

# Company Review

Nina Webster

CEO & Managing Director



Dimerix



# 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.*

# 2018 financial year achievements



**Excellent results from Phase 2 trials in Chronic Kidney Disease**



**Share entitlement offer and placement collectively raised \$7.5 million**



**Two Phase 2 trials initiated in different high potential indications**



**Executive management team restructure**



**US patent for DMX-200 granted, expiry in 2032**

# Opportunity for growth

## **Focal Segmental Glomerulosclerosis (FSGS)**

- A serious and rare kidney disease: orphan indication
- DMX-200 has US Orphan Drug Designation for FSGS

## **Diabetic Kidney Disease (DKD)**

- Also known as Diabetic Nephropathy
- Progressive disease, leading to kidney failure and blood dialysis

## **HIT technology platform**

- Scalable, globally applicable, proprietary technology
- Enables understanding of receptor interactions to rapidly screen and identify new drug opportunities

## **Pipeline programs**

- Expand and build product pipeline
- Business development focus



# Dimerix Corporate Overview

Financial information	
Share price(29Oct18)	11.5 cents
52 week low / high	8 cents / 24 cents
Shares on issue	158.8m
<b>Market Capitalisation</b>	<b>\$18.26 million</b>
Cash (as at 30Sep18)	\$5.34 million
Debt (as at 30Sep18)	\$0
<b>Enterprise value</b>	<b>\$12.92 million</b>



FSGS + DKD = >\$1.1 billion/year addressable market\*  
**No competitors currently on market**  
+ HIT technology platform

*The current  
enterprise valuation  
does not reflect the  
opportunity value*

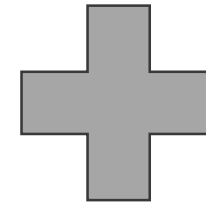


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# What is DMX-200

Co-administration of 2 drugs to achieve a **synergistic** renal effect:

- Irbesartan 300mg - angiotensin receptor blocker (ARB)
  - Small molecule
  - FDA (USA) approved for Diabetic Kidney Disease
- DMX-200 - CCR2 antagonist
  - Small molecule
  - PDMA (Japan) approved for chronic hepatitis B



Proven drugs\* – abbreviated development with lower cost and less risk



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# Proposed mechanism of action

DMX-200 addresses the three most important mechanisms whereby chronic kidney damage progresses

1

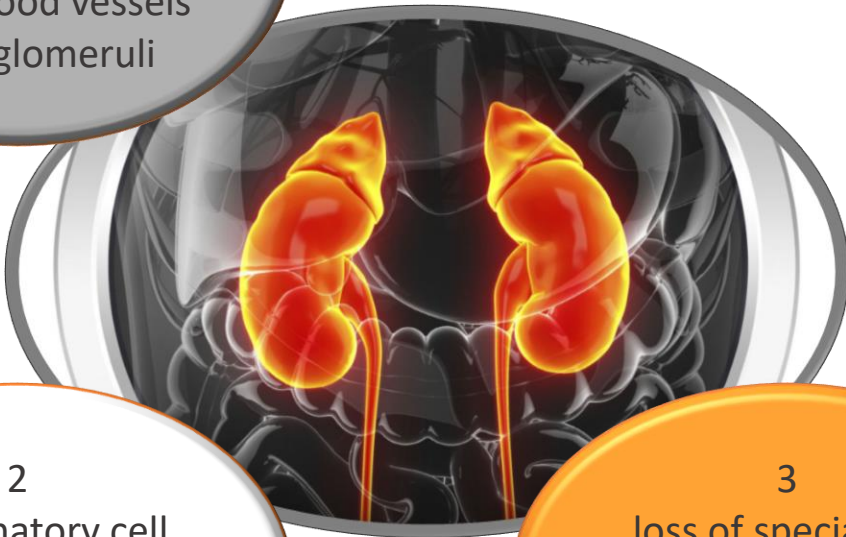
hyperfiltration of  
and hypertension  
within blood vessels  
of the glomeruli

