Dimerix

For Immediate Release

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights and operational activities

- Dimerix entered into second license agreement for DMX-200[1]
    - Dimerix eligible to receive up to ~AU$120.5 million[2] from Taiba in upfront and milestone payments, in addition to royalties:
        - US$350,000 (~AU$0.5 million[1, 3]) upfront payment
        - Up to US$80.4 million (~AU$120 million[2]) in milestone payments on certain development and sales milestones being achieved
        - Tiered royalties starting at 30% on net sales
    - Collectively the Advanz Pharma and Taiba license deals provide[1,4]:
        - ~AU$11.5 million in upfront payments
        - up to approximately AU$340 million in potential milestone payments
        - tiered royalties on net sales
- Following success of Part 1 of the ACTION3 Phase 3 clinical study, Dimerix began initiation of additional clinical sites, with ~170 clinical sites planned globally
- Following successful Part 1 an Open Label Extension study is planned for patients as they complete the blinded ACTION3 clinical study
- Dimerix continues to receive a significant amount of partnering interest from pharma companies globally, with multiple parties at various points in the licensing process for various territories, including the negotiation of potential agreements
- Dimerix received Paediatric Investigational Plan (PIP) approval from the UK MHRA[5]
- DMX-200 dose for adolescents in ACTION3 clinical trial confirmed[6]
- Patent position strengthened with a further US patent allowed[7]
- Dimerix presented at Melbourne Twilight Investor Briefing[8]
- Dimerix presented at Bioshares Biotech Summit, and received the Blake Award for Excellence 2024[9]
- Cash position of AU$22.1 million at 30 June 2024
- Net operating cash outflow for the June quarter was AU$13.3 million, including significant one-off costs relating to completion of study milestones

MELBOURNE, Australia, 23 July 2024: Dimerix Limited (ASX: DXB) (“Dimerix” or the “Company”), a clinical-stage biopharmaceutical company with late-stage clinical assets, today announced its Appendix 4C and Quarterly Activities Report for the period ended 30 June 2024. During the quarter Dimerix entered into its second license agreement for the commercialisation of Dimerix’ Phase 3 drug candidate, DMX-200, in focal segmental glomerulosclerosis (FSGS) kidney disease. In addition, following the successful outcome of Part 1 in its lead global program, ACTION3 Phase 3 clinical study in FSGS, where it was shown drug was outperforming placebo, Dimerix made significant progress in opening up a number of additional clinical sites globally.

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This has been a key quarter for the program, as clinical site initiation is fundamental to the overall operational success of a clinical trial. Opening up clinical trial sites is also the most significant cost component of the overall study. As more trial sites are opened and the rate of which opening trial sites slows (as the Company nears final recruitment), the Company anticipates a reduction in its cash expenditure each quarter. The Company currently remains funded for its ACTION3 Phase 3 clinical trial (see further commentary on ACTION3 Phase 3 study below).

Dimerix ended the quarter with cash of $22.1 million ($35.2 million at 31 March 2024), with net operating cash outflows for the period of $13.3 million ($3.3 million net operating cash inflows in the prior quarter). Cash outflow for the period predominately related to the trial costs of the Phase 3 FSGS Clinical Study, including significant one-off costs relating to completion of study milestones pre-agreed with IQVIA and in relation to opening new clinical sites globally.

Additionally, during the quarter, Dimerix received approximately $0.2 million in relation to the exercise of unlisted and listed options (the material terms of the options are set out in the Prospectus' as lodged with ASIC and released to ASX on 4 May 2023 and 26 June 2023).

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 director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.

Partnering

Dimerix has received a significant amount of partnering interest from pharma companies globally, following its two licencing agreements entered into with 1) Advanz Pharma in October 2023 for Europe, Canada, Australia and New Zealand, and valued at up to $230 million plus royalties on sales[10]; and 2) Taiba in May 2024 for the Middle East territories and valued up to $120 million plus royalties on sales.[1] Dimerix has multiple parties at various points in the licensing process for various territories, including the negotiation of potential licensing agreements. Following the successful first interim analysis, Dimerix will focus on the execution of potential licensing deals for those available jurisdictions including in the US and China.

