

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights

- Dimerix received Innovation Passport and Innovative Licensing and Access Pathway Designation in UK in June 2021
- Dimerix confirmed Phase 3 FSGS study design with EMA in June 2021
- DMX-200 confirmed it remains eligible for Accelerated Approval in US in May 2021
- DMX-200 study update in COVID-19 patients in India in May 2021
- COVID-19 study recruited multiple patients in Europe in April 2021
- Cash position of \$5.3 million at 30 June 2021
- Net operating cash flow for the June quarter was -\$3.2 million
- Net operating cash flow for 2021 financial year was -\$6.5 million

MELBOURNE, Australia, 27 July 2021: Dimerix Limited (ASX: DXB) (“Dimerix” or the “Company”), a clinical-stage biopharmaceutical company, today announced its Appendix 4C and Quarterly Activities Report for the period ended 30 June 2021. During the quarter, Dimerix made significant operational progress, in line with the strategic plan.

Dimerix ended the quarter with cash of \$5.3 million (\$8.5 million at 31 March 2021), with net operating cash outflows for the period of \$3.2 million, which was in line with company expectations (\$1.4 million net operating cash inflows in the prior quarter). The increase in total operating cash outflow for the quarter relative to the prior period is a result of increased clinical and manufacturing expenditure. Additionally, Dimerix received \$0.2m in grant funding from the Biomedical Translation Bridge (BTB) program (\$0.5m in prior period).

Dimerix is focused on building shareholder value by advancing clinical trials to provide treatments globally for patients with serious and life-threatening diseases, with two Phase 3 clinical trials in COVID-19 patients underway and one Phase 3 clinical study in FSGS expected to commence mid-2021. Whilst increasing R&D spend significantly versus previous year, overheads remain steady and the Company finished the year under budget. Cost management remains a key priority for the business, with the cost base being carefully managed to ensure delivery of a sustainable business beyond the current milestones.

Dimerix is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs

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In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C incorporates directors' fees, salaries and superannuation.

Dimerix has multiple assets in commercially attractive and growing markets that have a high unmet need, and with no current marketed competition, and with a potential fast pathway to market. Dimerix continues to undertake planning for the proposed Phase 3 pivotal program in FSGS, a rare kidney disorder without an approved pharmacologic treatment that often leads to end-stage kidney failure, as well as further progress the diabetic kidney disease, COVID-19 and COPD programs.

For further information, please visit our website at www.dimerix.com or contact:

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Authorised for lodgement by the Board of the Company

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About Dimerix

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product, DMX-200, for Diabetic Kidney Disease, Focal Segmental Glomerulosclerosis (FSGS) and Acute Respiratory Distress Syndrome (ARDS), and is developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-200 and DMX-700 were both identified using Dimerix' proprietary assay, Receptor Heteromer Investigation Technology (Receptor-HIT), which is a scalable and globally applicable technology platform enabling the understanding of receptor interactions to rapidly screen and identify new drug opportunities. 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.

About DMX-200

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

In 2017, Dimerix completed its first Phase 2a study in patients with a range of chronic kidney diseases. No significant adverse safety events were reported, and all study endpoints were achieved. The compelling results from this study prompted the decision to initiate 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). DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

Respiratory Complications associated with COVID-19

Patients hospitalised with COVID-19 typically have acute lung dysfunction due to the human immune response to the virus. However, while the long-term effects on the lung from COVID-19 remain largely unknown, it is widely accepted that COVID-19 will result in acute injury in the same way as previous coronavirus infections such as SARS and MERS. As such, it is likely to result in chronic lung fibrosis in many patients, leading to poor quality of life, high ongoing hospitalisation requirements and ultimately a poor prognosis.

Globally, and prior to COVID-19, ARDS affected more than 3 million people a year in 2019 accounting for 10-15% of intensive care unit admissions, and approximately 200 000 patients each year in the United States. The market size of Acute Respiratory Distress Syndrome (ARDS) in the seven major markets was US\$917.81 million in 2017. This has grown significantly because of the 2020 pandemic. The death rate associated with ARDS is high, with overall mortality between 30 and 40%. The estimated average costs of treatment in an ICU unit with artificial ventilation total approximately US\$100,000 per patient, with the average length of stay in ICU as a result of ARDS being 25 days, and the average length of hospitalisation being approximately 47 days. However, there are also significant costs associated with additional post-discharge treatment. There is no known prevention of ARDS currently available, nor is there any known cure.

FSGS

FSGS is a rare disease that attacks the kidney's filtering units, where blood is cleaned (called the 'glomeruli'), causing irreversible scarring. This leads to permanent kidney damage and eventual end-stage failure of the organ, requiring dialysis or transplantation. For those diagnosed with FSGS the prognosis is not good. The average time from a diagnosis of FSGS to the onset of complete kidney failure is only five years and it affects both adults and children as young as two years old. For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney. At this time, there are no drugs approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000, and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. This is a special status granted to a drug to treat a rare disease or condition; the designation means that DMX-200 can potentially be fast-tracked, and receive tax and other concessions to help it get to market.

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.

Dimerix reported positive Phase 2a data in FSGS patients in July 2020 and has progressed into a global Phase 3 program in 2021 following clear and consistent guidance from both FDA and EMA.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

DIMERIX LIMITED

ABN

18 001 285 230

Quarter ended ("current quarter")

30/06/2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(2,906)	(8,324)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(115)	(501)
(f) administration and corporate costs	(338)	(785)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	2
1.5 Interest and other costs of finance paid	(103)	(103)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	218	3,253
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(3,244)	(6,458)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(4)	(10)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	14
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(4)	4

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	46
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	5,000
3.6	Repayment of borrowings	-	(1,073)
3.7	Transaction costs related to loans and borrowings	-	(8)
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(13)	(43)
3.10	Net cash from / (used in) financing activities	(13)	3,922

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,510	7,786
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,244)	(6,458)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	4

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(13)	3,922
4.5	Effect of movement in exchange rates on cash held	1	(4)
4.6	Cash and cash equivalents at end of period	5,250	5,250

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	359	1,363
5.2	Call deposits	4891	7,147
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	5,250	8,510

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	143
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	5,000	5,000
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	Total financing facilities	5,000	5,000
7.5	Unused financing facilities available at quarter end		
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well. The loan facility is with major shareholder, Mr Peter Meurs. The loan facility is unsecured and accrues interest at a rate of 1% per month. Repayment date is the earlier of 31 December 2021, or in the event of a funding event such as a capital raise or other transaction exceeding \$10 million, or receipt of R&D rebate exceeding \$5 million. The facility has been in place since 30 March 2021.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,244)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,250
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	5,250
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.6
	<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	Answer: Future net operating cash flows is expected to be consistent with current levels of net operating cash flows.	
8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
	Answer: The Company is in the process of finalising its FY2021 R&D Tax Incentive application, which has been successfully granted in prior years. In addition, The Board continues to evaluate its capital requirements and options and is confident that it will be able to raise additional capital as required.	

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Yes, The Company expects to continue operations and meet its business objectives and continue to maintain eligibility for non-dilutive funding through the R&D Tax Incentive scheme, as well as evaluate its capital requirements and options.

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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.

Date: 27.07.2021

Authorised by: Board of Directors
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.