

# **DIMERIX QUARTERLY ACTIVITIES REPORT**

# **Quarter highlights**

- REMAP-CAP Phase 3 clinical study in patients with COVID-19 progresses
- DMX-200 FSGS competitive position further enhanced
- CLARITY 2.0 Phase 3 clinical study progresses in patients with COVID-19
- Dimerix plans for next study in Diabetic Kidney Disease
- Major Shareholder loan for \$5 Million
- Cash position of \$8.5 million at 31 March 2021 (\$4.9 million at 31 December 2020)

MELBOURNE, Australia, 08 April 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 31 March 2021. During the quarter, Dimerix made significant operational progress, in line with the strategic plan.

Dimerix ended the quarter with cash of \$8.5 million (\$4.9 million at 31 December 2020), with net operating cash outflows for the period of \$1.4 million, which was in line with company expectations (\$0.7 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 and the receipt in the prior quarter of the R&D Tax Incentive rebate for the 2019/2020 financial year (\$2.3 million).

The company's cash position was significantly bolstered with a A\$5M loan received from a major shareholder, which provides sufficient funding for Dimerix to progress current initiatives, in particular the FSGS Phase 3 program activities, and contributing to a total net cash inflow for the quarter of \$3.6 million.

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. 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.

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 is a biopharmaceutical company developing innovative new therapies in areas with unmet medical needs Dimerix HQ 425 Smith St, Fitzroy 3065 Victoria, Australia T. 1300 813 321 E. investor@dimerix.com 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), as well as 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. In a subsequent sub-group analysis, significant clinical efficacy signals were seen in the diabetic group. DMX-200 administered to patients already taking stable 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. 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.

It is estimated that 40% of people with diabetes have kidney disease and many may not know it yet. With the incidence of diabetes growing so rapidly globally, so too will the incidence of kidney disease. This is a rapidly growing market, with few treatment options at this time. Dimerix reported statistically and clinically significant outcomes in a Phase 2 study in diabetic kidney disease patients in September 2020.

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. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

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.

#### About DMX-700

COPD is a progressive and life-threatening lung disease. The most common cause of COPD is exposure to tobacco smoke (either active smoking or secondary smoke), however it is also caused by exposure to indoor and outdoor air pollution, occupational dusts and fumes and long-term asthma. COPD is the fourth-leading cause of death in the world and although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it. Moreover, among the top five causes of death globally, this disease is the only one with increasing mortality rates. The global COPD treatment market was valued at US\$14 billion in 2017 and is projected to increase at a compound annual growth rate of 4.9% to 2026.

Initial studies have been completed, and Dimerix has completed a key step in securing ownership over what it believes is an important new drug discovery by lodging a PCT patent application for DMX-700. Dimerix DMX-700 development plan continues to progress towards the clinical phase, with some further in vivo assessment in an appropriate COPD model to confirm target engagement, pharmacokinetics and pharmacodynamics in support of a robust product development pathway and patent position.

# Appendix 4C

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

| Name of entity  |                                   |  |  |
|-----------------|-----------------------------------|--|--|
| DIMERIX LIMITED |                                   |  |  |
| ABN             | Quarter ended ("current quarter") |  |  |
|                 |                                   |  |  |

| Consolidated statement of cash flows |  | Current quarter<br>\$A'000 | Year to date (9<br>months)<br>\$A'000 |  |
|--------------------------------------|--|----------------------------|---------------------------------------|--|
| 1.                                   | Cash flows from operating activities           |                            |                                       |  |
| 1.1                                  | Receipts from customers                        | -                          | -                                     |  |
| 1.2                                  | Payments for                                   |                            |                                       |  |
|                                      | (a) research and development                   | (1,669)                    | (5,418)                               |  |
|                                      | (b) product manufacturing and operating costs  | -                          | -                                     |  |
|                                      | (c) advertising and marketing                  | -                          | -                                     |  |
|                                      | (d) leased assets                              | -                          | -                                     |  |
|                                      | (e) staff costs                                | (114)                      | (386)                                 |  |
|                                      | (f) administration and corporate costs         | (168)                      | (447)                                 |  |
| 1.3                                  | Dividends received (see note 3)                | -                          | -                                     |  |
| 1.4                                  | Interest received                              | -                          | 2                                     |  |
| 1.5                                  | Interest and other costs of finance paid       | -                          | -                                     |  |
| 1.6                                  | Income taxes paid                              | -                          | -                                     |  |
| 1.7                                  | Government grants and tax incentives           | 580                        | 3,035                                 |  |
| 1.8                                  | Other (provide details if material)            | -                          | -                                     |  |
| 1.9                                  | Net cash from / (used in) operating activities | (1,371)                    | (3,214)                               |  |

