PITT STREET RESEARCH

Dimerix

A Phase 3 company priced like a Phase 2 company

Share Price: $0.175

Dimerix is an ASX-listed clinical stage drug developer whose lead candidate is DMX-200 for kidney disease.

ASX: DXB

Sector: Healthcare

30 January 2024

Market Cap. (A$ m)	74.6
# shares outstanding (m)	426.1
# shares fully diluted (m)	591.1
Market Cap Ful. Dil. (A$ m)	103.4
Free Float	100%
52-week high/low (A$)	0.205 / 0.057
Avg. 12M daily volume ('1000)	1,325.2
Website	https://dimerix.com

Source: Company, Pitt Street Research

DMX-200: DXB's flagship asset

DMX-200 is the adjunct therapy of a chemokine receptor (CCR2) antagonist administered to patients already receiving an angiotensin II type I receptor (AT1R) blocker – the standard of care treatment for hypertension and kidney disease. DMX-200 is patent protected in several territories. It has completed two Phase 2 studies - one in FSGS (Focal Segmental Glomerulosclerosis) and one in diabetic kidney disease. No significant adverse safety effects were reported in either trial, both studies recorded encouraging data suggesting DMX-200 could provide meaningful clinical outcomes for patients with kidney disease.

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

Source: Refinitiv Eikon, Pitt Street Research

DMX-200 is close to commercialisation

The company is currently in a Phase 3 clinical trial against FSGS and is expecting its first initial analysis in mid-March 2024. Successful results would see the trial continue to later stages. There is potential to submit for conditional marketing approval in some territories in CY2025 subject to successful results at the second planned analysis. The company recently sealed a licensing deal with Advanz Pharma that could bring A$230m, plus royalties.

Valuation range of A$0.58-0.77 per share

Notwithstanding its positive development since 2018, we still think DXB isn't priced like the Phase 3 company that it is. We value DXB at A$0.58 per share in a base case scenario and A$0.77 per share in an optimistic (or bull) case using a DCF methodology. These equate to equity values of $246.3m and $326.3m respectively, a figure more in line with a Phase 3 biotech. We would point to the examples of Telix (ASX: TLX) and Neuren (ASX: NEU) as examples of how biotechs can re-rate upon completing Phase 3 and obtaining successful regulatory approval. We think Dimerix can achieve a similar feat if it can follow the same course. Please see p. 17 for an outline of our valuation rationale and p. 20 for the key risks.

Valuation metrics	
DCF fair valuation range (A$)	0.58-0.77
WACC	15.5%
Assumed terminal growth rate	2%

Source: Pitt Street Research

Analysts: Stuart Roberts, Nicholas Sundich

Tel: +61 (0)447 247 909

stuart.roberts@pittstreetresearch.com

nick.sundich@pittstreetresearch.com

Table of Contents

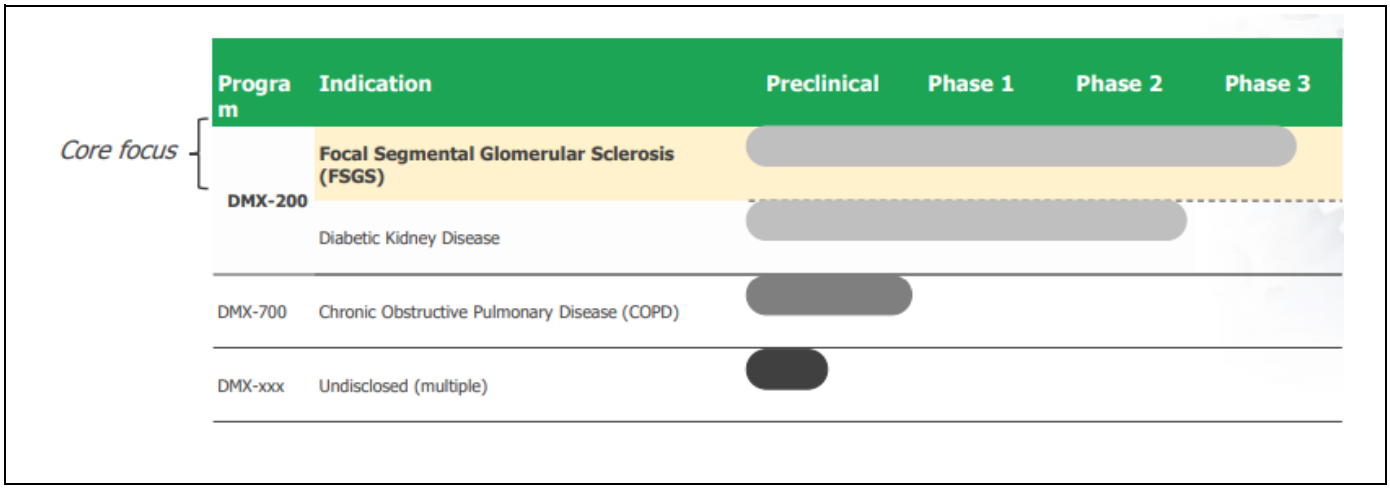
Introducing Dimerix (ASX: DXB)

Dimerix is a biotech company that is focused on fighting kidney diseases.

Dimerix is a biotech company focused on inflammatory diseases.

Dimerix's flagship asset, and the primary focus of this report, is DMX-200, a drug intended to fight kidney diseases. Although the company has a more comprehensive pipeline (Figure 1), DMX-200 is the closest to market, currently amidst a Phase 3 trial for a rare kidney disorder called focal segmental glomerulosclerosis, or 'FSGS' for short.

Figure 1: Dimerix's development pipeline



Source: Company

Dimerix's assets

DMX-200

DXB's lead drug candidate is DMX-200, the only drug candidate in Phase 3 development for FSGS.

DXB's lead drug candidate is DMX-200 and is the only drug candidate worldwide in Phase 3 development for FSGS (Focal Segmental Glomerulosclerosis). It is an oral anti-inflammatory drug called repagermanium, that is administered to patients with FSGS already taking the current standard of care of an angiotensin receptor blocker (ARB) such as Candesartan (Astra's Atacand), Irbesartan (Sanofi's Avapro) or Losartan (Merck's Cozaar).

FSGS is a rare type of kidney disease that attacks the kidney's filtering units where the blood is cleaned (called the glomeruli). This causes irreversible scarring and leading to permanent kidney damage and eventual end-stage kidney failure, requiring dialysis or a replacement. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old. 60% of those who receive a kidney transplant will get re-occurring FSGS in the transplanted kidney. It is a disease that can impact both adults and children and can be caused by a variety of conditions. There are currently no drugs specifically approved for FSGS anywhere in the world.

Dimerix has made significant progress with DMX-200. Drug development is a no easy feat, but it is fair to say Dimerix has made significant progress. Five years ago, in 2019, Dimerix was in the middle of two Phase 2 clinical studies – one for FSGS and the other for Diabetic Kidney Disease. The company has since entered Phase 3 for FSGS following successful results in Phase 2 for that indication.

This Phase 3 has been designated as the 'ACTION3' trial. It will enrol 286 patients with FSGS globally and is currently recruiting across 70 clinical sites in 11 countries. It is a multi-centre, randomised, double-blind, placebo-controlled study. Dimerix is expecting interim results (results from the first cohort) in March 2024 and may be able to apply for accelerated regulatory approval in some territories prior to the end of the study if the results of the second planned interim analysis are successful.

Close to commercialisation

Subject to FDA approval, it is plausible that DMX-200 could be commercialised against FSGS in 2-3 years.

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. Advanz has an exclusive license to commercialise DMX-200 in the European Economic Area, Switzerland, the UK, Australia, New Zealand, and Canada. This deal provides for up to A$230m in upfront and milestone payments, plus royalties on net sales of mid-teen to 20%. This includes $10.8m which was received in November 2023. DXB has retained all rights to DMX-200 in all other territories and all other indications and while DXB will continue to fund and execute the global ACTION3 Phase 3 study, Advanz will be responsible for submission and maintenance of the regulatory dossier in the licensed territories, as well as all sales and marketing activities.

Other assets

Dimerix's next most important asset is DMX-700, which it intends to study in Chronic Obstructive Pulmonary Disease (COPD), a life-threatening lung disease that is the third leading cause of death worldwide. Pre-clinical data in mouse models depicted solid results, with an 80% reduction in lung injury versus control. The company intends to take this drug into the clinic in 2024.

Dimerix's origins relate to its core technology, called **Receptor-Heteromer Investigation Technology (Receptor-HIT),** a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. This technology allows identification of pairs of different receptors that function in a joint manner (interact) when ligands, small molecule drugs, peptides, or antibodies, bind to them. This is what helped DXB identify DMX-200 in an internal drug development program. We think there is future potential for DXB to discover new opportunities with the asset.

Still priced like a Phase 2 stock 3 years on from its Phase 2 trials

Back in August 2019 Dimerix had a market capitalisation of barely $17m. Although the company has significantly re-rated the last few years – to the point where it is over three times that - we still think it is undervalued considering it is now a Phase 3 stock. Even the Biotech Bear market of 2022-23 has not stopped ASX-listed biotechs in the middle of Phase 3 from being valued over $100m, with examples outlined later in the report. Our valuation of Dimerix implies that there is upside that can be realised if the company successfully executes on its planned pathway to market. The first key to unlocking this value will be the successful passage of the current clinical stage.

Ten key reasons to look at Dimerix

DMX is one of the most advanced clinical stage biotech stocks on the ASX.

