NDF RESEARCH

Providing independent research coverage of
ASX-listed Life Science companies

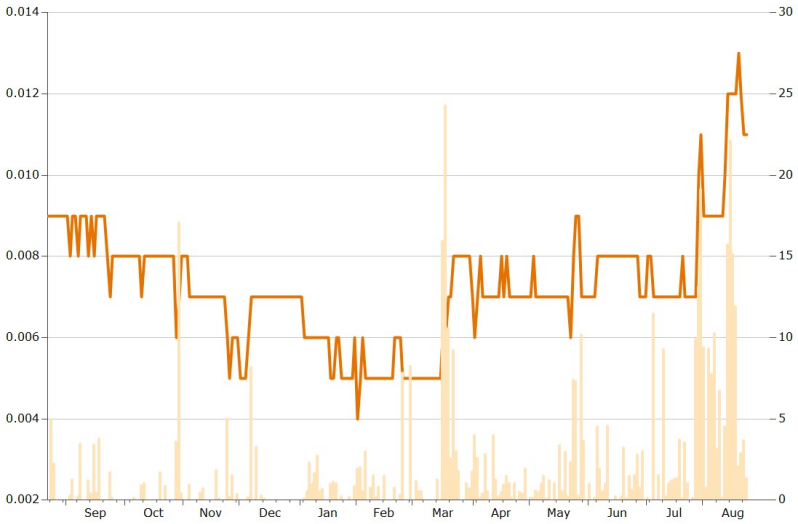
Dimerix (ASX: DXB)

Update note – Tuesday 18 October 2016

Favourable interim data with DMX-200

This note updates our 25 August 2016 note headlined 'Hitting the GPCR spot'. Dimerix's lead DMX-200 candidate, a combination of two existing drugs, irbesartan and propagermanium, is now in a Phase II study in patients with proteinuria, which is symptomatic of a range of kidney problems. Following recent guidance for the FDA, Dimerix is now making plans to take DMX-200 into a pivotal study in Focal Segmental Glomerulosclerosis, an Orphan kidney disease. Dimerix reported on 4 October that 21 out of 30 patients have now been dosed in this study. Of 11 patients who have reached or passed the mid-point of the study, three have shown a ~ 50% reduction or greater in proteinuria over and above standard of care, which is very encouraging. Final data from Part A of the Phase 2 study is expected in the second half of next year. We value Dimerix at 2.4 cents per share base case and 5.8 cents per share optimistic case. Our target price of 4.0 cents per share sits at the midpoint of our DCF range.

Rating	Risk	Current price	Target price
Buy	Speculative	$0.011	$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

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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.

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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

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Financial summary

Code	DXB
Analyst	Stuart Roberts
Date	17 October, 2016
Share price	$0.0110
Market capitalisation	$16m
Year end	30 June

Rating	BUY
Price target	$0.040
Upside/downside	263.6%
Valuation	$0.024 / $0.058
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	0.3	24.6	39.9
EBITDA	**-0.7**	**-5.3**	**-8.1**	**16.1**	**31.4**
D&A	0.0	0.0	-0.1	-0.3	-0.5
EBIT	**-0.7**	**-5.3**	**-8.1**	**15.8**	**30.9**
Net interest	0.0	0.0	0.0	0.0	0.1
Pre-tax profit	**-0.7**	**-5.3**	**-8.1**	**15.8**	**31.0**
Tax	0.0	0.0	0.0	0.0	-8.9
NPAT	-0.7	-5.3	-8.1	15.8	22.1
Minority interests	0.0	0.0	0.0	0.0	0.0
Net profit after minorities	-0.7	-5.3	-8.1	15.8	22.1

BALANCE SHEET (A$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Cash	2.9	2.0	4.1	18.5	40.4
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**	**4.6**	**20.9**	**43.6**
PPE	0.0	0.0	0.9	1.5	1.5
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	0.9	1.5	1.5
Total assets	3.0	2.5	5.5	22.4	45.1
Payables	0.2	0.3	0.3	0.9	1.2
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	0.3	0.9	1.2
Shareholders' equity	2.8	2.2	5.2	21.5	43.9
Minorities	0.0	0.0	0.0	0.0	0.0
Total shareholders funds	**2.8**	**2.2**	**5.2**	**21.5**	**43.9**
Total funds employed	**3.0**	**2.5**	**5.5**	**22.4**	**45.1**
W/A shares on issue	205	1,360	2,455	2,534	2,534

