TAYLOR COLLISON

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Dimerix (DXB)

Outperform

Two Phase II studies reporting Q220 create strong upside

Speculative Investment

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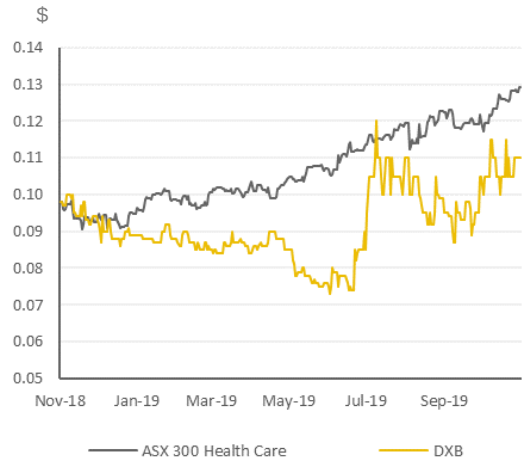
Summary (AUD)

Market capitalisation ($M)	$17.5
Share price	$0.11
52 week high	$0.13
52 week low	$0.07
Ordinary shares (M)	158.8
Fully diluted ordinary shares (M)	170.4
Ave daily vol (3 months, M)	0.2

Year end June	FY19 Act.	FY20 Est.	FY21 Est.
Revenue	**1.4**	**1.1**	**1.5**
R&D	**(2.8)**	**(2.8)**	**(6.7)**
SG&A	**(1.5)**	**(1.4)**	**(1.6)**
EBITDA	(2.9)	(3.1)	(6.8)
Reported NPAT	(2.9)	(3.0)	(6.8)
NPAT Adj.	**(2.9)**	**(3.0)**	**(6.8)**
EV/Sales	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a
PE ratio (x)	**n/a**	**n/a**	**n/a**
ROE	**n/a**	**n/a**	**n/a**

Share Price



Dimerix is in the fortunate position of having two Phase II studies of lead drug DMX-200 fully recruited and due to report results Q2 CY20. The first study is targeting the rare chronic kidney disease FSGS and the second is in diabetic kidney disease, a large patient population with a clear un-met need for more effective therapies. The company also has a patented drug discovery platform and a pipeline of potential new drug candidates. We initiate coverage with an **Outperform** recommendation and a valuation of $81m or $0.34/share (fully diluted). We suspect the market has ignored the potential value of DMX-200 due to what we view as unfounded concerns about the key ingredient in DMX-200 being sold as a dietary supplement. We do not believe dietary supplements will stop DMX-200 from generating multi-billion-dollar peak sales, if approved.

DMX-200 is the company's formulation of the compound known as propagermanium. Using its proprietary Receptor-HIT assay, Dimerix discovered that combining DMX-200, which blocks chemokine receptor 2 (CCR2), with the angiotensin receptor blocker irbesartan more effectively blocked activation of the CCR2 receptor and showed that the combination reduced the loss of key podocyte cells in a rat model of FSGS; it has patented the combined use of the two classes of drugs. In an exploratory Phase IIa study, five of the 10 patients with diabetic kidney disease achieved a 50% reduction in protein in the urine and were classified as responders to treatment, which prompted the initiation of a Phase IIb study in this indication.

Propagermanium was approved in Japan in the 1990s for treating hepatitis B, but has not been approved elsewhere and is classified as a New Chemical Entity (NCE). On first approval, all NCEs are granted five years of marketing and data exclusivity; approval for an orphan indication brings seven and 10 years of exclusivity in the US and EU respectively. The data exclusivity means that it would be illegal for an insurer in the US to reimburse an alternative formulation of propagermanium for the approved indication. We do not expect the potential availability of dietary supplements containing germanium compounds to have any effect on pricing and reimbursement negotiations with payers in the US.

The FDA has banned the import of germanium compounds and has stated that 'Supplements containing [propagermanium]… cannot be sold legally' in the US due to safety concerns. We think it unlikely that a doctor in the US would recommend that a patient take a dietary supplement containing propagermanium, in preference to an FDA approved product with established safety and efficacy.

We value Dimerix at $81m or $0.34/sh diluted for options and a potential $35m raise at $0.20/sh for a pivotal FSGS study, if trial results are positive. Our undiluted valuation is $0.51/sh. Our valuation is based on a risk-adjusted NPV of DMX-200 for FSGS and diabetic kidney disease. Pro-forma cash at 30 September was A$3.2m, which will fund operations until Phase II trial results report in Q220. We expect positive trial results would enable it to raise funds at a premium to the current share price. However, we note raising A$35m at 10c would dilute our valuation to $0.22/sh. Alternatively, Dimerix may seek a partner to fund future trials of DMX-200.

Dimerix - Summary of Forecasts DXB $ 0.11

PROFIT & LOSS SUMMARY (A$m)

Period	2018A	2019A	2020F	2021F
Sales, royalties, milestones	0.0	0.0	0.0	0.0
Other (includes R&D tax rebate)	0.8	1.4	1.1	1.5
Total Revenue	**0.8**	**1.4**	**1.1**	**1.5**
Growth (pcp)	-	*73%*	*-22%*	*32%*
R&D Expenses	(2.4)	(2.8)	(2.8)	(6.7)
SG&A expenses	(1.7)	(1.5)	(1.4)	(1.6)
EBITDA	**(3.3)**	**(2.9)**	**(3.1)**	**(6.8)**
Dep'n/Other Amort'n	(0.0)	(0.0)	(0.0)	(0.0)
EBIT	**(3.3)**	**(2.9)**	**(3.1)**	**(6.8)**
Net Interest	0.0	0.0	0.0	0.0
Pre-Tax Profit	**(3.3)**	**(2.9)**	**(3.0)**	**(6.8)**
Tax Expense	0.0	0.0	0.0	0.0
Minorities	0.0	0.0	0.0	0.0
NPAT	**(3.3)**	**(2.9)**	**(3.0)**	**(6.8)**
Growth (pcp)	-	-	-	-
Adjustments	0.0	0.0	0.0	0.0
NPAT Reported	(3.3)	(2.9)	(3.0)	(6.8)

PER SHARE DATA*

Period	2018A	2019A	2020F	2021F
EPS (c) - Reported	**(2.9)**	**(1.8)**	**(1.9)**	**(2.8)**
Growth (pcp)	-	*-37%*	*5%*	*44%*
EPS (c) - Adjusted	**(2.9)**	**(1.8)**	**(1.9)**	**(2.8)**
Growth (pcp)	-	*-37%*	*5%*	*44%*
Gross CF per share (c)	(2.8)	(1.7)	(2.0)	(2.8)
NTA per share (c)	4.4	2.6	0.9	9.0
Dividend (c)	0.0	0.0	0.0	0.0
Franking	0%	0%	0%	0%

KEY RATIOS

Period	2018A	2019A	2020F	2021F
Current ratio (x)	17.9	6.7	79.6	1,628.5
Net Debt : Equity (%)	-91.6%	-84.8%	-27.4%	-95.2%
Net Debt: EBITDA (x)	1.9	1.2	0.1	4.2
ROE (%)	-96.8%	-52.2%	n/a	n/a
ROIC (%)	n/a	n/a	n/a	n/a
Dividend Payout Ratio (%)	n/a	n/a	n/a	n/a

VALUATION MULTIPLES

Period	2018A	2019A	2020F	2021F
Reported PE Ratio (x)	**n/a**	**n/a**	**n/a**	**n/a**
Adjusted PE Ratio (x)	**n/a**	**n/a**	**n/a**	**n/a**
Dividend Yield (%)	0.0%	0.0%	0.0%	0.0%
EV/Sales (x)	n/a	n/a	n/a	n/a
EV/EBITDA (x)	n/a	n/a	n/a	n/a
EV/EBIT (x)	n/a	n/a	n/a	n/a

