



Immediate Release

DIMERIX PRESENTS KEYNOTE SPEECH AT BIO CONNECTIONS AUSTRALIA

MELBOURNE, Australia, 29 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 as the keynote speaker at the 7th Annual Bio Connections Australia in Melbourne on 29 July 2024.

The conference brings together key industry stakeholders from across the biotech ecosystem and focuses on translating medical research into commercialisation, including drug discovery and development, early phase clinical trials and expediting partnering transactions. In keeping with this purpose, Dr Webster was asked to talk to “Positioning for Success in Australian Biotech” in context of Dimerix clinical development pathway and licensing transactions.

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)

BIO CONNECTIONS
AUSTRALIA 2024

Positioning for Success: Australian Biotech

Bio Connections
29 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

Forward looking statements

This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Dimerix to be materially different from the statements in this presentation.

Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.

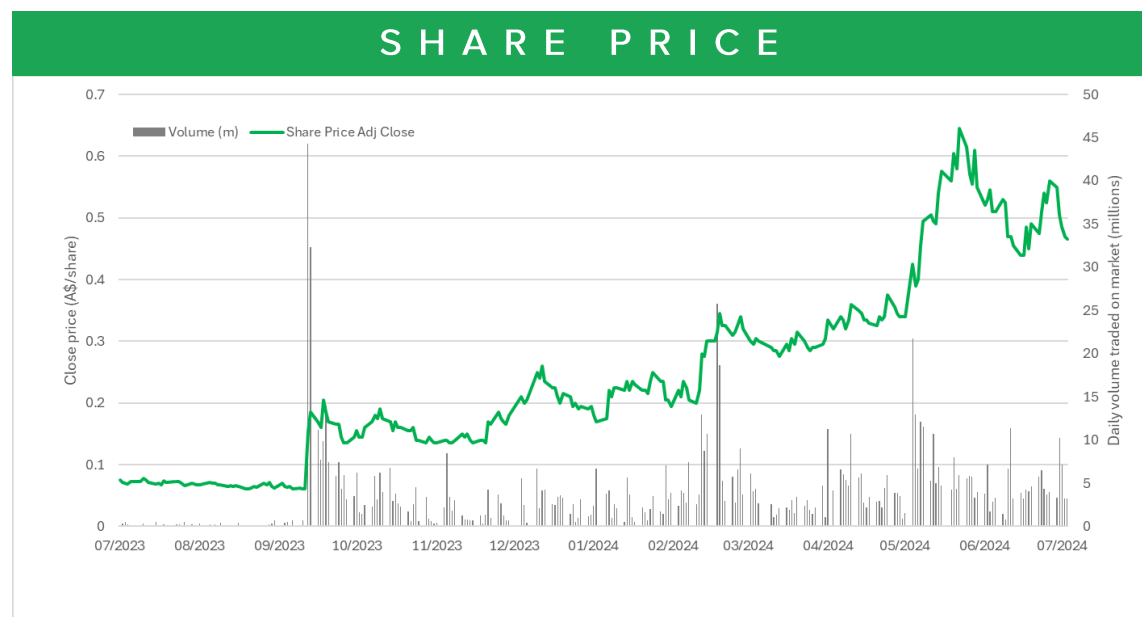
Corporate overview

Ticker Symbol	ASX: DXB
Cash Balance (Jun24)*	~A\$22.1 million
Market Capitalisation ²	~A\$267 million
Share price ¹	~A\$0.48
Total ordinary shares on issue ²	550,659,795
Average Daily Liquidity by value for past 30 trading days ²	~\$3.62 million

- * Cash balance includes payment of:
- significant one-off milestone payment for completion of Part 1 to IQVIA (~\$8.8 million of total prior quarter spend);

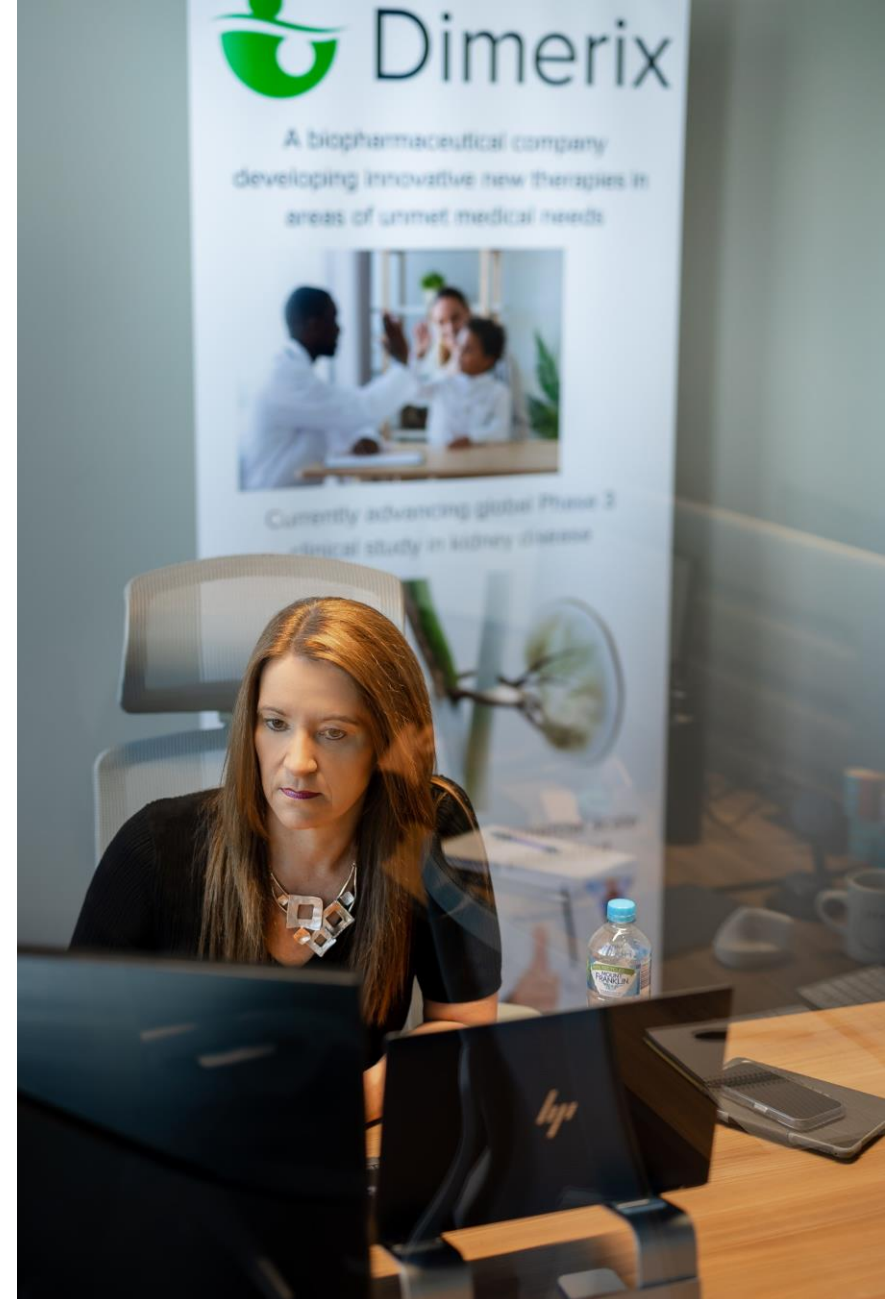
Cash balance does not include anticipated receipts of:

- ~AU\$500,000 up-front payment from Taiba partnership;
- FY24 R&D tax rebate; or
- Conversion of 49,625,053 DXB options currently exercisable at 15.4c per share with an expiry of 30 June 2025



SUBSTANTIAL SHAREHOLDERS ³			
Position	Holder Name	Holding	% IC
1	Mr P Meurs	75,304,506	13.7%
TOTAL (TOP 5) Shareholders		124,364,234	22.6%

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 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

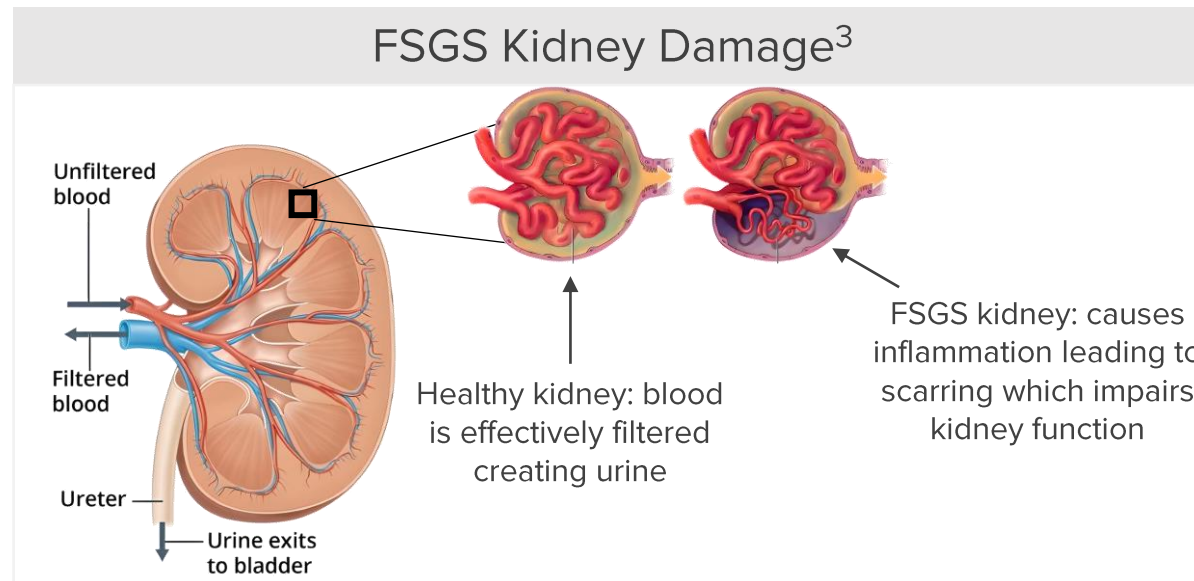
Focal Segmental Glomerulosclerosis (FSGS)

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

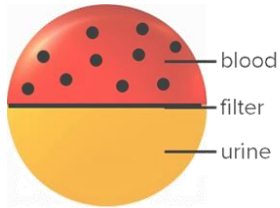


Primary endpoint: proteinuria

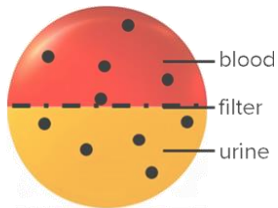
Why are kidneys important?

