Dimerix

For Immediate Release

CHAIRMAN'S ADDRESS – 2022 DIMERIX ANNUAL GENERAL MEETING

29 November 2022

Ladies and gentlemen,

The 2021-22 Financial Year was perhaps the most pivotal in our company's history as we completed the planning phase for our Phase 3 trial into Focal Segmental Glomerulosclerosis (FSGS) and began the daunting task of recruiting a global phase 3 study across a targeted 70 clinical sites, still on the background of the COVID-19 pandemic. I would like to take a couple of moments to give a little of my perspective on some of our undertakings.

Our lead DMX-200 program is targeting a disease that, once commenced, leads to renal failure, dialysis and ultimately the need for a kidney transplant. There are currently no drugs specifically approved to treat this disease that affects over 220,000 people around the world.

In addition to the enormous suffering of these patients, in being attached to a dialysis machine for a minimum of 4 hours a day, 3 times per week, the cost of providing this care is also substantial. Put simply, FSGS represents a significant unmet medical need for patients and healthcare providers.

Our Phase 3 clinical program for FSGS is one of only two such programs active today. Nina will touch on this a little more, but we are very comfortable that our product, DMX-200, will have substantial place in the market even in the event that the other program is also successful, given the benefits DMX-200 provides, but also because of the complementary nature of the two products.

Dimerix is one of relatively few Australian biotech companies to have progressed a drug candidate into Phase 3 clinical trials. This is an achievement that we as a company should rightly be proud of – but our work is not done until the trial concludes successfully. So, what are the chances of success? And what could this mean for shareholder returns?

A study completed in 2018, and reported in 2019 highlighted the following (*reference https://doi.org/10.1093/biostatistics/kxx069*)

Across all indications:

- The likelihood of getting a drug approved for market on commencement of Phase 1 is only 13.8%
- The likelihood of getting a drug approved for market on commencement of Phase 3 is almost 60%

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Of course each clinical study is different, but these statistics reflect the reality that in order to progress to Phase 3, a drug candidate must have demonstrated both safety and some aspects of efficacy, and so the odds of success go from 1 : 7.2 for Phase 1, to better than even (1 : 1.7) in Phase 3.

So how does this translate to shareholder returns? In addition to having a very much higher chance of success, this stage represents a very appealing stage of partnering for pharmaceutical companies, including large Pharma and smaller specialist companies perhaps focused on a particular clinical area.

Dimerix does not intend on establishing a sales and marketing team to launch DMX-200, rather we intend to partner this program. Of course, we are unable to disclose any details of the many partnering type discussions we have ongoing; however we can confirm there is significant and active interest in what we are doing, and the stage that we are at. We are confident that there is a deal, or deals, that can be done around DMX-200 to the benefit of all shareholders.

We look forward to providing further insight in due course.

I would like to formally thank Nina, and her whole team, for their commitment and effort on our behalf. Our feedback from stakeholders familiar with other FSGS trials is that our recruitment is exceeding the rate of recruitment by others – and this is a direct result of the planning and effort put in by the team. I also thank my fellow Directors for their regular counsel, both within the formalities of the Boardroom, but also when perhaps more specialist input is required to assist operations.

Finally, to our shareholders. Thank you for your ongoing support. We recognise that a challenge of being one of only a very few Phase 3 companies in the sector in Australia is that there may be some extended 'quiet' periods whilst we execute our program. Please be assured, these are not cause for concern, but the reality that we are doing exactly what we are supposed to be doing in delivering on this important trial and doing the groundwork required to realise the underlying value in our lead program.

We look forward to this time next year, having our first outcome into our Phase 3 study delivered, and most importantly, getting more comfort that we may help the patients so desperately in need of a treatment.

James Williams, Non-Executive Chairman, Dimerix

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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About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200, for Focal Segmental Glomerulosclerosis (FSGS), respiratory complications associated with COVID-19 and Diabetic Kidney Disease, and is 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. Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

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 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a study in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any study, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease. DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

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 40% 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 poor.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[3] and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year[3]. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. This is a special status granted to a drug to treat a rare disease or condition; the designation means that DMX-200 can potentially be fast-tracked, and receive tax and other concessions to help it get to market.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. 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 an abbreviated regulatory pathway to approval.

Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

References

1 Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/

2 DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030

3 Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/

Company Review

Dr Nina Webster
CEO & Managing Director

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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.