2

inflammatory cell  
infiltration of the  
kidneys:  
subsequent fibrosis

3

loss of specialised  
cells called Podocytes  
(cannot regenerate)  
from the glomeruli



Irbesartan blocks cellular receptors responsible for hyperfiltration & glomerular hypertension

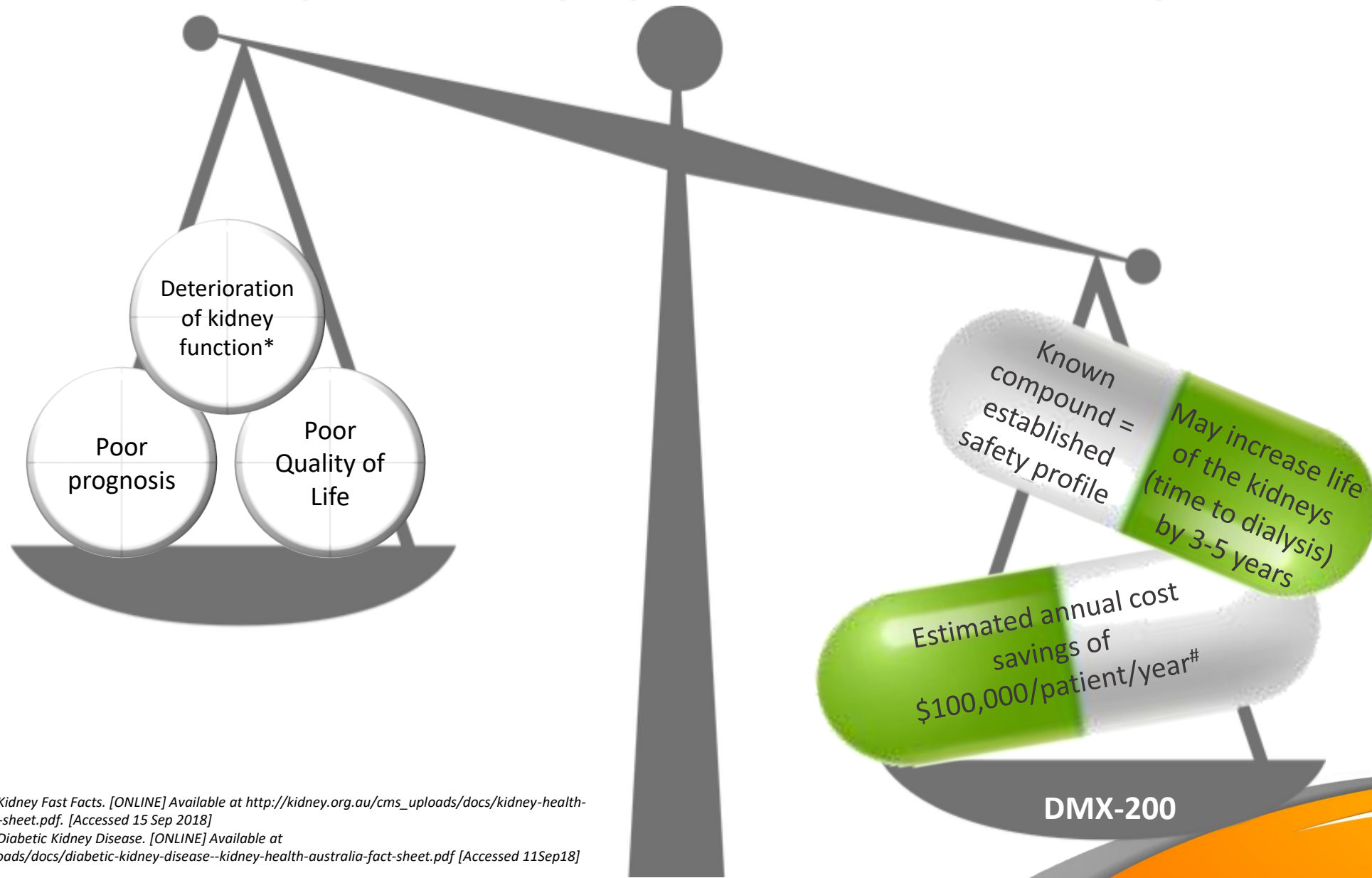
DMX-200 blocks chemokine receptor (CCR2) which initiates attraction of inflammatory cells into the kidneys

