



Immediate Release

DIMERIX PRESENTS AT BIOSHARES BIOTECH SUMMIT

MELBOURNE, Australia, 12 July 2024: Dimerix Limited (ASX: DXB), a biopharmaceutical company with a Phase 3 clinical asset in inflammatory disease, is pleased to advise that CEO and Managing Director, Dr Nina Webster, will be presenting at the 18th Bioshares Biotech Summit in Fremantle, WA on 12 July 2024.

The Bioshares Biotech Summit's unique format brings together biotechnology companies and equity capital markets participants to explore not just what biotechnology companies do but just as importantly, what outside influences can impact development programs. In keeping with this purpose, Dr Webster was asked to focus on approaches to licensing transactions and clinical trial data, including the two recent licensing transactions and the current Phase 3 clinical trial study.

A copy of the presentation is attached.

For further information, please visit our website at www.dimerix.com or contact:

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Authorised for lodgement by the Board of the Company

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Dimerix is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs.

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About ACTION3 FSGS Phase 3 Study
FSGS CLINICAL STUDY

The Phase 3 study, which is titled “**A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammatory **N**ephrosis”, or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients will be randomized to receive either DMX200 (120 mg capsule twice daily) or placebo.

The single Phase 3 trial in FSGS patients has interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support marketing approval.

Further information about the study can be found on ClinicalTrials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785).

About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including both kidney and respiratory diseases. Dimerix is currently focussed on developing its proprietary Phase 3 product candidate DMX-200 (QYTOVRA® in some territories), for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-200 and DMX-700 were both identified using Dimerix’ proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities.

About DMX 200

DMX 200 is the adjunct therapy of a chemokine receptor (CCR2) antagonist administered to patients already receiving an angiotensin II type I receptor (AT1R) blocker - the standard of care treatment for hypertension and kidney disease. DMX 200 is protected by granted patents in various territories until 2032, with patent applications submitted globally that may extend patent protection to 2042, in addition to any exclusivity period that may apply in key territories. In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a trial in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any trial, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease.

About FSGS

FSGS is a rare disease that attacks the kidney’s filtering units, where blood is cleaned (called the ‘glomeruli’), causing irreversible scarring. This leads to permanent kidney damage and eventual end-stage failure of the organ, requiring dialysis or transplantation. For those diagnosed with FSGS the prognosis is not good. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old.¹ For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.² At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are limited. FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,¹ and worldwide about 220,000.³ The illness has a global compound annual growth rate of 8%, with over 5,400 new

cases diagnosed in the US alone each year.⁴ Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX 200 in both the US and Europe for FSGS. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and a fast-tracked regulatory pathway to approval. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

References

- 1 Guruswamy Sangameswaran KD, Baradhi KM. (2021) *Focal Segmental Glomerulosclerosis*, online: <https://www.ncbi.nlm.nih.gov/books/NBK532272/>
- 2 *Front. Immunol.*, (July 2019) | <https://doi.org/10.3389/fimmu.2019.01669>
- 3 *Delve Insight Market Research Report (2022): Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032*; <https://www.delveinsight.com/report-store/focal-segmental-glomerulosclerosis-fsgs-market>;
- 4 *Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis*, online <https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/>



Dimerix

(ASX:DXB)

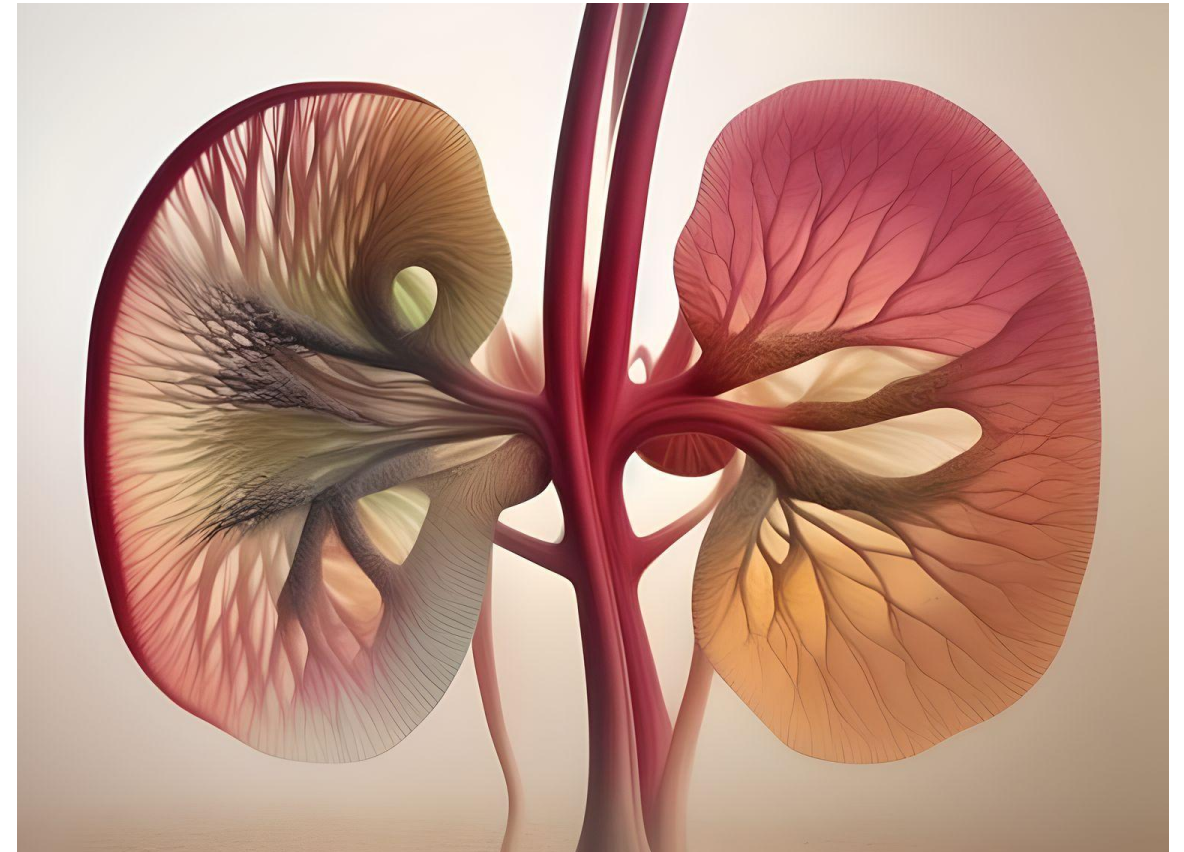


What's the big deal?