CAPITAL RAISING ASSUMPTIONS

Period	2018A	2019A	2020F	2021F
Shares Issued (m)	**62.9**	**0.0**	**0.0**	**175.0**
Issue Price (A$)	0.12	0.00	0.00	0.20
Cash Raised (A$m)	7.2	0.0	0.0	35.0

BALANCE SHEET SUMMARY

Period	2018A	2019A	2020F	2021F
Cash + Cash Equivalents	6.3	3.6	0.4	28.5
Receivables	1.0	1.4	1.1	1.4
Inventories	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Total Current Assets	7.3	4.9	1.5	29.9
Inventories	0.0	0.0	0.0	0.0
PP&E	0.0	0.0	0.0	0.0
Intangibles	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Total Non-Current Assets	0.0	0.0	0.0	0.0
TOTAL ASSETS	**7.3**	**4.9**	**1.5**	**30.0**
Accounts Payable	0.4	0.7	0.0	0.0
Borrowings	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Total Current Liabilities	0.4	0.7	0.0	0.0
Borrowings	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Total Non-Current Liabilities	0.0	0.0	0.0	0.0
TOTAL LIABILITIES	**0.4**	**0.7**	**0.0**	**0.0**
TOTAL EQUITY	**6.9**	**4.2**	**1.5**	**29.9**

CASH FLOW SUMMARY

Period	2018A	2019A	2020F	2021F
EBIT (excl Abs/Extr)	**(3.3)**	**(2.9)**	**(3.1)**	**(6.8)**
Add: Dep'n & Amort'n	0.0	0.0	0.0	0.0
Other non-cash items	0.8	0.2	(0.3)	0.4
Less: Tax paid	0.0	0.0	0.0	0.0
Net Interest	0.0	0.0	0.0	0.0
Change in Rec.	(1.0)	(0.4)	0.3	(0.4)
Change in Inv.	0.0	0.0	0.0	0.0
Gross Cashflows	(3.2)	(2.8)	(3.2)	(6.9)
Capex	(0.0)	(0.0)	(0.0)	(0.0)
Free Cashflows	(3.2)	(2.8)	(3.2)	(6.9)
Share Issue Proceeds	7.2	0.0	0.0	35.0
Other	0.0	0.0	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0
Net Cash Flow	**4.0**	**(2.7)**	**(3.2)**	**28.1**
FX Effect on Cash	0.0	0.0	0.0	0.0

DXB valuation summary

	Probability (%)	Valuation (A$m)	Valuation (A$/share)
DMX-200 diabetic kidney disease	15%	48.0	0.30
DMX-200 FSGS indication	15%	33.3	0.21
SG&A	-	(4.3)	(0.03)
Portfolio total	-	77.0	0.48
Cash (30 June 2019)	-	3.6	0.02
Total Valuation	-	**80.5**	**0.51**

(Source: Actuals + TC Estimates)

Company Overview

Dimerix is a clinical-stage biopharmaceutical company based in Melbourne, Australia, developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix has developed a proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which allows it to utilise its understanding of receptor interactions to rapidly screen and identify new drug opportunities. This has allowed it to identify new uses for existing drugs in order to develop new therapies and research programs.

Its proprietary lead compound, DMX-200, was discovered using the Receptor-HIT technology. Dimerix is currently developing DMX-200 for both Diabetic Kidney Disease and Focal Segmental Glomerulosclerosis (FSGS).

Receptor-HIT is licensed non-exclusively to Excellerate Bioscience, a UK-based pharmacological assay service provider with a worldwide reputation for excellence in the field of molecular and cellular pharmacology.

Dimerix has two Phase II studies of DMX-200 in kidney disease underway, plus a preclinical drug candidate and drug discovery platform, as summarised in Exhibit 1.

Exhibit 1: Dimerix development pipeline

Product	Indication	Description	Stage
DMX-200	Diabetic kidney disease	CCR2 antagonist propagermanium which is used in conjunction with the ARB irbesartan	Phase II study fully recruited fully recruited September 2019 (n=40). Results expected Q220.
DMX-200	Focal Segmental Glomerulosclerosis	As above	Phase IIa fully recruited July 2019 (n=10). Orphan disease. Results expected Q220.
DMX-700	Chronic Obstructive Pulmonary Disease (COPD).	Undisclosed drug combination	Preclinical proof of concept studies underway.
Receptor-HIT	Drug discovery	Platform to test effect of drug candidates or combinations on receptors that act in concert.	Used for in-house drug discovery and licensed non-exclusively to Excellerate Bioscience. Previously used under licence by global pharma companies.

Source: Taylor Collison, Dimerix. Note: CCR2= chemokine (C-C motif) receptor 2; ARB= angiotensin receptor blocker

Investment case

Dimerix has two Phase II studies underway in indications with clear un-met need for more effective therapies, including an orphan indication and a chronic disease with a large target patient population. It also has a patented drug discovery platform and a pipeline of potential new drug candidates.

Dimerix is trading at a deep discount to our undiluted rNPV valuation of DMX-200 of $0.51 per share. We suspect that investors may have been put off by the apparent availability of supplements or complementary medicines containing propagermanium in the US and other territories, despite FDA bans. In our view these concerns have been overstated.

The background to this is that the US FDA is concerned about the potential for propagermanium to be contaminated with highly toxic inorganic germanium salts during manufacture. The FDA's concerns are reviewed in detail later in this report; the key points are that it has:

- Stated that 'Supplements containing [propagermanium] are considered adulterated due to safety concerns and cannot be sold legally' in the US.
- Placed propagermanium on its list of bulk drug substances that raise significant safety risks and should not be used by pharmacists to make "compounded" medicines.
- Banned the import of germanium compounds with the sole exception of a Korean-manufactured product called Geranti Bio-Ge yeast, that contains yeast cells that were supplemented with inorganic germanium during growth

Despite all this, it appears that the FDA is not enforcing its ban on the sale of supplements containing Propagermanium, and at least one US-manufactured propagermanium supplement is available for purchase in the US.

However, it is important to note that even if propagermanium supplements were legally available in the US, they would not be considered interchangeable with DMX-200 because they have not been produced in the same rigorous, FDA-inspected manufacturing environment and have not undergone the rigorous quality and contamination testing before being released

for sale. In addition, there can be chemical variations between the different organic germanium compounds seen in dietary supplements, and they may differ from the composition of DMX-200.

Crucially, approval of DMX-200 as a New Chemical Entity (NCE) brings with it at least five years of marketing and data exclusivity, or for approval for an orphan indication at least seven years of exclusivity in the US and 10 years in the EU. One of the effects of this is that it would be illegal for an insurer to reimburse or recommend an alternative formulation of propagermanium for the approved indication.

For all of these reasons, we do not expect the potential availability of dietary supplements containing germanium compounds to have any effect on pricing and reimbursement negotiations with payers in the US. Rather, we expect pricing to be driven by the level of efficacy seen in the clinical studies and the benefit delivered to patients.

The final piece in the puzzle will be the prescribing patterns of doctors, whose primary concern will be the welfare of their patients. We think it unlikely that a doctor in the US would recommend that a patient take a dietary supplement containing Propagermanium, even if it was legally available, in preference to an FDA approved product with established safety and efficacy. A co-pay rebate program to reimburse patients for out-of-pocket costs can be an effective way to minimise the potential financial impact of expensive medications for patients, and thus reduce any incentive for doctors to consider recommending alternative treatments.

