EUROZ HARTLEYS

INITIATION OF COVERAGE | PUBLISHED ON 19 APRIL 2024

DXB: A Rare Opportunity

DXB | DIMERIX LTD | HEALTHCARE | BIOTECHNOLOGY

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$0.29/sh	**A$0.80/sh**	**SPECULATIVE BUY**	**SETH LIZEE**
			SLIZEE@EUROZHARTLEYS.COM

Initiation of Coverage

Dimerix Ltd (DXB) is a late stage biotechnology company focused on inflammatory diseases. The company's lead asset, DMX-200, is in a global phase 3 clinical trial for the treatment of Focal Segmental Glomerulosclerosis (FSGS), a rare kidney disease with granted orphan drug designation.

FSGS presents a significant unmet need. The disease progressively damages the kidney filtering units, leading to irreversible damage and eventually kidney failure (5-yrs on avg from onset), which can eventually be fatal. There are currently no approved treatments for FSGS, with DMX-200 being the most advanced drug in development.

In addition, DXB has a pipeline of other programs that include Diabetic Kidney Disease (DKD), Chronic Obstructive Pulmonary Disease (COPD), and other indications.

Investment Case

- **Late Stage Asset / Accelerated Approval Potential** – DMX-200 is currently in a phase 3 trial and may be eligible for accelerated approval if the interim results, expected mid-CY2025, are successful. Last month the trial was de-risked when DXB announced DMX-200 had passed the efficacy futility analysis, indicating it is performing better than placebo. Importantly, this analysis represents a patient cohort nearly 10x larger than that of the phase 2 trial.
- **Billion Dollar Market Opportunity** – We estimate there is a +A$5 billion total addressable market (TAM) for DMX-200 in the treatment of FSGS in total across the USA and Europe. Approximately 40k-85k patients in each region are estimated to suffer from FSGS. Drugs treating similar rare kidney diseases sell for between US$120k-US$170k p.a in the USA and circa US$100k p.a. in Europe.
- **Licensing Deal / Commercial Validation** - DXB executed a major $230m licensing deal last year with European speciality pharma company Advanz Pharma, covering the European Economic Area, and other select regions. The deal could yield up to $220m in milestone payments for DXB, plus royalties of 15-20% on net sales. Additionally, DXB has received multiple non-binding term sheets for global and regional licensing deals, with a USA deal poised to be a major catalyst.
- **Fully Funded** - The company is fully funded through to the completion of its phase 3 trial in FSGS with circa $38.6m in pro-forma cash, and an additional $7.7m of options in the money. Moreover, this cash could be supplemented by future licensing deals.

Price Target and Recommendation

We initiate with a Speculative Buy Recommendation and $0.80/sh Price Target.

Our risked-NPV$_{15}$ valuation assumes DMX-200 is granted accelerated approval for FSGS and captures 30% peak market share in the USA and Europe. This incorporates the A$230m Advanz Pharma Europe deal and assumes DXB executes a A$250m USA deal. **Our fully unrisked valuation is $1.31/sh.** We do not ascribe any value for DMX-200 in the rest of the world (RoW), or for DXB's development pipeline (incl. DKD or COPD).

Catalysts

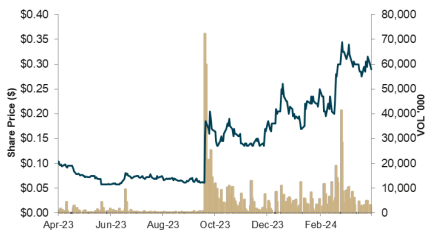
- DMX-200 Phase 3 (FSGS) Dosing Updates / Part 2 Interim Results (Mid-CY25)
- DMX-200 (FSGS) FDA/EMA Filing (2H'CY25)/ Accelerated Approval (1H'CY26)
- New Licensing Deals - USA/China/RoW

Share Price	**0.29**	**A$/sh**
Price Target	0.80	A$/sh
Valuation (SOTP)	0.80	A$/sh
WACC	15%	
Shares on issue	602.9	m,dil
Market Cap	**174.8**	**A$m**
Enterprise Value	**128.6**	**A$m**
Debt (inc. leases)	0.0	A$m
Pro-forma cash	38.6	A$m
Unpaid capital	7.7	A$m

Key Metrics	**24F**	**25F**	**26F**
Revenue (A$m)	4.1	4.3	31.9
EBITDA (A$m)	-12.4	-20.2	16.4
EBIT (A$m)	-12.5	-20.3	16.4
NPAT (A$m)	-12.5	-20.3	16.4
Gross CF (A$m)	-2.4	-3.2	89.6
Capex (A$m)	0.0	0.0	0.0
Op. FCF (A$m)	-1.1	-1.2	90.1
EPS (Ac)	-2.3	-3.7	3.0
Revenue Growth	-55%	5%	642%
PER (x)	na	na	9.7
EV/EBITDA (x)	na	na	7.8
EV/Revenue (x)	31.4	29.9	4.0
Net Cash*	29.2	27.9	118.0

**inc. leases*

Performance



Source: IRESS

Income Statement	24F	25F	26F	27F
Royalty Income	0.0	0.0	19.3	83.8
Milestone Payments*	0.8	3.0	11.7	18.3
Other (inc. R&D)	3.3	1.3	0.9	0.4
Total Revenue	**4.1**	**4.3**	**31.9**	**102.5**
(-) COGS	0.0	0.0	0.0	0.0
Gross Profit	4.1	4.3	31.9	102.5
(-) R&D	-12.5	-20.0	-10.0	-4.0
(-) SG&A	-4.0	-4.5	-5.5	-7.5
EBITDA	**-12.4**	**-20.2**	**16.4**	**91.0**
(-) D&A	-0.1	-0.1	-0.1	-0.1
EBIT	**-12.5**	**-20.3**	**16.4**	**91.0**
(-) Net finance	0.0	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
PBT	**-12.5**	**-20.3**	**16.4**	**91.0**
(-) Tax	0.0	0.0	0.0	-6.8
NPAT	**-12.5**	**-20.3**	**16.4**	**84.2**

Cash Flow Statement	24F	25F	26F	27F
NPAT	**-12.5**	**-20.3**	**16.4**	**84.2**
(+) D&A	0.1	0.1	0.1	0.1
(+) Upfront/Milestones	10.9	20.0	85.0	55.0
(-) leases	-0.1	-0.1	-0.1	-0.1
(+/-) Non-cash Rev/Exp	-0.8	-3.0	-11.7	-18.3
(+/-) Other	0.0	0.0	0.0	0.0
Gross Cash Flow	**-2.4**	**-3.2**	**89.6**	**120.9**
(-) Capital expenditure	0.0	0.0	0.0	0.0
(+/-) Working Capital	1.3	2.0	0.4	-5.6
Operating Free Cash Flow	**-1.1**	**-1.2**	**90.1**	**115.3**
(-/+) Acquisition/Disp	0.0	0.0	0.0	0.0
(+) Placement/Equity	24.2	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
Net Cash Flow	**23.1**	**-1.2**	**90.1**	**115.3**
BoP Net Cash / (Debt)	2.0	29.2	27.9	118.0
(+/-) Net Cash Flow	23.1	-1.2	90.1	115.3
(+/-) Other	4.0	0.0	0.0	0.0
EoP Net Cash / (Debt)	**29.2**	**27.9**	**118.0**	**233.3**

Balance Sheet	24F	25F	26F	27F
Cash	29.2	27.9	118.0	233.3
Receivables	3.3	1.3	1.7	6.9
ROUA	0.0	0.0	0.0	0.0
Total Current Assets	**32.5**	**29.2**	**119.7**	**240.2**
PP&E	0.0	0.0	0.0	0.0
Total Non-current Assets	**0.0**	**0.0**	**0.0**	**0.0**
Total Assets	**32.5**	**29.2**	**119.7**	**240.2**
Payables	0.5	0.5	1.3	0.9
Borrowing	0.0	0.0	0.0	0.0
Leases	0.0	0.0	0.0	0.0
Contract Liability	0.8	3.0	11.7	18.3
Provisions	0.1	0.1	0.1	0.1
Total Current Liabilities	**1.4**	**3.7**	**13.2**	**19.4**
Leases	0.0	0.0	0.0	0.0
Contract Liability	9.3	24.1	88.6	118.7
Provisions	0.0	0.0	0.0	0.0
Total Non-current Liab.	**9.4**	**24.1**	**88.6**	**118.8**
Total Liabilities	**10.8**	**27.8**	**101.8**	**138.2**
Net Assets	**21.7**	**1.5**	**17.8**	**102.0**
Issued Capital	83.7	83.7	83.7	83.7
Reserves	2.6	2.6	2.6	2.6
Retained Earnings	-64.6	-84.8	-68.4	15.8
Total Equity	**21.7**	**1.5**	**17.9**	**102.1**

Performance Ratios	24F	25F	26F	27F
Growth				
Revenue Growth (%)	-55%	5%	642%	221%
EBITDA Growth (%)	-10%	63%	-181%	453%
EBIT Growth (%)	-10%	62%	-181%	455%
NPAT Growth (%)	-10%	62%	-181%	414%
Margin				
EBITDA Margin (%)	-304%	-469%	51%	89%
EBIT Margin (%)	-305%	-471%	51%	89%
PBT Margin (%)	-305%	-471%	51%	89%
NPAT Margin (%)	-305%	-471%	51%	82%
Effective Tax Rate (%)	0%	0%	0%	7%
Liquidity				
Capex/depreciation (x)	0.0	0.0	0.0	0.0
Current ratio (x)	22.7	8.0	9.1	12.4
Quick ratio (x)	64.9	58.4	93.9	254.1
Receivable days	296	111	19	25
Payable days	11	7	30	30
Risk Measures				
Dividend Cover (x)	na	na	na	na
Payout ratio (%)	na	na	na	na
Net interest cover (x)	na	na	na	na
Net debt/equity (%)	Cash	Cash	Cash	Cash
Returns				
ROIC (%)	na	na	64%	62%
ROA (%)	na	na	14%	35%
ROE (%)	na	na	92%	82%

Share Data/Valuation	24F	25F	26F	27F
Share Data				
Issued shares (m)	549.6	549.6	549.6	549.6
Weighted ave shares (m)	468.8	549.6	549.6	549.6
Fully diluted shares (m)	602.9	602.9	602.9	602.9
Basic EPS (c)	-2.3	-3.7	3.0	15.3
YoY change (%)	-36%	62%	-181%	414%
Fully diluted EPS (c)	-2.1	-3.4	2.7	14.0
YoY change (%)	-42%	62%	-181%	414%
Fully dil norm EPS (c)	-2.3	-3.7	3.0	15.3
YoY change (%)	-36%	62%	-181%	414%
Dividend/share (c)	0.0	0.0	0.0	0.0
Franking (%)	na	na	na	na
Gross cash flow/share (c)	-0.4	-0.6	16.3	22.0
NBV/share (c)	4.0	0.3	3.3	18.6
NTA/Share (c)	4.0	0.3	3.3	18.6
Share Data				
PER (Basic) (x)	na	na	9.7	1.9
PER (Fully diluted) (x)	na	na	10.7	2.1
PER (Fully dil, norm) (x)	na	na	9.7	1.9
P/CFPS (x)	na	na	1.8	1.3
Price/NBV (x)	7.3	107.7	8.9	1.6
Price/NTA (x)	7.3	107.7	8.9	1.6
Dividend Yield (%)	0.0	0.0	0.0	0.0
EV/EBITDA (x)	na	na	7.8	1.4
EV/EBIT (x)	na	na	7.8	1.4
EV/Revenue (x)	31.4	29.9	4.0	1.3

**recognised over contract term*

Contents

Valuation and Price Target

We initiate coverage with a Speculative Buy Recommendation and an $0.80/sh Valuation and Price Target.

Our valuation assumes DMX-200 is granted accelerated approval in the United States and Europe in 1H'CY2026 and is subsequently commercialised in both regions under an out-licensing model.

Our valuation is derived using a sum of the parts (SOTP) risked net present valuation (rNPV). Our fully unrisked valuation is $1.31/sh (Figure 1).

Figure 1: Sum of the Parts (SOTP) Valuation

SOTP Valuation (Fully Diluted)	NPV15	NPV15	Risking (r)	rNPV15	rNPV15
	(A$m)	(A$/sh)	(%)	(A$m)	(A$/sh)
DMX-200 FSGS - EU (Advanz Pharma)	420.4	0.70	62%	261.5	0.43
DMX-200 FSGS - USA	391.9	0.65	62%	243.7	0.40
DMX-200 FSGS - RoW	0.0	0.00	62%	0.0	0.00
Other Assets/Indications*	0.0	0.00	100%	0.0	0.00
Corporate/R&D	-71.7	-0.12	100%	-71.7	-0.12
Enterprise Value	**740.6**	**1.23**		**433.6**	**0.72**
(+) Cash (pro-forma)**	38.6	0.06	100%	38.6	0.06
(-) Debt	0.0	0.00	100%	0.0	0.00
(+) Unpaid Capital	7.7	0.01	100%	7.7	0.01
Equity Value	**786.9**	**1.31**		**479.9**	**0.80**
Upside		350%			174%

Source: EH analysis
**Includes DMX-200 in DKD, DMX-700 in COPD, other undisclosed indications; **see page 42*

Our valuation is derived using a conservative 15% discount rate and is risk adjusted (r) based on the average probability of success from Phase 3 to approval for non-oncology orphan drugs (~62%, Figure 2). Our valuation does not include a terminal and is fully diluted for any options outstanding.

Figure 2: Non-oncology Orphan Drug Phase Success Rates

		Phase 1	Phase 2	Phase 3	NDA Approval
Orphan non-oncology					
Phase Success Rate	%	88%	81%	73%	85%
Phase Likelihood of Approval (LOA)	%	45%	50%	62%	85%

Source: Hay et al, January 2014

Our valuation incorporates the existing Advanz Pharma licensing agreement for the EU and assumes DXB executes a A$250m (~8% larger than Advanz Pharma) licensing deal for the United States (see page 34).

DXB could execute a larger USA licensing deal than we forecast, which currently assumes a deal similar to the European Advanz Pharma agreement (only ~8% larger), considering the USA is the largest FSGS market globally.

Moreover, the de-risking milestone achieved last month, showing DMX-200 was performing better than placebo in a cohort nearly 10 times larger than the Phase 2 study (see Page 22), could facilitate a larger deal. We note the Advanz Pharma agreement was done prior to this milestone.

Key assumptions driving our valuation include:

- ~19k target FSGS population across both US and EU.
- 30% peak market share.
- US$100k/US$70k pricing in United States and EU respectively (~30% discount to comparable rare kidney disease drugs).

We provided a full breakdown of our forecasts for DMX-200 in FSGS in the United States and Europe in Figure 46 and 47, with supporting analysis on the total addressable market of FSGS (including sizing and pricing) on page 26.

We do not ascribe any value for DMX-200 in FSGS in the rest of the world (RoW), including China. Further licensing deals present upside to our valuation.

Additionally, we do not ascribe any value for DXB's development pipeline, which includes DMX-200 in Diabetic Kidney Disease (DKD), DMX-700 in Chronic Obstructive Pulmonary Disease (COPD), or any of the other undisclosed programs. This also presents further upside to our valuation.

The risks surrounding our assumptions further drive our Speculative Buy recommendation.

Valuation Sensitivity

We have sensitised a handful of key inputs behind our $0.80/sh Valuation.