Inside a licensing deal

Bioshares Summit
July 2024

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



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 damage¹
- FSGS kidney damage can lead to dialysis, kidney transplants or death¹
- 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 royalties²
- **Successful Phase 3 interim analysis**: DMX-200 is performing better than placebo in reducing proteinuria³

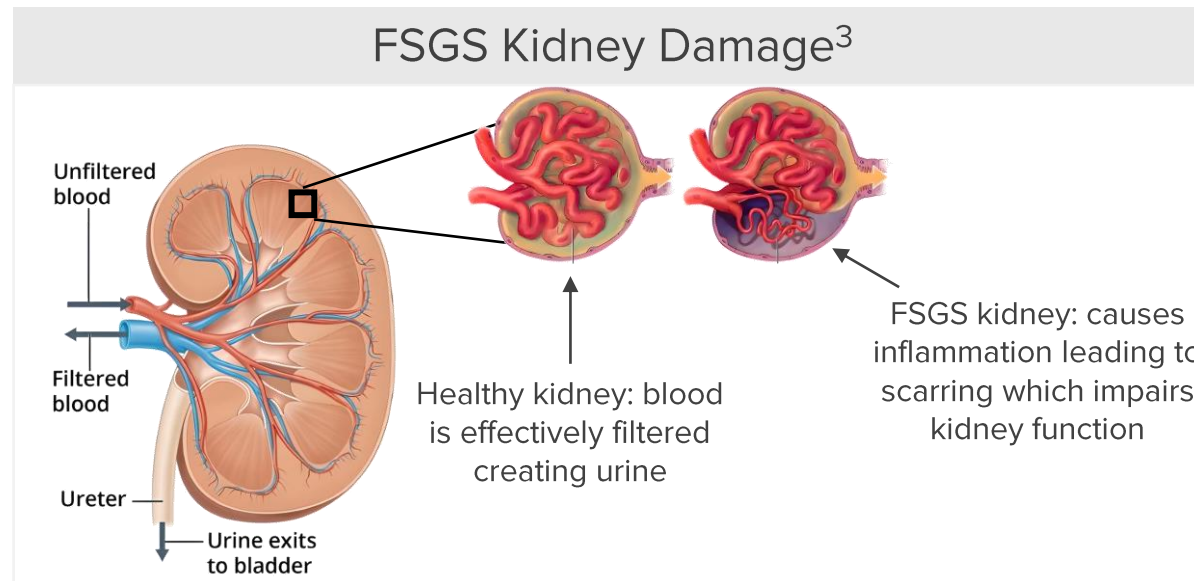
Focal Segmental Glomerulosclerosis (FSGS)

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 decades¹
- Regulatory agencies and national bodies now consider estimated glomerular filtration rate (eGFR) and proteinuria decline as surrogate end points for kidney failure in certain conditions²

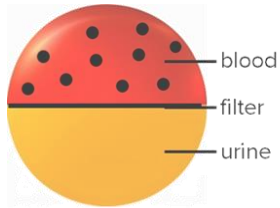


Primary endpoint: proteinuria

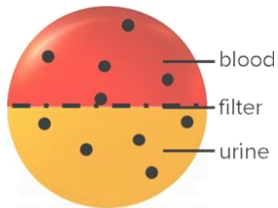
Why are kidneys important?

A healthy kidney is a good filter and allows little to no protein in the urine¹

Inside a *healthy* kidney



Inside a *damaged* kidney



● = Protein
(protein in the urine = proteinuria)

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 function²



proteinuria suggests damaged kidney

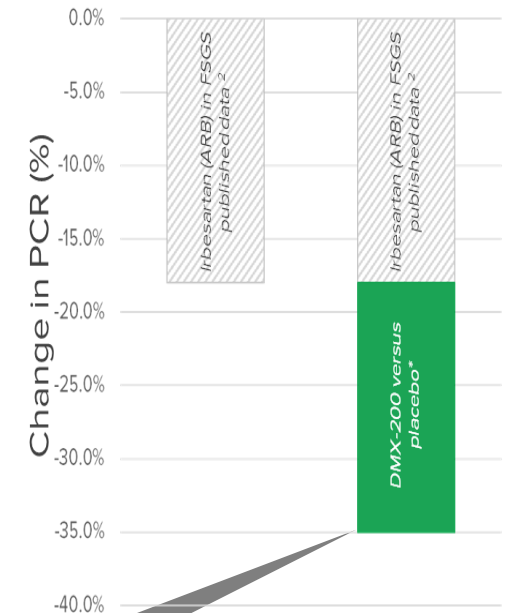


little / no proteinuria suggests healthy kidney

DMX-200 aims to reduce the inflammation of the kidneys:
if DMX-200 reduces inflammation = the amount of proteinuria should decrease