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

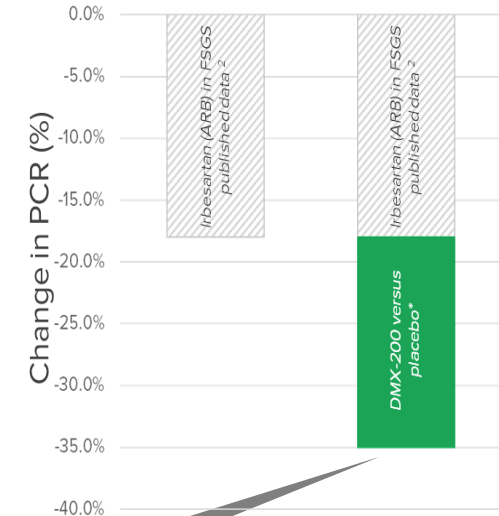


little / no proteinuria suggests healthy kidney

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

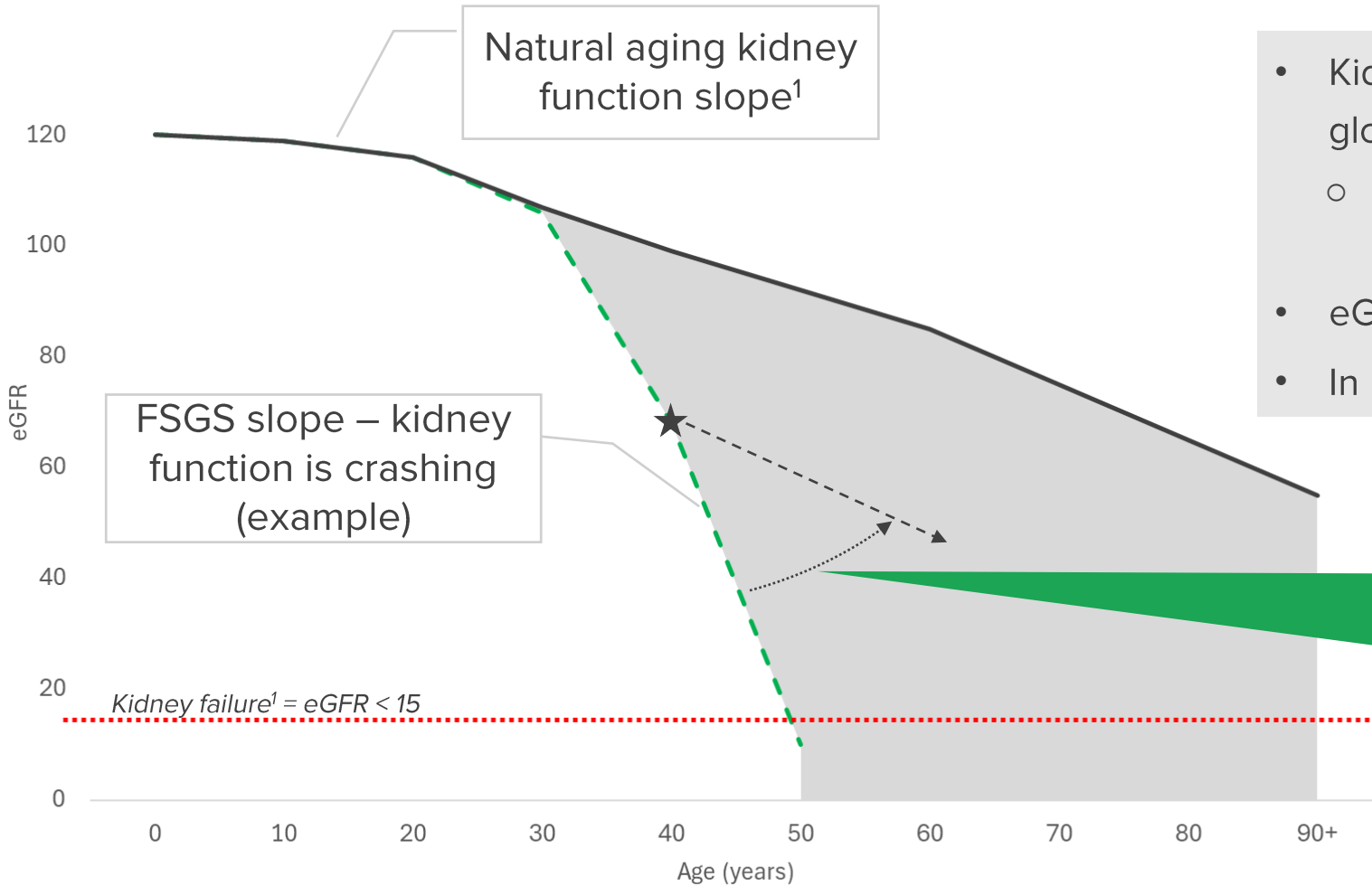
Proteinuria: an important endpoint for DMX-200 study

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



- 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

★ Assumes diagnosis occurs well into disease and treatment started immediately



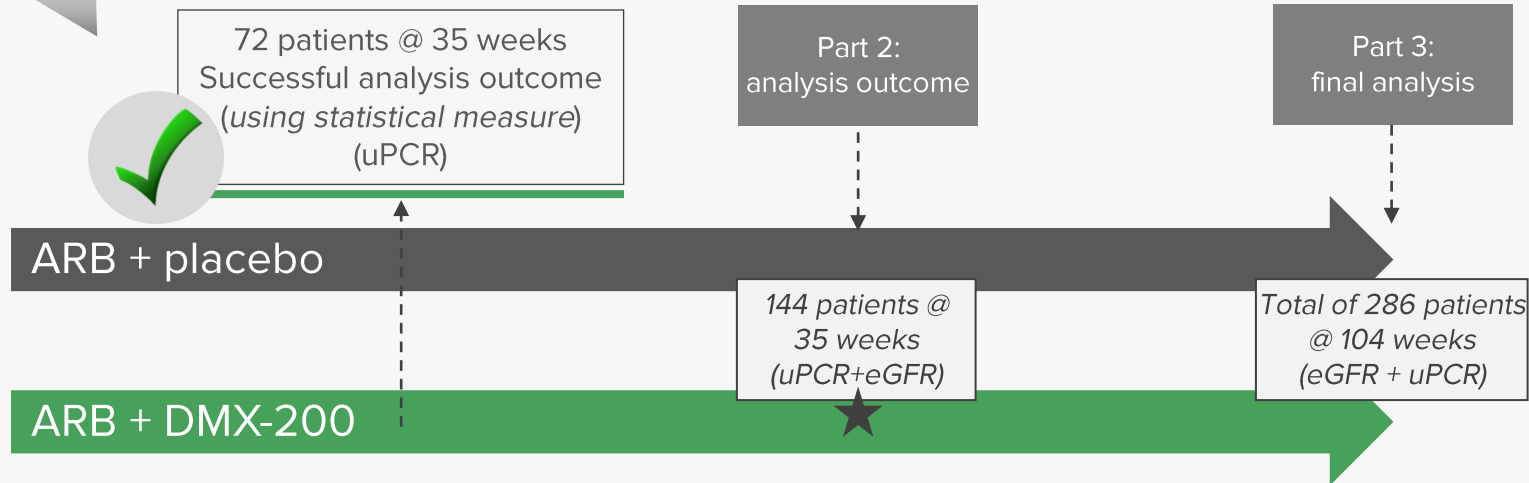
Phase 3 clinical trial – next steps

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

Background

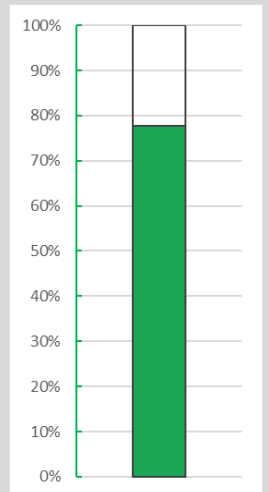
- Patients recruited, then screened and stabilised on background medications
- Patients randomised to receive drug or placebo
- DXB remains blinded at all times during study

Phase 3 Trial Timeline



Current recruitment

78%



Target (n=144)

