



A clinical-stage drug development company

Corporate Update
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General Manager

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Quick overview



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Key Assets

Who we are: A clinical-stage drug development company focused on commercialising new therapeutic treatments identified using our proprietary drug discovery platform.

Discovery Platform: Receptor-HIT technology to identify clinical opportunities from drug-receptor interactions, and potential revenue generation.

Lead Program: A therapy (DMX-200) currently in Phase II clinical trial for Chronic Kidney Disease (CKD) and US Orphan Drug Designation for Focal Segmental Glomerulosclerosis (FSGS).

- Pre IND meeting with FDA held 29th June 2016
- Therapeutic use patent **granted** in USA 19th April 2016

Leadership: Commercially focused and experienced board and management with a record of hitting milestones and creating significant shareholder value.

Corporate Snapshot

ASX Code:	DXB
Share Price (29 Jul):	\$.011
Market cap:	\$16.20m
Cash (30 Jun 16):	\$2.0m
Shares on issue:	1,473m
Performance Shares:	75m
Options:	111.7m

Top Shareholders

	%
Mr. Peter Meurs	21.52
Yodambao Pty Ltd	4.78
SRV Custodians Pty Ltd	3.93
J&L Peterson	3.31
White Family	2.74
Nullaki Services Pty Ltd	2.43
Mrs Wishney Sritharan Krishnarajah	2.24
Pfleger Family	2.12
Jampaso Pty Ltd (Williams Family)	1.88
Yodambao Investment	1.56

DMX-200: Phase 2 and IND

- **Pathway** to IND for **one** comparative PK (Extended release formulation)
- **Recognition** of potential value Australian Phase 2 trials for safety and **suggestions to optimise** the value of the data to support of efficacy and dose selection for Phase 3

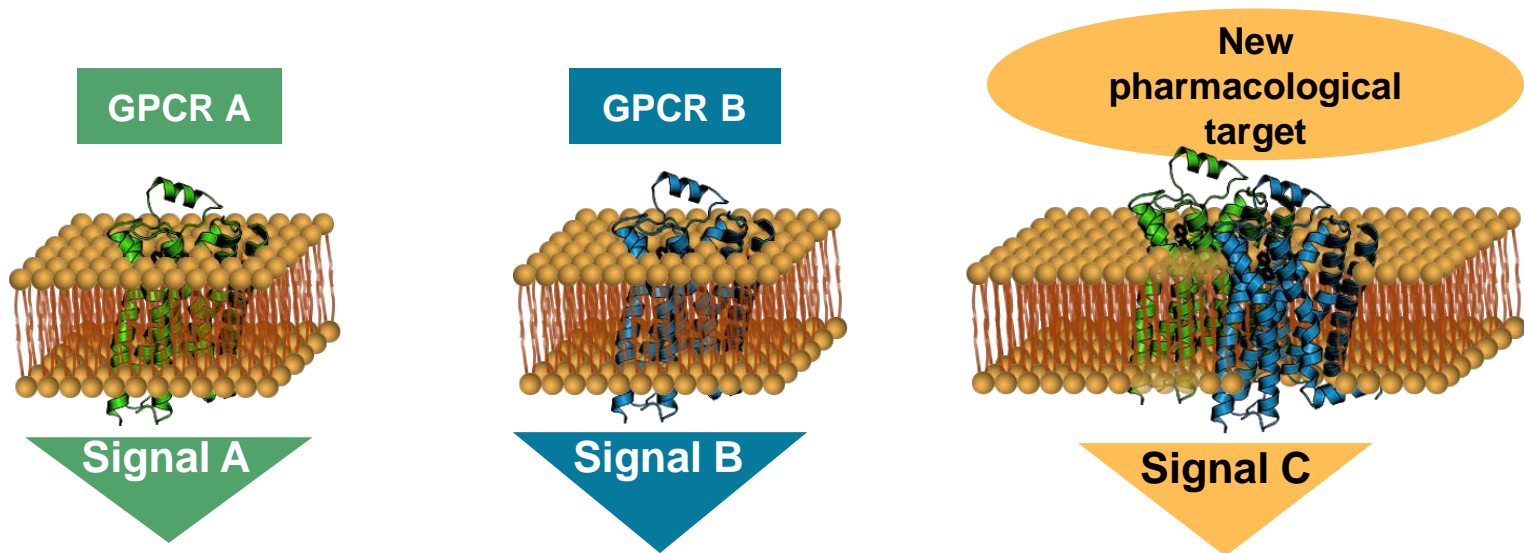
DMX-200: Phase 3 Development for FSGS – Orphan Indication

