A second licensing deal

Share Price: A$0.40

ASX: DXB

Sector: Healthcare

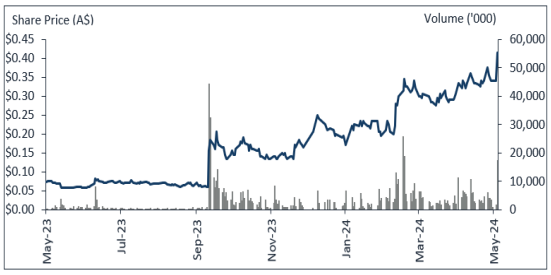
30 May 2024

ASX-listed kidney disease drug developer Dimerix (ASX: DXB) is well positioned to bring its DMX-200 drug to market for Focal Segmental Glomerulosclerosis (FSGS). The drug is in a Phase 3 trial which has shown solid interim results. The company secured its inaugural license deal in October 2023 with Advanz Pharma, and just secured a second deal with Taiba Middle East.

Market cap. (A$m)	218.9
# Shares outstanding (m)	547.2
# Share fully diluted (m)	672.6
Market cap full. dil. (A$m)	269.0
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

Another licensing deal

Taiba has gained exclusive rights to register and commercialise DMX-200 for the treatment of FSGS in 7 Middle Eastern markets: The United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq. Dimerix will receive up to ~A$120.5m in upfront and milestone payments in addition to tiered royalties, starting at 30% on net sales. The deal will also provide for Taiba to be responsible for submission and maintenance of the regulatory dossier in all of these territories, as well as all sales and costs of marketing activities. Collectively, these markets have a population of over 100m, and healthcare is free and government-sponsored. Companies can set the prices of orphan drugs according to either their price in the country of origin or in the US or Europe.

Strong prospects are ahead

DXB shareholders have much to look forward to in the months ahead. The company is in the middle of a Phase 3 trial that has released favourable interim data – few other ASX biotechs can boast of being in Phase 3. And there is potential for further licensing deals – in particular, the lucrative US and China markets. The next set of data from the trial is due in mid-CY25, and there is potential for DXB to apply for regulatory approval in the US thereafter. We see these as the key catalysts for the creation of shareholder value in the near-term, although the adding of the Middle East to the company's market will help the company when it gets to the point of commercialisation.

Updated range of A$0.84-1.07 per share

We previously valued of Dimerix at A$0.64 per share in a base case scenario and A$0.84 per share in an optimistic case scenario. We update this to A$0.84 and A$1.07 per share accounting for the market opportunity and utilising our independent assumptions on the market size and predictions of the company's market penetration. Please refer to pages 7-8 for more details on our valuation and the key risks to our thesis.

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Re-introduction to the Dimerix (ASX:DXB) story

Dimerix is a biotech company developing its proprietary product DMX-200 against kidney diseases. Focal Segmental Glomerulosclerosis (FSGS) is the indication where the company is most advanced, being amidst a Phase 3 trial with favourable interim results.

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.

FSGS is specific kidney disease that attacks the kidney's filtering units where the blood is cleaned (called the glomeruli). This causes irreversible scarring and can lead to permanent kidney damage as well as end-stage kidney failure, requiring dialysis or a replacement kidney. FSGS can affect both adults and children as young as 2 years old, and the average time from a diagnosis of the disease to the onset of complete kidney failure is only five years. Approximately 60% of those who receive a kidney transplant risk will get re-occurring FSGS in the transplanted kidney. 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 clinical endeavours with DXB-200

After a successful Phase 2 study in FSGS (and multiple other studies in other indications including Diabetic Kidney Disease), Dimerix entered a Phase 3 study. Dimerix only needs a single Phase 3 study of DMX-200 (ACTION3) to gain 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.

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.

