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# Dimerix

(ASX:DXB)

## Bioshares Presentation

July 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.*

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*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.*



# Conference theme: partnering and raising capital

Questions posed to Dimerix:

1. How is the company's program in FSGS progressing and what are the timelines?
2. What are the trends in licensing drug development?
3. What type of partnering deals are occurring in the kidney disease space?
4. How might Dimerix look to structure a deal or deals, and what level of data will be required?

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# ACTION3

FSGS CLINICAL STUDY

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## DIMERIX - IN CONTEXT



# Dimerix in context

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Lead candidate:

DMX-200  
in focal segmental  
glomerulosclerosis  
(FSGS) kidney disease

Near term **Phase 3** interim  
**analysis results**  
announced (Q124)

Advanced **partnering**  
**negotiations** with offers  
received from multiple  
parties for various  
territories<sup>1</sup>

**Orphan Drug** status  
providing protection  
through data exclusivity<sup>2</sup>  
for min 7-10 years, in  
addition to comprehensive  
patent/IP strategy

Estimated >\$3b **global**  
**market** size p.a.<sup>3</sup> –  
203,000<sup>3</sup> patients across  
7MM at example US  
pricing of US\$120,000  
p.a.<sup>4</sup>



# Benefits of targeting orphan diseases

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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 2018<sup>1</sup>
- ~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

Balanced against the challenges: recruitment (finding the patients)  
news flow (time between data points)

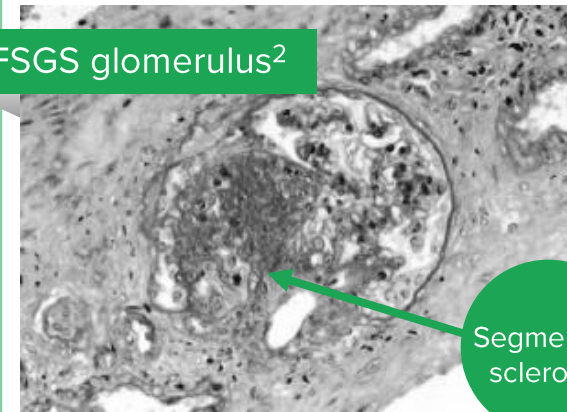
# What is Focal Segmental Glomerulosclerosis (FSGS)?

- On average FSGS progresses to kidney failure within 5 years after onset of proteinuria<sup>1</sup>
- Affects adults and children
- Caused by a variety of conditions - primary FSGS, genetic FSGS, FSGS of unknown cause and secondary FSGS<sup>3</sup>
- Currently no approved drugs for FSGS
  - patients are treated with medications off-label, including angiotensin receptor blockers
  - 60% patients have reoccurring FSGS even after first kidney transplant<sup>6</sup>

