



# Dimerix

*Developing new therapies to treat inflammatory  
causes of kidney disease with unmet clinical needs*

## Biotech Showcase 2025

*Melbourne, September 2025*



# Forward looking statements

*This presentation includes forward-looking statements that are subject to risks and uncertainties.*

*Although we believe that the expectations reflected in the forward looking statements are reasonable at this time, Dimerix can give no assurance that these expectations will prove to be correct. Readers are cautioned not to place undue reliance on forward-looking statements.*

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*Actual results could differ materially from those anticipated. Reasons may include risks associated with drug development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, results of clinical trials, contractual risks, risks associated with patent protection, future capital needs or other general risks or factors, along with those factors outlined in the most recent Dimerix Limited Annual Report.*

# Overview

## Phase 3 Global Opportunity

### Lead drug candidate

DMX-200 in a **Phase 3 clinical trial** for focal segmental glomerulosclerosis (FSGS)

### FSGS indication

a **rare disease** that causes scar tissue of kidneys, which leads to irreversible kidney damage<sup>1</sup>

### No approved treatments

available to treat FSGS: damage can lead to **dialysis, transplant or death**<sup>1</sup>

### Orphan drug designation

regulatory, marketing exclusivity and pricing **benefits** in key territories<sup>2</sup>

4

**DMX-200 licensing** partners across key territories<sup>3</sup>

**~\$1.4 billion**

in total upfront & potential development and sales milestone payments **plus** royalties<sup>3</sup>

**>\$65 million**










in total **payments received** to date<sup>1</sup>



**QYTOVRA®**  
[REPAGERMANIUM]

DMX-200 (QYTOVRA® in some territories)

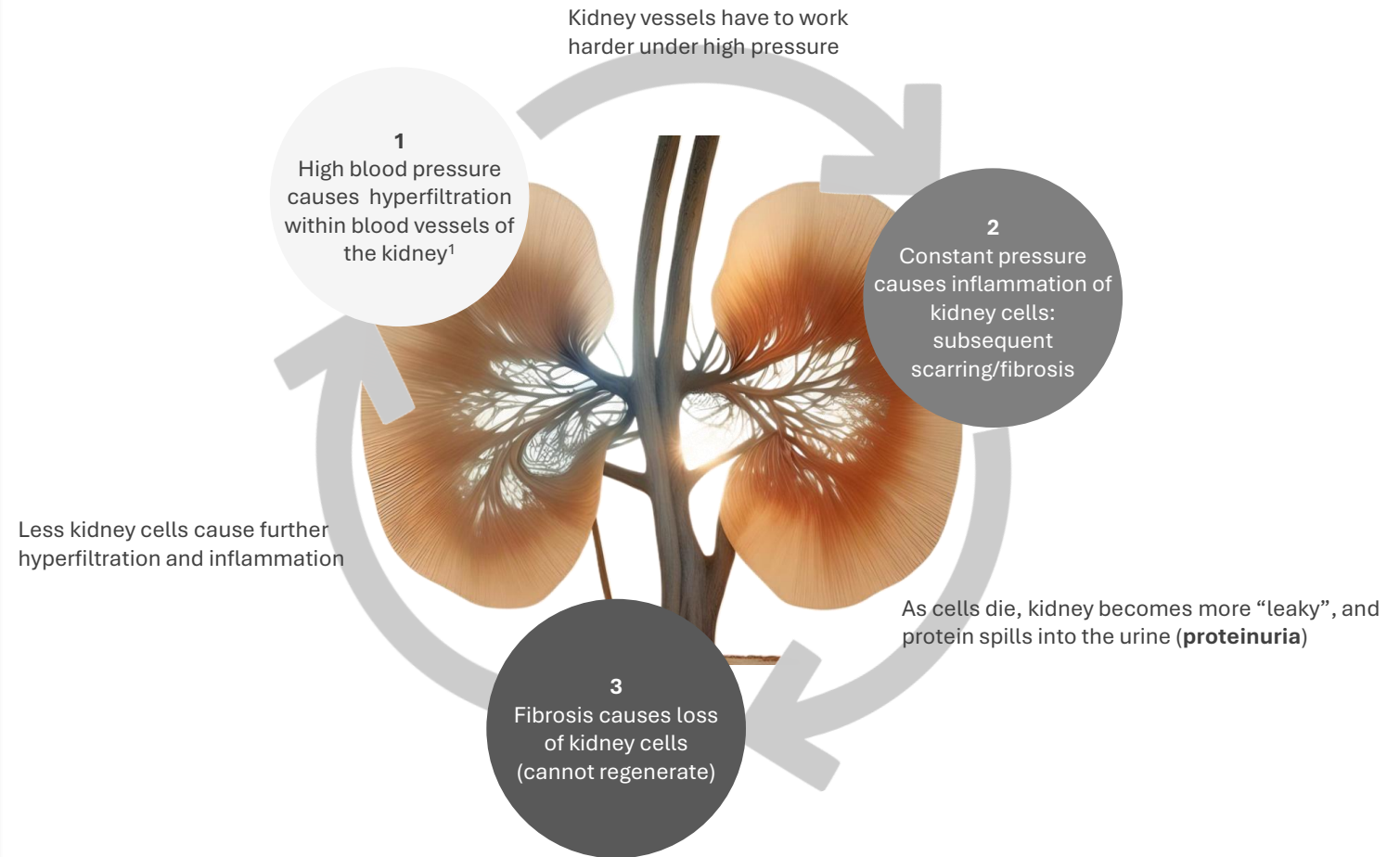
# Strong body of evidence with significant progress

