

**31 October 2017**

**ASX Announcement**

**QUARTERLY REVIEW – Q1 FY2018**

**Quarter highlights**

- Lead program DMX-200 met the primary endpoint (safety & tolerability) in our Phase 2a trial for Chronic Kidney Disease (CKD), with encouraging efficacy data
- Efficacy data warrants move to Phase 2b trial for DMX-200, with preparations already underway and recruitment expected to commence in Q1 calendar 2018
- Commenced manufacture of the extended release DMX-200 tablet, a more commercially attractive form of DMX-200
- Completed preparations for the pharmacokinetic (PK) trial for DMX-200, including filing applications for ethics approval to commence the trial (approval given post quarter end).
- Medical Advisory Board (MAD) appointed to guide the DMX-200 clinical program (post quarter end)
- Share consolidation (1:20) effective post quarter end in October
- Equity research coverage initiated by Baker Young, post quarter end
- Cash position boosted by a \$545k R&D tax rebate received post quarter end.

MELBOURNE, Australia, 31st October 2017: Dimerix Limited (ASX: DXB), is pleased to release its Appendix 4C Report for the three-month period ending 30 September 2017 and to provide a review of progress made during the quarter (Q1 FY2018).

**Summary of key developments**

In July 2017, Dimerix delivered top-line results for our Phase 2a clinical trial of DMX-200 in Chronic Kidney Disease (CKD). The primary endpoint (safety & tolerability) was met, and “clinically meaningful” efficacy data was achieved (a secondary endpoint), warranting further investigation, which will be in the form of a Phase 2b trial for DMX-200 to begin in late calendar 2017.

Preparations for the Phase 2b trial of DMX-200 are already underway. An extended release tablet of DMX-200 has been manufactured in readiness for use in the company’s pharmacokinetic (PK) study of DMX-200, and which will also be used in Phase 2b trials. A world class Medical Advisory Board (MAB) of kidney specialists was also been assembled post quarter end.

On the financial front, we announced a 1:20 share consolidation which came into effect post quarter end.

**Financial update**

Dimerix retained \$1.58m cash as at September 30, 2017, with a further \$545k added to this position in the form of an R&D tax rebate received post quarter end in early October.

Cash outflows were \$0.67m, during a busy period with expenditure related to a combination of close out and analysis activities for the Phase 2a trial, manufacturing the extended release tablet for the Pharmacokinetic (PK) and Phase 2b trial, start-up activities for the Pharmacokinetic (PK) trial (including preparing ethics applications) and preparation and design of our Phase 2b trial.

The Company estimates outgoings of ~\$0.80m over the coming quarter, October to December 2017.

**Operations update**

In July, we announced the top-line results of our Phase 2a study into CKD with our lead program, DMX-200. In summary:

- The trial achieved its primary endpoint (safety & tolerability)
- Clinically meaningful efficacy data was achieved (secondary endpoint), with 25% (or 6 of the 24 patients) of the trial participants achieving a 50% or more reduction in proteinuria over and above the current standard of care. Proteinuria is the most common symptom of CKD and a strong indicator of future kidney deterioration
- 45% of trial participants applied for and were granted Special Access to the program post the trials completion and continue to be administered with DMX-200
- Trial expected to being later this year and patient recruitment in Q1 calendar 2018.

Preparations are now underway for a Phase 2b trial which is expected to be a placebo controlled efficacy study, targeting three sub-groups of kidney disease: FSGS, diabetic nephropathy and IgA nephropathy.

The manufacture of extended release DMX-200 tablets will shortly be complete for use in the PK study and the Phase 2b trial. This will result in patients taking two tablets daily rather than three. Extended release tablets provide both additional intellectual property around the dosage form, and are also more commercially attractive in part due to anticipated increased patient compliance by removing the requirement to take a dose in the middle of the day.

New data will be presented at the American Society of Nephrology's (ASN) annual kidney week on the 2<sup>nd</sup> of November in New Orleans. The conference will be attended by over 13,000 kidney specialists globally. Dimerix has been granted a coveted Poster position at the event. This event is an opportunity to provide detailed insights into patient sub-group responses from the Phase 2a trial of DMX-200, which are guiding the Phase 2b clinical trial design.

### **Medical Advisory Board**

A Medical Advisory Board (MAB) was appointed post quarter end to provide clinical and strategic input into the Company's DMX-200 clinical trial program. The MAB consists of respected kidney experts (nephrologists) and will be led by Associate Professor David Packham as Chair.

The MAB has already provided invaluable input into the design of the upcoming Phase 2b trial for DMX-200.

### **Share consolidation**

A 1:20 share consolidation was announced in September, which took effect in late October, in order to increase the attraction to longer term institutional holders.

### **Equity research**

Baker Young Stockbroking initiated equity research coverage on Dimerix in October, post quarter end.

To read the report, visit the Dimerix website using the following link:

<http://dimerix.com/baker-young/>

### **Looking forward**

Activities in the December quarter will be centered around completing the pharmacokinetic (PK) trial and using these data to finalise preparations for our Phase 2b efficacy trial, due to commence patient recruitment in Q1CY18.

Along with the presentation at ASN's kidney week, we also have a Company Spotlight Presentation scheduled at Bio Europe in Berlin at 4:45pm on the 7<sup>th</sup> of November. BioEurope is one of the world premier partnering events for Biotech and Pharmaceutical companies, including three days of dedicated meetings scheduled to enable continued discussions with interested parties in DMX-200.

The business is well positioned to continue to make clinical and commercial progress in its lead program, DMX-200, and Dimerix is grateful for the ongoing support of our shareholders.

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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. In addition to its own therapeutic programs, the company also earns revenue by providing this technology to global pharmaceutical companies.

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. Preparations for a Phase 2b trial are underway which will test for efficacy and is expected to start by the end of calendar 2017.

### **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")**

**30/09/2017**

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date months) \$A'000</b> <sup>(3)</sup>
<b>1.0 Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(219)	(219)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(160)	(160)
(f) administration and corporate costs	(293)	(293)
1.3 Dividends received (see note 3)		
1.4 Interest received	3	3
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives		
1.8 Other (provide details if material)		
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(669)</b>	<b>(669)</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		
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		
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>3.1</b>	<b>Net cash from / (used in) financing activities</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	2,245	2,245
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(669)	(669)
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)	-	-
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>1,576</b>	<b>1,576</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>\$A'000</b>	<b>Previous quarter</b> <b>\$A'000</b>
5.1	Bank balances	26	28
5.2	Call deposits	1,550	2,217
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>1,576</b>	<b>2,245</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

57

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

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**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

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**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.

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**9.0 Estimated cash outflows for next quarter**

\$A'000

9.1 Research and development

(450)

9.2 Product manufacturing and operating costs

9.3 Advertising and marketing

9.4 Leased assets

9.5 Staff costs

(94)

9.6 Administration and corporate costs

(265)

9.7 Other (provide details if material)

**9.8 Total estimated cash outflows**

**(809)**

9.0 Estimated cash outflows for next quarter		\$A'000
9.1	Research and development	(450)
9.2	Product manufacturing and operating costs	
9.3	Advertising and marketing	
9.4	Leased assets	
9.5	Staff costs	(94)
9.6	Administration and corporate costs	(265)
9.7	Other (provide details if material)	
<b>9.8</b>	<b>Total estimated cash outflows</b>	<b>(809)</b>

<b>10.0</b>	<b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	<b>Acquisitions</b>	<b>Disposals</b>
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: 31 October 2017

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.