It is less easy to predict how pricing and reimbursement negotiations will play out outside the US. For this reason we model 60% of global revenue for DMX-200 being generated in the US, rather than the 50:50 split that is commonly seen between the US and ex-US sales of pharmaceuticals.

Potential trading opportunity in the lead up to Phase II results.

It is common to see a run up in the share price of biotech stocks ahead of the announcement of significant clinical trial results. With two Phase II trials expected to report in Q2 CY20, there are likely to be opportunities for investors who prefer not to take clinical trial outcome risk to take profits in the lead up to the announcement of the trial results.

Vascepa shows what can be achieved despite competing supplememts

One example of the commercial success that can be achieved despite the ready availability of dietary supplements is the fish oil product Vascepa (Amarin NASDAQ:AMRN, market cap US$7.5bn). Vascepa, is an omega-3 fatty acid drug product containing purified ethyl ester of eicosapentaenoic acid (EPA) extracted from fish oil. In comparison, fish oil dietary supplements typically contain 18% EPA.[1] Vasecpa was originally approved in the US in 2012 as an adjunct to diet to reduce triglyceride (saturated fat) levels in adult patients with severely elevated triglyceride levels in the bloodstream (severe hypertriglyceridemia, ≥500 mg/dL).

The FDA is currently considering whether to approve use of Vascepa to reduce the risk of cardiovascular events in patients with less severely elevated triglyceride levels combined with other risk factors, as an adjunct to statin therapy. This represents a much larger patient population, and approval for this indication would be expected to boost sales substantially.

Sales of Vascepa were US$228m in 2018 and US$287m in the first nine months of 2019, which represents 89% growth compared to the same period in the previous year. EvaluatePharma reports that the consensus sellside analyst forecast is for Vascepa sales to reach US$2.3bn in 2024; peak sales are forecast to reach double that figure if the FDA grants approval for the cardiovascular risk reduction label claim.

Receptor-HIT identifies drugs acting on receptor pairs

Dimerix's patented Receptor-HIT assay is able to identify differences in signalling behaviour when receptors interact as complexes, known as heteromers. Receptor-HIT can be applied to receptors such as G protein-coupled receptors (GPCRs), a large and important family of drug targets that play a central role in many biological processes and are linked to a wide variety of diseases.

The technology allows different receptors that functionally interact to be characterised when natural ligands or small molecule drugs, peptides or antibodies bind to them. This platform technology was used to identify and characterise the GPCRs targeted in Dimerix's lead clinical program, DMX-200, as well as its new drug candidate DMX-700. It was also

[1] NIH Office of Dietary Supplements. https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional/

used to identify preclinical drug candidates DMX-300, DMX-400, DMX-500 and DMX-600, but development of these products appears to have stalled at the preclinical stage and they are not discussed further in this report.

Receptor-HIT has previously been used under licence by leading global pharmaceutical companies to profile a wide range of receptor targets. Receptor-HIT was licensed non-exclusively to Excellerate Bioscience in June 2019.

DMX-200 – two Phase II trials underway

DMX-200 is the adjunct therapy of the chemokine receptor (CCR2) antagonist propagermanium administered to patients already receiving irbesartan, an angiotensin II type I (AT1) receptor blocker and the standard of care treatment for kidney disease. DMX-200 has granted patents in various territories until 2032.

The proposed mechanism of action is that irbesartan blocks cellular receptors responsible for hyperfiltration and glomerular hypertension, whereas DMX-200 blocks chemokine receptor 2 (CCR2) which initiates attraction of inflammatory cells to the kidney. Certain kidney cells express both receptors which interact and thereby allow activation of the angiotensin receptor to indirectly activate CCR2. This means that using only one compound does not completely block activation of CCR2 and results in only a partial therapeutic response. Thus the total benefit of combining DMX-200 with irbesartan is greater than the sum of the two individual effects.

Dimerix completed its first Phase 2a study in patients with a range of chronic kidney diseases in 2017, with no significant adverse safety events reported. In a subsequent sub-group analysis, significant clinical efficacy signals were seen in patients with kidney disease due to diabetes.

DMX-200 administered to patients already taking irbesartan reduced proteinuria levels by a further 36%. This reduction in proteinuria is highly correlated with improved renal function and delay in kidney failure and dialysis. It is on top of the 27% reduction in proteinuria reported for Irbesartan on its own compared to placebo in a Phase III diabetic nephropathy study.[2]

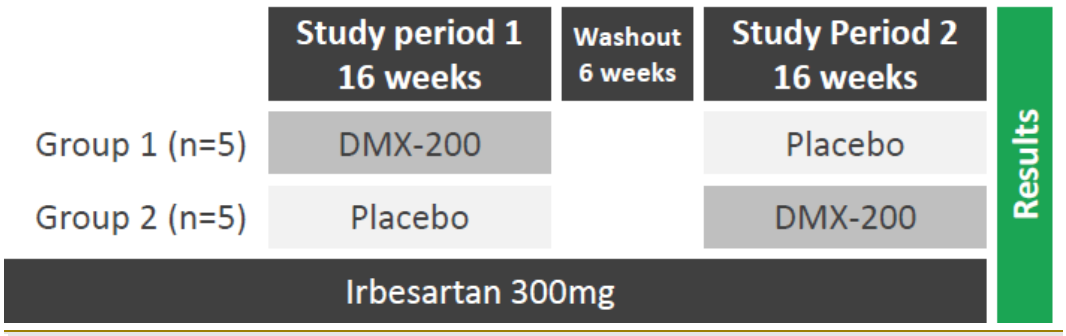
Following the encouraging results from the Phase IIa study, the company initiated two different clinical studies in 2018: one for patients with Diabetic Kidney Disease; and the second for patients with another form of kidney disease, Focal Segmental Glomerulosclerosis (FSGS).

FSGS Phase IIa fully recruited - results Q220

Dimerix completed recruitment of its Phase IIa study of DMX-200 in 10 patients with FSGS in July, and expects to report study results in Q2 CY20. The double-blind, randomised, placebo-controlled crossover study is designed to evaluate the safety and preliminary signs of efficacy of DMX-200 in patients with FSGS who are being treated with irbesartan. Each subject will receive DMX-200 for 16 weeks and placebo for 16 weeks, with a 6-week washout period in between, as shown in Exhibit 2. Subjects were randomly assigned to receive either DMX-200 or placebo in the first study period, with the alternative treatment given in the second study period. The study is targeting the subset of the FSGS population that is diagnosed with primary FSGS, which is believed to have an underlying inflammatory cause.

Patients will be followed for safety, reduction in protein in their urine and improvement in kidney function.

Exhibit 2: FSGS Phase IIa trial design



Source: Dimerix presentation

[2] Irbesartan prescribing information, page 9

FSGS is a serious and rare disease that attacks the kidney's filtering units (glomeruli) causing serious scarring which leads to permanent kidney damage and kidney failure and for which there is a recognised medical need for a new or improved treatment. FSGS affects both children and adults.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and an abbreviated regulatory pathway to approval.

If DMX-200 shows convincing efficacy in the Phase IIa study, the next step could be to progress to a pivotal study. As FSGS is a rare disease the clinical trial is likely to be relatively small, and Dimerix may be able to conduct the study itself, without needing to engage with a commercialisation partner. On the other hand, a partnering deal may be an attractive way of obtaining non-dilutive funding for the study.

Dimerix has scheduled a pre-IND (Investigational New Drug) meeting with the US FDA this month (November) in order to clarify the remaining development steps towards market authorization for DMX-200 in FSGS. This will give it insights as to what the regulator's expectations might be for a pivotal study program. These insights will aid Dimerix as it prepares strategies and activities to enter pivotal studies for the FSGS program. This should allow the company to avoid any unnecessary delay in initiating a pivotal study program, either alone or with a partner, if the current study produces positive data.

