

# **DIMERIX QUARTERLY ACTIVITIES REPORT**

# Quarter highlights and operational activities

- Dimerix announced a license agreement for DMX-200 with Amicus Therapeutics for DMX-200 in the United States<sup>1</sup>
  - Dimerix to receive up to U\$\$590 million (~AU\$940² million) in upfront, development and sales milestone payments, plus royalties
  - Received U\$\$30 million (~AU\$48 million) on execution in May 2025<sup>3</sup>
    - up to US\$75 million (~AU\$119 million²) in potential development milestones
    - US\$35 million (~AU\$56 million²) on first sale of DMX-200
    - up to \$410 million (~AU\$653 million²) in potential sales milestones
    - US\$40 million (~AU\$64 million²) in potential future indications milestone
    - Tiered low-teen to low-twenties royalties on net sales
- The license agreement with Amicus was the fourth deal executed for DMX-200<sup>1</sup> following the license deals with Advanz Pharma (announced October 2023)<sup>4</sup>, Taiba (announced May 2024)<sup>5</sup>, and Fuso (announced 7 January 2025)<sup>6</sup>
  - Collectively the license deals provide up to ~AU\$1.4 billion<sup>7</sup> in total upfront payments and potential milestone payments, plus royalties on net sales
  - Over AU\$65 million in total payments received to date<sup>7</sup>
- Dimerix received 1st Development Milestone payment of AU\$4.2 million before tax from FUSO<sup>8</sup> following activation of 1st ACTION3 site in Japan<sup>9</sup>
- 6<sup>th</sup> successful Independent Data Monitoring Committee (IDMC) review of ACTION3 complete<sup>10</sup>
- FDA confirmed Proteinuria as acceptable Primary Endpoint for US approval<sup>11</sup>
- 219 patients have currently been randomised/dosed in the ACTION3 Phase 3 clinical trial<sup>12</sup>
- Strong Cash position of AU\$68.3 million at 30 June 2025
- Net operating cash inflows for the June quarter was AU\$45.6 million
- Dimerix continues to focus on patient recruitment into the ACTION3 Phase 3 clinical trial, as well as licensing opportunities with potential partners in territories not already licensed

MELBOURNE, Australia, 25 July 2025: Dimerix Limited (ASX: DXB) ("Dimerix" or the "Company"), a biopharmaceutical company with a Phase 3 clinical asset in kidney disease, today announced its Appendix 4C and Quarterly Activities Report for the period ended 30 June 2025.

During the quarter Dimerix entered into an exclusive licensing agreement with its new commercial partner, Amicus Therapeutics,<sup>1</sup> and received the upfront payment from the deal of US\$30 million (~AU\$48 million<sup>2</sup>).<sup>3</sup> The license agreement with Amicus was the fourth deal executed for DMX-200<sup>1</sup> following the license deals with Advanz Pharma (announced October 2023),<sup>4</sup> Taiba (announced May 2024)<sup>5</sup>, and Fuso (announced 7 January 2025)<sup>6</sup>. Collectively the license deals provide up to ~AU\$1.4 billion<sup>7</sup> in total upfront payments and potential milestone payments, plus royalties on net sales, with over \$65 million in total payments already being received.<sup>1</sup>

In parallel, Dimerix continued to make significant progress with its lead program, ACTION3 Phase 3 clinical trial in focal segmental glomerulosclerosis (FSGS), including a positive Type C meeting with the US Food and Drug Administration (FDA)<sup>11</sup> which confirmed the acceptability of proteinuria as an appropriate endpoint for full (or traditional) marketing approval in the United States (US) for DMX-200 in Focal Segmental Glomerular Sclerosis (FSGS).<sup>11</sup>

Dimerix ended the quarter with cash of \$68.3 million (\$17.0 million at 31 March 2025), with net operating cash inflows for the period of \$45.6 million. It is anticipated that the next quarter will include one-off costs associated with the US licensing transaction and Clinical Research Organisation milestone payments (see more on this further below). Dimerix is in a strong cash position and is well funded to continue its ACTION3 Phase 3 clinical trial. The Company also continues to assess what it may apply any excess capital towards which may include new spend on the Company's Research and Development pipeline.

During the quarter, Dimerix received the following licensing related milestone payments:

- ~AU\$48 million<sup>2</sup> upfront milestone payment from Amicus Therapeutics in relation to the exclusive license agreement for the commercialisation of Dimerix's Phase 3 drug candidate DMX-200 for all indications, including FSGS, in the United States; and
- ~AU\$4.2 million (before tax) first development milestone payment from FUSO Pharmaceutical Industries Ltd in relation to the exclusive licensee of DMX-200 for FSGS in Japan.