Certain kidney cells express both receptors, thus using only 1 compound does not block activation and results in only a partial response

**DMX-200 Unique proprietary proposition: total benefit is greater than the sum of the two individual effects**



# DMX-200 value: patients, payers & healthcare system



<sup>#</sup> Kidney Health Australia. 2018. Kidney Fast Facts. [ONLINE] Available at [http://kidney.org.au/cms\\_uploads/docs/kidney-health-australia-kidney-fast-facts-fact-sheet.pdf](http://kidney.org.au/cms_uploads/docs/kidney-health-australia-kidney-fast-facts-fact-sheet.pdf). [Accessed 15 Sep 2018]

\* Kidney Health Australia. 2018. Diabetic Kidney Disease. [ONLINE] Available at [https://kidney.org.au/cms\\_uploads/docs/diabetic-kidney-disease--kidney-health-australia-fact-sheet.pdf](https://kidney.org.au/cms_uploads/docs/diabetic-kidney-disease--kidney-health-australia-fact-sheet.pdf) [Accessed 11Sep18]



# DMX-200 value: large market with low competition



Irbesartan 300mg:  
US market volume  
growing at ~5%/year  
Price: US\$550/unit<sup>#</sup>  
2.02million units/year\*

## Assumptions:

- Co-administration with Irbesartan 300mg, therefore valuation model based on Irbesartan 300 mg sales
  - *Hypertensive patients maintenance dose ~150 mg daily<sup>†</sup>*
  - *Kidney Disease patients maintenance dose ~300 mg daily<sup>†</sup>*
- Therefore assume >50% of Irbesartan 300 mg scripts due to kidney disease
- As diabetes rates rise, sales will continue to grow

Addressable market: \$1.1 billion/year  
with no current marketed competitors

<sup>#</sup> pre-genericization;

\*adjusted by 50% of 300mg data (total = 4.05 million); 2017, IQVIA

<sup>†</sup> Avapro prescribing information



# Current clinical trial designs

Both studies: double-blind, randomised, placebo-controlled, crossover study evaluating the safety and efficacy of DMX-200 in patients with diabetic kidney disease who are receiving Irbesartan

## Diabetic Kidney Disease

- Number of patients: 40
- Must be on 300 mg/daily of Irbesartan for >3months prior to screening
- All patients will receive DMX-200 and be followed for:
  - Safety;
  - Reduction in protein in patient's urine; and
  - Improvement in kidney function
- Subject to patient recruitment rates, efficacy analysis is anticipated in calendar year Q4 2019
- Interim efficacy results not planned as the study is designed to support validity of endpoint analysis

- FSGS
- Number of patients: 10
- Must be on 300 mg/daily of Irbesartan for >3months prior to screening
- All patients will receive DMX-200 and be followed for:
  - Safety;
  - Reduction in protein in patient's urine; and
  - Improvement in kidney function
- Subject to patient recruitment rates, efficacy analysis is anticipated in calendar year Q4 2019
- Interim efficacy results not planned as the study is designed to support validity of endpoint analysis

# Value driving events

## Upcoming milestones - 2019

- ✓ Ethics approvals for both clinical studies was achieved in July
- ✓ Clinical trial sites were opened and patient recruitment commenced in September
- EU orphan drug application outcome for FSGS anticipated in current quarter
- Partnering activities and discussions
- Receptor-HIT technology platform licensing activities
- Assess potential pipeline opportunities
- Preliminary DKD data anticipated in CY19Q4
- Preliminary FSGS data anticipated in CY19Q4