| 2.  | Cash flows from investing activitie | es |     |
|-----|-------------------------------------|----|-----|
| 2.1 | Payments to acquire or for:         |    |     |
|     | (a) entities                        | -  | -   |
|     | (b) businesses                      | -  | -   |
|     | (c) property, plant and equipment   | -  | (6) |
|     | (d) investments                     | -  | -   |
|     | (e) intellectual property           | -  | -   |
|     | (f) other non-current assets        | -  | -   |

| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date (9<br>months)<br>\$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 | -                          | 8                                     |

| 3.   | Cash flows from financing activities  |       |         |
|------|---|-------|---------|
| 3.1  | Proceeds from issues of equity securities (excluding convertible debt securities)             | 23    | 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<br>equity securities or convertible debt<br>securities | -     | -       |
| 3.5  | Proceeds from borrowings  | 5,000 | 5,000   |
| 3.6  | Repayment of borrowings   | -     | (1,073) |
| 3.7  | Transaction costs related to loans and<br>borrowings  | (8)   | (8)     |
| 3.8  | Dividends paid  | -     | -       |
| 3.9  | Other (provide details if material)   | (11)  | (30)    |
| 3.10 | Net cash from / (used in) financing activities  | 5,004 | 3,935   |

| 4.  | Net increase / (decrease) in cash and cash equivalents for the period |         |         |
|-----|---|---------|---------|
| 4.1 | Cash and cash equivalents at beginning of period                      | 4,876   | 7,786   |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above)       | (1,371) | (3,214) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above)       | -       | 8       |

| Consolidated statement of cash flows |  | Current quarter<br>\$A'000 | Year to date (9<br>months)<br>\$A'000 |
|--------------------------------------|--|----------------------------|---------------------------------------|
| 4.4                                  | Net cash from / (used in) financing activities (item 3.10 above) | 5,004                      | 3,935                                 |
| 4.5                                  | Effect of movement in exchange rates on cash held                | 1                          | (5)                                   |
| 4.6                                  | Cash and cash equivalents at end of period                       | 8,510                      | 8,510                                 |

| 5.  | Reconciliation of cash and cash<br>equivalents<br>at the end of the quarter (as shown in the<br>consolidated statement of cash flows) to the<br>related items in the accounts | Current quarter<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances   | 1,363                      | 24                          |
| 5.2 | Call deposits   | 7,147                      | 4,852                       |
| 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)   | 8,510                      | 4,876                       |

| 6.  | Payments to related parties of the entity and their associates  | Current quarter<br>\$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                               | -                          |
|     | if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ<br>ation for, such payments. | e a description of, and an |

7.

7.1

7.2

7.3

7.4

7.5

| <b>Financing facilities</b><br>Note: the term "facility' includes all forms of financing<br>arrangements available to the entity.<br>Add notes as necessary for an understanding of the<br>sources of finance available to the entity. | Total facility<br>amount at quarter<br>end<br>\$A'000 | Amount drawn at<br>quarter end<br>\$A'000 |
|--|---|---|
| Loan facilities  | 5,000   | 5,000                                     |
| Credit standby arrangements  |   |   |
| Other (please specify)   |   |   |
| Total financing facilities   | 5,000   | 5,000                                     |
| Unused financing facilities available at qu  | uarter end  |   |
| Include in the box below a description of eac  | ,   |   |

7.6 Incl 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.  | Estim           | nated cash available for future operating activities  | \$A'000                    |
|-----|-----------------|---|----------------------------|
| 8.1 | Net ca          | sh from / (used in) operating activities (item 1.9)   | (1,371)                    |
| 8.2 | Cash a          | and cash equivalents at quarter end (item 4.6)  | 8,510                      |
| 8.3 | Unuse           | ed finance facilities available at quarter end (item 7.5)   |                            |
| 8.4 | Total a         | available funding (item 8.2 + item 8.3)   | 8,510                      |
| 8.5 | Estim<br>item 8 | ated quarters of funding available (item 8.4 divided by 6.1)  | 6.2                        |
|     |                 | the entity has reported positive net operating cash flows in item 1.9, answer item<br>or the estimated quarters of funding available must be included in item 8.5.            | 8.5 as "N/A". Otherwise, a |
| 8.6 | If item         | 8.5 is less than 2 quarters, please provide answers to the follow   | ing questions:             |
|     | 8.6.1           | Does the entity expect that it will continue to have the current le cash flows for the time being and, if not, why not?   | evel of net operating      |
|     | Answe           | er:   |                            |
|     | 8.6.2           | Has the entity taken any steps, or does it propose to take any s<br>cash to fund its operations and, if so, what are those steps and<br>believe that they will be successful? |                            |
|     | Answe           | er:   |                            |

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:

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.
  - This statement gives a true and fair view of the matters disclosed.

# 08.04.2021

Date:

## Board of Directors

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

### Notes

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- 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.