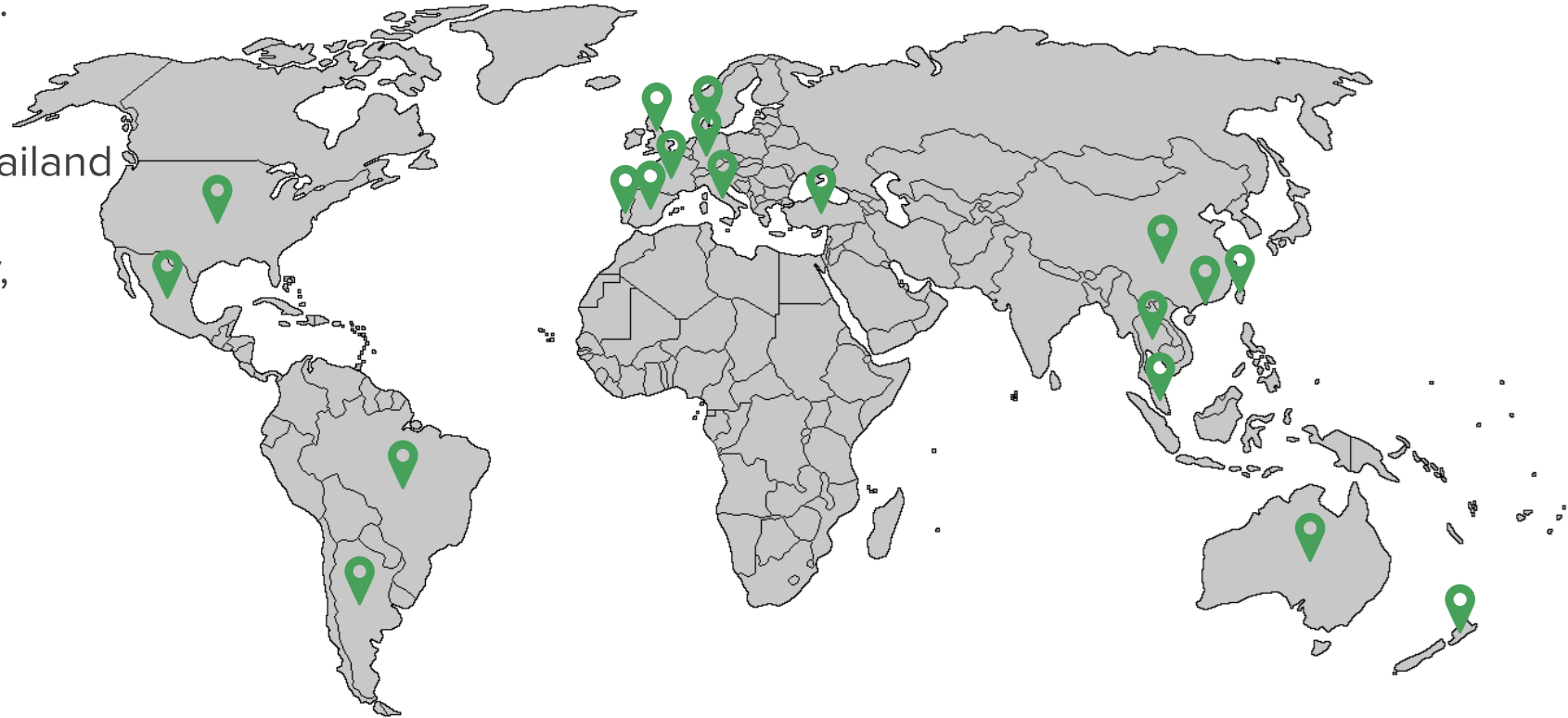
★ Potential to submit for conditional marketing approval*

Current and planned clinical sites

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

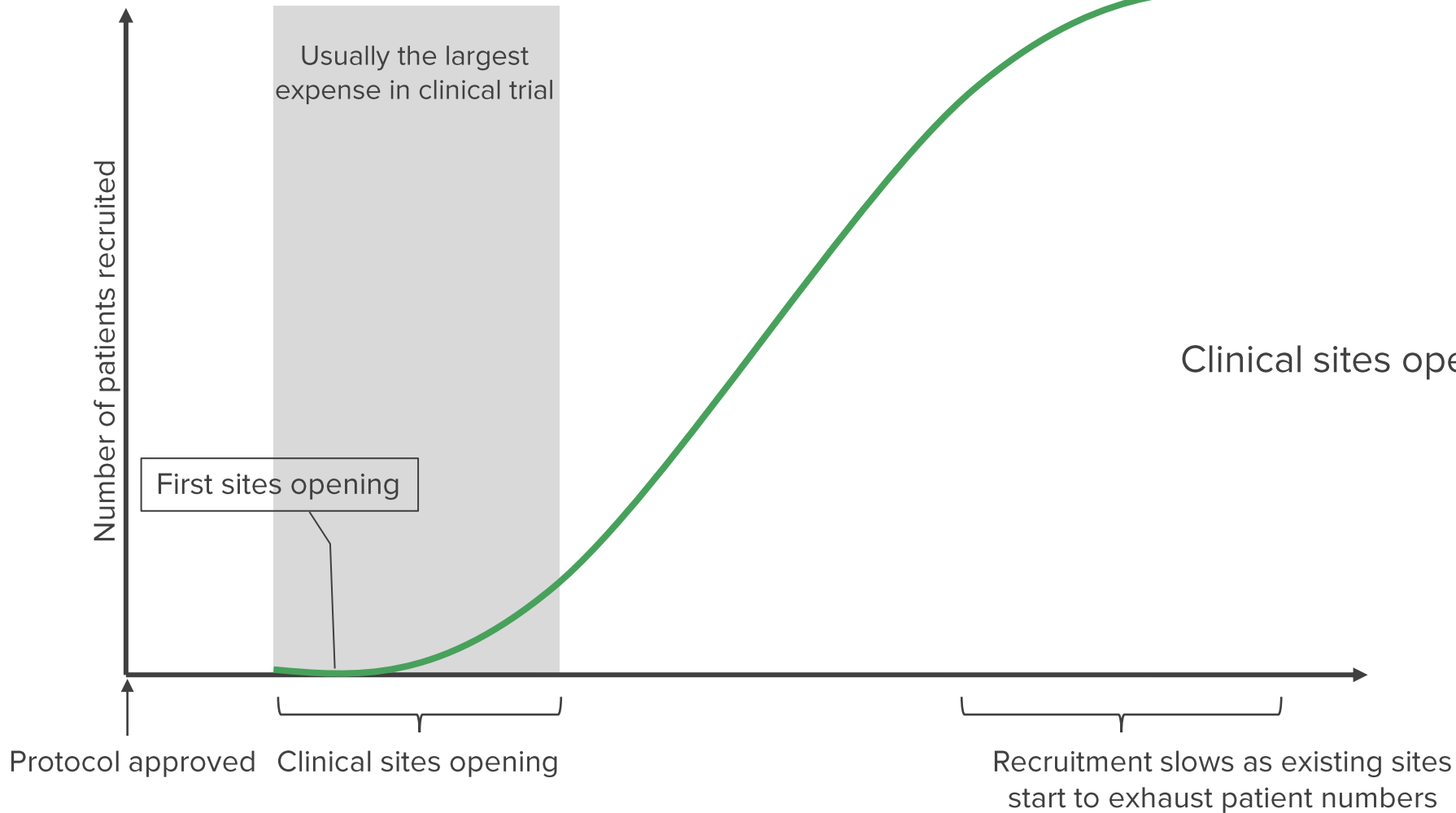
Recruitment planned at 170+ sites in:

- Australia, New Zealand
- Taiwan, Hong Kong, Malaysia, Thailand
- Mainland China
- France, Denmark, UK, Spain, Italy, Germany, Portugal
- Türkiye
- USA, Mexico
- Argentina, Brazil



Typical recruitment curve – S shape example

Subject to seasonal holidays



Clinical sites opening process:¹

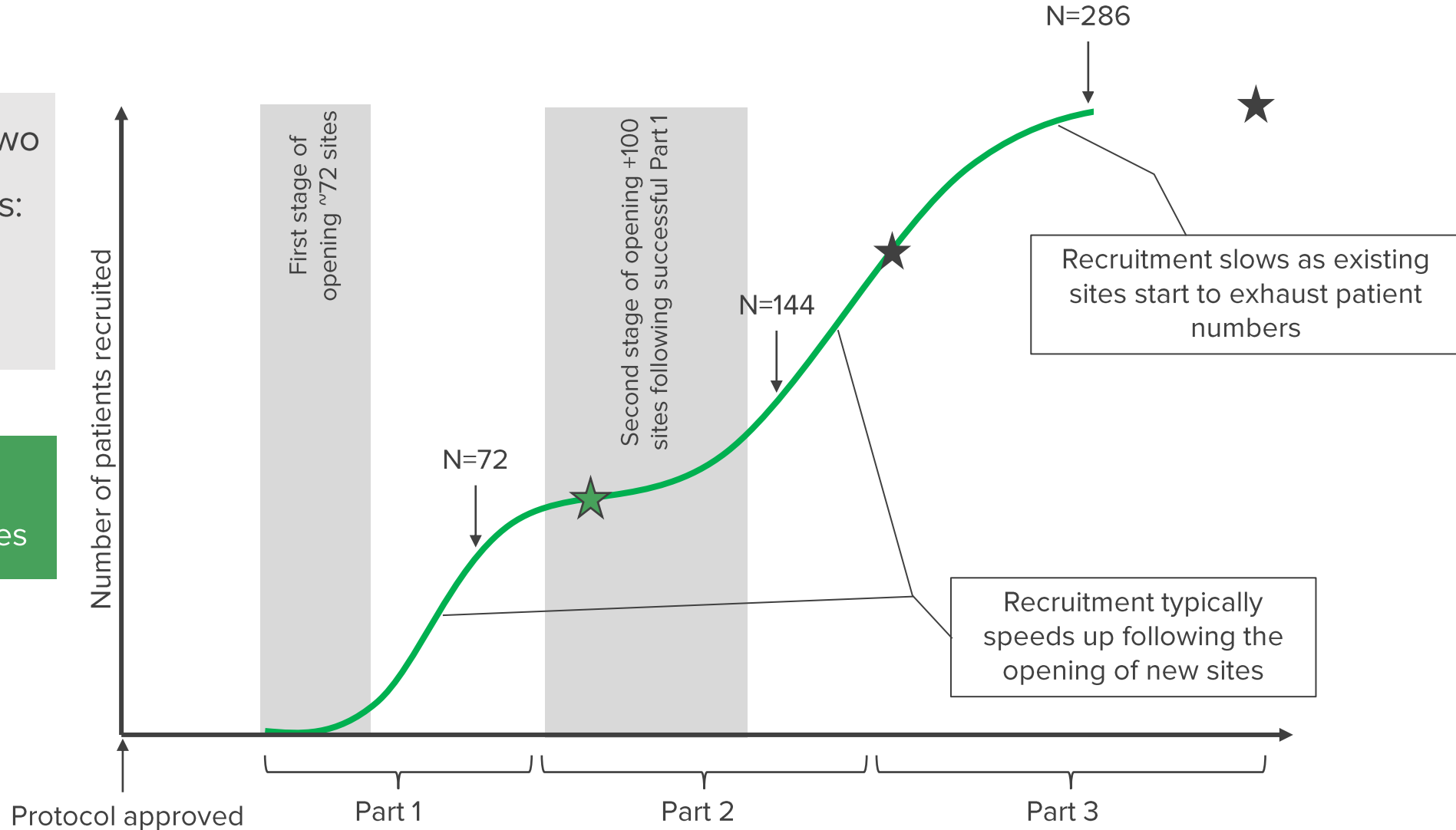


study operation – double recruitment curve

ACTION3 can anticipate two “S shape” recruitment curves:

1. During part 1; and
2. During parts 2 & 3

- ☆ Part 1 outcome successful
- ★ Anticipated analysis outcomes





CHALLENGES TO SUCCESS ALONG THE WAY

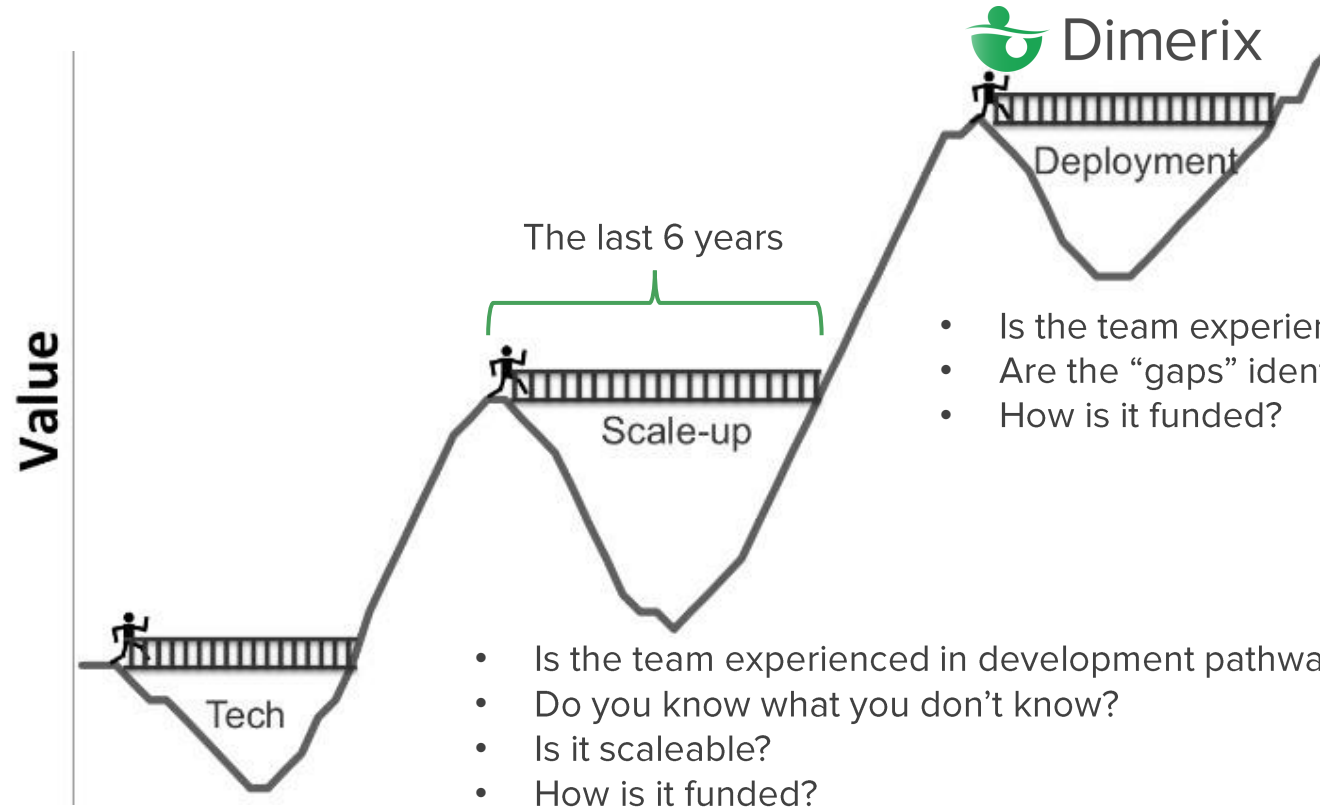
Three “valleys of death”

Good companies/technologies can fail:

- Lack of funding
- Lack of experienced team



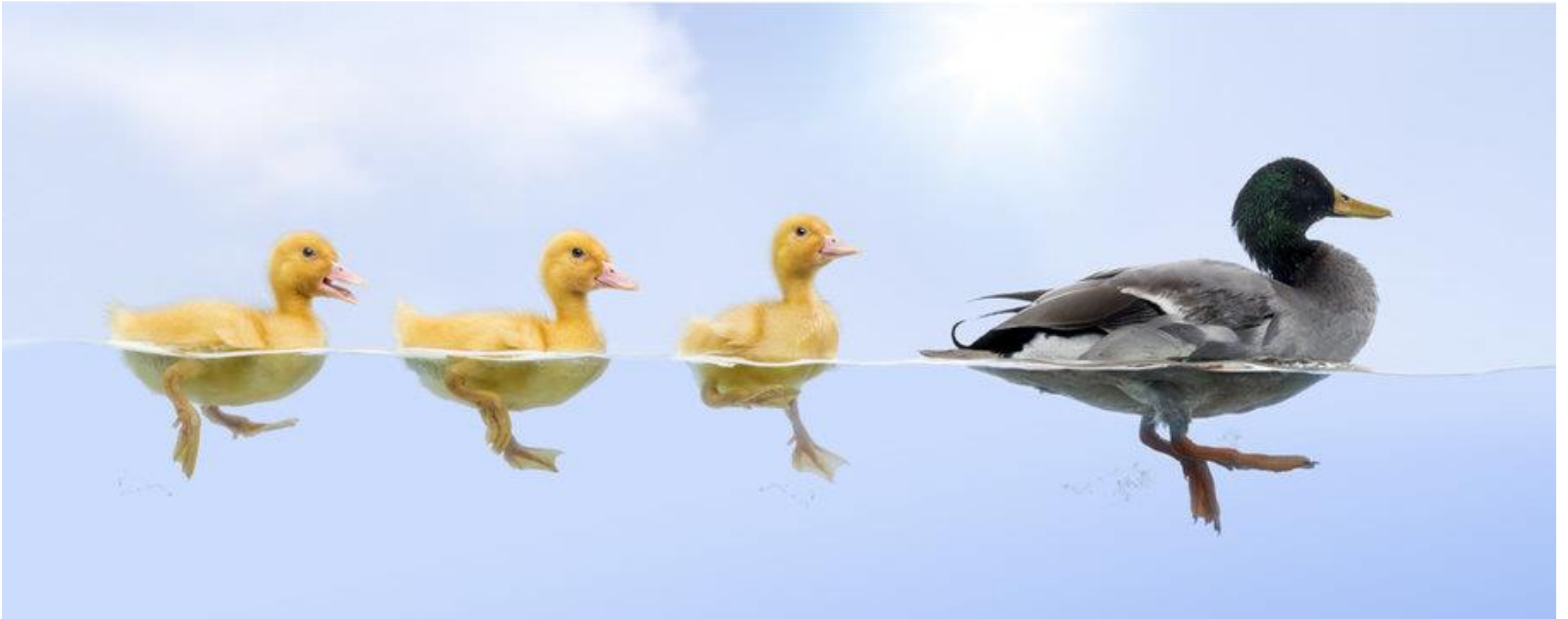
- ✓ Funding pathway in place
- ✓ Experienced team across all phases of development & commercialisation paradigm



- Does the science work?
- How is it funded?

- Is the team experienced in development pathway?
- Do you know what you don't know?
- Is it scaleable?
- How is it funded?

- Is the team experienced in commercialisation?
- Are the “gaps” identified and filled?
- How is it funded?