Diabetic nephropathy Phase IIb fully recruited - results Q220

Dimerix completed recruitment in a Phase IIb study of DMX-200 in patients with diabetic kidney disease in September 2019, and expects to complete the study in Q2CY20.

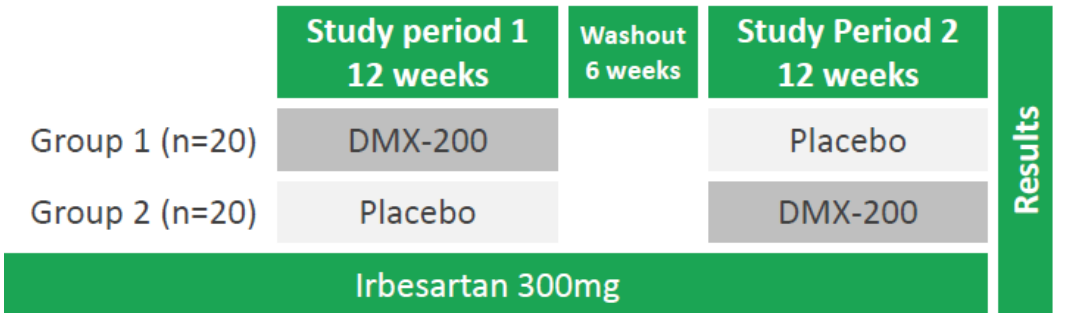
The double-blind, randomised, placebo-controlled study is evaluating the safety and efficacy of DMX-200 in patients with diabetic kidney disease who are receiving a stable dose of Irbesartan (NCT03649152). The study uses a crossover design, with each patient undergoing separate periods of treatment with either DMX-200 or placebo, in addition to ongoing Irbesartan therapy. Patients are randomised to receive either DMX200 or placebo during the first 12-week study period; they then received the alternative study drug in study period 2 after a 6-week washout period, as shown in Exhibit 3. Subjects who were not already being treated with irbesartan will be required to receive a stable dose of irbesartan for at least 3 months before they are administered the study drug. The study titled 'Safety and Effectiveness of propagermanium in Diabetic Kidney Disease Participants Receiving Irbesartan (ACTION)' is registered at Clinicaltrials.gov as trial NCT03627715.

Subjects with diabetes are eligible to participate in the study if they have kidney disease as evidenced by protein in their urine (proteinuria) and an estimated glomerular filtration rate in the range of 25-90 mL/min/1.73 m^2. These criteria encompass stage 2-3 (mild to moderate) or milder stage 4 (severe) chronic kidney disease.

The primary endpoint of the study is the percent reduction in albuminuria (protein in the urine) compare to baseline.

The company estimates that a 30% reduction in proteinuria may delay the need for dialysis by 3-5 years and thereby reduce health costs by US$100,000 per patient per year.

Exhibit 3: Diabetic kidney disease Phase II trial design



Source: Dimerix presentation

If the Phase IIb study is successful, the next step might be a larger Phase IIb study in which patients are treated for a longer period and which might also explore alternative doses of DMX-200. We expect that one or more relatively large

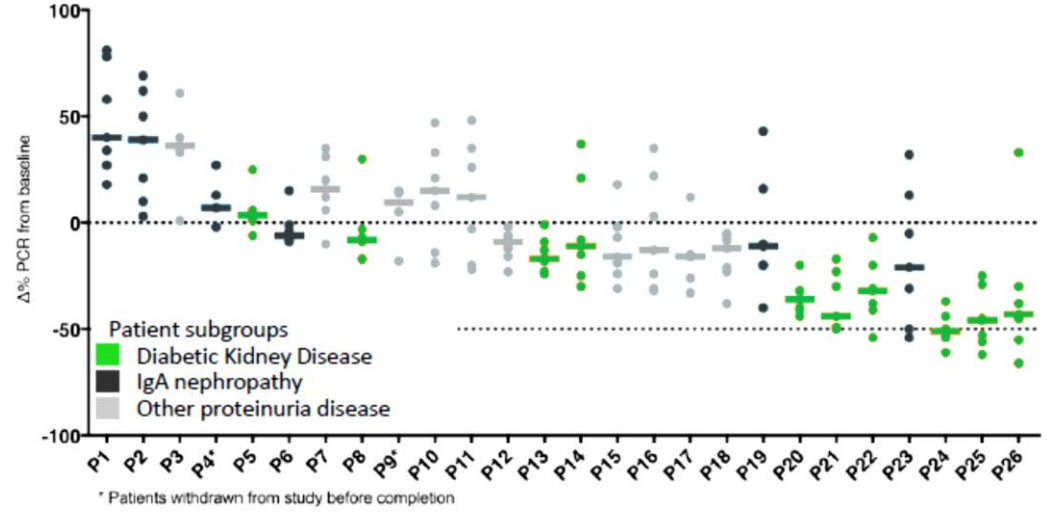
Phase III studies would also be required in order to gain approval from the FDA and other regulators. We would expect Dimerix to seek a partner to conduct the required studies.

DMX200 Phase I/II data supports the ongoing Phase II studies

Dimerix completed a Phase IIa study in 2017 that investigated safety and exploratory signals of efficacy for DMX-200 in patients with a range of chronic kidney diseases.

In the Phase IIa study, 6/24 patients achieved a 50% decrease in protein in the urine (proteinuria) as measured by the protein/creatinine ratio, and were categorised as responders to treatment. Five of the 6 responders had a primary diagnosis of diabetic kidney disease; the other responder had IgA nephropathy. Exhibit 4 shows the change in urinary protein/creatine ratio (PCR) from baseline for each response assessment for the subjects in the study, categorised by the disease subgroup.

Exhibit 4: Proteinuria (PCR) secondary efficacy endpoint in Phase IIa

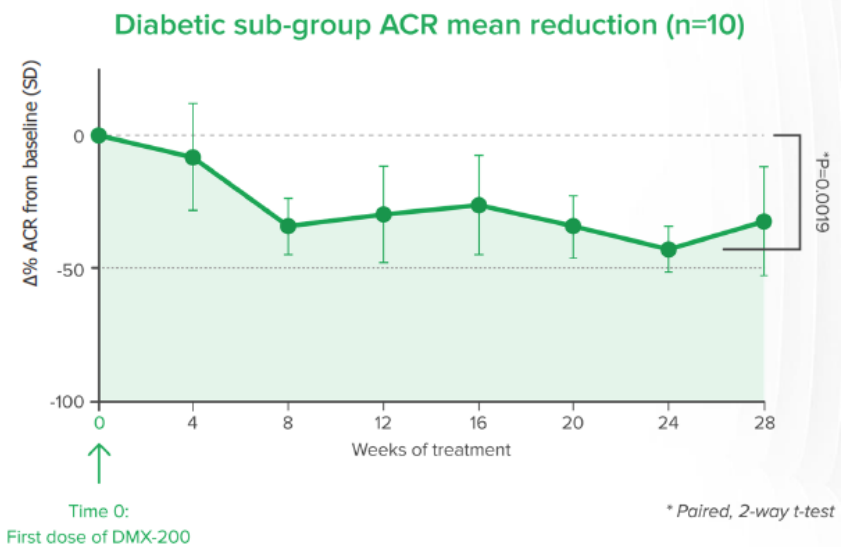


Source: Dimerix presentation

Ten subjects in the study had diabetic kidney disease, so 50% of subjects in this subgroup were responders. A retrospective subgroup analysis reported that proteinuria was decreased on average by 36% in the of the diabetic patient subgroup overall. This is in addition to the 24% to 27% reduction in proteinuria reported for patients with diabetic kidney disease treated with irbesartan on its own in a pivotal Phase III.