## Secure a licensing agreement – 2020

- Dimerix plans to seek a commercial partner(s) who will assist development, then market and sell the product
- Develop Dimerix pipeline

## Generate ongoing revenue stream

- Estimated \$1.1 billion addressable market per year for DMX-200
- **No current competitors on market**
- Multiple pharma companies active in kidney disease licensing/M&A with:
  - Upfront/milestones >\$200million<sup>#</sup>
  - + royalties

\* 2017, IQVIA

# Ionis, Vifor, Epigen deals in 2018

# DIMERIX

End of Presentation



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## **Meeting Transcript**

### **Annual General Meeting of Dimerix Limited**

**10.00am, Tuesday 30 October 2018 (Perth)**

#### **➤ CEO & Managing Directors Address**

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Thank you James, and good morning ladies and gentlemen. I am excited to be with you at my first Annual General Meeting for Dimerix so soon after joining the Company. By way of introduction I wanted to give you a brief summary of my own history before moving to today's presentation.

I have worked in the pharmaceutical industry for over 25 years, and hold a Bachelor's degree in Pharmacology, a PhD in Pharmaceutics, a Master's degree in Intellectual Property Law and a Master's degree in Business Administration. I started my pharmaceutical career at Wyeth Pharmaceuticals (now part of Pfizer), based in the UK, as a scientist in new product development, including research and development as well as pilot batch manufacture and scale-up to commercial manufacture.

In 2001, I moved to Australia and joined Acrux Limited, a Melbourne based ASX listed company, becoming the inventor of a number of Acrux patents, including for their most successful product, Axiron, which has since generated the company in excess of \$300 million. Whilst at Acrux, I held roles across project management and the intellectual property portfolio, and was the Director of Business Development from 2006 until 2011 during which time I saw 3 products commercialised globally. I then joined Immuron Limited, another Melbourne based ASX listed biotech company, as the Director of Commercialisation and Intellectual Property, focussing on commercialising the product Travelan, licensing negotiations and contracting through to investors relations and capital raising. I was invited to re-join Acrux in 2013, and returned as the Commercial Director, then heading up business development, investor relations, legal matters and the intellectual property portfolio, before joining Dimerix less than 2 months ago. I have joined the Company at what is a time of great momentum and will share more with you now about the opportunity I see ahead of us.

#### **➤ Slide 2 – Forward-Looking Statement**

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Please turn to slide 2.

I would like to formally note our Forward-Looking Statement caveat by stating that...

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.

➤ **Slide 3 – 2018 Financial Year Achievements**

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Please move to Slide 3

Turning to Dimerix, over the previous 12 months the company has reviewed and revised its strategy. That has led, in part, to the changes in management announced recently, including my own appointment.

As part of that review, and since my appointment, we have updated our internal company valuation model in order to understand the true value to the business of our major assets, DMX-200 in the two different indications, as well as the other levers available to help us create value for shareholders.

In 2017, DXB completed its first Phase 2a study in patients with a range of Chronic Kidney Diseases. No adverse safety events were reported, and all trial endpoints were achieved. In a subsequent sub-group analysis of these results, statistically and clinically significant efficacy signals were seen in the diabetic group. The best clinical marker of the rate of progression of kidney failure is an increase in protein in the urine (known as proteinuria), and a significant reduction in proteinuria demonstrates the progression of kidney failure as been slowed. Previous data has suggested that a reduction of greater than 30% proteinuria may increase time to dialysis by approximately 3 to 5 years.

Irbesartan, the current standard of care treatment for kidney disease which has been on the market since 2001, has been shown to reduce proteinuria levels by 24% in type 2 diabetics. It was exciting to see that DMX-200, when co-administered with Irbesartan, reduced proteinuria levels by a further 36%. To be clear, this 36% is in addition to the 24% already seen from Irbesartan and may result in patients having an additional 3 to 5 years of kidney function before requiring dialysis, compared to taking Irbesartan alone. The compelling results from this study prompted the decision to raise \$7.5 million in early 2018, through a share entitlement offer and placement, towards funding two different clinical trials in 2018: one for patients with Diabetic Kidney Disease; and the second for patients with another form

of kidney disease, Focal Segmental Glomerulosclerosis (or FSGS). Both of these studies were recently initiated and will be discussed in further detail later in this presentation.

