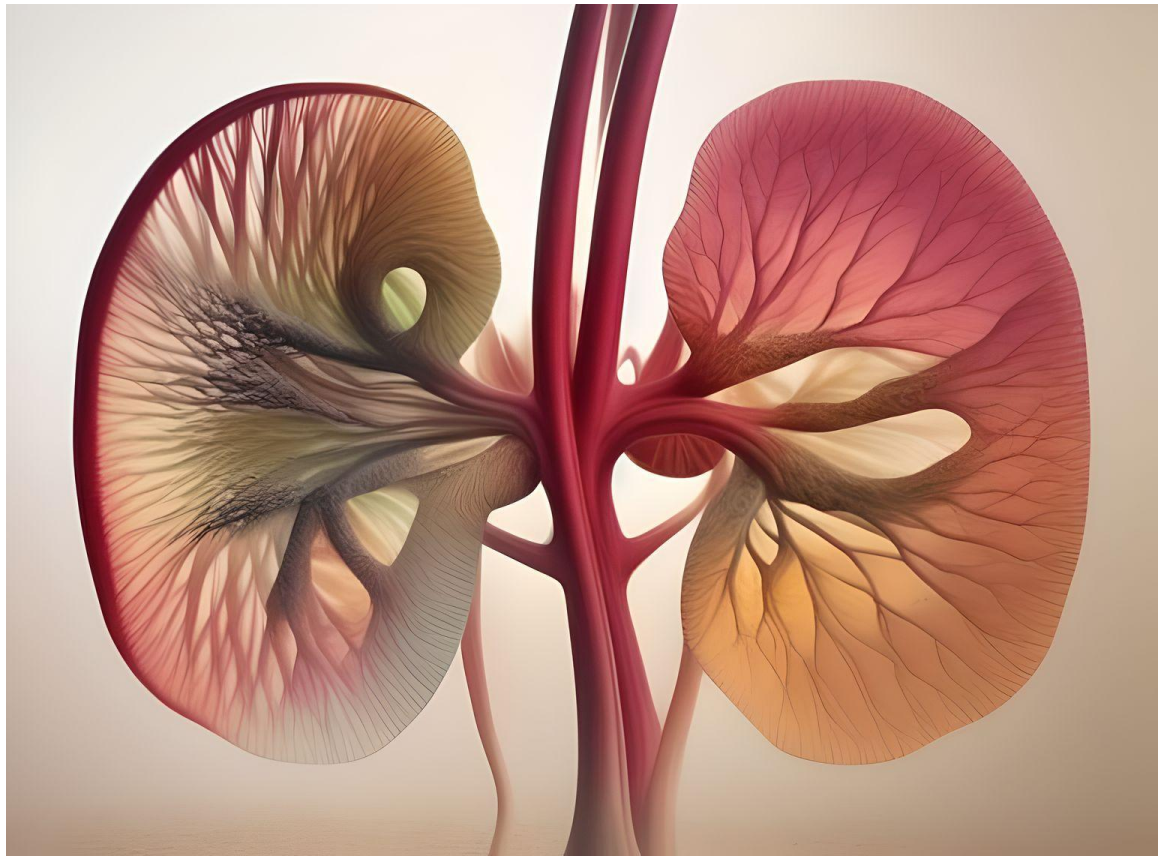
Dimerix

(ASX:DXB)

ACTION3

FSGS CLINICAL STUDY



What's the big deal?

Inside a licensing deal

Bioshares Summit
July 2024

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

Authorised for lodgement by the Board of the Company

Conference theme: Finding the Next Blockbuster Drug

discuss the approach to achieving this goal, including partnering and clinical trial data

Questions posed to Dimerix:

1. Two license deals: how long did these deals take to conclude, what were the main points to negotiate, how much due diligence was conducted by each company, and was it easier to secure the second deal following on from the Advanz deal?
2. What was behind the decision to license at this particular time, and not after the next interim read out; and what are the next regional deals the company is working on?
3. What are the decisions to be made at the next interim readout for Dimerix?

ACTION3

FSGS CLINICAL STUDY

DIMERIX - IN CONTEXT

Overview | Phase 3 Global Opportunity

Lead Drug Candidate

- DMX-200 is currently in a **Phase 3 clinical trial** for focal segmental glomerulosclerosis (FSGS)
- DMX-200 has **orphan drug designation** in key territories

FSGS Indication

- FSGS is a **rare disease** that causes scar tissue of kidneys, which leads to irreversible kidney damage[1]
- FSGS kidney damage can lead to dialysis, kidney transplants or death[1]
- There are currently **no approved treatments** available to treat FSGS

Commercial and Technical Validation

- **Two commercial licensing deals** achieved:
  - ~AU$11.5m in upfront payments, ~AU$340m in potential milestone payments + tiered royalties[2]
- **Successful Phase 3 interim analysis**: DMX-200 is performing better than placebo in reducing proteinuria[3]

Dimerix

1. Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/; 2. ASX release 05 October 2023 and 27 May 2024; 3. Predictive Power statistical model, using industry standard as set by the independent renal biostatistician consultant for Dimerix

Focal Segmental Glomerulosclerosis (FSGS)

