



#### **Investor Presentation**

August 2023

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



### 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.





### Late stage, phase 3 clinical development asset





### Significantly de-risked, late-stage development program



Strong safety profile<sup>1</sup> – no material adverse events in Phase 1/2



Proven efficacy<sup>1</sup> in Phase 2 studies – Met primary and secondary endpoints



Completed toxicology studies<sup>2</sup> expect no further work required by FDA



Completed commercial manufacturing scale-up<sup>3</sup>



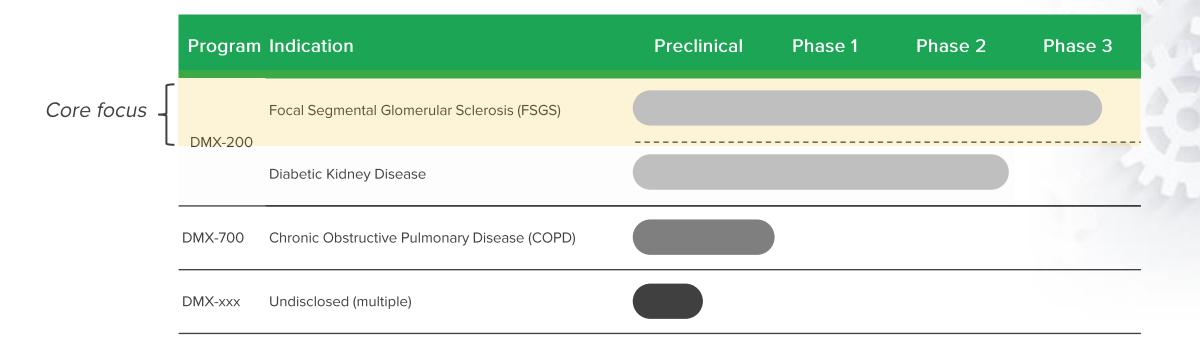
Clear development pathway to market<sup>4</sup>



Orphan Drug designations<sup>5</sup>



### Development pipeline





### Benefits of targeting orphan diseases









Orphan designation used by regulators to incentivise companies to develop new drugs for rare diseases

 Very little new drug development in rare kidney diseases over last 30 years Commercially attractive pricing structure for orphan drugs

- ~US\$84,000p.a average orphan drug price in 2018¹
- $\bullet\ ^{\sim}$  US\$120,000p.a average
- price for other rare kidney treatments<sup>2</sup> (US\$9,900 for recently approved Sparsentan in treatment of IgAN)

Marketing exclusivity period without generic competition or challenge

- 7 years in US
- 10 years in EU

Opportunity to extend exclusivity for another ~2 years on paediatric indication

 Paediatric population to be included in Part 2 of Phase 3 trial<sup>3</sup>

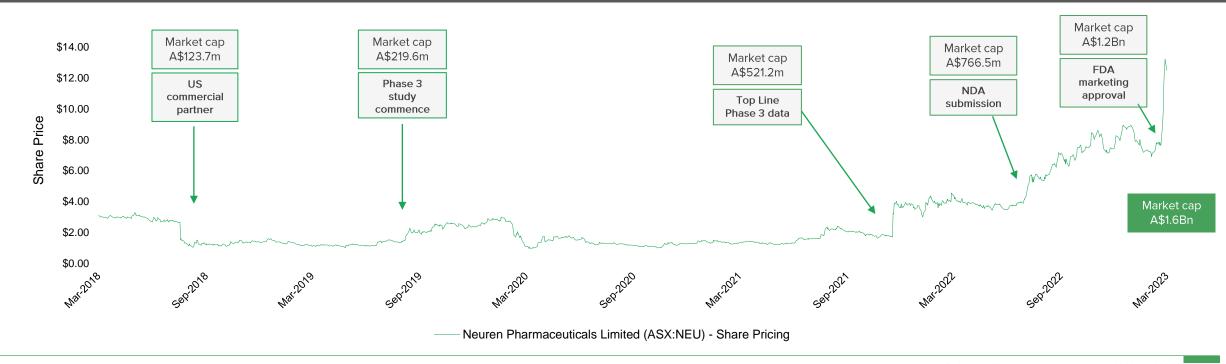
### Collaboration from global regulators including FDA