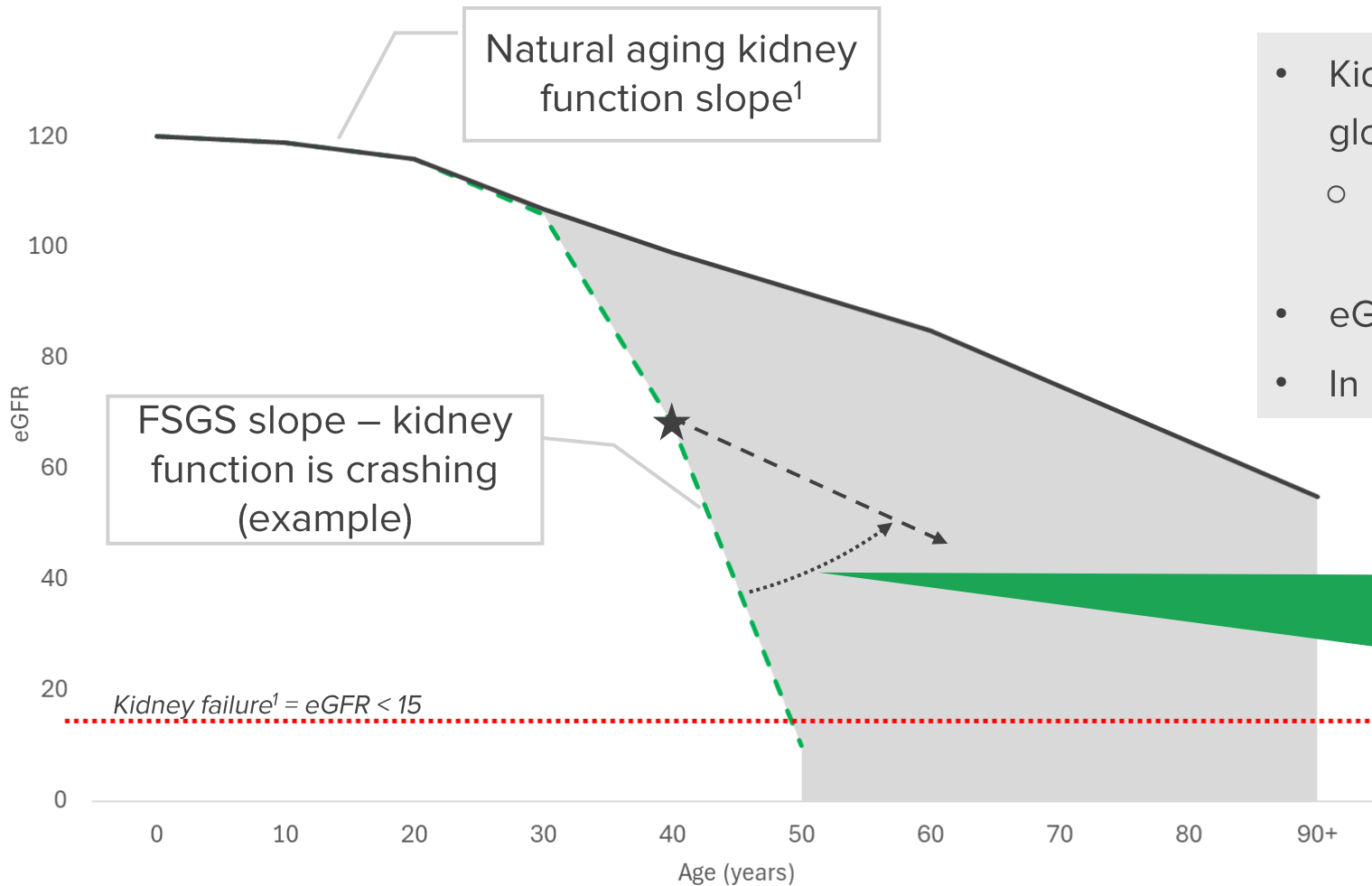
Proteinuria: an important endpoint for DMX-200 study

Average reduction of 17% in proteinuria after 16 weeks treatment on DMX-200 versus placebo¹



“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 2020³

Primary endpoint: eGFR (kidney function) - example



★ Assumes diagnosis occurs well into disease and treatment started immediately

- 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 age¹
- In FSGS patients, it is crashing

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

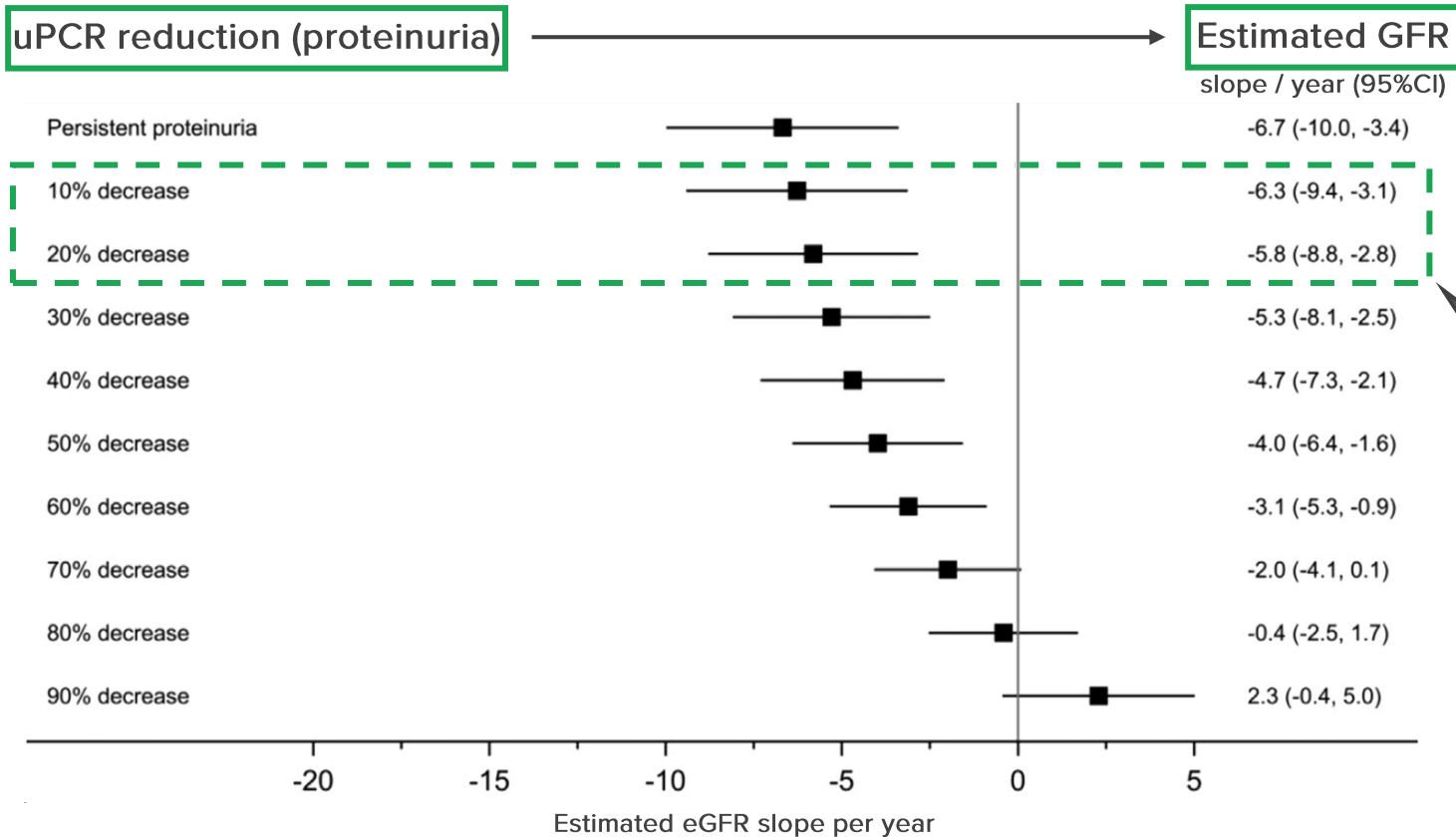
- This can add years to the life of the kidney
- Potential to delay dialysis and/or kidney transplant