CASH FLOW (A$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
NPAT plus discontinued ops.	-0.7	-5.3	-8.1	15.8	22.1
Non-cash items	0.0	4.1	0.4	0.7	0.9
Working capital	0.1	-0.2	0.0	-1.2	-0.6
Other operating cash flow	0.0	0.0	0.0	0.0	0.0
Operating cashflow	**-0.5**	**-1.4**	**-7.7**	**15.3**	**22.4**
Capex	0.0	0.0	-1.0	-1.0	-0.5
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**	**-1.0**	**-1.0**	**-0.5**
Change in borrowings	0.0	0.0	0.0	0.0	0.0
Equity raised	2.4	0.0	10.7	0.1	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**	**10.7**	**0.1**	**0.0**
Net change in cash	**1.7**	**-0.9**	**2.0**	**14.4**	**21.9**
Cash at end of period	2.9	2.0	4.1	18.5	40.4

EARNINGS (A$m)

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Net profit ($m)	-0.7	-5.3	-8.1	15.8	22.1
EPS (c)	-0.3	-0.4	-0.3	0.6	0.9
EPS growth (%)	N/A	N/A	N/A	N/A	40%
P/E ratio (x)	-3.3	-2.8	-3.3	1.8	1.3
CFPS (c)	-0.3	-0.1	-0.3	0.6	0.9
Price/CF (x)	-4.1	-10.8	-3.5	1.8	1.2
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	-19.0	-2.7	-1.5	-0.1	-0.8
EV/EBIT	-19.0	-2.7	-1.5	-0.1	-0.8

PROFITABILITY RATIOS

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
EBITDA/revenue (%)	N/A	N/A	N/A	65.6%	78.7%
EBIT/revenue (%)	N/A	N/A	N/A	64.2%	77.3%
Return on assets (%)	-22.9%	-208.1%	-148.6%	70.7%	48.9%
Return on equity (%)	-24.5%	-234.3%	-156.7%	73.6%	50.3%
Return on funds empl'd (%)	-24.5%	-234.3%	-156.7%	73.6%	50.3%
Dividend cover (x)	N/A	N/A	N/A	0%	0%
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	28.8%

LIQUIDITY AND LEVERAGE RATIOS

Y/e June 30	FY15A	FY16A	FY17E	FY18E	FY19E
Net debt/(cash) ($m)	-3	-2	-4	-19	-40
Net debt/equity (%)	-105.5%	-90.1%	-78.4%	-86.1%	-92.0%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	15.5	8.9	16.1	23.2	37.1

INTERIMS

Y/e June 30 ($m)	2H15A	1H16A	2H16A	1H17F	2H17F
Revenue	0.0	0.0	0.6	0.1	0.2
EBITDA	**-0.4**	**-4.8**	**-0.5**	**-4.0**	**-4.0**
D&A	**0.0**	**0.0**	**0.0**	**0.0**	**-0.1**
EBIT	**-0.4**	**-4.8**	**-0.5**	**-4.0**	**-4.1**
Net interest	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Pre-tax profit	-0.4	-4.8	-0.5	-4.0	-4.1
Tax	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
NPAT	-0.4	-4.8	-0.5	-4.0	-4.1
Minority interests	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Net profit after minorities	-0.4	-4.8	-0.5	-4.0	-4.1

VALUATION

	Base	Optimistic
Value of Dimerix technology	53.5	143.2
Value of tax losses	2.7	2.7
Corporate overhead	-7.1	-7.1
Cash now (A$m)	2.0	2.0
Cash to be raised (A$m)	10.0	10.0
Option exercises (A$m)	1.3	1.3
Total value (A$m)	62.4	152.1
Total diluted shares (million)	2631.9	2631.9
Value per share	$0.024	$0.058
Valuation midpoint	$0.041	
Share price now (A$ per share)	$0.011	
Upside to midpoint	272.7%	

Update on Dimerix - Favourable interim data with DMX-200

Who is Dimerix? Dimerix is a Melbourne and Perth-based drug discovery company being built around new ways to identify 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, a combination of two safe and approved drugs, irbesartan and propagermanium, is now in a Phase II study in patients with proteinuria, which is symptomatic of a range of kidney problems. Following recent guidance for the FDA, Dimerix is now making plans to take DMX-200 into a pivotal study in Focal Segmental Glomerulosclerosis, an Orphan kidney disease.

