



ASX ANNOUNCEMENT 29 JULY 2022

# **QUARTERLY ACTIVITES REPORT FOR THE PERIOD ENDING 30 JUNE 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 guarter ended 30 June 2022.

Key highlights for the quarter included:

- First ever trial studying NK cells in combination with IL-2 and Vactosertib is being undertaken with Chimeric's CORE NK platform cells
- Expanded license agreement with the University of Pennsylvania (Penn) related to CDH17 chimeric antigen receptor (CAR) therapies
- Manufacturing and quality release for CHM 1101 (CLTX CAR T) viral vector, a key development milestone, is complete
- Entered into strategic manufacturing partnership with Wuxi Advanced Therapies
- Exercised exclusive option for the CORE-NK platform from Case Western Reserve University (CWRU) and proceeded with negotiations for an exclusive license
- Entered into an Equity Placement Agreement for up to A\$30 million with L1 Capital

# First Phase 1B Trial of NK cells with IL-2 and Vactosertib

In June, Chimeric announced that a new clinical trial had been approved by the FDA studying Chimeric's CORE NK cells in combination with IL-2 and Vactosertib. This is the first clinical trial to study NK cells in combination with IL-2 and Vactosertib.

The phase 1B investigator-initiated trial has received approval by the U.S. Food and Drug Administration (FDA) and will enrol 12 patients at the UH Seidman Cancer Center in Ohio with either locally advanced/metastatic colorectal cancer or relapsed/refractory blood cancers.

Chimeric's CORE NK platform is a novel NK cell therapy platform of ex-vivo expanded non-HLA-matched universal donor NK cells. The CORE NK platform was previously studied in a phase 1A clinical trial that demonstrated safety and an early efficacy signal in patients with metastatic colorectal cancer and refractory haematological malignancies.

This new study seeks to build upon the responses seen in the initial CORE NK clinical trial by coadministering the CORE NK cells with subcutaneous IL-2 and oral Vactosertib. IL-2 is known to activate NK cells by stimulating proliferation and enhancing function. Vactosertib is an oral TGF- $\beta$  receptor inhibitor that can potentially disrupt the TGF- $\beta$  signalling pathway, which has been shown to limit the effectiveness of immune therapies like NK cells.

# <u>Viral Vector Technology Licensed for CDH17 CAR T Program</u>

Chimeric has expanded its license agreement with the University of Pennsylvania (Penn) related to CDH17 chimeric antigen receptor (CAR) therapies. Under the amended agreement, Chimeric has acquired a non-exclusive know-how license to use Penn's third-generation lentiviral vector plasmid system for the development and commercialization of CHM 2101 (CDH17 CAR T). Viral vector is a critical component



used in the manufacturing of CAR T cells, and third-generation lentiviral vectors offer improved safety over earlier generations.

The amended license will enable Chimeric to manufacture clinical-grade lentiviral vector for use in its planned phase 1 study of CHM 2101 (CDH17 CAR T) for gastrointestinal cancers.

In addition, Chimeric is able to cross-reference regulatory information on file with the US FDA to facilitate filing of an Investigational New Drug (IND) for CHM 2101.

Under the original license agreement in July 2021, Chimeric acquired the exclusive rights to develop and commercialize certain CDH17 CAR T cell therapies licensed from Penn.

# Completion of Manufacturing and Quality Release of Viral Vector for CHM 1101 (CLTX CAR T)

Chimeric completed the manufacturing and quality release for CHM 1101 (CLTX CAR T) viral vector in June, a key milestone in its development. The viral vector was developed and manufactured at City of Hope, a world-renowned cancer research and treatment organization near Los Angeles.

Chimeric is focused on expanding the CHM 1101 (CLTX CAR T) clinical program with new clinical sites for the Phase 1 glioblastoma trial requiring coordinated expansion of Chimeric's current technical operations.

One of the most challenging and critical components of cell therapy technical operations is the timely manufacturing and release of viral vector. Viral vector is considered the backbone for the manufacture of a CAR T cell therapy as it holds the genetic engineering instructions.