1. **DMX is one of the most advanced clinical stage biotech stocks on the ASX.** It is one of the few ASX companies undertaking a Phase 3 clinical trial, is expecting interim data in mid-March 2024, and may be eligible to apply for accelerated regulatory approval in some territories, dependant on the clinical data.
2. **The market opportunity for kidney disease is a large and lucrative opportunity**. This is particularly true with respect to FSGS, which Dimerix is targeting with DMX-200. The market for FSGS is estimated to become US$3bn by 2032 and has over 200,000 diagnosed patients in the major markets, which includes the US, EU, the UK, and Japan. China also presents a strong commercial opportunity for FSGS.
3. **DXB is targeting a condition with a compelling need**. Beyond the financial opportunity, there is a compelling need for FSGS treatments considering the damage the disease causes to the body and the lack of treatments currently on the market.
4. **Once commercialised, DMX-200 will have a market all to itself for some time**. There are currently no approved drugs for FSGS. Any treatments are off-label – with blood pressure medications such as the angiotensin receptor blockers (ARBs) being one such example. Although there are other drug candidates in development, none of them are in Phase 3 or close to Dimerix. Furthermore, as we outline in the Comparable Companies section below, these candidates are not all specifically targeted at FSGS, rather certain symptoms and genes that can cause or imply FSGS.

   On top of this, Dimerix has Orphan Drug Designation from both the FDA and EMA and the similar ILAP designation from the MHRA in the UK. So, the drug will have market exclusivity for seven years in the US and ten years in Europe, with the potential to extend this exclusivity after expanding the DMX-200 label to include the paediatric indication. In addition to the market exclusivity, DXB will receive other benefits including exemption from certain application fees, orphan drug pricing and potentially fast-tracked regulatory approval.
5. **Commercialisation is not far away.** In our view, DMX-200 could be commercialised within three years, obviously subject to successful clinical results. The company is expecting interim data from the current clinical trial in mid-March 2024. If a second interim analysis, which potentially could happen in 2025, comes back positive, there is potential for the company to apply for accelerated regulatory approval in some territories, given the compelling need for treatments against FSGS.
6. **Dimerix already has a commercial partner** in Advanz Pharma. The fact that Dimerix was able to obtain a partner while still being clinical stage speaks testament to the confidence Advanz has in this opportunity, the drug itself, and the market before it.

   Dimerix and Advanz have an exclusive license agreement that covers the European Economic Area, UK, Switzerland, Canada, Australia, and New Zealand once regulatory approval is obtained. This deal could deliver up to A$230m in upfront and milestone payments on top of tiered mid-teen-20% royalties on all sales. Just over two months after the deal was signed, the initial A$10m was received.
7. **Dimerix has other assets which could represent opportunities in the future.** Although the company is now focused on guiding DMX-200

through the clinic, it is important to note that it still has other assets. Most importantly, it still has Receptor-HIT, the proprietary platform that enabled it to develop DMX-200 in the first place. As the company continues its work on DMX-200, we still think there is potential for further commercial opportunities to be identified. The company has also made progress with DMX-700 in COPD.

8. **Dimerix has crucial research partnerships with Melbourne University, Monash University, the University of Western Australia, and the Harry Perkins Institute of Medical Research.** Dimerix began as a company with technology concepts they tested in laboratories at UWA and retains partnerships to this day that support the early-stage research.
9. **Dimerix has a quality leadership team** that has guided the company to where it is now, and we have every confidence that they can continue to steer the company in the right direction. Of note is CEO and Managing Director Dr Nina Webster who has served the company for over five years now and has been substantially responsible for the company's progress since that time.

Dimerix is undervalued, essentially priced as if it was still at Phase 2.

10. **Dimerix is undervalued, essentially priced as if it was still at Phase 2.** We have valued Dimerix at A$0.58 per share in a base case scenario and A$0.77 per share in a bull case scenario. These equate to equity values of $246.3m and $326.3m respectively.

    We see Dimerix re-rating off the back of successful clinical data, and continual advancement towards commercialisation, noting the examples of Telix (ASX: TLX) and Neuren (ASX: NEU) as to how biotechs can re-rate when they pass through this stage and go on to obtain clinical approval. Even as a company still amidst a Phase 3 trial, we would point to the examples of Opthea (ASX:OPT) and Paradigm (ASX: PAR) as how Phase 3 stocks can be truly priced.

Five years of progress for Dimerix

Dimerix (ASX: DXB) is an ASX-listed biotech company, focused on developing assets to fight kidney disease.

DXB was incorporated in 2004 and listed on the ASX in 2015 through the reverse takeover of Sun Biomedical. The company's original technology came out of work conducted by Dimerix using laboratories at the University of Western Australia. At the time the company listed, DMX-200 was in the pipeline, although it was not clear which specific kidney indication it would target. The umbrella focus of the company at the time was on its Receptor-HIT platform. As DMX-200 was identified as an opportunity and has progressed further and further, this has become the core focus of the company.

Dimerix has made significant progress on DMX-200 since our last report on the company in 2018.

As we have already noted, Dimerix has made significant progress on DMX-200 since our last report on the company in 2018[1]. Back then, it wasn't certain that FSGS would be the first indication to be developed, whether it would demonstrate efficacy and it was uncertain as to how long it would be before it was possible. We will recap some of our analysis from 2016-2018, although we will update it to reflect the progress the drug has made and the likelihood that it will be commercialised specifically against FSGS, whereas before it was unclear which indication could be first.

DMX-200

DMX-200 is an oral anti-inflammatory drug called repagermanium, co-administered with an ARB. In other words, is administered to patients already taking the current standard of care (the blood pressure medication known as an ARB) for the treatment of kidney disease. Patients ingest a 120 mg oral dose twice daily.

ARBs, such as irbesartan and losartan, are the current standard of care treatment for kidney diseases generally. Irbesartan itself was formerly a blockbuster drug for Sanofi and Bristol-Myers Squibb, known as Avapro when it was approved by the FDA in 1997 for the treatment of hypertension. It worked as an angiotensin II receptor blocker, being the second drug to be approved after Merck's losartan in 1995, but it was more efficient. Peak sales were US$2.7bn before the end of patent life in early 2012. Avapro gained FDA approval for the treatment of diabetic nephropathy (that is, kidney damage caused by high blood sugar levels) in 2002. In its clinical work to date Dimerix has added DMX-200 to irbesartan, but any approved ARB will do.

DMX-200 works as a blocker of angiotensin II receptor type 1 (AT1R) and chemokine receptor 2 (CCR2).

How does DMX-200 work? 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 scaring. 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, and this is highly relevant in kidney disease. After all, the AT1R is the target mechanism for the ARB, the current standard of care.

[1] See https://www.pittstreetresearch.com/dimerix.

The development history of DMX-200

The idea of DMX-200 (or more specifically, the idea of using repagermanium and an ARB together to fight kidney disease) came from work done by Dimerix using laboratories at the University of Western Australia prior to Dimerix's listing. The research identified that AT1R and CCR2, both GPCRs, form a GPCR heteromer that is highly relevant in kidney disease. ARBs work by binding AT1R, while repagermanium works by binding to CCR2.

On example of an ARB is Irbesartan, which was first FDA approved in 1995 works as angiotensin II receptor blocker, lowering blood pressure which damages kidneys over time. Propagermanium, a compound with a different crystal structure but closely related to DMX-200 (repagermanium), had been approved for the treatment of Hepatitis B in Japan, although this was back in 1994 and is no longer on market. The research done at the University of Western Australia indicated that an ARB and repagermanium was a match made in heaven.

Although the marriage was no certainty to be successful, DXB has made it happen. Initial animal data implied that the drug would need to be taken three-times daily, although the revised final formulation now allows for a single capsule twice daily. DXB secured a US-based GMP and FDA approved manufacturer capable of commercial scale manufacture, and commercial manufacturing was set up in 2018/2019. Earlier studies used a hand-filled prototype formulation.

Clinical data to date

Phase 2a from 2014 to 2017

Dimerix initiated a Phase 2a study in 2014 and completed it in 2017. This study[2], which dosed its first patient in September 2015[3] recruited patients with any Chronic Kidney Disease. Patients had to be on stable ARB (set as irbesartan in this study) at least three months before being dosed with DMX-200, such that the only effect then measured was DMX-200. 24 patients were available for evaluation in this study, which progressively raised the DMX-200 dose from 30 mg to 240 mg daily. Results from this Phase 2 became available in July 2017.

As we just noted, the indication was simply Chronic Kidney Disease (CKD), an umbrella term for many renal diseases encompassing various primary disorders and stages of progression. The crucial metric being sought was a reduction in **proteinuria** – elevated protein in the urine that can be indicative of certain kidney diseases (including FSGS) and/or damage.

We note that at the time of initiation, the company lacked Orphan Drug Designation for FSGS, but obtained it in the US December 2015, in Europe in 2018 and in the UK in 2021. Furthermore, the endpoints of the all-comer study would be exactly what it would need to measure in FSGS.

Dimerix achieved statistically and clinically significant results in Phase 2a.

This study achieved statistically and clinically significant results in the form of:

- The meeting of the primary endpoint of safety
- a 35% reduction in proteinuria on average.
- 25% of the patients recording a >50% reduction (being considered remission from the disease at the time).

[2] See ACTRN12614001132639 at anzctr.org.au.

[3] See the Sun Biomedical market release dated 14 September 2015 headlined '*Sun Biomedical initiates Phase II clinical trial of promising combination therapy for Chronic Kidney Disease*'. Sun Biomedical (ASX: SBN) was the vehicle that Dimerix used to list itself on ASX via a Reverse Takeover in 2015.

25% is worth boasting about because in kidney disease it's hard to move the needle and many of Dimerix's patients likely had very severe kidney disease, by virtue of the study being an all-comers study. Furthermore, many of them were on an average of nine medications other than repagermanium. There were also good results specifically in those patients with Diabetic Kidney Disease.