➤ **Slide 4 – Corporate Overview**

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Turning to Slide 4

At a high level we see the Dimerix business as having four distinct opportunities.

- Firstly, in DMX-200 for Diabetic Kidney Disease, which is currently in a Phase 2b clinical trial: There were 23 million diagnosed diabetics in the US in 2017, and the incidence of diabetes is estimated to grow by 54% by the year 2040. What I found quite confronting is that 10% of all diabetics will develop kidney disease within the first 10 years of diagnosis, and this figure grows by each year thereafter. As you can imagine, with the rate of diabetes growing so significantly, so to will the rate of diabetic kidney disease. The disease is progressive, and as such will ultimately lead to kidney failure and dialysis.
- Secondly, DMX-200 for FSGS, which is currently in a Phase 2a clinical trial and has been granted Orphan Drug Designation by the FDA: FSGS is a serious and rare kidney disease affecting approximately 120,000 people in the US. The disease progresses rapidly and results in kidney failure, requiring dialysis or kidney transplant. There are over 95,000 patients currently on the kidney transplant waiting list in the US alone;
- Thirdly, by leveraging the Dimerix proprietary Receptor-HIT platform technology, which enables us to understand the ways receptors interact and help to rapidly screen and identify new drug opportunities; and
- Fourthly, by boosting the company's pipeline in the longer term.

Ultimately, our goal is to create further value for our shareholders.

➤ **Slide 5 - Company Valuation**

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Turning to Slide 5.

The company is currently trading at 11.5 cents per share. With cash at 30 September 2018 totalling \$5.34 million, that infers an enterprise value of \$12.9 million. I believe that this does not reflect the current opportunity value, since the DMX-200 addressable market is greater than \$1.1 billion US dollars with no currently marketed competitors.

The current cash balance of \$5.34 million provides a solid base for the company to pursue the current clinical trials. We continue to assess the longer term strategy, including scale-up of DMX-200 manufacturing supply; progress towards submitting an Investigational New Drug (or IND) application to the FDA; and associated partnering activities, and the impact on future cash flow and funding.



➤ **Slide 6 – DMX-200**

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Turing to slide 6.

Dimerix is developing DMX-200, a chemokine receptor 2 (or CCR2) antagonist for co-administration with Irbesartan, for two different indications: Diabetic Kidney Disease and FSGS.

Irbesartan is approved by the FDA in the US for treatment of Diabetic Kidney Disease and is the current standard of care treatment.

DMX-200 has not been approved by the FDA in the US, and is considered a new chemical entity from a regulatory standpoint. However, the active ingredient in DMX-200 was approved for the treatment of chronic hepatitis B in Japan in 1994. As such, there is a large body of safety data publicly available which Dimerix may utilise and potentially allows Dimerix a lower risk and cost pathway to registration in the US and other relevant territories.

The DMX-200 product attributes are designed to deliver significant benefits for patients. As there is no approved competitor on the market at this time, there is a strong patient need to slow deterioration of the kidney. The twice daily dose is administered in an easy to swallow capsule form. Dimerix has a number of granted patents surrounding DMX-200, with the most recent US patent having been granted in August 2018 with expiry in 2032.

➤ **Slide 7 – Proposed Mechanism of Action**

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Turing now to slide 7.

So how does DMX-200 work? There are three primary mechanisms of chronic kidney disease progression. Firstly, hyperfiltration and subsequent hypertension within blood vessels of the filtration elements in the kidneys called glomeruli, which is essentially an increase in the filtration rate and pressure of the renal glomeruli. Secondly, this persistent pressure in the kidney cells results in inflammatory cells causing fibrosis, or scarring, of the kidney cells. Thirdly, the scarring leads to a loss of the specialised cells called podocytes from the glomeruli. Unlike other cells within the body, these cells cannot regenerate, hence kidney disease is progressive and ultimately leads to kidney failure when there are not enough podocytes left to effectively filter the blood.