Normal glomerulus<sup>2</sup>



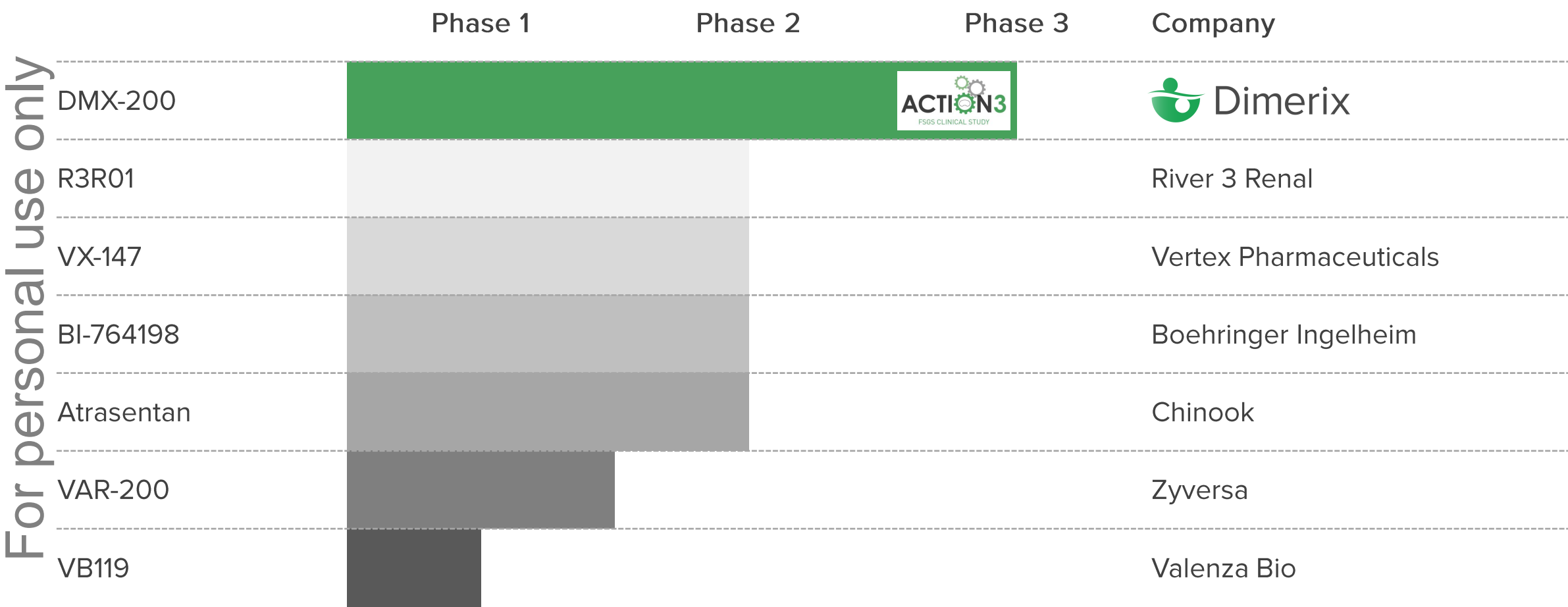
FSGS glomerulus<sup>2</sup>



Segmental sclerosis

Glomeruli are the tiny network of blood vessels that are the “cleaning units” of the kidney

# Competitive landscape in FSGS



DMX-200 is the only therapy in phase 3 development

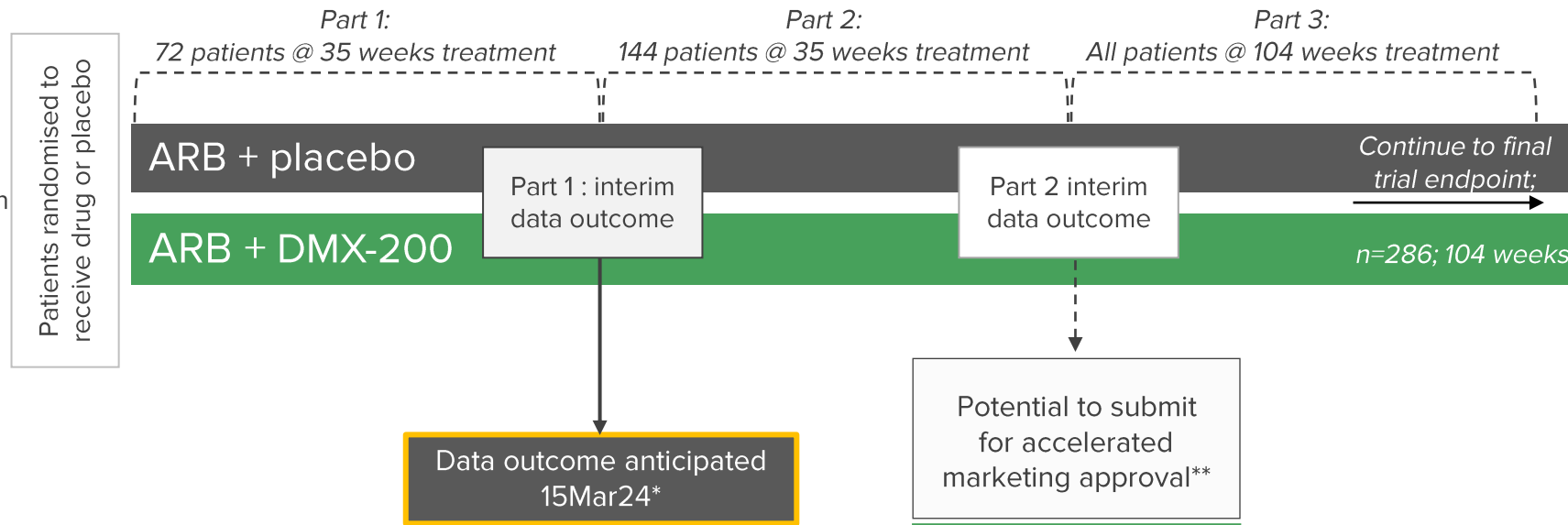


# ACTION3 Phase 3 clinical trial

FSGS CLINICAL STUDY

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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>

# 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

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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

