



NDF RESEARCH

Providing independent research coverage of ASX-listed Life Science companies

Dimerix (ASX: DXB)

Update note – Monday 24 March 2017

Progress with DMX-200

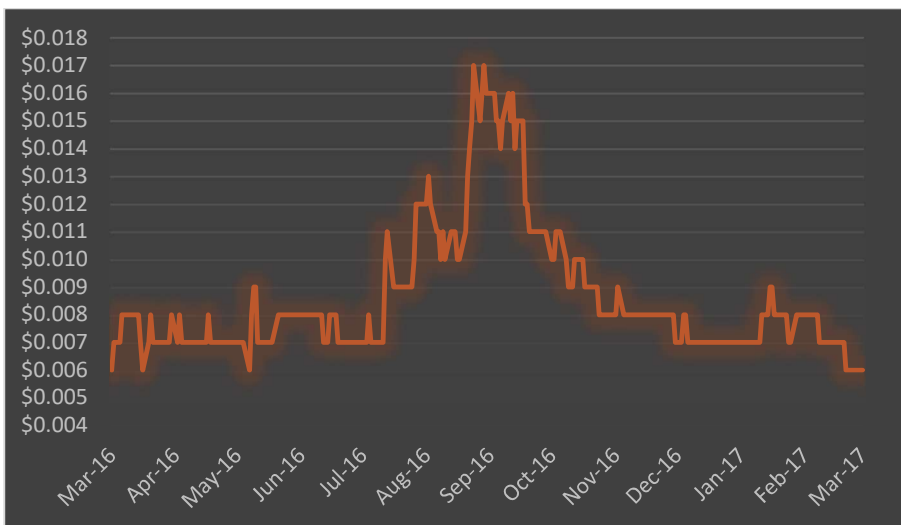
This note updates our 25 August 2016 note headlined 'Hitting the GPCR spot'. Dimerix's lead DMX-200 candidate, an adjunct therapy of propagermanium given to patients already on irbesartan, is now in a Phase 2 study in patients with proteinuria, which is symptomatic of a range of kidney problems. Irbesartan is routinely given as standard of care to patients with chronic kidney disease. Following recent guidance from the FDA, Dimerix is now making plans to take DMX-200 into a pivotal study in Focal Segmental Glomerulosclerosis, an Orphan kidney disease. Dimerix has now completed recruitment for the Phase 2 study and is expected to read out data in July 2017. Recently, a US drug developer called ChemoCentryx licensed its CCR2 antagonist drug CCX140 to Switzerland's Vifor Pharma (owned by Galenica Group) for US\$50m upfront. We think this transaction suggests upside for Dimerix given the fact that Galenica didn't take US rights where Dimerix may have IP that limits freedom to operate. Our 4-cent price target and Buy recommendation for Dimerix stays in place.

Rating
Buy

Risk
Speculative

Current price
\$0.006

Target price
\$0.04



Stock details

Daily Turnover: ~A\$28,000
Market Cap: A\$16.5m
Shares Issued: 1,496.6m
52-Week High: \$0.017
52-Week Low: \$0.005

Analyst: Stuart Roberts
stuart@ndfresearch.com
+61 447 247 909

Please note: Please refer below for risks related to Dimerix as well our General Advice Warning, disclaimer and full disclosures. Also please be aware that the investment opinion in this report is current as at the date of publication but that the circumstances of the company may change over time, which may in turn affect our investment opinion.



About NDF Research

NDF is an independent equity research firm based in Sydney, Australia. It focuses on Life Science companies that are publicly traded on the Australian Securities Exchange (ASX). This Exchange hosts one of the world's premier equity markets for biotech and medical device companies, and is home to world-beating companies such as CSL and ResMed and emerging pioneers such as Mesoblast and Impedimed.

NDF's Founder and Senior Analyst, Stuart Roberts, has been involved in Life Sciences since 2002 as a sell-side analyst as well as an executive of two ASX-listed immuno-oncology drug developers.

NDF believes that ASX-listed companies have been largely overlooked in the global Life Sciences boom that began in late 2008, partly because of insufficient quality research. NDF's goal is to provide such research, and introduce investors around the world to potential future billion dollar companies from 'Down Under'.

To learn more about the Life Sciences sector on the ASX and our firm, please visit ndfresearch.com.