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Key company metrics

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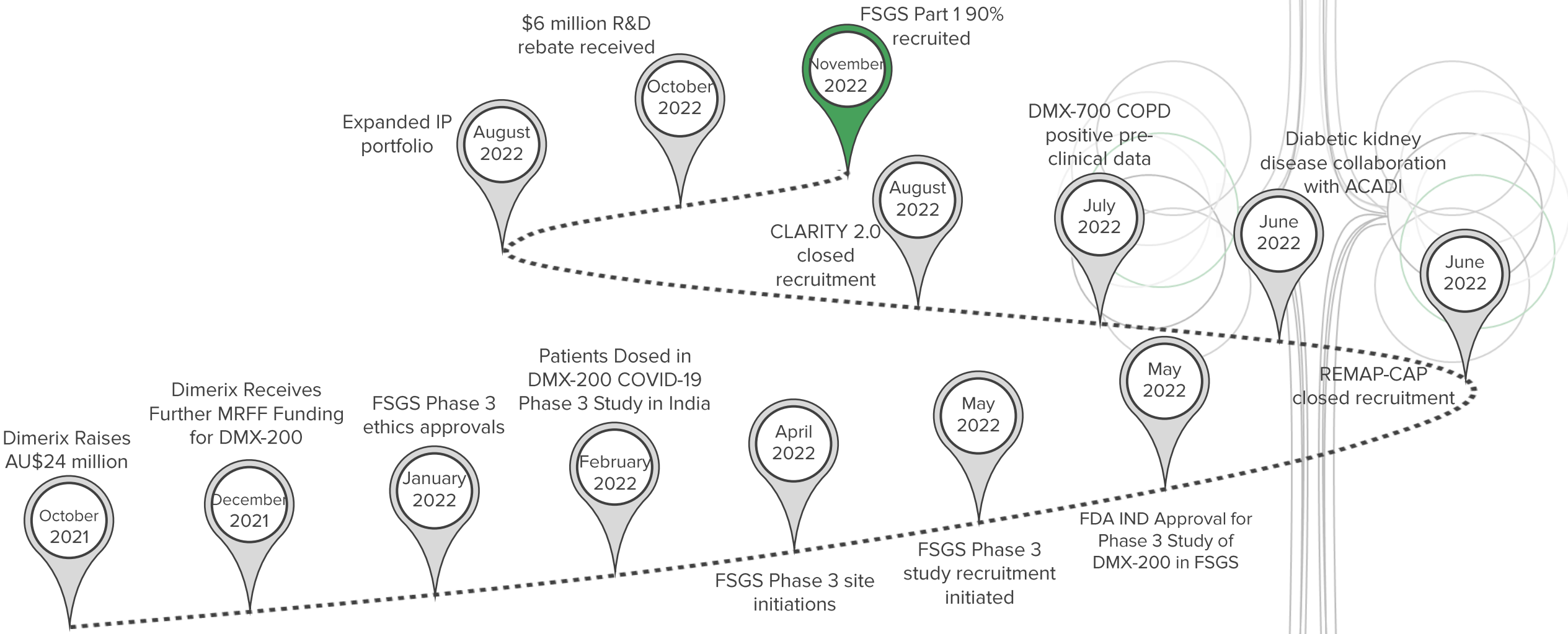
1. ASX release: 29Jul20
2. See slide 7 for market potential

Key achievements – FY22



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Development pipeline

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3
DMX-200	Focal Segmental Glomerular Sclerosis (FSGS)				
	Diabetic Kidney Disease				
	Late COVID pneumonia – Investigator-led REMAP-CAP	Recruitment closed - pending data			
	Early COVID respiratory – Investigator-led CLARITY 2.0	Recruitment closed - pending data			
DMX-700	Chronic Obstructive Pulmonary Disease (COPD)				
DMX-xxx	Undisclosed (multiple)				

