More progress lies ahead

Share Price: A$0.445

ASX: DXB

Sector: Healthcare

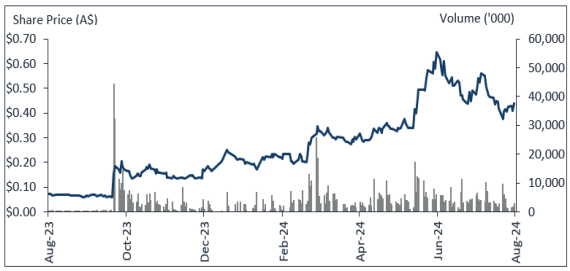
27 August 2024

Dimerix (ASX: DXB) and its shareholders have had a spectacular 12 months. The company is seeking to bring its DMX-200 drug to market for Focal Segmental Glomerulosclerosis (FSGS) and has taken major steps towards this goal.

Market cap. (A$m)	243.5
# Shares outstanding (m)	547.2
# Share fully diluted (m)	672.6
Market cap full. dil. (A$m)	299.3
Free float	727
12-months high/low (A$)	0.415 / 0.057
Avg. daily volume ('1000)	2,926.2
Website	https://dimerix.com

Source: Company, S&P Capital IQ, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: S&P Capital IQ, Pitt Street Research

Phase III data and multiple licensing deals worth over $300m

Dimerix's 500%+ share price gain can be put down to three feats by the company. Two of these are licensing deals secured for DMX-200. The first of these deals is with Advanz Pharma for the EU, UK, Switzerland, Canada, Australia and New Zealand. And the second is with Taiba Middle East for 7 Middle Eastern Countries. These two agreements could deliver up to $350m in milestone payments plus royalty payments. The other feat the company achieved was initial results from its pivotal phase 3 trial of DMX-200 in FSGS and the analysis was positive. These paved the way for the company to proceed to the next part of the global study.

Strong prospects are ahead

The next major date investors should have pencilled in is mid-CY25. This is when the next data read out will occur. The exact date will be about 35 weeks after the final patient (out of the ~144 anticipated to be enrolled) commences the study. A more approximate date will be able to be estimated at that time. If the data shows DMX-200 is successful, the company may be able to apple for conditional marketing approval.

Furthermore, even with the company holding 2 licensing deals, it has not yet licensed out the USA or China. We may see this in the next 12 months and these may be bigger deals than the Advanz or Taiba deals, because the USA and China are larger market opportunities for FSGS, and kidney disease generally.

Valuation of A$0.84-1.07 per share

We reiterate our previous valuation of DXB at A$0.84 and A$1.07 per share (base and optimistic cases). These assume successful commercialisation of DMX-200 and all that all promised milestones consequently eventuate. Please refer to pages 7-8 for more details on our valuation and the key risks to our thesis.

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Analysts: Stuart Roberts, Nick Sundich

Tel: +61 (0)4 4724 7909

Stuart.Roberts@pittstreetresearch.com

Nick.Sundich@pittstreetresearch.com

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Re-introducing to Dimerix (ASX:DXB) and DMX-200

FSGS is a specific kidney disease that attacks the kidney's filtering units where the blood is cleaned. This causes irreversible scarring and leads to permanent kidney damage and eventual end-stage kidney failure.

Dimerix is developing its proprietary product DMX-200 against kidney diseases. It is most advanced against Focal Segmental Glomerulosclerosis (FSGS), currently in a Phase 3 trial with favourable interim results. FSGS is a disease where the kidney's blood filtering units (the glomeruli) is attacked and there is irreversible scarring and permanent kidney damage. Patients, which can be both adults and children as young as 2 years old, may need dialysis or a replacement kidney – but even a replacement kidney may not be a permanent solution, with 60% of patients receiving a kidney transplant getting re-occurring FSGS. There are no drugs specifically approved for FSGS anywhere in the world. Any drugs that are used target symptoms rather than the disease itself. However, Dimerix's asset DMX-200 offers hope for patients.