- Feedback and assistance designing Phase 3 trial, including 2<sup>nd</sup> interim readout for the purposes of potential accelerated approval in some territories<sup>4</sup>
- Design of overall drug development plan



### Orphan drug case study - Neuren (NEU.ASX)

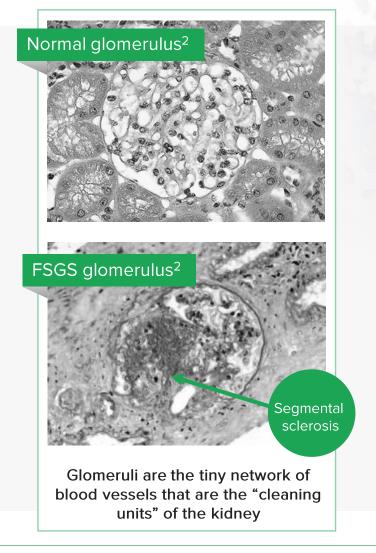
- Neuren are focussed on orphan disease treatment with a pipeline of rare neurodevelopmental disorders
- Lead program/drug, DAYBUE<sup>TM</sup> (trofinetide) has orphan designation and received significant valuation uplifts during and after its Phase 3 program
  - \$220m market cap at commencement of Phase 3
     \$520m market cap at read out of Phase 3 results (240% uplift)
  - \$767m market cap prior to New Drug Application (NDA) to FDA (further 150% uplift)
  - \$1.6b market cap post FDA approval (further 200% uplift)
- US market assumes pricing of  $^{\circ}$ US\$375,000 $^{\circ}$  and 5,000 diagnosed patients p.a $^{\circ}$





### What is Focal Segmental Glomerulosclerosis (FSGS)?

- Focal segmental glomerulosclerosis (FSGS) is one of the most common forms of acquired glomerular disease leading to end stage kidney disease (ESKD)
- FSGS makes up approximately 10% of all kidney diseases<sup>1</sup>
- On average FSGS progresses to kidney failure within 5 years after onset of proteinuria<sup>1</sup>
- Caused by a variety of conditions primary FSGS, genetic FSGS, FSGS of unknown cause and secondary FSGS<sup>3</sup>
- Prevalence of FSGS growing due to increase in:
  - Diabetes
  - Obesity
  - Ageing population
- Currently no approved drugs for FSGS
  - patients are treated with medications off-label, including angiotensin receptor blockers
- Significant burden on global health systems to support healthcare economics / drug pricing
  - Patients end up on dialysis (est cost US\$90,000/patient/year)4
  - Patients requiring kidney transplant (est cost US\$442,500 per transplant + ongoing medication fees)<sup>5</sup>
  - 60% patients have reoccurring FSGS even after first kidney transplant<sup>6</sup>





#### FSGS market size



- Assuming US\$9,900k/month as example pricing in the US (same pricing as Sparsentan in IgAN)<sup>2</sup>
- Current market specifically for FSGS does not exist

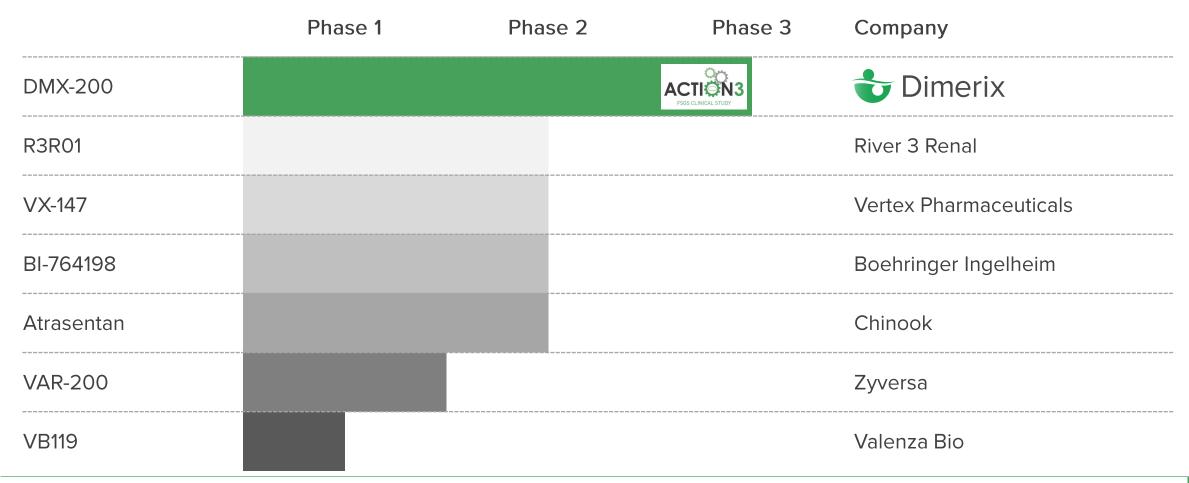
FSGS Market Size				
Region	Estimated diagnosed patients (2022)	\$US p.a (2032)		
US	85,342 <sup>1</sup>	US\$2.05 billion <sup>1</sup>		
EU/UK	85,014 <sup>1</sup>	US\$990 million <sup>1</sup>		
Japan	32,644 <sup>1</sup>	US\$225 million <sup>1</sup>		
China	>100,0004	US\$2.8 billion <sup>3</sup>		