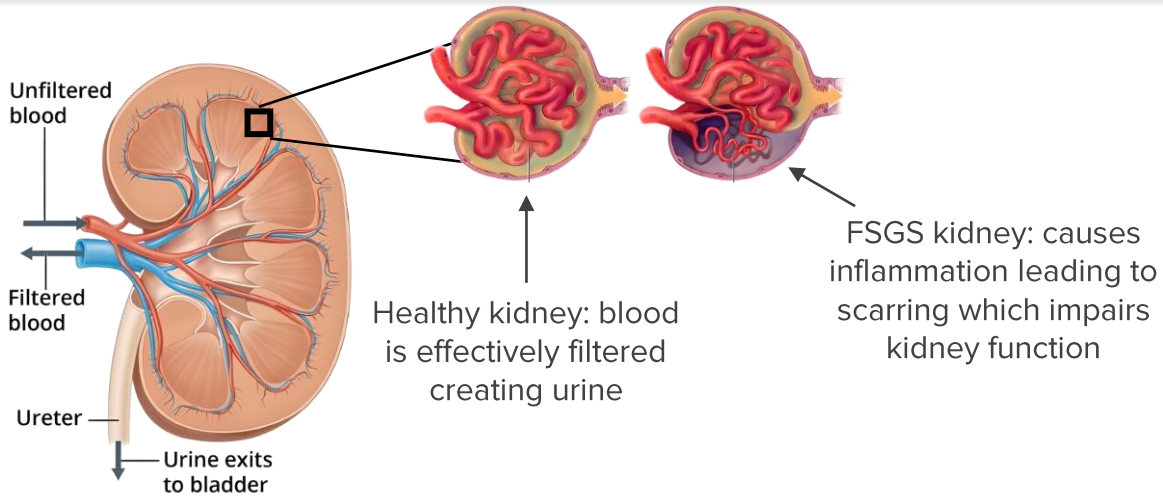
What is FSGS?

Focal	= some
Segmental	= sections
Glomerulo	= of the kidney filtering units
Sclerosis	= are scarred

How do you measure kidney function?

- Historically, measured using “hard” endpoints for kidney disease (kidney failure) -which may not be reached for decades[1]
- Regulatory agencies and national bodies now consider estimated glomerular filtration rate (eGFR) and proteinuria decline as surrogate end points for kidney failure in certain conditions[2]

FSGS Kidney Damage[3]



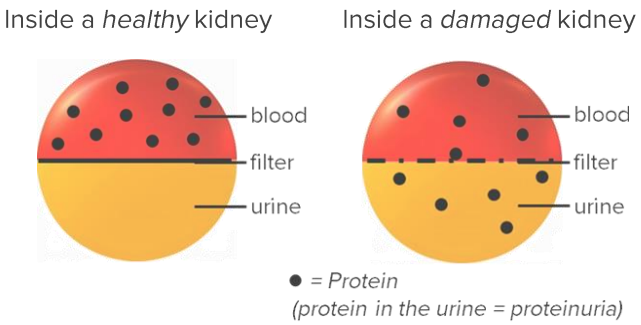
Dimerix

1. Hartung E, (2015), Pediatric Nephrology volume 31, pages381–391 DOI: 10.1007/s00467-015-3104-8; 2. Thompson A et al, (2019) Am J Kidney Dis.; 75(1):4-5: doi.org/10.1053/j.ajkd.2019.08.007; 3. Nephcure FSGS living with the disease (2024) at https://nephcure.org/livingwithkidneydisease/ns-and-other-glomerular-diseases/understanding-fsgs/

Primary endpoint: proteinuria

Why are kidneys important?

A healthy kidney is a good filter and allows little to no protein in the urine[1]



Why is proteinuria important?

When kidneys are damaged, protein can leak into the urine causing proteinuria, hence proteinuria can represent an important early marker of kidney function[2]

▲ proteinuria suggests damaged kidney

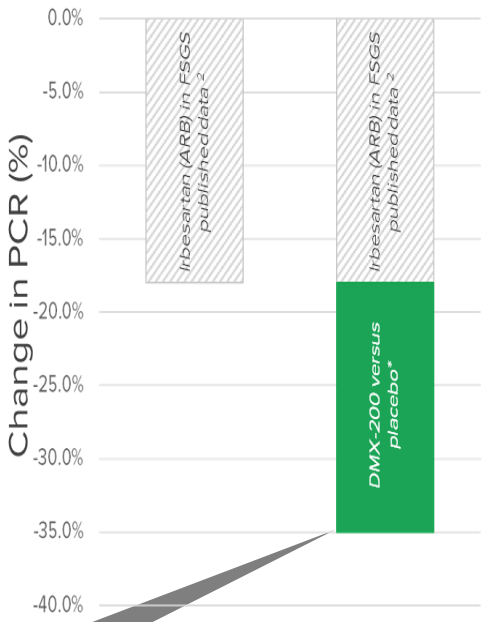
▼ little / no proteinuria suggests healthy kidney

DMX-200 aims to reduce the inflammation of the kidneys:

if DMX-200 reduces inflammation = the amount of proteinuria should decrease

Proteinuria: an important endpoint for DMX-200 study

Average reduction of **17%** in proteinuria after 16 weeks treatment on DMX-200 versus placebo[1]