What is DMX-200 and how does it work?

DMX-200 is an oral anti-inflammatory drug called repagermanium, administered to patients already taking the current standard of care (the blood pressure medication known as an ARB) for the treatment of kidney disease. The drug is administered as a single capsule twice daily to patients already on background standard of care treatment.

DMX-200 blocks the chemokine receptor 2 (CCR2) pathway, which stops immune cells from moving to areas of the body such as in the kidney where they cause abnormal scarring. Dimerix identified that the CCR2 receptor and the angiotensin II receptor type 1 (AT1R) are G Protein Coupled-Receptors (GPCRs). GPCRs in general are signalling molecules that pass the signals onto intracellular 'G proteins'. They are present in just about every organ system, and as a result have been considered as targets for a wide range of disease areas including heart disease, cancer, diabetes, inflammation, and CNS disorders. AT1R forms a GPCR heteromer with CCR2, therefore demonstrates a synergistic benefit when blocking both receptors at the same time. This is highly relevant in the kidney.

Dimerix's Phase 3 trial

Dimerix only needs a single Phase 3 study of DMX-200 to gain approval in both the US and EU.

Dimerix is in a Phase 3 study with DMX-200 for FSGS. Dimerix only needs a single Phase 3 study of DMX-200 (ACTION3) to gain potential approval in both the US and the EU. These results could also enable the company to enter other markets including China and the Middle Eastern markets, in that the data could be re-used in such a submission without a further clinical trial needing to be conducted. ACTION3 is currently being conducted at over 70 clinical sites in 11 countries including Australia, New Zealand, Taiwan, Hong Kong, France, Denmark, the UK, Spain, Argentina, Brazil, and the US. New clinical sites have also been planned for China, Malaysia, Italy, Germany, Portugal, and Mexico to further enhance the recruitment process.

There are 2 endpoints to ACTION3, both of which measure creatinine, a chemical waste produce of creatine and is removed from the body by kidneys.

1. The **uPCR (urinary Protein to Creatinine Ratio)**, which essentially measures protein that has leaked into the urine relative to creatinine.
2. **eGFR (estimated Glomerular Filtration Rate)**, the flow rate of filtered fluid through the kidney in millilitres per minute.

The last 12 months

The FY24 financial year was a spectacular year for the company.

The FY24 financial year was a spectacular year for the company, during which it laid some crucial foundations for DMX-200's future commercialisation.

Two licensing deals worth up to A$350m + royalties

In October 2023, the company signed a licensing deal with Advanz Pharma, a UK specialty pharma company. Advanz has the right to commercialise DMX-200 for FSGS in the UK, EU, Switzerland, Canada and New Zealand. In return Dimerix received A$10.8m in an upfront payment, followed by up to 132m euros in milestone payments, plus tiered royalties on sales. DXB retained the rights to DMX-200 in all other territories and indications. Although DXB would continue to fund an execute the ACTION3 Phase 3 study, Advanz assumed responsibility for submission and maintenance of the necessary regulatory filings in the applicable territories, along with all sales and marketing activities.

In May 2024, Dimerix signed another licensing agreement, partnering with Taiba – a privately owned Middle Eastern therapeutics company. Taiba obtained exclusive rights to register and commercialise DMX-200 for the treatment of FSGS in the United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq.

These 7 markets have a population of over 100m between them, a high presence of Chronic Kidney Disease (CKD) generally[1] as well as government-funded healthcare. Dimerix will receive up to A$120.5m in upfront and milestone payments, as well as tiered royalties starting at 30% on net sales and decreasing by 5% every 5 years down to 20% on net sales. The upfront payment was US$350,000 (or ~A$0.5m) with the balance to be received on certain development and sales milestones being achieved. As with the Advanz deal, Taiba assumed responsibility for sales, marketing and making the regulatory submissions in the licensed territories. With the Advanz deal, this takes the total milestone payments Dimerix is eligible for up to A$340m[2].