DMX-200: Phase 2 met primary and secondary endpoints



17% average reduction of proteinuria in Phase 2 is clinically meaningful¹

Adjusted models



“reductions ~10% in proteinuria translated to clinically meaningful differences in eGFR”
Kidney survival study – Troost et al., August 2020¹



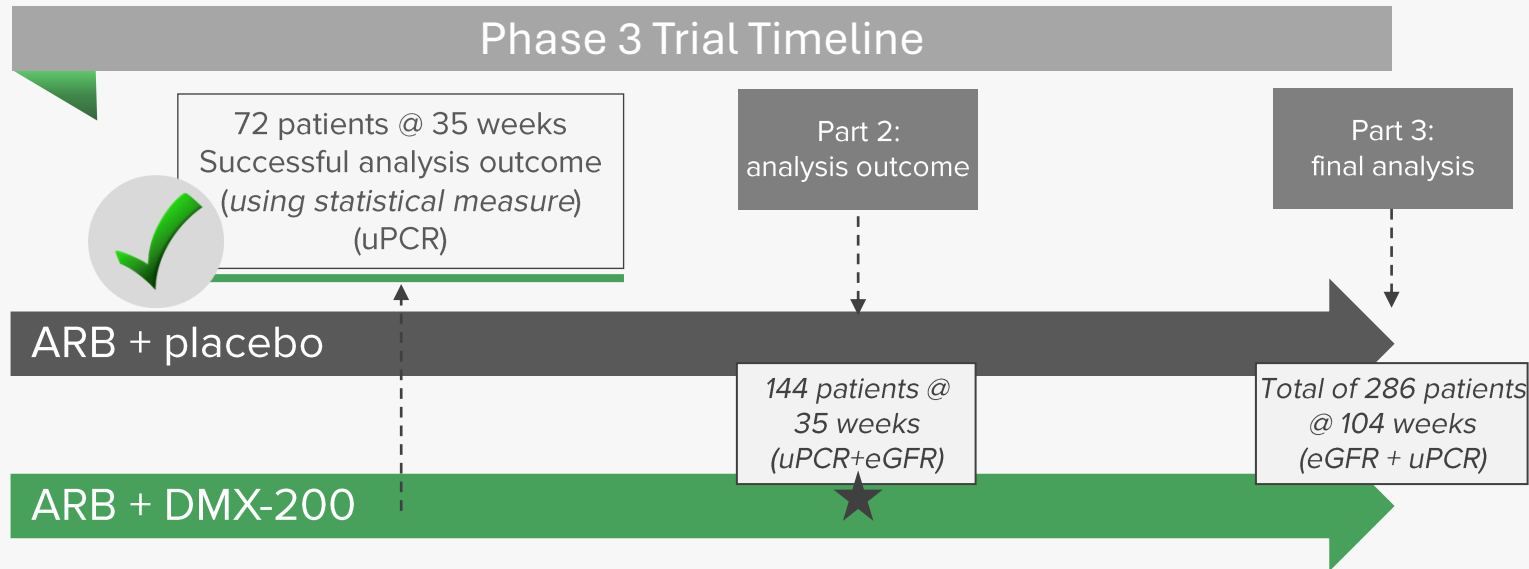
Phase 3 clinical trial – next steps

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

Background

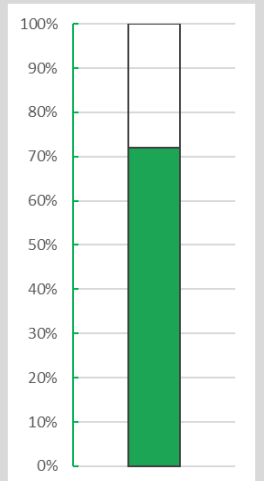
- Patients recruited, then screened and stabilised on background medications
- Patients randomised to receive drug or placebo
- DXB remains blinded at all times during study

Phase 3 Trial Timeline



Current recruitment

72%



Target (n=144)