The current standard of care, Irbesartan, blocks receptors responsible for hyperfiltration and hypertension. DMX-200 blocks chemokine receptor 2 to prevent inflammation. More importantly, within the kidney certain cells such as the podocytes express both receptors which show elevated activity when expressed in together. Using only Irbesartan or DMX-200

alone would block only one receptor and thus achieve only a partial response. This is where the co-administration of DMX-200 with Irbesartan is so exciting for Dimerix, in that both receptors on the same cell are targeted simultaneously. This unique proposition, and the crux of our DMX-200 patent position, is that the synergistic benefit of DMX-200, together with Irbesartan, is greater than the sum of the two individual effects. In other words, in this case one plus one does not equal two, but three.

➤ **Slide 8 – DMX-200 value to patients, payers and the healthcare system**

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Turing to slide 8.

Without adequate management, the progressive nature of kidney disease inevitably results in poor prognosis for patients. It most often results in total kidney failure and a poor quality of life. When the kidneys fail, it means they have stopped working well enough for the patient to survive without dialysis or a kidney transplant. A kidney transplant costs in the region of \$260,000 per patient, with ongoing and expensive anti-rejection drugs also costing thousands of dollars per year, and dialysis costs in the region of \$100,000 per patient per year and requires regular visits, totalling over 12 hours per week to the medical facility. This is a huge burden on both the patient and the healthcare system. DMX-200 has the potential to increase the life of the kidney by 3 to 5 years, which allows for a better prognosis and quality of life for a patient and reduces the financial burden on the healthcare system.

➤ **Slide 9 – DMX-200 market value**

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Turing to slide 9.

As I have mentioned earlier, there are no current competitors to DMX-200 on the market which means we need to use a surrogate to model the market potential. As mentioned, DMX-200 will be co-administered with Irbesartan 300mg, and so the DMX-200 market potential can be modelled on the Irbesartan 300mg market. Why 300mg? According to the product label, the maintenance dose for kidney disease is generally 300mg, therefore, it can be conservatively assumed that greater than 50% of the Irbesartan 300mg scripts are for kidney disease.

- In 2017, and according to IMS data, there were over 4 million units of Irbesartan 300mg sold in the US. Using the base 50% assumption, that equates to over 2 million being for kidney disease.
- Irbesartan itself is now available as a generic, however prior to genericisation, Irbesartan 300mg retailed for US\$550 per unit, which is in line with typical premium pricing for patent protected products in this space.

- Over 2 million units sold at US\$550 per unit provides us with a total addressable market of US\$1.1 billion per year in the US, with no current competitors based on the pricing structure of the patented version of Irbesartan. In fact, given the need for a treatment like DMX-200, we believe that it could potentially be priced at a premium to \$550 per unit, making the potential market larger, but I have shown you conservative estimates here.

The Irbesartan market is forecast to grow by at least 5% each year. This is supported by the fact that the diabetes incidence is forecast to grow by 54% by the year 2040, and that 10% of diabetics develop kidney disease within the first 10 years of diagnosis. This makes DMX-200 a very compelling, and currently undervalued proposition.

➤ **Slide 10 – Current Clinical Trial Designs**

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Turing to slide 10.

Dimerix currently has two clinical trials running, with multiple sites across Australia. Dimerix announced site initiation in September 2018, and currently 8 of the 10 clinical sites are actively recruiting:

- Firstly, in DMX-200 for Diabetic Kidney Disease; and
- Secondly, DMX-200 for FSGS.

Both trials are double-blind, randomised, placebo-controlled, crossover studies evaluating the safety and efficacy of DMX-200 in patients with either diabetic kidney disease (DKD) or FSGS, who are receiving Irbesartan. This means that every patient will receive treatment of DMX-200, and treatment of placebo, although both the patients and the physicians will not know which they will receive first. In both studies, every patient must also be receiving 300 mg daily of Irbesartan for at least 3 months prior to screening, so that any reduction in proteinuria seen in the trial can be solely attributed to DMX-200.