7 major markets (MM)



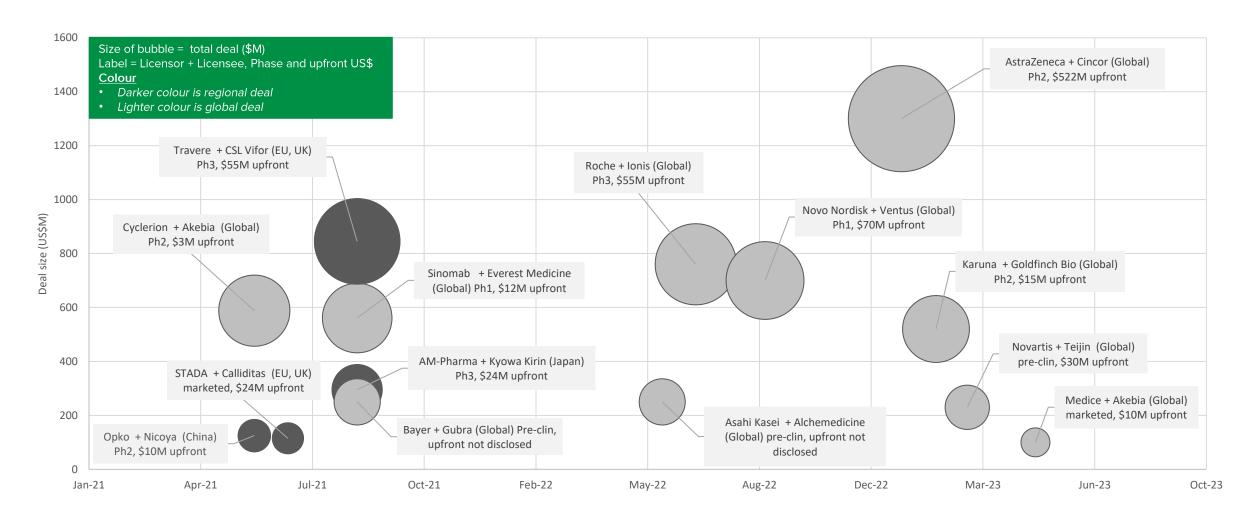
### Competitive landscape in FSGS

#### DMX-200 is the only therapy in phase 3 development



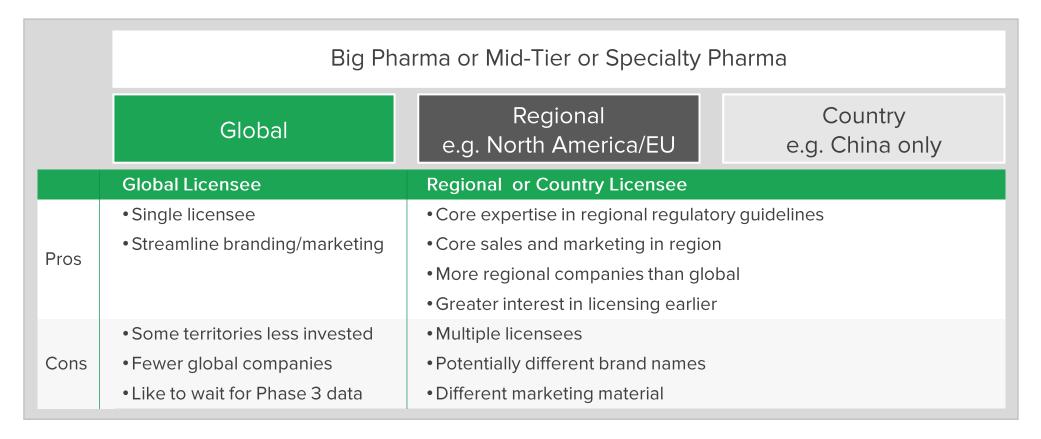


### Partnering deals in the kidney disease space





#### Deal structure



#### The ideal partner:

- Regulatory expertise in proposed territory
- Sales/marketing infrastructure in place to support indication



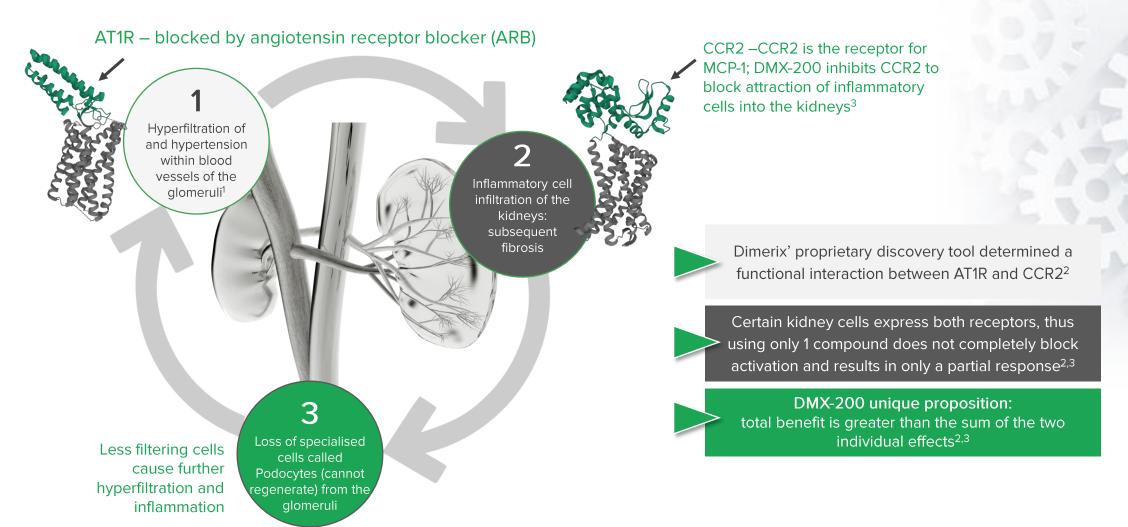




### PHASE 3 CLINICAL TRIAL



### 3 key mechanisms that cause sclerotic kidney disease

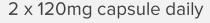




### DMX-200 – working on inflammatory signalling pathway

A CCR2 inhibitor working synergistically alongside the current standard of care (AT1R blocker): G protein-coupled receptor (GPCR)

New Chemical Entity status, with orphan exclusivity (7 years US/10 years EU)<sup>2</sup>; and with granted patents and applications across key countries





tolerated in both healthy volunteers and renal patients (total of 95 patients dosed)<sup>3</sup>

Consistently safe and well



4 clinical studies completed to date: positive efficacy signals across studies<sup>3</sup>



Small molecule

Easy & convenient dosing

Strong safety profile<sup>3</sup>

Proven efficacy<sup>3</sup>



### DMX-200: Phase 2 met primary and secondary endpoints

#### Clinically meaningful outcomes for patients



#### **EFFICACY**

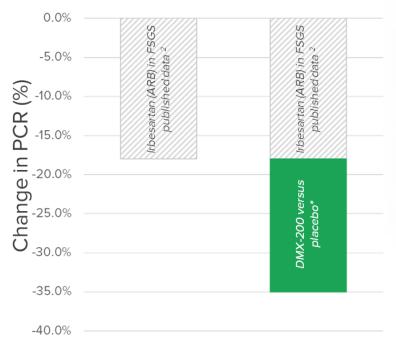
- 86% of patients demonstrated reduced proteinuria on DMX-200 versus placebo
- 29% of patients demonstrated >40% reduction in proteinuria