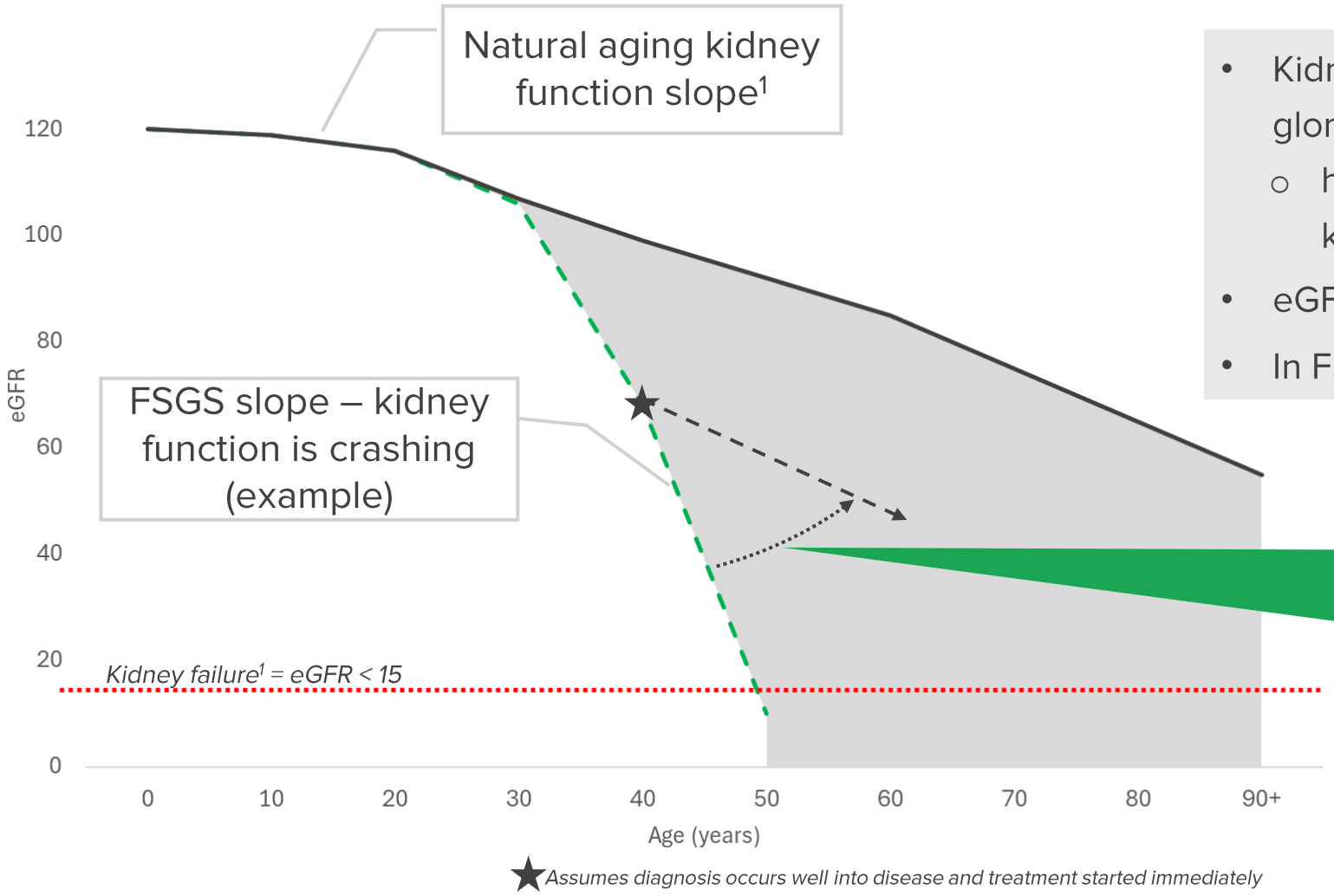


"Any reduction in proteinuria could yield years of preserved native kidney function and delay the onset of kidney failure and its attendant morbidity and mortality"
Kidney survival study – Troost et al, August 2020[3]

Dimerix

1. Nephcure FSGS living with the disease (2024) at https://nephcure.org/livingwithkidneydisease/ns-and-other-glomerular-diseases/understanding-fsgs/ 2. Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/; 3. Troost JP et al (August 2020); doi.org/10.1053/j.ajkd.2020.04.014

Primary endpoint: eGFR (kidney function) - example



- Kidney function can be measured using estimated glomerular filtration rate (eGFR):
  - how many millilitres of blood is filtered by the kidney per minute per year
- eGFR slope naturally declines as we age[1]
- In FSGS patients, it is crashing

Treatments, such as DMX-200, aim to bring the FSGS slope back up towards natural aging:

- This can add years to the life of the kidney
- Potential to delay dialysis and/or kidney transplant