Ferry at the end of a rainbow on Sydney Harbour, August 2014



In this report

Financial summary.....	4
Dimerix now has another competitor in FSGS.....	5
DMX-200 is progressing in the clinic.....	6
Who has the better drug for proteinuria?	7
Valuing Dimerix	10
Re-rating Dimerix	11
Risks related to Dimerix	12
General Advice Warning, Disclaimer & Disclosures.....	13



Financial summary

Code	DXB
Analyst	Stuart Roberts
Date	24 March, 2017
Share price	\$0.0060
Market capitalisation	\$11m
Year end	30 June

Rating	BUY
Price target	\$0.040
Upside/downside	566.7%
Valuation	\$0.021 / \$0.049
Valuation method	Probability-weighted DCF
Risk	Speculative

PROFIT AND LOSS (A\$m)

Y/e June 30 (A\$m)	FY15A	FY16A	FY17E	FY18E	FY19E
Revenue	0.0	0.6	0.1	24.1	38.9
EBITDA	-0.7	-5.3	-5.2	15.7	30.4
D&A	0.0	0.0	0.0	0.0	0.0
EBIT	-0.7	-5.3	-5.2	15.7	30.4
Net interest	0.0	0.0	0.0	0.0	0.1
Pre-tax profit	-0.7	-5.3	-5.2	15.7	30.5
Tax	0.0	0.0	0.0	-0.5	-9.2
NPAT	-0.7	-5.3	-5.2	15.2	21.4
Minority interests	0.0	0.0	0.0	0.0	0.0
Net profit after minorities	-0.7	-5.3	-5.2	15.2	21.4

BALANCE SHEET (A\$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Cash	2.9	2.0	0.3	24.3	45.5
Current receivables	0.0	0.5	0.5	1.4	1.8
Inventories	0.0	0.0	0.0	0.9	1.3
Other current assets	0.0	0.0	0.0	0.0	0.0
Current assets	3.0	2.5	0.8	26.6	48.6
PPE	0.0	0.0	0.0	0.0	0.0
Intangible assets	0.0	0.0	0.0	0.0	0.0
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	0.0	0.0	0.0	0.0	0.0
Total assets	3.0	2.5	0.8	26.6	48.6
Payables	0.2	0.3	0.1	0.7	1.0
Debt	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.0	0.0	0.0	0.0	0.0
Total liabilities	0.2	0.3	0.1	0.7	1.0
Shareholders' equity	2.8	2.2	0.6	25.8	47.6
Minorities	0.0	0.0	0.0	0.0	0.0
Total shareholders funds	2.8	2.2	0.6	25.8	47.6
Total funds employed	3.0	2.5	0.8	26.6	48.6
W/A shares on issue	205	1,360	1,600	2,929	2,929

CASH FLOW (A\$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
NPAT plus discontinued ops.	-0.7	-5.3	-5.2	15.2	21.4
Non-cash items	0.0	4.1	0.2	0.4	0.4
Working capital	0.1	-0.2	-0.1	-1.2	-0.5
Other operating cash flow	0.0	0.0	0.0	0.0	0.0
Operating cashflow	-0.5	-1.4	-5.1	14.4	21.2
Capex	0.0	0.0	0.0	0.0	0.0
Investments	-0.1	0.5	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	-0.1	0.5	0.0	0.0	0.0
Change in borrowings	0.0	0.0	0.0	0.0	0.0
Equity raised	2.4	0.0	3.3	9.6	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	0.0	0.0	0.0
Financing cashflow	2.4	0.0	3.3	9.6	0.0
Net change in cash	1.7	-0.9	-1.8	24.0	21.2
Cash at end of period	2.9	2.0	0.3	24.3	45.5

EARNINGS (A\$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Net profit (\$m)	-0.7	-5.3	-5.2	15.2	21.4
EPS (c)	-0.3	-0.4	-0.3	0.5	0.7
EPS growth (%)	N/A	N/A	N/A	N/A	40%
P/E ratio (x)	-1.8	-1.6	-1.9	1.2	0.8
CFPS (c)	-0.3	-0.1	-0.3	0.5	0.7
Price/CF (x)	-2.2	-5.9	-1.9	1.2	0.8
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-11.3	-1.7	-2.1	-0.8	-1.1
EV/EBIT	-11.3	-1.7	-2.1	-0.8	-1.1

