

# Appendix 4C

Quarter Ended 31 March 2022 Chimeric Therapeutics Limited ACN 638 835 828

**ASX: CHM** 





ASX ANNOUNCEMENT

#### QUARTERLY ACTIVITES REPORT FOR THE PERIOD ENDING 31 MARCH 2022

Chimeric Therapeutics (ASX:CHM, "Chimeric" or the "Company"), an Australian leader in cell therapy, is pleased to provide a summary of its activities for the quarter ended 31 March 2022.

Key highlights for the quarter included:

- Encouraging initial data for 2nd dose cohort of CHM 1101 (CLTX CAR T) phase 1 dose escalation study for patients with recurrent/progressive glioblastoma
- Initiated dosing of 1st patient in the 3rd dose cohort of CHM 1101 (CLTX CAR T) phase 1 dose escalation study for patients with recurrent/ progressive glioblastoma
- Strategic partnership with Be The Match BioTherapies to support Chimeric's expanded clinical development of CHM 1101 through expedited collection, transport and delivery of cellular starting material and clinical drug products
- Final results of Phase 1 clinical trial of its CORE NK platform demonstrated an optimal safety profile and strong early signs of clinical benefit for patients
- CDH17 CAR T preclinical data featured as cover story for prestigious journal Nature Cancer
- Signed Sponsored Research Agreement with the University of Pennsylvania to support the continued research and development of CHM 2101 for preclinical studies in gastrointestinal cancers
- US patent and trademark office granted patent covering CLTX CAR technology used in CHM 1101 and CHM 1301
- Conducted non-renounceable entitlement offer and follow up shortfall placement to raise approximately \$14.4 million (before costs)
- Chimeric appointed Kelly Thornburg to the position of Vice President, Head of Quality. Mr Thornburg has been advising the company as a consultant and will now serve in a leadership role to develop the Company's quality systems and oversee all quality functions

#### CHM 1101 (CLTX CAR T) phase 1 dose escalation study produces further encouraging data

In February, Chimeric reported encouraging initial data for the 2nd dose cohort of the CHM 1101 (CLTX CAR T) phase 1 dose escalation study for patients with recurrent/progressive glioblastoma at the City of Hope<sup>®</sup>, one of the largest cancer research and treatment organizations in the United States.

In the 2nd dose cohort, dual routes of intratumoral and intraventricular CLTX CAR T cell administration were introduced at a total dose of 88 X 106 CLTX CAR T cells. City of Hope developed and manufactured the therapy. Four patients were enrolled in dose cohort 2 with three patients meeting the U.S. Food and Drug Administration (FDA) approved criteria for evaluation. The initial response data that has been provided at this time indicates that the 2nd dose cohort demonstrated local disease stability in two of the three patients.

The primary objective for this trial is safety. Positive initial safety was seen as patients generally well tolerated the dual routes (intratumoral and intraventricular) of CLTX CAR T cell administration introduced in this dose cohort. As previously announced, all patients advanced past the 28-day follow-up without



experiencing dose limiting toxicities. Additionally, an encouraging activity signal was demonstrated with two of the three evaluable patients treated achieving local stability of disease.

#### CHM 1101 (CLTX CAR T) Initiates 3rd Dose Cohort

In February the first patient in the 3rd dose cohort initiated their CHM 1101 (CLTX CAR T) cell therapy. Recurrent/ progressive glioblastoma patients in this dose level will receive CHM 1101 (CLTX CAR T) cells through the dual routes of administration at a total dose of 240 X 106 CLTX CAR T cells.

#### Partnership with Be The Match BioTherapies® to advance CHM 1101

In March, Chimeric announced it had entered a strategic partnership with Be The Match BioTherapies, an organization offering supply chain solutions for companies developing and commercializing cell and gene therapies.

Be The Match BioTherapies provides end-to-end services that ensure expedited collection, transport and delivery of cellular starting material and clinical drug product, which will support Chimeric's expanded clinical development of CHM 1101 (CLTX CAR T).

CHM 1101 (CLTX CAR T) is currently being evaluated in a single-site phase 1 clinical trial to treat patients with recurrent or progressive glioblastoma. This new partnership with Be The Match BioTherapies will enable the accelerated expansion of the program to additional clinical trial sites.

To support the advancement of CHM 1101 (CLTX CAR T), Be The Match BioTherapies will draw on more than 30 years of experience in collection network, supply chain and logistics management developed by the National Marrow Donor Program (NMDP) <sup>®</sup>/Be The Match<sup>®</sup>. Be The Match BioTherapies plans to leverage its established relationships and resources, including its Quality System Audit Program (QSAP), to swiftly grow Chimeric's network of apheresis centers and ensure the entire network is appropriately qualified, onboarded, trained and supervised in order to meet accelerated timelines for the trial.