The first endpoint is improvement in the **uPCR (urinary Protein to Creatinine Ratio)**, which essentially measures protein that has leaked into the urine

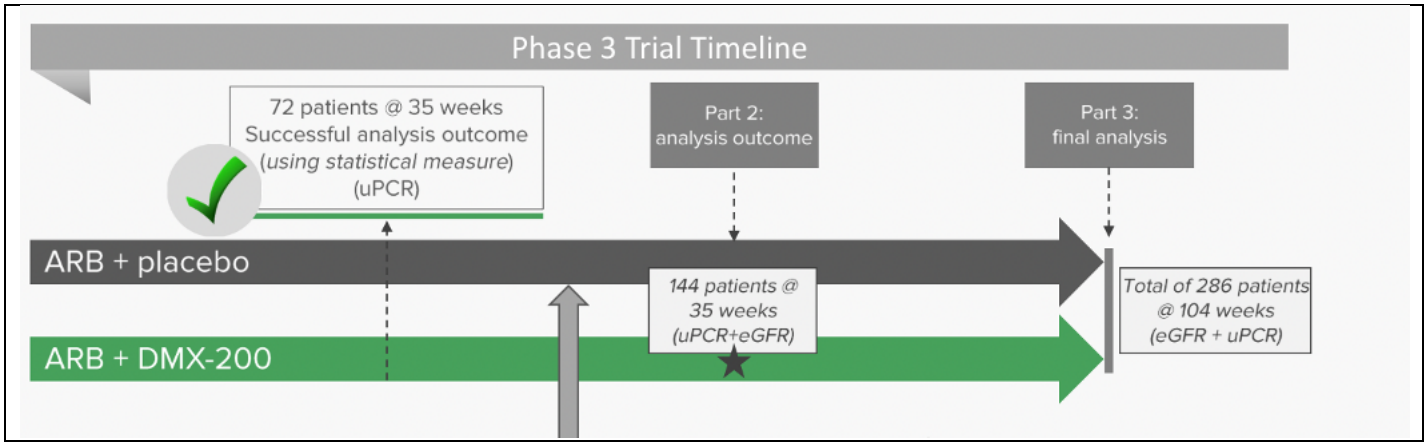
relative to creatinine. This can represent an important early indicator of deteriorating kidney function, given that proteins in the urine are typically at lower levels because healthy kidneys ensure they remain in the body and do not exit the body through urination.

The second is **eGFR (estimated Glomerular Filtration Rate)**, the flow rate of filtered fluid through the kidney in millilitres per minute. Specifically, the rate 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 has to be estimated (the 'e' in eGFR) by testing for the blood levels of creatinine. 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. A lower level indicates that the kidneys are not working properly and can indicate this earlier than physical symptoms such as painful or frequent urination.

In March, Dimerix announced the first interim analysis to gauge whether the drug was showing efficacy and whether or not it was on track to meet its objective if completed. These results were positive. The analysis, measuring proteinuria from the trial's first 72 patients, showed DMX-200 was performing better than the placebo in reducing proteinuria. This analysis was a pivotal point as poor results could have meant the trial would be discontinued. Not only could the trial continue but it allowed Dimerix and its stakeholders to be optimistic that a statistically significant and clinically meaningful result was possible. The Independent Data Monitoring Committee formally recommended the trial continued in light of the results, and also because there were no safety concerns.

The positive results from the Phase 3 Part 1 trial paved the way to move ahead with Part 2 of the study. Part 2 will enrol ~144 patients enrolled for 35 weeks' treatment and will include children up to 12 years old as well as adults (Figure 1).