Additionally, during the quarter, Dimerix received approximately AU\$6.0 million in relation to the exercise of listed options which expired 30 June 2025).

Cash outflow for the period predominately related to Clinical and CMC costs associated with the Phase 3 FSGS Study.

#### **ACTION3 Phase 3 study**

Dimerix remains focussed on developing its lead Phase 3 product candidate DMX-200 (QYTOVRA® in some territories). In March 2024, Dimerix announced that the ACTION3 Phase 3 trial of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) was successful in the pre-specified interim analysis of the proteinuria (efficacy) endpoint from the trial's first 72 randomised patients. The analysis indicated that, using a statistical measure, DMX-200 was performing better than placebo in terms of reducing proteinuria (a surrogate marker of kidney disease progression that point in time in patients with FSGS. 15

The ACTION3 Phase 3 trial in FSGS kidney disease patients continues to recruit across clinical sites globally, with over 190 clinical sites activated, 19 of which are specialist paediatric kidney clinics. Clinical site opening is typically the most significant cost of a clinical study, <sup>16,17</sup> and consequently it should be noted that clinical trial spend is not linear with expenditure higher in some periods than others. It is anticipated that the next quarter will include one-off costs associated with the US licensing transaction, CRO milestone(s) and potentially new R&D pipeline costs. In addition to these outlays, given a number of territories around the world require compulsory access to the experimental treatment for patients as they complete a clinical trial, following the successful Part 1, Dimerix has an open label extension (OLE) study in place, with over 90% of patients who have completed the full

ACTION3 Phase 3 clinical trial now having entered into the OLE. The OLE allow all patients continued access to DMX-200, if consented, once they have completed the ACTION3 clinical trial and will follow them for a further 2 years. This should provide further study risk mitigation and long-term data.

The ongoing Phase 3 is a double-blind, randomised (1:1) trial and is currently being conducted across multiple study sites globally, with the primary endpoints currently being estimated glomerular filtration rate (eGFR) and/or proteinuria. Proteinuria (the measure of how much protein is in the urine), is used along with the eGFR in both the classification of kidney diseases and the effectiveness of therapies. Proteinuria can serve as an indicator of renal disease, and the degree of proteinuria correlates with disease progression.<sup>18</sup> Following the October 2024 PARASOL Scientific Workshop, Dimerix met with the FDA in March 2025 and confirmed the acceptability of proteinuria endpoints for DMX-200 in the ACTION3 Phase 3 clinical trial.<sup>11</sup>

#### About the trial

The Phase 3 study, which is titled "Angiotensin II Type 1 Receptor (AT1R) & Chemokine Receptor 2 (CCR2) Targets for Inflammatory Nephrosis", or ACTION3 for short, is a pivotal (Phase 3), multi-centre, randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker (ARB). Once the ARB dose is stable, patients will be randomized to receive either DMX200 (120 mg capsule twice daily) or placebo.

Further information about the trial can be found on ClinicalTrials.gov (Study Identifier: NCT05183646) or Australian New Zealand Clinical Trials Registry (ANZCTR) (Study Identifier ACTRN12622000066785).

#### **Partnering**

Dimerix now has four high quality partners across multiple territories, providing strong support for Dimerix in advancing and commercialising DMX-200 as a potential new treatment for FSGS. Collectively across all licences, Dimerix may become eligible for up to ~AU\$1.4 billion<sup>7</sup> in total upfront payments and potential milestone payments, plus royalties on net sales, with over \$65 million in total payments already being received.<sup>1</sup>. Dimerix continues to pursue licensing opportunities with potential partners in territories not already licensed

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

Dr Nina Webster Rudi Michelson

Dimerix Limited Monsoon Communications

Chief Executive Officer & Managing Director Tel: +61 3 9620 3333

Tel: +61 1300 813 321 Mob: +61 (0)411 402 737 E: investor@dimerix.com E: rudim@monsoon.com.au

Follow us on **LinkedIn** and **X** 

Authorised for lodgement by the Board of the Company

#### **About Dimerix Limited**

Dimerix (ASX: DXB) is a clinical-stage biopharmaceutical company working to improve the lives of patients with inflammatory diseases, including kidney diseases. Dimerix is currently focused on developing its proprietary Phase 3 product candidate DMX-200, for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for respiratory disease. 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. For more information, please visit the company's website at www.dimerix.com.