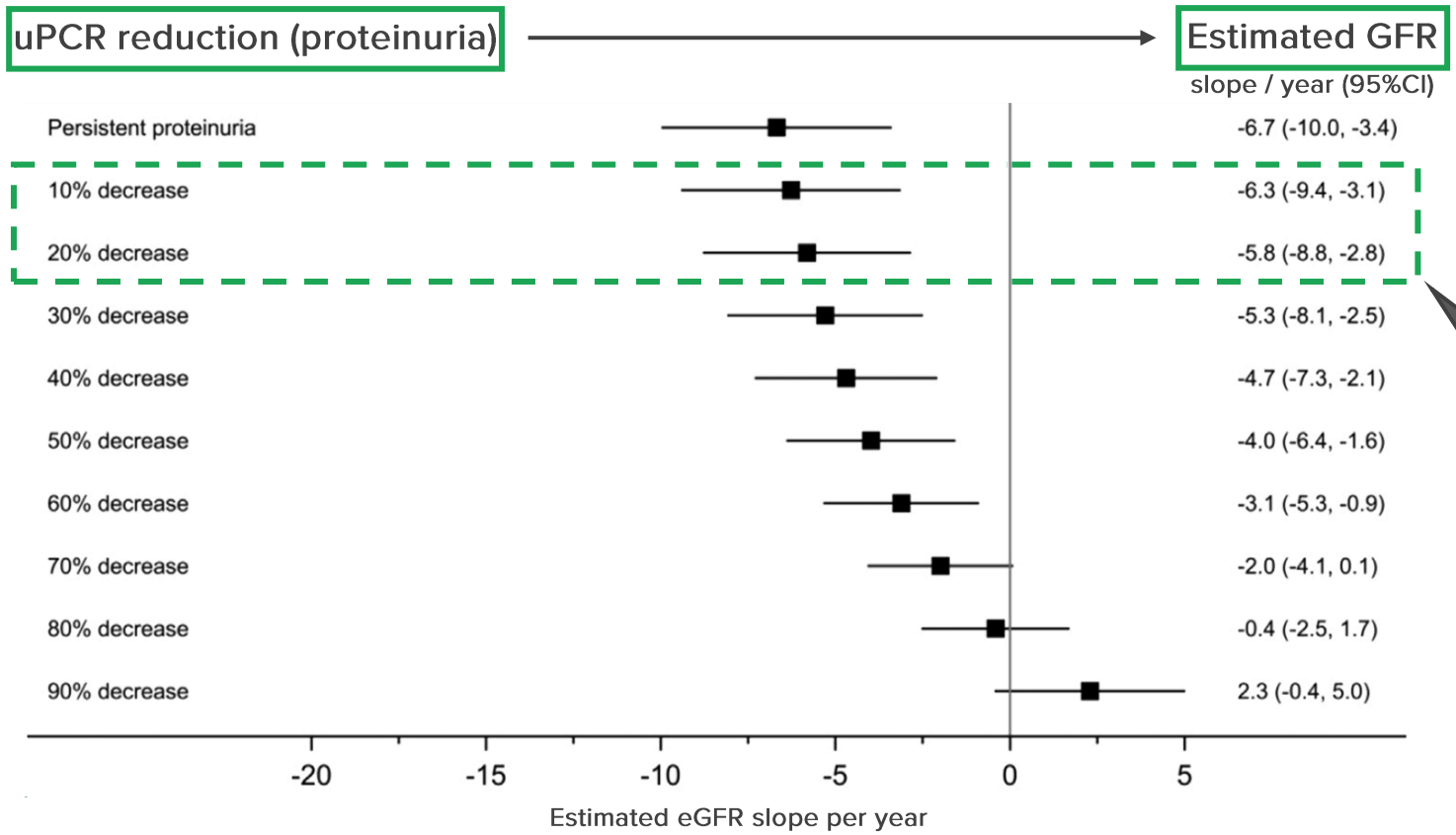
Dimerix

1. National Kidney Foundation: Estimated Glomerular Filtration Rate (eGFR): https://www.kidney.org/atoz/content/gfr

DMX-200: Phase 2 met primary and secondary endpoints

17% average reduction of proteinuria in Phase 2 is clinically meaningful[1]

Adjusted models



"reductions ~10% in proteinuria translated to clinically meaningful differences in eGFR" Kidney survival study – Troost et al., August 2020[1]

uPCR = protein creatinine ratio; eGFR: estimated Glomerular Filtration Rate – measure of kidney function; 1. Troost JP et al (August 2020); doi.org/10.1053/j.ajkd.2020.04.014

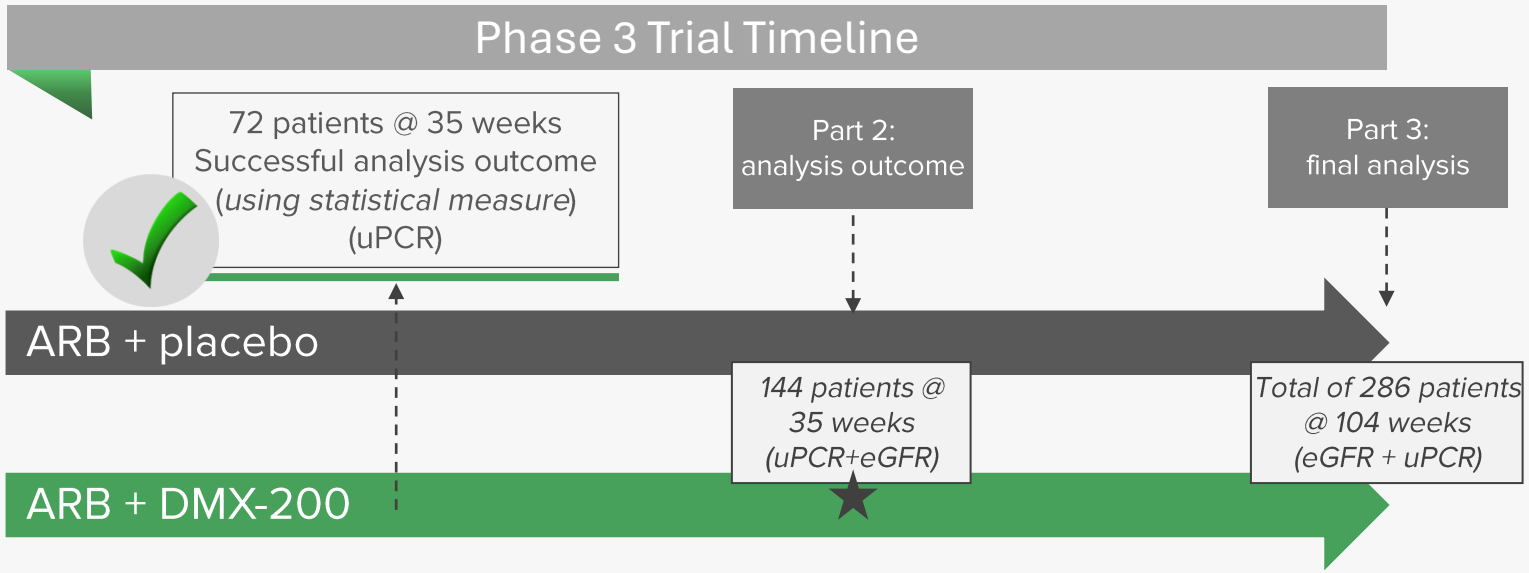
ACTION3 FSGS CLINICAL STUDY Phase 3 clinical trial – next steps

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

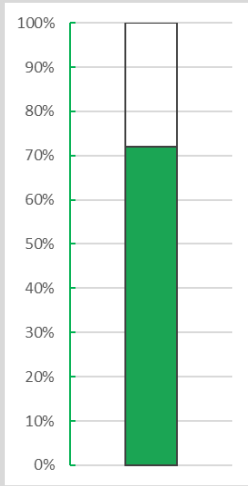
Background

- 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



Current recruitment
72%



Target (n=144)