PROFITABILITY RATIOS

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
EBITDA/revenue (%)	N/A	N/A	N/A	65.0%	78.2%
EBIT/revenue (%)	N/A	N/A	N/A	65.0%	78.2%
Return on assets (%)	-22.9%	-208.1%	-678.3%	57.3%	44.0%
Return on equity (%)	-24.5%	-234.3%	-824.4%	58.9%	44.9%
Return on funds empl'd (%)	-24.5%	-234.3%	-824.4%	58.9%	44.9%
Dividend cover (x)	N/A	N/A	N/A	0%	0%
Effective tax rate (%)	0.0%	0.0%	0.0%	3.0%	30.0%

LIQUIDITY AND LEVERAGE RATIOS

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Net debt/(cash) (\$m)	-3	-2	0	-24	-45
Net debt/equity (%)	-105.5%	-90.1%	-41.6%	-93.9%	-95.6%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	15.5	8.9	5.6	35.9	48.4

INTERIMS

Y/e June 30 (\$m)	2H15A	1H16A	2H16A	1H17F	2H17F
Revenue	0.0	0.0	0.6	0.0	0.1
EBITDA	-0.4	-4.8	-0.5	-1.1	-4.0
D&A	0.0	0.0	0.0	0.0	0.0
EBIT	-0.4	-4.8	-0.5	-1.1	-4.0
Net interest	0.0	0.0	0.0	0.0	0.0
Pre-tax profit	-0.4	-4.8	-0.5	-1.1	-4.0
Tax	0.0	0.0	0.0	0.0	0.0
NPAT	-0.4	-4.8	-0.5	-1.1	-4.0
Minority interests	0.0	0.0	0.0	0.0	0.0
Net profit after minorities	-0.4	-4.8	-0.5	-1.1	-4.0

VALUATION

	Base	Optimistic
Value of Dimerix technology	51.6	138.1
Value of tax losses	2.7	2.7
Corporate overhead	-6.8	-6.8
Cash now (A\$m)	3.0	3.0
Cash to be raised (A\$m)	10.0	10.0
Option exercises (A\$m)	1.3	1.3
Total value (A\$m)	61.8	148.3
Total diluted shares (million)	3003.7	3003.7
Value per share	\$0.021	\$0.049
Valuation midpoint	\$0.035	
Share price now (A\$ per share)	\$0.006	
Upside to midpoint	483.3%	



Dimerix now has another competitor in FSGS

Who is Dimerix? Dimerix is a Melbourne and Perth-based drug discovery company being built around new ways to identify drugs acting on G Protein-Coupled Receptors, the target of a significant number of the world's best-selling drugs. Dimerix's Receptor-Heteromer Investigation Technology (Receptor-HIT) allows druggable GPCR combinations to be identified. Dimerix's lead DMX-200 candidate, an adjunct therapy of two safe and approved drugs, irbesartan and propagermanium, is now in a Phase 2 study in patients with proteinuria, which is symptomatic of a range of kidney problems. Following recent guidance from the FDA, Dimerix is now making plans to take DMX-200 into a pivotal study in Focal Segmental Glomerulosclerosis, an Orphan kidney disease.

ChemoCentryx have validated CCR2 as a target in kidney disease. ChemoCentryx¹ is a US drug developer focused on chemokines. Their lead molecule is CCX140, a CCR2 inhibitor that has completed Phase 2 in diabetic nephropathy. In December 2014 ChemoCentryx reported a statistically significant reduction in proteinuria for patients treated on the lower of two doses of CCX140 over 52 weeks (p=0.0148) that were also on the standard-of-care of either ACE inhibitors or angiotensin receptor blockers. ChemoCentryx's investigators also noted an improvement in eGFR alongside the reduction in proteinuria². The Phase 2 data were published in August 2015³ and quantified the 52-week reduction at 18%. We believe that ChemoCentryx's work validates the approach that Dimerix is taking with the use of a CCR2 antagonist to reduce proteinuria⁴.

ChemoCentryx has licensed CCX140 to Galenica. In December 2016 ChemoCentryx announced that it had licensed CCX140 to the major Swiss healthcare company Galenica⁵, with Galenica's Vifor Pharma unit to develop CCX140 in rare kidney diseases, with an option to developing it in Chronic Kidney Disease (CKD) at a later stage. Galenica paid US\$50m upfront for this programme with other terms undisclosed. Under the agreement, Vifor Pharma's rights for CCX140 in rare renal disease is global except for two jurisdictions – the US and China, which remain with ChemoCentryx. We think the answer for this split lies in a Dimerix patent.

