EUROZ HARTLEYS

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DXB: FDA Confirms Proteinuria for Full Approval, Increasing Likelihood of USA Deal?

DXB.ASX | DIMERIX LIMITED | HEALTHCARE | BIOTECHNOLOGY

PRICE	TARGET PRICE	RECOMMENDATION
A$0.46/sh	**A$1.06/sh** (UNCHANGED)	**SPECULATIVE BUY** (UNCHANGED)

Event

DXB has received formal meeting minutes from the US FDA confirming proteinuria (i.e., protein in the urine) can be used as a primary endpoint for full US approval. The Agency had previously required estimated Glomerular Filtration Rate (eGFR) to be used.

The FDA has confirmed that, alongside defining what constitutes a meaningful difference, suitable proteinuria-based primary endpoints for full approval can be either:

- The proportion of patients achieving a defined proteinuria reduction (e.g., reaching below a specific g/g urine protein-to-creatinine ratio) vs placebo a 2-years; or
- The percentage change in proteinuria from baseline at 2-years.

The FDA also confirmed it remains open to discussions on accelerated approval endpoints. DXB is now working with PARASOL to generate additional data to support an appropriate endpoint for accelerated approval. This work is expected to take 3-6 months.

As of this update, 183 of 286 patients have been dosed into phase 3 study. DXB remains well funded with ~$35 million in pro forma cash (Dec'Q), including in-the-money options.

Impact

This is a highly positive development on multiple fronts, which we believe enhances the appeal of DMX-200 and increasing the likelihood of DXB securing a US licensing deal – a significant catalysts, considering the US is the largest FSGS market globally.

Not only did the FDA confirm that proteinuria is an appropriate endpoint for full approval, but the agency went further by proposing the use of percentage reduction in proteinuria – a very positive surprise, given all the data presented by the PARASOL working group to date has been on reaching a defined proteinuria thresholds (e.g., 0.7 g/g).

We view this among the best outcomes, given proteinuria is less variable than the previously required estimated Glomerular Filtration Rate (eGFR), effectively lowering the hurdle for full US approval. Moreover, all of DXB's prior preclinical and clinical data has demonstrated encouraging percentage reductions in proteinuria from baseline, including: **1)** In key animal renal disease models, DMX-200 showed statistically significant reductions in proteinuria, **2)** In the prior Phase 2a study, DMX-200 demonstrated a 24% reduction in proteinuria from baseline (17% adj. for placebo) at 16-weeks, and **3)** The part 1 phase 3 interim analysis confirmed DMX-200 was showing a reduction in proteinuria vs placebo at 35-weeks, in a magnitude larger patient cohort than the prior phase 2a study.

Separately, we believe the outcome bodes very well for using proteinuria as an accelerated approval endpoint. However, we interpret the commentary provided as suggesting the FDA will require data which links the use of an earlier proteinuria endpoint (e.g., 35-weeks as currently planned) with the 2-year full approval endpoint. Based on the guided timeline for this analytical work, we now expect a potential interim readout (for accelerated approval) to occur between September (as currently planned) and late CY25.

Action

We maintain our Speculative Buy Recommendation and $1.06 Price Target

Catalysts

Part 2 Interim Results (Sept - late CY25) / DMX-200 (FSGS) FDA/EMA Filing (late CY25 to early CY26) / Accelerated Approval (CY26) / New Licensing Deals - USA/China/RoW

Analyst

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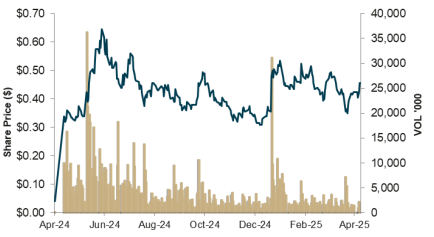
Share Price	**0.46**	**A$/sh**
Price Target	**1.06**	**A$/sh**
Risked Valuation	**1.06**	**A$/sh**
Unrisked Valuation	**1.72**	**A$/sh**
WACC	15.0%	%
Shares on issue	605.5	m,dil
Market Cap	**275.5**	**A$m**
Enterprise Value	**240.8**	**A$m**
Debt (inc. leases)	0.1	A$m
Cash (pro forma)*	28.3	A$m
Unpaid capital	6.5	A$m
**incl Japan License*		