A current shortage of vector manufacturing capacity challenges both development programs and commercial manufacturers. Given these difficulties this is a critical milestone for Chimeric in supporting the broader Phase 1 clinical program expansion of CHM 1101 (CLTX CAR T).

# Strategic Manufacturing Partnership Established with Wuxi Advanced Therapies

In April, Chimeric entered into a strategic manufacturing partnership with WuXi ATU, a global contract testing and manufacturing organization (CTDMO).

Under the agreement, Chimeric will transfer certain manufacturing and analytical testing technologies to WuXi ATU, who will support process development, analytical development, and cGMP (Good Manufacturing Practices) manufacturing and testing activities for Chimeric's CAR T cell programs.

The new partnership will enable Chimeric to accelerate clinical manufacturing readiness for new CAR T assets and to scale CAR T manufacturing to support multiple, simultaneous, multi-centre CAR T clinical trials in the future.

Based in Philadelphia, PA, USA, WuXi ATU is the advanced therapies business unit of WuXi AppTec and offers integrated platforms to transform the discovery, development, testing, manufacturing, and commercialization of cell and gene therapies for customers worldwide. It has over 1,300 employees across four sites worldwide.



The initial focus under the agreement will be on Chimeric's two autologous CAR T-cell therapies for solid tumours:

- CHM 2101 (CDH17 CAR T) currently in late preclinical development for multiple gastrointestinal (GI) cancers, including colorectal cancer, gastric cancer, pancreatic cancer, and GI neuroendocrine tumours (NETs) will leverage WuXi ATU's end-to-end platform process for CAR T manufacturing and testing to enable accelerated cGMP manufacturing readiness for the planned first-in-human study of CHM 2101.
- CHM 1101 (CLTX CAR T) currently being evaluated in a single-site phase 1 clinical trial to treat
  patients with recurrent or progressive glioblastoma will leverage WuXi ATU's scalable
  manufacturing and analytical testing capacity to enable future expansion of the program to
  multiple additional clinical trial sites.

# **Option Exercised for CORE-NK Platform**

In May, Chimeric exercised its exclusive option for the CORE-NK platform from Case Western Reserve University (CWRU) and proceeded with negotiations for an exclusive license.

The Clinically validated, Off the shelf, Robust, Enhanced Natural Killer (CORE-NK) cell platform technology provides an excellent foundation for accelerated development of multiple next generation NK and CAR-NK products.

In March, Chimeric announced positive final results from a Phase 1 trial of the platform conducted in blood cancers and solid tumours. Chimeric expects to use the CORE-NK platform while leveraging its existing portfolio of CARs to pursue new clinical trials in blood cancers and solid tumours beginning in 2023.

# **Enters A\$30 million Equity Placement Agreement with L1 Capital**

Chimeric has established an equity funding agreement with leading global investor, L1 Capital Global Opportunities Master Fund ('L1 Capital' or L1), which further strengthens the Company's balance sheet as Chimeric rapidly moves forward with a portfolio of four Phase 1 clinical trials.

The Company has entered into an Equity Placement Agreement ('Placement Agreement') for up to A\$30 million with L1 Capital. L1 Capital is a leading global investor, based in Melbourne, Australia with over A\$5 billion in funds under management.

The Placement Agreement follows the Company's successful completion of the entitlement offer announced on 21 February 2022, which raised A\$14.4 million and boosted the Company's current cash position to approximately A\$23.7 million.

Bell Potter Securities Limited acted as advisor to the Company in respect of the Placement Agreement.



## **Financial Update**

An Appendix 4C is attached to this announcement.

As detailed in the attached ASX Appendix 4C, the Company had \$18.4 million in cash and equivalents as at 30 June 2022, decreasing from \$23.7 million compared to 31 March 2022. This will support the Company's activities 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 \$3.5 million with direct Research and Development expenditure and Staff costs accounting for over 88% of the \$3.5 million. Additionally, during the quarter the Company had net cash outflows in financing activities of \$2m after the payment of licence fees.

