

DIMERIX QUARTERLY ACTIVITIES REPORT

Quarter highlights and operational activities

- Phase 3 FSGS ACTION3 clinical trial now recruited 11 patients (15%) across multiple territories
- 60% of global ACTION3 sites open and actively recruiting; remaining sites anticipated to come online in the next 4-6 weeks
- DMX-700 Study Shows Significant 80% Reduction in Lung Injury¹
- REMAP-CAP COVID-19 Study Analysis Underway²
- New Clinical Trial announced for DMX-200 in Diabetic Kidney Disease³
- Dimerix Presented at BIO International Partnering Convention⁴
- Phase 3 FSGS Kidney Trial Recruited First Patient⁵
- Dimerix presented at Bioshares Biotech Summit⁶
- FDA IND Approved for Phase 3 Study of DMX-200 in FSGS⁷
- Cash position of \$9.6 million at 30 June 2022
- Net operating cash flow for the June quarter was -\$7.2 million

MELBOURNE, Australia, 27 July 2022: 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 2022. During the quarter Dimerix made significant progress with its lead program, ACTION3 Phase 3 clinical study in focal segmental glomerulosclerosis (FSGS), with a number of the ~75 clinical sites actively recruiting globally. This has been a key quarter to the program, as an effective study start-up process is fundamental to the overall operational success of a clinical trial. It is also the largest cost component of the overall study that is reflected in the larger cash outflow for this quarter.

Dimerix ended the quarter with cash of \$9.6 million (\$16.8 million at 31 March 2022), with net operating cash outflows for the period of \$7.2 million (\$0.5 million net operating cash inflows in the prior quarter). The increase in total operating cash outflows for the quarter relative to the prior period is due to clinical trial start-up costs incurred in the current period in relation to the Phase 3 FSGS Study. Additionally, in the prior period \$3.7 million was received relating to the FY21 R&D Tax Incentive Refund in conjunction with the receipt of \$0.3 million relating to the Biomedical Translation Bridge (BTB) grant.

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 remains on track to deliver on its growth strategy, by advancing clinical trials to provide treatments globally for patients with serious and life-threatening inflammatory diseases. Dimerix is well positioned to deliver on its commitment towards bringing the potential benefits of DMX-200 to these patients globally, while building value for our stakeholders.

FSGS Phase 3 study - ACTION3

The ACTION3 Phase 3 study is actively recruiting across clinical sites globally, with 11 patients (15%) having now been recruited to its DMX-200 phase 3 trial in patients with Focal Segmental Glomerulosclerosis (FSGS) kidney disease. The ACTION3 Phase 3 trial will recruit across 75 sites in 12 different countries, with ethics and regulatory submissions having been made in all 12 countries. Of those sites, 60% are now open and actively recruiting patients to the study, with the remaining sites anticipated to complete protocol training and activation in the next 4-6 weeks

About the study

The Phase 3 study, which is titled “**A**ngiotensin II Type 1 Receptor (AT1R) & **C**hemokine Receptor 2 (CCR2) **T**argets for **I**nflammatory **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, aged 18 to 80 years, will be randomized to receive either DMX-200 (120 mg capsule twice daily) or placebo. The first interim analysis is anticipated in the first half of 2023.

Diabetic kidney disease study

On 7 June 2022, Dimerix announced that it has entered into an agreement with The Australian Centre for Accelerating Diabetes Innovations (ACADI) to progress DMX-200 into a new clinical trial in patients with diabetic kidney disease. This new trial provides another potential market opportunity for Dimerix in addition to its other Phase 3 trials underway. The clinical trial protocol is currently being finalised and is expected to be a 12-24 month study of proteinuria and eGFR (kidney function) in patients with diabetic kidney disease, with an interim analysis. The study plans to recruit across Australia and is expected to commence late 2022.

