A pivotal 2025 lies ahead

Share Price: A$0.32

Dimerix (ASX: DXB) is in the middle of a Phase III clinical trial for its DMX-200 drug to market for Focal Segmental Glomerulosclerosis (FSGS).

ASX: DXB

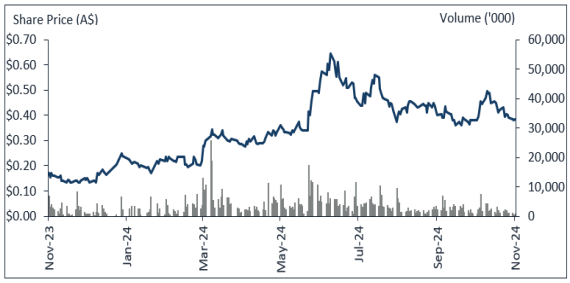
Sector: Healthcare

27 November 2024

Market cap. (A$m)	175.1
# Shares outstanding (m)	547.2
# Share fully diluted (m)	672.6
Market cap full. dil. (A$m)	215.2
Free float	72%
12-months high/low (A$)	0.645 / 0.135
Avg. daily volume ('1000)	3,606.7
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

The company is one of a kind

Dimerix is the only company with a drug in Phase III specifically for this condition and one of the few ASX stocks in a Phase III trial with results anticipated around mid-CY25. Moreover, it is fighting a condition that can be fatal and for which there are no approved drugs that directly address the condition, rather than just relieve the symptoms. It has licensing deals for several jurisdictions in the EMEA region as well as Australia, New Zealand and Canada that could deliver up to A$350m in milestone payments plus royalty payments on sales, and this does not even include the US and China. And results to date have been unanimously positive, including interim results of the current clinical trial.

Advancing ahead

Since our last report on Dimerix in August 2024, the company has taken several steps forward in its clinical trial. These include opening new sites for the trial, continuing to recruit patients and advancing in collaborations that could help recruit patients and also advance the company's efforts towards obtaining regulatory approval (by conceiving alternative or supplementary endpoints for the study). DXB has also continued to expand its Scientific Advisory Board. And finally, it has enrolled the first patient in the open label extension part of the study that will continue to monitor patients that have completed the 2 year Phase III study.

The next catalyst for the company will be the release of results from current stage of the study, which are due 35 weeks after the last patient is enrolled – an event expected around mid-CY25. This event means, if the data is compelling, it is possible the company could apply for accelerated regulatory approval. We think investors should also look out for licensing deals for the US and China, which will be far larger and lucrative markets than any the company has licensed out to date.

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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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Dimerix's ACTION3 trial recapped

Dimerix is advancing DMX-200, its proprietary oral anti-inflammatory drug, in a pivotal clinical trial against FSGS.

Dimerix is advancing DMX-200, its proprietary oral anti-inflammatory drug, in a pivotal clinical trial against FSGS (Focal Segmental Glomerulosclerosis). Results are due around mid-CY25. We will first overview the trial and recap how the company reached this point.

There are two basis endpoints for the Phase 3 study, uPCR and eGFR:

- **uPCR is urinary Protein to Creatinine Ratio**, the standard way of measuring proteinuria. uPCR is kidney protein concentration in milligrams in a patient's urine, divided by the creatinine concentration in grams. Creatinine is a breakdown product of creatine phosphate from muscle which is routinely excreted through the kidneys and provides a good reference to how hydrated a patient is.
- **eGFR is estimated Glomerular Filtration Rate**, the flow rate of filtered fluid through the kidney in millilitres per minute. Specifically, it is millilitres per minute per 1.73m^2, the latter figure being the average body surface area for an adult. GFR can't be measured directly so is estimated (the 'e' in eGFR) by testing for the blood levels of creatinine, which, we noted above, is normally cleared from the blood by the kidneys. When kidney function is declining the level of creatinine in the blood goes up. A normal GFR in a young adult is greater than 90 mL/min/1.73m^2. For ACTION3 the primary endpoint is the 'eGFR slope', meaning the level of decline in a year.

Dimerix's ACTION3 pivotal study[1] was designed to run in three parts:

- In the first part, around 72 patients were be recruited and treated as per the 240 mg/day dose of DMX-200 from Phase 2, on the background of any ARB. An interim analysis performed after 35 weeks of treatment for these 72 patients will determine if the study should continue, with proteinuria being tracked via the Protein to Creatinine Ratio (PCR).

  In March 2024, 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 and is now in Part 2.

Results for the trial are due in mid-CY25.