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ACTION3

FSGS CLINICAL STUDY

Phase 3 Update

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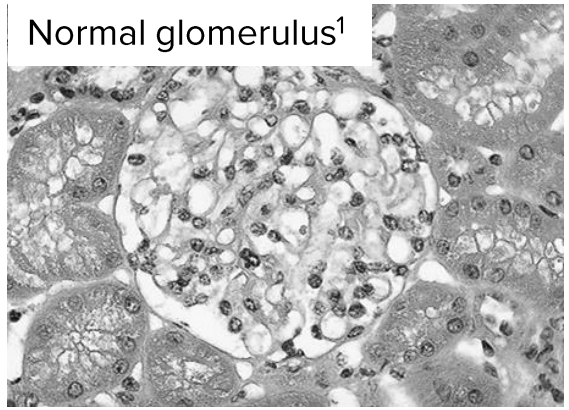
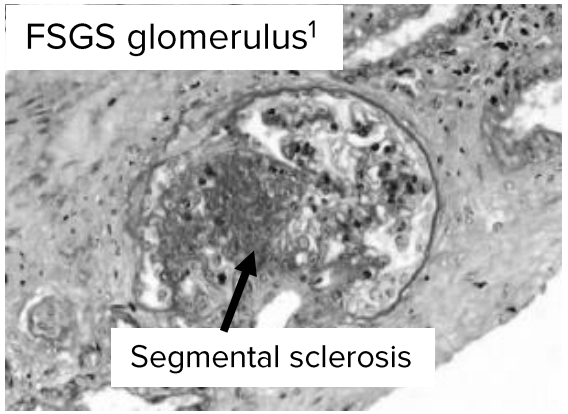
Focal Segmental Glomerulosclerosis – rare kidney disease

Normal glomerulus[1]



FSGS glomerulus[1]



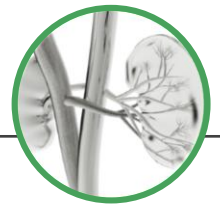
Glomeruli are the tiny network of blood vessels that are the “cleaning units” of the kidney

220,000

Total incident population of FSGS across 7 major markets in 2021[2]

20%

of child nephrotic syndrome cases caused by FSGS[3]



60%

patients have reoccurring FSGS after first kidney transplant[4]

>US$7,000

cost of average orphan drug per month in US[5] (US$84,000/yr)

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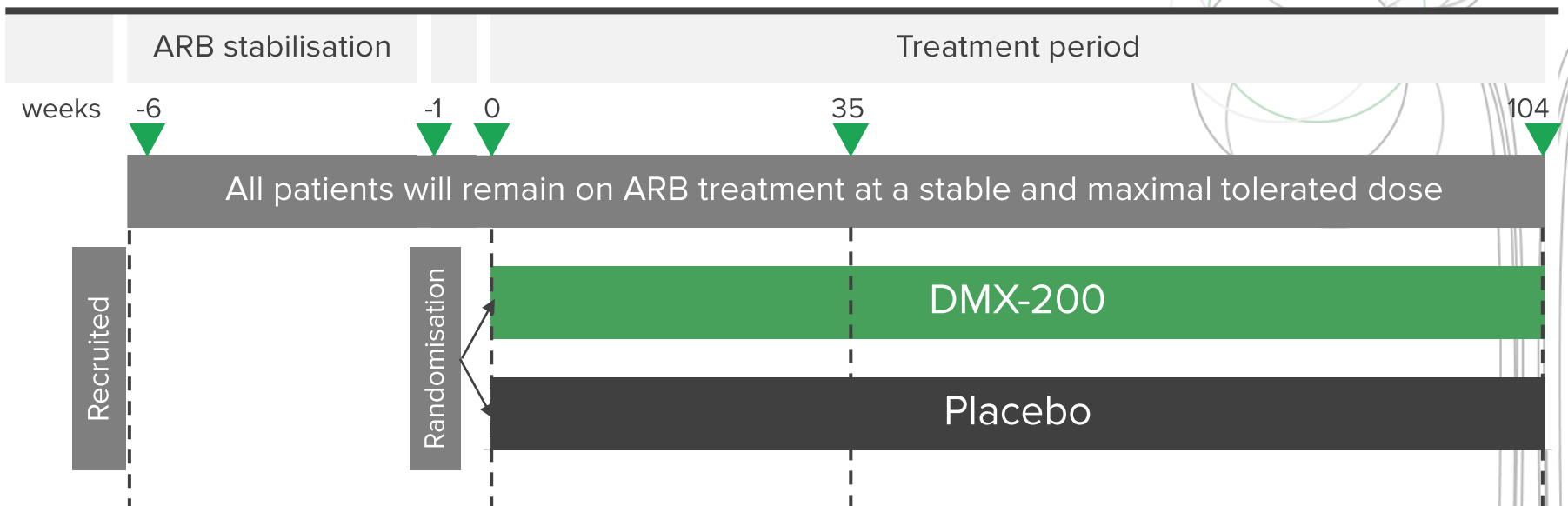
1. J Korean Soc Pediatr Nephrol 2012;16:21-31 http://dx.doi.org/10.3339/jkspn.2012.16.1.21; 2. Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032 (2022) Delve Insight: https://www.delveinsight.com/report-store/focal-segmental-glomerulosclerosis-fsgs-market; 3. Nephcure FSGS factsheet 2022: https://2eu46v1q93c11mayx1nfvwg6-wpengine.netdna-ssl.com/wp-content/uploads/2021/02/nc.factSheet.FSGS_210106.pdf; 4. Front. Immunol., July 2019 | https://doi.org/10.3389/fimmu.2019.01669; 5. 2018, IQVIA , Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments;