**CCX140 IS AN
IMPORTANT
NEW FSGS
DRUG**

ChemoCentryx is going after Focal Segmental Glomerulosclerosis. In January 2017 ChemoCentryx announced that the first of the rare kidney diseases that it intended to go after with the Vifor alliance with CCX140 was Focal Segmental Glomerulosclerosis (FSGS)⁶. This was interesting because it is the same Orphan indication that Dimerix will ultimately pursue after its current Phase 2.

Dimerix may have prior art over ChemoCentryx in kidney disease. Dimerix's intellectual property protection for DMX-200 is encompassed by a PCT patent application⁷ called WO/2012/094703 with a January 2011 priority date⁸. This application was granted in the US as Patent No. 9,314,450 in April 2016. US Patent 9,314,450 covers

¹ Mountain View, Ca., Nasdaq: CXXI, www.chemocentryx.com.

² See the company's market release dated 12 December 2014 and headlined 'ChemoCentryx announces positive results in Phase 2 diabetic nephropathy trial with CCR2 inhibitor CCX140'.

³ Lancet Diabetes Endocrinol. 2015 Sep;3(9):687-96Epub 2015 Aug 9.

⁴ There are potentially also lessons on patient selection from this study which Dimerix will likely consider, such as the use of biomarkers that indicate the best responses to a CCR2 antagonist.

⁵ Bern, Switzerland, SIX: GALN, www.galenica.com.

⁶ See the ChemoCentryx press release dated 9 January 2017 and headlined 'ChemoCentryx provides corporate update including development strategy for lead programs in rare renal diseases'.

⁷ PCT stands for the 'Patent Cooperation Treaty', under which inventors are able to file a single 'international' patent application before taking it to individual jurisdictions asking for a patent.

⁸ *Combination therapy*, priority date 11 January 2011, Invented by Kevin Pflieger, James Williams and Liddy McCall.



combinations of angiotensin 1 receptor blockers and chemokine receptor 2 inhibitors for the treatment of various diseases including those of the kidneys. The now-granted Claims 4, 8 and 13 of the patent lists a number of CCR2 inhibitors that could be used, and that list includes Dimerix's current candidate, propagermanium, but also includes ChemoCentryx's CC140⁹. This doesn't mean that ChemoCentryx necessarily infringes Dimerix's patent, but it does limit the way in which CCX140 can be used, because in kidney disease, including FSGS, most patients will be managed either with old-fashioned ACE inhibitors or with newer generation angiotensin receptor blockers¹⁰. Given that ChemoCentryx is in the clinic with FSGS and diabetic nephropathy, this could be a freedom-to-operate problem for the US company which it may have to rectify by seeking a license to WO/2012/094703.

DMX-200 is progressing in the clinic

DMX-200 is in Phase 2a in kidney disease. Dimerix is currently in a Phase 2a study of DMX-200 in patients with proteinuria. This initial dose-ranging study had initially intended to recruit up to 30 patients whose condition is being managed with irbesartan. These patients are then administered ascending doses of propagermanium¹¹ in order to show that the combination is not only safe but can reduce or bring about remission of proteinuria. The intention is to maintain the dose that achieves normalisation of proteinuria, or the maximum dose, for at least eight weeks, so each patient will be on the study for between 12 and 24 weeks¹².

- In October 2016 Dimerix announced that 3 of the 11 patients who had passed the halfway mark (ie the 90 mg propagermanium dose, as against the 240 mg top dose) in this study had seen proteinuria reduced by >50%. This was the first clinical sign of the potential ability of this treatment to improve outcomes for patients over and above the current standard of care;
- In December 2016, the company announced that it had finished recruitment into the study. This puts the company on track to complete the study and read out data in July 2017, as per our view of August 2016.

**DMX-200's
PHASE 2A HAS
COMPLETED
RECRUITMENT**

After Phase 2a comes a short pharmacokinetic study. Dimerix will need to conduct pharmacokinetic work in animals to show that its extended-release formulation of propagermanium is equivalent to the current formulations, after which it intends to file the IND, then complete formal human PK studies of the extended release formulation. We understand that Dimerix's development of extended-release propagermanium is nearing completion.

DMX-200 will likely be in Phase 2b before the end of 2017. After the PK study Dimerix can proceed to Phase 2b, in which DMX-200 is administered to another 30 patients over 84 days at the propagermanium dose established in Phase 2a. We believe that study will be able to recruit its first patient before the year is out. As with Phase 2a, the primary endpoint of the Phase 2 is safety, but Dimerix will also be looking for Complete or Partial

⁹ Also included is Takeda's MLN1202, Incyte's INCB8696, Merck & Co.'s MK-0812, Pfizer's PF-4136309 and Bristol-Myers Squibb's BMS-741672.