Figure 3: Discount Rate vs Risk adjustment (r)

DMX-200 US/EU NPV Risking (r)	Discount Rate 10%	11%	12%	13%	14%	15%
30%	0.47	0.44	0.42	0.40	0.38	0.36
40%	0.64	0.61	0.58	0.55	0.52	0.50
50%	0.82	0.78	0.73	0.70	0.66	0.63
62%	1.03	0.98	0.93	0.88	0.84	0.80
70%	1.17	1.11	1.05	1.00	0.95	0.90
80%	1.35	1.27	1.21	1.15	1.09	1.04

Source: EH analysis

Figure 4: US DMX-200 Pricing vs Peak Market Share

USA Market Share (Peak, %)	USA DMX-200 Pricing (US$'000s p.a.) 80	90	100	110	120	130
10%	0.52	0.53	0.54	0.57	0.58	0.60
20%	0.62	0.64	0.66	0.71	0.73	0.76
30%	0.73	0.77	0.80	0.82	0.85	0.89
40%	0.81	0.85	0.90	0.93	0.97	1.01
50%	0.90	0.94	0.99	1.03	1.08	1.12
60%	0.97	1.02	1.08	1.13	1.19	1.25

Source: EH analysis

Figure 5: EU DMX-200 Pricing vs Peak Market Share

EU Market Share (Peak, %)	EU DMX-200 Pricing (US$'000s p.a.) 50	60	70	80	90	100
10%	0.49	0.50	0.52	0.54	0.56	0.58
20%	0.58	0.61	0.65	0.69	0.73	0.78
30%	0.67	0.73	0.80	0.85	0.92	0.97
40%	0.78	0.85	0.93	1.00	1.07	1.15
50%	0.88	0.97	1.05	1.15	1.23	1.32
60%	0.97	1.07	1.18	1.28	1.38	1.48

Source: EH analysis

Figure 6: Overall US FSGS Prevalence vs Peak Market Share

USA Market Share (Peak, %)	Overall USA FSGS Prevalence ('000s)* 30	40	50	60	70	80
10%	0.52	0.54	0.59	0.61	0.64	0.66
20%	0.61	0.66	0.74	0.80	0.84	0.90
30%	0.71	0.80	0.87	0.94	1.01	1.08
40%	0.80	0.90	0.99	1.08	1.17	1.27
50%	0.87	0.99	1.10	1.22	1.34	1.45
60%	0.94	1.08	1.22	1.36	1.50	1.63

*Source: EH analysis, *Drives target patient population assuming 80% are primary FSGS and 60% are steroid resistant*

Figure 7: Overall EU FSGS Prevalence vs Peak Market Share

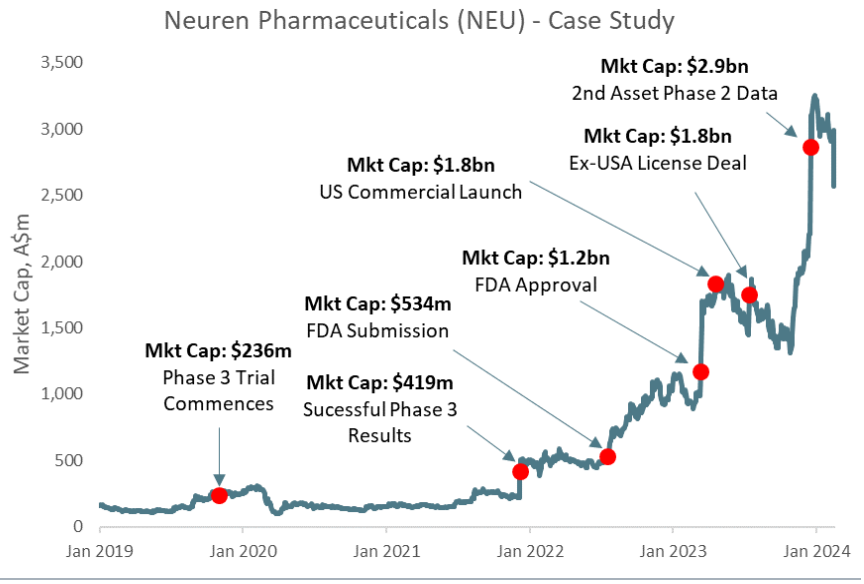
EU Market Share (Peak, %)	Overall EU FSGS Prevalence ('000s)* 30	40	50	60	70	80
10%	0.49	0.52	0.55	0.59	0.62	0.65
20%	0.59	0.65	0.73	0.80	0.87	0.93
30%	0.68	0.80	0.90	0.99	1.08	1.18
40%	0.80	0.93	1.05	1.18	1.30	1.42
50%	0.90	1.05	1.21	1.36	1.51	1.66
60%	0.99	1.18	1.36	1.54	1.72	1.90

*Source: EH analysis, *Drives target patient population assuming 80% are primary FSGS and 60% are steroid resistant*

Case Study – Potential Revaluation

Neuren Pharmaceuticals (ASX: NEU) presents a compelling case study of the revaluation that can follow a successful phase 3 study and subsequent regulatory approval for a biotech company like DXB (Figure 8).

Figure 8: Neuren Pharmaceuticals (NEU) Market Cap



Source: Bloomberg LP, company announcements, EH analysis

While no comparison is perfect, we see a number of similarities between NEU and DXB (Figure 9).

Figure 9: Neuren Pharmaceuticals (NEU) / Dimerix (DXB) Comparison

Company	Neuren Pharmaceuticals (NEU)	Dimerix (DXB)
Lead Asset	DAYBUE (trofinetide)	DMX-200
Rare Disease Focus / First Approved Treatment	DAYBUE is the first FDA-approved treatment for Rett Syndrome, a rare neurological disorder, and has orphan drug designation.	DMX-200 is being developed as the first potential FDA approved treatment for FSGS, a rare kidney disease, and has orphan drug designation.
Total Addressable market (TAM)	USA*: ~US$1.9 billion (A$2.9 billion)	USA**: est. US$1.9 billion (A$3.0 billion) EU/UK**: est. US$1.3 billion (A$2.1 billion)
Licensing Agreement Prior to Phase 3 Results	NEU secured a US licensing agreement for DAYBUE with Acadia Pharmaceuticals (NASDAQ: ACAD), including an initial US$10m upfront, up to US$455m in milestone payments, and a 10-15% tiered royalty on net sales, prior to its phase 3 study. Following DAYBUE'S US approval and launch, NEU expanded the agreement with Acadia into a worldwide license.	DXB secured a licensing agreement in Europe and select regions for DMX-200 with Advanz Pharma (private), receiving an initial €6.5m upfront, up to €132.5m in potential milestone payments, and a 15-20% tiered royalty on net sales. The company has also received multiple non-binding term sheets for global and regional deals, with the USA and China representing multi-billion-dollar markets still to be licensed.

Source: EH analysis, NEU company announcements, DXB company announcements
**based on 5,000 currently identified patients with Rett and US$375,000 price; **EH estimates, see Figure 36 for details; 0.65 AU/US*

For illustrative purposes, if DXB achieved market valuations similar to NEU at comparable milestones, the equivalent diluted share price for DXB would be as follows:

- Daybue Phase 3 success – $0.70 equivalent DXB share price
- Daybue FDA Submission – $0.89 equivalent DXB share price
- Daybue FDA Approval –$1.94 equivalent DXB share price
- Daybue US Launch – $3.04 equivalent DXB share price

Clearly, NEU and DXB differ in various other ways. However, we believe this case study highlights the significant potential upside possible for DXB, should it attain a level of success comparable to NEU. Conversely, it also underscores the low success currently priced into DXB's $175m diluted market cap.

Key Risks

We outline key risks to our investment case below:

- **Clinical Development** – The success of the Phase 3 clinical trial of DXB's lead asset, DMX-200, for the treatment of Focal Segmental Glomerulosclerosis (FSGS) is key to our investment case. There is also risk in the development of DXB's other pipeline programs.
- **Regulatory –** Securing regulatory approval in key jurisdictions, including the United States and Europe, is required to commercialise DMX-200 in FSGS. Moreover, regulatory benefits that come with orphan drug designation are key to the commercial value of DMX-200 in FSGS. Any changes to the regulatory landscape could impact the business.
- **Intellectual Property –** DXB maintains an extensive intellectual property portfolio, loss or issues surrounding these patents could impact the business.
- **Key Personnel** – The company has a number of experienced key personnel. Loss of any key individuals could impact the business.
- **Commercialisation** – The future commercial success of DMX-200 in FSGS is key to our investment case.
- **Competition** – While DXB is the most advanced and promising asset in development for FSGS, the development of competing drugs is a potential risk. We have extensively evaluated key competitors in this report (see page 35).
- **Funding** – While we estimate the company is fully funded to complete the phase 3 trial of DMX-200 in FSGS, funding will remain a potential risk until the business is cash flow positive.

Company Overview

Dimerix Ltd (DXB) is a late stage biotechnology company focused on inflammatory diseases, with programs targeting kidney and respiratory conditions.

Figure 10: Company logo

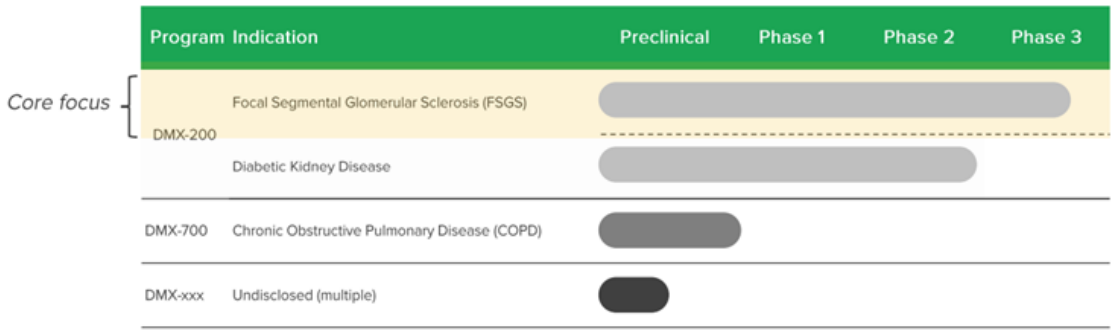
Source: company website

The company's lead asset, DMX-200 (QYTOVRA®), is being evaluated in a global phase 3 clinical study as a treatment for Focal Segmental Glomerulosclerosis (FSGS), a rare kidney disease with granted orphan drug designation.

In 2023, DXB executed a landmark $230m licensing agreement for DXM-200 in FSGS covering the European Economic Area and other select regions. The company is in active negotiations over potential licensing deals for other regions, having received various non-binding offers to date.

Dimerix has a development pipeline of other programs targeting Diabetic Kidney Disease (DKD), Chronic Obstructive Pulmonary Disease (COPD), and other undisclosed indications (Figure 11).

Figure 11: DXB Development Pipeline



Source: Company presentation

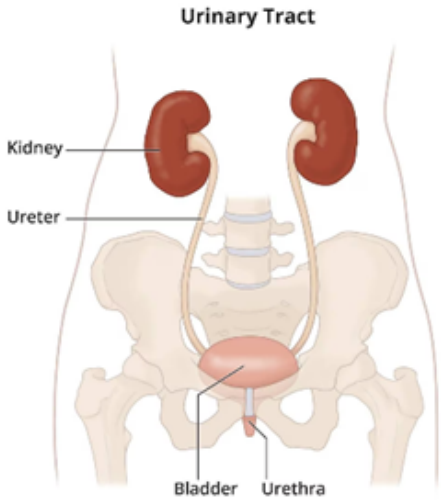
The company was founded in 2004 around its cell-based assay technology, Receptor-HIT (Heteromer Investigation Technology). The platform technology enables the identification of pairs of different receptors that function in a joint manner, compared to traditional cell-based assays which only focus on a single receptor target.

Using this technology, DXB has been able to identify new drug targets with unique pharmacology, enabling the development of its key assets including DMX-200 and DMX-700. See page 37 for further discussion.

Kidneys & Damage

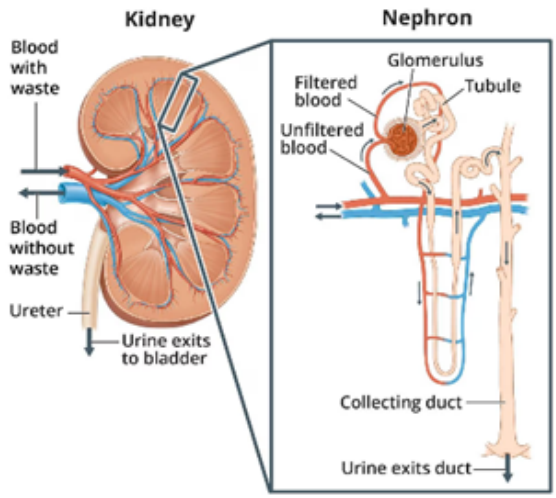
Kidneys play a vital role in filtering waste from the blood, regulating blood pressure, and producing hormones, amongst other functions.

Figure 12: Kidney Location Diagram



Source: NIH

Figure 13: Kidney and Nephron Diagram

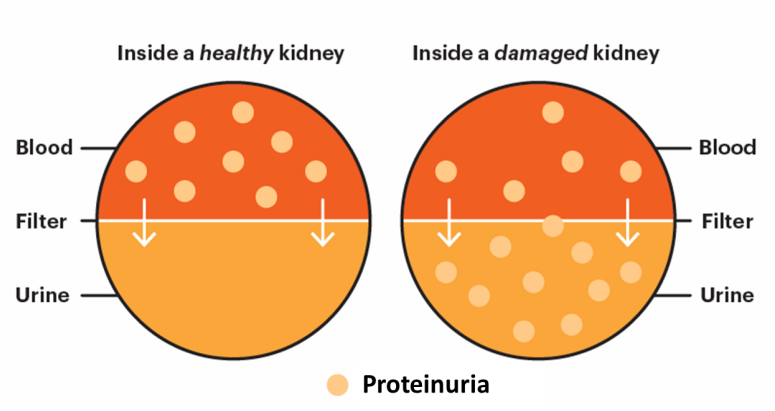


Source: NIH

Each kidney is made up of over a million specialised filtering units called glomeruli. As blood flows through the glomeruli, they retain proteins and other essential nutrients and minerals, while removing excess fluid and waste.

When these filtering units become damaged (Figure 14), protein can start to leak into the urine. This is known as proteinuria (any type of protein in the urine) or albuminuria (a specific type of protein in urine called albumin).

Figure 14: Damaged Kidney Illustration



Source: National Kidney Foundation

The presence of proteinuria is an early marker of kidney damage

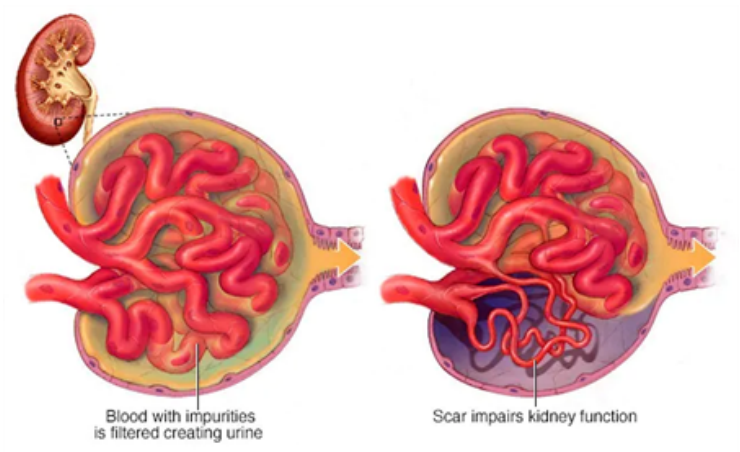
Over a longer reference period, the overall function of the kidneys is best characterised by its filtration rate, known as the glomerular filtration rate (GFR), and calculated as an estimated glomerular filtration rate (eGFR). However, eGFR can be a relatively slow indicator of kidney damage, often only becoming apparent in the later stages of kidney damage.

Focal Segmental Glomerulosclerosis (FSGS)

Focal Segmental Glomerulosclerosis (FSGS) is a rare disease that attacks the kidney filtering units (glomeruli) causing progressive and irreversible kidney damage.