ACTION3 - FSGS phase 3 study design

FSGS CLINICAL STUDY

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



- Stabilise ARB and any other medications (as appropriate)
- 1st dose
- Part 1: 1st interim analysis; n=72, proteinuria at week 35
- Part 2: 2nd analysis Accelerated Approval endpoint; n=144* (72 1st analysis + 72), proteinuria + eGFR at week 35
- Final analysis (n=286) eGFR slope at week 104

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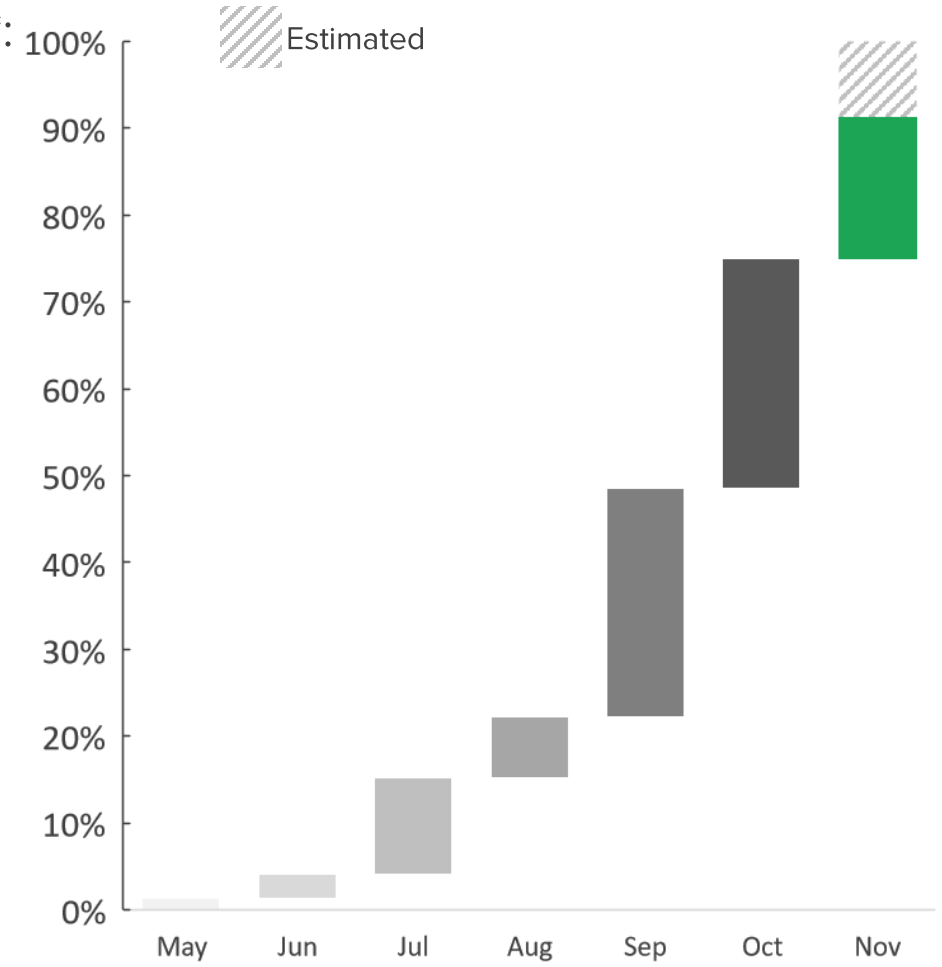
ARB: Angiotensin Receptor Blocker
**Subject to recruitment rate and conditional power*
Accelerated endpoint: Marketing approval for serious conditions that fill an unmet medical need based on a surrogate or an intermediate clinical endpoint