- In Part 2, another 72 patients are being recruited, to give a total of 144 patients (Part 1 and Part 2). Across those 144 patients from Parts 1 and 2 at week 35, an analysis of both PCR and estimated Glomerular Filtration Rate (eGFR) is generated. If compelling, it is this analysis that could support accelerated (or conditional) approval and early marketing in some territories.
- In the final part, a further 142 patients are recruited to give 286 patients in total (Part 1 + Part 2 + Part 3), with the final analysis at 104 weeks of treatment. At this final analysis the primary endpoint will be estimated Glomerular Filtration Rate (eGFR), to support full approval.
- An Open Label Extension Study (OLE) has also opened for those patients completing the full ACTION3 Phase III study, providing further treatment data for up to a further 2 years. The first patients completing the ACTION3 2 years study have now they entered into the voluntary extension study.

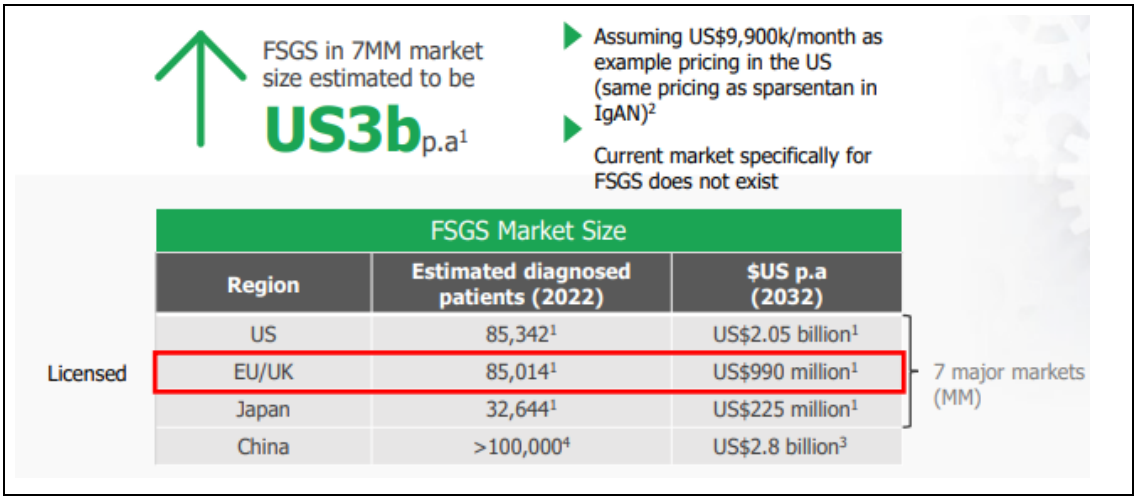
[1] See NCT05183646 at clinicaltrials.gov.

Why should ACTION3 be watched closely?

There are five reasons. Namely:

- **There are no existing drugs for FSGS**. Any other drugs are at an earlier stage and there's precedent for other drugs to have failed – including DMX-200's main competitor, Filspari in mid-2023, which missed the primary endpoint by a wide margin.
- As per 2021 guidance, **Dimerix only needs a single Phase 3 study of DMX-200 to gain approval in both the US and the EU**, and potentially in China too.
- **Mere success of the trial will be a major catalyst for the creation of shareholder value**, let alone when DXB-200 receives regulatory approval. There is precedent for companies with successful Phase 3 results to be re-rated, even when they have experienced substantial growth up to that point – including Telix and Neuren.
- **Success in the trial will likely lead to milestone payments in its existing commercial deals** with Advanz Pharma and Taliba Middle East, even prior to regulatory approval which would lead to further payments. Furthermore, it is possible DXB could license out China and the USA and any potential deal could include milestone payments at the point the trial is read out.
- **The market opportunity that awaits**. FSGS is a major market with approximately 220,000 diagnosed sufferers worldwide, about 80,000 of which are in the US. There are ~5,400 new cases in the US alone each year. Data from ResearchAndMarkets estimates that the seven biggest markets are worth US$3bn (Figure 1). $2bn of this is from the US, with $990m from the EU and UK and US$225m in Japan. It has also been estimated that the market in China is worth another US$2.8bn. This is assuming US pricing of US$9,900 per month, which is what sparsentan costs.

Figure 1: The FSGS market



Source: Company

Dimerix has been laying the foundations

In recent months, Dimerix has been progressing the enrolment of patients. It is planned that there will be approximately 170 sites across the globe, 22 of which will be specialist paediatric kidney centres. As of the end of October 2024, 129 out of the Part 2 target population of 144 were enrolled and the timing of the interim analysis is on track. While the company has not been giving a daily running commentary on the progress on the trial, some notable steps since our last note in August 2024 have included:

- Opening further sites including the first paediatric-only site in Mexico;
- Advancing the OLE study with patients who have successfully completed ACTION3, to evaluate the safety and efficacy of DMX-200 over a longer-time frame compared to ACTION3 (i.e. 2 years). The first patient entered this study in September 2024.
- Engaging in external collaborations to identify further patients for potential recruitment, and to identify alternative endpoints as a basis for approval including:
    - i) PARASOL (Proteinuria and GFR as Clinical Trial Endpoints in Focal Segmental Glomerulosclerosis) Scientific Workshops held in June and October 2024. The aim has been to define the quantitative relationships between changes in biomarkers such as proteinuria and eGFR and long-term outcomes for FSGS patients and further support alternative proteinuria-based endpoints as a basis to provide both accelerated and traditional marketing approval in FSGS kidney disease.
    - ii) The University of Michigan's NEPTUNE Match (Nephrotic Syndrome Study Network of Rare Kidney Diseases). In the immediate term, it will help identify patients with FSGS across the USA who meet the inclusion/exclusion criteria and potentially bring them into the trial if they wish to participate. Looking forward, there will be the opportunity for DXB and NAPTUNE to jointly address key research questions using the NAPTUNE knowledge network of patients with FSGS;
    - iii) The UK's National Registry of Rare Kidney Diseases (RaDaR) to prospectively identify suitable FSGS patients for ACTION3. RaDaR is the largest, rare kidney disease registry in the world.
- Expanding its Medical Advisory Board by appointing:

i) Dr Howard Trachtman. Dr Trachtman has extensive experience in clinical research, co-authoring over 195 reviewed articles in the kidney disease space in the past 15 years;

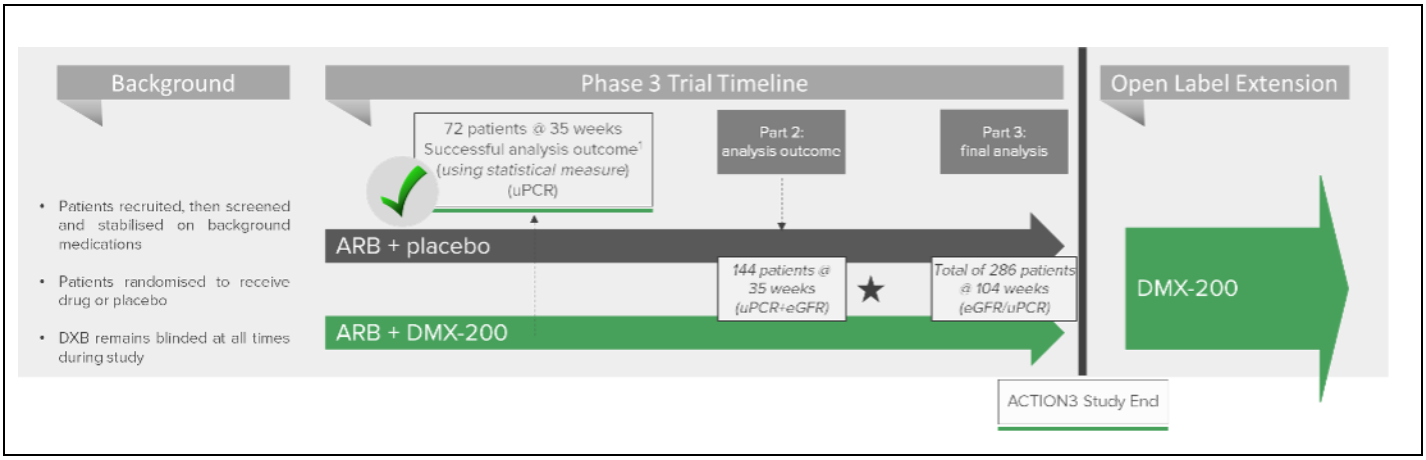
ii) Dr Laura Mariani, an expert nephrologist and Co-Chair of the PARASOL Working Group

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

What's next?

The key event for the company will be the read-out of Part 2. If successful, it the company may apply to the FDA for accelerated approval. Although this is not until mid-CY25 - specifically, 35 weeks after the last of the 144 patients has entered the study (Figure 2).

Figure 2: ACTION3 Phase 3 clinical trial – next steps



Source: Company, Pitt Street Research

Another potential key event could be licensing deals for the US and/or China which are bigger markets than all those that have been licensed out to date, both not only possessing populations larger but also markets potentially worth over US$2bn based on market penetration and potential pricing.

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. They also demonstrate that even prior to regulatory approval, successful results alone can lead to a re-rate. Telix's share price increased over 50% between November 2022 and May 2023 when its ZIRCON Phase III results were released. Neuren roughly doubled in the week after its Phase III results in December 2021.

The company has a strong cash position. It was $19.2m as at 30 September 2024 and has been boosted with a $7.9m FY24 R&D tax incentive rebate. There are a further $6.5m worth of options[2] due to be expired which provides anticipated cash conversion of $33.6m.

[2] 42,446,923 DXB options exercisable at 15.4c per share, expiring 30 June 2025

Valuation of $0.84-$1.07 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.

Our current valuation of Dimerix 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 is predicated on the assumption that DXB-200 is 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 and that this occurs in the next 3 years. 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)	0.32	0.32
Upside (%)	162.5%	234.4%

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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