Key Metrics	**24A**	**25F**	**26F**
Revenue (A$m)	8.6	4.8	36.5
EBITDA (A$m)	-17.0	-19.7	21.0
EBIT (A$m)	-17.1	-19.7	20.9
NPAT (A$m)	-17.1	-19.7	20.9
Gross CF (A$m)	-4.3	4.1	106.4
Capex (A$m)	0.0	0.0	0.0
Op. FCF (A$m)	-7.3	7.8	109.3
EPS (Ac)	-3.1	-3.6	3.8
Revenue Growth	-5%	-44%	658%
PER (x)	na	na	12.0
EV/EBITDA (x)	na	na	11.5
EV/Revenue (x)	28.1	50.1	6.6
Net Cash**	22.0	29.8	139.1
***inc. leases*			

Performance



Source: IRESS

Income Statement	24A	25F	26F	27F
Royalty Income	0.0	0.0	21.0	91.0
Milestone Payments*	0.4	3.5	14.6	23.3
Other (inc. R&D)	8.2	1.3	0.9	0.4
Total Revenue	**8.6**	**4.8**	**36.5**	**114.7**
(-) COGS	0.0	0.0	0.0	0.0
Gross Profit	8.6	4.8	36.5	114.7
(-) R&D	-21.1	-20.0	-10.0	-4.0
(-) SG&A	-4.5	-4.5	-5.5	-7.5
EBITDA	**-17.0**	**-19.7**	**21.0**	**103.2**
(-) D&A	0.0	0.0	0.0	0.0
EBIT	**-17.1**	**-19.7**	**20.9**	**103.2**
(-) Net finance	0.0	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
PBT	**-17.1**	**-19.7**	**20.9**	**103.2**
(-) Tax	0.0	0.0	0.0	-10.6
NPAT	**-17.1**	**-19.7**	**20.9**	**92.6**

Cash Flow Statement	24A	25F	26F	27F
NPAT	**-17.1**	**-19.7**	**20.9**	**92.6**
(+) D&A	0.0	0.0	0.0	0.0
(+) Upfront/Milestones	11.0	27.2	100.0	70.2
(-) leases	0.0	0.0	0.0	0.0
(+/-) Non-cash Rev/Exp	1.8	-3.5	-14.6	-23.3
(+/-) Other	0.0	0.1	0.0	0.0
Gross Cash Flow	**-4.3**	**4.1**	**106.4**	**139.6**
(-) Capital expenditure	0.0	0.0	0.0	0.0
(+/-) Working Capital	-3.0	3.7	3.0	-6.0
Operating Free Cash Flow	**-7.3**	**7.8**	**109.3**	**133.5**
(-/+) Acquisition/Disp	0.0	0.0	0.0	0.0
(+) Placement/Equity	24.3	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
Net Cash Flow	**17.0**	**7.8**	**109.3**	**133.5**
BoP Net Cash / (Debt)	2.0	22.0	29.8	139.1
(+/-) Net Cash Flow	17.0	7.8	109.3	133.5
(+/-) Other	3.0	0.0	0.0	0.0
EoP Net Cash / (Debt)	**22.0**	**29.8**	**139.1**	**272.6**