#### Final Results from the Phase 1 Trial of CORE NK Platform

The results of the phase 1 clinical trial of its CORE NK platform, a Clinically validated, Off the shelf, Robust, Enhanced Natural Killer cell platform completed at Case Comprehensive Cancer Center, were published released in March.

Over the course of the phase 1 clinical trial 9 heavily pretreated patients with blood cancers (n=3) and solid tumors (n=6) were administered two infusions (day 0 and day 14) at one of three different CORE NK dose levels,  $10 \times 106$  (n=3),  $25 \times 106$  (n=3) and  $50 \times 106$  (n=3).

The results saw all three of the patients with blood cancers that were treated achieve a best response of stable disease at day 28. 1 of the 3 patients deepened their response to achieve a Complete Response (CR) by the 100-day assessment. This patient received an allogeneic transplant as a consolidation therapy and more than 15 months later remains in remission. Of the other two patients who achieved stable disease at day 28, one had progressed by day 100 while the other maintained their disease stability.

Of the 6 patients with solid tumors (Colorectal cancer and Colon cancer) treated with Chimeric's CORE NK, a 33% Disease Control Rate (DCR) was demonstrated with 2 of the 6 patients achieving a best response of



stable disease by day 28. 1 of the 2 patients who had achieved stable disease at day 28 maintained their disease stability at day 100.

All patients tolerated CORE NK well, with no dose limiting toxicities, no cytokine release syndrome, and no graft versus host disease. All observed events were expected events attributable to the lymphocytedepleting chemotherapy regimen.

The CORE NK cells are ex vivo expanded "universal donor" NK cells that utilize a novel feeder cell line (NKF) generated through the expression of membrane-bound interleukin 21 (mbIL-21) on the acute myeloid leukemia cell line, OCI-AML3. The CORE NK cell products generated using this novel feeder cell platform exhibited in vivo persistence for 4 weeks promoted by preparative lymphodepletion alone in the phase 1 clinical trial.

Chimeric is now advancing the development of its CORE NK platform with plans to increase the administered NK cell doses, provide optimized exogenous cytokine support or other complementary agents and promote tumor bed infiltration in solid tumors through the development of CAR NK therapies.

#### CDH17 CAR T preclinical data featured in Nature Cancer

During the period Chimeric announced that the discovery and preclinical characterization of its CAR T targeting CDH17, currently under development as CHM 2101, was published as the cover story for the highly prestigious journal Nature Cancer.

Key findings highlighted in the publication included:

- <u>Strong preclinical safety and efficacy</u>: the CDH17 CAR T completely eradicated tumours, with no relapse or toxicity, in 8 different in vivo models including colorectal cancer (CRC), gastric cancer, pancreatic cancer, and neuroendocrine tumours (NETs).
- <u>Optimal CAR T construct design</u>: the CDH17 CAR T as a third-generation CAR T cell construct was shown to be superior to the 2nd-generation CAR T cell construct, demonstrating complete elimination of solid tumours in vivo. Construct optimization with a very short linker domain further enhanced tumour cell killing.
- <u>Tumour-specific activity</u>: CDH17 CAR T cells infiltrated and destroyed CDH17+ tumours, but not normal CDH17-expressing tissues such as small and large intestines, creating a therapeutic window for CAR T treatment of solid tumours.

The authors conclude that their "findings indicate that CDH17 is an ideal target of CART therapy for GICs (Gastrointestinal Cancers) and NETs (Neuroendocrine Tumours)" and that their studies "suggest that CDH17 is a safe and efficacious target for developing CART therapy to treat GICs and NETs, without toxicity to healthy tissues, motivating further clinical investigation."

The Nature Portfolio publishes a range of academic journals, magazines and online databases covering science and medicine, and is known to publish some of the world's most highly prestigious scientific journals.



#### Sponsored research agreement with University of Pennsylvania

In February, Chimeric signed a Sponsored Research Agreement with the University of Pennsylvania ("Penn") to support the continued research and development of CHM 2101, a novel 3rd generation CDH17 CAR T cell therapy.

The research will be led by one of the inventors of CHM 2101, Xianxin Hua, MD, PhD. Dr Hua is a professor of Cancer Biology in Penn's Perelman School of Medicine, and an investigator at the Abramson Family Cancer Research Institute.

The research will focus on furthering the development of CHM 2101 with preclinical studies in gastrointestinal cancers, enhancing the understanding of CHM 2101 through correlative studies and investigating CDH17 directed follow on candidates. The research complements and is consistent with the Company's announcement on 28 July 2021 of receiving the exclusive license for CDH17.