	<b>Mechanism of Action</b>	Precision therapy to disrupt inflammatory feedback loops in the kidney of patients with FSGS <sup>1</sup>
	<b>Pre-clinical</b>	FDA confirmed proposed pre-clinical safety package sufficient to support marketing submission <sup>2</sup>
	<b>Manufacturing</b>	Commercial scale up in place – manufacturing sites in USA <sup>3</sup>
	<b>Phase 1 / Phase 2 clinical trials</b>	Encouraging efficacy and positive safety signals across Phase 1 & Phase 2 studies (n=>100), including demonstrating a reduction in proteinuria and inflammatory markers in FSGS patients <sup>4</sup>
	<b>ACTION3 Phase 3: Part 1 interim analysis</b>	Interim analysis (n=72 @ 35 weeks) showed DMX-200 performing better than placebo in reducing proteinuria <sup>5</sup>
	<b>FDA and Project PARASOL</b>	Alignment on proteinuria as primary endpoint for final approval <sup>6</sup>
	<b>3rd Party Validation</b>	4 licensing deals executed for various key territories, all of whom conducted independent, extensive due diligence <sup>7</sup>
	<b>ACTION3 Phase 3: Part 2 interim analysis</b>	Blinded data collection and analysis expected after PARASOL project outcomes and FDA feedback <sup>6</sup>
	<b>ACTION3 Phase 3: Part 3 final analysis</b>	2-year proteinuria (potential primary endpoint) and eGFR (primary and/or secondary endpoint) data serves as basis for full approval (n=~286)

# Cycle of damage : in glomerular diseases

## What is FSGS?

<b>Focal</b>	<b>= some</b>
<b>Segmental</b>	<b>= sections</b>
<b>Glomerulo</b>	<b>= of the kidney filtering units</b>
<b>Sclerosis</b>	<b>= are scarred</b>



# Cycle of damage :

## What is FSGS?

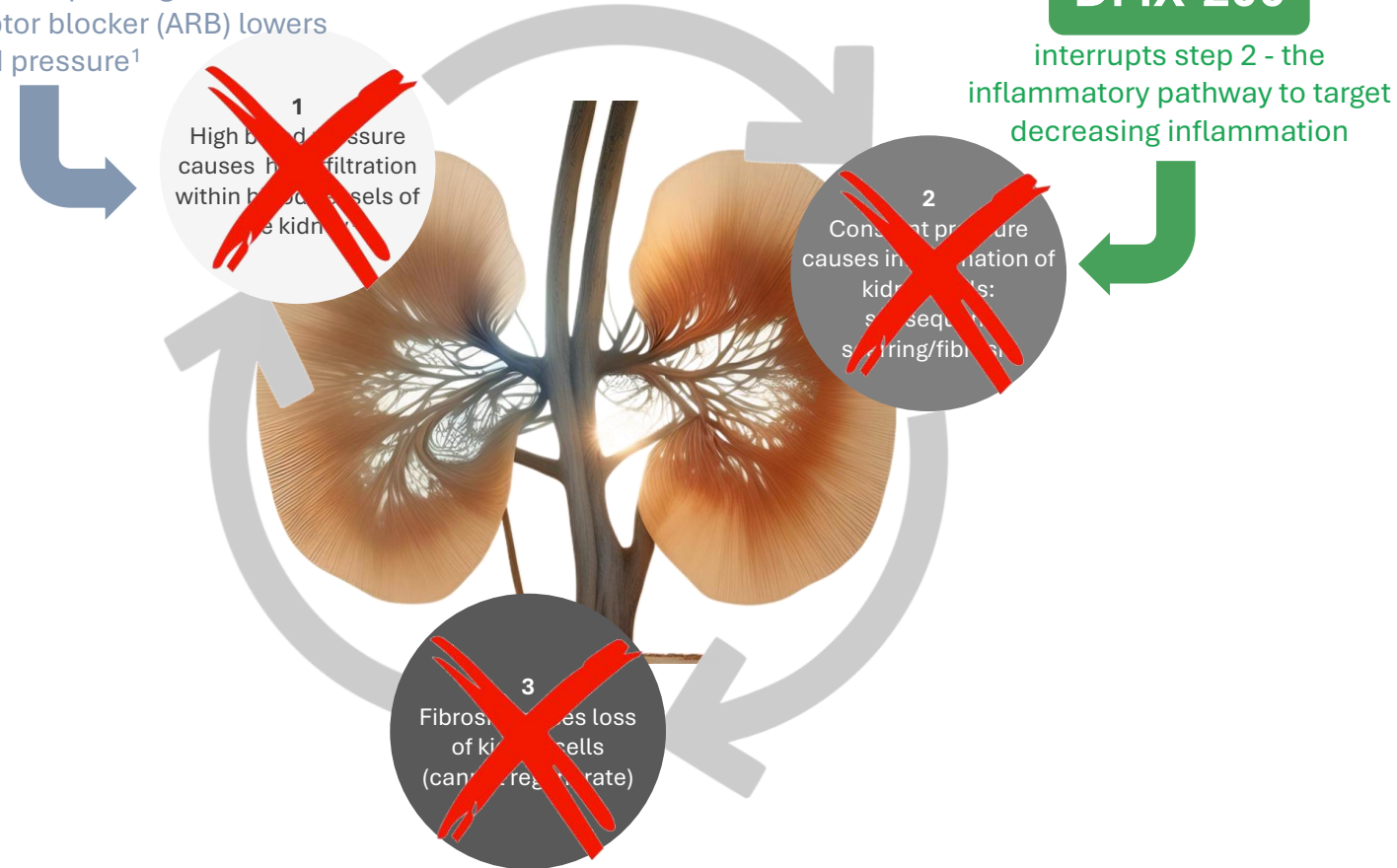
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This synergistic activity of both agents disrupts the cycle of damage in FSGS