The DMX-200 clinical trial for Diabetic Kidney Disease is a Phase 2b trial, and follows on from the compelling diabetic sub-group data seen the 2017 Phase 2a study. Sites were initiated, and recruitment commenced in September, in line with the anticipated timelines. 40 patients are expected to be enrolled in the diabetic kidney disease study, and be followed for safety, reduction in protein in patient's urine and improvement in kidney function. Safety endpoints will be monitored throughout the study and efficacy analysis is planned to occur 8 months after the last patient is enrolled. As of yesterday, 18 patients are at some stage in the screening process.

DMX-200 for FSGS is currently in a Phase 2a clinical trial and has been granted Orphan Drug Designation in the US by the FDA. Sites were initiated, and recruitment commenced in September, in line with the anticipated timelines.

Orphan drug designation is granted by the FDA in order to support the development of products for rare diseases. Orphan drug designation qualifies the sponsor of the drug for various development incentives by the FDA, including: seven years of market exclusivity if regulatory approval is received, exemption from FDA application fees, and an abbreviated regulatory pathway to approval.

10 patients are expected to be enrolled in the FSGS study, all of whom will receive DMX-200 and be followed for safety, reduction in protein in patient's urine and improvement in kidney function. Safety endpoints will be monitored throughout the study and efficacy analysis is planned to occur 10 months after the last patient is enrolled. As of yesterday, 6 patients are at some stage in the screening process.

For both studies, subject to patient recruitment rates, preliminary results are anticipated in Q4 calendar year 2019. If recruitment occurs faster, results may be available earlier, and the converse is also true. It is unlikely that we will see interim efficacy results given both studies are blinded and designed to support validity of endpoint analysis.

➤ **Slide 11 – Key Value Drivers**

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Turing to slide 11.

Looking ahead, there are several key drivers of financial value for Dimerix.

In terms of DMX-200 clinical trials, we currently expect preliminary data from both trials in this quarter next year. The data from these results will help attract a commercial partner, who will likely complete development, then market and sell the product on our behalf. Dimerix is also assessing any other activities that may be required to attract high calibre partners, such as manufacturing supply and progress towards submitting an Investigational New Drug (or IND) application to the FDA.

There have been a number of licensing activities in the kidney disease space in the last 12 to 18 months. In each case, the upfront and milestone payments have been in excess of US\$200 million in addition to on-going royalties. This provides Dimerix with confidence in two ways: 1) that kidney disease is an active licensing market, with mid- to large Pharma companies very interested in this space; and 2) that there is recent precedence in the potential deal structure and valuation for products in this space.

In terms of the proprietary Receptor-HIT platform technology, which enables understanding of receptor interactions to rapidly screen and identify new drug opportunities; Dimerix is currently assessing ways of leveraging this asset for potential near term opportunities. There are two ways of looking at this opportunity: one is to provide a service to other parties in screening candidates on their behalf; and the other is to license out the proprietary platform so other parties might screen their own compounds.

In terms of the company's pipeline in the longer term, Dimerix continues to assess potential opportunities that fit with the company strategy. We intend to focus on selecting appropriate pipeline candidates within our resource and funding capabilities. All potential opportunities screened are commercially attractive and could result in patient preferred products.

Of course, we will update the market should our expenditure profile change as a result of any of the above activities.

Before I conclude, I want to summarise and emphasise that Dimerix is a company with an experienced management team and Board, two strong Phase II assets and has a solid track record of delivering on promise. Our goal is to develop commercially attractive products for an unmet need and to create further value for our shareholders.

We look forward to sharing milestone successes with you in the future. I thank you for listening.

➤ **Slide 12 – Close of Presentation**

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We will be happy to now take questions or have further discussion over coffee. We thank you all for your time, and to those who dialled in to listen to the Dimerix AGM, you may now hang up.