#### SAFETY

- No safety concerns reduced development risk
- DMX-200 compares favourably to compounds currently in development<sup>2,4</sup>

Average reduction in proteinuria after 16 weeks treatment on DMX-200 versus placebo compared to standard of care alone in FSGS patients<sup>1</sup>

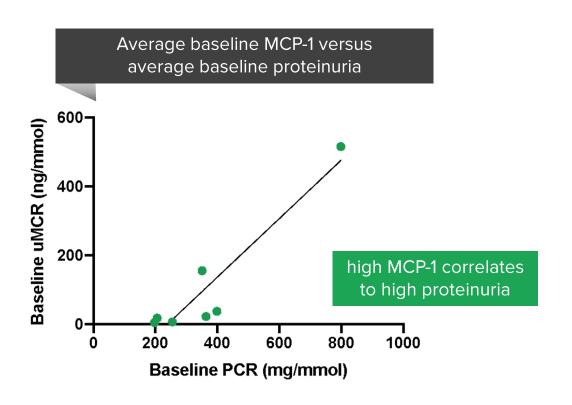


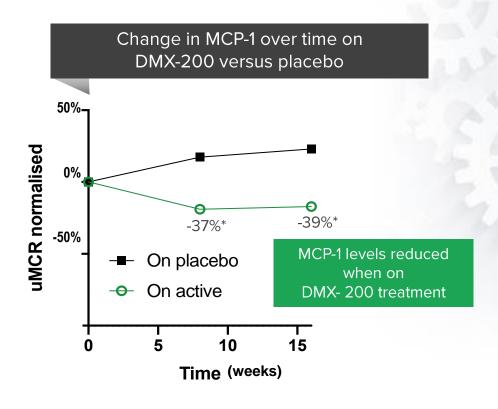
See: https://dimerix.com/wp-content/uploads/2022/12/FINAL-The-ACTION-\_AT1R-and-CCR2-Targets-for-Inflammatory-Nephrosis\_-program-in-focal-segmental-glomerulosclerosis.pdf





### DMX-200: effect on inflammatory biomarker



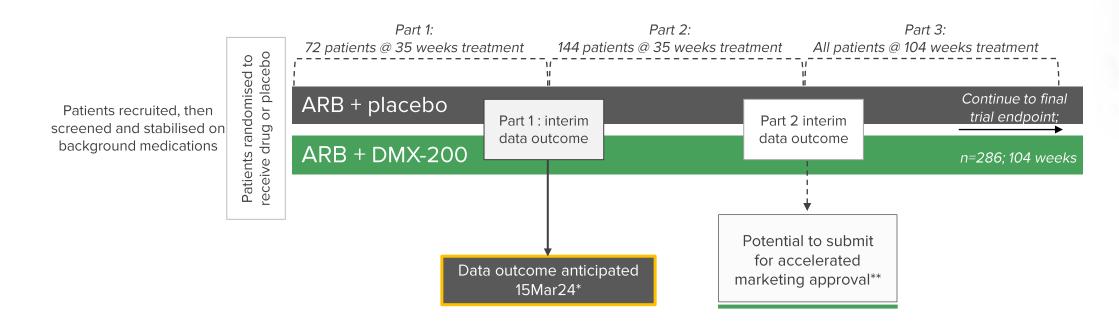


- 16 weeks treatment with DMX-200 vs placebo reduced inflammatory biomarker by 39%:
  - DMX-200 blocks receptor responsible for inflammation
  - translates to reduced inflammation and subsequent fibrosis (scarring) in the kidney



# ACTION3 Phase 3 clinical trial

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





See: https://dimerix.com/wp-content/uploads/2022/12/FINAL-ACTION3-pivotal-Phase-3-study-assessing-the-CCR2-inhibitor-DMX-200-in-patients-with-focal-segmental-glomerulosclerosis.pdf



