

27 April 2018

## ASX Announcement

### QUARTERLY REVIEW – Q3 FY2018

#### Quarter highlights

- **Dimerix finished the March quarter in a strong position with \$7.7m in cash, following the close of an oversubscribed capital raise in February 2018**
- **Inaugural Chief Medical Officer, Associate Professor David Packham appointed to support the company with trial design and key opinion leader engagement through Dimerix's coming Phase 2 clinical trials for lead, DMX-200**
- **Preparations well advanced to enable Dimerix to shortly commence its Phase 2 clinical studies in FSGS and diabetic nephropathy**
- **Late stage negotiations in place to appoint a manufacturer to produce DMX-200 to prepare DMX-200 for eventual registration with the US FDA and support pharmaceutical partnering discussions**

**MELBOURNE, Australia, 27 April 2018:** Dimerix Limited (ASX: DXB) (Dimerix or the Company), a clinical stage biotechnology company is pleased to release its Appendix 4C Quarterly Report for the three-month period ending 31 March 2018, together with a review of activities and developments for the quarter.

On 20 February 2018, the Company was delighted to announce that it had received strong support from existing shareholders and a combination of new and existing institutional, professional and sophisticated which enabled it to close a significantly oversubscribed entitlement offer and placement, which raised \$7.55m.

Dimerix is now funded to further the Company's development plans and to take its lead compound, DMX-200 into a Phase 2 trial for focal segmental glomerulosclerosis (FSGS), an orphan disease which is the cause of nephrotic syndrome in children and adolescents, as well as a leading cause of kidney failure in adults. The funding will enable Dimerix to complete the steps required to develop commercial scale batches of DMX-200, and complete the remaining non-clinical studies to take DMX-200 to Phase 3 ready for FSGS.

Importantly, the Company is now in a strong position to continue its partnering discussions and exploit the full commercial potential for DMX-200 in diabetic nephropathy, and other pipeline opportunities.

Key activities and developments during the quarter are discussed in detail below:

#### **Chief Medical Officer appointed**

In late March, Dimerix was pleased to advise that Associate Professor David Packham had been appointed to the newly created role of Chief Medical Officer. Associate Professor Packham is a specialist clinician in the area of Chronic Kidney Disease (CKD), and was one of the Principal Investigators on Dimerix's successful Phase 2a trial in CKD, which reported results last year.

Through this new role, Associate Professor Packham will be responsible for the identification and engagement of clinical trial sites in Australia and will help to define patient populations, particularly with respect to the rare disease, FSGS. He will also be tasked with designing the phase 2 trials to maximise interest from patients and clinicians and leading communications with international key opinion leaders.

### **DMX-200 Phase 2 trials – in late planning stage**

Dimerix reported during the quarter that a series of activities were underway to prepare for the commencement of its Phase 2 trial in FSGS, and to take DMX-200 into a Phase 2b trial in diabetic nephropathy.

In consultation with its Medical Advisory Board and with input from external key opinion leaders, the Company is working through a review of past and current FSGS trials and the proposed protocol to ensure it is optimally structured to be attractive for patient recruitment, provide quality efficacy data and support partnering activities. Details of both study design is expected to be released in Q2 calendar 2018.

In parallel with trial design and protocol finalisation, selection of a contract research organisation (CRO) and trial sites are progressing. The Company is now in the late stages of quoting and negotiations with potential CROs. Identification of both the lead site and a number of additional sites for both the FSGS and diabetic nephropathy studies is underway. Site engagement will be closely followed by ethics committee submissions, under which Dimerix will seek approval to commence the trial.

### **Pharmacokinetic data being analysed from increased dose formulation**

In January, Dimerix announced top line data from its recent pharmacokinetic (PK) study of an extended release tablet formulation for the DMX-200 program.

The study found a newly formulated extended release tablet of DMX-200 increased the duration of release of DMX-200 in the human body, making it suitable for twice daily dosing.

Taking two instead of three tablets daily is expected to support compliance rates from patients both in the Company's upcoming Phase 2 trials and also for the marketed product, once commercially available. The extended release product also offers further intellectual property protection for DMX-200.

Dosing data from the PK study is currently being analysed by pharmacometric specialists to finalise the dosing for the Phase 2b clinical trials.

### **Manufacturer identified for commercial-scale product**

In line with activities necessary to prepare DMX-200 to be commercially ready, Dimerix has identified a third party manufacturer, who can produce the compound at commercial scale. The Company is in late stage contract negotiations with the manufacturer and expects to execute an agreement shortly. This activity is important for potential pharmaceutical partners, the filing of an Investigational New Drug Application (IND) and to prepare DMX-200 for eventual registration with the US FDA.