The name refers to some (**focal, F)** sections (**segmental, S**) of the kidneys filtering units (**glomerulo-, G**) becoming scarred (**sclerosis, S**).

Figure 15: Normal Glomeruli vs Glomeruli with FSGS



Source: Mayo Clinic

FSGS eventually leads to kidney failure, requiring dialysis or a kidney transplant, or ultimately resulting in death. Moreover, **60% of patients who receive a kidney transplant have recurring FSGS**.

On average, patients with FSGS progress to kidney failure within five years following the onset of proteinuria.

FSGS is defined as a histological pattern of glomerular injury caused by a variety of conditions. The underlying cause of FSGS is often unknown.

FSGS is diagnosed through a kidney biopsy.

The classification of FSGS has evolved in recent years, causing some confusion. Nevertheless, the current clinical guidelines from KDIGO categorise FSGS into four broad types:

- **Primary FSGS** – Most common type; underlying cause often unknown with nephrotic syndrome.
- **Genetic FSGS** – Rare form of FSGS caused by genetic mutation. Several genes are known to involved (e.g. APOL1 gene).
- **FSGS of Unknown Cause** – Less common type of FSGS that is distinct from primary FSGS based on its clinical and histological manifestations. Could be patients with genetic or secondary FSGS not yet known.
- **Secondary FSGS** – Less common (estimated to be 20% of overall FSGS cases). Can be caused by another disease (e.g. HIV) or drug (e.g. steroids).

Data on the distribution of FSGS cases between these categories is limited and further complicated by recent changes in the classification system. However, we estimate 80% of cases are either primary FSGS, genetic FSGS or FSGS of unknown cause (otherwise put, 20% of cases are secondary FSGS).

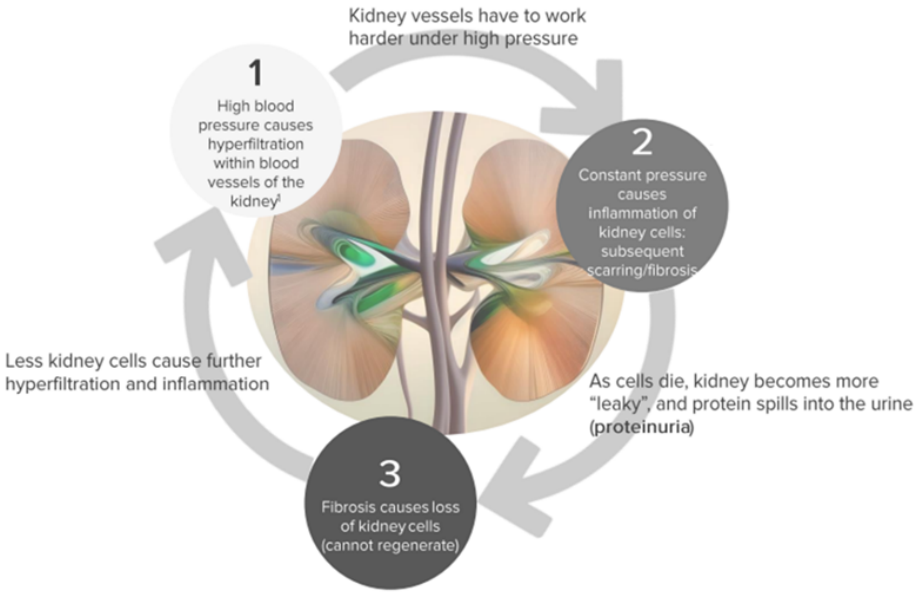
DMX-200 is effective in treating all forms of FSGS except for secondary FSGS, covering an estimated 80% of FSGS cases. For secondary FSGS, treatment focuses on addressing the underlying condition (e.g. treating HIV).

FSGS Pathogenesis

Although the underlying cause of FSGS remains unknown (idiopathic) in most cases, the leading hypothesis suggests that one or several circulating factors might be involved in causing the damage. The strongest support for this hypothesis comes from the significant number of patients who see a recurrence of FSGS after receiving a kidney transplant.

Patients with FSGS experience a progression of damage in a self-perpetuating cycle, where initial damage exacerbates the strain on the kidneys, thereby accelerating further deterioration. The progression of FSGS is illustrated in Figure 16.

Figure 16: Progression of FSGS Kidney Disease



Source: Company presentation, EH analysis

FSGS Current Standard of Care

There are currently no approved treatments specifically for FSGS.

Standard of care for primary FSGS is currently limited to immunosuppressants. These medications have limited efficacy and can have serious side effects.

- **Glucocorticoids** – High-dose oral glucocorticoids (part of corticosteroids class of drugs), such as prednisone, are recommended as a first line therapy. Glucocorticoids work by suppressing inflammation, however less than 30% of patients see a response, and most relapse following treatment. Glucocorticoids cannot be used long term and have various potential serious side effects including endocrine disruption, increased infection risk, cardiovascular and neurological issues, amongst others things.
- **Calcineurin Inhibitors (CNIs)** – Calcineurin inhibitors, such as cyclosporine or tacrolimus, are recommended as a second line therapy. Relapse rates are common. CNIs also have various potential side effects, including nephrotoxicity which can cause kidney damage.

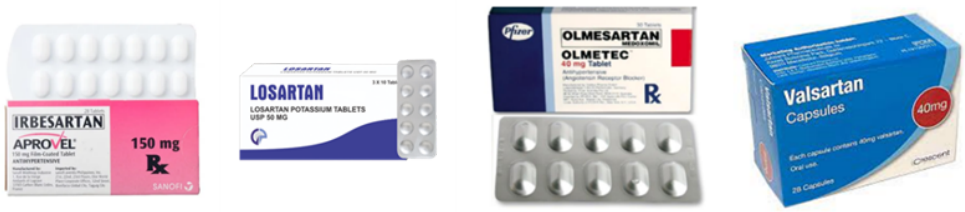
As previously discussed, secondary FSGS is treated by addressing the underlying condition.

More broadly, any patient with a glomerular disease including FSGS, will typically receive a Renin-Angiotensin System (RAS) blocker, such as:

- **Angiotensin Receptor Blockers (ARBs)** – ARBs effectively manage blood pressure by reducing the effect of angiotensin II, a powerful hormone with vasoconstriction effects; or
- **Angiotensin-Converting Enzyme (ACE) inhibitors** – ACE's have a similar effect to ARBs in reducing blood pressure, however work on a different pathway.

The use of ARBs in particular are highly relevant to the mechanism of DMX-200 in FSGS, as we will discuss in following sections (see page 15).

Figure 17: Angiotensin Receptor Blockers (ARBs)



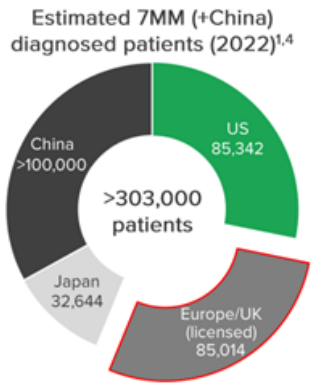
Source: Various websites

As patients progress to end-stage renal disease (ESRD), where the kidneys fail to function, patients must undergo dialysis or receive a kidney transplant to survive. While dialysis can temporarily replace the kidney's function, it significantly shortens life expectancy, usually to 5-10 years. Moreover, kidney transplant recipients face their own challenges, with up to 60% experiencing a recurrence of FSGS.

FSGS Prevalence

FSGS is a rare disease. Estimates range from circa 40,000 to 85,000 patients living with FSGS in the United States alone, and a similar number in Europe. Globally, there may be more than 303,000 patients living with FSGS in the seven major markets including China (Figure 18).

Figure 18: FSGS Estimated Prevalence



Source: company presentation

Incidence rates can vary and are likely understated as FSGS is diagnosed by kidney biopsy. Moreover, incidence has likely increased and will continue to increase with growing rates of kidney biopsies. For instance, Australia has reported one of the highest incidence rates of FSGS, attributable to its liberal use of kidney biopsies.

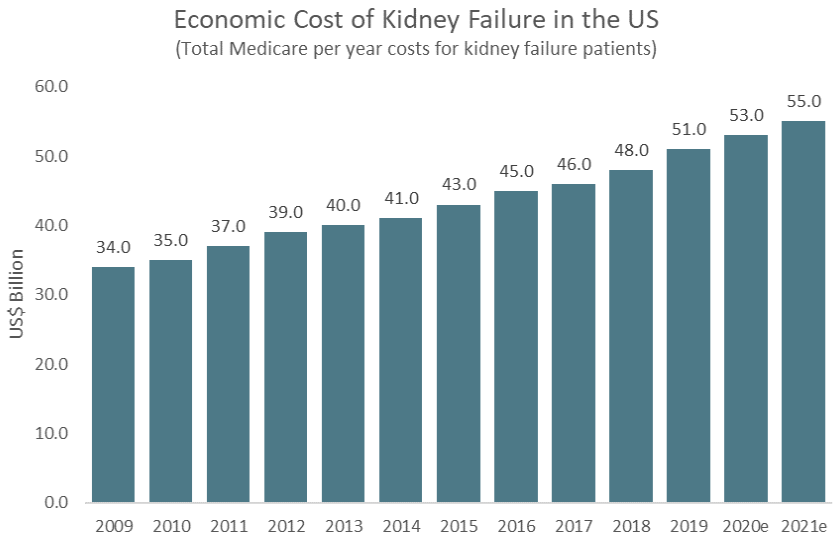
Importantly, given FSGS is diagnosed by a kidney biopsy, a medical procedure. These same patient estimates likely represent patients who would also have reimbursement coverage for emerging treatments such as DMX-200.

Kidney Disease Economic Impact

Kidney disease has one of the highest burdens on healthcare systems globally.

Treatment following kidney failure constitutes a significant portion of the overall spending on kidney disease. In the United States alone, kidney failure amounts to US$55 billion in annual expenses to Medicare.

Figure 19: Kidney Failure Burden in the United States



Source: company presentation, The United States Renal Data System (USRD), EH analysis

The cost of treating kidney failure are as follows in the United States:

- **Dialysis** – Estimated to cost US$90,000 per patient per year.
- **Kidney Transplant** – Estimated to cost US$442,500 per transplant in addition to ongoing medication costs.

As previously discussed, patients with FSGS on average will progress to kidney failure within five years from the onset of proteinuria. Moreover, 60% of patients who receive a kidney transplant will have recurring FSGS, compounding the above costs.

DMX-200

Overview

DMX-200 (branded as QYTOVRA® in some territories, Figure 20, also known as repagermanium) is an orally active small molecule C-C chemokine receptor type 2 (CCR2) antagonist (blocker).

Figure 20: DMX-200, or QYTOVRA® in some territories

QYTOVRA® [REPAGERMANIUM]

Source: Company website

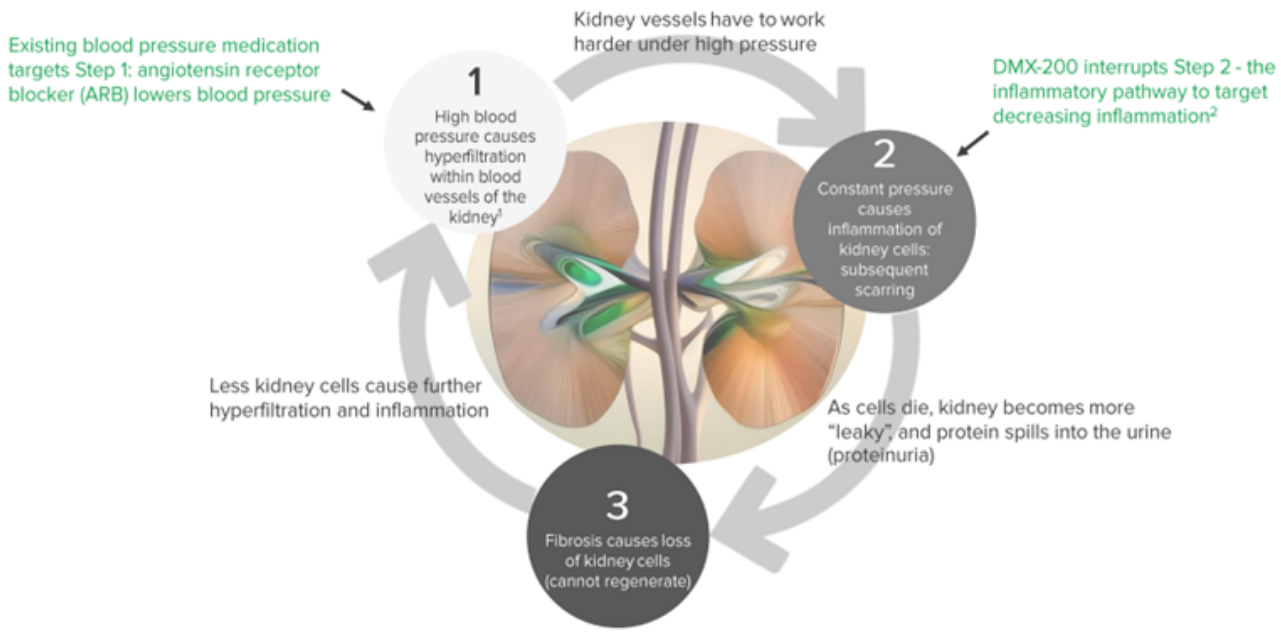
DMX-200 is designed to be administered as an adjunct therapy to patients receiving angiotensin II type I receptor (AT1R) blockers (ARBs), the standard of care for any glomerular disease, including FSGS.

DMX-200 inhibits the recruitment of inflammatory cells to the kidneys, while the ARB reduces hyperfiltration through mediating vasoconstriction (reducing blood pressure) – both are key aspects in the progression of FSGS (Figure 21).

Importantly, the co-administration of DMX-200 and an ARB generates a synergistic, more than additive, therapeutic benefit in slowing FSGS disease progression.

We view this mechanism as particularly ideal for FSGS as it is agnostic to the upstream causes and instead targets the downstream drivers of the disease.

Figure 21: DMX-200/ARB in FSGS Disease Progression



Source: company presentation

DMX-200 is currently being evaluated in a global phase 3 clinical trial, with interim results (potentially enabling accelerated approval) anticipated mid-CY2025.

If successful, DMX-200 could be on market sometime in 1H CY2026 as the first approved treatment for FSGS.

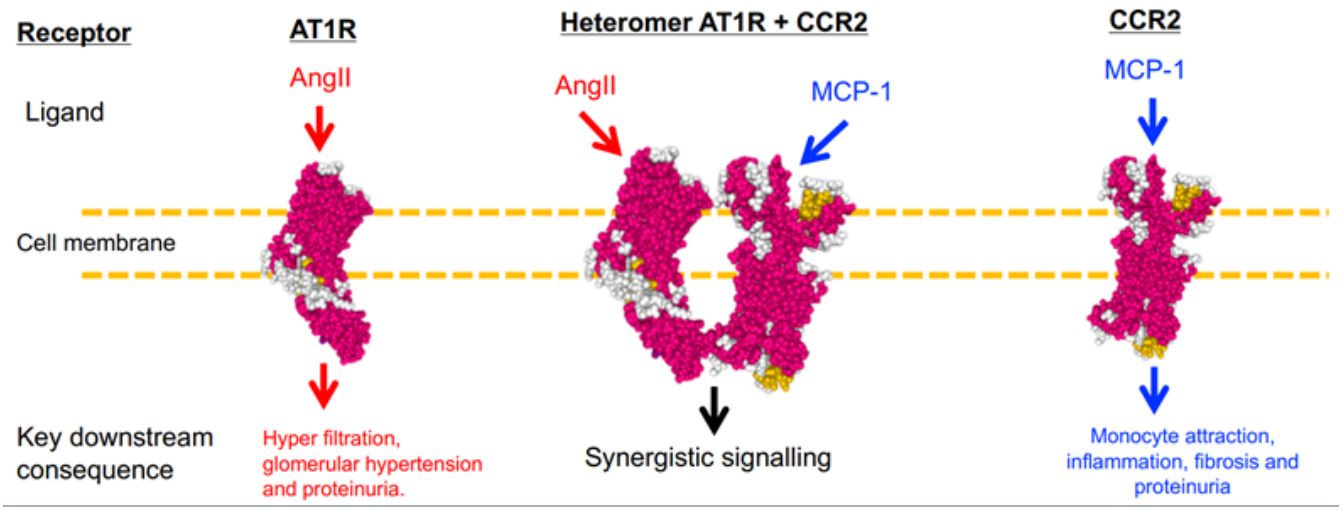
Mechanism of Action

DMX-200 is a C-C chemokine receptor type 2 (CCR2) inhibitor, whereas ARBs, which are standard treatment for any glomerular disease, are angiotensin II type I receptor (AT1R) inhibitors.