¹⁰ Adv Chronic Kidney Dis. 2011 Sep;18(5):332-8.

¹¹ 30mg, 60mg, 90mg, 150mg, 240mg per day with the dose ascending every four weeks.

¹² Which means that patients are going to be on therapy for between 12 weeks (if their proteinuria normalises at 30mg) and 28 weeks (if they get to the top dose of 240 mg).



Remissions of proteinuria as either a co-primary or a secondary endpoint, before moving into a pivotal study in FSGS which we think will kick off in 2019.

Who has the better drug for proteinuria?

Dimerix reckons it can cut proteinuria by at least 50% in a significant number of patients. When Dimerix tested DMX-200 in the 'gold-standard' animal model of CKD, the STNx mode, it was able to show a >60% drop in the level of proteinuria in the treated rats. This was something neither irbesartan and propagermanium on their own could achieve¹³, and important given that reductions in proteinuria of greater than 50% have long been considered clinically meaningful¹⁴. The very early clinical data which Dimerix reported back in October 2016 provided a hint that this was possible in patients. However, we will have to wait until probably the September 2017 quarter for the full data from Phase 2 to confirm this.

DMX-200'S PRE-CLINICAL DATA LOOKED GOOD

ChemoCentryx can bring down proteinuria by 18% over 52 weeks, as we noted above. The way this was tracked was by measuring the 'first morning void urinary albumin to creatinine ratio'. The first morning void referred to a urine sample taken first thing in the morning, and the albumin to creatinine ratio (ACR) from that sample was calculated by dividing albumin concentration in milligrams by creatinine concentration in grams. Creatinine is a breakdown product of creatine phosphate in muscle that is routinely excreted through the kidneys. It tends not to be impacted by kidney disease, making it a convenient denominator with which to track protein excretion, which in this case is represented by albumin. Measuring the ACR once a day (spot ACR) is good for patient convenience (ie only once a day collection) and ACR is able to correct for variations in urinary concentration due to hydration. There is also evidence that spot ACR tends to correlate well with 24 hour ACR¹⁵. The trouble with ACR is that it tends to not to work so well in showing absolute albumin excretion rates¹⁶.

Retrophin can bring down proteinuria by 45%. In September 2016 Retrophin¹⁷ was able to show, in a Phase 2 study called DUET in patients with Focal Segmental Glomerulosclerosis, that its Sparsartan drug (which is both an angiotensin receptor blocker and an endothelin receptor type A blocker), that it could cut proteinuria by 44.8%, as against only 18.5% with 300 mg/day of irbesartan¹⁸. In this study¹⁹ the change in proteinuria was measured by tracking PCR (protein to creatinine concentration) and it was tracked over 24-hours. We argue that Dimerix potentially has a superior product. In the DUET study the Sparsartan patients received their drug after a two-week washout period, meaning that the patients had gone off irbesartan first, which may have had the effect of increasing their baseline levels of proteinuria. We argue that if patients in Dimerix's current study can register a >50% reduction in proteinuria by keeping patients on irbesartan and adding propagermanium, the drug can be said to be broadly competitive with Retrophin's drug. One can also make the case that, potentially, Dimerix has a superior therapy because it does not take patients off the current standard-of-care for the management of

¹³ PLoS One. 2015 Mar 25;10(3):e0119803. eCollection 2015.

¹⁴ See, for example, Kidney Int. 2004 Jun;65(6):2309-20.

¹⁵ J Res Med Sci. 2011 May; 16(5): 634-639.

¹⁶ Am J Kidney Dis. 2002 Jun;39(6):1183-9.

¹⁷ San Diego, Ca., Nasdaq: RTRX, www.retrophin.com.

¹⁸ See the press release dated 7 September 2016 and headlined 'Retrophin announces positive top-line results from Phase 2 DUET study of Sparsentan in patients with Focal Segmental Glomerulosclerosis'.

¹⁹ See NCT01613118 at www.clinicaltrials.gov.



hypertension, which is what around four-fifths of patients with chronic kidney disease will have as a co-morbidity²⁰.