★ *Potential to submit for conditional marketing approval**

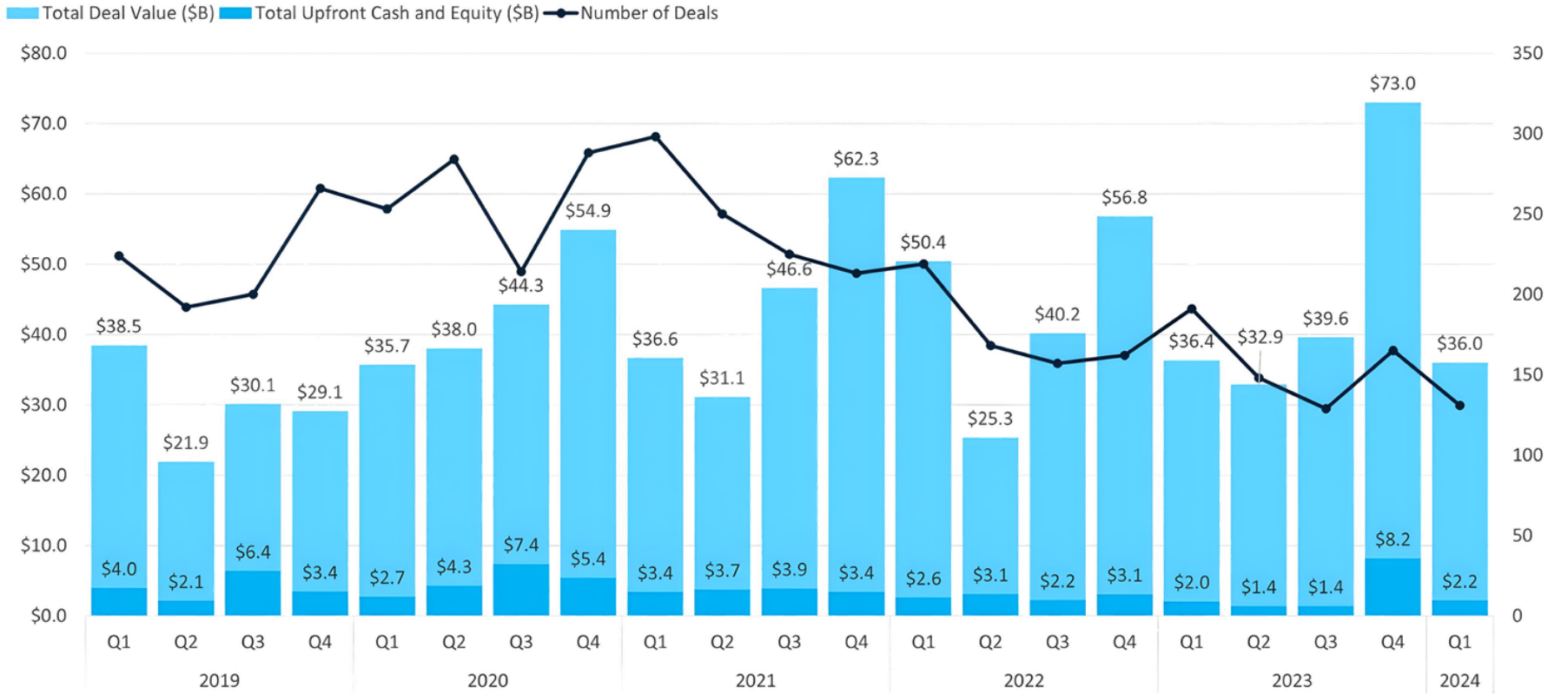
Dimerix

*subject to project PARASOL outcomes, recommendations of the IDMC (based on review of emerging data from ACTION3) and subsequent discussions with the appropriate regulatory authorities such as the FDA in the US. uPCR = urinary proteinuria; eGFR = estimated glomerular filtration rate (kidney function);

WHAT ARE THE TRENDS IN LICENSING THERAPEUTICS?

Global partnering trends – Q1 2024

R&D Partnerships – Global Healthcare and Life Sciences[1]



Source: DealForma Database

DEALFORMA

The total number of deals across the sectors is declining[2]

- 2023 and Q1 2024 dealmaking environment shows fewer, but higher-value, transactions[3]
- Pharma is placing bigger bets on fewer, later stage and more strategic assets and platforms[3]

Dimerix

1. Healthcare & Life Sciences Quarterly Overview – Q1 2024, DealForma database : https://dealforma.com/healthcare-life-sciences-quarterly-overview-q1-2024/
2. JP Morgan Q1 2024 Biopharma Licensing and Venture Report: www.jpmorgan.com/content/dam/jpmorgan/documents/cb/insights/outlook/jpm-biopharma-deck-q1-final.pdf;
3. Clarivate, Pharma is placing bigger bets on fewer, more strategic assets and platforms, May 2024: https://clarivate.com/blog/pharma-is-placing-bigger-bets-on-fewer-more-strategic-assets-and-platforms/