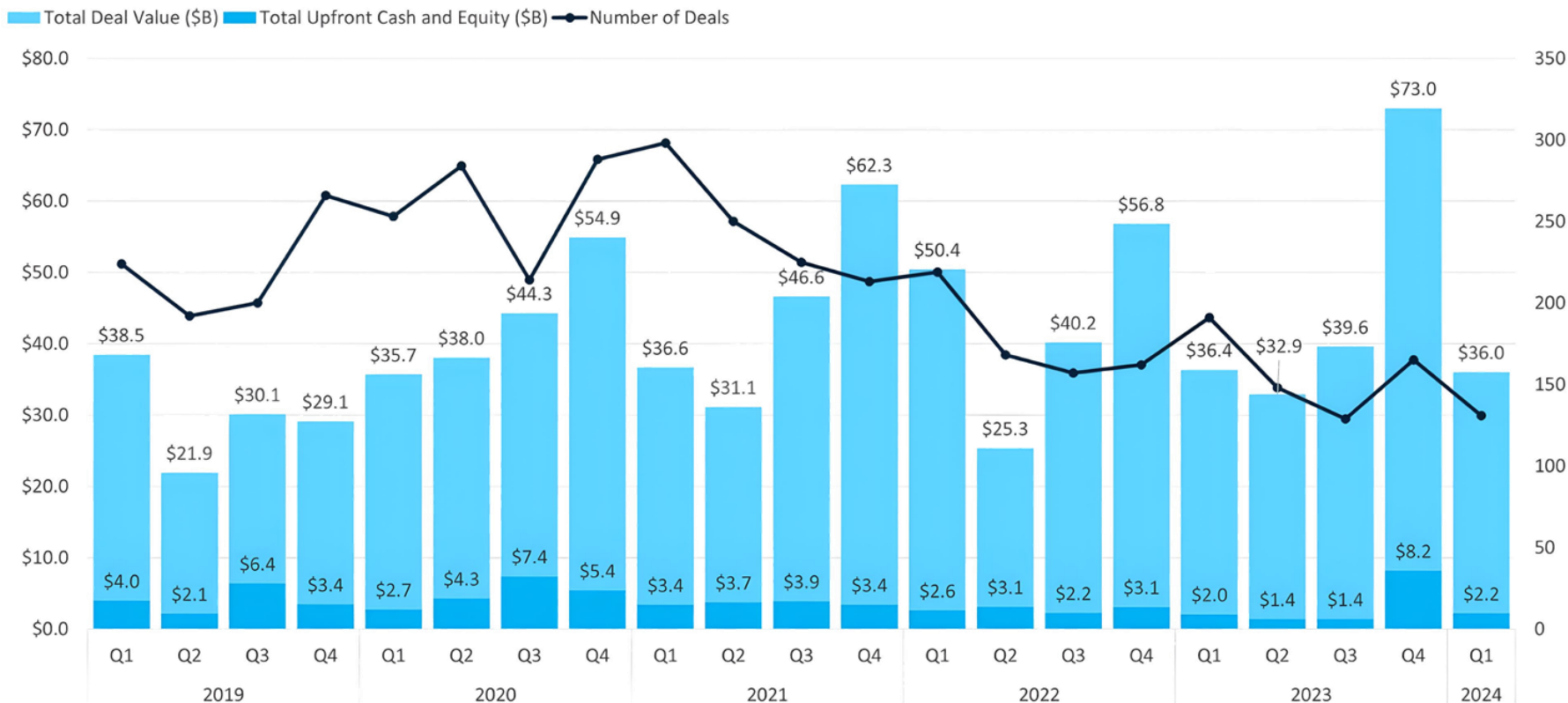
★ Potential to submit for conditional marketing approval*



WHAT ARE THE **TRENDS IN LICENSING** THERAPEUTICS?

Global partnering trends – Q1 2024

R&D Partnerships – Global Healthcare and Life Sciences¹



The total number of deals across the sectors is declining²

- 2023 and Q1 2024 dealmaking environment shows fewer, but higher-value, transactions³
- Pharma is placing bigger bets on fewer, later stage and more strategic assets and platforms³

Source: DealForma Database

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Kidney disease is high interest area for pharma

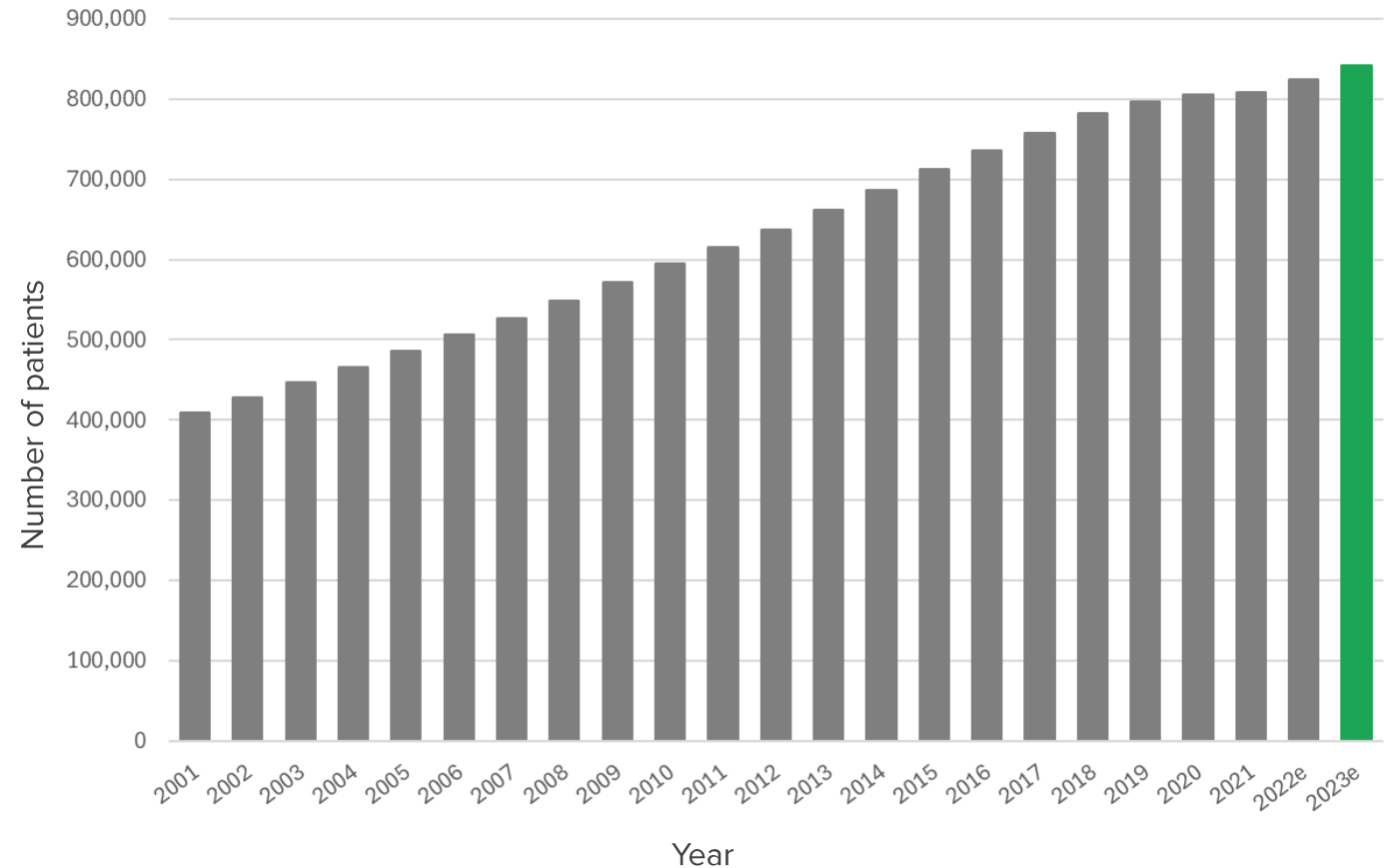
Kidney disease is the third-fastest-growing cause of death globally¹