ACTION3 Study part 1 status

FSGS CLINICAL STUDY

Patients recruited*:



- Recruiting globally
- On track to complete Part 1 recruitment Q4 2022
- Part 1 completion anticipated Q3-2023**

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*Actual and estimated as at 27Nov2022; Patients recruited undergo ~6 weeks background medication stabilisation period
** Subject to recruitment

Dimerix partnering objectives

Dimerix intends to partner DMX-200

No plans for a sales and marketing team, but partner to support sales and marketing activities

Global interest in DMX-200

Actively engaged with potential licensing partners, with the aim to provide the best outcome for both patients and shareholders

Enhance potential of DMX-200

Mitigate capital obligations as well as commercial risk;
Status of potential partners and discussions remain confidential

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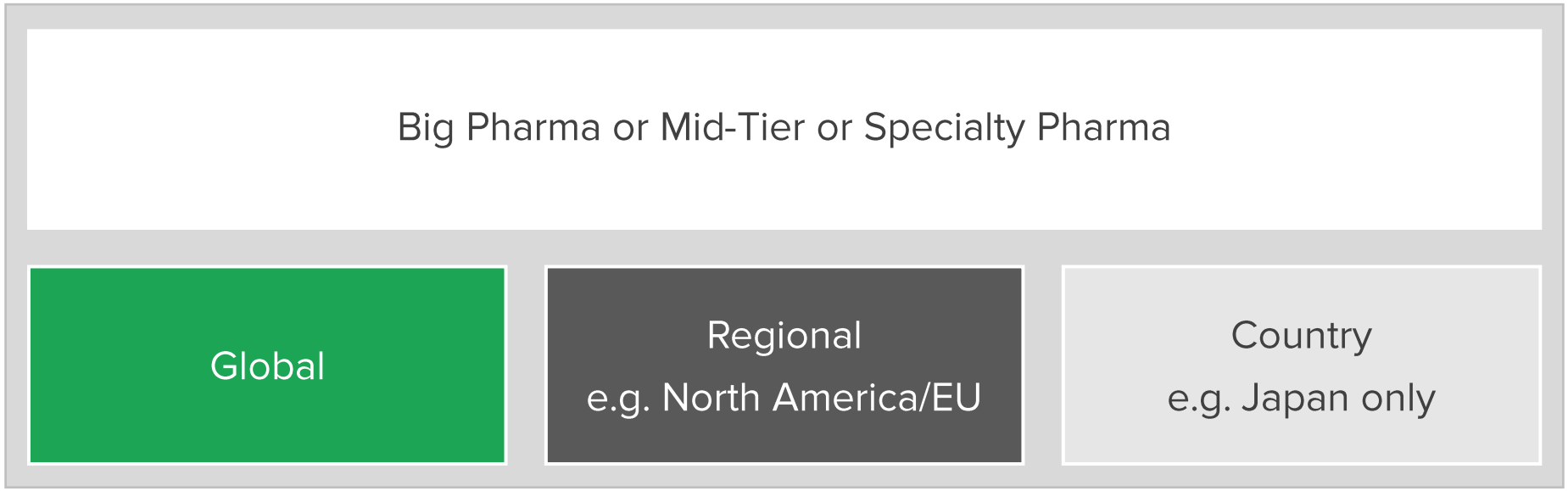
What does commercialisation look like?



Transactions typically comprises:

- A cash payment upon execution of a definitive agreement
- A cash payment on future key inflection events e.g. data outcome
- Series of payments which could be contingent on events such as sales performance
- Royalty payments on product sales

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Renal licensing deals details – last 18 months

(only deals where financials disclosed included)