Exhibit 5 shows the average change from baseline for the diabetic subgroup at each time point for another measure of proteinuria, the urinary albumin/creatinine ratio (ACR).

Exhibit 5: Reduction in proteinuria (ACR) in diabetic sub-group (n=10)



Source: Dimerix presentation

FDA changes make kidney disease more attractive to pharma

Recent moves by the FDA to accept biomarker data as acceptable primary endpoints to support applications for marketing authorization for treatments for chronic kidney disease have increased pharma interest in the space.

Following a joint workshop with the National Kidney Council in 2012, the FDA now accepts a surrogate endpoint based on the decline in estimated glomerular filtration rate (eGFR, a measure of kidney function) as an alternative to clinical endpoints as basis for drug approval. The accepted surrogate endpoint as a basis for drug approval in common chronic kidney diseases is a confirmed 40% decline in eGFR; the criterion for rare chronic kidney diseases is a 30% decline.

For a number of primary glomerular diseases associated with significant proteinuria (which would include FSGS and IgA nephropathy), the FDA has indicated that it will accept treatment effects on proteinuria as an end point and as a basis for either accelerated or traditional approval, depending on the circumstances.

Two key advantages of surrogate endpoints for drug developers are that the pivotal studies are likely to be of shorter duration and may require fewer subjects than would be need for studies with clinical endpoints. Another advantage is that the biomarker endpoints can usually be measured directly in Phase II studies, which should make the Phase II studies a better guide to the likely outcome of Phase III studies.

As an example of the type of clinical endpoint that was previously required for pivotal studies of drugs for chronic kidney disease, we note that the Phase III Irbesartan Diabetic Nephropathy Trial recruited 1715 patients and had a composite clinical endpoint of "the time to occurrence of any one of the following events: doubling of baseline serum creatinine, end-stage renal disease (ESRD; defined by serum creatinine ≥6 mg/dL, dialysis, or renal transplantation) or death."[3] The FDA label (prescribing information) notes that the change in proteinuria observed during the study was evident within three months of starting therapy.

FSGS background and market size

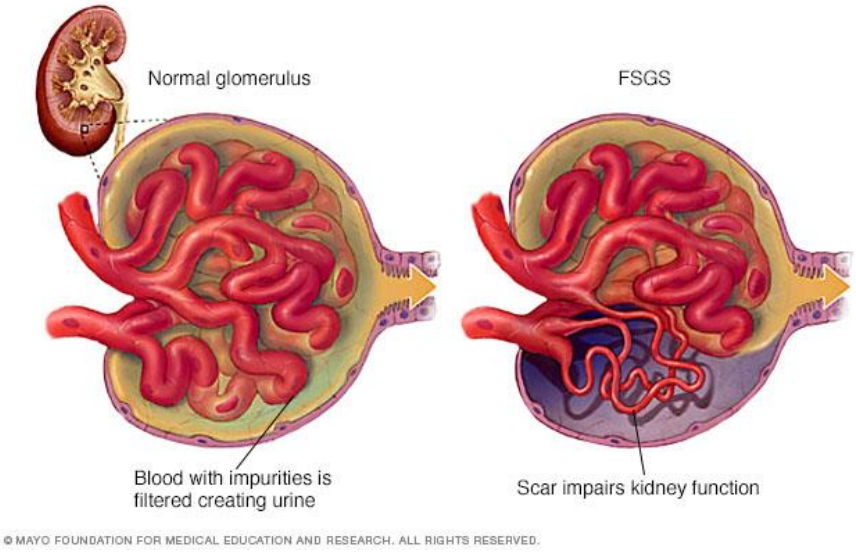
FSGS is a chronic, progressive form of kidney disease characterised by scarring (sclerosis) of the glomeruli, the tiny filtering units inside the kidney where blood is cleaned. The scarring in FSGS only takes place in small sections of each glomerulus, as shown in Exhibit 6, and only a limited number of glomeruli are damaged at first. A key factor is damage to the podocyte cells that form part of the filtering basket in the glomerulus.

The most common clinical presenting feature of FSGS (>70% of patients) is a set of symptoms known as nephrotic syndrome, characterized by generalized oedema (swelling), massive proteinuria, hypoalbuminemia (low plasma protein), and hyperlipidaemia. However, the natural history of FSGS is variable and can range from oedema that is difficult to manage, to proteinuria that is refractory to corticosteroids and other immunosuppressive agents, to worsening hypertension and a progressive loss of kidney function. Definitive diagnosis requires a kidney biopsy and examining the tissue sample under a microscope.

Primary FSGS, where there is no other disease process that can be identified as the cause, is attributed to factors circulating in the bloodstream that damage the kidney, somewhat like an autoimmune disease. Secondary FSGS can have many different causes. The scarring may happen due to an infection, a drug such as anabolic steroids, or a systemic disease such as diabetes, HIV infection, sickle cell disease or lupus. FSGS affects men slightly more often than women and can affect children or adults. It most often occurs in adults about 45 years or older.

[3] Irbesartan prescribing information page 7

Exhibit 6: FSGS causes scarring of part of the glomerulus filter basket



Source: Mayo Foundation, NephCure

FSGS is referred to as a chronic disease because the scarred glomeruli cannot be repaired, although treatment can slow the process of the disease. Over time, many patients with FSGS gradually get worse until they reach kidney failure, when they will need either dialysis or a kidney transplant in order to survive.

There are no therapies that have been approved for treating FSGS. Commonly used treatment regimens for FSGS patients may include:

- Corticosteroids
- Immunosuppressive drugs
- Plasmapheresis
- ACE inhibitors and ARBs
- Diuretics
- Diet change

Incidence and Prevalence of FSGS

FSGS is a rare disease, with about 7 people per million in the general population estimated to be diagnosed with the disease in the US each year. A systematic review of the scientific literature reported that the annual incidence of new cases of FSGS in various countries ranged from 2 to 18 per million people, with an estimated global incidence of 8 new cases per million people.[4] That study reported that Australia had the highest incidence of diagnosed disease in the world, which may be due to the higher rate of diagnostic kidney biopsies performed.

FSGS patients are at a high risk of developing end stage renal disease (ESRD). Estimates of the 10-year risk of progressing to ESRD from cohort studies range from 30% to 70%, with most estimates in the range of 50% to 70%. (Kityakara). There typically is an interval of 3 to 15 years (and possibly longer) between the onset of FSGS, manifested by proteinuria, and onset of ESRD.

Based on the incidence of diagnosed disease in the US of 7 per million and a US population of 330m, we estimate that there are 2,310 new cases of FSGS diagnosed in the US each year.

We could not find any estimates in the scientific literature of the prevalence of FSGS, ie the total number of patients with the disease, including those diagnosed in previous years. Retrophin, which is also developing a treatment for FSGS, estimates that there are 40,000 FSGS patients in the US. Retrophin's estimate implies an average duration of the disease of 17 years, which seems reasonable in light of the 50-70% 10-year risk of developing ESRD. Furthermore, assuming that it takes on average 9 years to develop ESRD, we estimate that there are 20,800 patients in the US who have FSGS but have not yet developed ESRD.

[4] McGrogan et al 2011. Nephrol Dial Transplant. 2011 Feb;26(2):414-30.

We assume that 60% of FSGS patients have primary FSGS rather than the secondary form.[5] Thus we model an addressable patient population in the US as 12,500 patients who have been diagnosed with primary FSGS but have not yet developed ESRD.

The market research group Transparency Market Research estimated that the global FSGS market was worth US$7.8bn in 2016 and forecast it to grow to US$15.8 bn by 2025. It estimated that primary FSGS accounted for 80% of the market in 2016.