The research will be led by one of the inventors of CHM 2101, Xianxin Hua, MD, PhD. Dr Hua is a professor of Cancer Biology in Penn's Perelman School of Medicine, and an investigator at the Abramson Family Cancer Research Institute.

As part of the agreement, Chimeric has the first right of negotiation to license Penn intellectual property arising from the conduct of the sponsored research.

#### US patent granted for CLTX CAR technology

United States Patent and Trademark Office issued a patent covering certain applications of chimeric antigen receptor (CAR) technology using chlorotoxin (CLTX), including Chimeric's clinical-stage CAR T asset CHM 1101 and preclinical-stage CAR NK asset CHM 1301.

The patent has been granted under patent number US 11,230,577 B2 and entitled "Chimeric antigen receptors containing a chlorotoxin domain."

Chimeric holds the exclusive worldwide license to develop and commercialize US 11,230,577 B2 and related patent applications filed in other global territories.

#### Entitlement Offer and Shortfall Placement conducted, raising approximately \$14.4 million

On 21 February 2022, Chimeric announced the details of an accelerated non-renounceable 1 for 3.15 entitlement offer with free attaching options.

The Company ultimately raised approximately \$7.4m from the institutional component of the entitlement offer, \$4.3m from the retail component of the entitlement offer and a further \$2.7m from a follow up Shortfall Placement raising, in total, approximately \$14.4m (before costs).

The Board intends to use the proceeds of the capital raising to fund payments under the Company's licence and sponsored research agreements as well as Phase I clinical trials. Funds will also be applied for ongoing working capital and the costs of the Entitlement Offer.



#### Kelly Thornburg appointed Vice President, Head of Quality

During the period, Chimeric appointed Kelly Thornburg to the position of Vice President, Head of Quality. Mr Thornburg has been advising the company as a consultant and will now serve in a leadership role to develop the Company's quality systems and oversee all quality functions.

Mr Thornburg has extensive US and global experience in the development and management of quality systems. Previously Mr Thornburg has served as the Quality Site Head at Kite, a world leader in cell therapy, where he oversaw the commercial manufacturing facility located in El Segundo, California. Mr Thornburg has also served in senior quality roles at Amgen, XBiotech and AGC Biologics.

#### **Financial Update**

An Appendix 4C is attached to this announcement.

As detailed in the attached ASX Appendix 4C, the Company had \$23.7 million in cash and equivalents as at 31 March 2022, increased from \$17.4 million compared to 31 December 2021. This will support the Company's efforts to progress the development of CLTX CAR T and initiate the development of a cell therapy pipeline.

The net cash used in operating activities during the quarter was \$3.2 million with direct Research and Development expenditure and Staff costs accounting for over 84% of the \$3.2 million. Additionally, during the quarter the Company had net cash inflows in financing activities of \$13.5m on the back of a successful capital raise in March 2022.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C include payments for remuneration of director fees to executive and non-executive directors in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

Pursuant to Listing Rule 4.7C.2, the Company confirms that, for the period since listing on the ASX, it has incurred expenditure largely in line with the Use of Proceeds set out in its Prospectus, as detailed below.



Use of Funds under Prospectus	Funds allocated under Prospectus	Prospectus Funds to 31 Mar 2022	Actual Funds expended from admission to 31 Mar 2022	Varia	ince
Offer Costs <sup>1</sup>	\$2,918,758	\$2,918,758	\$2,663,979	\$254,779	9%
Admin, Corporate and general working capital <sup>2</sup>	\$5,454,318	\$5,132,017	\$6,537,335	(\$1,405,318)	(27%)
Employment <sup>2</sup>	\$5,714,163	\$4,603,452	\$6,023,489	(\$1,420,037)	(31%)
Licence Fees to City of Hope <sup>1</sup>	\$6,966,611	\$6,944,444	\$4,628,694	\$2,315,750	33%
Research and Development on other cancer targets <sup>3</sup>	\$5,601,101	\$4,736,108	\$1,961,674	\$2,774,434	59%
Phase 1 clinical trial and manufacturing <sup>3</sup>	\$1,875,006	\$1,562,505	\$496,458	\$1,066,047	68%
Opening new additional Phase 1 sites <sup>1</sup>	\$5,000,000	\$0	\$0	\$0	0%
Other commercial and academic collaborations <sup>1</sup>	\$5,000,000	\$2,172,743	\$1,968,875	\$203,868	9%
Total	\$38,529,957	\$28,070,027	\$24,280,504	\$3,789,523	14%

<sup>1</sup>Costs remain in line with expected use of funds.