Date	Licensor	Licensee	Total Deal Value	Upfront	Geography	Development Stage	Disease Targets	Assets
Sep 2022	Ventus	NovoNordisk	$700.0M	$70.0M	Worldwide	Phase 1	Renal diseases (Primary)	NLRP3
Jul 2022	Roche	Ionis Pharmaceuticals	Undisclosed	$55.0M	Worldwide	Phase 3	IgA nephropathy	IONIS-FB-L_{Rx}
Jun 2022	Alchemedicine, Inc.	Asahi Kasei Pharma	$250M	Undisclosed	Worldwide	Pre-clinical	Renal diseases	Endothelin A antagonist
Sep 2021	Travere Therapeutics	Vifor Pharma	$845.0M	$55.0M	Australia, New Zealand, Europe	Phase 3	Focal segmental glomerulosclerosis (Primary); IgA nephropathy; Renal disease	Sparsentan
Sep 2021	AM-Pharma Holding	Kyowa Kirin	$295.1M	$24.1M	Japan	Phase 3	Renal injury (Primary); Sepsis	Ilofotase alfa
Sep 2021	Sinomab Bioscience, Suzhou Sinovent Pharmaceuticals	Everest Medicine	$561.0M	$12.0M	Worldwide	Phase 1	Renal disease (Primary)	XNW1011 (SN1011)
Jul 2021	Stada Arzneimittel	Calliditas Therapeutics	$115.0M	$24.0M	Europe; Switzerland; UK	Pre-registration	IgA nephropathy (Primary)	Budesonide
Jun 2021	Opko Health	Nicoya Therapeutics	$125.0M	$10.0M	China	Phase 2	Hyperparathyroidism in chronic kidney disease	Rayaldee
Jun 2021	Cyclerion Therapeutics	Akebia Therapeutics	$588.0M	$3.0M	Worldwide	Phase 2	Cognitive disorder (Primary); Diabetic nephropathy;	Praliciguat

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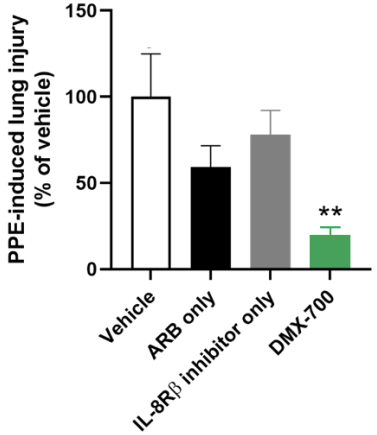
Sources: Clarivate, BiosciDB, Press, Company Documents, Statutory and Regulatory Filings. Only deals with disclosed financials are included

Advancing the broader pipeline

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

DMX-700 for Chronic Obstructive Pulmonary Disease (COPD)

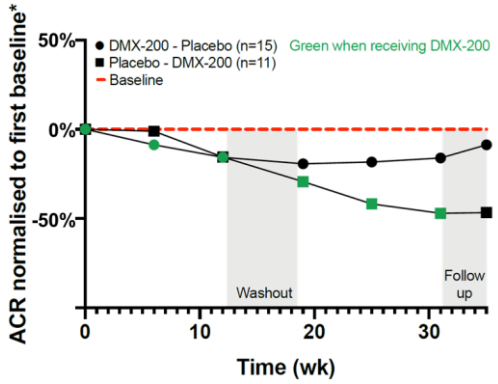
Preclinical studies show that DMX-700 significantly reduced lung injury by 80% ($p<0.01$) after 21 days treatment[1]



Currently designing first clinical study along with any further required nonclinical safety studies

DMX-200 for Diabetic Kidney Disease

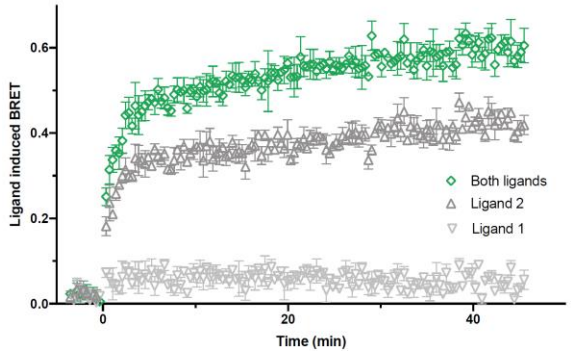
Phase 2 demonstrated promising efficacy & safety[2], proteinuria declined after treatment with DMX-200 in both treatment periods[2]



Next study planned with support form Australian Centre for Diabetes Innovation; pre-IND meeting planned with FDA Q123

Undisclosed Opportunities

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



Additional target opportunities identified using Receptor-HIT® platform technology; focus on inflammatory diseases

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1. ASX release: 04Jun22
2. ASX release 28Jan21

Investment highlights

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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 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.