- In the US alone, the number of people with kidney failure increased by >200% from 2001 to 2023²
- 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}

Prevalence of Kidney Failure, 2001-2023²







DIMERIX - IN DEAL MAKING MODE

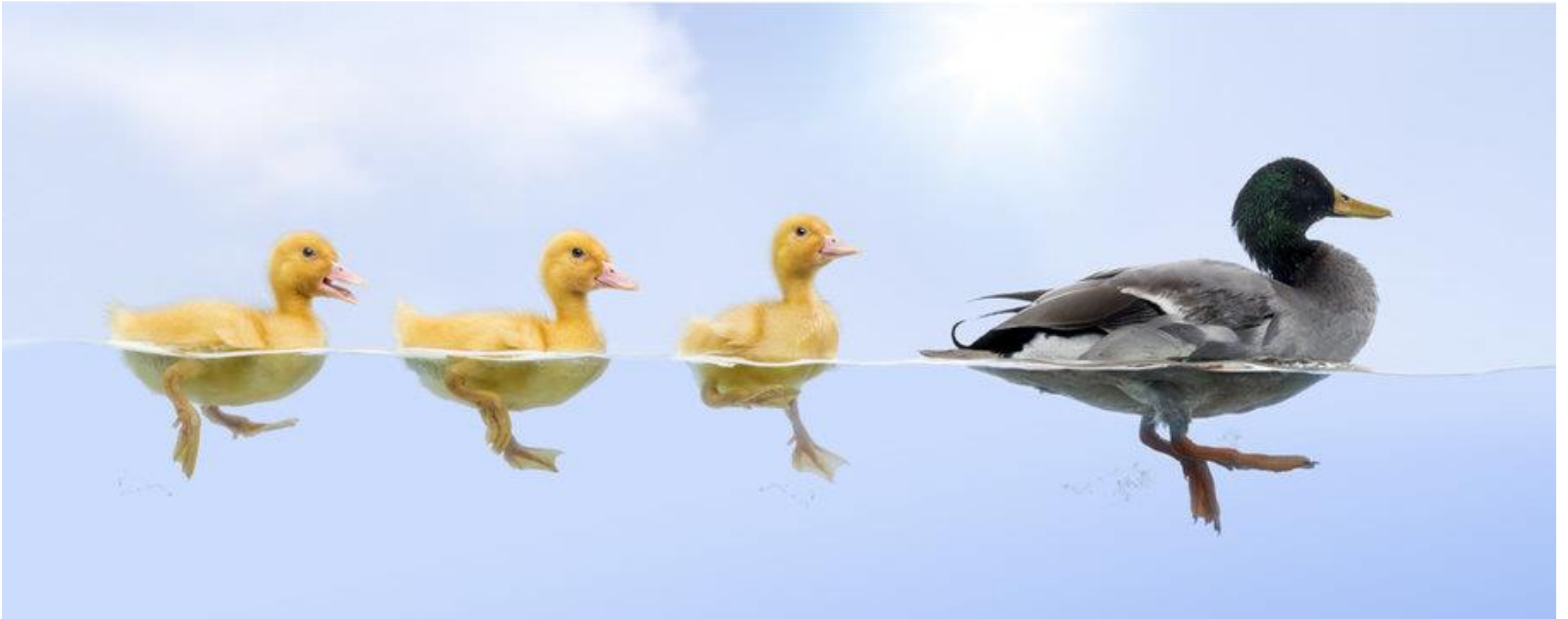
Summary of DMX-200 licensing deals

Dimerix has validated the technology¹ and proven its ability to licence multiple territories, with more deals anticipated