CCR2 and AT1R are both known to play roles in the development of glomerulopathies, including FSGS. However, the key breakthrough lies in how these receptors can form functional heteromer complexes in certain cells with pharmacology that differs from their respective units – which DXB discovered using their proprietary tool (Receptor-HIT, see page 37).

In these CCR2/AT1R heteromer complexes, AT1R activation can activate CCR2, known as transactivation. Therefore, to effectively inhibit CCR2, it requires inhibiting both CCR2 and AT1R. This also illustrates the mechanism behind how a greater than additive benefit is created when DMX-200 is administered alongside an ARB (Figure 22).

Figure 22: CCR2/AT1R Heteromer Complex



Source: company presentation

CCR2's ligand, MCP- 1 (monocyte chemoattractant protein 1, also known as CCL2), is a signalling protein responsible for movement of immune cells throughout the body, including the kidneys.

Through inhibiting the CCR2 receptor, DMX-200 is able to reduce the inflammation of kidney cells and subsequent scarring.

Additionally, the CCR2/CCL2 system has been shown to play a role in the depletion of certain kidney cells (podocytes) and the development of protein in the urine (proteinuria).

Angiotensin II type 1 receptor, AT1R, is a well-established therapeutic target within the renin-angiotensin system (RAS), involved in regulating blood pressure and fluid balance. Its ligand, a hormone called angiotensin II, has powerful vasoconstriction (narrowing of blood vessels) effects, which increases blood pressure. Angiotensin II also drives salt and water retention, which further increases blood pressure.

ARBs, through their inhibition of AT1R, are able to reduce blood pressure and by extension hyperfiltration in the kidneys.

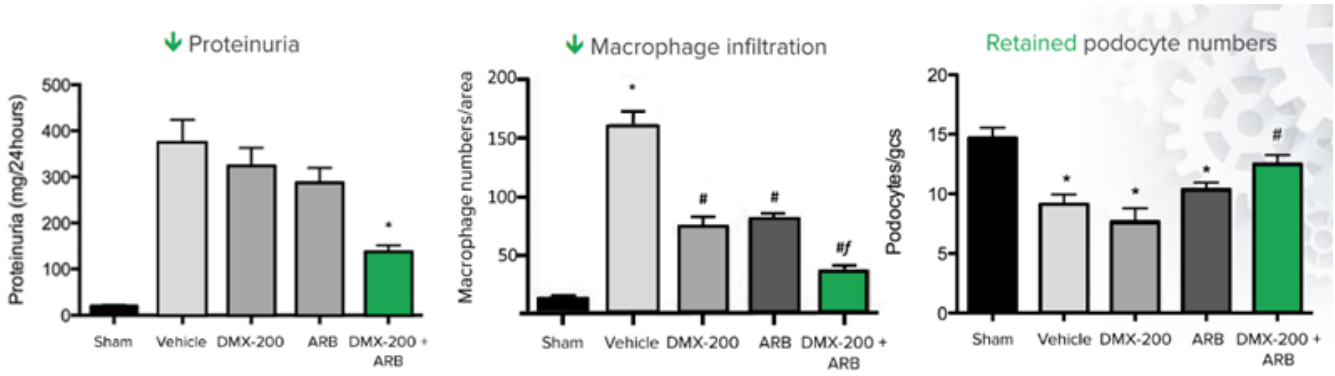
Preclinical Studies

DMX-200 has been evaluated in various preclinical animal models.

We highlight below results across three biomarkers highly relevant in FSGS disease progression, which show the synergistic effect of DMX-200 when administered alongside an ARB (Figure 23). These biomarkers include:

- Decreased proteinuria (protein in the urine; hallmarker of kidney damage);
- Decreased macrophage (immune cells) infiltration; and
- Retained podocyte (retention of important kidney cells)

Figure 23: Preclinical Results Across Select Biomarkers



Source: company presentation

Clinical Development Overview

DMX-200 is currently in a global phase 3 clinical trial for FSGS, having previously been evaluated across a number of human clinical trials.

The company anticipates interim results from this phase 3 trial around mid-CY2025 based on current recruitment rates. If successful, the results could provide a pathway for accelerated approval as a treatment for FSGS and potentially enable the drug to be on market sometime in 1H'CY2026.

We have explored these clinical studies below.

Defining Clinically Meaningful in FSGS

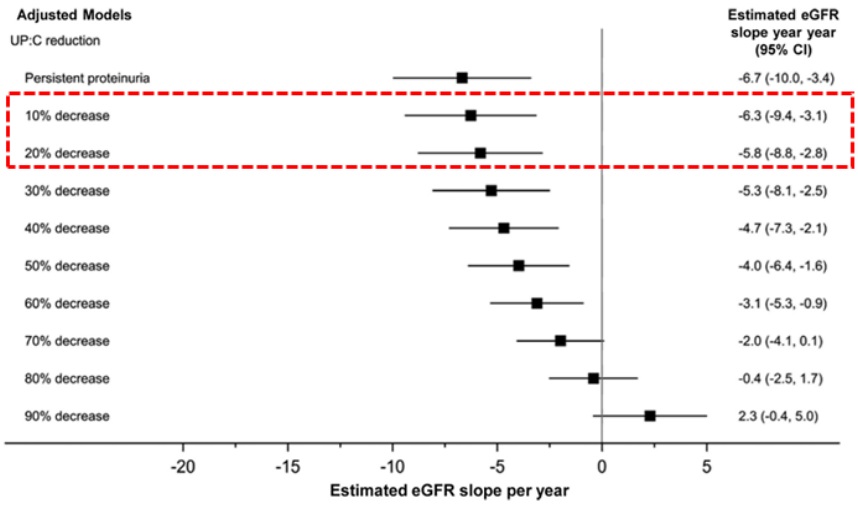
Every 10% reduction in proteinuria (protein in the urine; marker of kidney damage) has been shown to be clinically meaningful.

This has evolved as regulators have concluded incremental changes in kidney function are clinically meaningful.

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

In a subsequent publication, it was shown every 10% reduction in proteinuria correlated to an eGFR slope reduction of 0.5-1.0 ml/min/1.73m^2/year (Figure 24).

Figure 24: eGFR slope relationship to proteinuria change



Source: Troost et al, August 2020

Phase 2 Clinical Study (ACTION) – Completed 2020

DXB successfully completed a Phase 2a clinical trial of DMX-200 in FSGS in 2020 (ID: NCT03649152), termed the ACTION (AT1R and CCR2 targets for inflammatory nephrosis) study.

The double-blind, randomised, placebo-controlled, crossover study evaluated the safety and efficacy of DMX-200 in 8 patients with primary FSGS receiving a stable dose of irbesartan (an angiotensin receptor blocker; ARB).

In a cross over study, each patient serves as their own control. This effectively doubled the study's size to an equivalent of 16 patients, as well as also minimising variability among patients.

The study's primary endpoint was safety, with a secondary efficacy endpoint based on proteinuria. MCP-1 (inflammatory cells) were also measured as an exploratory endpoint. eGFR was not collected as the study was too short.

Patients first underwent a screening visit and a baseline assessment prior to randomisation, which required:

- Confirmation of primary FSGS by renal biopsy. We note the classification of primary FSGS has since changed. The equivalent being the combination of primary FSGS, genetic FSGS, and FSGS of unknown cause.
- Stabilisation of irbesartan 300 mg/day treatment for a minimum of 3 months prior to, and throughout the study, including during the washout period.

Once randomised, patients received treatment over two 16-week periods, separated by a 6-week washout period and a final follow up (Figure 25).

Figure 25: Phase 2a Study Design

Source: ACTION study poster
B/L = baseline (1 week), WO = washout (6 weeks), Follow = follow up period (4 weeks after last dose of treatment)

Efficacy

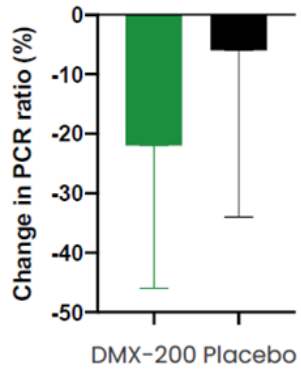
FSGS patients treated with DMX-200 saw a clinically meaningful 17% geometric mean reduction in proteinuria against placebo (figure 26).

In total, 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo, with 29% of patients showing a greater than 40% reduction in proteinuria.

Moreover, given patients are also on irbesartan, the equivalent total mean reduction in proteinuria is more like 35% (based on published data on irbesartan, figure 27).

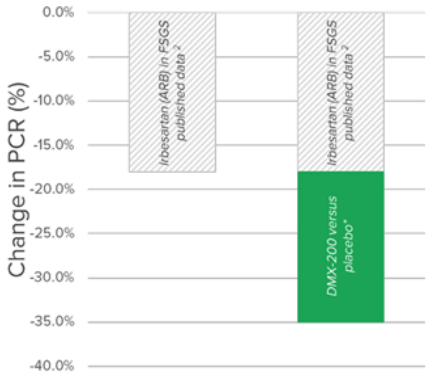
The primary limitation of these results is the small sample size (not uncommon for a rare disease), which also meant it was not sufficiently powered to produce a statistical result. Additionally, the cross-over design and short length could be understating the full potential of DMX-200.

Figure 26: Change in Proteinuria (using PCR)



Source: ACTION poster

Figure 27: Equivalent Change in Proteinuria (using PCR)

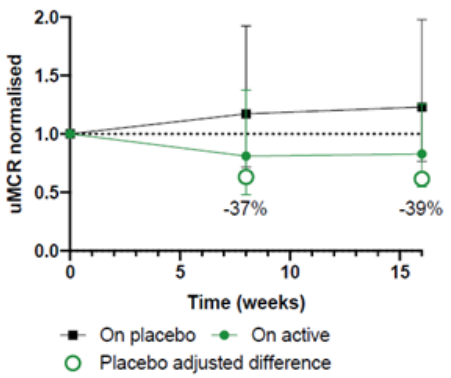


Source: ACTION poster

The small placebo effect may be due to the short trial length and initial lifestyle changes by participants, leading to a temporary proteinuria improvement that is likely to fade out in a longer study.

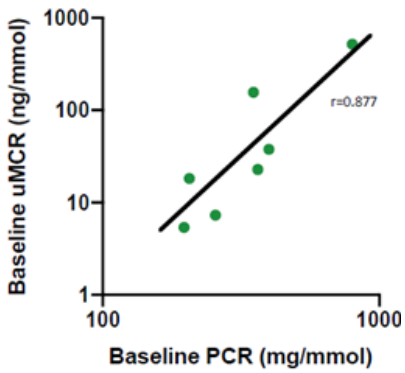
These results were further supported by a 39% reduction in inflammatory biomarker MCP-1 in DMX-200 treated patients (figure 28), collected as an exploratory endpoint. As discussed on page 11, inflammation is a key aspect in the progression of FSGS.

Figure 28: MCP-1 Reduction



Source: ACTION poster

Figure 29: MCP-1/Proteinuria Correlation



Source: ACTION poster

This data also demonstrated a correlation between MCP-1 and proteinuria (Figure 29).

Safety

DMX-200 was well tolerated with no treatment-emergent adverse events (TEAEs) related to the drug and no patient withdrawals from the study.

Any adverse events were consistent with the underlying patient and population comorbidities.

Figure 30: Patients with Treatment Emergent Adverse Events (TEAEs)

	DMX-200	Placebo
Any	7	6
Drug-related	0	0
Serious	1^	0
Leading to dose interruption	0	0
Leading to study withdrawal	0	0
Death	0	0

^tendonitis

Source: company presentation

Pivotal Phase 3 (ACTION3) – Ongoing

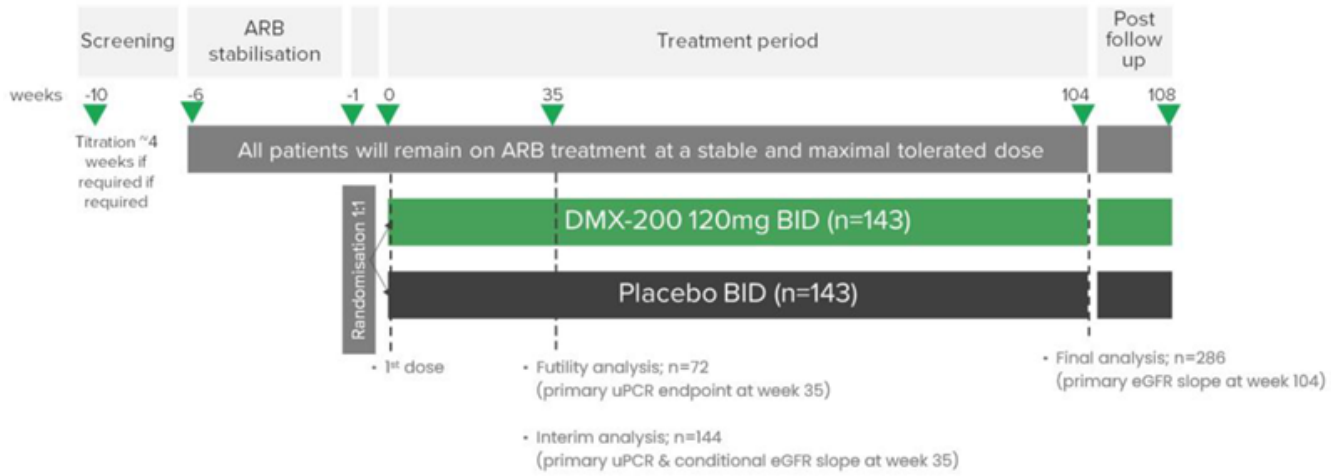
DXB initiated a pivotal global phase 3 clinical trial of DMX-200 in FSGS in 2022 (ID: NCT05183646), termed the ACTION3 study.

The study aims to replicate the phase 2a results with a significantly larger patient cohort, to enable regulatory approval of DMX-200 in key markets such as the United States and Europe.

The multicentre, randomised, double-blind, placebo-controlled study is investigating the safety and efficacy of DMX-200 in patients with FSGS on a stable ARB (angiotensin receptor blocker).

The trial is being run by IQVIA, the world's largest contract research organisation, with extensive and recent experience in running late-stage global FSGS clinical studies.

Figure 31: Phase 3 Trial Design



Source: ACTION3 poster

The study, initiated in 2022, is currently recruiting in 11 countries across 70 sites with plans to open up to 167 sites in 18 countries (figure 32). The study will look to recruit a total of 286 patients for the final readout, with interim readouts at 72 (completed) and 144 (expected mid-CY2025) patients. To date, 97 patients have been recruited.

Figure 32: ACTION3 Recruitment Sites

Source: company presentation

The trial has been designed with an inclusion/exclusion criteria broadly similar to the previous phase 2 study.