# in glomerular diseases

## Existing blood pressure medication

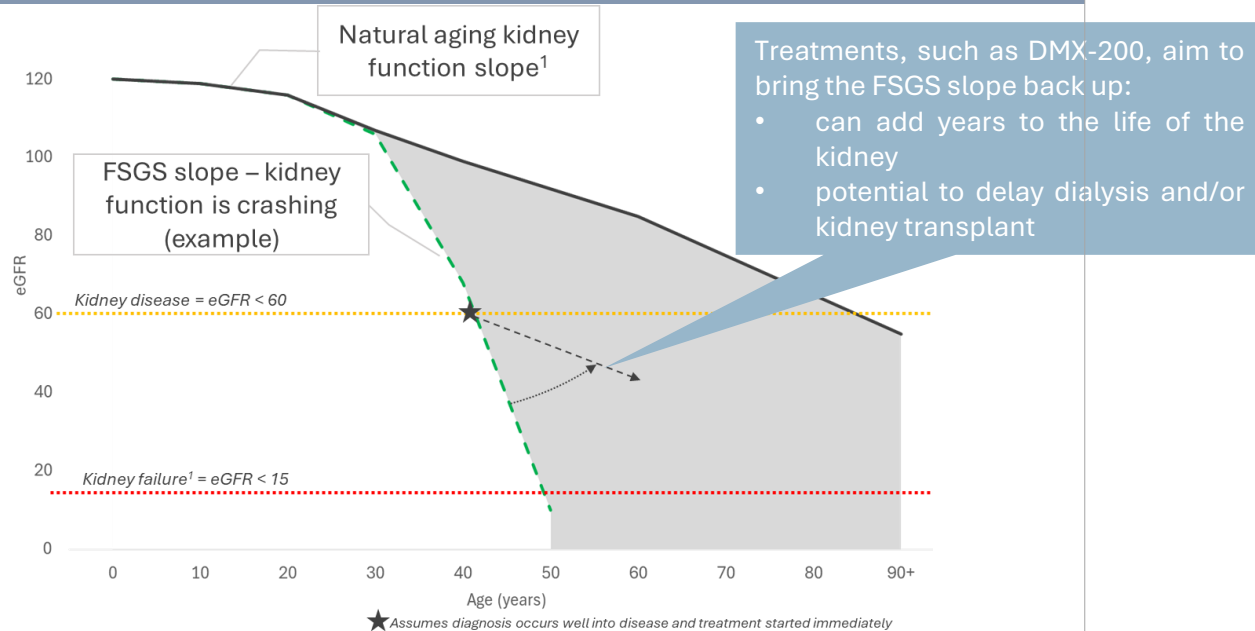
targets step 1: angiotensin receptor blocker (ARB) lowers blood pressure<sup>1</sup>





# Measuring kidney damage – surrogate endpoints

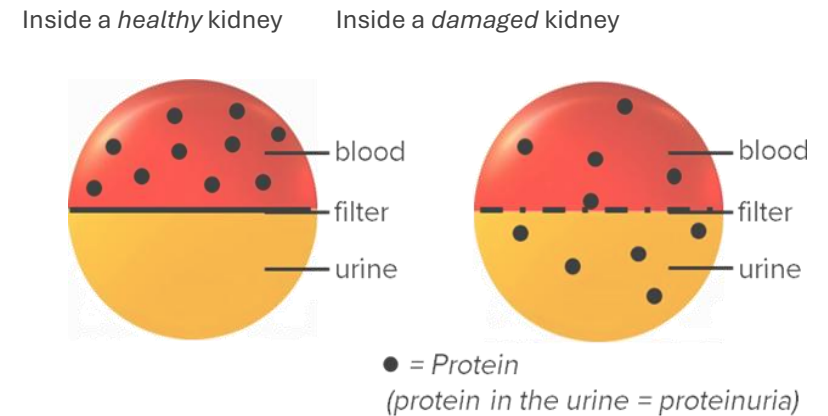
## 1. Estimated glomerular filtration rate (eGFR)



- Kidney function can be measured using eGFR:
  - how many millilitres of blood is filtered by the kidney per minute
- eGFR slope naturally declines as we age¹
- In FSGS patients, it is crashing

## 2. Proteinuria

- A healthy kidney is a good filter and allows little to no protein in the urine²



- When kidneys are damaged, protein can leak into the urine causing proteinuria
- Proteinuria represents an important early marker of kidney function³

# ACTION3 phase 3 clinical trial

FSGS CLINICAL STUDY

A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB



~286  
Total number of patients required - anticipated H2 2025<sup>1</sup>

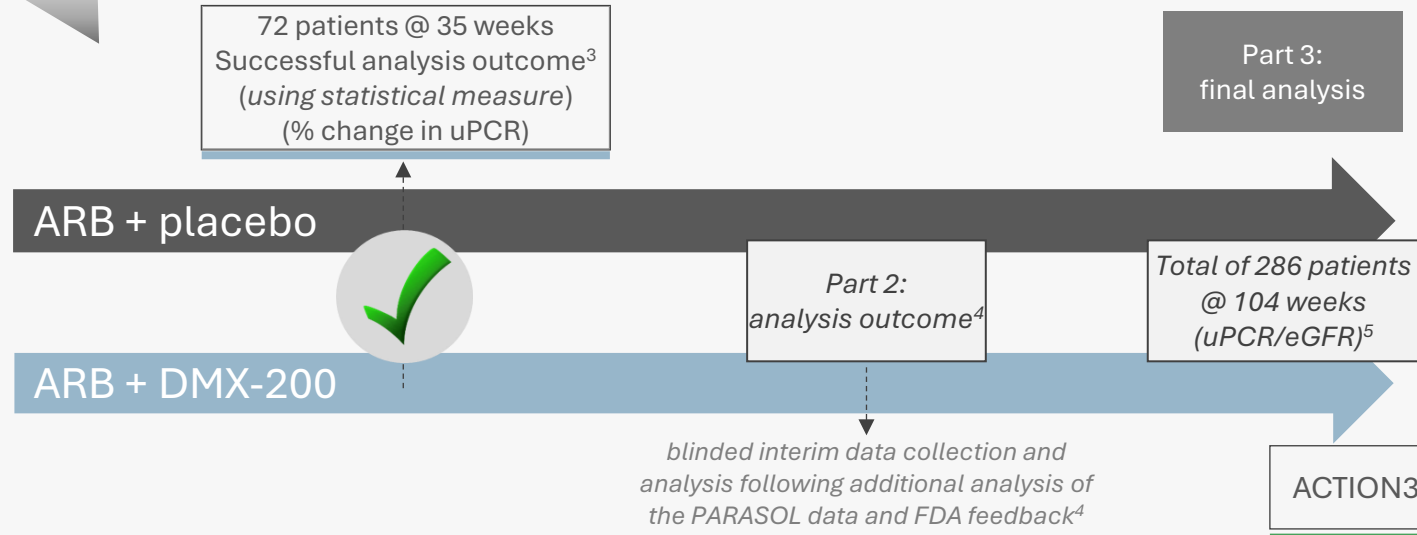
230  
Patients recruited, randomised and dosed<sup>2</sup>