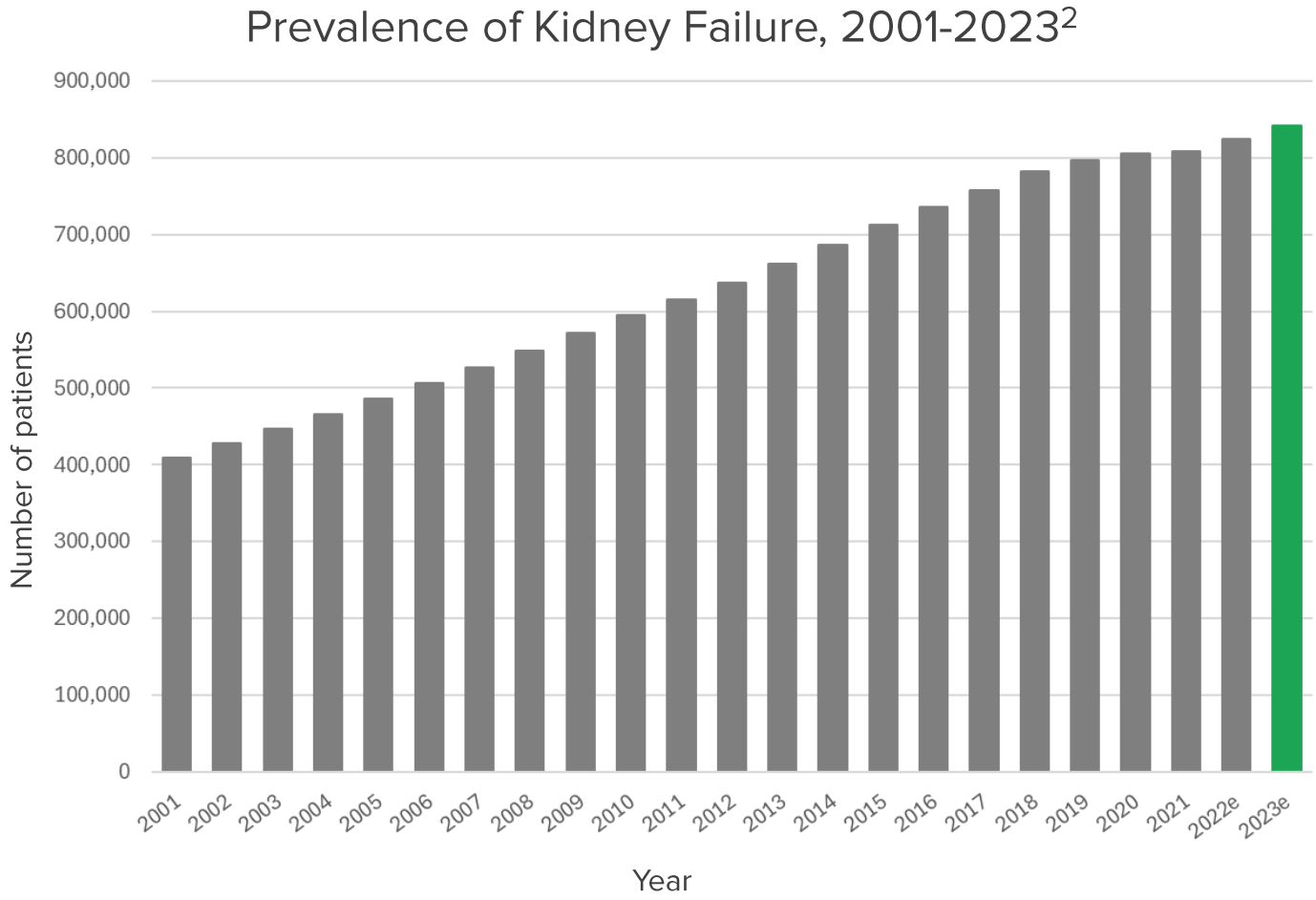
Kidney disease is high interest area for pharma

Kidney disease is the third-fastest-growing cause of death globally[1]

- In the US alone, the number of people with kidney failure increased by >200% from 2001 to 2023[2]
- By 2040, it is expected to become the fifth-highest cause of years of life lost[1,2]

The US government-funded health-care plan (Medicare) spent US$130 billion in 2023 to treat kidney disease patients

- the majority being on dialysis[1,3]



1. Editorial, Time to sound the alarm about the hidden epidemic of kidney disease, Nature 628, 7-8 (2024) doi: https://doi.org/10.1038/d41586-024-00961-5; 2. The United States Renal Data System (USRDS) Annual Report 2023; (2022 & 2023 estimates based on average growth 2001-2021)
3. Francis et al. (2024), Nature Rev. Nephrol. https://doi.org/10.1038/s41581-024-00820-6

DIMERIX - IN DEAL MAKING MODE

Summary of DMX-200 licensing deals

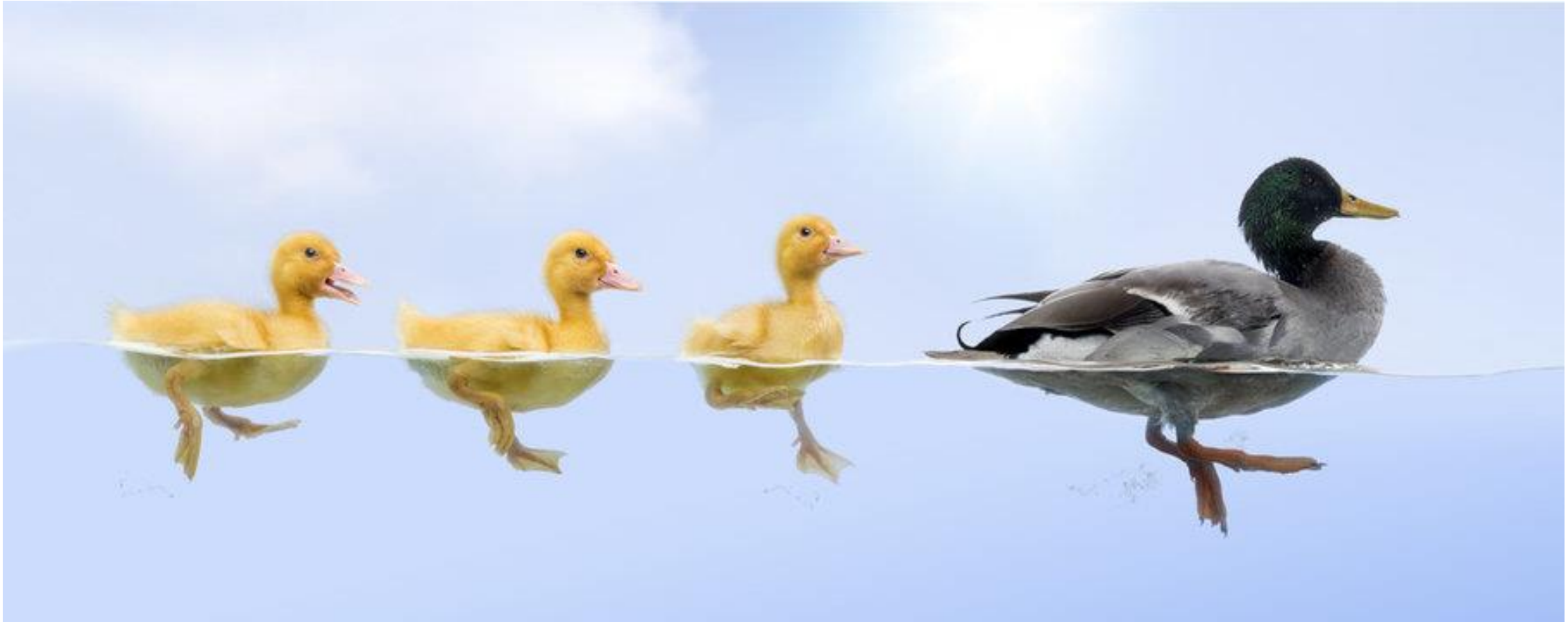
Dimerix has validated the technology[1] and proven its ability to licence multiple territories, with more deals anticipated

