clinical support from key opinion leaders in the United States, nevertheless any new medical technology, particularly a diagnostic tool faces a long period in which its commercial and clinical benefits require validation.

In our view the key risk areas are:

- Funding – The company commenced commercialisation of its products in mid 2020 in the US and is yet to generate meaningful revenues or positive cash flow generation from operating activities. It is competing in a well established industry and there is no guarantee that it will achieve either of these financial objectives. 4DMedical may be required to raise additional funds from time to time to finance the development and commercialisation of its products and other longer-term objectives.
- Third Party Providers – 4DX will rely on the services of numerous third party providers to render its services. These include cloud service providers Amazon Web Services and Microsoft, software providers and services including Laurel Bridge and various providers of PACS systems, all of which provide critical pieces of infrastructure for modern radiology services. Each of these providers must be HIPAA compliant as well as provide a continuous reliable services at rates which allow 4DX to earn the margins included in our forecast. There are numerous risk factors which may prevent any of these providers from being able to deliver these services. Fortunately, the company has the ability to diversify its risk among several competing parties.
- Superseding Technology - There is a risk that new technology will be developed that will supersede 4DMedical's technology. In addition to the 20 years of monopoly rights granted by 4DMedical's extensive patent portfolio, 4DMedical will continue to invest heavily in research and development to mitigate the risk that other competitor technologies will supersede the current and future product offerings developed by 4DMedical. However, 4DMedical cannot guarantee that its technology will not be superseded.

Regulatory risk - Although the FDA has provided its clearance for the XV LVAS, the additional VQ (Perfusion) and CFPA (Vasculature) products still require FDA clearance. Failure to receive regulatory clearance will have a negative impact on 4DMedical's future revenue streams.

Table 1 - Financial summary

A\$m	FY21	FY22	FY23e	FY24e	FY25e	Valuation Ratios (A\$m)	FY21	FY22	FY23e	FY24e	FY25e
Year Ending 30 June						Reported EPS (cps)	-6.5	-8.4	-9.4	-8.4	-5.5
Commercial (SaaS) revenues	0.2	1.1	1.2	1.8	20.2	Normalised EPS (cps)	-6.5	-8.4	-9.4	-8.4	-5.5
Scanner sales	-	-	0.6	1.8	4.5	EPS growth (%)	nm	nm	nm	nm	nm
Total Revenue	0.2	1.1	1.8	3.6	24.7	PE(x)	nm	nm	nm	nm	nm
Revenue growth	-88%	603%	69%	104%	579%	EV/EBIT (x)	nm	nm	nm	nm	nm
COGS	-0.1	-0.8	-0.6	-1.8	-5.0	P/NTA (x)	3.0	4.4	4.1	7.1	13.8
Gross profit	0.1	0.3	1.2	1.8	19.7	Book Value Per Share (cps)	28.5	20.3	21.3	13.0	7.4
GP Margin	67%	27%	66%	51%	80%	Price/Book (x)	2.9	4.1	3.9	6.4	11.2
Other income	5.5	12.3	10.4	9.3	3.0	DPS (cps)	-	-	-	-	-
Employee expenses	-11.4	-19.2	-20.2	-21.2	-22.2	Payout ratio %	0%	0%	0%	0%	0%
R&D spend	-3.0	-4.4	-7.2	-4.0	-4.0	Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Depreciation and amortisation	-0.7	-1.5	-1.3	-1.3	-1.3	Franking %	0%	0%	0%	0%	0%
Other expenses	-9.3	-12.0	-12.8	-13.4	-14.1	FCF yield %	nm	nm	nm	nm	nm
EBIT	-18.8	-24.5	-29.9	-28.8	-19.0	Net debt/Equity	0%	0%	0%	0%	0%
Interest expense	-2.6	-0.1	0.0	0.0	0.0	Net debt/Assets	0%	0%	0%	0%	0%
Other items	0.0	0.0	0.0	0.0	0.0	Gearing	na	net cash	net cash	net cash	net cash
Pre tax profit	-21.4	-24.6	-29.9	-28.8	-19.0	Net debt/EBITDA (x)	na	net cash	net cash	net cash	Net Cash
Tax expense	-	-	-	-	-	Interest cover (x)	na	na	na	na	na
NPAT- reported	(21.4)	(24.6)	(29.9)	(28.8)	(19.0)						
Add back											
Non recurring items net of tax	-	-	-	-	-						
Normalised NPAT	(21.4)	(24.6)	(29.9)	(28.8)	(19.0)						

Cashflow (A\$m)	FY21	FY22	FY23e	FY24e	FY25e
Gross cashflow	-14.5	-25.2	-25.2	-26.0	-19.3
Net interest	0.0	-0.1	0.0	0.0	0.0
Operating cash flow	-14.5	-25.3	-25.2	-26.0	-19.3
Maintenance capex	-0.6	-2.6	-1.0	-1.0	-1.0
Capitalised R&D	0.0	-0.4	-0.7	-1.0	-1.0
Other capitalised intangible	0.0	-0.4	0.0	0.0	0.0
Free cash flow	-15.1	-28.8	-26.9	-28.0	-21.3
Proceeds from issuance	89.6	0.0	43.7	0.0	0.0
Movement in lease debt	-0.5	-1.0	-1.0	-1.0	-1.0
Change in cash held	74.0	-29.8	15.7	-29.0	-22.3
Cash at beginning of period	8.4	80.9	51.1	66.8	37.7
FX adjustment	0.0	0.0	0.0	0.0	0.0
Cash at year end	80.9	51.1	66.8	37.7	15.4

Interim Results	1H22	2H22	1H23	2H23e
Revenues	0.2	0.9	0.5	1.3
EBIT	-12.3	-12.2	-16.2	-13.7
NPAT	-12.4	-12.3	-16.2	-13.7

Balance Sheet (A\$m)	FY21	FY22	FY23e	FY24e	FY25e
Cash	80.9	51.1	66.8	37.7	15.4
Receivables	0.4	2.1	0.3	0.7	4.5
Other current assets	3.6	5.6	5.6	5.6	5.6
Inventory	0.9	-	-	-	-
Property, Plant and Equipment	1.2	5.5	6.2	6.8	7.5
Intangibles	3.9	5.1	4.8	4.8	4.8
Other non current assets	1.7	4.9	4.9	4.9	4.9
Total assets	92.5	74.3	88.6	60.5	42.6
Trade payables	6.0	7.2	8.6	10.4	12.4
Other liabilities	1.5	1.4	1.5	1.6	1.7
Lease liabilities	1.7	6.2	5.2	4.2	3.2
Total Liabilities	9.2	14.8	15.3	16.2	17.3
Net Assets	83.4	59.5	73.2	44.4	25.3
Share capital	141.6	141.7	185.4	185.4	185.4
Other equity	1.8	2.4	2.4	2.4	2.3
Retained earnings	(60.0)	(84.6)	(114.6)	(143.3)	(162.3)
Reserves	-	-	-	-	-
Shareholders Equity	83.4	59.5	73.2	44.4	25.4

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

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