56  
Patients enrolled over into open label extension study<sup>2</sup>

## Background

- Patients recruited, then screened and stabilised on background medications
- Patients randomised to receive drug or placebo
- DXB remains blinded at all times during study

## Phase 3 Trial Timeline



## Open Label Extension

DMX-200

★ Potential to submit for conditional marketing approval, subject to FDA discussion<sup>3</sup>



# Project PARASOL – an FDA-led working group

Working groups not uncommon to review and recommend potential endpoints for indications without any approved therapies as new information comes to light, for example, results from other trials or identification of better biomarkers or surrogate outcome measures<sup>1</sup>

1

## Project PARASOL: 24-month data analysis



- PARASOL formed to address the need to **validate alternative surrogate endpoints** for FSGS
- Coalition of nonprofit organisations, academia, registries, trials and Sponsors<sup>2</sup>

- PARASOL confirmed: eGFR slope is a valid endpoint for predicting progression of kidney disease
- PARASOL demonstrated proteinuria is a valid endpoint for predicting progression of kidney disease
- FDA confirmed: a reduction in proteinuria is a validated endpoint for DMX-200 for **full marketing approval for FSGS at 24-months**

2

## DIMERIX & PARASOL project: earlier data point analysis

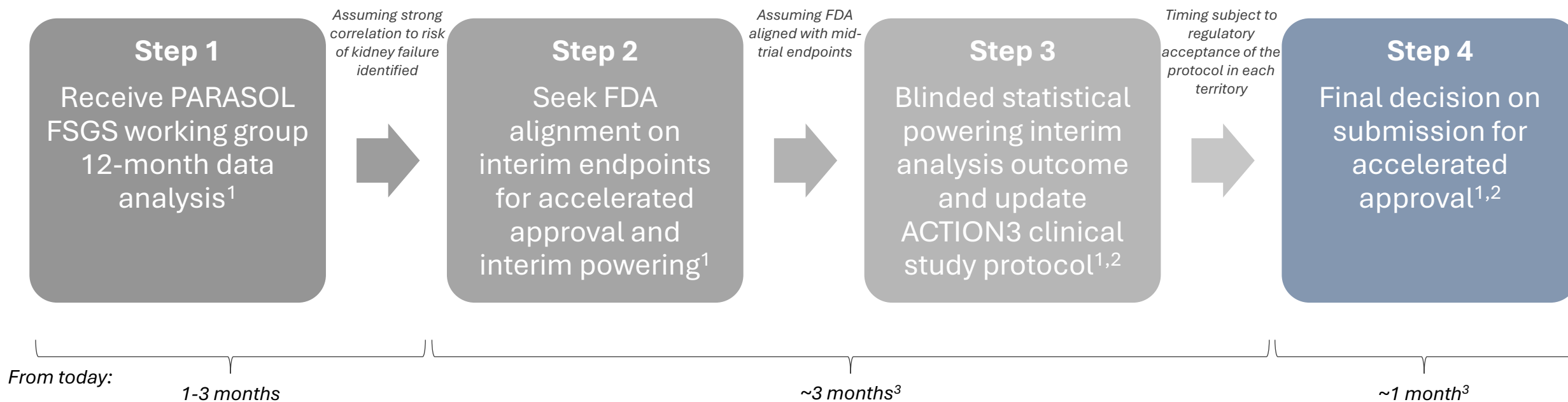


- Initial analysis conducted primarily on available 24-month data
- Initial analysis conducted on population similar, but not identical, to ACTION3

- Analysis of PARASOL population overlaid on ACTION3 population required
- Relationship between earlier time points, such as 12-month, and 24-month data required
- Assuming strong correlation to risk of kidney failure identified at 12-months, **seek FDA alignment for accelerated approval**

# Interim analysis process




Positive Type C meeting held in March 2025 with US Food & Drug Administration (FDA) on proteinuria trial endpoints for **full** approval, and potential for accelerated approval for DMX-200<sup>1</sup>



In line with best practice, endpoints must be set prior to any potential unblinding of data, to maintain integrity of the study

# Competitive landscape in FSGS

- ✓ No approved therapies for FSGS
- ✓ Low competition
- ✓ DMX-200 is the only inflammatory modulator in development

	Phase 1	Phase 2	Phase 3	Company
DMX-200 	<i>Inflammatory modulator</i>			
Sparsentan	<i>AT<sub>1</sub>R/ET<sub>A</sub>R dual inhibitor – Failed Phase 3 eGFR endpoint: resubmitted to FDA on proteinuria endpoints</i>			Travere Therapeutics
VX-147	<i>APOL1 inhibitor – specific type of genetic FSGS</i>			Vertex Pharmaceuticals
BI-764198	<i>TRPC inhibitor</i>			Boehringer Ingelheim
Atrasentan	<i>AT<sub>1</sub>R / ET<sub>A</sub> antagonist</i>			Chinook
R3R01	<i>Lipid modifying</i>			River 3 Renal