How is Dimerix measuring proteinuria? Dimerix is tracking proteinuria by the PCR method as per Retrophin's approach, with urine samples taken over 24-hour periods²¹. We think Dimerix's approach will allow the data to be credible once it becomes available from mid-2017. Going forward we expect that regulators including the FDA will be doing some work on its preferred way of tracking proteinuria given the increasing interest in new drugs for rare kidney disorders like FSGS.

Background to Dimerix (ASX: DXB)

- **What are G Protein-Coupled Receptors and why are they commonly the target of blockbuster drugs?**
A great many cellular functions are controlled by molecular signalling pathways that begin with a cell surface receptor and the associated natural binding partner of that receptor, called its 'ligand'. When these two join together, the result is a change in the shape of the interior part of the receptor, which allows it to activate another signalling molecule inside the cell. This signalling molecule in turn passes the signal to other molecules in a cascade of signalling activity until the required changes in the cell's behaviour or characteristics are effected. G Protein-Coupled Receptors, so-called because they pass the signals they receive onto intracellular 'G proteins', are amongst the most important of these cell surface receptors, because they seem to have a role in the whole of physiology. They are present in just about every organ system, and as a result have been considered as targets for a wide range of disease areas including heart disease, cancer, diabetes, inflammation and CNS disorders. This ubiquity explains why the Royal Swedish Academy of Sciences, in awarding the 2012 Nobel Prize for Chemistry to the American scientists Robert Lefkowitz and Brian Kobilka for their work on GPCRs, commented that *'about half of all medications achieve their effect through G protein-coupled receptors'*²².
- **How is Dimerix a player in the G Protein-Coupled Receptor space?** Dimerix is being built on a platform called Receptor-Heteromer Investigation Technology (Receptor-HIT) that allows druggable 'dimers' of GPCRs, known as GPCR heteromers, to be identified. Until recently the pharma industry had more or less been interested in drugging only individual GPCRs. However, it is now becoming apparent that many different GPCRs complex together, with these heteromers having a different functionality to the constituent GPCRs. This opens up the potential for many new GPCR targets, and may also explain some unexpected effects of drugs thought to act on a single receptor. Since Dimerix's platform is cell-based and real-time, it arguably has the most world's most efficient way of identifying GPCR heteromers, and is therefore a corporate 'thought leader' in this new field. Importantly, Dimerix owns granted patents in major jurisdictions protecting this assay.
- **What new drugs has Dimerix discovered with its Receptor-HIT platform?** Dimerix's lead candidate, DMX-200, is the former blockbuster blood pressure drug irbesartan plus a less-well-known anti-

**ABOUT HALF OF
ALL
MEDICATIONS
ACHIEVE THEIR
EFFECT
THROUGH G
PROTEIN-
COUPLED
RECEPTORS**

²⁰ Semin Nephrol. 2005 Nov;25(6):435-9.

²¹ ANZCTR trial ID ACTRN12614001132639.

²² Source: Royal Swedish Academy of Sciences press release dated 10 October 2012.



inflammatory drug called propagermanium that is approved in Japan for the treatment of Hepatitis B infection. DMX-200 originated from the discovery by Dimerix's scientists that a GPCR called AT₁R, which is targeted by irbesartan, forms a GPCR heteromer with CCR₂, which is the target of propagermanium, and that this GPCR heteromer is highly relevant in kidney disease. To test its hypothesis that DMX-200 can treat kidney disease, Dimerix has taken the product into a Phase 2 study in patients with proteinuria, that is, excessive protein in the urine, which is symptomatic of a range of kidney problems. Dimerix's *in vivo* data suggests that DMX-200 can lower proteinuria by at least 50%, a clinically meaningful outcome in kidney disorders such as nephrotic syndrome, which is characterised by damage to the glomeruli that provide part of the kidney's blood filtering function. Patients with nephrotic syndrome and Chronic Kidney Disease are already routinely treated with irbesartan. Dimerix is developing an extended-release formulation of propagermanium that will be additive to irbesartan. Dimerix's Phase 2 study in proteinuria patients is currently in the dose finding stage, with a second stage expected to be run at the optimal dose. After this, following on from guidance obtained from the FDA in June 2016, the company intends to run a single pivotal study in Focal Segmental Glomerulosclerosis (FSGS) a rare nephrotic syndrome disorder for which Dimerix has obtained Orphan Drug Status from the FDA. Dimerix's original irbesartan-plus-propagermanium product has patent protection until 2032 with further patent life available once the extended-release formulation of propagermanium is completed.