## **Investor and partnering discussions**

In January 2018, Chairman, Dr James Williams and CEO, Kathy Harrison attended JP Morgan Healthcare week in San Francisco. During the trip, significant meetings were held with potential partners, including in follow up to initial partnering meetings that took place at Bio Europe in late 2017 and the American Society of Nephrology's kidney week conference. Partnering discussions are ongoing.

During the quarter, a high degree of investor-focused activity took place to promote the availability of DXB stock through Dimerix's entitlement offer. Together with an active retail shareholder outreach campaign, CEO Kathy Harrison and now CMO, Associate Professor David Packham presented to briefing sessions with nephrologists and high net worth investors in Brisbane and on the Gold Coast. These meetings, and other roadshow meetings across the country, led to Dimerix being able to successfully close its entitlement offer and placement in late February 2018.

## **Funding activities and cash position**

Following the strong support from investors in the Company's oversubscribed placement and entitlement offer which closed in February 2018, Dimerix finished the March quarter with \$7.7m in cash.

Current estimated outflows for the June quarter stand at around \$1.68m, with major costs expected to be associated with the start-up of the Phase 2 trials, and CMC manufacturing.

## **Share sale facility initiative for shareholders with "unmarketable parcels"**

On 9 March, Dimerix advised shareholders who held shares valued at less than \$500 as at close of trade on 8 March, that a facility had been established through which those shareholders could opt to sell their shares, without the need to pay brokerage fees or other expenses (aside from any tax expenses, related to the individual shareholder's situation.)

Shareholders were advised that unless they advised the Company that they did not wish to sell their shares by 5:00pm on 26 April 2018, the Company would sell their shares through the facility in accordance with Clause 2.6 and Schedule 4 of the Company's Constitution and the ASX Listing Rules. During the campaign period, shareholders could also elect to combine separate parcels of shares or top up their holding to a marketable level.

For more information on the initiative, which concluded at COB 26 April, please see our announcement dated 9 March, entitled "*Sale of your Unmarketable Parcel of Dimerix Limited Shares*".

## **Looking forward**

The next quarter is set to be one of significant progress with the commencement of clinical trials and the start-up of manufacturing activities in the USA. With the funding secured to execute on the DMX-200 program, we look forward to sharing significant updates over the next quarter.

For further information, please visit our website at [www.dimerix.com](http://www.dimerix.com) or contact the individuals outlined below.

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For more information please contact:

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**About Dimerix Bioscience Pty Ltd**

Dimerix Limited's (ASX: DXB) wholly owned subsidiary Dimerix Bioscience Pty Ltd is a clinical-stage pharmaceutical company committed to discovering and developing new therapeutic models identified using its proprietary assay, termed Receptor-Heteromer Investigation Technology (Receptor-HIT). This assay enables the identification of pairs of receptors that function in a joint manner (interact) when ligands, small molecule drugs, peptides or antibodies, bind to them.

The Receptor-HIT technology was used to identify DMX-200 in an internal drug development program, initially for the treatment of a subset of patients with chronic kidney disease.

For more information see [www.dimerix.com](http://www.dimerix.com)

**About the DMX-200 program**

DMX-200, which successfully completed a Phase 2a clinical trial in humans, is being developed as an adjunct therapy, adding propagermanium to a stable dose of irbesartan. Irbesartan is an off-patent angiotensin II type I receptor blocker indicated for the treatment of hypertension and nephropathy in Type II diabetic patients. Propagermanium (PPG) is a chemokine receptor (CCR2) blocker, which has been used for the treatment of Hepatitis B in Japan and is available in the USA for its anti-inflammatory properties. DMX-200 has been shown to improve the outcome of chronic kidney disease by reducing proteinuria by more than 50 per cent in animal models <sup>(1)</sup>.

Dimerix released the results of its Phase 2a clinical trial in humans for DMX-200 in July 2017. The trial met its primary endpoint of safety and tolerability in the participating patient group, which included patients with diabetic nephropathy (10), IgA nephropathy (6), and other proteinuric diseases (11). As a secondary endpoint, DMX-200 was shown to reduce levels of proteinuria in a number of patients. This was deemed a "clinically meaningful" result by leading clinicians. Sub set analysis released in November 2017 showed both a statistically significant and clinically meaningful reduction in proteinuria in the diabetic nephropathy cohort of patients

Dimerix intends to take DMX-200 into clinical trials to test efficacy in calendar 2018 starting with its lead program in focal segmental glomerulosclerosis (FSGS), for which it has orphan drug designation in the US. Dimerix plans to take DMX-200 for diabetic nephropathy (DN) into a Phase 2b trial in H2 calendar 2018 or early calendar 2019.