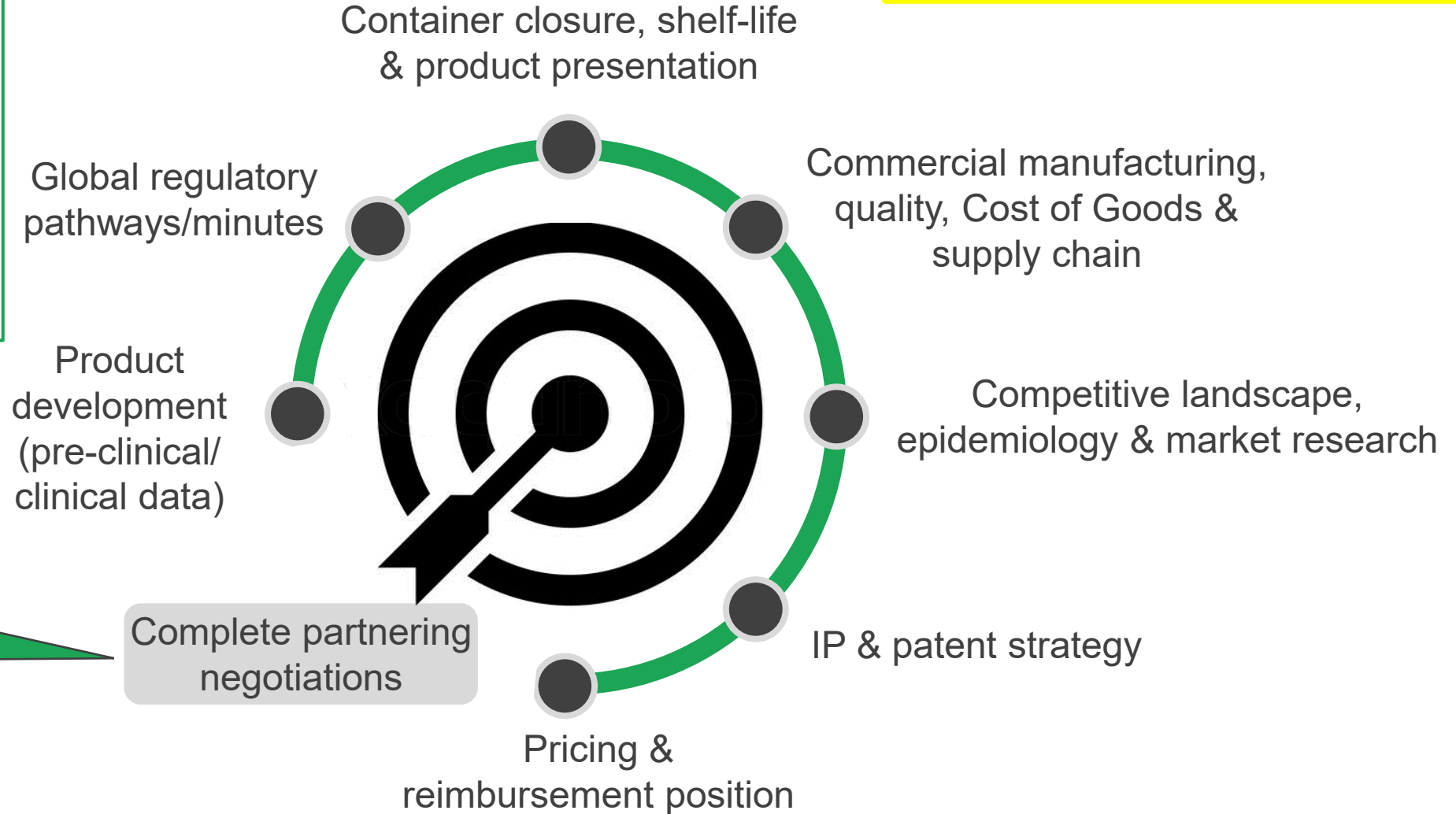


GETTING OUR DUCKS IN A ROW

Competitive positioning summary

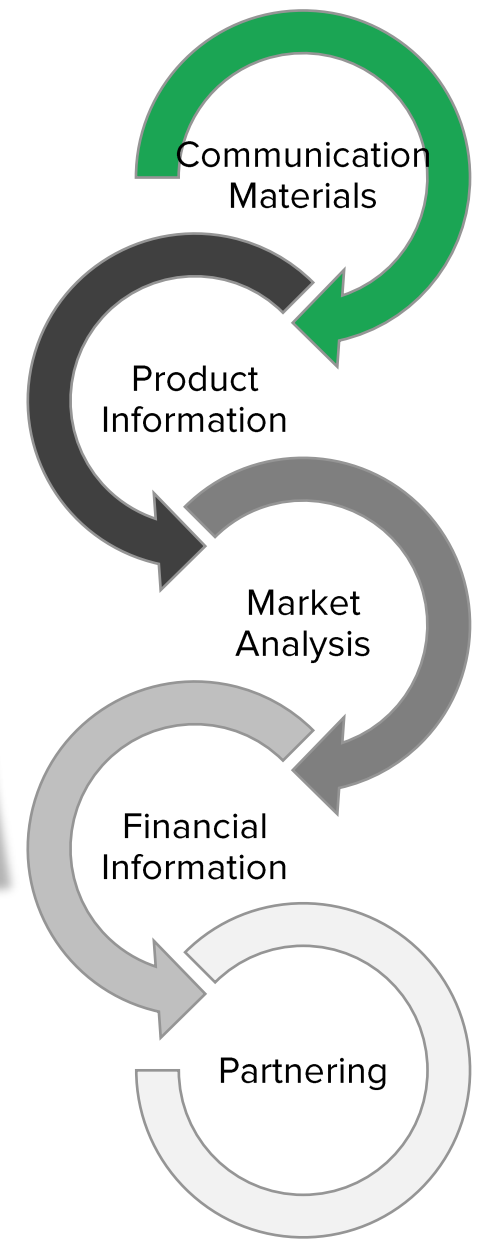
Slide from Bioshares 2019:
We did exactly what we
said we would do