- **What is the upside for Dimerix with DMX-200?** With DMX-200 there is potential for Dimerix to quickly become a Phase 3 drug developer by 2019. The actual drug could be game-changing in kidney disease given the lack of new drugs in this space and the fact that ~12% of the US adult population has some sort of Chronic Kidney Disease. Consequently, there is potential for DMX-200 to branch out from FSGS to other larger-market indications.
- **What is the upside for Dimerix with its Receptor-HIT platform?** Other than DMX-200 we see two main upsides from the platform. Dimerix is currently working on a pipeline of GPCR heteromer-targeting candidates for nonalcoholic steatohepatitis (NASH), diabetic retinopathy, cancer fatigue and multiple sclerosis. In addition to this, it's not unreasonable to expect Big Pharma to be interested in the platform for its own GPCR drug discovery efforts, particular after two GPCR platform companies, Receptos and Heptares, were acquired in 2015. Two 'Top 10' pharma companies, along with Takeda²³, Japan's largest pharmaceutical company, have in the past used Receptor-HIT in paid collaborations with Dimerix scientists.

**TWO TOP-TEN
PHARMA
COMPANIES
HAVE IN THE
PAST USED
DIMERIX'S
PLATFORM**

²³ Osaka, Japan, TSE: 4502, www.takeda.com. Takeda was the world's 18th largest pharma company in 2015 (source Pharmaceutical Executive magazine).



Valuing Dimerix

We previously valued Dimerix at \$0.024 per share base case and \$0.59 per share optimistic case using a probability-weighted DCF approach. With this note we are reducing our valuation slightly, to \$0.021 per share base case and \$0.049 per share optimistic case, but only due to a change in our discount rate because the Australian ten-year bond rate has risen slightly since August 2016, and the recent A\$2m raising at 0.6 cents per share in February 2017. Our approach was as follows:

- Our WACC was 15.4% (Speculative)²⁴.
- We conservatively modelled a payoff only for DMX-200 and allowed no value for the Dimerix pipeline. We believe *in vivo* data from the pipeline will allow us to gradually add value from this platform.
- We assume another US\$5-10m in expenditure for Dimerix to mature the DMX-200 programme.
- We model around 14 years of commercial exclusivity for DMX-200.

Risk weighting

- We modelled DMX-200 with a 50% probability of clinical success. This may seem high given the product is still only at Phase 2, however the *in vivo* evidence of efficacy in lowering proteinuria, and the importance of this endpoint to disease outcomes in FSGS, as well as the ease with which DMX-200 can enter Phase 3 in FSGS, suggested a more favourable risk weighting for this product.

Commercial outcomes

- We assume that the product can license to a pharma partner in FY19 (base case) or FY18 (optimistic case) for US\$30-50m upfront, US\$100-200m in milestones and an 8-12% royalty.
- We assume a product launch in FSGS in FY22 (base case) or FY21 (optimistic case) in the US and FY23 (base case) or FY22 (optimistic case) in Europe.
- We assume peak sales for DMX-200 of US\$300-600m, initially in FSGS and then branching out into other kidney disorders.

Further capital

- An admirable feature of Dimerix since listing has been the low burn rate, averaging only ~A\$165,000 per months for the last twelve months. The company raised A\$2m at 0.6 cents per share in February 2017. However we believe it will be necessary for Dimerix to raise further capital. For modelling purposes, we assume that the company raises another \$10m at \$0.01 per share in order to complete both halves of the current Phase 2 for DMX-200 as well as move other pipeline elements forward.

**WE MODEL
DMX-200's
CHANCES OF
SUCCESS AT
50%**

²⁴ For a relevant discount rate, we use WACCs of between ~11% and ~15% depending on the risk for Life Science companies. This is derived from a RFR of 2.8%; a MRP of 7.5%-11.5% (7.5% for 'medium risk' companies, 9.5% for 'high risk' companies and 11.5% for 'speculative' companies like Dimerix); and an ungeared beta of 1.1. We regard Life Science companies with existing businesses, or who have enough capital to reach the market with their products, as 'Medium' risk. Companies that have small revenue streams from marketed products but that are still potentially in need of capital are 'High' risk. Everything else is 'Speculative'.