Summary	ADVANZ PHARMA [2]	taiba access rare [3]	Other Licensing Deals (incl. US & China)
Territories Covered	EEA, Canada, Switzerland, UK, Australia and New Zealand	United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq	?
Upfront Payment	~AU$10.8 million	~AU$500,000	?
Milestone Payments	Up to ~AU$219 million	Up to ~AU$120 million	?
Royalties on net sales	Escalating mid-teen-20%	Starting at 30%	?

Dimerix has achieved up to AU$350 million[2,3] in upfront payments and potential milestones payments from two licensing deals

Major focus on US & China which, collectively, could represent ~70% of the global value[4]

1. ASX release 5 March 2024; 2. Based on Euro conversions & further terms outlined in ASX Announcement on 5 October 2023
3. Based on US dollar conversions & further terms outlined in ASX Announcement on 27 May 2024; 4. see slide 9

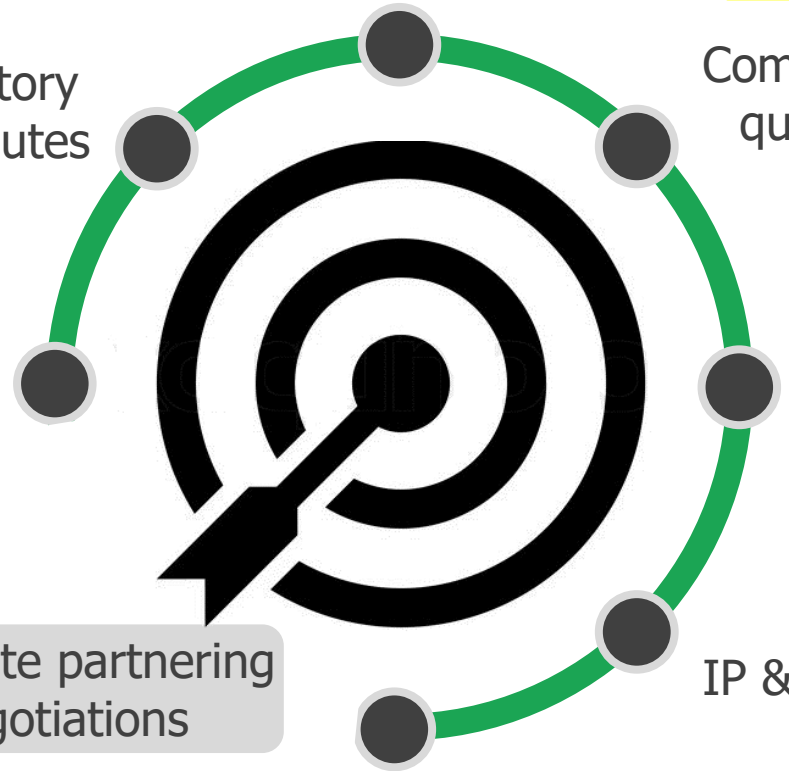


GETTING OUR DUCKS IN A ROW

Competitive positioning summary

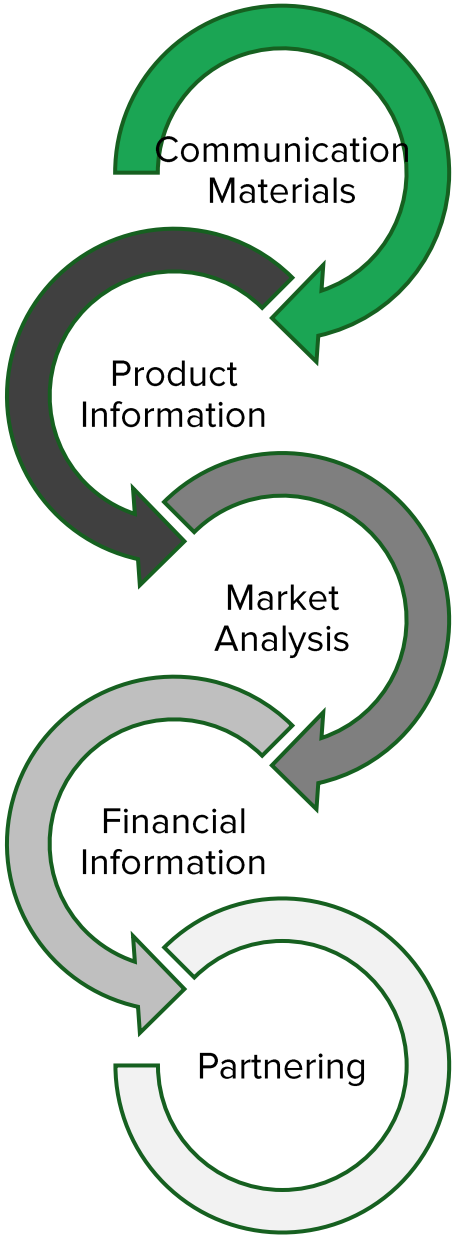
Slide from Bioshares 2019 presentation on what we intended to do to prepare for partnering – we did exactly what we said we would do