Once recruited, patients initially undergo a background medication stabilisation period, which includes a minimum of 6-weeks on a stable ARB. Patients are then rescreened and randomised into either receiving DMX-200 120 mg or placebo twice daily (BID).

The trial has been designed with three analysis points, using two separate primary endpoints:

- **Blinded Futility Analysis**, successfully completed March 2024 – blinded analysis of first 72 patients at 35 weeks based on proteinuria.
- **Interim Analysis**, anticipated mid-CY2025 – interim analysis using a primary endpoint of percentage change in proteinuria from baseline in first 144 patients at 35 weeks, supported by an eGFR trend. Potential for accelerated approval.
- **Final Analysis**, anticipated CY2026/ CY2027 – Final analysis using a primary endpoint of change in eGFR slope (kidney function) from baseline in 286 patients at 104 weeks. Used for final approval.

Secondary endpoints include safety and tolerability, as well as evaluating the effect of DMX-200 on kidney function parameters.

Exploratory endpoints include various kidney function biomarkers, DMX-200 pharmacokinetics, and quality of life measures.

Futility Analysis (Part 1 Analysis) - Complete

Last month, DXB announced they successfully passed the futility analysis (part 1 analysis), showing DMX-200 was performing better than placebo in reducing proteinuria, based on a pre-specified statistical measure. This suggests a statistically and clinically meaningful result in reducing proteinuria at the end of the study may be possible.

This was a significant de-risking milestone, demonstrating DMX-200 was working in a patient cohort nearly 10x larger than the phase 2a study (72 patients vs 8 patients).

Moreover, no safety concerns were noted, consistent with the existing and growing safety profile of DMX-200.

This first analysis was blinded to maintain study integrity, with the data reviewed by an independent data monitoring committee (IDMC). We note DXB remains blinded at all times during the Phase 3 study.

Interim Readout (Part 2 Analysis) – Accelerated Approval Potential

The study will now progress onto the part 2 analysis, an interim analysis of the first 144 patients at 35 weeks. This being the first point where DXB can seek accelerated regulatory approval of DMX-200 subject to the analysis outcome and regulatory feedback.

Interim results are expected mid-CY2025. This timeline assumes the 144th patient is recruited on or before the end of October 2024 (requires 47 patients recruited over next ~175 days).

The primary endpoint of the interim analysis (statistically powered) is percentage change in proteinuria (based on PCR, 24-hour collection) from baseline at week 35. Change in eGFR (kidney function) from baseline will also be collected (not statistical powered).

Considering every 10% reduction in proteinuria is clinically meaningful (page 17), a result similar to the phase 2a could enable accelerated approval. However, based on FDA/EMA feedback this would likely also require a trend in eGFR.

Final Readout (Part 3 Analysis)

The final part 3 analysis will occur once the last of 286 patients completes 104 weeks of treatment. The primary endpoint for the final analysis is change in eGFR slope (kidney function) from baseline to week 104.

We anticipate the final readout sometime CY2026/ CY2027, subject to recruitment.

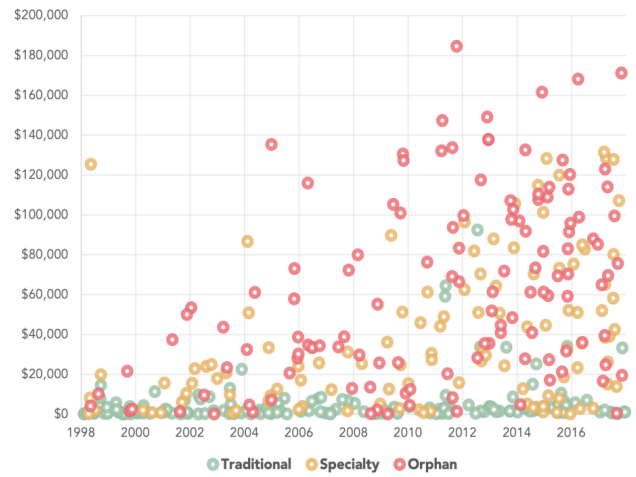
Orphan Drug Designation

FSGS is a rare disease with granted orphan drug designation. Orphan drugs come with significant regulatory and commercial incentives.

Pricing

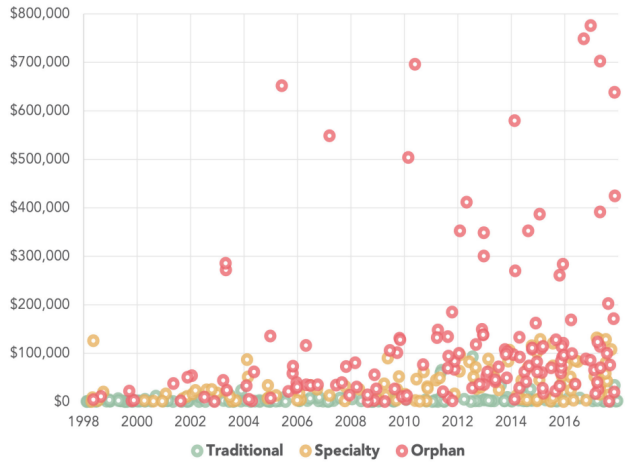
The primary benefit of orphan drugs is the commercially attractive pricing. The average annual cost for orphan drug at launch is ~US$123,500 (AHIP, 2019). The higher pricing is a function of the significantly smaller patient populations.

Figure 33: Annual Cost of Drugs at Launch: 1998-2017



Source: AHIP, The Rise of Orphan Drugs

Figure 34: Annual Cost of Drugs at Launch: 1998-2017, Expanded Axis



Source: AHIP, The Rise of Orphan Drugs

Regulatory

DMX-200 has been granted Orphan Drug Designation (ODD) status in both the United States and Europe, and the equivalent Innovative Licensing and Access Pathway (ILPA) designation in the UK, for the treatment of FSGS.

This designation comes with substantial regulatory and financial benefits to help bring new drugs to market faster, including:

- Reduced fees during the product development phase,
- Protocol assistance from the regulatory authorities; and
- Extended Market exclusivity: 7-years (United States) and 10-years (Europe)

Moreover, DXB has outlined a plan to expand the DMX-200 label to paediatric patients with the US FDA and EMA (paediatric investigation plan; PIP), which if approved will further extend the market exclusivity in the United States by 6-months (to 7.5-years) and in Europe by 2-years (to 12-years).

Regulatory Pathway

Accelerated Approval

DXB could potentially seek accelerated approval (known as conditional marketing approval in Europe) for DMX-200 at the part 2 analysis outcome (interim analysis), which is anticipated around mid-CY2025, subject to recruitment.

In advice provided to DXB, the FDA confirmed that improvement in proteinuria was an acceptable surrogate endpoint for accelerated approval in the United States, subject to sufficient demonstration of the relationship to kidney functions (based on eGFR slope). The European Medicines Agency (EMA) similarly confirmed this pathway could support conditional marketing approval (equivalent to accelerated approval) in Europe.

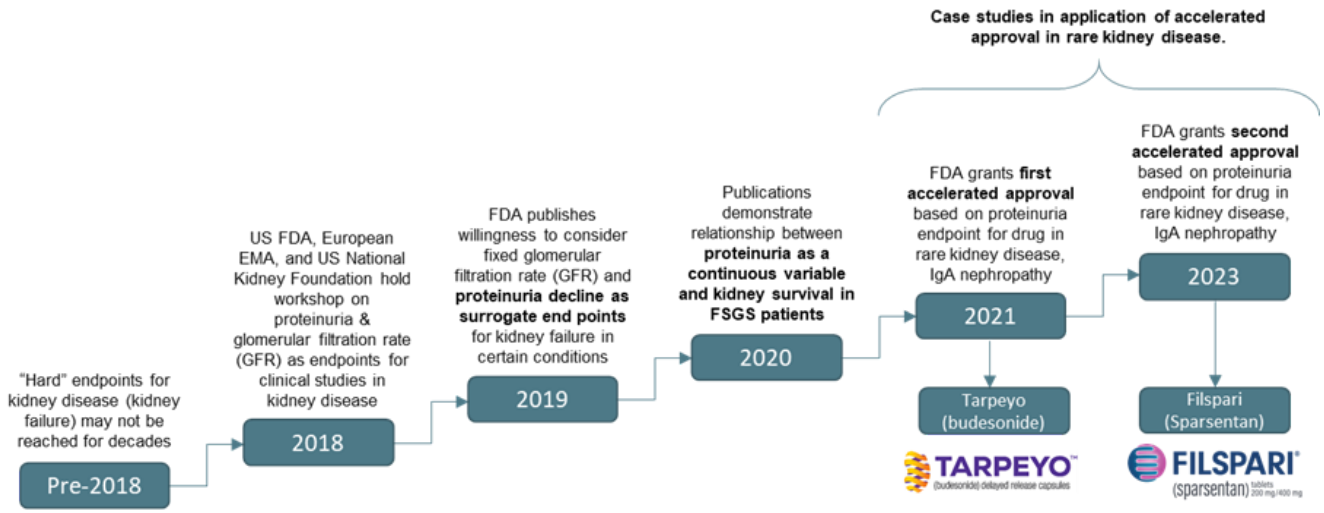
Moreover, we note there is recent precedent in other rare kidney diseases where the FDA granted accelerated approval based on a proteinuria surrogate endpoint. This includes:

- **Tarpeyo (budesonide)** – FDA granted first ever accelerated approval in 2021 for a drug based on a proteinuria endpoint in IgA nephropathy, a rare kidney disease; and
- **Filspari (sparsentan)** – FDA granted second accelerated approval in 2023 for a drug based on a proteinuria endpoint in IgA nephropathy.

We note IgA nephropathy has a similar rarity to FSGS and prior to the approval of these therapies also had a significant unmet need. Arguably, FSGS has a greater unmet need as there are currently no approved treatments.

More broadly, this highlights the significant changes to the regulatory landscape in recent years, which has simplified the process for advancing therapies for rare kidney diseases. This is shown in Figure 35.

Figure 35: Regulatory Landscape, Use of Surrogate Endpoints in Kidney Disease



Source: EH analysis, company presentation, other sources

The only difference to the above examples is DXB's requirement to further support the relationship between proteinuria and kidney function (eGFR). Whereas considerable work was done in IgA nephropathy to show a relationship prior to the approvals of Tarpeyo and Filspari. As we illustrate in Figure 24, there is existing evidence on this relationship.

We note DXB would still be required to finish the ACTION3 phase 3 clinical trial if accelerated approval is received. The final results of the trial would then be used to secure a traditional approval. If the results do not show a benefit, the accelerated approval can be revoked.

Priority Review

We believe DMX-200 could qualify for FDA priority review as FSGS has no approved treatments and presents a significant unmet need. This would reduce the review time of the New Drug Application (NDA) from the standard 10 months down to 6 months. The EMA has a similar pathway known as the Accelerated Assessment Procedure, which reduces the review time frame from 210 days to 150 days.

Similarly, we note there is precedent in another rare kidney disease where the FDA and EMA granted priority review (or Accelerated Assessment Procedure).

In 2021, the FDA granted priority review for an accelerated approval application of Tarpeyo (budesonide) in IgA nephropathy, a rare kidney disease. In that same year, the EMA also granted Accelerated Assessment Procedure for Tarpeyo.

Assuming successful Part 2 interim results in mid-CY2025 and being granted priority review as part of an accelerated approval application, DMX-200 could potentially be approved and on market sometime in 1H'CY2026. Clearly this is subject to recruitment, successful interim results and regulatory feedback.

Market Opportunity

We estimate the total addressable market (TAM) for DMX-200 in the treatment of FSGS could be worth **+A$5 billion per annum in total across the US and Europe.**

Figure 36: Estimated Total Addressable Market (TAM)

	Units	USA	EU/UK	Combined
Diagnosed FSGS Patients	**'000s**	**40.0**	**40.0**	**80.0**
(x) Est Primary FSGS	%	80%	80%	
Primary FSGS	**'000s**	**32**	**32**	**64.0**
(x) Est Steroid Resistant	%	60%	60%	
Treatment Resistant FSGS	**'000s**	**19.2**	**19.2**	**38.4**
(x) Assumed Pricing	US$'000s/pa	100	70	
Est Total Addressable Market	**US$m**	**1,920**	**1,344**	**3,264**
Est Total Addressable Market	**A$m**	**2,954**	**2,068**	**5,022**

Source: EH analysis, 0.65 AUD/USD

Eligible Patient Population

We estimate there are circa 19,000 patients likely eligible to be treated with DMX-200 in both the United States and Europe.

Estimates range from 40,000 to 85,000 patients living with some form of FSGS in the United States alone, and a similar number in Europe.

Taking the lower end figure, we estimate 80% of these patients either have primary FSGS, genetic FSGS or FSGS of unknown cause. These types of FSGS are applicable to DMX-200, whereas a patient with secondary FSGS (estimated to be 20% of total FSGS cases) would not be treated with DMX-200.

Further narrowing our estimates, we have assumed 60% of patients have steroid resistant FSGS. This being patients who do not see a response to standard of care, although, we note most of these patients eventually relapse. Hence, this estimate could be expanded.

As a cross check, we note Travere Therapeutics (NASDAQ: TVTX), which had been developing a drug for FSGS, quotes a US addressable market ranging from 15,000-30,000 patients. This aligns with our estimates.

Pricing

We conservatively assume DMX-200 will sell for US$100,000 per patient per annum in the United States, and US$70,000 per patient per annum in the EU/UK.

This pricing assumption is based on the market price of drugs for a similar rare kidney disease, IgA nephropathy (Figure 37). We have conservatively assumed a price ~30% below the average selling prices of these comparable drugs.

Figure 37: Comparable Rare Kidney Disease Pricing

Pricing		USA	EU/UK
Drug Name (Brand names)	Company	(US$/pa)	(US$/pa)
budesonide (TARPEYO, KINPEYGO)	Calliditas Therapeutics	169,920	99,487
sparsentan (FILSPARI™)	Travere Therapeutics	118,800	TBD*
Average		**144,360**	**99,487**

*Source: EH analysis; *Not yet approved by EMA*

This comparison is particularly relevant as IgA nephropathy has a similar rareness (~150k estimated cases in USA) and clinical unmet need as FSGS. Furthermore, these drugs were granted accelerated approval and commercialised based on a proteinuria endpoint, as we expect to occur with DMX-200.

That said, given FSGS is slightly rarer, DMX-200 may be able to achieve a higher price point. This represents additional upside to the potential market opportunity.

Commercialisation

DXB is pursuing a strategic out-licensing approach to commercialise DMX-200 in FSGS.

Advanz Pharma – Europe and Other Select Regions

As part of this strategy, the company executed a major $230m licensing agreement with Advanz Pharma in October last year, covering the European Economic Area (EEA), Switzerland, UK, Canada, Australia and New Zealand.

Commercial terms of the deal included:

- €6.5m ($10.8m) upfront payment
- Up to €132.5m ($219m) in potential development and sales milestone payments; and
- Tiered 15-20% royalty on net sales.

Advanz Pharma is a global pharmaceutical company, with a strategic focus on speciality, hospital and rare disease medicines.

Figure 38: Advanz Pharma logo

Source: company website

The private UK headquartered company has direct sales, marketing and medical capabilities with an established commercial presence in over 20 countries, including Europe, US, Canada and Australia. Latest public figures state the company had circa $1.1 billion (€665 million) of revenues in 2022. The company is backed by Nordic Capital (~A$49 billion AUM) and the Ontario Teachers' Pension Plan (~A$277 billion AUM).

We viewed this deal, which likely entailed considerable due diligence, as a significant commercial endorsement of DMX-200. This is a key pillar of our investment case.

This first agreement could drive substantial revenues. We provide a simple sensitivity analysis below illustrating potential royalty revenues based on the lower end royalty rate (15% of net sales) alone. We note these revenues fall straight to the bottom line as they have no associated costs.