The total milestone payments Dimerix is eligible for under the Advanz and Taiba deals is up to A$340m.

Phase III results: So far, so good

In March, Dimerix announced the first interim analysis of the ACTION3 trial. The results showed DMX-200 was performing, and the all clear was given for the trial to proceed to the next stage by the Independent Data Monitoring Committee. The company has proceeded to Part 2 of the study which will enrol ~144 patients enrolled for 35 weeks' treatment and will include children up to 12 years old as well as adults (Figure 1).

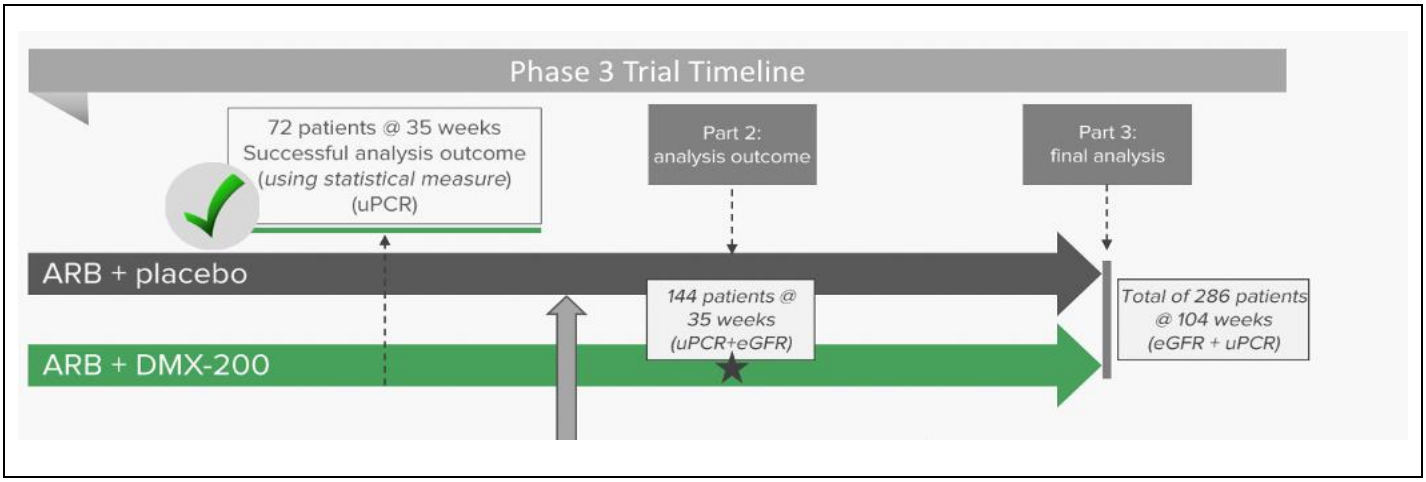
[1] https://www.theisn.org/wp-content/uploads/media/gkha/Middle%20East/2.%20GKHA%202019%20regional%20slides_Middle%20East%20v1.2.pdf
[2] This figure excludes the initial A$10m milestone payment Dimerix received upon execution of the deal.

The next 12 months

Investors should expect results in the middle of CY25.

The key milestone investors have to look forward to is the outcome of Part 2 of the trial. Investors should expect results in the middle of CY25. Specifically, around 35 weeks after the final patient is enrolled in the trial, a step anticipated in the current quarter, considering it had over 100 patients enrolled as of late-May[3]. Dimerix has indicated that it will announce when this has occurred, and investors will be able to pencil in an approximate date (Figure 1). The company does not plan on announcing interim results prior to that, although there could be news flow prior to that.