Two COVID-19 Feasibility/Phase 3 studies

Dimerix' lead drug candidate, DMX-200, was being studied as part of two different investigator-led feasibility/Phase 3 studies in COVID-19 patients with respiratory complications. The inclusion of DMX-200 in these investigator-led studies is based on a clear scientific rationale, is unique and potentially complementary to others being investigated globally, and importantly if effective in this study, would likely be effective against any strain as well as potentially other pneumonias with a common mechanism of action.⁸

As investigator-led trials, both studies have been a relatively low-cost source of potential clinical data for Dimerix, with the REMAP-CAP and CLARITY teams being responsible for initiation, resourcing, project management and budgeting the clinical study. Dimerix proactively supported the study driven by the studies in providing them information for the regulatory submissions and in supplying DMX-200 to the study sites.

1 REMAP-CAP Feasibility/Phase 3 study

The REMAP-CAP study was an investigator-led study in patients hospitalised with moderate to severe COVID-19 pneumonia (in Intensive Care Units (ICU) or on ward), driven by a consortium of global trialists, clinicians and experts through the study sponsor, REMAP-CAP.

On 27 June 2022 Dimerix announced that REMAP-CAP had formally close all recruitment of COVID-19 patients to the ACE2 RAS Domain clinical study (including DMX-200) to allow for the full results of this domain to be analysed and reported. The results of this study will be analysed by the REMAP-CAP team and prepared for publication. Dimerix will report the outcome as soon as it has been received from REMAP-CAP.²

2 CLARITY 2.0 Feasibility/Phase 3 study

The CLARITY 2.0 study is an investigator initiated, prospective, multi-centre, randomised, double blind, placebo-controlled study, which aims to enrol patients diagnosed with COVID-19.

Dimerix is currently working with the CLARITY team on the study plans and expected timing, and anticipates updating the market on that outcome in the next 2-3 weeks.

Chronic obstructive pulmonary disease study

On 04 June 2022, Dimerix announced that its pipeline candidate, DMX-700, resulted in a statistically significant 80% ($p < 0.01$, $n=6$) reduction in the PPE-induced lung injury in mice. The very encouraging and statistically significant pre-clinical data strongly supports further development of DMX-700. The clinical trial is now being designed, along with any further required nonclinical safety studies, with the initial clinical study expected to commence first half 2023

Dimerix has multiple assets in commercially attractive and growing markets that have a high unmet need, no current marketed competition, and with a potential fast pathway to market. Dimerix continues to drive the FSGS Phase 3 program, further progress the diabetic kidney disease and COPD programs, as well as support the investigator-led COVID-19 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 Focal Segmental Glomerulosclerosis (FSGS), respiratory complications associated with COVID-19 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. 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 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 study in patients with a range of chronic kidney diseases in 2017. No significant adverse safety events were reported in any study, 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.⁹ For those who are fortunate enough to receive a kidney transplant, approximately 40% will get re-occurring FSGS in the transplanted kidney.¹⁰ 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 80,000,¹¹ and worldwide about 210,000. The illness has a global compound annual growth rate of 8%, with over 5,400 new cases diagnosed in the US alone each year¹¹. Because there is no effective treatment, Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe for FSGS. This is a special status granted to a drug to treat a rare disease or condition; the designation means that DMX-200 can potentially be fast-tracked, and receive tax and other concessions to help it get to market.

DMX-200 for FSGS has been granted Orphan Drug Designation by the FDA and EMA. Orphan Drug Designation is granted to support the development of products for rare diseases and qualifies Dimerix for various development incentives including: seven years (FDA) and ten years (EMA) of market exclusivity if regulatory approval is received, exemption from certain application fees, and an abbreviated regulatory pathway to approval.