**About Chronic Kidney Disease**

Chronic Kidney Disease (CKD) is a disorder in which patients show progressive loss of renal function usually accompanied by excess protein in the urine (proteinuria). Levels of proteinuria predict rate of decline of renal function (higher levels = more rapid decline). In part this is believed to reflect direct toxicity, or damage, to the kidneys by proteinuria itself. This establishes a cycle of worsening renal function leading in turn to increasing proteinuria and further kidney damage. Many CKD patients progress to a need for renal replacement therapy or dialysis and / or experience excessive morbidity and mortality from cardiovascular-related diseases.

The prevalence of CKD is rising and as such there is urgent need for treatments that can benefit CKD patients, including reducing proteinuria. In most cases of CKD residual proteinuria continues even with optimal use of existing therapies. Accordingly, therapies designed to further reduce, or abolish, proteinuria, are eagerly sought.

The rationale behind the DMX-200 program is to provide patients with a therapy that can reduce proteinuria in addition to that achieved with standard best therapy. The unmet need of CKD patients is reinforced by Dimerix's Orphan Drug Designation.

<sup>(1)</sup> Functional interaction between angiotensin II receptor type 1 and chemokine (C-C motif) receptor 2 with implications for chronic kidney disease. Ayoub MA, Zhang Y, Kelly RS, See HB, Johnstone EK, McCall EA, Williams JH, Kelly DJ, Pflieger KD. PLoS One. 2015 Mar 25;10(3):e0119803. doi: 10.1371/journal.pone.0119803.

## Appendix 4C

+Rule 4.7B

### Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

**Name of entity**

**DIMERIX LIMITED**

**ABN**

**18 001 285 230**

**Quarter ended ("current quarter")**

**31/03/2018**

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
<b>1.0 Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(231)	(1,109)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(122)	(394)
(f) administration and corporate costs	(247)	(846)
1.3 Dividends received (see note 3)		
1.4 Interest received	6	13
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	-	546
1.8 Other (provide details if material)		
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(594)</b>	<b>(1,790)</b>
<b>2.0 Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment		
(b) businesses (see item 10)		
(c) investments		
(d) intellectual property		
(e) other non-current assets		
2.2 Proceeds from disposal of:		
(a) property, plant and equipment		
(b) businesses (see item 10)		
(c) investments		
(d) intellectual property		
(e) other non-current assets		
2.3 Cash flows from loans to other entities		

2.4	Dividends received (see note 3)		
2.5	Other (provide details if material)		
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	-	-

<b>3.0</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of shares	7,556	7,618
3.2	Proceeds from issue of convertible notes		
3.3	Proceeds from exercise of share options		
3.4	Transaction costs related to issues of shares, convertible notes or options	(371)	(371)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>7,185</b>	<b>7,247</b>

<b>4.0</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter/year to date	1,111	2,245
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(594)	(1,790)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,185	7,247
4.5	Effect of movement in exchange rates on cash held		
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>7,702</b>	<b>7,702</b>

<b>5.0</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter</b>	<b>Previous quarter</b>
		<b>\$A'000</b>	<b>\$A'000</b>
5.1	Bank balances	17	32
5.2	Call deposits	7,685	1,079
5.3	Bank overdrafts		
5.4	Other (provide details)		
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>7,702</b>	<b>1,111</b>

**6.0 Payments to directors of the entity and their associates**

Current quarter  
\$A'000

6.1 Aggregate amount of payments to these parties included in item 1.2

61

6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Payments represent director's fees.

**7.0 Payments to related entities of the entity and their associates**

Current quarter \$A'000

7.1 Aggregate amount of payments to these parties included in item 1.2

7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

**8.0 Financing** facilities available  
*Add notes as necessary for an understanding of the position*

Total facility amount at quarter end	Amount drawn at quarter end
\$A'000	\$A'000

8.1 Loan facilities

8.2 Credit standby arrangements

8.3 Other (please specify)

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

**9.0 Estimated cash outflows for next quarter**

\$A'000

9.1 Research and development

(1,056)

9.2 Product manufacturing and operating costs

9.3 Advertising and marketing

9.4 Leased assets

9.5 Staff costs

(171)

9.6 Administration and corporate costs

(452)

9.7 Other (provide details if material)

**9.8 Total estimated cash outflows**

**(1,679)**

10.0	<b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	Acquisitions	Disposals
10.1	Name of entity		
10.2	Place of incorporation or registration		
10.3	Consideration for acquisition or disposal		
10.4	Total net assets		
10.5	Nature of business		

**Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Sign here:



Company secretary/ Director

Date: 27 April 2018

Print name:

**Notes**

- 1 The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- 2 If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3 Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.