Figure 39: EU Royalty Revenue Sensitivity (A$m)

Potential Advanz Royalty Revenue (A$m)							
		EU Market Share (Peak)					
		15%	30%	45%	60%	75%	90%
Price (US$'000s/pa	60	40	80	120	160	199	239
	70	47	93	140	186	233	279
	80	53	106	160	213	266	319
	90	60	120	179	239	299	359
	100	66	133	199	266	332	399
	110	73	146	219	292	366	439

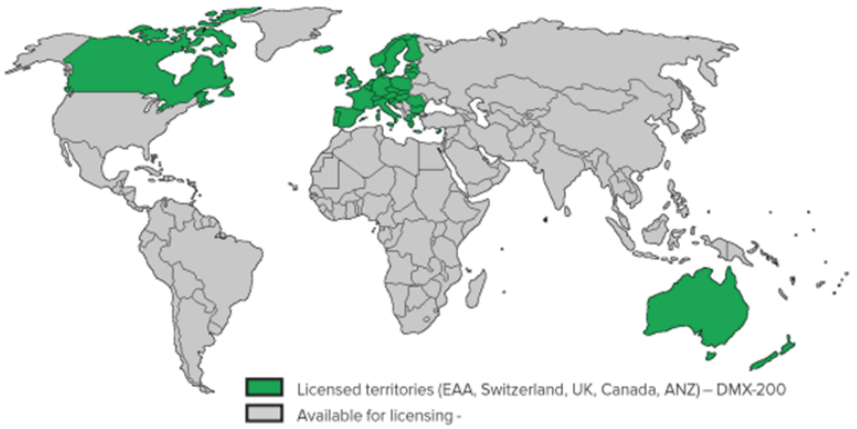
Source: EH analysis
**Assuming ~19k target EU FSGS population, 0.65 AUD/USD*

The potential $219m of milestone payments represent further upside to these revenues.

Future Licensing – USA, China, Other

The United States and China represent multi-billion-dollar markets still to be licensed. DXB has indicated these are regions of focus.

Figure 40: Licensed Regions



Source: company presentation

DXB has disclosed they have received multiple non-binding term sheets for global and regional deals. Moreover, multiple parties are currently in their data room conducting due diligence, with ongoing negotiations covering various territories.

Additionally, the company is likely in a significantly stronger negotiating position following the successful part 1 analysis, which showed DMX-200 is working better than placebo in a patient cohort nearly 10x larger than the Phase 2 trial.

We would expect a US licensing deal sometime prior to mid-CY2025. This would ensure a partner is in place, in the scenario accelerated approval is granted following a successful part 2 interim analysis (anticipated mid-CY2025).

A United States licensing deal could be considerably larger than the Advanz Pharma agreement, given the United States is the largest market globally.

In recent years, there has been considerable licensing activity in the kidney space, with some agreements featuring upfront payments reaching as high as US$100 million (Figure 41).

Figure 41: Recent Renal Licensing Activity

Year	Licensee	Licensor	Drug	Indication	Upfront (US$m)	Milestone (US$m)	Total Deal (US$m)	Royalty Rate	Region	Stage
2020	CSL Vifor	Cara Therapeutics	difelikefalin	CKD-aP	100	290	390	Undefined	US	Pre registration
2021	Calliditas	STADA Arzneimitte	Nefecon	IgAN	24	91	115	Undefined	EEA, CH, UK	Pre registration
2023	Medice	Akebia Therapeutics	Vafseo	Anemia CKD	10	100	110	Tiered up to 30%	EU, AU	Market
2018	CSL Vifor	Cara Therapeutics	difelikefalin	CKD-aP	50	470	520	Undefined	Ex-US, JP, KR	Phase 3
2020	CSL Vifor	Angion Biomedica	Ang-3777	CSA-AKI	30	280	310	Tiered up to 40%	Global (ex. CN)	Phase 3
2021	Kyowa Kirin	AM-Pharma	ilofotase alfa	SA-AKI	24	265	289	Double-digit	Japan	Phase 3
2021	CSL Vifor	Travere therapeutics	sparsentan	FSGS/IgAN	55	135	190	Double-digit to 40%	EU, AU, NZ	Phase 3
2022	Roche	Ionis Pharmaceuticals	IONIS-FB-LRx	IgAN	55	n.d	n.d	Undefined	Global	Phase 3
2021	Akebia Therapeutics	Cyclerion Therapeutics	praliciguat	kidney disease	n.d	585	585	Single-digit to high-teen	Global	Phase 2
2021	Nicoya Macau	OPKO Health	RAYALDEE	CKD-SHPT	10	115	125	Double digits	China	Phase 2
2022	Novo Nordisk	Ventus Therapeutics	NLRP3	CKD/Other	70	633	703	Tiered	Global	Phase 1
2021	Everest Medicine	Sinovent/SinoMab	XNW1011	CKD	12	549	561	High single-digit to low double-digit	Global	Phase 1
2019	Gilead	Goldfinch	Undefined	Various (inc DKD)	50	1,950	2,000	tiered	Global	Pre-clinical
2022	Asahi Kasei Pharma	Alchemedicine	Undefined	Various (inc CKD)	n.d	n.d	266	Single- to double-digits	Global	Pre-clinical
2021	Bayer	Gubra	Undefined	Various (inc. kidney)	n.d	n.d	253	Undefined	Global	Pre-clinical
2023	Novartis	Tejin Pharma	Undefined	Proteinuric KD	30	200	230	Tiered	Global	Pre-clinical
2018	Novo Nordisk	Epigen Biosciences	EPGN696	Various (inc CKD)	n.d	n.d	200	Tiered	Global	Pre-clinical

Source: Company presentation, Bloomberg LP, filings, news articles, EH analysis
n.d.: not defined; EEA: European Economic Area; US: United States; EU: Europe; CN: China; JP: japan; KR: Korea;CH: Switzerland; UK: United Kingdom; AU: Australia; NZ: New Zealand

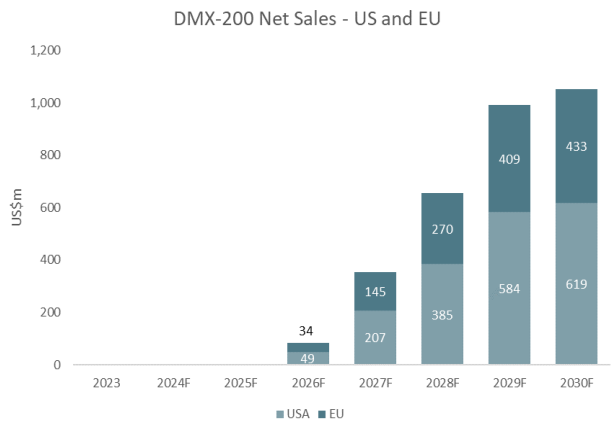
Forecasts

We have modelled royalty and milestone payment revenues based on DMX-200 being commercialised in FSGS across Europe and the United States. Our forecasts are based on the Advanz Pharma agreement and assume DXB executes an additional licensing agreement covering the United States.

Our forecasts are premised on a successful part 2 interim analysis and subsequent accelerated approval (conditional marketing approval) being granted to DMX-200 for FSGS in both the United States and Europe.

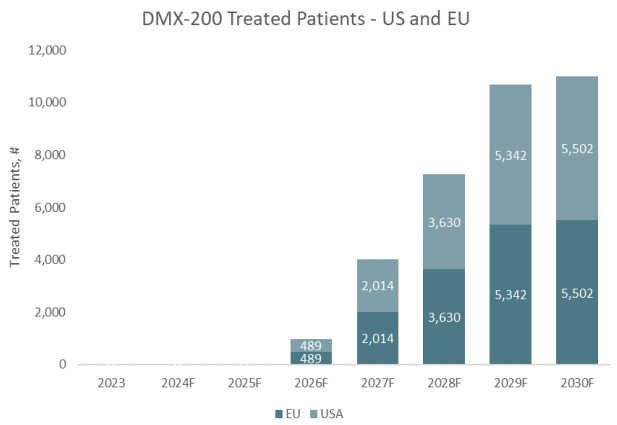
We have segmented our forecasts by region and detailed our key assumptions below.

Figure 42: DMX-200 Net Sales Forecasts, USA & EU (US$m)



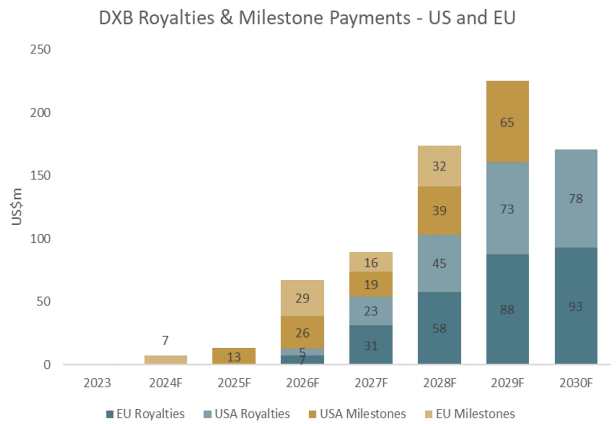
Source: EH analysis

Figure 43: DMX-200 Treated Patients Forecasts, USA & EU



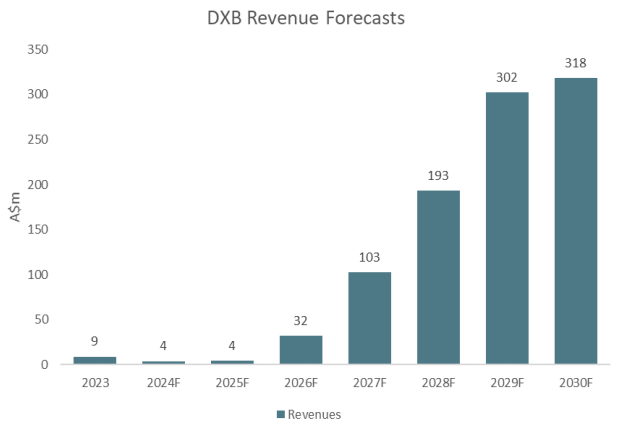
Source: EH analysis

Figure 44: DXB Royalty and Milestones, US and EU (US$m)



Source: EH analysis

Figure 45: DXB Revenue Forecasts, US and EU (A$m)



Source: EH analysis
note: milestone payment revenue is recognised over contract term

Europe – Advanz Pharma

Figure 46: Europe DMX-200 FSGS Forecasts

Financial Year	Units	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Commercial Period	Yrs			1	2	3	4	5	6	7	8	9	10	11	12
EU/UK Patients with FSGS	**'000s**	**40.0**	**41.2**	**42.4**	**43.7**	**45.0**	**46.4**	**47.8**	**49.2**	**50.7**	**52.2**	**53.8**	**55.4**	**57.0**	**58.7**
…Growth	%		3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%
% with primary FSGS	%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
% with setroid resistant FSGS	%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Target Patient Population	'000s	19.2	19.8	20.4	21.0	21.6	22.3	22.9	23.6	24.3	25.1	25.8	26.6	27.4	28.2
% market penetration	%			3%	12%	21%	30%	30%	30%	30%	30%	30%	30%	30%	30%
% Adherence	%			80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Patients treated with DMX-200	**'000s**			**0.5**	**2.0**	**3.6**	**5.3**	**5.5**	**5.7**	**5.8**	**6.0**	**6.2**	**6.4**	**6.6**	**6.8**
Net Pricing	US$'000s			70.0	72.1	74.3	76.5	78.8	81.1	83.6	86.1	88.7	91.3	94.1	96.9
…Growth	%			0%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%
Net Sales	**US$m**			**34.2**	**145.2**	**269.6**	**408.6**	**433.5**	**459.9**	**487.9**	**517.6**	**549.1**	**582.6**	**618.1**	**655.7**
Royalties to DXB	US$m			5.1	22.9	45.2	73.0	77.9	83.2	88.8	94.8	101.1	107.8	114.9	122.4
Milestone payments to DXB	US$m	6.9	0.0	29.0	16.1	32.3	0.0	0.0	0.0	0.0	63.9	0.0	0.0	0.0	0.0
Total DXB EU Revenue*	**US$m**	**6.9**	**0.0**	**34.2**	**39.0**	**77.4**	**73.0**	**77.9**	**83.2**	**88.8**	**158.6**	**101.1**	**107.8**	**114.9**	**122.4**
Total DXB EU Revenue*	**A$m****	**10.9**	**0.0**	**53.0**	**60.5**	**120.0**	**113.1**	**120.9**	**129.0**	**137.7**	**245.9**	**156.7**	**167.1**	**178.1**	**189.8**

Source: EH analysis
**Revenue from milestone payments are recognised over contract term; **AUD/USD: 0.65*

Key EU forecasts assumptions:

- Successful part 2 interim analysis by mid-CY2025, EMA filing 2H'CY2025, conditional marketing approval (equivalent to accelerated approval) 1H'CY2026.
- Commercial launch CY2026, 12-year commercial period (EU orphan drug exclusivity period, assuming 2-year paediatric extension received).
- Circa 19,000 target patient population, based on lower-end estimate of total FSGS prevalence (~40,000). Assumes (1) 80% of these patients either have primary FSGS, genetic FSGS or FSGS of unknown cause; and (2) 60% of patients have steroid resistant FSGS, where no response is seen from the standard of care. However, we note even patients who see a response often relapse, therefore this figure could be expanded. (see page 26).
- 30% peak market share by year 4. Considering FSGS is a rare disease with a significant unmet need, peak market share could exceed +50% and be achieved much sooner. Adjusted for 80% treatment adherence.
- US$70,000 per patient per annum net price, circa 30% discount to comparable rare kidney disease drug prices (see page 26). 3% annual price escalation.
- Tiered royalties from 15% to 20% based on net sales.
- Model ~€15m (~A$25m) milestone payment on EMA approval, and ~€120m (~A$195m) balance on sales milestones.

United States

Figure 47: United States DMX-200 FSGS Forecasts

Financial Year	Units	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Commercial Period	Yrs			1	2	3	4	5	6	7	8				
US Patients with FSGS	**'000s**	**40.0**	**41.2**	**42.4**	**43.7**	**45.0**	**46.4**	**47.8**	**49.2**	**50.7**	**52.2**	**53.8**	**55.4**	**57.0**	**58.7**
…Growth	%		3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%
% with primary FSGS	%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
% with setroid resistant FSGS	%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Target Patient Population	'000s	19.2	19.8	20.4	21.0	21.6	22.3	22.9	23.6	24.3	25.1	25.8	26.6	27.4	28.2
% market penetration	%			3%	12%	21%	30%	30%	30%	30%	30%				
% Adherence	%			80%	80%	80%	80%	80%	80%	80%	80%				
Patients treated with DMX-200	**'000s**			**0.5**	**2.0**	**3.6**	**5.3**	**5.5**	**5.7**	**5.8**	**6.0**				
Net Pricing	US$'000s			100.0	103.0	106.1	109.3	112.6	115.9	119.4	123.0				
…Growth	%			0%	3%	3%	3%	3%	3%	3%	3%				
Net Sales	US$m			48.9	207.5	385.2	583.7	619.3	657.0	697.0	739.4				
Royalties to DXB	US$m		0.0	7.3	31.1	57.8	87.6	92.9	98.5	104.6	110.9				
Milestone payments to DXB	US$m		12.9	25.8	19.4	38.7	64.5	0.0	0.0	0.0	0.0				
Total DXB US Revenue*	**US$m**	**0.0**	**12.9**	**33.1**	**50.5**	**96.5**	**152.1**	**92.9**	**98.5**	**104.6**	**110.9**				
Total DXB US Revenue*	**A$m****	**0.0**	**20.0**	**51.4**	**78.2**	**149.6**	**235.8**	**144.0**	**152.8**	**162.1**	**172.0**				

Source: EH analysis
**Revenue from milestone payments are recognised over the contract term; **AUD/USD: 0.65*

Key US forecasts assumptions:

- Successful part 2 interim analysis by mid-CY2025, FDA filing 2H'CY2025, Accelerated approval 1H'CY2026.
- Commercial launch CY2026, 7.5-year commercial period (US orphan drug regulatory exclusivity, assuming 6-month paediatric extension received).
- Circa 19,000 target patient population, based on lower-end estimate of total FSGS prevalence (~40,000). Assumes (1) 80% of these patients either have primary FSGS, genetic FSGS or FSGS of unknown cause; and (2) 60% of patients have steroid resistant FSGS, where no response is seen from the standard of care. However, we note even patients who see a response often relapse, therefore this figure could be expanded. (see page 26).
- 30% peak market share by year 4. Considering FSGS is a rare disease with a significant unmet need, peak market share could exceed +50% and be achieved much sooner. Adjusted for 80% treatment adherence.
- US$100,000 per patient per annum net price, circa 30% discount to comparable rare kidney disease drug prices (see page 26). 3% annual price escalation.
- Execution of a A$250m (~8% larger than Advanz Pharma deal) US licensing deal before mid-CY2025, assuming following deal structure:
  - A$20m upfront payment on deal signing;
  - A$20m milestone payment on FDA approval;
  - $210m in sales milestone payment; and
  - Flat 15% royalty on net sales.