Balance Sheet	24A	25F	26F	27F
Cash	22.1	29.8	139.1	272.6
Receivables	9.8	5.0	1.8	7.5
Total Current Assets	**31.9**	**34.8**	**140.9**	**280.1**
ROUA	0.1	0.1	0.1	0.1
PP&E	0.0	0.0	0.0	0.0
Total Non Current Assets	**0.2**	**0.2**	**0.2**	**0.2**
Total Assets	**32.1**	**35.0**	**141.1**	**280.3**
Payables	2.5	1.5	1.3	0.9
Borrowing	0.0	0.0	0.0	0.0
Leases	0.1	0.1	0.1	0.1
Contract Liability	0.6	3.5	14.6	23.3
Provisions	0.2	0.2	0.2	0.2
Total Current Liabilities	**3.4**	**5.3**	**16.1**	**24.5**
Leases	0.1	0.1	0.1	0.1
Contract Liability	10.4	31.1	105.5	143.7
Provisions	0.0	0.0	0.0	0.0
Total Non-current Liab.	**10.5**	**31.2**	**105.6**	**143.8**
Total Liabilities	**13.9**	**36.5**	**121.7**	**168.3**
Net Assets	**18.2**	**-1.6**	**19.4**	**112.0**
Issued Capital	83.4	83.4	83.4	83.4
Reserves	4.0	4.0	4.0	4.0
Retained Earnings	-69.2	-88.9	-68.0	24.6
Total Equity	**18.2**	**-1.6**	**19.4**	**112.0**

Performance Ratios	24A	25F	26F	27F
Growth				
Revenue Growth (%)	-5%	-44%	658%	215%
EBITDA Growth (%)	24%	16%	-206%	393%
EBIT Growth (%)	24%	16%	-206%	394%
NPAT Growth (%)	24%	16%	-206%	343%
Margin				
EBITDA Margin (%)	-199%	-409%	57%	90%
EBIT Margin (%)	-199%	-410%	57%	90%
PBT Margin (%)	-199%	-410%	57%	90%
NPAT Margin (%)	-199%	-410%	57%	81%
Effective Tax Rate (%)	0%	0%	0%	10%
Liquidity				
Capex/depreciation (x)	0.3	0.3	0.3	0.3
Current ratio (x)	9.5	6.6	8.8	11.4
Quick ratio (x)	12.6	23.2	110.6	296.4
Receivable days	416	379	18	24
Payable days	36	22	30	30
Risk Measures				
Dividend Cover (x)	na	na	na	na
Payout ratio (%)	na	na	na	na
Net interest cover (x)	na	na	na	na
Net debt/equity (%)	Cash	1918%	Cash	Cash
Returns				
ROIC (%)	na	985%	75%	64%
ROA (%)	na	na	15%	33%
ROE (%)	na	1271%	108%	83%

Share Data/Valuation	24A	25F	26F	27F
Share Data				
Issued shares (m)	550.2	550.2	550.2	550.2
Weighted ave shares (m)	469.1	550.2	550.2	550.2
Fully diluted shares (m)	550.2	605.5	605.5	605.5
Basic EPS (c)	-3.1	-3.6	3.8	16.8
YoY change (%)	-13%	16%	-206%	343%
Fully diluted EPS (c)	-3.1	-3.3	3.5	15.3
YoY change (%)	-13%	5%	-206%	343%
Fully dil norm EPS (c)	-3.1	-3.6	3.8	16.8
YoY change (%)	-13%	16%	-206%	343%
Dividend/share (c)	0.0	0.0	0.0	0.0
Franking (%)	na	na	na	na
Gross cash flow/share (c)	-0.8	0.7	19.3	25.4
NBV/share (c)	3.3	-0.3	3.5	20.4
NTA/Share (c)	3.3	-0.3	3.5	20.4
Share Data				
PER (Basic) (x)	na	na	12.0	2.7
PER (Fully diluted) (x)	na	na	13.2	3.0
PER (Fully dil, norm) (x)	na	na	12.0	2.7
P/CFPS (x)	na	61.7	2.4	1.8
Price/NBV (x)	13.8	na	12.9	2.2
Price/NTA (x)	13.8	na	12.9	2.2
Dividend Yield (%)	0.0	0.0	0.0	0.0
EV/EBITDA (x)	na	na	11.5	2.3
EV/EBIT (x)	na	na	11.5	2.3
EV/Revenue (x)	28.1	50.1	6.6	2.1

**recognised over contract term*

Analysis

Background

Dimerix (DXB) is currently running a global phase 3 clinical trial (ACTION3) evaluating its lead asset, DMX-200, as a treatment for Focal Segmental Glomerulosclerosis (FSGS), a rare type of kidney disease.