| Summary |  ² |  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 value⁴

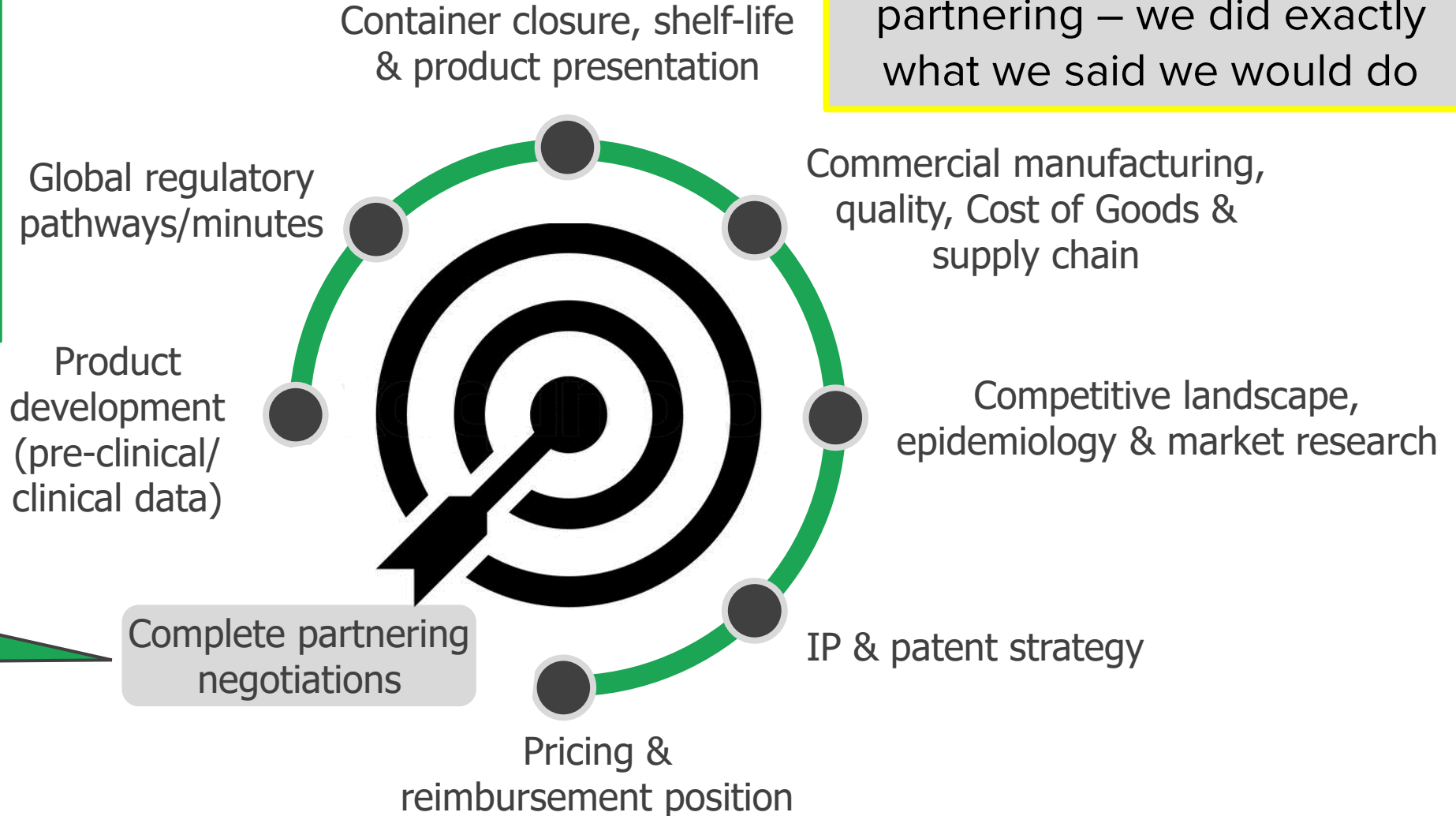


GETTING OUR DUCKS IN A ROW

Competitive positioning summary

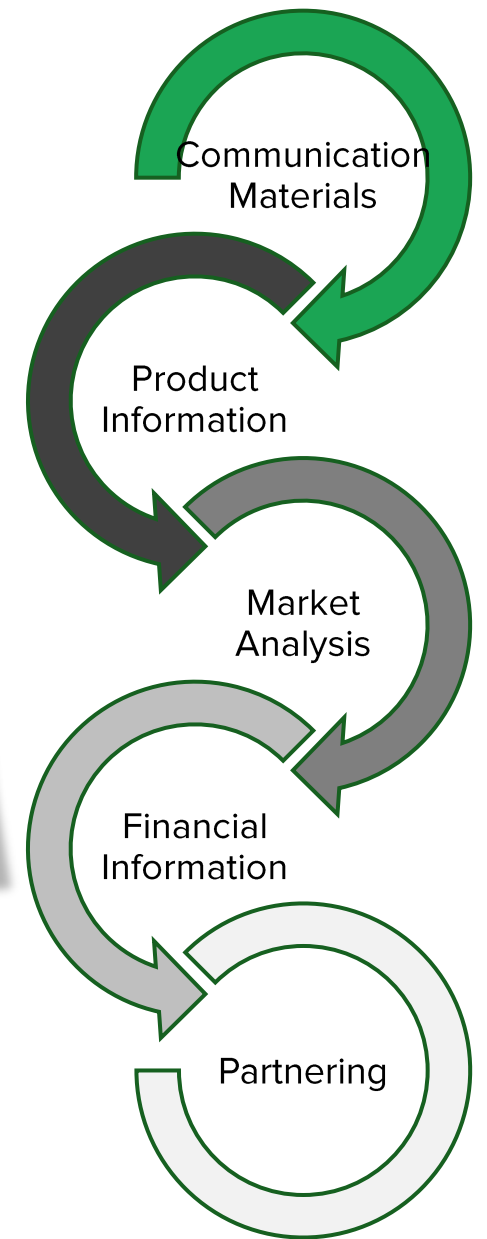
Slide from Bioshares 2019 presentation on what we intended to do to prepare for partnering – we did exactly what we said we would do