What has happened? Dimerix announced on 4 October 2016 that its Phase II study of DMX-200 in patients with proteinuria had generated favourable interim data. This initial dose-ranging study, initially intended for up to 30 patients, has been treating irbesartan-managed patients with ascending doses of propagermanium[1] 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 weeks[2]. Dimerix announced on 4 October that it had now dosed 21 patients in this study (as against only 10 in June 2016), and that 11 patients had passed the halfway mark. The company was able to report:

- DMX-200 has good safety and tolerability;
- 3 of the 11 patients who had passed the halfway mark (ie the 90 mg dose) had seen proteinuria reduced by >50%. This is the first clinical sign of the potential ability of this treatment to improve outcomes for patients over and above the current standard of care;
- Only one patient had ceased treatment. In order to emphasise that this outcome may not have been related to DMX-200 therapy, Dimerix told the market that 'an 87-year-old participant has ceased the study due to the emergence of anaemia secondary to a gastrointestinal bleed, thought to be associated with a pre-existing polyp whilst on the blood thinning drug, warfarin'.
- Recent recruitment to the trial has 'been excellent and exceeded expectations', which suggests physician confidence in the therapy based on the early experience of patients.

RECRUITMENT TO THE DMX-200 STUDY HAS BEEN EXCELLENT AND EXCEEDED EXPECTATIONS

Our analysis. We think this encouraging data provides strong, albeit early validation of Dimerix's approach of treatment kidney disease via a drug that hits the AT1R/CCR2 GPCR heteromer.

- The patients in this study were already well-managed, as evidenced by the fact that they are on an average of nine medications other than propagermanium. To be able to show that some patients could have their proteinuria cut in half is therefore a strong achievement.

[1] 30mg, 60mg, 90mg, 150mg, 240mg per day with the dose ascending every four weeks.
[2] 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).

- Irbesartan is already known to have powerful effects on proteinuria. Dimerix has suggested that 'Irbesartan has been shown in large-scale clinical trials to reduce proteinuria on average by approximately 25% from baseline in patients with chronic kidney disease'. Probably the best evidence of its effect on proteinuria which we have seen in the literature is the 33% reduction in proteinuria with 300 mg/day of irbesartan in the 1,715-patient study completed in 2001 which gained the drug its diabetic nephropathy indication[3].
- In a recent Phase II study in patients with Focal Segmental Glomerulosclerosis, Retrophin[4] was able to show, with 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 irbesartan. In this 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 further patients in Dimerix's current study can register a >50% reduction in proteinuria by keeping patients on irbesartan and adding propagernaium, 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 hypertension, which is what around four-fifths of patients with chronic kidney disease will have as a co-morbidity[5].

What happens now? Dimerix will proceed to wind up recruitment into the dose ranging study, and move to commence the Phase IIb of the study in patients with Chronic Kidney Disease. We believe the company will be in a position to report further interim data on the dose-ranging study in the current quarter, followed by full data in mid-2017. In the meantime, the company's main focus will be preparation for the Phase IIb. 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 for DMX-200, then complete formal human PK studies of the extended release formulation. The Phase IIb 'expansion study', expected to begin in the second half of 2017. With this study the average successful dose from Part A will be administered to another 30 patients over 84 days. The primary endpoint of the Phase II is safety, but Dimerix will also be looking for Complete or Partial Remissions of proteinuria as either a co-primary or a secondary endpoint.

Our recommendation remains unchanged. We maintain our previous Buy recommendation on the stock with a target price of 4 cents per share.

[3] As against only 10% with placebo - see N Engl J Med. 2001 Sep 20;345(12):851-60.
[4] San Diego, Ca., Nasdaq: RTRX, www.retrophin.com.
[5] Semin Nephrol. 2005 Nov;25(6):435-9.

Background to Dimerix 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*'[6].

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

- **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-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 II 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

[6] Source: Royal Swedish Academy of Sciences press release dated 10 October 2012.

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 II 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 III 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 Takeda[7], 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

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

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 II 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.

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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.