DMX-200's initial Phase 2a study was encouraging

After the headline results were analysed and released to the market, Dimerix conducted a sub-group analysis of the cohort, finding that five of the six patients with a >50% reduction in proteinuria had a primary diagnosis of Diabetic Kidney Disease. The sixth had IgA nephropathy. 10 of the 24 total patients in the study were DKD patients where the reduction in the ACR, that is, the albumin to creatinine ratio commonly used to measure changes in urinary protein excretion, was 36%.

This gave Dimerix confidence to progress into further studies in two conditions: in Diabetic Kidney Disease and FSGS. There were two pieces of underlying logic for pivoting towards FSGS. First, proteinuria is the recognised measure of the rate of kidney disease progression, so demonstrating a reduction in proteinuria indicates a slowing in disease progression which would make a significant difference in FSGS patients[4]. Second, FSGS had (and still has) a high unmet medical need, with no approved treatments. It also helped that (as noted above) DMX-200 already had Orphan Drug status in FSGS by the FDA in December 2015. It didn't have Orphan status in the EU at the time, but ultimately obtained it in November 2018. Therefore, the company likely viewed FSGS as a low-hanging fruit to go after. Six years on, FSGS is the primary focus of the company. The key to how it got to its current point lies in the subsequent clinical work.

Two Phase 2 studies from 2017 to 2020, and a new formulation

Dimerix ran two more Phase 2 studies between 2018 and 2020, giving them the code name 'ACTION', short for ' AT1R and CCR2 Targets for Inflammatory Nephrosis'. ACTION for FSGS was a small Phase 2a study of 10 patients while ACTION for DKD was a 40-patient Phase 2b. Both studies were 'cross-over' studies conducted in Australia. In March 2020, after these studies had completed recruitment, Dimerix announced that some patients had stayed on the drug (including some from the 2017 study) via a 'Special Access Scheme' authorised by Australia's Therapeutic Goods Administration. Data from ACTION for FSGS and ACTION for DKD read out in July 2020 and September 2020 respectively.

After the initial Phase 2a Dimerix developed a new formulation for DMX-200. The company took repagermanium and created a revised, commercially viable formulation that only needed to be taken twice daily rather than three times daily as before[5]. Not only was the revised formulation more convenient for the patients, but the reformulation was also scalable meaning it was now suitable for commercial manufacturing. Under the relevant laws covering generic drugs a New Chemical Entity can attract five years exclusivity in the US and the EU regardless of patent protection and, for an Orphan Drug, there is seven- and ten-years exclusivity respectively which can be extended by a further 2 years in Europe and 6 months in US for a paediatric indication. However, Dimerix also has granted patent protection in key territories until

[4] It is estimated that proteinuria in FSGS patients can be 25 times higher than in diabetic nephropathy patients – see Am J Physiol Renal Physiol. 2008 Dec;295(6):F1589-600. Epub 2008 Jun 25. One Canadian study has found that a reduction in proteinuria is the main factor in renal survival for FSGS patients – see J Am Soc Nephrol. 2005 Apr;16(4):1061-8. Epub 2005 Feb 16

[5] See the Dimerix market release dated 8 January 2018 and headlined *DMX-200 dosage optimisation study successfully completed in preparation for Phase 2b trial*.

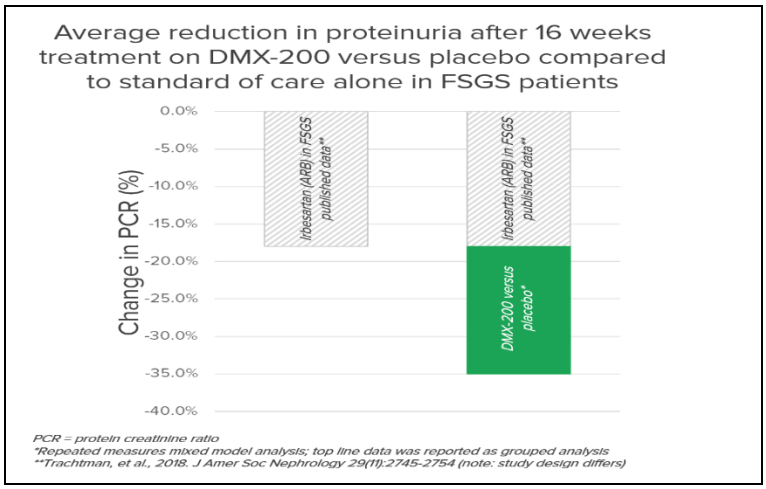
at least 2032 (method of use) and further patent applications in that could extend that to 2042 if granted (formulation and method of use). The relevant patent application was published in 2023[6].

In 2020 Dimerix obtained solid clinical data on the impact of DMX-200 on inflammation. After the results of ACTION for FSGS was reported, Dimerix was able to show that there had not only been a reduction in proteinuria thanks to DMX-200, but that the drug reduced an inflammatory biomarker called Monocyte Chemoattractant Protein-1 (MCP-1) by 39% versus placebo[7]. Less inflammation likely means less kidney fibrosis, suggesting favourable long-run outcomes with DMX-200.

DXB decided to enter a Phase 3 trial for FSGS first because of the orphan designation and high unmet need.

The Phase 2 studies determined that FSGS was the better lead indication. The bottom line is that DXB decided to enter a Phase 3 trial for FSGS first because Orphan Drug designation meant a single Phase 3 clinical study with the potential for accelerated approval in a disease with no approved treatments (Figures 2 & 3).

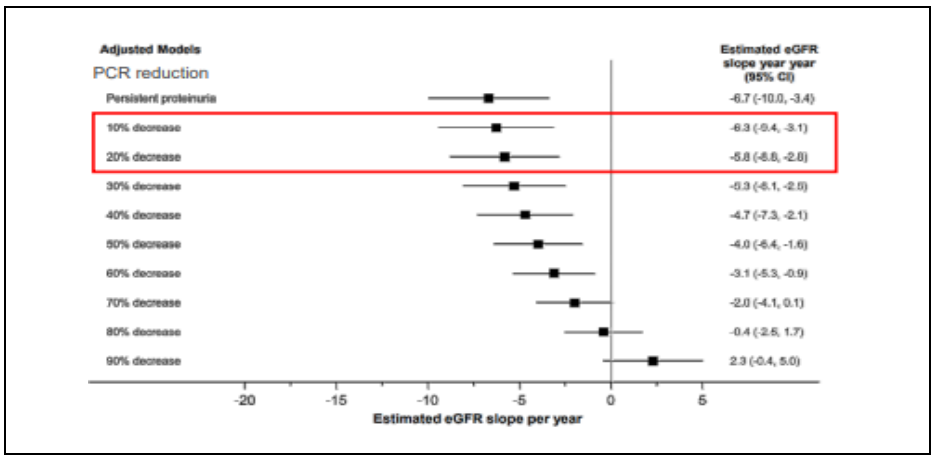
Figure 2: DMX-200's Phase 2 clinical trial result



Source: Company

[6] WO/2023/133607, *Compositions comprising a chemokine receptor pathway inhibitor*, priority date 14 January 2022.
[7] See the Dimerix market released dated 27 October 2020 and headlined 'Dimerix Announces positive additional data to support DMX-200 development in kidney disease'.

Figure 3: DMX-200's Phase 2 clinical trial result



Source: Troost, J. P. et al. Proteinuria Reduction and Kidney Survival in Focal Segmental Glomerulosclerosis. Am J Kidney Dis (2020).

DMX-200 performed well in Phase 2a in Focal Segmental Glomerulosclerosis. ACTION for FSGS, which was initiated in November 2018[8] and completed recruitment in July 2019, evaluated 10 patients with FSGS. The cross-over study involved the same three-month 'run-in' with 300 mg daily of the ARB irbesartan as the previous Phase 2a 'all comers' study, to ensure stable disease management prior to randomisation. After that patients were treated daily for 16 weeks with either 240 mg of DMX-200 or placebo. After a six week 'wash out' period, the patients switched from one to the other for another 16 weeks. Data became available in July 2020.

- The drug was safe and well-tolerated in FSGS patients.
- Six of the seven evaluated patients, or 86%, saw a reduction in proteinuria with DMX-200 versus placebo, with the average reduction being 29%, while two of the seven patients achieved a reduction of greater than 40%.
- While there were only small patient numbers, that allowed Dimerix to work towards a Phase 3.

The Diabetic Kidney Disease trial found that, yes, DMX-200 was safe and well-tolerated. And yes, the drug was effective in reducing proteinuria and albuminuria. However, the trial failed to show the treatment was statistically better than the placebo, seeing a strong placebo response in the short study.

While investors were disappointed with the initial results, subsequent assessment of the data depicted all hope was not lost. Far from it. You see, a greater effect was seen in patients after the completion of the trial, leading the company to believe that that a longer study treatment duration was warranted and would have got better results. Dimerix expected to be able to revisit Diabetic Kidney Disease after the FSGS indication is live.

[8] See ACTRN12618000910202 at anzctr.org.au.

The ACTION3 trial (2022 -)

Dimerix is now in Phase 3 with DMX-200 for FSGS. 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. Dimerix's ACTION3 pivotal study[9] runs in three parts:

- In the first part, around 72 patients will 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 the second part, another 72 patients are recruited, giving 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 third 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.
- In January 2023, the FDA gave its support for ACTION3 to recruit paediatric patients over 12 years of age, as well as adults. The EMA gave its approval for paediatric patients in July 2023. Patients from 12-17 years old will be recruited into the study post the March 2024 analysis outcome and could help support a paediatric indication.
- Figure 4 below shows the timeline for the study.

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.