Figure 1: ACTION3 Phase 3 clinical trial – next steps



Source: Company, Pitt Street Research

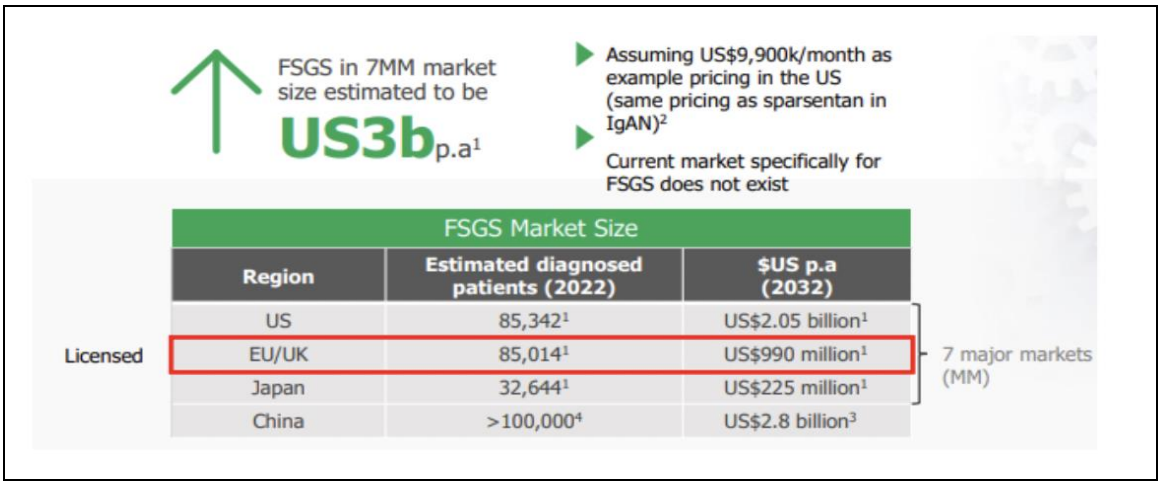
What else is there for shareholders to look forward to?

The company is seeking licensing deals for China and the USA, even more lucrative markets for DXB.

Two key markets remain unlicensed - China and the USA. The company has indicated it will seek licensing deals for all territories with a focus on these jurisdictions, and it would not be unreasonable to assume that the deal could be even more revenue-generating than the Advanz deal, considering the size of the US market. The EU/UK markets have been estimated by the company to be US$990m, but the US $2.05bn and China $2.8bn (Figure 2)[4]. Although data from China is difficult to come by, it is estimated that 80,000 of the 220,000 diagnosed FSGS patients globally are in the US.

[3] Announced on the company's investor call on May 27, 2024.
[4] Data from ResearchAndMarkets

Figure 2: ACTION3 Phase 3 clinical trial – next steps



Source: Company

If the ACTION3 trial is successful, subject to FDA (or other regulatory agency) approval, it is plausible that DMX-200 could be commercialised for FSGS in 2-3 years.

It is crucial to note that even though there are other drugs in development, none of them are in Phase 3 and none are treating the same pathway as DMX-200. Some of them include Inaxaplin (which is being developed by Vertex Pharmaceuticals for a sub-set of a specific type of genetic FSGS), VAR200 (from ZyVersa Therapeutics) and Atrasentan (owned by Chinook Therapeutics until its August 2023 acquisition by Novartis for US$3.2bn). The latter drug's acquisition indicates that an acquisition prior to commercialisation would not be surprising, but any such suitor would need to pay a significant premium for Dimerix to entertain such an offer.

If the ACTION3 trial is successful, subject to FDA (or other regulatory agency) approval, it is plausible that DMX-200 could be commercialised for FSGS in 2-3 years. This assumes it would take approximately 6 months from the results of the trial for the company to prepare a regulatory submission, with the FDA taking another ~8 months to consider the case put forward. The recent case studies of Neuren (ASX:NEU) and Telix (ASX:TLX) depict that a company can quickly generate substantial sales - as well as shareholder value - if a drug has proven efficacy and there are no alternatives out there.

Valuation of $0.84-$0.107 per share reiterated

We value the company at A$0.84 per share in our base case and A$1.07 per share in our bull case.