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.[11] The analysis indicated that, using a statistical measure,[12] DMX-200 was performing better than placebo in terms of reducing proteinuria (a surrogate marker of kidney disease progression[16]) in patients with FSGS. This analysis is extremely valuable as it is based on a significantly larger cohort than the prior Dimerix Phase 2 study which was conducted in 8 patients.[13]

Following the first interim analysis results, the ACTION3 Phase 3 trial in FSGS kidney disease patients continues to recruit across clinical sites globally, with approximately 170 clinical sites planned globally. During the period, Dimerix focused on the opening a number of those additional clinical sites, before

initiating the patient recruitment and screening process once opened. Clinical site opening is typically the most significant cost of a clinical study,[14,15] and consequently it should be noted that clinical trial spend is not linear with expenditure higher in some periods than others. In addition, 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 now has an open label extension (OLE) study in place. The OLE study will allow all patients access to DMX-200 once they have completed the ACTION3 clinical trial and follow them for a further 2 years. This provides further study risk mitigation and long-term data. It is anticipated that the OLE study is to be funded through current cash reserves as well as future licensee milestone payments under the existing partnering arrangements.

The ongoing Phase 3 is a double-blind, randomised (1:1) trial and is currently being conducted across multiple study sites in more than 18 countries, with the primary endpoints currently being both eGFR and proteinuria. Proteinuria (the measure of how much protein is in the urine), is used along with the estimated glomerular filtration rate (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.[16]

Project PARASOL

Project PARASOL is a collaborative international effort which has been established with the aim to define the quantitative relationships between short-term changes in biomarkers (such as proteinuria and GFR) and long-term outcomes for FSGS patients and further support the use of alternative proteinuria-based endpoints as a basis to provide both accelerated and traditional approval in FSGS kidney disease.[17] Dimerix is supporting this working group, with Dimerix and other industry sponsors participating in the initial workshop in June 2024 and also invited to participate in the second and final workshop in October 2024. The outcomes of PARASOL may support and/or influence the ACTION3 endpoints and the study's statistical analysis plan.

As previously announced, patients, physicians and Dimerix staff will remain blinded to patient allocation (i.e. which patients are receiving DMX-200 and which are receiving placebo) at all times during study, including at the second interim analysis timepoint which will assess the statistical powering of the ACTION3 study. The potential for accelerated (or conditional) approval submissions in, or around, 2025 following the second interim analysis (and any required unblinding) will be assessed based on project PARASOL outcomes, recommendations of the IDMC (based on review of emerging data from ACTION3) and subsequent discussions with the appropriate regulatory authorities such as the FDA in the US.

About the trial

The Phase 3 study, which is titled **"A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammat**o**ry **N**ephrosis", 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).

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 working to improve the lives of patients with inflammatory diseases, including both kidney and respiratory diseases. Dimerix is currently focussed on developing its proprietary Phase 3 product candidate DMX-200 (QYTOVRA® in some territories), for Focal Segmental Glomerulosclerosis (FSGS) kidney disease, and is also developing DMX-700 for Chronic Obstructive Pulmonary Disease (COPD). DMX-700 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.

About DMX 200

DMX 200 is the adjunct therapy of 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 any exclusivity period that may apply in key territories. In 2020, Dimerix completed two Phase 2 studies: one in FSGS and one in diabetic kidney disease, following a successful Phase 2a trial in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any trial, and all studies resulted in encouraging data that could provide meaningful clinical outcomes for patients with kidney disease.

About 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.[18] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[19] At this time, there are no drugs specifically approved for FSGS anywhere in the world, so the treatment options and prognosis are limited.