According to a report by the clinical research and data analytics company IQVIA (formerly IMS and Quintiles) the mean annual invoice price for an orphan drug in the US in 2017 was US$87,300 per year and the median price was US$46,800 per year[6].

We model DMX-200 being priced at US$70,000 per year if approved for use in the orphan FSGS indication, which is 20% below the average price for an orphan medication in the US reported by IQVIA.

Competing FSGS products in development

There are two drugs with related mechanisms of action to DMX-200, sparsentan (Retrophin) and CCX140 (ChemoCentryx), in Phase II or Phase III studies in FSGS.

Retrophin is conducting Phase III studies of sparsentan in FSGS and IgA nephropathy. Sparsentan is a dual-acting angiotensin receptor blocker and endothelin receptor antagonist. As it has an ARB activity, it is used as an alternative to irbesartan rather than as an add-on to it.

The DUPLEX Phase III FSGS study (NCT03493685) will enrol approximately 300 subjects who will be randomly assigned to receive either sparsentan or irbesartan. It is expected to report top-line data for the 36-week proteinuria endpoint in Q121. The proteinuria end-point is the proportion of patients achieving a modified partial remission of proteinuria after 36 weeks of treatment, defined as achieving a urinary protein/creatinine ratio ≤1.5 g/g and a >40% reduction from baseline at week 36.

The study also has a confirmatory efficacy endpoint based on kidney function (eGFR) assessed from week 6 to week 108 at the final analysis. We suspect that the two-year treatment period for the confirmatory efficacy endpoint may be in part due to the need to collect long-term safety data for sparsentan.

Sparsentan is also being studied in the PROTECT Phase III trial (NCT03762850) in 280 patients with IgA nephropathy. Top-line data for the change in proteinuria (UPCR) from baseline primary endpoint is expected to report in H122.

Retrophin has commented that it expects that this single pivotal study with proteinuria as the primary endpoint will support submission of a New Drug Application (NDA) for accelerated approval in the US and for Conditional Marketing Authorisation in Europe.

Retrophin reported top-line 8-week proteinuria results for the Phase II DUET study of sparsentan in FSGS patients in 2016. Pooled analysis of the two highest doses showed sparsentan reduced proteinuria by 28% more than irbesartan ($p=0.01$).[7] The analysis of the individual dose cohorts was not statistically significant. The study tested 200, 400 or 800 mg/day of sparsentan or 300mg irbesartan active control. The subjects were required to discontinue all ARBs or ACE inhibitors for a two-week wash-out period before commencing the study drug.

ChemoCentryx is developing CCX140, which, like DMX-200 is a CCR2 inhibitor. This means that usage of CCX-140 in combination with an ARB inhibitor such as irbesartan may breach Dimerix's patents.

ChemoCentryx is conducting two Phase II trials of CCX140 in two different sub-populations of FSGS: one in patients with FSGS and nephrotic syndrome; and another in patients with less severe, sub-nephrotic primary FSGS.

The LUMINA-1 study in 40 patients with FSGS (NCT03536754) (10 subjects per dose cohort) is fully enrolled, with top-line data expected H120. The primary endpoint is change in UPCR from baseline to week 12.

The LUMINA-2 trial focuses on patients with FSGS and nephrotic syndrome (NCT03703908). The study has a target enrolment of 13 subjects and is still recruiting, but the company expects to report top-line data in 2020. The primary

[5] Based on Figure 2 in Rosenberg and Kopp 2017, Clin J Am Soc Nephrol 12: 502–517, and assuming that the majority of patients they classify as APOL1 FSGS would fall into the primary FSGS category.
[6] Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments
[7] Trachtman et al 2018. J Am Soc Nephrol 29: 2745–2754.

endpoint is the same as the other FSGS study. ChemoCentryx suggests that LUMINA-2 could potentially be a pivotal study as it is focused on patients with more severe forms of the disease.

In 2014 ChemoCentryx reported a statistically significant 16% reduction in proteinuria at the lower of the two doses tested in a Phase II study of CCX140 in patients with diabetic nephropathy (NCT01447147). In the 52-week study CCx140 was added to standard of care treatment with an ACE inhibitor or ARB, with 29% to 39% of each dose cohort being treated with ARBs. Any recommendation to combine CCX140 with an ARB could potentially breach Dimerix's patents.

The 16% reduction in proteinuria reported for CCX140 is substantially lower than the 36% reduction reported from the diabetic patient subgroup of the DMX-200 study.

ChemoCentryx and Dimerix could be in a race to be first CCR2 inhibitor to market if both drugs report positive trial results next year.

Diabetic Kidney disease background and market size

Diabetic kidney disease, also known as diabetic nephropathy (DN), is a complication of diabetes and a leading cause of chronic kidney disease (CKD). DN is typically characterised by damage to the capillaries supplying the kidney glomeruli, which leads to declining filtering efficiency in the kidney and progressive loss in renal function. Over 30% of patients with diabetes (type 1 and type 2) develop kidney disease.

Therapeutic interventions in diabetic nephropathy primarily seek to suppress inflammation and oxidative stress in order to reduce the decline in glomerular filtration rate (GFR) and stabilise kidney function. Current treatment focuses on underlying contributing factors such as hypertension using both angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs).

Patients with chronic kidney disease are categorised into five stages, according to the measure of kidney function known as the glomerular filtration rate (GFR). Patients with Stage 1 disease have a GFR in the normal range but have abnormalities such as protein or blood in the urine. The five stages of CKD and GFR for each stage are shown below[8]:

- **Stage 1** with normal or high GFR (GFR > 90 mL/min)
- **Stage 2** Mild CKD (GFR = 60-89 mL/min)
- **Stage 3A** Moderate CKD (GFR = 45-59 mL/min)
- **Stage 3B** Moderate CKD (GFR = 30-44 mL/min)
- **Stage 4** Severe CKD (GFR = 15-29 mL/min)
- **Stage 5** End Stage CKD (GFR <15 mL/min)

Incidence and Prevalence of diabetic kidney disease

According to the US Centers for Disease Control (CDC) 15% of US adults (37m people) are estimated to have CKD[9]. Diabetes-associated nephropathy, which typically presents 10-20 years after the initial diagnosis with diabetes, is one of the two main causes of CKD. The CDC reports that there are 23m people diagnosed with diabetes in the US.[10] The prevalence of CKD with or without proteinuria in adults with diagnosed diabetes was 36.5% in 2011–2012, while the prevalence of CKD with proteinuria was 24.9%. This means that there were approximately 5.7m people with diabetic kidney disease with proteinuria in the US, 3.7m of whom would have had stage 2 or stage 3 CKD, based on the breakdown by stage shown in Exhibit 7.

The CDC estimates that in 2016 nearly 125,000 people in the US started treatment for end-stage renal disease, and more than 726,000 people with end-stage renal disease were on dialysis or living with a kidney transplant.

[8] Source: https://www.davita.com/education/kidney-disease/stages/stage-1-of-chronic-kidney-disease
[9] CDC: Chronic Kidney Disease in the United States, 2019
[10] National Diabetes Statistics Report, 2017

Exhibit 7: Prevalence of CKD in the US in 2015-2016 by CKD stage

Stage 1	Stage 2	Stage 3	Stage 4	Total
4.68%	3.41%	5.79%	0.36%	14.23%

Source: Taylor Collison, CDC: https://nccd.cdc.gov/CKD/detail.aspx?Qnum=Q8

Dimerix reports that irbesartan was priced at US$550/month (US$6,600/year) before patent expiry, and that there were 4.05m scripts for irbesartan 300mg in 2017. If 50% of those scripts were for kidney disease, that would represent a market of US$1.1bn/yr.