The willingness of regulators to accept a surrogate endpoint as 'approvable' for a drug is only recent in the kidney disease space. It was only in 2019 that FDA indicated its willingness to consider eGFR and proteinuria as endpoints in clinical trials[10] and only in 2021 that the Agency granted accelerated approval of Tarpeyo, for the treatment of IgA nephropathy, based on eGFR[11]. Before then clinical trials would be obliged to use a composite endpoint of

[9] See NCT05183646 at clinicaltrials.gov.
[10] See Am J Kidney Dis. 2020 Jan;75(1):4-5. Epub 2019 Oct 28.
[11] Generic name budesonide, see tarpeyo.com. Taryepo was developed by the Swedish company Calliditas Therapeutics (Stockholm, Sweden, Nasdaq: CALT, calliditas.se).

death, End-Stage Renal Disease (ESRD), and serum creatinine doubling, resulting in huge and lengthy clinical studies. Out of eGFR and proteinuria, eGFR is considered the 'harder' endpoint because a stronger correlation with death and ESRD[12].

ACTION3 reads out first data soon. The ACTION3 study kicked off in May 2022 after the relevant IND was cleared by the FDA. The Clinical Research Organisation (CRO) overseeing the trial is IQVIA, a major player in the field. A notable aspect of ACTION3 is the number of trial sites needed, to compensate for the rare nature of FSGS – the first 72 patients will be recruited over 70 sites in 12 countries. Those 72 patients had been dosed by July 2023. ACTION3 completed planned Drug Safety Monitoring Board (DSMB) reviews in February and August 2023 which both recommended that the study continue as planned. Dimerix is now on track to report the first interim analysis, for the first 72 patients, in March 2024.

There is potential for Dimerix to apply for accelerated regulatory approval in CY25.

The March 2024 interim analysis does not allow for accelerated approval, but the next data point does. It's important to note that the interim analysis coming in March 2024 only provides a good clue that the drug is working as planned. It won't be until the second interim analysis, where the endpoint is both eGFR and PCR, that the possibility of an accelerated approval is real. That said, we see potential for Dimerix stock to re-rate based on that first interim analysis because the second interim analysis can potentially come before the end of calendar 2025.

DMX-200's main competitor in FSGS, Filspari, failed in mid-2023. Travere Therapeutics[13] has been developing Filspari[14], generic name Sparsentan, a small molecule which targets the endothelin A receptor (ETAR) and the angiotensin II subtype 1 receptor (AT1R).

- Filspari gained accelerated approval from the FDA in February 2023 for the treatment of primary IgA nephropathy (a different type of rare kidney disease) and Travere is going after full approval even though, in the Phase 3 PROTECT study, which compared Filspari to irbesartan, Filspari narrowly failed to reach statistical significance on an eGFR total slope measure[15]. Travere argues that the data shows long-term kidney function preservation in IgA Nephropathy.
- Filspari failed in FSGS in May 2023[16], with the Phase 3 DUPLEX study showing the drug missing its primary endpoint of eGFR reduction at week 108 by a wide margin[17]. Secondary endpoints had favourable trends[18] which is why Travere is persisting with the programme. We argue that the reason for May 2023 primary endpoint miss lies in the fact that Filspari was compared to irbesartan 1:1, rather than being additive to it. With patients on irbesartan doing better than expected, Filspari was not able to make strong enough contribution in its arm of the study.
- It's noteworthy that Sparsentan carries a black box safety warning for liver and foetal toxicity.

[12] Nephrol Dial Transplant. 2016 Sep;31(9):1425-36.
[13] San Diego, Ca., Nasdaq: TVTX, travere.com. Travere was formerly known as Retrophin.
[14] filspari.com.
[15] Lancet. 2023 Dec 2;402(10417):2077-2090. Epub 2023 Nov 3.
[16] Rheault et. al. (2023), *Sparsentan versus Irbesartan in Focal Segmental Glomerulosclerosis*, NEJM, November 3, 2023.
[17] At week 108 sparsentan had a -5.4 mL/min/1.73m2 per year eGFR slope versus compared to the active control irbesartan of -5.7. This slight advantage didn't even come close to statistical significance (p=0.7491).
[18] At 36 weeks, 42% of sparsentan patients had partial remission of proteinuria but only 26.0% of irbesartan patients (p=0.009).

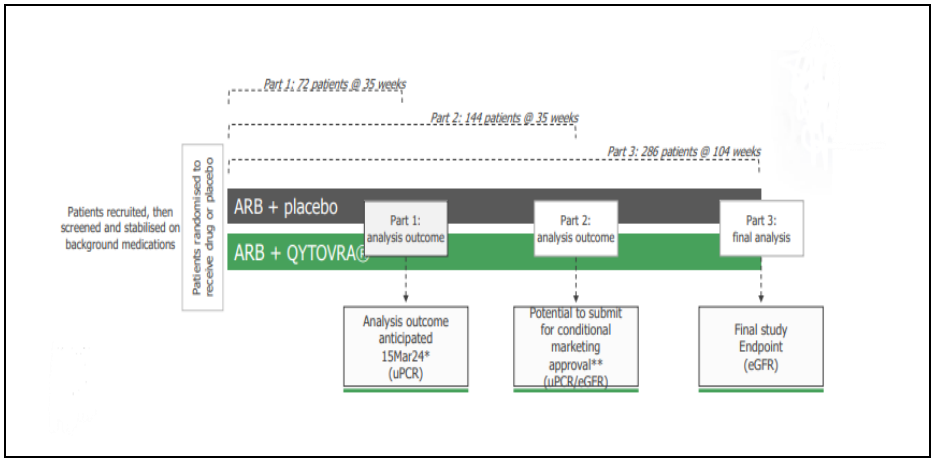
There are other products in development in FSGS, but they are earlier stage than Dimerix's product.

There are other products in development in FSGS, but they are earlier stage. For example:

- Vertex Pharmaceuticals (Nasdaq: VRTX) is in Phase 2 with Inaxaplin, which inhibits the function of the APOL1 protein, often a cause of a sub-set of genetic FSGS cases[19].
- ZyVersa Therapeutics (Nasdaq: ZVSA) is moving into Phase 2 with VAR200, a 'cholesterol efflux mediator' that can pull excess cholesterol out of the renal glomeruli podocytes.
- Chinook Therapeutics, which in August 2023 was acquired by Novartis for US$3.2bn, came with Atrasentan for IgA Nephropathy, is in Phase 2 with the same compound in FSGS.

Dimerix's product, which has tentatively been given the brand name Qytovra[20], is the only one in Phase 3 development.

Figure 4: Dimerix's ACTION3 profile



Source: Company

The CLARITY Studies (2021-2)

DMX-200 has also undergone a study (CLARITY) in COVID-19 patients. CLARITY was intended to assess 80 patients. It ended up being scaled back to 49 due to recruitment challenges, driven in part by falling rates of CVID-19 cases requiring hospitalisation in 2022.

Data was made available in December 2022. The investigators found that DMX-200 was safe and well-tolerated, and noted that 92% of participants on Day 14 did not require hospitalisation and had no limitation on theie daily activities.

As Dimerix's focus is on its FSGS trial, and COVID-19 cases involving hospitalisation have become even rarer still, this study may appear an afterthought to many investors. Nonetheless, it is important to note that CLARITY was instigated by external parties[21] which bore the bulk of the costs. It therefore shows that there is significant interest in DMX-200 from outside the company.

[19] N Engl J Med. 2023 Mar 16;388(11):969-979.
[20] See the Dimerix 25 September 2023 market release headlined '*FDA approves commercial brand name for Dimerix Phase 3 drug candidate*'.
[21] The study was led by Professor Meg Jardine, Director of the NHMRC Clinical Trials Centre at University of Sydney, Australia, in collaboration with Professor Vivek, Jha, Director of The George Institute in India.

The opportunity for Dimerix in kidney disease

There is a major opportunity for Dimerix against the specific indications DMX-200 is targeting, as well as kidney disease more broadly. We noted above that earlier stage trials of DMX-200 looked at Chronic Kidney Disease (CKD) more generally. This is an umbrella term for several conditions affecting the kidneys. The kidneys are an important part of the body that remove wastes, toxins, and excess fluid. They also help to control blood pressure, stimulate production of red blood cells, keep bones healthy and regulate blood chemicals.

>800m people in the world, or 10% of the population, are estimated to have Chronic Kidney Disease.

37 million people are estimated to have CKD in the US[22] with a further 7.2 million in the UK[23] – both equating to over 10% of the population. If this figure is true of all the world, that would amount to >800m people, a figure that has been used in certain academic research[24]. CKD is one of the few non-communicable diseases that has seen an increase in mortality over the last two decades. Tragically, many of these cases go undiagnosed until later stages. So-called stages are measured by eGFR (estimated Glomerular Filtration Rate) and proteinuria, a metric measured through blood test and urine tests.

FSGS

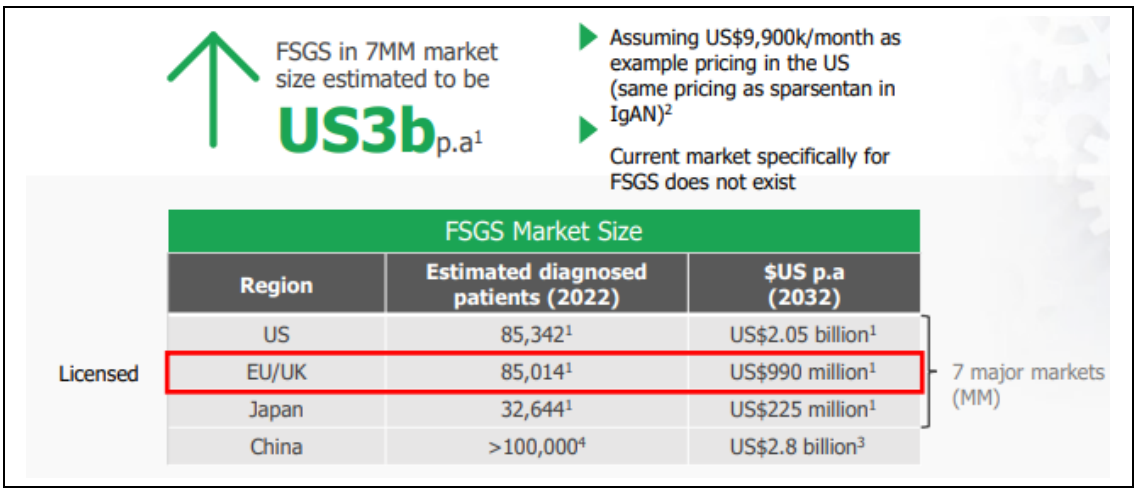
FSGS is a specific kidney disease that attacks the kidney's filtering units where the blood is cleaned (called the glomeruli). This causes irreversible scarring and leads to permanent kidney damage and eventual end-stage kidney failure, requiring dialysis or a replacement. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old. 60% of those who receive a kidney transplant risk will get re-occurring FSGS in the transplanted kidney. It is a disease that can impact both adults and children and can be caused by a variety of conditions. There are no drugs specifically approved for FSGS anywhere in the world. Any drugs that are used target symptoms rather than the disease itself.