Competitors

There are currently no approved therapies specifically for FSGS,

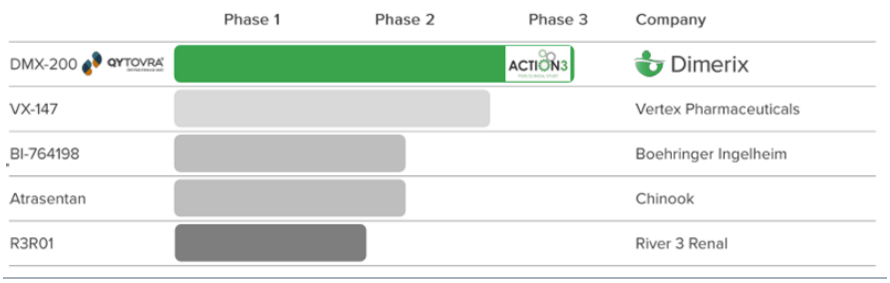
The competitive landscape is relatively small (Figure 48), with DMX-200 being the most advanced drug in development.

The next most advanced is VX-147 (inaxaplin), developed by Vertex Pharmaceuticals (NASDAQ: VRTX), which targets a genetic subset of FSGS mediated by the APOL1 gene. We don't view this as material competition to DXB given this would only target a small subset of the broader FSGS market.

Other programs in development are at least 3-4 years behind DXB, if not more. They are targeted at genetic FSGS subsets or work on different mechanisms of action likely complimentary to DMX-200.

Additionally, sparsentan, developed by Travere Therapeutics (NASDAQ: TVTX), recently failed its Phase 3 trial in FSGS, positioning DMX-200 as the new front-runner. The company has stated that it will engage with regulators to evaluate potential regulatory pathways forward. Although unlikely, if approved, DMX-200 would be complementary, as sparsentan represents a new type of ARB.

Figure 48: Competitive landscape



Source: Company presentation

We discuss these key players below.

VX-147 (inaxaplin) – Vertex Pharmaceuticals (NASDAQ: VRTX) – Phase 2/3

VX-147 is a small molecule apolipoprotein L1 (APOL-1) inhibitor aimed at treating the underlying cause of APOL1-mediated kidney disease (AMKD).

AMKD can result in various types of kidney disease including FSGS. APOL-1 mediated FSGS is a type of genetic FSGS. We don't view this as material competition to DXB given this would only target a small subset of the broader FSGS market.

VX-147 is currently being evaluated in global, multi-centre, randomised, double-blind, placebo-controlled phase 2/3 pivotal clinical trial (AMPLITUDE, ID: NCT05312879).

The phase 2B portion of the study has been completed. In this first part, two doses of VX-147 were evaluated, with one selected to take into the phase 3 portion.

The phase 3 has been designed with a pre-planned interim analysis at 48 weeks evaluating eGFR slope, supported by percentage change in proteinuria (UPCR) in drug vs placebo. If positive, the interim analysis may serve as a basis to seek accelerated approval in the United States. The primary endpoint of the final analysis is eGFR slope in drug vs placebo at 2 years.

In April 2024, Vertex announced they advanced into the phase 3 portion of the study.

The US FDA has granted VX-147 breakthrough drug designation for APOL1-mediated FSGS and the European Medicines Agency (EMA) has granted Priority Medicines (PRIME) designation for AMKD.

BI-764198 – Boehringer Ingelheim (Private) – Phase 2

BI-764198 is a select oral TRPC6 (transient receptor potential cation channel, subfamily C, member 6) inhibitor aimed at treating genetic FSGS mediated by the TRPC6-gene.

BI-764198 is currently being evaluated in a global, multi-centre, randomised, double-blind, parallel-group, placebo-controlled Phase 2 clinical trial (ID: NCT05213624).

The study is evaluating three doses of BI-764198 administered over 12-weeks in patients with primary or TRPC6 monogenic FSGS. The primary endpoint is percentage of patients reaching ≥25% decrease in 24-hour urinary protein creatinine ratio (UPCR) from baseline.

The trial is currently recruiting and is estimated to be completed sometime in CY2025.

Atrasentan – Chinook Therapeutics (now Novartis, SWX: NOVN) – Phase 2

Atrasentan is an oral endothelin A receptor antagonist (ERA).

The drug is being evaluated in a phase 2, open-label, basket study to evaluated efficacy and safety in patients with proteinuric glomerular disease (AFFINITY, ID: NCT04573920), including FSGS, IgA nephropathy (IgAN), Alport syndrome, and diabetic kidney disease (DKD). The primary endpoint is change in proteinuria (for FSGS, IgAN, Alport syndrome patients) or albuminuria (for DKD patients).

Atrasentan shares similarities with sparsentan (an ERA combined with an ARB; currently approved for IgA nephropathy, recently failed phase 3 in FSGS), which appears to work by managing hyperfiltration by way of vasoconstriction.

Given the different mechanism of action, we believe atrasentan would be complementary to DMX-200 if ultimately successful.

We note ERAs as a drug class (e.g. sparsentan) currently carry a category black box warning, as some of these drugs have been associated with increased aminotransferase levels, hepatotoxicity, and liver failure. This suggests Atrasentan would likely also require a black box warning.

R3R01 – River 3 Renal (Private) – Open-label Phase 2

R3R01 is an oral small molecule drug targeted at increasing levels of functional ABCA1 and cholesterol efflux with the aim of reducing lipid (fatty compounds) levels in certain cells of the kidneys to improve kidney function and reduce damage.

Given the different mechanism of action, we also believe R3R01 would be complementary to DMX-200 if ultimately successful.

R3R01 is currently being evaluated in a multi-centre, open-label phase 2 study in patients with Alport Syndrome and primary steroid-resistant FSGS (ID: NCT05267262).

The study is currently recruiting with a completion estimated sometime in CY2025.

Technology Platform: Receptor-HIT

DXB was originally founded around its cell-based technology platform, Receptor-HIT (Heteromer Investigation Technology).

This technology has enabled the company to identify new drug targets with unique pharmacology, and has been used in the development of its key clinical programs including DMX-200 in FSGS.

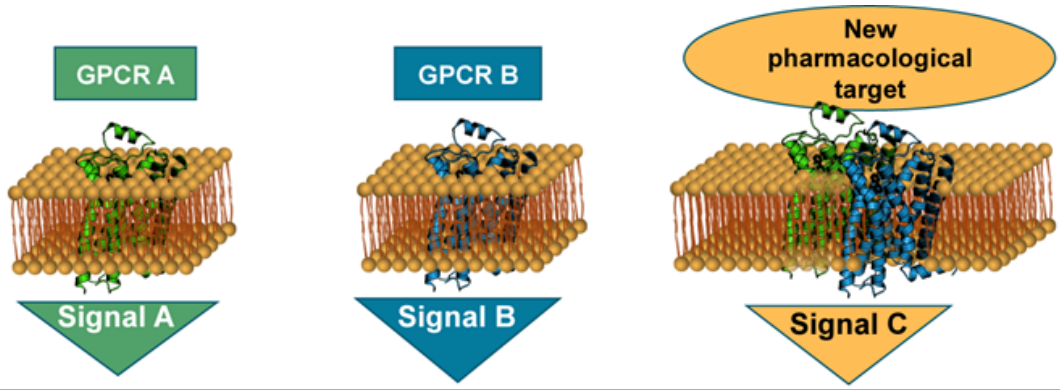
Traditional cell assays typically focus on a single receptor target, whereas DXB's technology (Receptor-HIT) can identify pairs of receptors that operate together in a joint manner, called functional heteromers.

These functional heteromers can be novel drug targets with unique pharmacology and biological function.

DXB has been applying this technology in particular to G-protein coupled receptors (GPCR's), a class of drug targets involved in various physiological processes and diseases.

Below is an illustrative example of a heteromer G-couple protein receptor target (figure 49).

Figure 49: Individual vs Heteromer G-couple Protein receptor target



Source: Company presentation

As discussed earlier, DXB has used this technology to identify a heteromer between GPCRs chemokine receptor 2 (CCR2) and angiotensin II receptor type 1 (AT1R). Both targets are known to play roles in the pathogenesis of glomerulopathies, including FSGS

Development Pipeline

DXB has a pipeline of secondary programs targeting: Diabetic Kidney Disease (DKD), Chronic Obstructive Pulmonary Disease (COPD), and other undisclosed indications.

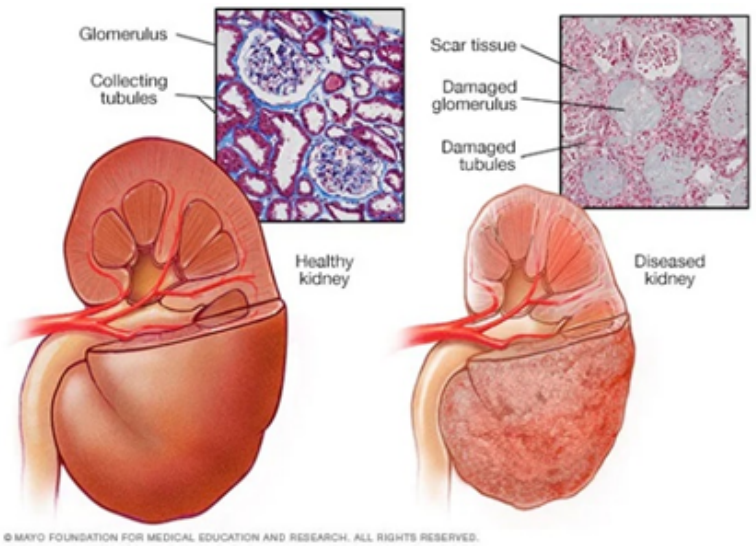
DMX-200 – Diabetic Kidney Disease (DKD)

In addition to DXB's lead program in FSGS, DMX-200 is being developed as a potential treatment for diabetic kidney disease (DKD).

DKD is the leading cause of chronic kidney disease and end-stage renal failure (ESRD). As of 2021, an estimated 537 million people were living with diabetes worldwide. This figure is projected to increase to 784 million by 2045. Up to 40% of diabetes patients will go onto develop DKD.

DKD is a serious complication of poorly managed type 1 or 2 diabetes. Over time, high glucose (sugar) levels, as well as high blood pressure and other factors in diabetes patients can cause progressive and irreversible damage (scarring) to the kidneys (figure 50), specifically affecting the blood vessels and filtering units (glomeruli). As DKD progresses, the kidneys are placed under increasing strain, perpetuating a cycle of damage. In the context of DMX-200, we note inflammation and subsequent scarring play an important role in the pathogenesis of DKD.

Figure 50: Normal Kidneys vs Kidneys with DKD



Source: Mayo clinic

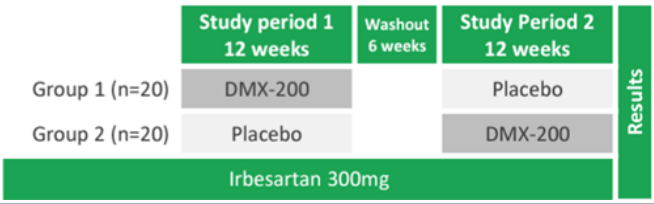
DMX-200's mechanism of action in DKD is the same as FSGS. DMX-200 is a CCR2 antagonist designed to be administered as an adjunct therapy to patients receiving angiotensin II type I receptor (AT1R) blockers (ARBs). DMX-200 inhibits the recruitment of inflammatory cells to the kidneys, while the ARB reduces hyperfiltration through mediating vasoconstriction (reducing blood pressure). Importantly, the co-administration of DMX-200 and an ARB generates a synergistic, more than additive, therapeutic benefit in slowing disease progression.

In 2020, DXB announced mixed top-line results from its Phase 2 study in DKD.

The phase 2, was a double-blind, randomised, placebo-controlled, cross-over study designed to evaluate the safety and efficacy of DMX-200 in DKD patients receiving a stable ARB.

A total of 45 patients were enrolled in the study, with 40 patients meeting the pre-defined criteria for inclusion in the final analysis. All participants were required to be on a stable 300mg/day dose of irbesartan (type of ARB). Upon enrolment, patients were randomised into either being dosed 240mg/day of DMX-200 for 12-weeks, followed by a 6-week washout period and another 12-weeks on placebo, or the reverse.

Figure 51: Phase 2 DKD Study Design



Source: company presentation

While the full patient cohort showed no statistically significant benefit, patients with higher starting baseline albuminuria (>500mg/g, 57mg/mmol, n=26) reported a statistically significant 18% reduction in albuminuria vs placebo (p=0.03). Moreover, 64% of these same patients demonstrated a reduction in albuminuria, with 56% achieving a >25% reduction above that achieved by the standard best therapy.

On reflection the study was likely impacted by a few factors, including:

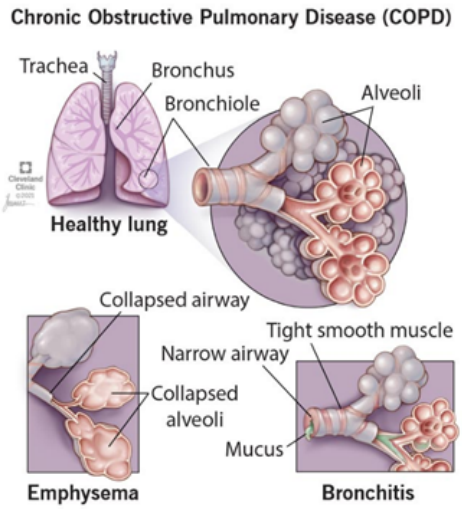
- **Broader Cohort** – while the prior phase 2a dose ranging study had a 30mg/mmol albuminuria inclusion threshold, this study was the first study to enrol DKD patients with an albuminuria below 100mg/mmol.
- **Short Trial Duration** – the trial ran for 12 weeks, which may not have been enough to demonstrate the full effect of DMX-200, particularly in patients with a more moderate form of DKD.

DMX-700 – Chronic Obstructive Pulmonary Disease (COPD)

DMX-700 is a preclinical asset identified using receptor-HIT aimed at treating chronic obstructive pulmonary disease (COPD).

COPD is a chronic inflammatory disease of the lungs that results in restricted airflow and breathing problems. Tobacco smoking is the main cause, responsible for 40-70% of cases, however long-term exposure to irritating gases or particulate matter can also cause COPD. There are genetic disorders that cause COPD, however these represent a small minority of overall cases.