FSGS CLINICAL STUDY

## WHAT ARE THE TRENDS IN LICENSING DRUG DEVELOPMENT?



# Global partnering trends – Q1 2023

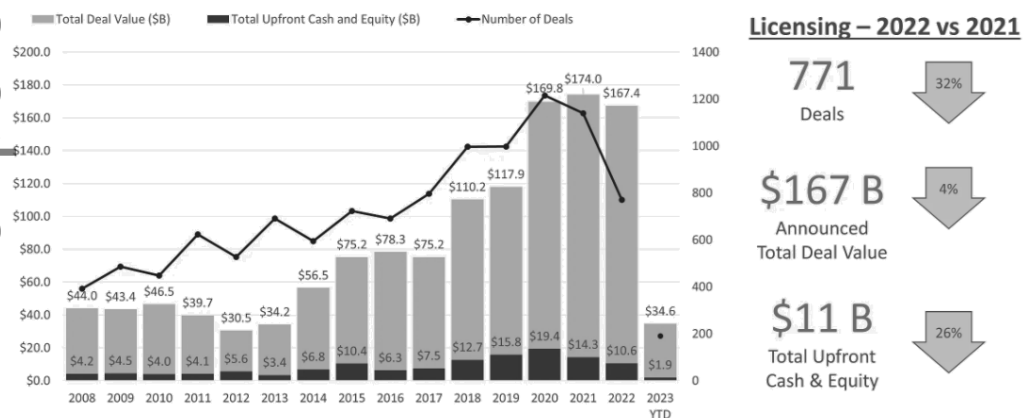
- Some picking up bargain assets, but large majority “business as usual” licensing deals

Biopharma R&D licensing partnership activity picked up slightly while venture continued to decline<sup>1</sup>

149 biopharma R&D licensing partnerships signed

## Licensing Terms are Shifting to More in Milestones<sup>2</sup>

Development and Commercialization of Biopharma Therapeutics and Platforms

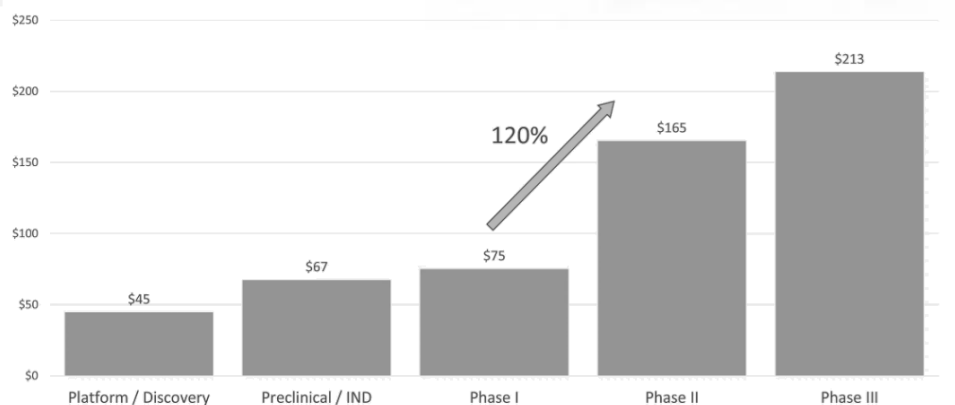


Source DealForma.com Database. Financials based on disclosed figures as of 3/29/2023  
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## Big Pharma Pays Well for Phase II as POC Returns<sup>2</sup>

Median Upfront Cash & Equity by Stage at Signing by Big Pharma – 2018-2022 (\$M)



Source DealForma.com Database. Financials based on disclosed figures as of 3/29/2023  
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- US\$34.3 billion in total announced deal values
  - milestones continued to make up the value difference
- 25 biopharma deals with upfront US\$10m - US\$100m
  - higher than recent quarters