Figure 1: ACTION3 Phase 3 clinical trial – next steps



Source: Company, Pitt Street Research

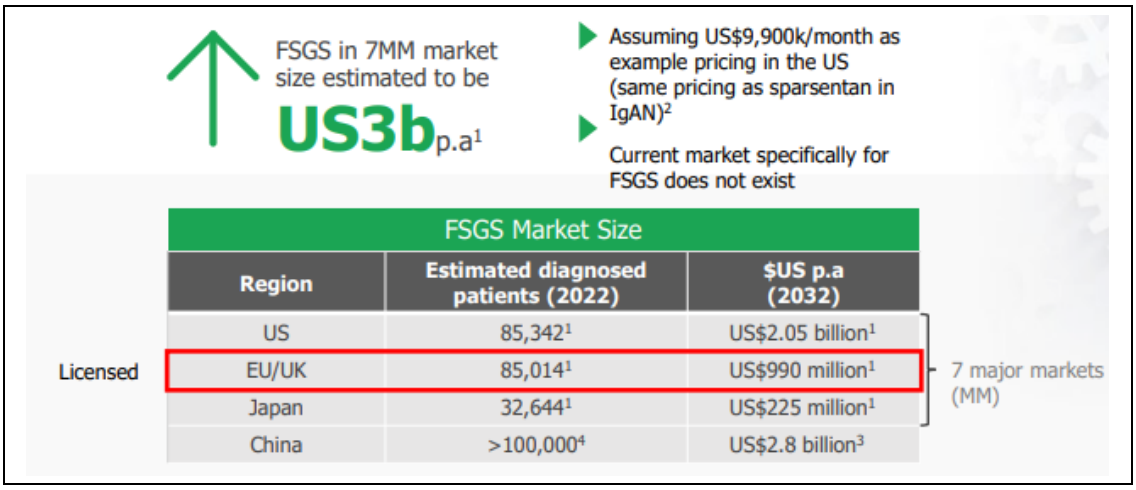
Although Dimerix doesn't plan on announcing further interim results prior to mid-CY25, the company will announce when it has enrolled all patients – something which is anticipate in the September quarter of CY24. This would provide a closer estimate as to when exactly these results would be expected. On the investor call of 27 May, to discuss the licensing deal, DXB indicated that it has enrolled roughly 100 patients so far. Earlier in May 2024, Dimerix was permitted by UK regulators to include children from ages 12-17 into the

ACTION3 study in the UK, in approving the company's Paediatric Investigation Plan (PIP) for the UK. The company previously had plans for paediatric treatment approved in Europe and the USA.

The market opportunity

After a successful Phase 2 study in FSGS (and multiple other studies in other indications including Diabetic Kidney Disease), Dimerix entered a Phase 2 study. Dimerix only needs a single Phase 3 study of DMX-200 (ACTION3) to gain approval in both the US and the EU/UK. These results could also enable the company to enter other markets including China and the Middle Eastern markets, although the US and the EU are the most important markets (Figure 2).

Figure 2: The FSGS market



Source: Company

Subject to FDA (or other regulatory agency) approval, it is plausible that DMX-200 could be commercialised for FSGS in 2-3 years. The company has laid the foundations, signing a partnership with Advanz Pharma for commercialisation in certain territories. In return for royalties on sales and milestone payments of up to $230m, Advanz has an exclusive license to commercialise DMX-200 in the European Economic Area, Switzerland, the UK, Australia, New Zealand, and Canada. The deal with Taiba for the Middle Eastern markets, to which we will come to shortly, is another boost. But DXB has thus far not secured a licensing deal for the US, nor for China. We expect this will happen and it will be a catalyst for the creation of shareholder value, given the opportunity in these markets.

We think it is also plausible that Dimerix could be acquired prior to commercialisation, or shortly thereafter. There have been several notable transactions in the kidney space including Novartis buying Chinook Therapeutics in mid-2023 for US$3.2bn, and CSL (ASX:CSL) buying Vifor Pharma for US$11.7bn.

The Middle East opportunity facing Dimerix

Dimerix has secured its second licensing agreement, partnering with Taiba – a privately owned Middle Eastern company that provides therapeutics for rare diseases, and was the first company to do so. Taiba has 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 and a high presence of Chronic Kidney Disease (CKD) generally (Figure 3). Healthcare in these markets is free and government funded, and DXB can set the pricing exactly the same as is in the US, provided the drug has been approved by the FDA. We have used these assumptions in our updated valuation of the company.

Figure 3: The Population and CKD Prevalence in Taiba's Middle Eastern markets

Country	Total Population (m)	CKD Prevelance
UAE	9.44	7.67%
Saudi Arabia	36.41	7.20%
Oman	4.58	7.42%
Kuwait	4.27	8.39%
Qatar	2.70	7.13%
Bahrain	1.47	9.28%
Iraq	44.50	7.38%
TOTAL	**103.37**	**7.78%**

Source: Pitt Street Research, World Bank and International Society of Nephrology Data[1]

Dimerix is eligible $120.5m in milestone payments, plus royalties on sales

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 will be US$350,000 (or ~A$0.5m) with the balance to be received on certain development and sales milestones being achieved. The exact milestones have been kept commercial in confidence by both parties to the agreement, although we do not think it would be unreasonable to assume that the release of the next set of Phase 3 data, and FDA approval would be among those milestones. With the Advanz deal, this takes the total milestone payments Dimerix is eligible for to A$340m[2].