#### **About DMX-200**

DMX-200 is a chemokine receptor (CCR2) antagonist administered to patients already receiving an angiotensin II type I receptor (AT1R) blocker, the standard of care treatment for hypertension and kidney disease. DMX-200 is protected by granted patents in various territories until 2032, with patent applications submitted globally that may extend patent protection to 2042, in addition to Orphan Drug Designation granted by the FDA in the United States.

#### **About FSGS**

FSGS is a rare, serious kidney disorder characterized by progressive scarring (sclerosis) in parts of the glomeruli—the kidney's filtering units. This scarring leads to proteinuria, progressive loss of kidney function, and often end-stage renal disease. FSGS is increasingly understood to have an inflammatory component, with monocyte and macrophage activation contributing to glomerular injury. In the United States, more than 40,000 people are estimated to be living with FSGS, including both adults and children.<sup>19</sup> There are no therapies specifically approved for FSGS in the U.S., and management relies on non-specific immunosuppressive and supportive therapies. In patients with progressive or treatment-resistant FSGS, the average time from diagnosis to end-stage kidney disease can be as short as five years. Even among those who undergo kidney transplantation, disease recurrence occurs in up to 60% of cases, 20 underscoring the urgent need for new, disease-modifying treatments.

#### **Dimerix Forward Looking Statement**

This release includes forward-looking statements that are subject to risks and uncertainties. Although management believes that the expectations reflected in the forward looking statements are reasonable at this time, Dimerix can give no assurance that these expectations will prove to be correct. Readers are cautioned not to place undue reliance on forward-looking statements. Actual results could differ materially from those anticipated. Reasons may include risks associated with drug development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, results of clinical trials, contractual risks, risks associated with patent protection, future capital needs or other general risks or factors, along with those factors outlined in the most recent Dimerix Limited Annual Report.

#### References

1 ASX release 01 May 2025

<sup>2</sup> Based on 30 day Wall Street Journal average exchange rate of 1 USD = 1.5924 AUD from 28 March - 28 April 2025

<sup>3</sup> ASX release 06 May 2025

<sup>4</sup> ASX release 5 October 2023

<sup>5</sup> ASX release 27 May 2024

<sup>6</sup> ASX release 7 January 2025

- 7 Based on XE exchange rates & further terms outlined in ASX Announcements on 5 October 2023, 27 May 2024, 07 January 2025, and 01 May 2025;
- 8 ASX release 30 June 2025, using XE exchange rate of 100 Japanese Yen = 1.05 AUD as at 26 June 2025, before tax
- 9 ASX release 30 May 2025
- 10 ASX release 22 May 2025
- 11 ASX release 28 April 2025
- 12 As at 24 Jul 2025, including both adults and children
- 13 ASX release 11 March 24
- 14 Predictive Power statistical model, using industry standard as set by the independent renal biostatistician consultant for Dimerix
- 15 Interim analysis data does not guarantee a statistically significant outcome at the end of the trial
- 16 The Impact on Clinical Site Budgeting, IQVIA White Paper (2023), https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/sky-high-inflation-and-the-great-resignation-impact-on-clinical-site-budgeting.pdf
- 17 Sertkaya, A (2016), Key cost drivers of pharmaceutical clinical trials in the United States, Clinical Trials 13(2) DOI: DOI: 10.1177/1740774515625964
- 18 Haider M, Aslam A (2023) Proteinuria; PMID: 33232060 online https://pubmed.ncbi.nlm.nih.gov/33232060/
- 19 Nephcure FSGS Facts (https://nephcure.org/)
- 20 Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669

# **Appendix 4C**

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

## Name of entity

| DIMERIX LIMITED |                                   |  |
|-----------------|-----------------------------------|--|
| ABN             | Quarter ended ("current quarter") |  |
| 18 001 285 230  | 30/06/2025                        |  |