- 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

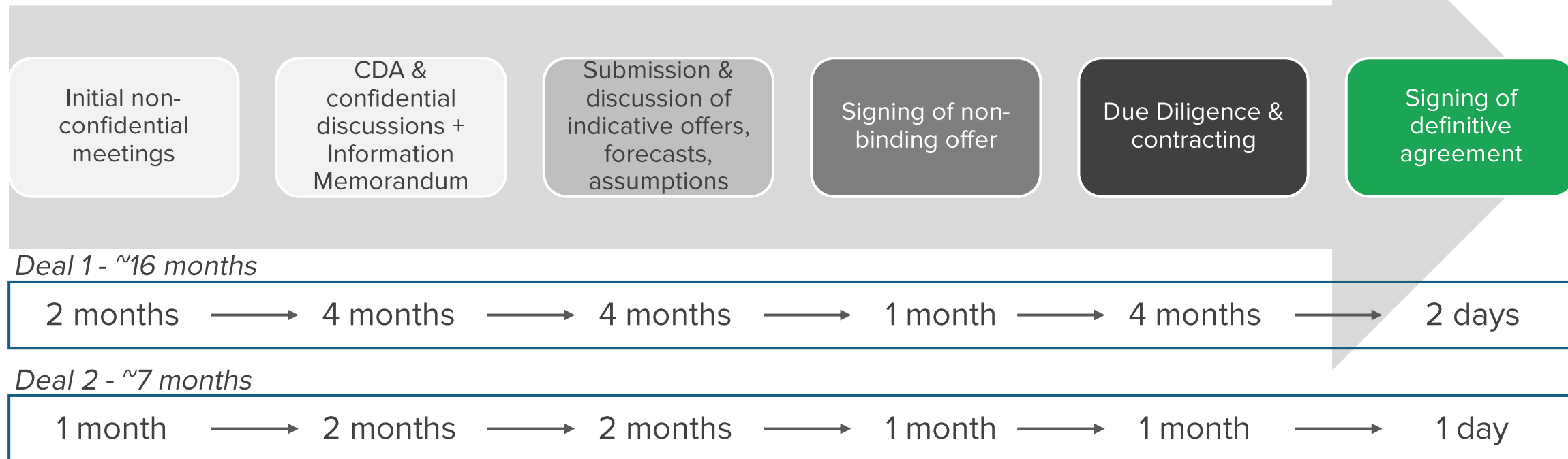
Time to deal – actual timeline experience

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 process¹



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 value¹**

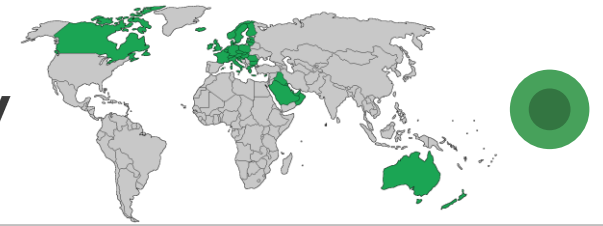
3

Potential Marketing

Part 2 analysis anticipated mid-2025²

Potential to submit for conditional **marketing approval³**

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 damage¹
- FSGS kidney damage can lead to dialysis, kidney transplants or death¹

Market Opportunity



- Estimated ~>200,000 people with FSGS in the 7 major markets (makes **FSGS a rare disease**)²
- Estimated 40,000¹ – 80,000² people in the US alone
- Drugs for rare kidney diseases can be priced at **~US\$120,000 per annum** in the US³
- There are currently **no approved treatments** available to treat FSGS

Commercial Validation



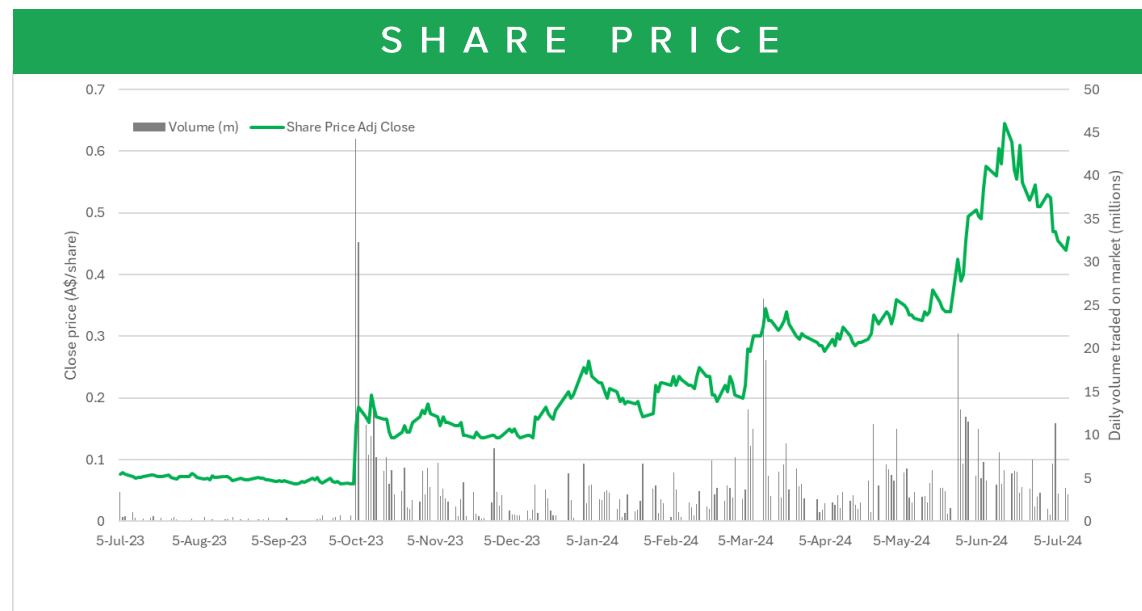
- Two commercial licensing deals achieved:**
 - ~AUD\$11.5m in upfront payments, ~\$340m in potential milestone payments + tiered royalties
- Phase 3 interim analysis: **DMX-200 is performing better than placebo** in reducing proteinuria (using a statistical measure⁵) in a significantly larger cohort than DXB prior Phase 2 study

Upcoming FSGS Milestones

- Execution of potential licensing deals** for available jurisdictions, including the US & China⁶
- Recruitment** and dosing of 144 patients for Part 2
- Part 2 – **second interim analysis** outcome estimated mid-2025

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 |



| 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% |