Previously, the US Food and Drug Administration (FDA) had typically required clinical trials in FSGS to use change in estimated Glomerular Filtration Rate (eGFR) slope as the primary endpoint for full marketing approval, including in the ACTION3 trial of DMX-200.

While we have always had confidence in DMX-200's ability to feasibly demonstrate this eGFR slope change, the mechanics of eGFR slope mean it is a slower moving data point which requires measurement over longer reference periods. As a result, it can inherently be a bit more variable.

Since there are currently no FDA-approved drugs for FSGS, a scientific working group co-sponsored by the FDA, called Project PARASOL, was formed to support the use of alternative proteinuria (i.e., protein in the urine) endpoints for accelerated and traditional approvals, compared to the existing eGFR slope-based endpoints. The idea being, proteinuria is easier to measure/less variable and can therefore make it easier to get new drugs approved in FSGS.

Last year, the PARASOL group presented its data analysis at the American Society of Nephrology (ASN) meeting, where it highlighted strong evidence linking reductions in proteinuria to a decreased risk of kidney disease progression.

On the back of these findings DXB requested a Type C meeting with the US FDA to reach an agreement on the appropriate use of proteinuria endpoints.

FDA Meeting Minutes

DXB has now received formal meeting minutes from the US FDA confirming proteinuria can be used as a primary endpoint for full US approval.

The FDA has confirmed that suitable proteinuria primary endpoints for full approval can be either:

- The proportion of patients achieving a defined proteinuria reduction (e.g., reaching below 0.7 g/g urine protein-to-creatinine ratio) vs placebo a 2-years; or
- The percentage change in proteinuria from baseline (i.e., percentage reduction in urine protein-to-creatinine ratio) at 2-years

Alongside this, the FDA has requested a justification for what constitutes a meaningful difference between treatment arms.

In parallel, the FDA confirmed it remains open to discussions on endpoints for accelerated approval. Based on current discussions, DXB is now working with the PARASOL working group to generate additional data to support an appropriate endpoint for accelerated approval. This analytical work is expected to take 3-6 months to complete.

Implications: Increasing Likelihood of USA Deal

This is a highly positive development on multiple fronts, which we believe enhances the appeal of DMX-200 and increasing the likelihood of DXB securing a US licensing deal – a significant catalysts, considering the US is the largest FSGS market globally.

Not only did the FDA confirm proteinuria was an appropriate endpoint for full approval, but the agency went further by proposing using a percentage reduction in proteinuria – a very positive surprise, considering all the data presented by the PARASOL working group to date has been on reaching a defined proteinuria thresholds (e.g., 0.7 g/g)

We see this among the best outcomes possible given as discussed above proteinuria is less variable than the previously required estimated Glomerular Filtration Rate (eGFR), effectively lowering the hurdle to secure US approval.

Moreover, all DXB's prior preclinical and clinical data has demonstrated encouraging percentage reductions in proteinuria levels from baseline, including:

- In key animal models of renal disease, DMX-200 has shown statistically significant reductions in proteinuria.
- In the prior Phase 2a study, DXM-200 demonstrated a 24% reduction in proteinuria from baseline at 16-weeks (17% when adjusted for placebo).
- The part 1 phase 3 interim analysis confirmed DMX-200 was showing a reduction in proteinuria vs placebo at 35-weeks, in a magnitude larger patient cohort than the prior phase 2a study.