We note that Novartis's Entresto heart failure drug, which targets a serious disease with a large addressable patient population with some characteristic similar to the diabetic kidney disease population, was launched in 2015 at a price of $4,600 per year.

We take a conservative approach and model DMX-200 for the diabetic kidney disease indication being priced at US$4,600/year, in line with Entresto launch pricing.

Propagermanium supplements banned by the FDA but still on sale

Key points

- Propagermanium and other germanium compounds have been used as dietary supplements and complementary medicines for many years
- There is a risk that Propagermanium supplements can be contaminated during manufacture with toxic inorganic germanium compounds that have been associated with renal failure and even death.
- The FDA has banned the import of all germanium compounds, although it recently excluded yeast grown on media fortified with germanium from the ban
- The FDA has stated that supplements containing [propagermanium] are considered adulterated due to safety concerns and cannot be sold legally in the US.
- The FDA concluded that propagermanium should be excluded from the list of bulk drugs that can be used by pharmacists to make compounded medicines
- Instead, the FDA has placed it on the list of bulk drug substances that raise significant safety risks
- It appears that the FDA is not enforcing its ban on the sale of supplements containing Propagermanium, and that Propagermanium is able to be purchased in the US.
- Given the FDA statements about the dangers involved, it seems unlikely that a doctor in the US would recommend that a patient take a dietary supplement containing Propagermanium, even if it was legally available, in preference to an FDA approved product with established safety and efficacy.

Propagermanium was approved in Japan in 1994 under the brand name Serocion (Yamanouchi, Japan) for treating hepatitis B.[11] It has not been approved in any other jurisdiction and is considered to be a new chemical entity (NCE) in all other countries and therefore is not a generic drug.

The FDA refers to Propagermanium as germanium sesquioxide; other names used for various forms of the compound used in supplements include proxigermanium, Ge-132, germanium sesquioxide, 2-carboxyethylgermasesquioxane and SK-818.

Potential toxic contaminants in propagermanium supplements

The FDA's chief safety concern is the likelihood that Propagermanium products could be contaminated with highly toxic inorganic germanium salts during manufacture. Two inorganic germanium salts, germanium dioxide and germanium citrate lactate, are well known to cause kidney damage. The FDA noted that prolonged intake of germanium products has been associated with at least 31 cases of renal failure, some of which led to death.

[11] thePharmaletter 1994 https://www.thepharmaletter.com/article/new-hep-b-drug-approved-in-japan

FDA import ban

Furthermore, there is an active FDA import alert (#54-07) for all germanium compounds except those used for semiconductors. However, in December 2018 an exclusion was added to the FDA import alert permitting the import of a Korean-manufactured product called Geranti Bio-Ge yeast, that contains yeast cells that were supplemented with inorganic germanium during growth. We could not determine whether or not the Geranti Bio-Ge yeast product contains Propagermanium.

FDA rejects use of Propagermanium in compounded medicines

In 2015 the FDA considered whether Propagermanium (which it referred to as germanium sesquioxide) should be allowed to be used as an ingredient for compounding treatments for patients with cancer and chronic illnesses.

The FDA's presentation to the review committee noted that while Propagermanium is sometimes seen in dietary supplements:

> 'Supplements containing [Propagermanium] are considered adulterated due to safety concerns and cannot be sold legally' in the US.[12]

The FDA has included Propagermanium in its list of bulk drug substances that raise significant safety risks.[13]

Propagermanium available for sale as a supplement in the US despite bans

On the other hand, despite the FDA statement that it cannot be sold legally in the US, it appears that Propagermanium (labelled as Bis-Carboxyethyl Germanium Sesquioxide) is available for sale in the US. We found a website advertising NutriCology OrganoGermanium Ge-132 100mg, 100 tablets for US$73.98.

Unlikely that doctors would recommend or prescribe Propagermanium supplements as an alternative to the FDA approved medicine.

Given the FDA statements about the dangers involved, it seems unlikely that a doctor in the US would recommend that a patient take a dietary supplement containing Propagermanium, even if it was legally available, in preference to an FDA approved product with established safety and efficacy. However, while is seems unlikely, it is not possible to rule it out in every instance, particularly for patients who lack adequate health insurance cover. Pharmaceutical companies can use a number of strategies to ensure that insurers and not patients pay the high cost of drugs, including by establishing co-pay rebate programs and by providing the drug for free to uninsured patients.

Market exclusivity and patents to protect competitive position

Dimerix holds a US granted patent with broad claims claims covering use of any CCR2 inhibitor with any angiotensin receptor 2 blocker, and which will be valid until at least 2033. The patent strengthens the company's position and may be able to be used to block some competitor product development plans, for example ChemoCentryx's CCX140.

The company expects new patents to be granted, further strengthening its competitive position.

In addition to the method of use patents, DMX-200's status as a new chemical entity would attract five years of market exclusivity in the US. Its Orphan Drug status would ensure seven years of market exclusivity in the US and 10 years exclusivity in the EU for use in FSGS patients.

DMX-700 for COPD

In October 2019 Dimerix announced that it had added a new candidate drug for the treatment of chronic obstructive pulmonary disease (COPD) to its development pipeline. The new therapy, which it named DMX-700, was identified using the company's Receptor-HIT assay, which identified a heteromer association between two different G protein-coupled receptors (GPCR) expressed in the lung. Both of these receptors have previously been independently implicated in COPD, but investigations targeting each receptor individually have produced disappointing results. Dimerix has discovered that simultaneously blocking both receptors with DMX-700 therapy may significantly improve efficacy, as illustrated in Exhibit 8.

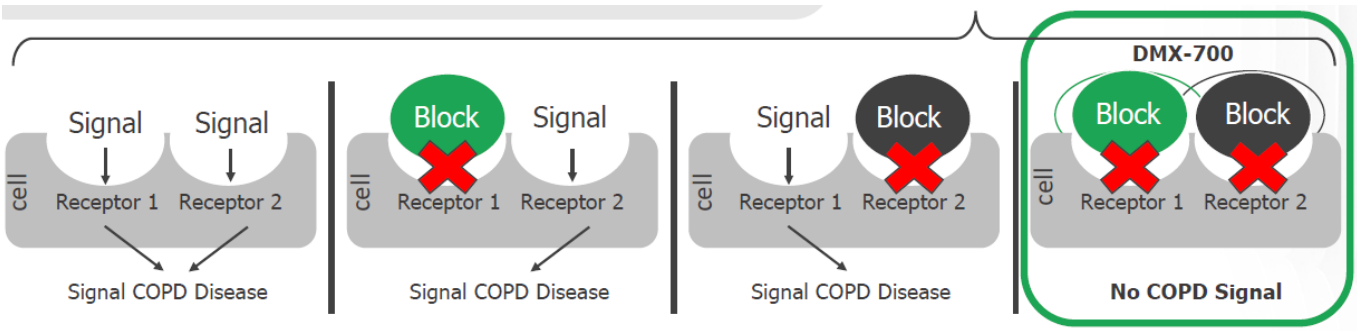
[12] 2015 Meeting Materials, Pharmacy Compounding Advisory Committee

[13] FDA: Bulk Drug Substances Nominated for Use in Compounding. Updated March 21 2019

Dimerix has completed initial studies and has lodged a provisional patent application for DMX-700. The provisional patent application, number 2019903606, would expire post 2040, if granted. The receptor targets and the composition of DMX-700 will remain undisclosed pending additional data and patent positioning. While DMX-700 is a new chemical entity, all of the active ingredients in it have been investigated in clinical studies and have well-understood safety profiles, although they are not currently FDA-approved.

Dimerix will conduct further proof of concept studies over the next 12 months and expects to initiate human clinical studies in less than two years. The known safety profile means a reduced time to commencement of clinical studies.