| Con | nsolidated statement of cash flows \$A'000     |         | Year to date 12<br>months)<br>\$A'000 |  |
|-----|--|---------|---------------------------------------|--|
| 1.  | Cash flows from operating activities           |         |                                       |  |
| 1.1 | Receipts from customers                        | 51,084  | 54,562                                |  |
| 1.2 | Payments for                                   |         |                                       |  |
|     | (a) research and development                   | (4,734) | (22,388)                              |  |
|     | (b) product manufacturing and operating costs  | -       | -                                     |  |
|     | (c) advertising and marketing                  | -       | -                                     |  |
|     | (d) leased assets                              | -       | -                                     |  |
|     | (e) staff costs                                | (128)   | (648)                                 |  |
|     | (f) administration and corporate costs         | (1,373) | (3,287)                               |  |
| 1.3 | Dividends received (see note 3)                | -       | -                                     |  |
| 1.4 | Interest received                              | 32      | 327                                   |  |
| 1.5 | Interest and other costs of finance paid       | (3)     | (16)                                  |  |
| 1.6 | Income taxes paid                              | -       | -                                     |  |
| 1.7 | Government grants and tax incentives           | -       | 7,932                                 |  |
| 1.8 | Other (GST)                                    | 707     | 2,550                                 |  |
| 1.9 | Net cash from / (used in) operating activities | 45,585  | 39,032                                |  |

| 2.  | Cas                         | sh flows from investing activities |     |      |
|-----|-----------------------------|------------------------------------|-----|------|
| 2.1 | Payments to acquire or for: |                                    |     |      |
|     | (a)                         | entities                           | -   | -    |
|     | (b)                         | businesses                         | -   | -    |
|     | (c)                         | property, plant and equipment      | (6) | (20) |
|     | (d)                         | investments                        | -   | -    |
|     | (e)                         | intellectual property              | -   | -    |
|     | (f)                         | other non-current assets           | -   | -    |

ASX Listing Rules Appendix 4C (17/07/20)

Page 1

| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date 12<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                   | -                          | -                                     |
| 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 | (6)                        | (20)                                  |

| 3.   | Cash flows from financing activities  |       |       |
|------|---|-------|-------|
| 3.1  | Proceeds from issues of equity securities (excluding convertible debt securities)       | -     | -     |
| 3.2  | Proceeds from issue of convertible debt securities                                      | -     | -     |
| 3.3  | Proceeds from exercise of options   | 6,046 | 7,547 |
| 3.4  | Transaction costs related to issues of equity securities or convertible debt securities | -     | -     |
| 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)   | (31)  | (117) |
| 3.10 | Net cash from / (used in) financing activities  | 6,015 | 7,430 |

| 4.  | Net increase / (decrease) in cash and cash equivalents for the period |        |        |
|-----|---|--------|--------|
| 4.1 | Cash and cash equivalents at beginning of period                      | 16,995 | 22,141 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above)       | 45,585 | 39,032 |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above)       | (6)    | (20)   |

| Con | solidated statement of cash flows                                | Current quarter<br>\$A'000 | Year to date 12<br>months)<br>\$A'000 |
|-----|--|----------------------------|---------------------------------------|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | 6,015                      | 7,430                                 |
| 4.5 | Effect of movement in exchange rates on cash held                | (305)                      | (299)                                 |
| 4.6 | Cash and cash equivalents at end of period                       | 68,284                     | 68,284                                |

| 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<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances   | 66,226                     | 14,093                      |
| 5.2 | Call deposits   | 2,058                      | 2,902                       |
| 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)   | 68,284                     | 16,995                      |

| 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 | 180                        |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | -                          |

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.

The amount at 6.1 includes Director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.

| 7.  | Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the 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 |
|-----|---|--|---|
| 7.1 | Loan facilities   |  |   |
| 7.2 | Credit standby arrangements   | -  | -   |
| 7.3 | Other (please specify)  | -  | -   |
| 7.4 | Total financing facilities  |  |   |
| 7.5 | Unused financing facilities available at qu   | ıarter end   | -   |
| 7.6 | Include in the box below a description of each rate, maturity date and whether it is secured facilities have been entered into or are proposinclude a note providing details of those facilities.                     | or unsecured. If any add<br>osed to be entered into af | itional financing                         |

| 8.  | Estimated cash available for future operating activities   | \$A'000                    |
|-----|--|----------------------------|
| 8.1 | Net cash from / (used in) operating activities (item 1.9)  | 45,585                     |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6)  | 68.284                     |
| 8.3 | Unused finance facilities available at quarter end (item 7.5)  | -                          |
| 8.4 | Total available funding (item 8.2 + item 8.3)  | 68,284                     |
| 8.5 | Estimated quarters of funding available (item 8.4 divided by item 8.1)   | N/A                        |
|     | Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for 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 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: N/A

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: N/A

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: N/A

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**

- 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:          | 25 July 2025   |
|----------------|--|
|                |  |
| 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.
- 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".
- 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.