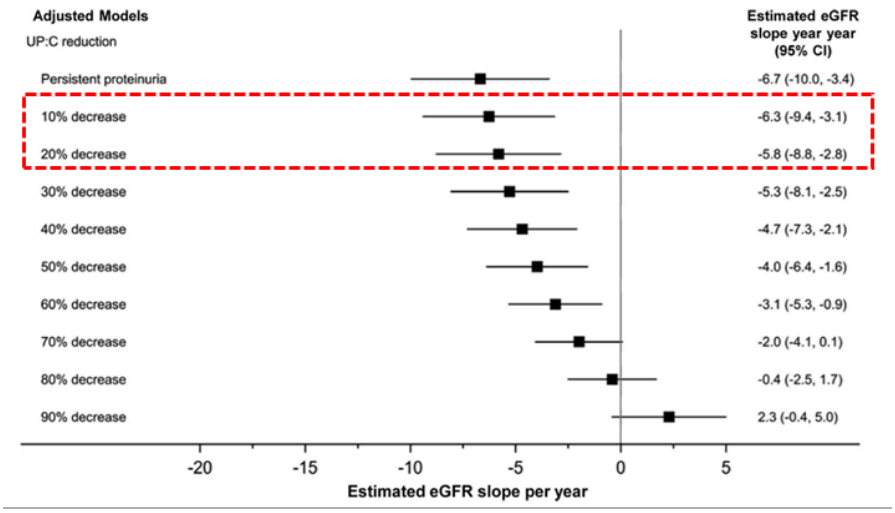
As for what is potentially defined as a "meaningful difference" as required by the FDA, we have previously discussed in our initiation data which suggests every 10% reduction in proteinuria is clinically meaningful.

The logic being in 2018, the National Kidney Foundation sponsored a workshop in collaboration with the US FDA and the European EMA which concluded an eGFR slope reduction of 0.5-1.0 ml/min/1.73m^2/year was associated with lower end stage renal disease (ESRD) risk (hazard ratio of 0.7).

In a subsequent publication, it was shown every 10% reduction in proteinuria correlated to an eGFR slope reduction of 0.5-1.0 ml/min/1.73m^2/year (Figure 1).

Therefore, it can be concluded that every 10% reduction in proteinuria can be viewed as as clinically meaningful.

Figure 1: eGFR slope relationship to proteinuria change



Source: Troost et al, August 2020

As we discussed above, in the previous phase 2a study, DMX-200 showed a 17% placebo adjusted reduction in proteinuria from baseline at 16-weeks.

In parallel, the FDA confirmed it remains open to discussions on endpoints for accelerated approval. We believe the agency's confirmation on using proteinuria as a full approval primary endpoint likely also bodes well for its use as an accelerated approval endpoint.

However, we interpret the commentary provided as suggesting the FDA will require data which links the use of an earlier proteinuria endpoint (e.g., 35-weeks as currently planned, or some other time point) with the now confirmed 2-year full approval endpoint. To do this, DXB is now working with the PARASOL working group to generate additional data to support an appropriate endpoint for accelerated approval. This analytical work is expected to take 3-6 months to complete.

Based on this projected analytical work timeline, we now expect a potential interim readout (to support a potential accelerated approval application) to occur sometime between September 2025 (as currently planned) and late CY2025, subject to confirmation from the FDA.

No additional changes are planned for the study, as both eGFR and proteinuria will still be collected for a total of 2-years. As a reminder, the changes we have discussed so far only apply to regulatory filings with the FDA in the United States, as other regulatory bodies, such as the European Medicines Agency (EMA) in Europe will still currently require eGFR slope change for full marketing approval.

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 there been any adverse or undue influence on the Analyst in the preparation of this report.

Company disclosures

The companies and securities mentioned in this report, include:

Dimerix Limited (DXB.ASX) | Price A$0.46 | Target price A$1.06 | Recommendation Speculative Buy;

Price, target price and rating as at 28 April 2025 (not covered)*

Additional disclosures

The analyst declares that they have a beneficial interest in: Dimerix Limited (DXB.ASX)

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

Other disclosures, disclaimers and certificates

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