Estimating a market size for DMX-200 for FSGS

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 5). $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.

[22] CDC data from February 2022.
[23] Data from Kidney Research UK and Kidney Care UK.
[24] See for example http://www.ncbi.nlm.gov/pmc/articles/PMC9073222 & http://pubmed.ncbi.nlm/nih.gov/35529086

Figure 5: The FSGS market



Source: Company

Dimerix has now done its first serious partnering deal for DMX-200

Dimerix is ready for commercialisation once approval is granted

The Advanz Pharma deal of October 2023 has laid part of the foundations for the eventual regulatory approval of DMX-200. In October 2023 Dimerix announced that it had partnered DMX-200 in the EU plus the UK, Switzerland, Canada, Australia, and New Zealand. The partner is Advanz Pharma[25], a UK specialty pharma company owned since 2021 by Nordic Capital, a Swedish private equity firm. Under this deal Dimerix received €6.5m upfront and can receive up to €132m in milestone payments, plus tiered royalties. Importantly, Advanz only gets the rights to FSGS in the specified regions. The €6.5m, which translated to A$10.8m, was received at the end of November 2023. DXB has retained all rights to DMX-200 in all other territories and other indications and while DXB will continue to fund and execute the global ACTION3 Phase 3 study, Advanz will be responsible for submission and maintenance of the regulatory dossier in the licensed territories, as well as all sales and marketing activities.

The Chinese opportunity is significant. Dimerix intends to go after the Chinese market for DMX-200 because the opportunity is significant, given the high relative prevalence of kidney disease in a large population. The company announced in July 2023 that China's drug regulator, the National Medical Products Administration (NMPA), had confirmed a single Phase 3 with Chinese sites would be required for NMPA approval, with that Agency able to rely on early safety and CMC data from outside China. Dimerix's IND for China was cleared in November 2023, and the company is now planning to open Chinese sites for Part 2 of the ACTION3 study.

There are likely to be other partnering deals, with rights in US, Japan, and Korea, for example, still available. We see potential for 2024 to be a significant year in terms of partnering activity. The Advanz deal only represents around one fifth of the total opportunity.

[25] advanzpharma.com. Advanz Pharma, formerly traded on TSX, enjoyed 2020 revenue of US$526m, with strong franchises in anti-Infectives and endocrinology. Nordic Capital paid US$846m at the time.

The opportunity in diabetic kidney disease

Diabetic Kidney Disease is a big deal because there are so many people out there with diabetes

Diabetic Kidney Disease is a kidney disease caused by diabetes, which is itself a major cause of kidney disease. Indeed, out of 1 in 3 adults with diabetes has kidney disease[26]. Diabetes occurs when blood glucose, or blood sugar, is too high. This can damage blood vessels in one's kidneys, and when they are damaged, they do not work as well.

It is more difficult to estimate a market for Diabetic Kidney Disease, at least based on market valuation, given there are various treatments not just for DKD specifically but also for diabetes. Nonetheless, it is not impossible to suggest that if it is correct that 1 in 3 adults with diabetes has kidney disease this could mean:

- Over 600,000 people in Australia[27]
- Over 12m people in the USA[28]
- Over 1.4m people in the UK[29]
- Over 18m people in the European region[30]

These figures demonstrate why Dimerix has persisted with this opportunity, when it could have easily put these ambitions out to pasture.

The potential commercial payoff in kidney disease is significant

Several kidney-related programmes have licensed for high prices in recent years. Consider:

- **Ionis Pharmaceuticals / AstraZeneca, February 2018**. Ionis Pharmaceuticals[31] licensed to AstraZeneca an antisense drug called IONIS-AZ5-2.5Rx for a 'genetically associated form of kidney disease'. AstraZeneca paid US$30m upfront and US$300m in milestones. The product at the time was in Phase 1.
- **Epigen Biosciences / Novo Nordisk**, May 2018. Epigen Biosciences[32] licensed EPGN69, an orally available LPA1 receptor antagonist, to Novo Nordisk in May 2018 for US$200m in milestones. This related to a pre-clinical programme.
- **Vera Therapeutics / Merck & Co., November 2020**. Merck outlicensed a Phase 2b-ready drug called atacicept to Vera Therapeutics[33] for a 10% equity and up to €605m in development and commercial milestones. Atacicept has shown promise in IgA nephropathy.
- **Cara Therapeutics / Vifor Pharma, October 2020.** Cara Therapeutics[34] licensed to Vifor the US commercial rights for intravenous Korsuva. That drug treats dialysis patients with pruritus (ie itching). Vifor paid US$100m million and made a US$50m equity investment. The product at the time was in Phase 3.
- **Angion Biomedica / Vifor Pharma, November 2020.** Angion granted Vifor a worldwide license, excluding Greater China, to ANG-3777, a hepatocyte

[26] National Institute of Diabetes and Digestive and Kidney Diseases
[27] According to Diabetes Australia, 1.9 million Australians have some form of diabetes, whether Type 1 or Type 2 and both those diagnosed and undiagnosed.
[28] The CDC estimates that 38 million Americans have diabetes, 90-95% of which have Type 2.
[29] Diabetes UK estimates that 4.3m people in the UK live with diabetes.
[30] The World Health Organization estimates 60m people live with diabetes in he European region
[31] Carlsbad, Ca., Nasdaq: IONS, ionispharma.com.
[32] San Diego, Ca., private held, epigenbiosciences.com.
[33] Brisbane, Ca., Nasdaq: VERA, veratx.com.
[34] Stamford, Ct, Nasdaq: CARA, caratherapeutics.com.

growth factor mimetic useful in treating cardiac surgery-associated acute kidney injury, for US$30m upfront, a US$30m equity investment and US$20m in clinical milestones and US$260m in market access milestones. ANG-3777 was in Phase 3 when this deal was struck[35].

- **Travere Therapeutics / CSL Vifor Pharma, September 2021.** Travere licensed the rights in Europe, Australia, and New Zealand for sparsentan to Vifor for US$55m upfront and up to up to US$135min regulatory and market access related milestones. Vifor Pharma will also make further sales milestones payments and pay tiered double-digit royalties of up to 40%.
- **Ionis Pharmaceuticals / Roche, July 2022**. Ionis Pharmaceuticals licensed IONIS-FB-LRx for IgA nephropathy after it had completed Phase 2 in IgA nephropathy. Only the US$55m upfront was disclosed. IONIS-FB-LRx is an antisense oligonucleotide to complement factor B, long known as a factor in kidney disease[36].
- **Ventus Therapeutics / Novo Nordisk, September 2022**. Ventus Therapeutics[37] licensed a portfolio of NLRP3 inhibitors to Novo Nordisk for US$70m upfront and milestones of up to $633 million plus potential royalty payments and R&D funding. At the time Ventus only had one clinical-stage NLRP3 inhibitor, at Phase 1. The NLRP3 inflammasome is potentially important in a range of cardiometabolic conditions including chronic kidney disease[38].
- **Goldfinch Bio / Karuna Therapeutics, February 2023.** Karuna Therapeutics[39] licensed several drugs targeting TRPC4/5 from Goldfinch Bio in February 2023 for $15m upfront and up to $520m in potential milestone payments, plus royalties for each candidate. Goldfinch's GFB-887 candidate, which was included in this deal, was previously studied in Phase 2 in FSGS and diabetic nephropathy, with some success in lowering proteinuria in FSGS[40]. The failure in diabetic nephropathy prompted a decision to shut down Goldfinch before Karuna picked up the programme[41]. Karuna will now evaluate GFB-887 for the treatment of mood and anxiety disorders.
- **Teijin Pharma / Novartis, March 2023**. Teijin Pharma [42] licensed to Novartis an unnamed preclinical candidate for proteinuric kidney diseases for US$30m upfront and US$200m in milestones in March 2023.
- **Akebia Therapeutics / MEDICE Arzneimittel Pütter, May 2023**. Akebia Therapeutics[43] licensed to MEDICE, a German specialty pharma company, the European rights to Vafseo, for the treatment of anemia due to chronic kidney disease. The price was US$10m upfront and up to US$100m in milestone payments, plus, notably, tiered royalty payments up to 30% of net sales. Vafseo, generic name vadadustat, is part of the new class of HIF-PH inhibitors useful in CKD-related anemia[44].