- **Agreed** development as a **adjunct** (not combination) therapy (Irbesartan treated as a co-administered drug)
- **Primary endpoint** discussions positive with special options and considerations for the rare disease discussed
 - ***“A substantial change in proteinuria in patients with marked proteinuria at baseline may be an acceptable endpoint for traditional or accelerated approval...” – and reiterated it.***
- **Potential for a single Phase 3 pivotal study**
- Advice on design considerations for achieving valid study with **low patient** numbers (<100 patients - TBC in final study design), and for **early data review**

The Dimerix drug paradigm

G Protein Coupled Receptors (GPCRs)

- ≈ 50% of all approved drugs act through GPCRs
- Act as single units (monomers) or in complexes (heterodimers)



- Dimerix owns **Receptor-HIT**: a method for identifying **GPCR heterodimers - identified as the most exciting untapped opportunity in new therapeutic development**
- Dimerix is unlocking new knowledge & opening a pipeline for new therapies

Dimerix lead program – Why kidneys?



Chronic Kidney Disease (CKD) – the big opportunity

- A global unmet medical need leading to kidney failure, cardiovascular disease and premature death.
- Currently affects an estimated 26 million people in the US
- Est. \$2.6 billion spent in the US each year, mainly on late stage therapies due to lack of early stage treatment options

The Orphan Pathway

- Enables shorter trials with fewer patients and agency cost benefits
- Registration entitles the owner to seven years of exclusivity in the US market

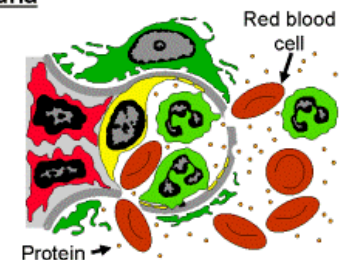
DMX-200 secured orphan drug designation for Focal Segmental Glomerulosclerosis (FSGS)

- Scarring of kidney (glomerulus)
- Leakage of blood and protein
- Serious & chronic disease leading to kidney failure
- Current therapy:
 - First line: Steroids – not suitable for long term use, serious side effects, resistance & non-response is common
 - Followed by a cocktail of off-label treatments

Proteinuria and Hematuria



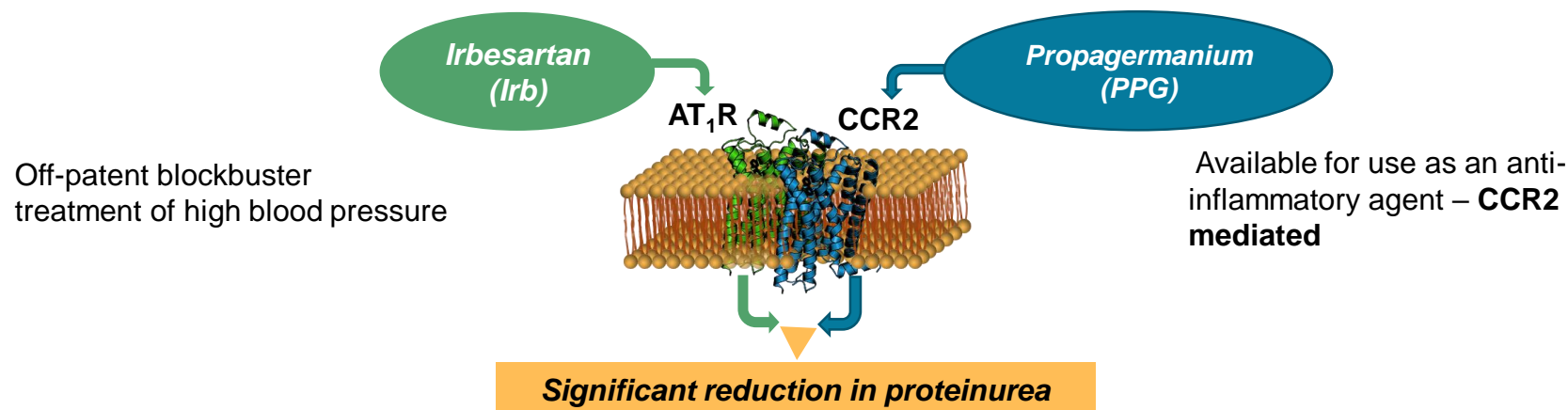
A normal capillary in a glomerulus keeps red blood cells, white blood cells and most proteins in the blood and only lets watery fluid into the urine.



A capillary in a diseased glomerulus lets protein into the urine (proteinuria) and red blood cells into the urine (hematuria).

