Dimerix

For Immediate Release

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights and operational activities

- ACTION3 FSGS Phase 3 clinical trial continues to recruit globally
- Part 1: Last patient data collection for Phase 3 study scheduled for 26 February 2024
- Part 1: First interim data outcome expected to be reported on, or around, 15 March 2024[1]
- 133 patients having entered the screening and/or stabilisation process, with 72 patients randomised to receive drug or placebo
- Approval received for Paediatric Investigation Plan from EMA[2]
- Dimerix confirms Phase 3 study design appropriate for China[3]
- Dimerix to present at BIO International Convention[4]
- Dimerix Announces Update on Successful Capital Raise[5]
- Entitlement offer and Convertible Note to raise $12 million[6]
- Dimerix Announces New Board Member[7]
- Cash position of $8.0 million at 30 June 2023
- Net operating cash flow for the June quarter was -$4.3 million

MELBOURNE, Australia, 28 July 2023: Dimerix Limited (ASX: DXB) ("Dimerix" or the "Company"), a clinical-stage biopharmaceutical company with multiple late-stage clinical assets, today announced its Appendix 4C and Quarterly Activities Report for the period ended 30 June 2023. During the quarter Dimerix continued to recruit patients to its lead global program, ACTION3 Phase 3 clinical study in focal segmental glomerulosclerosis (FSGS). With randomisation of the first cohort of patients complete, the final data collection is scheduled on 26 February 2024, with the Part 1 interim outcome expected to be announced on, or around, 15 March 2024.[1] The trial continues to recruit patients for Part 2 of the trial.

Dimerix ended the quarter with cash of $8.0 million ($4.0 million at 31 March 2023), with net operating cash outflows for the period of $4.3 million ($4.5 million net operating cash outflows in the prior quarter). Cash outflow for the period predominately related to Clinical and CMC costs related to the Phase 3 FSGS Study.

During the quarter, Dimerix raised a total of $8.7 million (before costs), through a combination of a partially underwritten non-renounceable pro-rata entitlement offer [$5.2 million] and Convertible Notes [$3.5 million]. Dimerix may access a further optional tranche of Convertible Note funding of up to $8.5 million by mutual agreement.

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.

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FSGS Phase 3 study - ACTION3

The ACTION3 Phase 3 trial in FSGS kidney disease patients continues to recruit across clinical sites globally, with 133 patients having now been recruited, and 72 patients having been randomised to receive either drug or placebo.

The single Phase 3 trial in FSGS patients has two interim analysis points built in that are designed to capture evidence of proteinuria and kidney function (eGFR slope) during the trial, aimed at generating sufficient evidence to support accelerated marketing approval. A successful outcome in the first interim analysis outcome, expected on or around 15 March 2024[1], would see the Company announce a clinically significant and statistical meaningful improvement in proteinuria in patients on DMX-200 vs placebo and that the trial is continuing to Part 2. On success, the study will then proceed formally into Part 2, with additional clinical sites expected to open in further countries, including China.

As part of Dimerix' active business development program, in June, Dimerix attended the BIO partnering meeting that was geld in Boston, where meetings were held with representatives from pharmaceutical and biotechnology companies, including with those companies who have submitted offers for the asset, to increase and progress interest in Dimerix' DMX-200 program.

About the trial

The Phase 3 trial, 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 trial 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, aged 18 to 80 years (broadening to 12 to 80 years), will be randomized to receive either DMX-200 (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 developing innovative new therapies in areas with unmet medical needs for global markets. Dimerix is currently developing its proprietary product DMX-200, for Focal Segmental Glomerulosclerosis (FSGS), and Diabetic Kidney Disease, 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.

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 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. DMX-200 is also under investigation as a potential treatment for acute respiratory distress syndrome (ARDS) in patients with COVID-19.

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.[8] For those who are fortunate enough to receive a kidney transplant, approximately 60% will get re-occurring FSGS in the transplanted kidney.[9] At this time, there are no drugs specifically 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,[8] and worldwide about 220,000.[10] The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year.[11] 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 *Current independent Data Safety Monitoring Board (DSMB) scheduled meeting*
2 *ASX release 05/07/2023*
3 *ASX release 03/07/2023*
4 *ASX release 06/06/2023*
5 *ASX release 05/06/2023*
6 *ASX release 04/05/2023*
7 *ASX release 01/05/2023*
8 *Guruswamy Sangameswaran KD, Baradhi KM. (2021) Focal Segmental Glomerulosclerosis), online: https://www.ncbi.nlm.nih.gov/books/NBK532272/*
9 *Front. Immunol., (July 2019) | https://doi.org/10.3389/fimmu.2019.01669*

10 *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;*

11 *Nephcure FSGS factsheet 2022: https://2eu46v1q93c11mayx1nfvwg6-wpengine.netdna-ssl.com/wp-content/uploads/2021/02/nc.factSheet.FSGS_210106.pdf*

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	30/06/2023

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	(4,007)	(17,720)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(108)	(514)
	(f) administration and corporate costs	(491)	(1,769)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	4	38
1.5	Interest and other costs of finance paid	-	(2)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	6,083
1.8	Other (GST)	314	1,170
1.9	**Net cash from / (used in) operating activities**	**(4,288)**	**(12,714)**

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

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5,207	5,207
3.2	Proceeds from issue of convertible debt securities	3,500	3,500
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(444)	(444)
3.5	Proceeds from borrowings	-	2,843
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	(1)
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(13)	(52)
3.10	**Net cash from / (used in) financing activities**	**8,250**	**11,053**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,029	9,630
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,288)	(12,714)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(2)

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)	8,250	11,053
4.5	Effect of movement in exchange rates on cash held	1	25
4.6	**Cash and cash equivalents at end of period**	**7,992**	**7,992**

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	6,930	2,971
5.2	Call deposits	1,062	1,058
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)**	**7,992**	**4,029**

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	148
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	2,843	2,843
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**2,843**	**2,843**

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 Radium Capital and is an advance on 80% of the Company's estimated R&D Tax Incentive (RDTI) for the period 1 July 2022 – 31 December 2022. The loan facility accrues interest at a rate of 14% per annum. Repayment date is the earlier of 30 September 2023, or receipt of FY2023 R&D rebate. The facility has been in place since 17 February 2023.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(4,288)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,992
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,992
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.9

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: 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 FY2022 R&D Tax Incentive application for which $6 million was received in Q2 FY23, and has no reason to believe it will not receive an R&D rebate for eligible FY2023 expenses. Additionally, the Company reserves the right to offer and issue New Shares and free-attaching New Options from the Rights Issue Shortfall at its discretion, up to three months after the closing date of the Rights Issue Offer (refer to Prospectus released to ASX on 04 May 2023).

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: 28 July 2023

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.