[35] ANG-3777 subsequent failed in a series of studies in kidney disease. Angion was then the subject of a Reverse Takeover by Elicio Therapeutics (Nasdaq: ELTX).
[36] Adv Chronic Kidney Dis. 2020 Mar; 27(2): 86–94.
[37] Waltham Ma. And Montreal, Qc, privately held, ventustx.com.
[38] Front Immunol. 2021; 12: 714340.
[39] Boston, Ma., Nasdaq: KRTX, karunatx.com.
[40] Kidney Int Rep. 2021 Jul 23;6(10):2575-2584.
[41] In May 2019 Goldfinch had announced a partnering deal with Gilead Sciences for products emerging from its Kidney Genome Atlas platform. Gilead paid US$55m upfront and agreed to more than US$1bn in milestones.
[42] Tokyo, Japan, TSE: 3401, teijin.com
[43] Cambridge, Ma., Nasdaq: AKBA, akebia.com.
[44] Such drugs reversibly inhibit the oxygen-sensing prolyl hydroxylase (PH) enzymes to stabilise the hypoxia-inducible factors (HIF), leading to increased transcription of the EPO and other genes involved in the correction of anaemia.

The pricetags for developers of kidney-related drugs can be high

We noted above the US$3.2bn which Novartis paid In mid-2023 to acquire Chinook Therapeutics. There have been other notable transactions in the kidney space which indicates the growing importance of the field to the pharmaceutical industry:

- Retrophin, now Travere Therapeutics, bought Orphan Technologies in October 2020 for $90m upfront and $427m in milestones. The milestones accrue if OT-58, an enzyme replacement therapy for classical homocystinuria that in 2020 was in Phase 1/2, gains approval.
- Australia's CSL Ltd (ASX: CSL) bought Vifor Pharma of Switzerland for $11.7bn in late 2021 in part because of Vifor's renal portfolio, which includes products such as Veltassa for the treatment of hyperkalemia in adults with chronic kidney disease.
- Amgen paid US$3.7bn for Chemocentryx in August 2022 to get hold of Tavneos, a drug for the treatment of ANCA vasculitis[45]. That orphan condition often leads to kidney damage.
- AstraZeneca bought CinCor Pharma in January 2023 for upfront and contingent value payments worth around US$1.8bn. The attraction was a blood pressure drug in Phase 2 called baxdrostat[46]. That drug is being studied in chronic kidney disease as well as the main indication in treatment-resistant hypertension.

Dimerix's other assets

DMX-700

DMX-700 is an orally administered anti-inflammatory drug Dimerix has in pre-clinical development for Chronic Obstructive Pulmonary Disease (COPD). DMX-700 was first identified in 2019, using the Receptor-HIT technology. Receptor-HIT identified a heteromer association between two receptors expressed on the lung – these were Interleukin 8 receptor beta (IL-8Rβ), and an angiotensin II type 1 (AT1R). Although investigations into the two single receptors when investigated individually provided disappointing results, the company anticipated that simultaneous inhibition of both receptors would improve efficacy.

Dimerix undertook a preclinical study in mice which showed an 80% reduction in lung injury in treated mice compared to the placebo. Because of these results, Dimerix has plans for a human clinical study and has applied for patent protection for DMX-700.

COPD is a progressive and life-threatening lung disease. It is most often caused by tobacco exposure but can be caused by other things such as pollution, occupational dusts, and fumes, as well as long-term asthma. COPD is the third-leading cause of death globally[47] and although treatments exist to improve certain symptoms of COPD, there is no way to slow progression of the condition of the condition or cure it. There were in the excess of 200 million cases of CPD globally in 2019 and 3.3 million deaths[48].

[45] ANCA vasculitis is an autoimmune disease affecting small blood vessels in the body. It is caused by autoantibodies called ANCAs, or Anti-Neutrophilic Cytoplasmic Autoantibodies. Tavneos, generic name avacopan, is a complement 5a receptor inhibitor which is understood to work by its inhibition of C5aR activity on neutrophils.
[46] Baxdrostat is an inhibitor of aldosterone synthase, the enzyme which synthesises aldosterone in the adrenal gland. Aldosterone controls sodium and potassium balance in the blood, so that excess aldosterone leads to high blood pressure.
[47] who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd).
[48] https://www.bmj.com/content/378/bmj-2021-069679

COPD is a billion-dollar market opportunity

COPD has been an area of unmet medical need for some time now. A star product in recent years in the respiratory space has been AstraZeneca's Symbicort, a combination of budesonide and a long-acting beta agonist called formoterol. Symbicort was first approved by the FDA in 2006 for asthma and then in 2009 for COPD[49]. Since 2009, however there have been no new products for COPD despite the market opportunity. In 2023 Sanofi and Regeneron have had Phase 3 success in COPD[50] with Dupixent[51] (dupilumab), a monoclonal antibody which targets IL-4 and IL-13 and is already on the market for atopic dermatitis and allergic asthma. For COPD patients on the standard-of-care inhalation products, Dupixent can cut moderate or severe exacerbations by 30%. Dupixent has growth into a blockbuster since 2017, with 2022 sales of US$9.8bn, but with the new data Dupixent is expected to enjoy peak sales just for COPD north of US$3bn[52].

What's next for Dimerix with DMX-700? Dimerix has done some pre-clinical development for DMX-700, including formulation work, but with DMX-200 the company's top priority it has yet to move the product into toxicology studies. We believe that can change once DMX-200 passes its first interim analysis in FSGS.

Receptor-HIT

Receptor-HIT is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. The company's core technology allows identification of pairs of different receptors that function in a joint manner (interact) when ligands, small molecule drugs, peptides, or antibodies, bind to them. Functionally interacting receptors of this type are known as heteromers. If these receptors are drug targets, then this could potentially result in a unique pharmacology and therefore biological function.

Compared with the traditional analysis of single target receptors in isolation, Dimerix can identify differences in signalling behaviour when receptors interact as heteromers.

Dimerix is applying its technology to receptors such as G-protein coupled receptors (GPCRs); a large and important family of drug targets that play a central role in many biological processes and are linked to a wide variety of diseases. Of the more than 800 GPCR's in the human genome, over 150 are orphan receptors, meaning their natural (or endogenous) ligand has not been identified and the exact mechanism the receptor plays is yet to be discovered.

What might come from Receptor-HIT?

We think it would not be unreasonable to expect Big Pharma to be interested, and indeed it has been. Prior to the pandemic:

- Two 'Top 10' Pharma companies, along with Takeda and used Receptor-HIT in paid collaborations with Dimerix.
- UK-based Excellerate Bioscience signed a deal to license on a nonexclusive basis, and
- Two GPCR platform companies, Receptos and Heptares, were acquired in 2015.

[49] In 2022, Symbicort generated $2.5bn worldwide and goes generic in the US in 2023.
[50] N Engl J Med. 2023 Jul 20;389(3):205-214. Epub 2023 May 21.
[51] Generic name dupilumab, see dupixent.com.
[52] See *Dupixent aces second COPD study, setting up FDA filing* by Phil Taylor, Pharmaforum, 27 November 2023

This optimism is all the stronger in 2023. Consider:

- Vertex's September 2023 acquisition of Septerna's GPCR program for an upfront sum of US$47.5m.
- The US$161m IPO of Structure Therapeutics in February 2023, a company developing GPCR-based drug candidates.
- Eli Lilly penning a deal with Sosei Heptares in December 2022 to license the latter company's technology, in a deal that could bring up to US$730m, with $37m up front and the balance in development and commercial milestones on top of royalties.

We're not suggesting that the main catalyst for Dimerix will be an M&A deal for Receptor-HIT. At the same time, we don't think this asset should be completely ignored since it has strong potential in just identifying future clinical candidates.

Valuing DXB

We value Dimerix at A$0.58 per share in a base case scenario and A$0.77 per share in a bull case scenario.

We have valued Dimerix at A$0.58 per share in a base case scenario and A$0.77 per share in a bull case scenario. These equate to equity values of $246.3m and $326.3m respectively.

We admit that these figures are a significant premium to the current valuation of DXB, although we stress three observations.

- First, this valuation is not unprecedented for companies at the Phase 3 stage. To illustrate, Opthea (ASX:OPT) is just over A$300m as one example and it is expecting to report results during CY24. Another company at Phase 3, Paradigm Biopharmaceuticals (ASX: PAR) is capped at over $100m. Granted, PAR is several months behind Opthea and Dimerix as far as completing its clinical trial is concerned.
- Second, many of our assumptions are conservative, including that it only captures a small share of the market and only commercialises in some of the potential jurisdictions over the life of our model.
- Third, 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 (Figure 6).

Figure 6: Our key DCF assumptions

DCF Assumptions	Base	Bull
Launch (US)	FY26	FY26
Launch (EU/UK)	FY28	FY28
Estimated market size (patient numbers)	173,780	173,780
Market penetration	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)	2,405	3,006
Peak royalty revenue (A$m)	361	451
Period of pre-terminal cash flows (years)	7	7
Discount rate	15.5%	15.5%
Royalty rate	15.0%	15.0%
Tax rate	25.0%	25.0%
AUD/USD	1.50	1.50
Net margin	14%	14%

Estimates: Pitt Street Research

Go-to-market assumptions

Regulatory approval: We assume DMX-200 applies for regulatory approval in CY25. This will be 35 weeks after the 144th patient is dosed, Part 1 will be revealed in March 2024, while Part 2 will be revealed 35 weeks after the 144th patient is dosed. We assume the results of the second interim analysis are successful, and it applies for approval thereafter. We assume it occurs within 12 months and the company enters the market. We then assume the company enters the EU/UK within a couple of years. We have not accounted for other markets at this stage,

although note that the markets we have assumed will be the most important and value-creating.

Pathway to market: The current arrangement with Advanz will provide for tiered royalties on net sales. We assume starting at 15%, in line with the 'mid-teens' estimate DXB has told investors.

Milestone revenue: We assume the estimated A$230m in upfront and milestone payments is received in full by FY27, with payments received intermittently at various milestones including different stages of Phase 3 data, regulatory approval, the first sale and 1st anniversary of sales. We note that Neuren Pharmaceuticals received an A$58m payment from its own partner when it achieved its first sales in the US, so we do not believe our assumptions here are without precedent.