# FSGS market – potential for growth

## Biopsy

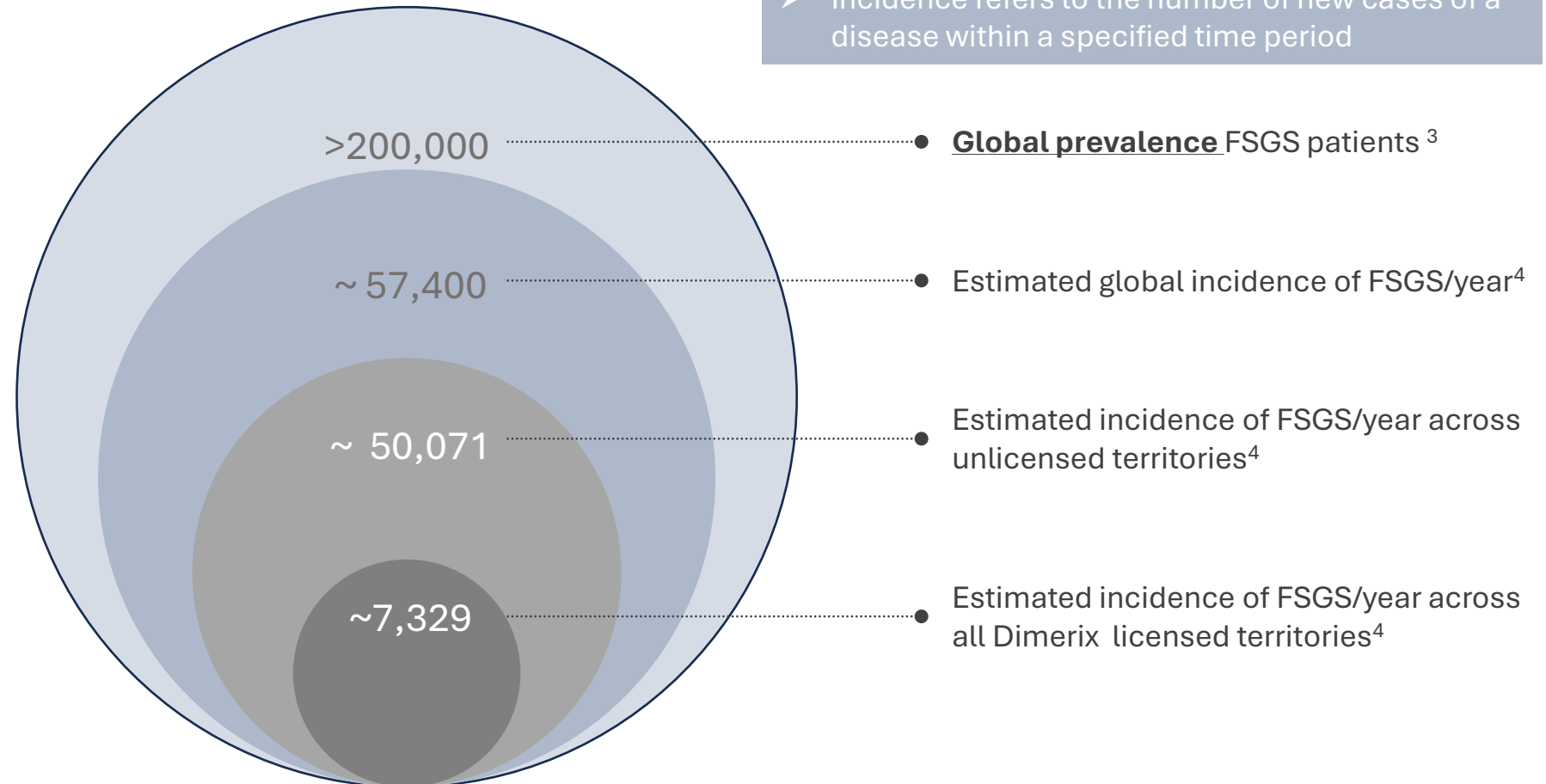
FSGS diagnosis driven by rates of biopsy - growth potential as biopsy rates increase

**7 per 1,000,000**

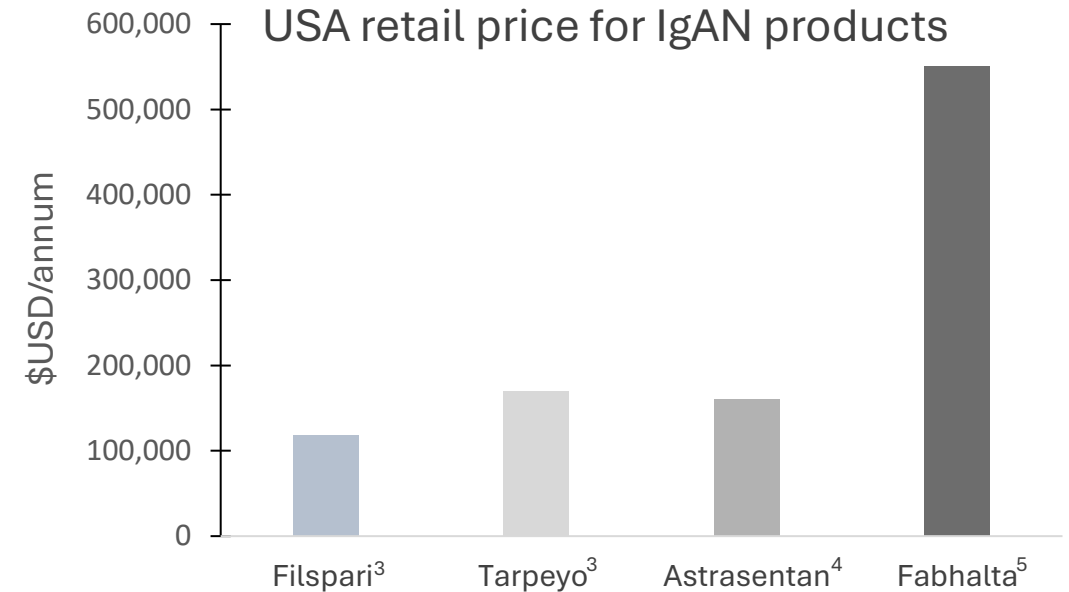
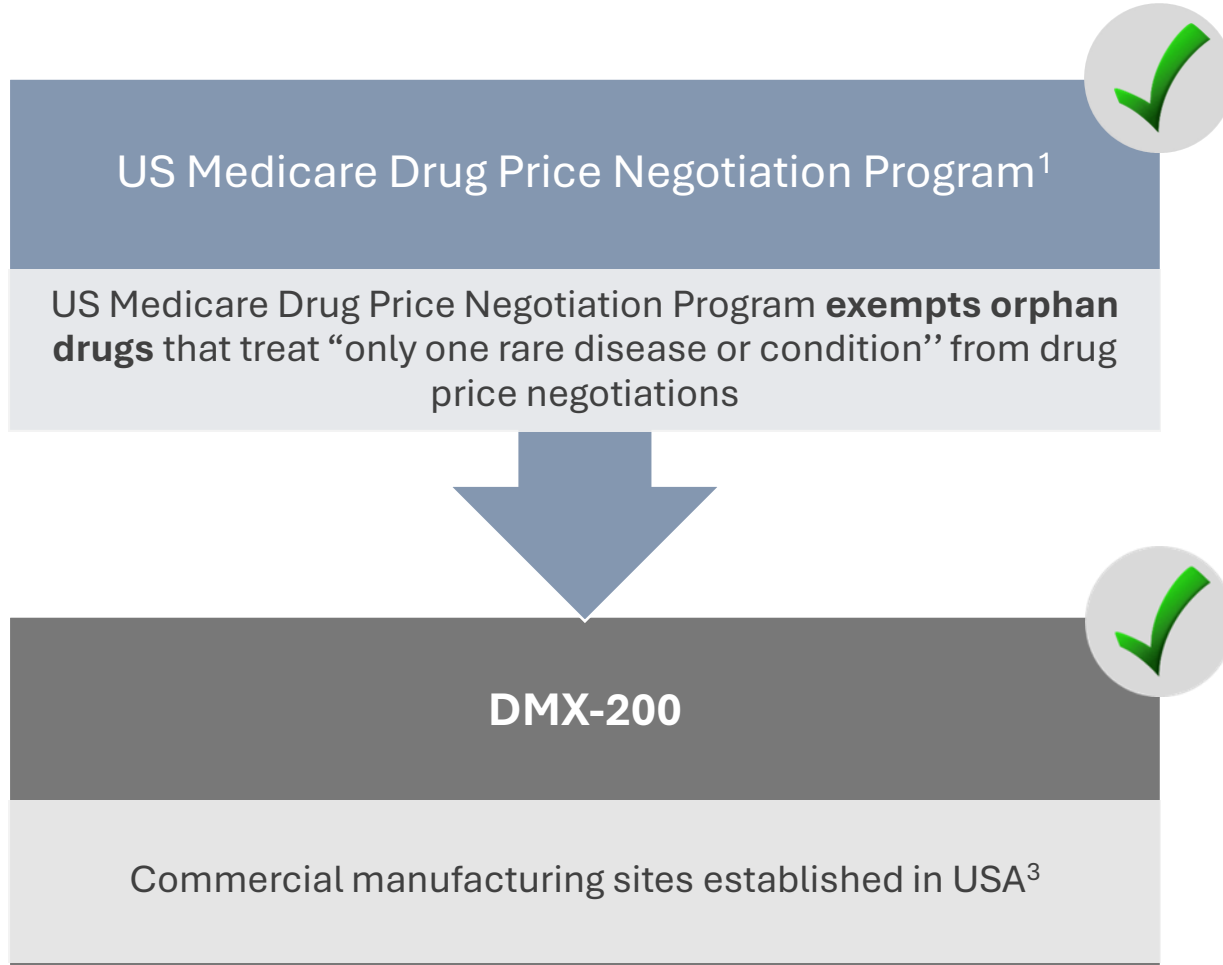
Global incidence rate of FSGS per capita per year<sup>1</sup>