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 30 Jun 2022	Actual Funds expended from admission to 30 Jun 2022 <sup>4</sup>	Varia	nce
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	\$5,235,067	\$6,603,781	(\$1,368,714)	(26%)
Employment <sup>2</sup>	\$5,714,163	\$5,194,886	\$6,981,023	(\$1,786,137)	(34%)
Licence Fees to City of Hope <sup>1</sup>	\$6,966,611	\$6,944,444	\$6,674,520	\$269,924	4%
Research and Development on other cancer targets <sup>3</sup>	\$5,601,101	\$5,430,552	\$1,093,625	\$4,336,927	80%
Phase 1 clinical trial and manufacturing <sup>3</sup>	\$1,875,006	\$1,875,006	\$804,355	\$1,070,651	57%
Opening new additional Phase 1 sites <sup>1</sup>	\$5,000,000	\$1,400,000	\$1,390,411	\$9,589	1%
Other commercial and academic collaborations <sup>3</sup>	\$5,000,000	\$4,085,743	\$3,426,089	\$659,654	16%
Total	\$38,529,957	\$33,084,456	\$29,637,783	\$3,446,673	10%

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

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

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

<sup>&</sup>lt;sup>4</sup>Some of the above items have been reallocated to better align to the prospectus classifications as opposed to operating line items.



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 or via the L1 Capital Facility.

Authorised on behalf of 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

## **Investors**

Jennifer Chow Chief Executive Officer and Managing Director Chimeric Therapeutics

T: + 1 9087238387

E: jchow@chimerictherapeutics.com W: www.chimerictherapeutics.com

Paul Hopper Executive Chairman Chimeric Therapeutics T: + 61 406 671 515

E: paulhopper@lifescienceportfolio.com



<u>Media</u>

Matthew Wright NWR Communications P: +61 451 896 420

E: matt@nwrcommunications.com.au

# **Appendix 4C**

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

# Name of entity

Chimeric Therapeutics Limited			
ABN	Quarter ended ("current quarter")		
68 638 835 828	30 June 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	(2,042)	(5,922)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(991)	(5,371)
	(f) administration and corporate costs	(521)	(2,017)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	15
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)	90	189
1.9	Net cash from / (used in) operating activities	(3,459)	(13,106)

1.2a (research and development) payments for the year to date incorporates a reclassification of \$260k of consulting expenditure that was previously coded to 1.2e (staff costs) and 1.2f (administration and corporate costs). The Company recognises this reclassification as appropriate to provide more relevant information to stakeholders. The reclassification did not have an impact on net cash from/(used in) operating activities.

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(6)
	(d) investments	-	-
	(e) intellectual property	-	(527)
	(f) other non-current assets	-	-
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	-	(533)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	500	14,891
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	8	8
3.4	Transaction costs related to issues of equity securities or convertible cdebt securities	(470)	(1,329)
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 – payments of licence fee liabilities	(2,046)	(4,087)
3.10	Net cash from / (used in) financing activities	(2,008)	9,483

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	23,716	22,410
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,459)	(13,106)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(533)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2,008)	9,483
4.5	Effect of movement in exchange rates on cash held	133	128
4.6	Cash and cash equivalents at end of period	18,382	18,382

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	18,382	14,676
5.2	Call deposits	-	9,040
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)	18,382	23,716

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	277
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.		

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.	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)	30,000	30,000
7.4	Total financing facilities	30,000	30,000
7.5	Unused financing facilities available at quarter end		30,000

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.

7.3 Other refers to \$30 million Equity Placement Agreement with L1 Capital announced 9 June 2022. Commitment period to issue equity under the Agreement ends 9 June 2024. The Company has complete discretion regarding timing of placements and has no obligation to undertake placements.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,459)
8.2	Cash and cash equivalents at quarter end (item 4.6)	18,382
8.3	Unused finance facilities available at quarter end (item 7.5)	30,000
8.4	Total available funding (item 8.2 + item 8.3)	48,382
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	14.0
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

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

# **Compliance statement**

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

Date: 29 July 2022

Authorised by: The Board

(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".
- 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.



Phone +61 3 98245254 Email info@chimerictherapeutics.com

# **Chimeric Therapeutics Limited**

ACN 638 835 828

**ASX: CHM** 