<sup>2</sup> Increased expenditure relates to hiring additional employees and engaging in additional corporate activities consistent with the previous quarter.

<sup>3</sup> Costs incurred are lower than forecast. Delays in R&D due to staffing challenges during the pandemic.

Expenditure in the above table relates only to the \$38.5m allocated under the IPO Prospectus and does not include the expenditure of funds raised in the March 2022 capital raise.

#### Authorised by the Chimeric Therapeutics board of directors.

#### **ABOUT CHIMERIC THERAPEUTICS**

Chimeric Therapeutics, a clinical stage cell therapy company and an Australian leader in cell therapy, is focused on bringing the promise of cell therapy to life for more patients with cancer. We believe that cellular therapies have the promise to cure cancer not just delay disease progression.

To bring that promise to life for more patients, Chimeric's world class team of cell therapy pioneers and experts is focused on the discovery, development, and commercialization of the most innovative and promising cell therapies.



CHM 1101 (CLTX CAR T) is a novel and promising CAR T therapy developed by scientists at the City of Hope Medical Centre in California for the treatment of patients with solid tumours. CHM 1101 is currently being studied in a phase 1 clinical trial in recurrent/ progressive glioblastoma. A 2<sup>nd</sup> CLTX CAR T phase 1 clinical trial is planned to begin in 2022 in additional solid tumours.

CHM 2101 (CDH17 CAR T) is a novel, 3rd generation CDH17 CAR T invented at the University of Pennsylvania. CHM 2101 (CDH17 CAR T) is currently in preclinical development with a planned phase 1 clinical trial in 2022 in Neuroendocrine Tumours, Colorectal, Pancreatic and Gastric Cancer.

Recently Chimeric announced the addition of the CORE-NK platform, a clinically validated, off the shelf natural killer (NK) cell therapy platform to their portfolio (CHM 0201). From the CORE-NK platform, Chimeric will initiate development of four new next generation NK and CAR NK assets with plans for phase 1 clinical trials to begin in 2023 in solid tumours and blood cancers.

Chimeric Therapeutics continues to be actively engaged in further developing its oncology pipeline with new and novel cell therapy assets that will bring the promise of cell therapy to life for more patients with cancer.

#### CONTACT

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## Appendix 4C

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

## Name of entity

**Chimeric Therapeutics Limited** 

#### ABN

68 638 835 828

Quarter ended ("current quarter")

31 March 2022

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,493)	(3,620)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(1,222)	(4,414)
	(f) administration and corporate costs	(532)	(1,722)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	10
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	47	99
1.9	Net cash from / (used in) operating activities	(3,198)	(9,647)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	
	(b) businesses	-	
	(c) property, plant and equipment	-	
	(d) investments	-	
	(e) intellectual property	(49)	(!
	(f) other non-current assets	-	

ASX Listing Rules Appendix 4C (17/07/20) + See chapter 19 of the ASX Listing Rules for defined terms.

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 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	(49)	(533)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	14,391	14,391
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(859)	(859)
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 – repayment of debt	-	(2,041)
3.10	Net cash from / (used in) financing activities	13,532	11,491

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	13,431	22,410
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,198)	(9,647)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(49)	(533)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	13,532	11,491
4.5	Effect of movement in exchange rates on cash held	-	(5)
4.6	Cash and cash equivalents at end of period	23,716	23,716

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	14,676	2,889
5.2	Call deposits	9,040	10,542
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)	23,716	13,431

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	335
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include ation for, such payments.	e a description of, and an

Item 6.1 – Include payments for remuneration of director fees to executive and non-executive directors in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

7.	<b>Financing facilities</b> 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 qu	larter 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.		itional financing
	N/A		

8.	Estim	nated cash available for future operating activities	\$A'000
8.1	Net ca	sh from / (used in) operating activities (item 1.9)	(3,198)
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	23,716
8.3	Unuse	d finance facilities available at quarter end (item 7.5)	-
8.4	Total a	available funding (item 8.2 + item 8.3)	23,716
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)		7.4
		the entity has reported positive net operating cash flows in item 1.9, answer iter or the estimated quarters of funding available must be included in item 8.5.	m 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		
	<ul> <li>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?</li> </ul>		
	Answe	er: 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?		
	Answe	er: N/A	
	Note: w	here item 8.5 is less than 2 guarters, all of guestions 8.6.1, 8.6.2 and 8.6.3 abo	we must be approved

#### **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 April 2022

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

#### Notes

- 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.



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# **Chimeric Therapeutics Limited**

ACN 638 835 828



**ASX: CHM**