Market size and penetration assumptions: We have modelled the market as a size of the number of patients. We have started with 85,342 patients in the US and 85,014 in the EU/UK, with these figures growing by 1% a year, even prior to regulatory approval. We assume a gradual ramp up over the first 3 years of commercialisation, and that Dimerix reaches 6% of both markets in our base case and 8% in our bull case.

Operating assumptions

Pricing: We have assumed US$118,800 per treatment – a multiple of US$9,900 per month as example pricing in US (it is the same pricing as sparsentan in IgAN). We have started with this price in FY23 and assumed 2% inflation per annum.

AUD/USD: We assume US$1 is A$1.50.

Operating model and expenses: We assume expenses as a fixed percentage of revenue once commercialised. We assume a cost of sales/inventory sold as 42% of sales, 10% on corporate administration costs and that 35% is spent on R&D. The latter may not be commercially necessary, although we assume that the company continues its clinical endeavours with DMX-200 and with other assets. This gives an ~18% pre-tax margin.

Tax: We assume a 25% corporate tax rate in line with the highest of the 3 jurisdictions we assume commercialisation in – namely, the UK. This derives a post-tax profit margin of 14%.

Other DCF inputs: In relation to: Depreciation & Amortisation, Capex, Working Capital, these are all immaterial to the company right now and we forecast to continue to be. We assume depreciation to be 22% of the fixed opening book and capex to be 27%. The latter figure is derived from DXB's statutory results. For right of use assets, we assume new leases to be 80% of the opening book and for depreciation to be 55%. Changes in Working Capital was 6% in FY23, we assume working capital declines over time so that it reaches 0.4% by FY30.

Differences between our base and bull cases

The key difference is the higher market penetration – 6% in our base case and 8% in our bull case. As Figure 5 notes, this leads to higher sales, and therefore higher royalty revenue, specifically 25%. Sales peak at A$2.4bn and royalty revenue at A$361m in our base case, while sales peak at A$3.0bn and royalty revenue at A$451m in our bull case.

Valuation inputs

Discount rate: We have used a 15.5% discount rate. This is derived from a 5% risk-free rate of return, a 1.5 beta and a 7% equity premium.

Terminal value: We have assumed terminal growth and used a 2% rate. Although DMX-200's current patent protection does not expand past 2032, we have still used one on the assumptions that:

- The company's application to extend the patents will be successful,
- It will have a small share of the market opportunity, and;
- Even though there are candidate drugs in the pipeline, there is no guarantee that they will make it to market or be more effective than DMX-200. The failure of Travere's candidate sparsentan to meet its Phase 3 primary end point illustrates this, albeit also opening up the door for DMX-200 to be the first drug to be approved for the condition.

Figure 7 outlines our DCF calculation while Figure 8 outlines the impact of using various WACCs on our valuation, ceteris paribus.

Figure 7: DXB's DCF calculation

Cannasouth Valuation (A$m)	Base Case	Bull case
Present Value of FCF	118.8	155.3
Present Value of Terminal Value	120.9	164.4
Enterprise Value (A$ m)	**239.7**	**319.7**
Net (debt) cash	(6.6)	(6.6)
Minority Interest	-	-
Other Investments	-	-
Equity value (A$ m)	**246.3**	**326.3**
Shares outstanding	426.1	426.1
Implied price (A$ cents)	**0.58**	**0.77**
Current price (A$ cents)	0.175	0.175
Upside (%)	230.3%	337.6%

Source: Pitt Street Research

Figure 8: Sensitivity analysis of DCF calculation (base case)

		WACC						
		12.5%	13.5%	14.5%	15.5%	16.5%	17.5%	18.5%
Terminal Rate	0.5%	0.74	0.67	0.60	0.55	0.50	0.46	0.42
	1.0%	0.76	0.68	0.62	0.56	0.51	0.47	0.43
	1.5%	0.79	0.70	0.63	0.57	0.52	0.48	0.44
	2.00%	0.81	0.72	0.65	**0.58**	0.53	0.48	0.44
	2.5%	0.84	0.74	0.66	0.60	0.54	0.49	0.45
	3.0%	0.87	0.77	0.68	0.62	0.55	0.50	0.46
	3.5%	0.90	0.79	0.70	0.63	0.57	0.51	0.47

Source: Pitt Street Research

Catalysts for re-rating

We see the key catalyst as being successful clinical data being read out in mid-March as being the key catalyst for the stock. Thereafter, we expect momentum as the company advances the current trial into the next stage and eventually applies for regulatory approval. DXB's efforts with FSGS aside, we think there is also potential for upside from success with its endeavours against Diabetic Kidney Disease.

Key risks facing DXB

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.
- **Uptake risk**. There is the risk that DXB products are still too expensive in the healthcare markets in which it wants to participate.
- **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 DXB.

Comparable companies

We have looked at both biotechs listed on the ASX with Phase 3 trials in operation as well as global companies (public and private alike) developing kidney disease treatments that could aid the fight against FSGS.

Phase 3 companies on the ASX

Opthea (ASX: OPT) – Opthea has a drug called OPT-302 that is in a Phase 3 trial for wet-AMD, an eye condition where fluid leaks in the back of the eye and blindness occurs as a result. The company announced successful Phase 2 results for this condition in mid-2019 and started the current Phase 3 trial in 2021.

Paradigm Biopharmaceuticals (ASX: PAR) – Paradigm has an injectable drug for knee osteoarthritis. A Phase 3 clinical trial commenced in May 2022.

Telix Pharmaceuticals (ASX: TLX) – Although this company has got a drug on the market, it has a significant pipeline, led by an early-stage Phase 3 trial for kidney cancer imaging agent TLX-250-CDx. The first patient in the trial was dosed in early December.

Kidney disease companies

Boehringer Ingelheim – Boehringer Ingleheim is one of the world's largest biopharmaceutical companies. It has BI-764198 in a phase 2 trial against FSGS. It is orally administered and works as a TRPC6 inhibitor. TRPC6 is a human gene that regulates calcium entry into the cell, with defects being a common cause of FSGS. The current trial has followed four Phase 1 studies that have depicted the drug is generally well tolerated at single and multiple rising doses administered once daily for up to 14 days. This drug has also been shown to reduce risk and severity of ARDS due to COVID-19.

Chinook Therapeutics – Chinook is a subsidiary of Novartis, which bought it for US$3.2bn. The drug in question is Atrasentan, which is administered orally works as an endothelin A receptor antagonist. Although it is only in Phase 2 for FSGS, it reported successful Phase 3 results for IgAN, a separate kidney disease, back in October 2023. This company intends to apply for accelerated FDA approval shortly.

ProKidney – ProKidney[53]is a regenerative medicine company whose REACT product, short for Renal Autologous Cell Therapy, is being developed for Chronic Kidney Disease. ProKidney expands and isolates the patient's renal cells from a biopsy and formulates them into a personalised cell therapy re-injected into the damaged kidney. REACT is currently in Phase 3.

Valenza Bio – Valenzia was bought by Acelyrin in January 2023. Valenza's drug is VB119, which is administered as an intravenous infusion and seeks to reduce B-cells and anti-PLAR2R autoantibodies to thereby reduce proteinuria. A Phase 1 trial was completed in 2022.

Vertex Pharmaceuticals – This company is working on VX-147, an apolipoprotein L1 inhibitor. This is most advanced of all the candidates, having passed a Phase 2a trial, but undertaking a Phase 2/3 trial at the present point in time. It is not specifically focused on FSGS, but on people with kidney disease of which mediated by two mutations in the APOL1 gene (AMKD). This is the first drug aimed at treating the underlying cause of AMKD.

[53] Winston-Salem, NC, Nasdaq: PROK, prokidney.com.

Zyversa – ZyVersa's drug VAR-200. It works to reduce renal cholesterol and lipid accumulation that damages the kidney filtration system and thereby causing diseases including (but not limited to) FSGS. In mid-2023, it was granted a European patent for the purpose of commencing a Phase 2a trial.

DXB's leadership team

DXB has the ideal leadership team to advance its clinical programs. The current board members are listed below (Figure 9):

Figure 9: PTX's Board members and senior management

Name and Designation	Profile
Mark Diamond Non-Executive Chairman	• Mr Diamond is a senior pharmaceutical executive with a demonstrated record of achievement and leadership over more than thirty years within the pharmaceutical and biotechnology industries. • He served Antisense Therapeutics Limited as Managing Director and CEO for 22 years, making him at the time of his retirement in May 2023 as the longest serving CEO of a publicly traded Healthcare Company on the ASX. At Antisense, Mr Diamond was responsible for capital market engagement, pipeline development, product out-licensing and clinical trial conduct among other significant accomplishments. • In 2022, Mr. Diamond was the recipient of The Biotech Daily CEO of the Year award. • Prior to his time at Antisense, Mr Diamond served in senior product and business development roles at Faulding Pharmaceuticals (now Pfizer) within their US, European and international pharmaceutical operations. Mr Diamond holds a Bachelor of Science degree from Monash University and an MBA from Macquarie University.
Nina Webster Chief Executive Officer and Managing Director	• Dr Webster has over thirty years of experience in the pharmaceutical industry, with leadership roles in investor relations, business development, and prosecution of intellectual property matters, as well as leading and managing the strategic, scientific and operational aspects of product development. • She was formerly the Commercial Director for Acrux Limited (ASX: ACR), an Australian drug pharmaceutical company that has successfully developed and commercialised multiple products globally. Prior to Acrux, Nina was Director of Commercialisation and Intellectual Property for Immuron Limited (ASX: IMC), and previously spent 6 years in new product development with Wyeth Pharmaceuticals in the UK. Nina is also a Non-Executive Director for Linear Clinical Research Limited. Nina holds a Ph.D in Pharmaceutics from Cardiff University, a Bachelor degree in Pharmacology, a Masters degree in Intellectual Property Law from Melbourne University and an MBA from RMIT.
Hugh Alsop Non-Executive Director	• Mr Alsop is an accomplished pharmaceutical and biotechnology executive with 20 years of experience in international business development, partnering, drug development and leadership of scientific teams. • Mr Alsop was two significant exit transactions for the Australian life sciences industry,– namely at Hatchtech, where he as CEO helped secure a $200 million commercialisation agreement for its lead development product with global Indian pharmaceutical company Dr Reddy's. In 2010, as Director of Business Development at Acrux Limited, Hugh was a key member of the team that licensed the testosterone product Axiron™, to Eli Lilly for up to US$335m in potential milestones plus royalties.