- Clinical studies play large part in the commercialisation plan but are by no means the only piece of the puzzle
- In due diligence: everything here was reviewed in the Dimerix dataroom!



Many years behind the scenes to get here

Dimerix partnering executed to plan



Potential partners identified as part of business development plan

All materials are ready at the start of a partnering exercise

Time to deal – actual timeline experience

The time from first meeting to executing a license agreement takes time - it can take up to 2 years

It is all in the planning and experience in doing deals:

- Structure, tactics & outreach
- Process management
- Negotiation and execution

Dimerix has a number of parties engaged along this process[1]

Deal 1 - ~16 months

2 months → 4 months → 4 months → 1 month → 4 months → 2 days

Deal 2 - ~7 months

1 month → 2 months → 2 months → 1 month → 1 month → 1 day

1. Offers are non-binding and subject to due diligence, an agreed definitive agreement and board approval

Order of deals was strategic

1 Commercial Validation

1st deal – EU selected: commercially **validate** asset and prove partnering capabilities before Part 1 analysis

2nd deal – GCC selected: commercial validation and flagged partnering mode post Part 1 analysis

2 Negotiation Leverage

Further deals anticipated **before** Part 2 analysis; Dimerix negotiation position strengthened by Part 1 outcome

Major focus on US & China which, collectively, could represent **~70% of the global value**[1]

3 Potential Marketing

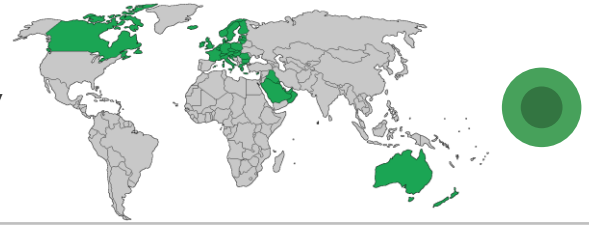
Part 2 analysis anticipated mid-2025[2]

Potential to submit for conditional **marketing approval**[3]

Dimerix

*1. Investor presentation ASX release 16 June 2024; 2. subject to recruitment; 3. *subject to project PARASOL outcomes, recommendations of the IDMC (based on review of emerging data from ACTION3) and subsequent discussions with the appropriate regulatory authorities such as the FDA in the US.*

Summary | Phase 3 Global Opportunity



Lead Drug Candidate	• DMX-200 is currently in a **Phase 3 clinical trial** for focal segmental glomerulosclerosis (FSGS)
FSGS Indication	• FSGS is a disease that causes scar tissue of kidneys, which leads to irreversible kidney damage[1] • FSGS kidney damage can lead to dialysis, kidney transplants or death[1]
Market Opportunity	• Estimated ~>200,000 people with FSGS in the 7 major markets (makes **FSGS a rare disease**)[2] • Estimated 40,000[1] – 80,000[2] people in the US alone • Drugs for rare kidney diseases can be priced at **~US$120,000 per annum** in the US[3] • There are currently **no approved treatments** available to treat FSGS
Commercial Validation	• **Two commercial licensing deals achieved:** ○ ~AUD$11.5m in upfront payments, ~$340m in potential milestone payments + tiered royalties • Phase 3 interim analysis: **DMX-200 is performing better than placebo** in reducing proteinuria (using a statistical measure[5]) in a significantly larger cohort than DXB prior Phase 2 study
Upcoming FSGS Milestones	• **Execution of potential licensing deals** for available jurisdictions, including the US & China[6] • **Recruitment** and dosing of 144 patients for Part 2 • Part 2 – **second interim analysis** outcome estimated mid-2025

Dimerix

1. Nephcure Understanding FSGS 2022: https://nephcure.org/livingwithkidneydisease/ns-and-other-glomerular-diseases/understanding-fsgs/; 2. Focal segmental glomerulosclerosis – Market Insight (2022), Epidemiology and market forecast – 2032 Delve Insight;; 3. Cost of Sparsentan - approved for IgAN https://endpts.com/fda-clears-traveres-rare-kidney-disease-drug-will-come-with-rems-program; 4. ASX release 05Oct23; 5. Predictive Power statistical model, using industry standard as set by the independent renal biostatistician consultant for Dimerix; 6. Offers are non-binding and subject to due diligence, a definitive agreement and board approval

Corporate overview

Ticker Symbol	ASX: DXB
Cash Balance (Mar24)	~A$35.2 million
Market Capitalisation	~A$250 million
Share price	~A$0.46
Total ordinary shares on issue	550,211,758
Average Daily Liquidity by volume[1]	~5.1 million

SHARE PRICE

SUBSTANTIAL SHAREHOLDERS[2]

Position	Holder Name	Holding	% IC
1	Mr P Meurs	75,304,506	13.7%
TOTAL (TOP 5)		123,994,526	22.5%

1. Past 30 trading days liquidity as at 09 July 2024; 2. Shareholder register as at 09 July 2024

Dimerix