Re-rating Dimerix

We see a number of events helping to re-rate Dimerix to our target price over the next 12-18 months:

- Completion of the extended-release formulation of propagermanium;
- Data from the Phase 2a study;
- Research agreements and collaborations related to the Receptor-HIT platform;
- Pre-clinical data from DMX-250 in NASH;
- Data from the other pre-clinical programmes from Receptor-HIT;
- Filing of the IND for DMX-200;
- Ethics approval and initial patient recruitment for the first Part B sites.

**DATA FROM
DMS-200's
PHASE 2
STUDY WILL
BE AVAILABLE
IN MID-2017**



Risks related to Dimerix

Risks specific to Dimerix. We see five major risks for Dimerix as a company and as a listed stock.

- **Timing risk.** There is the risk that Dimerix may take longer to complete the first part of the clinical work for DMX-200 than the time we have postulated in our research;
- **Clinical risk.** There is the risk that the current Phase 2 or the forthcoming pivotal study for DMX-200 may miss its primary or secondary endpoints.
- **Regulatory risk.** There is the risk that the FDA and other regulators may decline to approve DMX-200 even if Dimerix consider the data submitted to be adequate.
- **Formulation risk.** There is the risk that propagermanium may not be adaptable in to an extended release formulation.
- **Commercial risk.** There is the risk that DMX-200 may be displaced by other more advance therapies in kidney disease, particularly those related to regenerative medicine.

Risks related to pre-revenue Life Science companies in general.

- The stocks of biotechnology and medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character.
- Since most biotechnology and medical device companies listed on the Australian Securities Exchange fit this description, the 'term' speculative can reasonably be applied to the entire sector.
- The fact that the intellectual property base of most biotechnology and medical device lies in science not generally regarded as accessible to the layman adds further to the riskiness with which the sector ought to be regarded.

Caveat emptor. Investors are advised to be cognisant of the abovementioned specific and general risks before buying any the stock of any biotechnology and medical device stock mentioned on this report, including Dimerix.



General Advice Warning, Disclaimer & Disclosures

The information contained herein ("Content") has been prepared and issued by NDF Research the business name of Stuart Dean Roberts, ABN 11 209 563 517 ("NDF Research"), an Authorised Representative (no: 1245466) of Belmont Securities ABN 47 119 852 890 AFSL 331625. All intellectual property relating to the Content vests with NDF Research unless otherwise noted.

Disclaimer

The Content is provided on an as is basis, without warranty (express or implied). Whilst the Content has been prepared with all reasonable care from sources we believe to be reliable, no responsibility or liability shall be accepted by NDF Research for any errors or omissions or misstatements howsoever caused. Any opinions, forecasts or recommendations reflect our judgment and assumptions at the date of publication and may change without notice. NDF Research will not accept any responsibility for updating any advice, views, opinions or recommendations contained in this document.

No guarantees or warranties regarding accuracy, completeness or fitness for purpose are provided by NDF Research, and under no circumstances will any of NDF Research, its officers, representatives, associates or agents be liable for any loss or damage, whether direct, incidental or consequential, caused by reliance on or use of the Content.

General advice warning

The Content has been prepared for general information purposes only and is not (and cannot be construed or relied upon as) personal advice nor as an offer to buy/sell/subscribe to any of the financial products mentioned herein. No investment objectives, financial circumstances or needs of any individual have been taken into consideration in the preparation of the Content.

Financial products are complex, entail risk of loss, may rise and fall, and are impacted by a range of market and economic factors, and you should always obtain professional advice to ensure trading or investing in such products is suitable for your circumstances, and ensure you obtain, read and understand any applicable offer document.

Disclosures

NDF Research has been commissioned to prepare the Content. From time to time, NDF Research's representatives or associates may hold interests, transact or hold directorships in, or perform paid services for, companies mentioned herein. NDF Research and its associates, officers, directors and employees, may, from time



to time hold securities in the companies referred to herein and may trade in those securities as principal, and in a manner which may be contrary to recommendations mentioned in this document.

NDF Research may receive fees from a company referred to in this document, for research services and other financial services or advice we may provide to that company. The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation.

Where NDF Research has been commissioned to prepare Content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid will either directly or indirectly impact the Content provided.

Recommendations

NDF Research issues a BUY recommendation in case of an expected total shareholder return (TSR, share price appreciation plus dividend yield) in excess of 25% within the next twelve months, an ACCUMULATE recommendation in case of an expected TSR between 5% and 25%, a HOLD recommendation in case of an expected TSR between -5% and +5% within the next twelve months and a SELL recommendation in case of an expected total return lower than -5% within the next twelve months.