FSGS is the most frequent primary glomerular disease that reaches end-stage renal failure in the US<sup>2</sup>

- Prevalence refers to the total number of existing cases (new and old)
- Incidence refers to the number of new cases of a disease within a specified time period



# Rare kidney disease pricing examples



Example ex-US pricing for other rare kidney disease drugs:

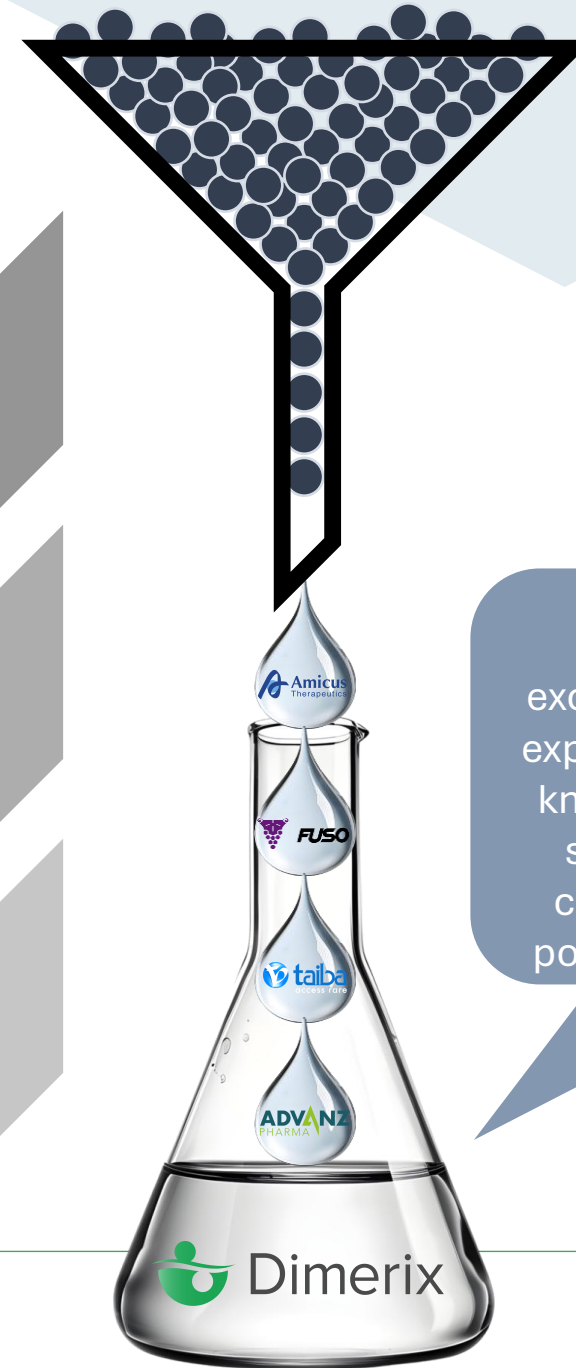
- ▶ in the US (i.e. Filspari in IgAN)<sup>6</sup> : **US\$9,900 p/month**
- ▶ in Europe/UK (i.e. Kinpeygo/Tarpeyo)<sup>7</sup> : **US\$8,267 p/month**
- ▶ Other key territories, including Middle East and China, use US and/or Europe as pricing reference<sup>8,9</sup>

# Selecting our partners

A partner that has existing/proven infrastructure to deliver DMX-200 to as many FSGS patients in need of treatment

A partner that recognises the overall value of the asset and views it as a strategic priority

A partner with a collaborative approach who will work almost as an extension of the Dimerix team to achieve the best outcome for the product and the patient