FSGS is a billion-dollar plus market: the number of people with FSGS in the US alone is just over 80,000,[18] and worldwide about 220,000.[20] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[21] Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX 200 in both the US and Europe for FSGS. 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 a fast-tracked regulatory pathway to approval. Dimerix reported positive Phase 2a data in FSGS patients in July 2020.

References

1 ASX release 27 May 2024
2 Based on exchange rate of 1 US$ = 1.509 AUD as at 27 May 2024
3 In the event that EMA or FDA do not approve a marketing authorization within 2 years of a Regulatory Submission, Dimerix shall have the option to either issue to Taiba Dimerix ordinary shares equal to US$350,000 divided by the Share Value or pay the amount of US$350,000 in cash
4 ASX release 05 October 2023
5 ASX release 01 May 2024
6 ASX release 04 July 2024
7 Method for Treating Inflammatory Disorders; United States Divisional Patent Application 17/662,866, Notice of Allowance received from USPTO 15 May 24, with grant anticipated August 2024
8 ASX release 13 June 2024
9 ASX release 12 July 2024
10 ASX release 05Oct23
11 ASX release 11Mar24
12 Predictive Power statistical model, using industry standard as set by the independent renal biostatistician consultant for Dimerix
13 Interim analysis data does not guarantee a statistically significant outcome at the end of the trial
14 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
15 Sertkaya, A (2016), Key cost drivers of pharmaceutical clinical trials in the United States, Clinical Trials 13(2) DOI:10.1177/1740774515625964
16 Haider M, Aslam A (2023) Proteinuria; PMID: 33232060 online https://pubmed.ncbi.nlm.nih.gov/33232060/
17 See Project PARASOL website: https://www.is-gd.org/parasol
18 Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/
19 Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669
20 Delve Insight Market Research Report (2022): Focal segmental glomerulosclerosis (FSGS) – Market Insight, Epidemiology and market forecast – 2032; https://www.delveinsight.com/report-store/focal-segmental-glomerulosclerosis-fsgs-market;
21 Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/

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	30/06/2024

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	-	10,872
1.2	Payments for		
	(a) research and development	(12,765)	(25,166)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(118)	(554)
	(f) administration and corporate costs	(840)	(2,475)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	88	176
1.5	Interest and other costs of finance paid	(4)	(244)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	8,971
1.8	Other (GST)	361	1,169
1.9	**Net cash from / (used in) operating activities**	**(13,278)**	**(7,251)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(4)	(15)
	(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	-	-
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)**	**(15)**

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3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	20,281
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	219	5,426
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(9)	(1,403)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(2,843)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(18)	(47)
3.10	**Net cash from / (used in) financing activities**	**192**	**21,414**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	35,233	7,992
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(13,278)	(7,251)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(15)

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)	192	21,414
4.5	Effect of movement in exchange rates on cash held	(2)	1
4.6	**Cash and cash equivalents at end of period**	**22,141**	**22,141**

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	1,517	5,254
5.2	Call deposits	20,624	29,979
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)**	**22,141**	**35,233**

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	171
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 amount at quarter end $A'000**	**Amount drawn at quarter end $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 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.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(13,278)
8.2	Cash and cash equivalents at quarter end (item 4.6)	22,141
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	22,141
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.7

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.

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: Quarterly expenditure includes a one-off cost to vendor and trial site initiation, as outlined in the quarterly activities report. Future net operating cash outflows is expected to differ to current net operating cash outflows due to the non-linear nature of clinical trial costs.

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 has been successful in its FY2023 R&D Tax Incentive application for which $8.9 million was received in Q1 FY24, and has no reason to believe it will not receive an R&D rebate for eligible FY2024 expenses. Additionally, the Company expects to receive further funding from 49,625,053 listed options, which are exercisable at $0.154.

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 is sufficiently funded to continue its operations and meet its business objectives. The Company will continue to maintain eligibility for nondilutive 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: 23 July 2024

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.