Exhibit 8: DMX-700 proposed mechanism of action



Source: Dimerix presentation

COPD represents a large target market with few treatments

COPD is a progressive and life-threatening lung disease that is characterised by an abnormal inflammatory response and progressive reductions in lung airflow that are not fully reversible. The majority of cases of COPD are associated with cigarette smoking. There is no cure available and existing treatments are aimed at relieving symptoms, such as bronchodilators to open the airways, or reducing the risk of disease exacerbation.

COPD is an important cause of mortality and disability worldwide, and represents a large addressable market. The World Health Organisation estimates 3.17m deaths were caused by COPD globally in 2015, representing 5% of all deaths in that year.[14] According to the Centers for Disease Control, 16m people in the US have been diagnosed with COPD[15], and millions more have it and don't know. COPD-related patient care costs in the US are projected to grow to US$49bn by 2020.

Risks

Dimerix is subject to clinical trial, regulatory and funding risks common to all biotech companies. The key risk is the possibility that the two ongoing Phase II studies of DMX-200 may both fail to show statistically significant improvements in the proteinuria endpoints. The encouraging indications of efficacy of DMX-200 in patients with diabetic kidney disease was based on a small sample of only 10 patients, which increases the risk that the favourable results may have been arisen due to chance rather than being due to the efficacy of the DMX-200 therapy. DMX-200 has not previously been studied in patients with FSGS.

Dimerix faces significant funding risks. It had A$2.0m of cash at 30 September 2019 and received a $1.2m R&D rebate after the quarter end; estimated cash expenditure in Q4 CY19 is $0.6m. It has sufficient funds to support operations until the Phase II trial results are reported in Q220, but it may choose to raise additional funds before then to ensure it can commence preparations for a possible pivotal Phase III study in FSGS. It may subsequently need to raise substantial funds in the order of $35m if it chooses to conduct a pivotal Phase III study in FSGS without a development partner. This will be a significant challenge for a company with a current market capitalisation of ~$18m, although this would be expected to be significantly higher if the trial results are positive. There is a risk that it may not be able to raise the funds at a reasonable price, or at all.

[14] WHO https://www.who.int/news-room/fact-sheets/detail/chronic-obstructive-pulmonary-disease-(copd)
[15] CDC Morbidity and Mortality weekly report https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a1.htm

Valuation

Our initial valuation of Dimerix is $81m based on a risk-adjusted discounted cash flow model, which includes our estimates of the future milestone payments and royalty streams for DMX-200, as listed in Exhibit 17. We do not include DMX-700 in our valuation model at this stage. Our valuation is equal to $0.51 per share on an undiluted basis and $0.49/share after diluting for the 11.7m options on issue. If the company reports positive results from the Phase IIa study of DMX-200 in FSGS in Q2 CY20, one option would be for it to raise capital to fund a pivotal Phase III study in FSGS on its own. We model the full cost of a FSGS pivotal study at A$35m. Taking account of the potential issue of shares to raise $35m following positive trial results at 30c, 20c or 10c would dilute our valuation to $0.41, $0.34 or $0.22/share, respectively. Alternatively, Dimerix may seek a partner to fund future trials of DMX-200.

We have extended our cash flow forecasts out to 2035 (supported by 10 years of Orphan Drug market exclusivity for the FSGS indication in Europe) but have not included any terminal valuation. We assume a long-term exchange rate of US$0.70/A$ and apply a 12.5% discount rate.

We model Dimerix outlicensing DMX-200 in a single transaction while the pivotal FSGS study is underway. We assume that the licence deal includes an upfront payment of US$85m and US$540m of milestone payments. We assume that 50% (US$270m) of the milestone payments are for the achievement of clinical and regulatory milestones, with the remaining 50% assumed to be based on sales hurdles. We split the US$85m upfront and US$270m clinical and regulatory milestones equally between the FSGS and diabetic kidney disease indications, adjusted with a 15-30% probability (30% probability of signing a license deal, 15% for approval milestones). We do not include any potential sales-based milestones in our forecasts, and instead model a 20% royalty rate for the FSGS indication and 15% for diabetic kidney disease, as it is further from approval. The modelled deal terms are based on relevant benchmarks over the last few years (sourced from EvaluatePharma and a report produced by the industry group BIO).

We model DMX-200 being priced at US$70,000 per year if approved for use in the orphan FSGS indication, which is 20% below the US$87,300 average annual price for an orphan medication in the US reported by IQVIA.

We assume that DMX-200 marketed for use in diabetic kidney disease would be differentiated from the FSGS product, possibly by formulating propagermanium plus irbesartan as a combination medication. We model the diabetic kidney disease formulation of DMX-200 being priced at US$4,600 per year, in line with the launch price of Novartis's Entresto heart failure medication.

Exhibit 17 shows our market assumptions for the FSGS and diabetic kidney disease indications for DMX-200, and the rNPV for each indication. We have offset the risk-adjusted trial cost against revenue for each indication.

Exhibit 17: Dimerix risk-adjusted DCF base case valuation and assumptions

	Base case success likelihood (%)	rNPV (A$m)	rNPV/share (A$)	Assumptions
DMX-200 FSGS	15%	33.3	$0.21	Global peak sales of US$430m. For the US assumes prevalence of 40,000 diagnosed patients, 36% eligible for treatment (primary FSGS, not yet in end stage renal disease), 20% penetration; pricing US$70k per patient; launch Q3 2025; patents expire 2033; assume receives 20% net royalty. R&D cost: A$35m for pivotal Phase III, out-license while the study is underway. Assume US 60% of global sales.
DMX-200 diabetic kidney disease	15%	48.0	$0.30	Global peak sales of US$1.5bn. For the US assumes prevalence of 5.7m patients diagnosed with diabetic kidney disease with proteinuria, 65% eligible for treatment, 4% penetration; pricing US$4,600 per patient; launch H2 2028; patents expire 2033; assume receives 15% net royalty. Assume out-licence after current Phase IIb study; R&D costs paid by partner: Assume US 60% of global sales.
SG&A to 2024		-4.3	-$0.03	
Portfolio total		**77.0**	**$0.48**	
Cash end FY19e		3.6	$0.02	
Enterprise total		**80.5**	**$0.51**	

Source: Taylor Collison. Note: NPV adjusted for tax at an effective tax rate of 27.5%. We assume that the addressable markets grow at 2% per year.

Financials

Dimerix reported a pre-tax loss of $2.9m in FY19, vs a loss of $3.3m for the previous corresponding period (pcp). Expenses associated with R&D projects were $2.8m, and corporate and administration expenses were $1.3m. We model Dimerix self-funding a pivotal Phase III study of DMX-200 in FSGS, assuming that the ongoing Phase IIa study produces positive results. This sees our loss estimates grow to $6.8m in FY21, due to increased R&D expenditure as Dimerix initiates the pivotal study, partly offset by the Australian R&D rebate scheme.

Dimerix had A$2.0m of cash at 30 September 2019 and received a $1.2m R&D rebate after the quarter end; guidance for cash expenditure in Q4 CY19 is $0.6m. It may choose to raise additional funds before it reports results of the Phase II DMX-200 studies in Q2 CY20, in order to ensure that preparations for a potential pivotal FSGS study are on track. We estimate that it may need to raise funds in the order of $35m for a pivotal Phase III study in FSGS if it chooses to conduct the study without a development partner. For convenience, we model the funding being raised in FY21 through the issue of 117m shares at A$0.30/share, but note that the issue price will depend on the Phase II trial results and other factors. A licence deal with a development partner which funds the pivotal studies is an alternative strategy that may be more attractive to the company and shareholders, depending on the circumstances and deal terms.

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