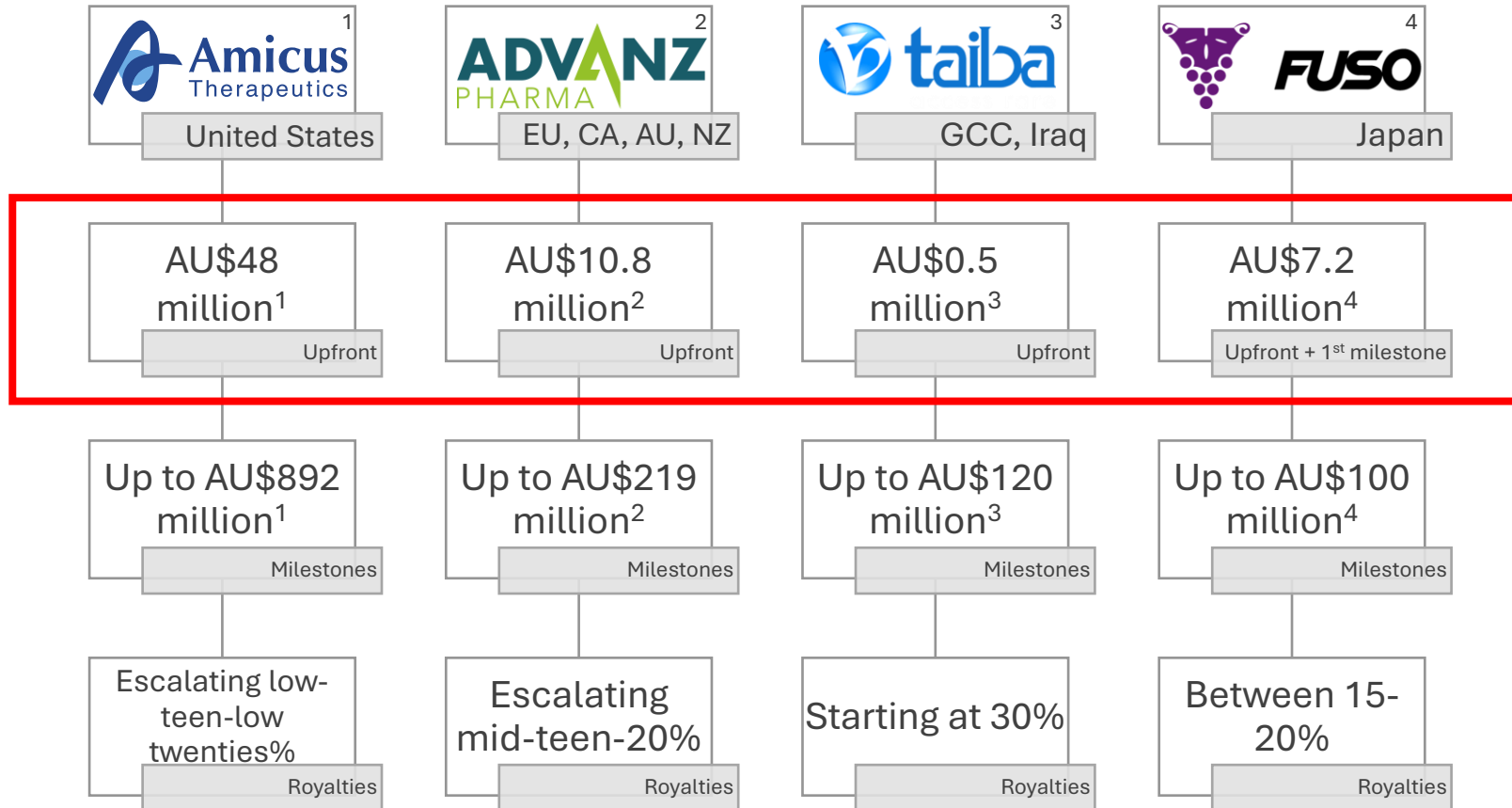


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exceptional, high quality partners, exponentially increasing collective knowledge & expertise, providing strong support in advancing & commercialising DMX-200 as a potential new treatment for FSGS

# Summary of licensing deals for DMX-200 to date

Dimerix has successfully partnered DMX-200 across key markets



Licensing deals collectively valued up to  
**~AU\$1.4 billion**  
in total upfront and potential milestone fees *plus* royalties<sup>1</sup>

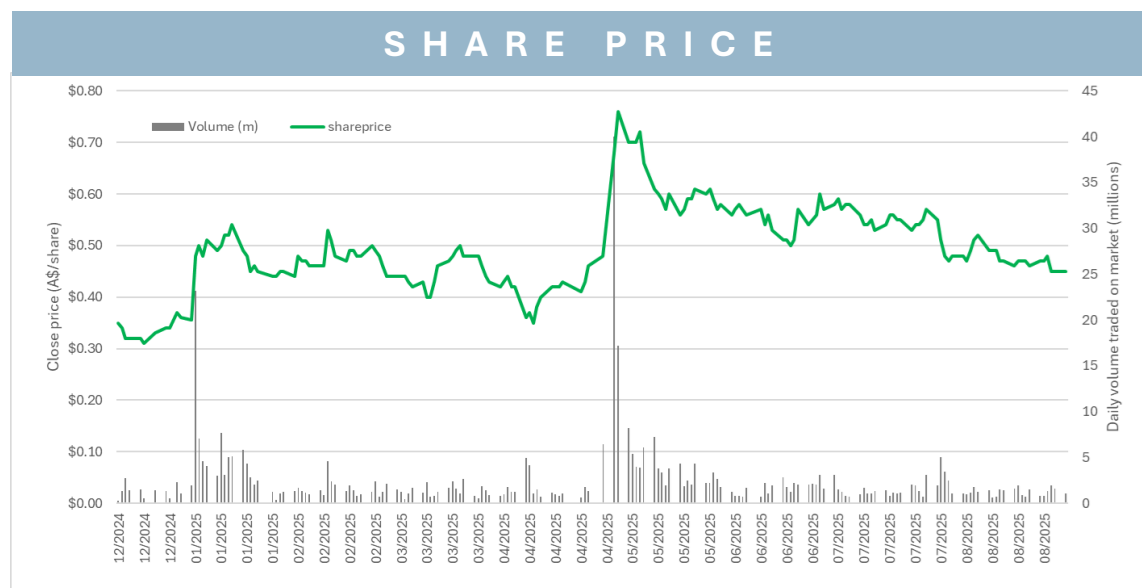
Over  
**AU\$65 million**  
in total payments received