We reiterate our previous valuation of Dimerix, last updated in March 2024 following the signature of the Taiba deal. Our value of the company is A$0.84 per share in our base case and A$1.07 per share in our bull case, or $461.8m in our base case and $584.9m in our bull case (Figure 3). This assumed DXB-200 was successfully commercialised for FSGS in Europe, the USA and the 7 Middle Eastern markets, under a licensing model with tiered royalties on net sales, with all promised milestone payments received prior to commercialisation and within months of commercialisation. The key inputs are in Figure 4 and are explained these inputs (and all others) in further detail in our previous reports on Dimerix.

Figure 3: DXB's DCF calculation

Valuation (A$m)	Base Case	Bull case
Present Value of FCF	202.6	181.5
Present Value of Terminal Value	252.6	268.7
Enterprise Value (A$ m)	**455.3**	**450.2**
Net (debt) cash	(6.6)	(6.6)
Minority Interest	-	-
Other Investments	-	-
Equity value (A$ m)	**461.8**	**456.8**
Shares outstanding	547.2	547.2
Implied price (A$ cents)	**0.84**	**1.07**
Current price (A$ cents)	0.45	0.45
Upside (%)	88.7%	141.6%

Estimates: Pitt Street Research

Figure 4: Assumptions underpinning our valuation

DCF Assumptions	Base Case	Bull Case
Launch (US)	FY26	FY26
Launch (EU/UK)	FY28	FY28
Launch (Middle East)	FY28	FY28
Estimated market size (patient numbers)	213,618	213,618
Market penetration (All markets)	6%	8%
Realised price (US$k)	119	119
Total milestone payments (A$m)	219	219
R&D costs until approval (A$m)	72	72
Peak sales (A$m)	2,940	3,719
Peak royalty revenue (A$m)	441	558
Period of pre-terminal cash flows (years)	7	7
Discount rate	12.2%	12.2%
Royalty rate	15.0%	15.0%
Tax rate	25.0%	25.0%
AUD/USD	1.50	1.50
Net margin	13%	14%

Source: Company

Even prior to the forthcoming milestones, we still think Dimerix is undervalued compared to companies in Phase 3, especially considering Dimerix has interim data. And this does not account for future indications DMX-200 could target, although we do not envision the company pursuing any further indications until it is able to conclude the current trial successfully.

Catalysts for DXB's re-rating

- The read-out of the results of Stage II of the ACTION3 Study. This will be some time in the middle of CY25, specifically 35 weeks after the 144th patient had been recruited.
- Future licensing deals for unlicensed jurisdictions, particularly the USA and China.
- Potential M&A interest in the company or in its competitors.

Key risks facing Dimerix

Risks specific to DXB - We see the following major risks for DXB as a company and as a listed stock:

- **Timing risk.** There is the risk that the company's products may take longer than expected to move through the clinic, especially with clear time frames that are imminent – in particular, clinical data in mid-CY25.
- **Regulatory risk**. There is the risk that regulators may decline to approve DXB products. Even if the study is successful, regulators may decline for other reasons such as potential negative interaction with other compounds in a patients' body.
- **Commercial risk**. There is the risk that DXB may fail to find commercial partners for its products in China and the USA, which would reduce the potential for the creation of shareholder value. There is also the risk for commercial partnerships to fall apart.
- **Funding risk**. There is the risk of future capital raisings proving dilutive to existing shareholders.
- **Key personnel risk**. There is the risk that the company may lose key personnel and be unable to replace them and/or their contribution to the business.

Risks related to pre-revenue Life Science companies in general.

The stocks of biotechnology and medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character. Since most biotechnology and medical device companies listed on stocks exchanges in Australia and around the world fit this description, the 'term' speculative can reasonably be applied to the entire sector. The fact that the intellectual property base of most biotechnology and medical device lies in science not generally regarded as accessible to the layman adds further to the riskiness with which the sector ought to be regarded. Caveat emptor. Investors are advised to be cognisant of the abovementioned specific and general risks before buying any the stock of any biotechnology and medical device stock mentioned in this report, including Dimerix.

Appendix I - Analyst certification

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

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