Source: kidneyfailurewe.com

Dimerix identified DMX-200 using Receptor-HIT:



- AT1R and CCR2 both expressed in the kidney
- **Pre-clinical data show** significant reduction in proteinuria when both receptors are targeted
- **Standard of care treatment** for CKD is angiotensin receptor blockers (ARB) or ACE inhibitors (ACEi)
- **Adjunct** (NOT combination) therapy comprising *Irbesartan* + *Propagermanium*
- Current Proof of Concept Phase 2 clinical trial underway in Australia – **interim data due Q3 2016**

Market interest in CKD treatments



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- Acthar gel (injection only, steroid)
- Approved in 2011 for treating proteinuria in Nephrotic Syndrome
- Headline pricing of \$100,000 per treatment for the orphan indication
- 2013 sales: \$761 million
- **Acquired by Mallinckrodt in August 2014 for US\$5.6B**



- Phase I asset for treating kidney fibrosis
- Acquired by Shire Pharmaceuticals in 2014
- **US\$75 million upfront, US\$482.5 million in milestones**
- Shire pursuing FSGS as initial indication



- Completed Phase II for CCX140 in diabetic nephropathy – a CCR2 antagonist
- Significant improvement in proteinuria on background of standard of care (ACE Inhibitor or ARB)
- NASDAQ Listed: CCXI
- **Market Cap: ~US\$215 million**

Current Phase 2 POC – Part A

- Treatment of proteinuria in chronic kidney disease (CKD) patients taking irbesartan
- Dose escalation to find best dose of propagermanium
- Recruitment on target
- Initial safety and efficacy data to be reported Q3 2016
- Complete study mid 2017

Formulation of Extended Release Propagermanium

- Reduce from current three times per day dosing

NEXT STEPS

IND for PK

- Comparison of three time daily version with extended release version

Phase 2 POC – Part B

- Best dose(s) from Part A – using extended release formulation
- Commence 2H 2017

DMX-200 Product

- Development path to registration as an orphan drug, broader CKD licensing opportunities

Licensing Opportunity “DMX-200”

- **US patent** covers use of **any** CCR2 antagonist with **any** angiotensin receptor blocker (ARB)
- **Standard Of Care** in renal disease is ACEi or ARB

Technology

- **FDA stated recognition** of the **importance** of heterodimers in drug development

Partnering / Co-development Opportunity

- Multiple potential indications based on **multiple heterodimers** discovered using platform
- Assay technology enables novel approach to **drug repurposing**

Dimerix key value drivers

- **Ethics** approval for additional clinical sites
- **Australian patent** for lead candidate granted
- Fast-track for **US patent** under Pathway Prosecution Highway
- **First patient** in Phase 2 Part A study treated
- Patients at **new clinical sites** recruited in Phase 2
- **Orphan designation** application
- Second program animal **PoC completed**
- Phase 2 Part A **data out** (1H 2016)
- **US patent allowed**
- Research **agreements and collaborations** around the assay
- Pre-IND meeting
- **Second** program start of **Phase 2** (NASH or diabetic retinopathy)



Due Q3 2016



DMX-200 Program

- Interim analysis for DMX-200 Phase 2 dose escalation trial
- Complete extended release formulation for propagermanium
- Complete DMX-200 Phase 2 dose escalation trial
- Open IND for PK study
- Commence Phase 2 Part B

Multiple catalysts ahead

- Multiple other indications and therapies
 - Second indication NASH (non-alcoholic steatohepatitis)
 - Huge unmet medical need
 - No therapeutic intervention available
 - Estimated 6 million sufferers in the USA alone
 - Further potential indications include diabetic retinopathy, cancer fatigue and multiple sclerosis
- Research collaborations and assay licensing opportunities.

Experienced board and management



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Executive Chairman:

Dr James Williams

BSc(Hons), PhD, MBA,
GAICD

- 15 years experience starting, funding, running and exiting biotechnology companies
- Co-founder of Dimerix and iCeutica (acquired in 2011 and now with 3 FDA drug approvals)
- Co-founder and Investment Director of Yuuwa Capital (\$40M venture capital fund)

Director:

Dr Sonia Poli

MSc, PhD

- Former Senior Management at Hoffman la Roche and Executive at Addex Therapeutics (Switzerland)
- 20 years international experience in small molecule drug design, optimization and clinical development
- Expertise encompassing multiple therapeutic areas.

Director:

Dr Liz Jazwinska

PhD, MBA, GAICD

- 25 years experience in R&D management and drug portfolio business development
- Led Asia Pacific Partnering Group at Johnson and Johnson Research
- Director Industry Engagement at Institute of Medical Biology, A*STAR, Singapore

Director:

Mr David Franklyn

BEcon

- Experienced Director of ASX-listed companies in a variety of sectors
- Extensive experience in financial analysis, corporate advice, business management and IR
- Managing Director of Village National Holdings Limited

General Manager:

Ms Kathy Harrison

MSc, Cert.Gov.(Prac), FIPTA

- 20 years experience in Biotech: AMRAD, Cytobia Research Pty Ltd, Phosphagenics Limited
- Registered Patent and Trademark Attorney



Dimerix



Further Information

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