Significant potential additional global **deal value remains**, as Dimerix pursues and progresses **licensing opportunities** with potential partners outside the licensed territories



# Corporate overview

Ticker Symbol	ASX: DXB
Cash Balance (Jun25)	\$68.3 million
Market Capitalisation <sup>1</sup>	\$270 million
Share price <sup>1</sup>	\$0.45
Total ordinary shares on issue <sup>1</sup>	600,184,606
Average Daily Liquidity by value for past 30 trading days <sup>2</sup>	\$1.1 million

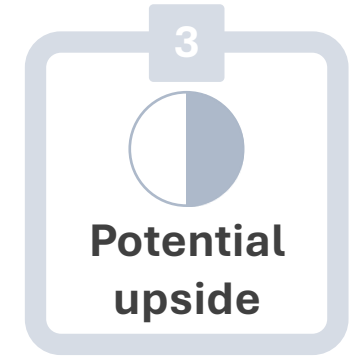
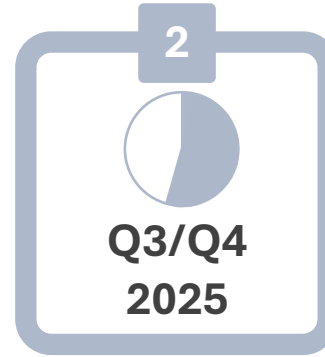


SUBSTANTIAL SHAREHOLDERS <sup>3</sup>			
Position	Holder Name	Holding	% IC
1	Mr P Meurs	87,259,311	14.5%
TOTAL (TOP 5) Shareholders		139,752,905	23.3%

# Potential catalysts



## CY 2025



- ✓ DMX-200 **licensed in US** for up to ~AU\$940 million<sup>1</sup>
- ✓ DMX-200 **licensed in Japan** for up to ~AU\$107 million<sup>2</sup>
- ✓ Positive Type C meeting: **FDA confirmed** proteinuria-based endpoint acceptable for full marketing approval in the US<sup>3</sup>
- ✓ First **development milestone** received from FUSO of AU\$4.1 million<sup>4</sup>

- Outcome of PARASOL working group analysis anticipated Q3 2025<sup>5</sup>
- FDA feedback anticipated Q4 2025<sup>5</sup>
- Blinded **interim data collection** anticipated in Q4 2025<sup>3</sup>
  - Potential for **accelerated (or conditional) approval** submission, subject to PARASOL outcomes, FDA feedback and interim analysis outcomes<sup>3,6</sup>
- **Full study recruitment** of 286 adult patients anticipated in H2 2025<sup>6</sup>
- Additional **pipeline** opportunity(s) identified

- Additional **licensing partners** for DMX-200: Dimerix continues to pursue potential licensing opportunities in un-licensed territories, including China
- Additional development **milestone payments** from existing licensees if milestone achieved

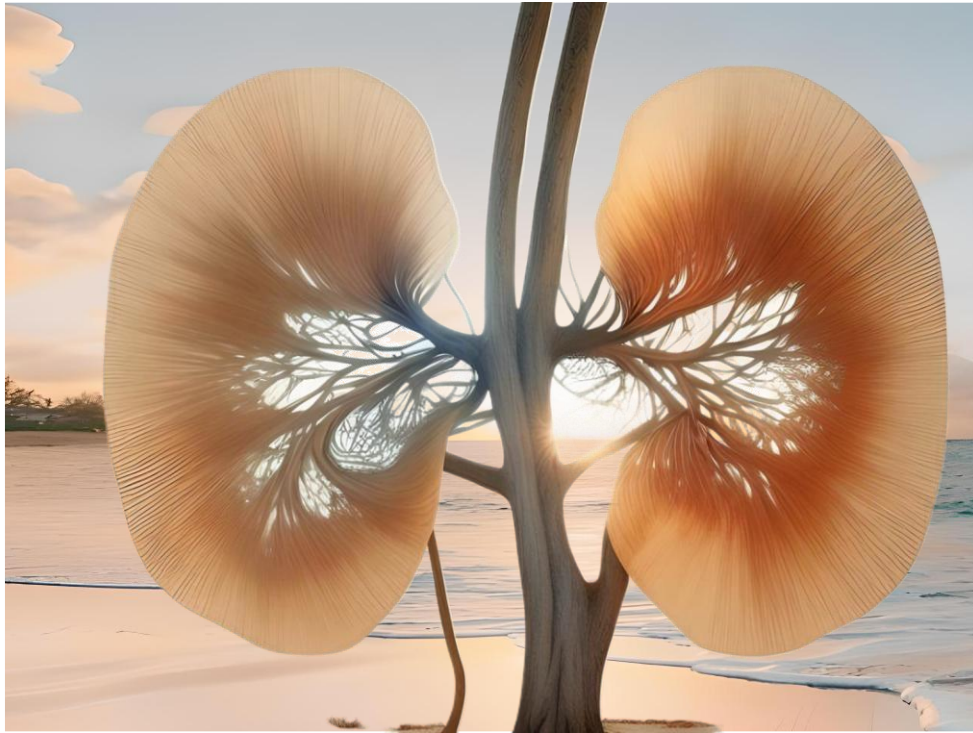


# Dimerix

(ASX:DXB)



## WELL POSITIONED TO DELIVER AGAINST STRATEGIC PLAN



A biopharmaceutical company developing innovative new therapies in areas with unmet medical needs, with a core focus on inflammatory disease treatments such as kidney and respiratory diseases.

### **ESG Statement**

*Dimerix is committed to integrating Environmental, Social and Governance (ESG) considerations across the development cycle of its programs, processes and decision making. The Dimerix commitment to improve its ESG performance demonstrate a strong, well-informed management attitude and a values led culture that is both alert and responsive to the challenges and opportunities of doing business responsibly and sustainably.*

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