- 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

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

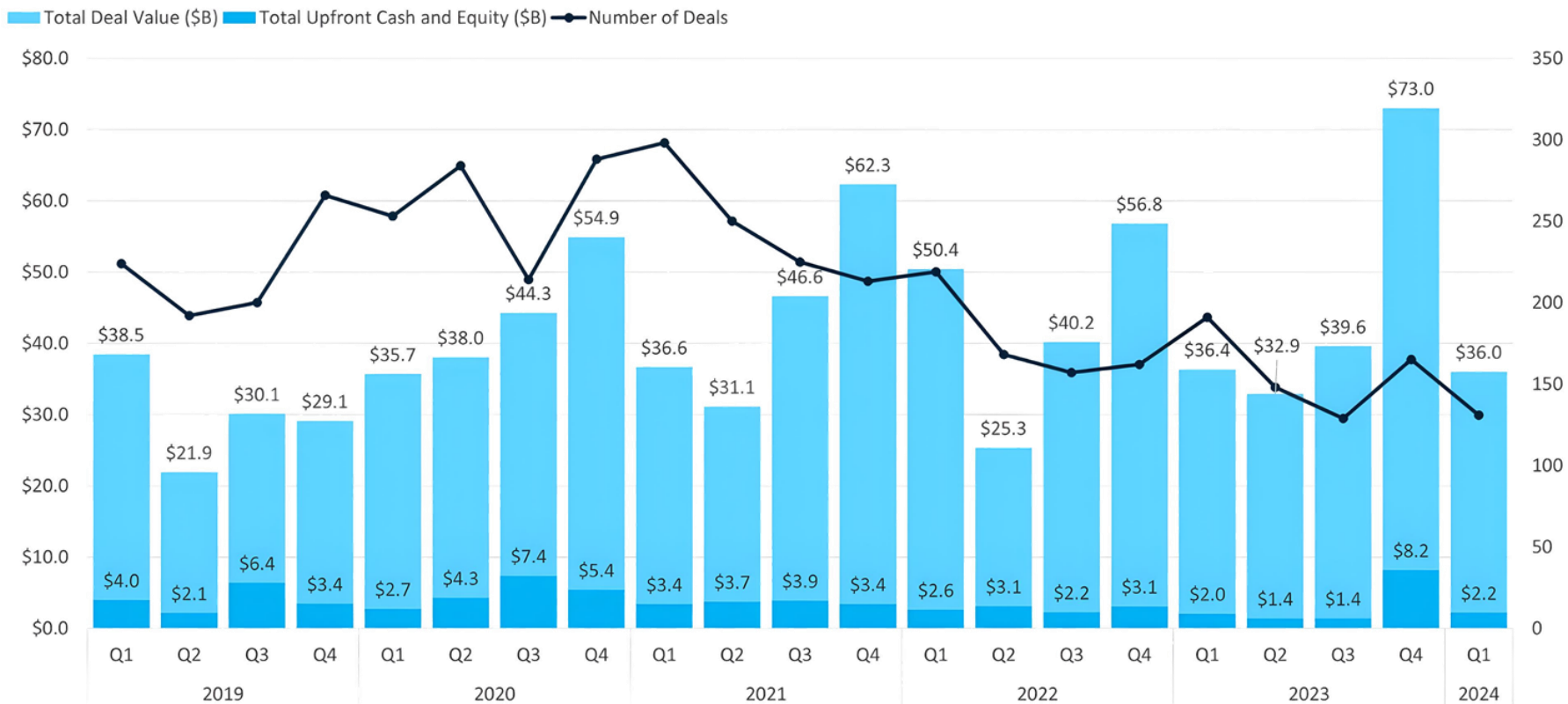




DIMERIX - IN DEAL MAKING MODE

Global partnering trends – Q1 2024

R&D Partnerships – Global Healthcare and Life Sciences¹



Source: DealForma Database

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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

Kidney disease is high interest area for pharma

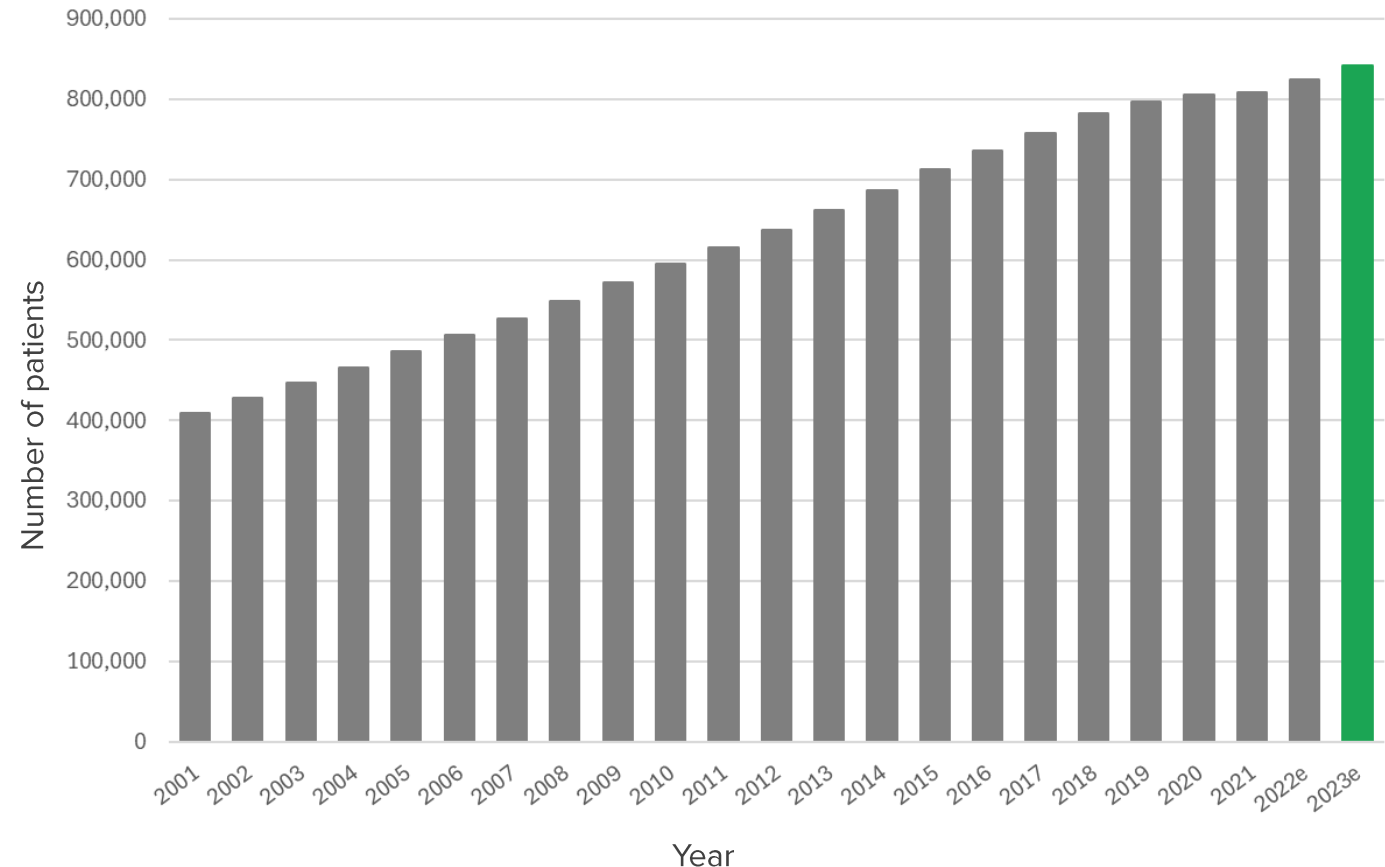
Kidney disease is the third-fastest-growing cause of death globally¹

- 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



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

Summary | Phase 3 Global Opportunity



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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.



WELL POSITIONED TO DELIVER OUR STRATEGIC PLAN



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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.