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

Respiratory Complications associated with COVID-19

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

Globally, and prior to COVID-19, ARDS affected more than 3 million people a year in 2019 accounting for 10-15% of intensive care unit admissions, and approximately 200,000 patients each year in the United States.¹² The global ARDS market is expected to grow at 10.1% (CAGR) between 2022 and 2029 and is expected to reach over US\$18 billion by 2029.¹³ Increasing prevalence and incidence of acute lung injury, wide range of risk factors for ARDS and acceleration in patient pool of COVID-19 with ARDS acts as driver for the ARDS market. The death rate associated with ARDS is high, with overall mortality between 30 and 40%.¹² The estimated average costs of treatment in an ICU unit with artificial ventilation total approximately US\$100,000 per patient, with the average length of stay in ICU as a result of ARDS being 25 days, and the average length of hospitalisation being approximately 47 days.¹⁴ However, there are

also significant costs associated with additional post-discharge treatment. There is no known prevention of ARDS currently available, nor is there any known cure.

References

- ¹ ASX release 04Jul2022
- ² ASX release 27Jun2022
- ³ ASX release 07Jun2022
- ⁴ ASX release 06Jun2022
- ⁵ ASX release 31May2022
- ⁶ ASX release 12May2022
- ⁷ ASX release 09May2022
- ⁸ Based on Szabo, et al., 2020; Merad, et al., 2020; Xiong, et al, 2020; Wu, et al., 2021; Chen, et al., 2009; Yong, et al., 2016
- ⁹ Guruswamy Sangameswaran KD, Baradhi KM. Focal Segmental Glomerulosclerosis (July 2021), online: <https://www.ncbi.nlm.nih.gov/books/NBK532272/>
- ¹⁰ DelveInsight Market Research Report (2020); Focal Segmental Glomerulosclerosis (FSGS)- Market Insight, Epidemiology and Market Forecast -2030
- ¹¹ Nephcure Kidney International (2020); Focal Segmental Glomerulosclerosis, online <https://nephcure.org/livingwithkidneydisease/understanding-glomerular-disease/understanding-fsgs/>
- ¹² REMAP-CAP background: <https://www.remapcap.org/background>
- ¹³ DataBridge Market Research 2022, <https://www.databridgemarketresearch.com/reports/global-acute-respiratory-distress-syndrome-ards-market>
- ¹⁴ Bice, T et al, (2013) Cost and Healthcare Utilization in ARDS – Different from Other Critical Illness?, *Semin Respir Crit Care Med.* 2013; 34(4): 529–536.

Appendix 4C

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

Name of entity

DIMERIX LIMITED

ABN

18 001 285 230

Quarter ended ("current quarter")

30/06/2022

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	(6,818)	(15,951)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(106)	(494)
(f) administration and corporate costs	(648)	(2,092)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	2
1.5 Interest and other costs of finance paid	(1)	(201)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	22	4,169
1.8 Other (GST)	333	815
1.9 Net cash from / (used in) operating activities	(7,217)	(13,752)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(4)	(11)
(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)	(11)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	24,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	180
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(1,124)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(5,000)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(12)	(48)
3.10	Net cash from / (used in) financing activities	(12)	18,008

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	16,788	5,250
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,217)	(13,752)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(11)

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)	(12)	18,008
4.5	Effect of movement in exchange rates on cash held	75	135
4.6	Cash and cash equivalents at end of period	9,630	9,630

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	3,342	4,667
5.2	Call deposits	6,288	12,121
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)	9,630	16,788

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	144
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<p><i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i></p> <p><i>The amount at 6.1 includes Director fees and salaries (including superannuation).</i></p>		

7. Financing facilities <i>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.</i>	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)	(7,217)
8.2 Cash and cash equivalents at quarter end (item 4.6)	9,630
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	9,630
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.3
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: Future net operating cash outflows is expected to be lower than current net operating cash outflows due to a number of one-off payments in relation to Phase 3 Clinical trial set-up costs occurring in the current operating period.	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: The Company is in the process of finalising its FY2022 R&D Tax Incentive application, which has been successfully granted in prior years.	

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, Dimerix Limited is sufficiently funded to continue its operations and meet its business objectives based on the anticipated reduced quarterly spend referred to in question 1. Additionally, Dimerix Limited will continue to maintain eligibility for non-dilutive funding through the R&D Tax Incentive scheme, as well as evaluate its capital requirements and options.

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

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 27 July 2022

Board of Directors

Authorised by: _____
(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.