

# Corporate Factsheet



## Developing novel therapies for unmet medical needs

Dimerix Limited (ASX: DXB) is a clinical-stage drug development company discovering and developing new therapeutic treatments identified using its proprietary drug discovery platform. Our lead program, DMX-200, is currently in Phase II clinical trials for Chronic Kidney Disease (CKD). We have secured US Orphan Drug Designation for Focal Segmental Glomerulosclerosis (FSGS) for this program. Dimerix is guided by an experienced board and management with track records of delivering significant long-term shareholder value and returns.

## Receptor – HIT a proprietary and powerful drug discovery platform

Receptor Heteromer Investigation Technology (Receptor – HIT) enables in depth analysis of drug-target pharmacology. Applying this technology to G-protein coupled receptors (GPCR's), Dimerix is able to identify differences in signalling behaviour when receptors interact as heterodimers (pairs of different receptors), as expected in the body, rather than the analysis of single receptors in isolation.

Receptor – HIT enables the identification of new therapeutic uses of existing drugs and the discovery of new drugs with innovative pharmacological action. Access to this technology is an attractive proposition for pharma and other biotech companies in their internal discovery programs.

## What's so special about G-Protein Coupled Receptors?

There are a vast number of GPCRs in the human body, which provide key targets for drug therapy. Approximately 30% of all modern medicinal drugs target GPCRS, and they remain a large untapped source for new drug target opportunities. GPCRS act as single units (monomers) or higher order complexes, including heterodimers. Dimerix's Receptor-HIT technology is able to identify GPCRS that work together, referred to as heterodimers, thereby opening multiple opportunities for new therapeutic development.

Dimerix is focussed on utilising this proprietary technology to further understand the role of GPCRS and develop a pipeline of new therapeutic products.

## Clinical programs

DMX-200 is being developed as a treatment for persistent proteinuria (abnormally high levels of protein in the urine) caused by chronic kidney diseases.

## Snapshot

ASX Code	DXB	Top 10 shareholders	%
Share Price (3 Jan 17)	\$0.007	Mr Peter Meurs	21.19
52 week high/low	\$0.017 – \$0.004	Yodambao Pty Ltd	4.71
Market Cap.	\$10.5 million	Mrs Wishney Sriitharan	
Cash (30 Sep 16)	\$1.55 million	Krishnarajah	3.41
Shares on issue	1,497 million	J&L Peterson	2.87
Performance shares	75 million	White Family	2.70
Options	98.7 million	SRV Custodians Pty Ltd	2.53
		Pfleger Family	2.08
		Jampaso Pty Ltd	
		(Williams Family)	1.85
		Yodambao Investment	1.54
		JGC Super Pty Ltd	1.43

### Key Dates

Accounts Close	30 June
AGM	November
Listing Date	4 Feb 1993

Dimerix has secured orphan drug designation for DMX-200 in Focal Segmental Glomerular Sclerosis (FSGS) in the US. Discussions with the US Food & Drug Administration (FDA) indicate a willingness to consider a relatively short path to registration for this major unmet medical need. DMX-200 is being developed as an adjunct therapy of a widely used compound with a known safety profile, propagermanium, on top of the standard of care drug irbesartan. Additionally, the development path on successful completion of the current Phase II program could require only a single pivotal Phase III trial with a proteinuria based end point. Registration of a drug with Orphan Drug Status entitles the owner to seven years of exclusivity in the US market, as well as an opportunity to receive FDA grants and tax incentives associated with Orphan Drugs.

Irbesartan is an off-patent blockbuster currently used for treatment of high blood pressure. Propagermanium is available in the US as a dietary supplement, used for its anti-inflammatory properties for various ailments. Irbesartan and propagermanium act through the angiotensin II type 1 receptor and C-C chemokine receptor 2 (CCR2); GPCRS that Dimerix identified as having synergistic interactions as a heterodimer.

## Pre-clinical programs

In addition to our lead program in chronic kidney disease, Dimerix has identified multiple functional receptor interactions, which may be of clinical relevance. These so-called heterodimers have resulted in several new additional programs in our pipeline including those for the treatment of conditions such as:

- NASH
- Cancer Fatigue
- Multiple Sclerosis

## Chronic Kidney Disease

CKD is a large and complex group of conditions, characterised by a gradual loss of kidney function over time, resulting in kidney damage. It can lead to kidney failure, necessitating dialysis or kidney transplant. There are currently an estimated 26 million people in the US affected by these conditions.

## Focal Segmental Glomerulosclerosis (FSGS)

FSGS is a sub-group of kidney disease characterised by leakage of protein to the urine, caused by scarring of the kidney filters (glomeruli). It currently affects 150,000 people in the US each year. Current treatment options are limited, with first line therapy typically steroid based, followed by a cocktail of off-label treatments. Where disease progression cannot be slowed, renal failure may follow.

## Strong market interest in CKD treatments



- 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



- 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)**
- Measured urine albumin creatinine ratio (ACR) change from baseline by **16% over 'active control'** (standard of care) at best dose (geometric mean reduction at 12 weeks of 24%)
- CCX140 was partnered in December 2016 for US\$50 million up plus royalties for non-US rights
- NASDAQ Listed: CCXI, Market Cap: ~US\$215 million



- Phase II asset, sparsentan, for treating FSGS – a **dual angiotensin endothelin receptor blocker**
- Patients removed from Standard of Care treatment 2 weeks prior to dosing
- Top line positive data showing improved proteinuria **compared with** standard of care (irbesartan) at 8 weeks
- Standard of Care (irbesartan) reduced total protein urine excretion per day by 19% and sparsentan by 47.4%
- NASDAQ Listed: RTRX, Market cap: ~US\$817 million

## Dimerix is meeting its clinical development milestones

- Australian and US patents for lead candidate granted
- US Orphan drug designation granted for DMX-200 in FSGS
- Phase II Part A interim data released October 2016
- Completion of recruitment with 27 patients commenced dosing by November 2017
- Part A full readout on track (Due Q3 2017)
- Pre-IND meeting completed with positive guidance from the FDA
- Second program animal PoC produced encouraging data
- Established research agreements and collaborations associated with our Receptor-HIT assay

## Market interest in drug discovery platforms



- Phase Ib plus multiple pre-clinical leads
- GPCR discovery platform
- Acquired by Sosei Feb 2015 for US\$400
- Early Phase III and two Phase II assets



- GPCR discovery platform
- NASDAQ Listed: TRVN
- Market Cap: US\$375 million



- Phase III and Phase II assets
- GPCR discovery platform
- Acquired by Celgene Jul 2015 for US\$6 billion

## Leadership

Dimerix is guided by an experienced drug development team and a board and management with a record of hitting milestones and creating significant shareholder value.

### Board and management

**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)

**CEO: Ms Kathy Harrison** MSc, Cert.Gov.(Prac), FIPTA

- 20 years experience in Biotech: AMRAD, Cytosia Research Pty Ltd, Phosphagenics Limited
- Significant operational and drug development experience
- Registered Patent and Trademark Attorney

**Director: Dr Sonia Poli** MSc, PhD

- Former Senior Manager with Hoffman la Roche and Executive at Addex Therapeutics (Switzerland)
- 20 years international experience in small molecule drug design, optimization and clinical development in multiple therapeutic areas
- Expertise in establishing R&D/Pharma collaborations

**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

## Contact Details

### Dimerix Limited

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