Figure 52: Healthy Lungs vs Lungs with COPD Illustration



Source: Cleveland Clinic,
Illustrates healthy lungs with open airways vs lungs with emphysema and bronchitis, conditions grouped under COPD.

COPD is the third-leading cause of death worldwide, responsible for more than 3.2 million deaths in 2019 alone (World Health Organisation; WHO). Reducing exposure to risk factors such as tobacco smoke can slow the progression of COPD. However, there is no cure for COPD, current treatments aim to manage symptoms and slow the progression of the disease.

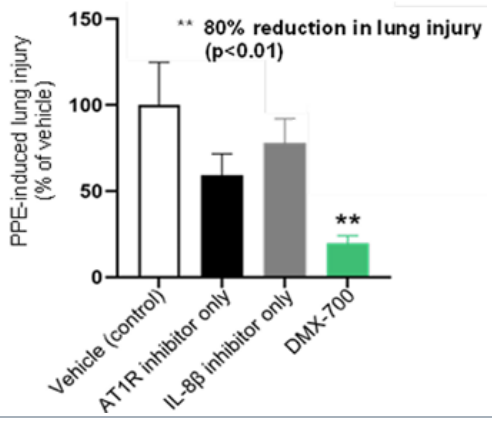
The COPD treatment market is expected to grow at an annual 7.3% CAGR between 2021 and 2027 to US$27 billion.

DMX-700 uses two compounds to target signalling by an interleukin 8 receptor beta (IL-8Rβ, also known as CXCR2) and an angiotensin II type 1 receptor (AT1R) heteromer in COPD. Both receptors have been independently implicated in the pathophysiology of COPD. Moreover, DMX-700 generates a synergistic effect by simultaneously blocking receptors co-expressed in certain cells.

Interleukin 8 (IL-8) is a chemokine expressed at elevated levels in COPD, leading to the recruitment of neutrophils (type of white blood cell) which cause damage to the tissue of the lungs. In prior studies, it has been shown that neutrophil recruitment can be reduced by inhibiting the signalling of interleukin 8 receptor beta.

In a 2022 preclinical study involving six mice, DMX-700 demonstrated a statistically significant 80% reduction ($p<0.01$) versus control in a induced lung injury model in mice. The study utilised the porcine pancreatic elastase (PPE) model, the most common model for COPD, as it replicates the inflammatory response in lungs of mice.

Figure 53: DMX-700 Preclinical Results



Source: company announcement

In this study, three different IL-8Rβ inhibitors were evaluated with an AT1R inhibitor. All three demonstrated strong efficacy and are covered by DXB's intellectual property. Further, DXB has noted these compounds individually have a known safety profile in humans, potentially enabling DMX-700 to move directly into clinical studies.

Intellectual Property

DXB maintains an extensive intellectual property (IP) portfolio with various layers of coverage.

Key patent families include:

- **Method of Use** granted for any CCR2 antagonist (DMX-200 is a CCR2 antagonist) with any angiotensin receptor blocker (ARB) for any kidney disease (e.g. FSGS) – Granted, expiring 2033.
- **Method of Use** global application for any CCR2 antagonist and any endothelin A receptor blocker in any disease – Pending, expiring 2042 if granted.
- **Formulation** global application for any CCR2 antagonist with excipients for use in Kidney (e.g. FSGS) or respiratory (e.g. COPD) disease – Pending, expiring 2042 if granted.

The patent coverage is particularly strong as it extends to the broader mechanism of action, and potential permutations of it.

DXB could seek a patent term extension through the Hatch-Waxman Act, which provides a mechanism to compensate for time lost during the development and regulatory review periods. We estimate DMX-200 could be eligible for 2-3 years of patent term extension.

Above all of this, DMX-200 if approved will be eligible for a significant period of regulatory exclusivity based on its orphan drug designation. This being:

- **United States** – 7 Years + additional 6 months with a paediatric indication; and
- **Europe** – 10 years + additional 2 years with a paediatric indication.

DXB has established a plan to support a paediatric indication, including a Paediatric investigation plan (PIP) with the EMA.

Importantly, unlike patents, regulatory exclusivity cannot be challenged, enabling a significant commercial life to be realised before patent challenges can even become a question.

Manufacturing

DMX-200 is commercial manufacturing ready, with DXB having progressed commercial manufacturing capabilities through an FDA approved global contract manufacturing organisation based in the United States.

Further, the company has already completed the production of registrational batches of pharmaceutical-grade DMX-200, which are necessary for obtaining global marketing approvals, including from the US FDA. This process confirms the stability and shelf-life of DMX-200 prior to submitting it for regulatory approval.

Balance Sheet

We estimate DXB has $38.6m in pro-forma cash, with a further $7.7m of options currently in-the-money.

The company had $14.8m in cash as of the December quarter, which was supplemented by a $20.0m placement last month, and an estimated $5.0 from the exercise of options.

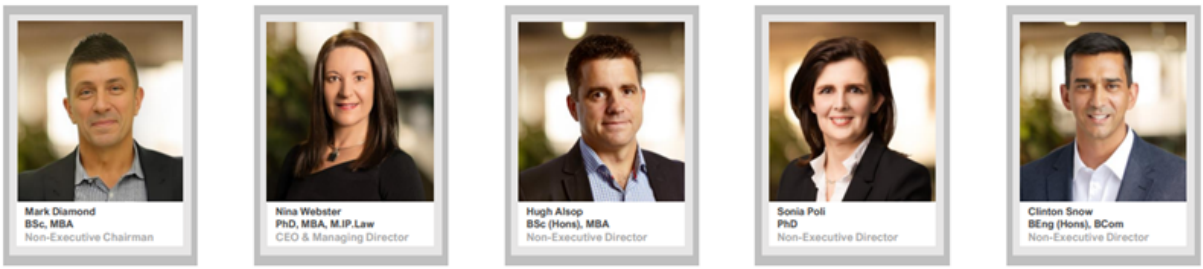
DXB currently has no debt, following the conversion of outstanding convertible notes earlier this year.

We estimate the company is now fully funded to complete its phase 3 trial. We estimate it will cost a further $25.0m through to the part 2 interim results, based on a similar estimated amount invested opening sites and recruiting the first 72 patients.

Board, Management, and Advisors

Board of Directors

Figure 54: DXB Board of Directors



Source: Company presentation

Non-executive Chairman – Mark Diamond, BSc, MBA

Nil Shares / Nil Options

Background: Mr Mark 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.

In May 2023, Mr Diamond retired from ASX listed Antisense Therapeutics Limited as Managing Director and CEO, a position he had held since 2001, making him at the time of his retirement 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.

Managing Director / Chief Executive Officer – Nina Webster, PhD, M IP Law, MBA

0.4m Shares / 2.2m Options

Background: Nina 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.

Nina 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 the Non-Executive Chairperson for SYNthesis BioVentures and 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.

Non-Executive Director – Hugh Alsop, BSc (Hons), MBA

Nil Shares / 0.2m Options

Background: Hugh is an accomplished pharmaceutical and biotechnology executive with 20 years of experience in international business development, partnering, drug development and leadership of scientific teams. Hugh has demonstrated commercial management skills, profit accountability, and senior oversight of drug development programs for the international market.

Hugh has a track record of being part of two significant exit transactions for the Australian life sciences industry, including two successful Phase 3 programs and two FDA approvals for Australian developed products.

Hugh is currently CEO of Kinoxis Therapeutics, a private company developing novel therapeutics for substance use disorders and other neurological conditions. Prior to Kinoxis, Hugh was CEO of venture-backed private company Hatchtech Pty Ltd, where he 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 global pharmaceutical company Eli Lilly for up to US$335m in potential milestones plus royalties.

Non-Executive Director – Clinton Snow, BEng (Hons), BCom

Nil Shares / Nil Options

Background: Clinton Snow has nearly 20 years' experience as a technology leader with a focus in engineering management, project delivery, risk management, and assurance. Clinton is currently a non-executive director for Icetana Ltd (ASX:ICE) and provides advisory services to a family office with multiple Australian biotech investments.

Clinton holds a Bachelor of Chemical Engineering (honours) and Bachelor of Commerce degree from The University of Melbourne.

We note Clinto Snow is related to Peter Meurs, the largest shareholder of DXB with ~13.8% interest.

Non-Executive Director – Sonia Poli, PhD

0.4m Shares / 0.3m Options

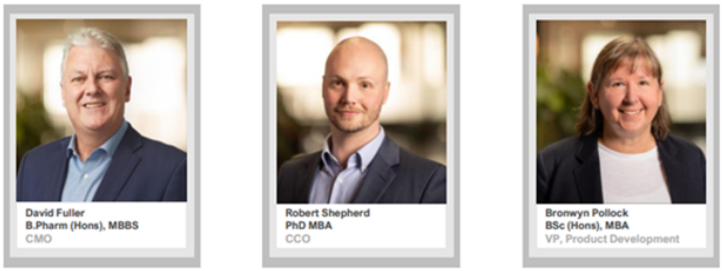
Background: Dr. Poli is an accomplished R&D executive with 25+ years progressive experience in private and publicly listed pharmaceutical companies. She has broad expertise which encompasses multiple therapeutic areas, in large indications as well as rare orphan indications and has an established track record of leading projects through key scientific, regulatory, and partnership milestones.

Sonia is currently Chief Scientific Officer at Sibylla Biotech, a preclinical stage company focused on developing small molecule degraders with a novel Mechanism of Action.She previously held various management positions AC Immune, Minoryx, Addex therapeutics, and Hoffmann la Roche.

Dr. Poli holds a PhD in Industrial Chemistry from the University of Milan and is co-author of several patents and more than 50 scientific publications.

Executive Team

Figure 55: DXB Executive Team



Source: company presentation

Chief Medical Officer – David Fuller, B.Pharm (Hons), MBBS

Background: David is an internationally experienced pharmaceutical executive and physician, with over 35 years of international experience in drug development and commercialisation. David has a strong background product development, as well as a successful history of securing multiple INDs/NDAs (or equivalent) with both the FDA and EMA. He has led teams that successfully obtained major market product approvals for Renagel (chronic kidney disease, EU, including post-approval support) Moraxen (cancer pain, UK), Busulfex (haematologic oncology; US Paediatrics and EU Adult indications), Xyrem (narcolepsy; US).

David has extensive experience in product development and commercialization, from Planning, Financing, Pre-clinical, Clinical Development, Regulatory Approval, Product Launch, Pharmacovigilance, and Medical Affairs. He has designed and executed multiple GCP Phase 1-3 studies across the US, EU, and Asia for both orphan and major market products.

David has a proven track record of creating value across private and ASX listed large and small-cap environments. David was the former CMO of Race Oncology, and is also a Non-Executive Director at AdAlta Limited and EpiAxis Therapeutics Pty Ltd. David holds Bachelor of Medicine/Bachelor of Surgery and Bachelor of Pharmacy degrees from University of Sydney.

Chief Commercialisation Officer – Robert Shepherd, PhD, MBA

Background: Robert is an experienced pharmaceutical executive having lead multidisciplinary research and development teams for over 11 years.

Prior to joining the Dimerix team, Robert was a Senior Development Manager at Medicines Development for Global Health, a non-profit organisation focused on efficiently developing drugs for orphan and neglected indications. In this role, he supported biotechnology and academic groups in project management roles spanning research, manufacturing, nonclinical, clinical and regulatory fields in pain, immunology, infectious diseases, and oncology. Robert has previously held roles as a Business Analyst at the Monash Vision Group, Communications Advisor at the Australian Society of Plant Scientists, and Sessional Lecturer at Monash University.

Robert holds a BS in Genetics (Honours), PhD in molecular cell biology and immunology, an MBA and a graduate certificate in science commercialisation from Monash University, Australia.

VP Product Development – Bronwyn Pollock, BSc (Hons), MBA

Background: Bronwyn Pollock is an experienced biotech and pharmaceutical professional with over 20 years in the industry.

Prior to leading the Product Development work at Dimerix, Bronwyn was Director of Product Development at Prota Therapeutics. She has also held Senior Management positions in pharmaceutical companies including Neuren Pharmaceuticals Ltd, Hospira Australia (now Pfizer), Acrux Ltd and CSL. Her CMC (Chemistry, Manufacturing and Controls) experience comes from working in R&D, quality and program management, and she has been involved in leading teams in the development and submission of numerous dossiers to EMA, US FDA, Asia and Sth America, technology transfers and launch.

Medical Advisory Board

Figure 56: DXB Medical Advisory

Source: Company presentation

Top Shareholders

Figure 57: Top 20 Shareholders

Twenty (20) largest shareholders of quoted ordinary shares

Position	Holder Name	Holding	% IC
1	MR PETER FLETCHER MEURS	35,572,412	9.08%
2	SKIPTAN PTY LTD <P&M MEURS FAMILY A/C>	29,357,028	7.50%
3	FREEDOM TRADER PTY LTD	9,375,152	2.39%
4	BAVARIA BAY PTY LTD	7,316,992	1.87%
5	YODAMBAO PTY LTD <YODAMBAO INVESTMENT A/C>	6,362,603	1.62%
6	MRS MELINDA JANE COATES & MR ANDREW JOSEPH COATES <MELINDAJCOATES SUPERFUND A/C>	5,000,000	1.28%
7	MR PHILIP ROBERT SCOTT	4,425,000	1.13%
7	MRS JULIE MAREE SCOTT	4,425,000	1.13%
8	MR ANDREW JOSEPH COATES & MRS MELINDA JANE COATES <AJ & MJ COATES S/F A/C>	4,311,500	1.10%
9	MR RICHARD STANLEY DE RAVIN	4,200,000	1.07%
10	TAMER YIGIT PROPERTY GROUP PTY LTD	3,870,000	0.99%
11	MR TAYLOR NICHOLAS GREEN	3,500,000	0.89%
12	MR ANTHONY MARK VAN DER STEEG	3,090,519	0.79%
13	LIMNOS 34 PTY LTD	3,000,728	0.77%
14	MRS GWEN MURRAY PFLEGER <PFLEGER FAMILY A/C>	2,807,984	0.72%
15	RUBI HOLDINGS PTY LTD <JOHN RUBINO SUPER FUND A/C>	2,500,000	0.64%
16	COATES FAMILY OFFICE PTY LTD <COATES FAMILY OFFICE A/C>	2,300,000	0.59%
17	TOROHA PTY LTD <THE WHITE FAMILY A/C>	2,137,753	0.55%
18	MOORE FAMILY NOMINEES PTY LTD <MOORE FAMILY SUPER FUND A/C>	2,000,000	0.51%
18	SOLEQUEST PTY LTD	2,000,000	0.51%
19	CITICORP NOMINEES PTY LIMITED	1,953,707	0.50%
20	JAMPASO PTY LTD <WILLIAMS FAMILY A/C>	1,778,742	0.45%
	Total	**141,285,120**	**36.08%**

Source: DXB 2023 annual Report

Personal disclosures

We hereby certify that all of the views expressed in this report accurately reflect our personal views about the subject company or companies and its or their securities, and we are not in possession of, nor does this Research contain any inside information.

No part of our compensation was, is or will be directly or indirectly, related to the specific recommendations or views expressed by the authoring analyst in this research, nor has any attempt been made to influence this Research.

Company disclosures

The companies and securities mentioned in this report, include:

Dimerix Ltd (DXB) | Price A$0.29 | Target price A$0.80 | Recommendation Speculative Buy;

Price, target price and rating as at 19 April 2024 (not covered)*

Additional disclosures

The analyst declares that they have a beneficial interest in: Dimerix Ltd (DXB)

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

Euroz Hartleys declares that it has acted as underwriter to, and/or arranged an equity issue in, and/or been engaged in a capital raising during the last year. Euroz Hartleys has received a fee for these services from: Dimerix Ltd (DXB)

Other disclosures, disclaimers and certificates