Clinton Snow Non-Executive Director	• Mr Snow has nearly 20 years experience as a technology leader with a focus in engineering management, project delivery, risk management, and assurance. • He is currently a non-executive director for Icetana Ltd (ASX:ICE) and provides advisory services to a family office with multiple Australian biotech investments. • He holds a Bachelor of Chemical Engineering (honours) and Bachelor of Commerce degree from The University of Melbourne.
Sonia Poli Non-Executive Director	• Dr Poli is currently Executive Manager at AC Immune, a Nasdaq listed company, and has previously worked within Swiss Stock Exchange listed companies Hoffman la Roche and Addex Therapeutics, where she has held leadership and executive positions across various disciplines in drug discovery, pre-clinical development and translational science and has interacted with regulatory authorities, investors and public funding institutions. • Sonia has held various corporate responsibilities such as outsourcing and out-licensing, and she has promoted academic collaborations and supported R&D collaborations with external partners. Sonia is an accomplished R&D professional with 20 years international experience in large and small pharmaceutical companies. She has broad knowledge of small molecule drug design, optimisation and early clinical development, with expertise which encompasses multiple therapeutic areas. Sonia is co-author of more than 50 scientific papers and several patents. Sonia holds a Masters degree and a PhD in industrial chemistry from Milan University (IT).
Hamish George CFO and Company Secretary	• Mr George has experience in providing financial advice and CFO services to businesses ranging from small start-ups to large established businesses with turnover of over $50 million. He brings expertise in areas including financial/management reporting, Company Secretarial, cash flow management, taxation including (R&D Tax Incentive), Company Establishments, company valuations, budgeting and forecasting. • He is also a member of the senior management team at Bio101, a financial services firm providing outsourced CFO, tax and company secretarial solutions to the life science sector. • He holds a Bachelor of Commerce from the University of Melbourne, a Diploma in Financial Planning from Kaplan Professional, a Masters Degree in Professional Accounting from RMIT, a Certificate in Governance Practice from the Governance Institute of Australia and is a qualified Chartered Accountant.

Appendix I – Glossary

Adjunct therapy – Therapy that is given in addition to the initial therapy. In studies of DMX-200 propagermanium is considered adjunctive to an angiotensin receptor blocker (ARB).

Albuminuria – When the albumin protein normally found in the blood is found in the urine. A healthy kidney does not let albumin pass from the blood to the kidney, and therefore, albumin in the urine is seen as a sign of kidney disease.

Angiotensin – A hormone involved in the maintenance of blood pressure and fluid balance. There are various types of angiotensin. The one that raises blood pressure, through the constriction of blood vessels, is angiotensin II.

Angiotensin II receptor type 1 (AT1R) - An angiotensin receptor important in the control of blood pressure. AT1R is the target of irbesartan.

ARB – An Angiotensin Receptor Blocker, which a hypertensive medication used to reduce blood pressure (e.g. irbesartan).

Chemokine receptor 2 (CCR2) – A type of G Protein Coupled-Receptor (GPCR) that binds the CCL2 gene and neutralises its biological activity.

Comparator-arm study – Another term for a study that tests a drug against the placebo.

Diabetic Kidney Disease - Kidney damage resulting from diabetes, which can often lead to kidney failure.

DMX-200 – Dimerix's lead candidate, which is also known as repagermanium.

Double blind – In the context of a clinical trial, alludes to trials where neither the researchers nor patient knows what they are getting, whether placebo of the drug that is the subject of the study. Either is allocated randomly, typically through a code number issued by a computer.

eGFR (estimated Glomerular Filtration Rate) - A metric measured through blood tests that looks at the levels of waste product creatinine in a patient's blood to determine how much blood the kidney is estimated to be filtering.

Focal Segmental Glomerulosclerosis (FSGS) – A kidney disease that attacks the kidney's filtering units where the blood is cleaned (called the glomeruli), causing irreversible scarring and leading to permanent kidney damage and eventual end-stage kidney failure, requiring dialysis or a replacement.

G Protein Coupled-Receptors (GPCRs) – These 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.

Glomeruli - The kidney's filtering units where the blood is cleaned, and the waste products transferred into the urine.

Heteromer - In biology, a complex formed from several types of subunits. For example, the Mu/Delta Opioid Receptor Heteromer is a complex of the Mu Opioid Receptor and the Delta Opioid Receptor.

Immunoglobulin A nephropathy (IgAN) – A kidney disease that occurs when a germ-fighting protein known as immunoglobulin A builds up in the kidneys, causing inflammation that makes it harder for the kidneys to filter waste from the blood.

Interleukin 8 receptor beta (IL-8Rβ) – A receptor that is thought to transduce signals by coupling to GTP-binding proteins.

Irbesartan – An Angiotensin Receptor Blocker that, by relaxing blood vessels, can lower blood pressure.

Kidneys – Organs which filter blood and carry waste to the bladder.

Open label – A clinical trial in which both patients and doctors know what treatment is being administered.

Phase – A stage of the clinical trialing process for a drug candidate. Phase 1 tests for safety. Phase 2 tests for efficacy in a small sample. Phase 3 tests for efficacy in a large sample.

Repagermanium – An anti-inflammatory 'organometallic' drug derived from the metal germanium, has a different crystal structure to related compound, propagermanium. Repagermanium works through blocking the chemokine receptor CCR2. Repagermanium is Dimerix's lead DMX-200 product.

Proteinuria – Protein in the urine. The presence of protein in the urine demonstrates the rate of kidney function impairment over time.

Receptor-Heteromer Investigation Technology (Receptor-HIT) – Dimerix's technology for identifying GPCR Heteromers. The platform uses BRET to identify GPCRs that interact.

Statistical significance - The probability, measured by the 'p-value', that an observed outcome of an experiment or trial is due to chance alone. Generally, p-values below 0.05 are taken as markers of statistical significance.

Appendix II – Capital Structure

Class	In millions	% of fully diluted
Ordinary fully paid shares	426.1	72%
Options	165.0	28%
Fully diluted shares	**591.1**	

Appendix III – Analyst Qualifications

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.

General advice warning, Disclaimer & Disclosures

Terms & Conditions

The information contained herein ("Content") has been prepared and issued by Pitt Street Research Pty Ltd ACN 626365615 ("Pitt Street Research"), an Authorised Representative (no: 1265112) of BR Securities Australia Pty Ltd. ABN 92 168 734 530, AFSL 456663. All intellectual property relating to the Content vests with Pitt Street Research unless otherwise noted.

Disclaimer

Pitt Street Research provides this financial advice as an honest and reasonable opinion held at a point in time about an investment's risk profile and merit and the information is provided by the Pitt Street Research in good faith. The views of the adviser(s) do not necessarily reflect the views of the AFS Licensee. Pitt Street Research has no obligation to update the opinion unless Pitt Street Research is currently contracted to provide such an updated opinion. Pitt Street Research does not warrant the accuracy of any information it sources from others. All statements as to future matters are not guaranteed to be accurate and any statements as to past performance do not represent future performance.

Assessment of risk can be subjective. Portfolios of equity investments need to be well diversified and the risk appropriate for the investor. Equity investments in a listed or unlisted company yet to achieve a profit or with an equity value less than $50 million should collectively be a small component of an individual investor's equity portfolio, with smaller individual investment sizes than otherwise. Investors are responsible for their own investment decisions, unless a contract stipulates otherwise.

Pitt Street Research does not stand behind the capital value or performance of any investment. Subject to any terms implied by law and which cannot be excluded, Pitt Street Research shall not be liable for any errors, omissions, defects or misrepresentations in the information (including by reasons of negligence, negligent misstatement or otherwise) or for any loss or damage (whether direct or indirect) suffered by persons who use or rely on the information. If any law prohibits the exclusion of such liability, Pitt Street Research limits its liability to the re-supply of the Information, provided that such limitation is permitted by law and is fair and reasonable.

General advice warning

The Content is General Financial Advice but has been prepared for general information purposes only and is not (and cannot be construed or relied upon as) Personal Financial Advice nor as an offer to buy/sell/subscribe to any of the financial products mentioned herein. No investment objectives, financial circumstances or needs of any individual have been taken into consideration in the preparation of the Content.

Financial products are complex, entail risk of loss, may rise and fall, and are impacted by a range of market and economic factors, and you should always obtain professional advice to ensure trading or investing in such products is suitable for your circumstances, and ensure you obtain, read and understand any applicable offer document.

Disclosures

Pitt Street Research has been commissioned to prepare the Content. From time to time, Pitt Street Research representatives or associates may hold interests, transact or hold directorships in, or perform paid services for, companies mentioned herein. Pitt Street Research and its associates, officers, directors and employees, may, from time to time hold securities in the companies referred to herein and may trade in those securities as principal, and in a manner which may be contrary to recommendations mentioned in this document.

Pitt Street Research receives fees from the company referred to in this document, for research services and other financial services or advice we may provide to that company. The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation. Where Pitt Street Research has been commissioned to prepare Content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid will either directly or indirectly impact the Content provided.