# ACTION3

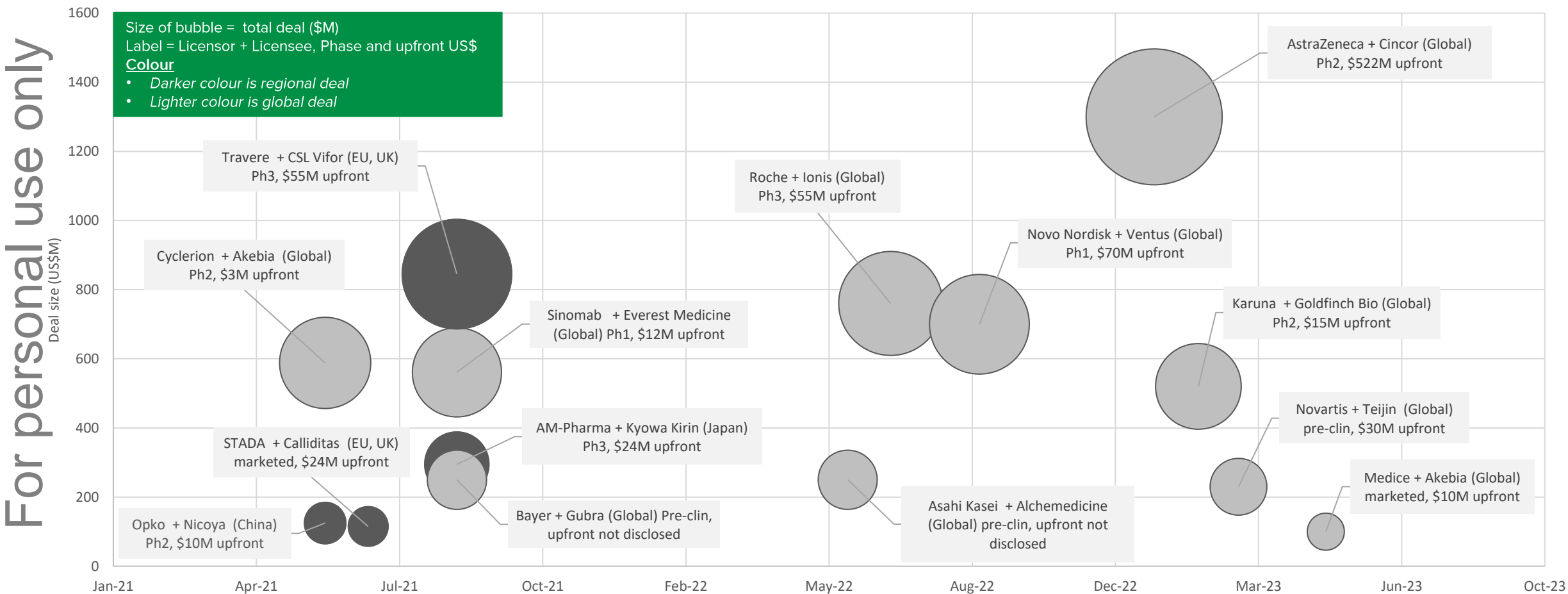
FSGS CLINICAL STUDY

WHAT TYPE OF **PARTNERING DEALS** ARE OCCURRING IN THE KIDNEY DISEASE SPACE?





# Partnering deals in the kidney disease space



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# ACTION3

FSGS CLINICAL STUDY

HOW MIGHT DIMERIX LOOK TO **STRUCTURE A DEAL,**  
AND WHAT LEVEL OF DATA WILL BE REQUIRED?

# Deal structure

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Big Pharma or Mid-Tier or Specialty Pharma			
	Global	Regional e.g. North America/EU	Country e.g. China only
	Global Licensee	Regional or Country Licensee	
Pros	<ul style="list-style-type: none"> <li>• Single licensee</li> <li>• Streamline branding/marketing</li> </ul>	<ul style="list-style-type: none"> <li>• Core expertise in regional regulatory guidelines</li> <li>• Core sales and marketing in region</li> <li>• More regional companies than global</li> <li>• Greater interest in licensing earlier</li> </ul>	
Cons	<ul style="list-style-type: none"> <li>• Some territories less invested</li> <li>• Fewer global companies</li> <li>• Like to wait for Phase 3 data</li> </ul>	<ul style="list-style-type: none"> <li>• Multiple licensees</li> <li>• Potentially different brand names</li> <li>• Different marketing material</li> </ul>	

# Dimerix partner

The ideal partner:

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

## Due diligence

- A key part of the negotiation process
- Stakeholder identification & management
- Key decision maker engagement
- Benefits of in person versus virtual

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# Late stage, phase 3 clinical development asset

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Near term **Phase 3** interim **analysis results** announced (Q124)

Advanced **partnering negotiations** with offers received from multiple parties for various territories<sup>1</sup>

**Orphan Drug** status providing protection through data exclusivity<sup>2</sup> for min 7-10 years, in addition to comprehensive patent/IP strategy

Estimated >\$3b **global market** size p.a.<sup>3</sup> – 203,000<sup>3</sup> patients across 7MM at example US pricing of US\$120,000 p.a.<sup>4</sup>





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.

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## WELL POSITIONED TO DELIVER AGAINST STRATEGIC PLAN

### *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.*



SCAN ME

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