Taiba has assumed responsibility for sales and costs of marketing activities as well as the submission and maintenance of the regulatory dossier in its licensed territories. Taiba has the right to negotiate a license to develop and commercialise DMX-200 in any additional indications in the licensed territories that Dimerix may achieve for DMX-200.

[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 deal is positive for Dimerix for several reasons including that it:

- Validates the optimism the company has had in DMX-200 and the results it has achieved,
- Will provide a further financial buffer to fund further clinical efforts and thus reduce the likelihood of further dilutive capital raisings,
- Opens up a lucrative market of over 100m people where healthcare is government-funded, ensuring that would-be patients won't hesitate to take up the treatment purely over cost concerns,
- Provides hope that a licensing deal for the US market can be reached.

Shareholders in Dimerix have every reason to be optimistic in the company's future and its hopes for commercialising DMX-200.

Our valuation of Dimerix

Our most recent equity value is $346.7m in our base case and $456.8m in our bull case, equating to $0.64 per share in our base case and $0.84 in our bull case following the company's capital raising in March 2024. This assumed DXB-200 was successfully commercialised for FSGS in Europe and the USA, 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 were:

- Commercialisation in FY26 in the USA and FY28 in Europe,
- A market penetration of 6% in our base case and 8% in our bull case,
- A 15% royalty rate,
- A price of US$118,800 per treatment
- An exchange rate of US$1=A$1.50
- A corporate tax rate of 25%.

We explained these inputs (and all others) in further detail in our initiation report.

How much the Middle Eastern market is worth?

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

In light of the Taiba deal, we have updated our valuation to account for the Middle Eastern market (Figure 4) and now value the company at 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. The Middle East has increased our valuation by A$0.20 per share (or $107.5m) in our base case and A$0.23 in our bull case (or $128.1m).

We assume sales begin in FY28 and that the company ultimately penetrates 6% of the Middle Eastern market, or 8% in our bull case – just as we estimated for the US and European markets. We assume gradual ramp up over 5 years and that DXB-200 attracts the same price as in the USA, which drugs in the Middle East previously approved by the FDA can. We use the royalty rates specified in the deal between Taiba and Dimerix, and conservatively assume a market of 1% of total persons in the Middle East suffering from Chronic Kidney Disease.

Using these inputs, we forecast that sales could reach $535m by FY33 in that region alone. This remains a fraction of the $2.4bn in sales we previously assumed the company could reach in the US and Europe combined by FY33.

Figure 4: 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)	0.40	0.40
Upside (%)	111.0%	167.2%

Estimates: Pitt Street Research

We reiterate a couple of points we made in our initiation report. First, Dimerix is still behind other companies that are at Phase 3. Opthea (ASX:OPT) is just over A$400m as one example and Opthea has not reported any interim data. Second, we have only modelled for the market opportunity for FSGS. If DXB can make progress against other indications (such as Diabetic Kidney Disease), this could lead to further shareholder value being created. Our key assumptions are as follows

Catalysts for DXB's re-rating

We see the key clinical catalyst as being the next set of successful interim data being read out. The company has told investors this would be 35 weeks after the 144th patient had been recruited, and based on current recruitment timelines is expected around mid-CY25. Investors will have fairer idea of when this will happen once that 144th patient is recruited, and this is expected in the September quarter of 2024.

We previously observed that future partnerships could be a key catalyst for the creation of shareholder value, and so it was with the Taiba for the Middle East. But there remains a deal to be done for the US and China markets, and these will be critical for the company, given the market opportunity.

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 by mid-March.

- Regulatory risk. There is the risk that regulators may decline to approve DXB products, even if DXB considers the data submitted to be adequate.

- Commercial risk. There is the risk that DXB may fail to find more commercial partners for its products. We note it has been de-risked for some jurisdictions, although 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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