# ACTION3 Current and planned clinical site locations

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

- Part 1 recruiting at 70 sites:
  - Australia, New Zealand
  - Taiwan, Hong Kong
  - France, Denmark, UK
  - Argentina, Brazil
  - USA
- Part 2 new countries:
  - China
  - Malaysia
  - Italy, Germany, Portugal
  - Mexico





## ACTION3 Part 1 interim analysis set for Q1 2024

- Announcement of interim analysis of Phase 3 trial expected on, or around, 15 March 2024\*
- A successful outcome would see the Company announce a clinically significant and statistical meaningful improvement in proteinuria vs placebo and the trial is continuing to Part 2
- Dimerix expect commercial partnering interest to further intensify post positive interim analysis





**FSGS CLINICAL STUDY** 

### Late stage, phase 3 clinical development asset





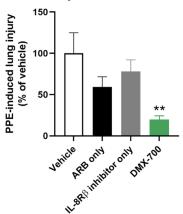


### Advancing the broader pipeline

#### Additional longer term pipeline opportunities diversify risk and potential sources of revenue

#### DMX-700 for Chronic Obstructive Pulmonary Disease (COPD)

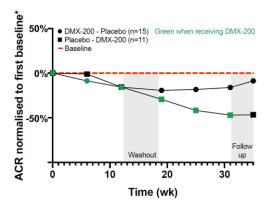
Preclinical studies show that DMX-700 significantly reduced lung injury by 80% (p<0.01) after 21 days treatment<sup>1</sup>



Pre-clinical asset

#### DMX-200 for Diabetic Kidney Disease

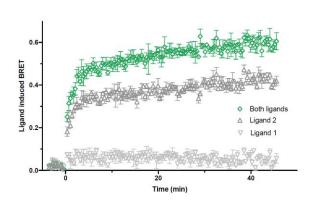
Phase 2 demonstrated promising efficacy & safety<sup>2</sup>, proteinuria declined after treatment with DMX-200 in both treatment periods<sup>2</sup>



Phase 2 asset

#### **Undisclosed Opportunities**

Commercially attractive pipeline of G Protein-Coupled Receptors (GPCR) targets of inflammatory diseases with an unmet need



Pre-clinical identified opportunities



### Corporate overview

ASX	Ticker Symbol	ASX:DXB	
<b>9</b>	Cash Balance (Jun23)	~A\$8.0 million	
9	Market Capitalisation	^A\$28 million	
7004	Share price	~A\$0.73	
	Total ordinary shares on issue	388,059,039	



SHAREHOLDERS				
Position	Holder Name	Holding	% IC	
1	Mr Peter Meurs	64,929,440	16.7%	
2	Mr Andrew Coates & Mrs Melinda Coates	11,613,500	3.0%	
3	Philip & Julie Scott	9,546,667	2.5%	
4	FREEDOM TRADER PTY LTD	9,432,763	2.4%	
5	BAVARIA BAY PTY LTD	7,316,992	1.9%	
TOTAL (TOP 5)		102,839,362	26.5%	



#### Dimerix board



PhD, MBA, M.IP.Law
CEO & Managing Director

#### Wyeth (Pfizer), Acrux, Immuron

- Experienced in product development, commercial strategy development & execution
- Successfully commercialised multiple pharmaceutical products globally
- ✓BSc (Hons) Pharmacology
- ✓PhD Pharmaceutics
- ✓MBA Business
- ✓M.IP.Law Intellectual Property Law



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

#### Mayne Pharma, Acrux, Hatchtech, Kinoxis

- Extensive biotech drug development & commercial manufacturing experience
- Responsible for successful global commercialisation programs & NDA registrations
- ✓BSc (Hons) Chemistry
- ✓MBA Business



Sonia Poli PhD Non-Executive Director

#### Hoffman la Roche, Addex, AC Immune, Minoryx

- Experienced executive in pharmaceutical operations
- Background in small molecules development and analytical development
- ✓BSc (Hons) Chemistry
- ✓PhD Industrial Chemistry



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

#### Woodside Energy, iCetana

- ~20 years experience as a leader with a focus in management, project delivery, risk management, & assurance
- Provides advisory services to a family office with multiple Australian biotech investments
- ✓ BEng (Hons) -Chemical Engineering
- ✓BCom Commerce





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 AGAINST 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.