Chimeric Therapeutics – Positive Momentum Continues as Pipeline Advances

Chimeric Therapeutics (ASX:CHM)

Share Price: A$0.14

Valuation: A$0.93

Key Statistics

52 Week Range	A$0.09 - $0.36
Avg. Volume (3 months)	664.16K
Shares Outstanding	425.28M
Market Capitalization	A$59.53M
EV/Revenue	N/A
Cash Balance*	A$18.38M
Analyst Coverage	5

***Cash balance as of June 2022**

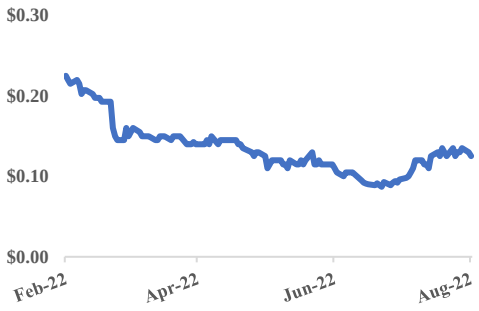
Revenue (in A$mm)

June - FY	2021A	2022E	2023E
1Q	N/A	N/A	N/A
2Q	N/A	N/A	N/A
3Q	N/A	N/A	N/A
4Q	N/A	N/A	N/A
FY	N/A	N/A	N/A

EPS (in A$)

June – FY	2021A	2022E	2023E
1Q	N/A	N/A	N/A
2Q	N/A	N/A	N/A
3Q	N/A	N/A	N/A
4Q	N/A	N/A	N/A
FY	(0.08)	(0.05)	(0.05)

Stock Price Chart



Investment Highlights

- **Clinical Trial Progress Update -** With licensing of the CORE-NK platform, the company currently has two candidates in Phase 1 clinical trial. The CLTX CAR-T clinical trial targeting Glioblastoma is progressing well. Chimeric recently announced the completion of key manufacturing milestones supporting the expansion of the clinical program. The completion of manufacturing and quality release of the CLTX CAR-T viral vector marks a key milestone in its development. The company is currently focused on expanding the clinical program across multiple clinical sites for the phase 1 Glioblastoma trial and also the phase 1 clinical basket trial in solid tumors. The company recently announced the receipt of a patent from the Japan Patent Office covering its CLTX CAR Technology. After successful completion of the phase 1 trial of the CORE NK platform in blood cancers and solid tumors, the company will initiate a phase 1B trial to study NK cells with IL-2 & Vactosertib. Approved by the U.S. FDA, the trial is expected to be initiated shortly, enrolling 12 patients at UH Seidman Cancer Center in Ohio with either locally advanced/metastatic colorectal cancer or relapsed/refractory blood cancers. While NK cells and Vactosertib are experimental, the use of IL-2 (Proleukin®) has been approved by the FDA for treating other cancers. With a deep clinical pipeline, the company has four clinical trials in progress or planned within nine months.

- **Licenses Viral Vector Technology -** The company has expanded its licensing agreement with the University of Pennsylvania related to CDH 17 CAR therapies. To advance its CDH17 CAR-T therapy, the company acquired a non-exclusive license to use Penn's third generational lentiviral vector plasmid system. The viral vector is a critical component in the development and manufacturing of CAR-T cells. The management believes the cost of licensing amendment is not financially material and will be financed from the current cash reserves.

- **Changes in Senior Management -** The company appointed Dr. Jason B. Litten to the position of Chief Medical Officer (CMO) who brings with him 15 years of extensive experience in drug development. He has worked on numerous CAR T and NK cell therapies and has served as the Chief Medical Officer (CMO) at Artiva Biotherapeutics, where he held the development of a portfolio of allogeneic NK cell therapies.

- **Q4 Cash Flow and Valuation Update -** The operating cash burn for Q4 and the year ended 2022 came in at A$3.45 million and A$13.10 million, respectively. The company reported cash and cash equivalents at $18.38 million for the year ended 2022. We have updated our financial model, reducing our estimates for expected cash burn. Given the company's exposure to a number of clinical trials, we have shifted our expectations for the commercialization of CLTX CAR-T GBM from 2026 to 2027. Additionally, updating the comparable company analysis yielded a value of A$0.93 per share contingent on successful execution by the company.

Company Description

Chimeric Therapeutics is an Australian clinical-stage cell therapy company established in 2020. The company researches and develops innovative and promising cell therapies that they believe can cure cancer and not just delay disease progression

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CORE-NK platform – Expansive Platform Technology

Chimeric therapeutics expands pipeline with a platform technology

Immunotherapy holds a lot of promise in treating and curing cancer. The company believes in that vision and has decided to expand its T-cell immunotherapy portfolio with a new addition of a recently licensed NK platform. Natural Killer (NK) cells are an integral part of a human's innate immune system and are part of the first line of defense against foreign bodies and pathogens. These cells show spontaneous cytolytic activity against cells under stress and tumor-infected cells. Their natural ability to eliminate tumor cells has led to NK-based cell therapies being studied aside from T-cell-based therapies. The established safety profiles in the early clinical trials and fast-acting ability have led to an emerging effort for developing "off the shelf" NK-based cell immunotherapy. While there are challenges to such a setting that includes difficulty to meet clinical-grade ex-vivo expansion, limited ability to infiltrate solid tumors, and NK cells not being naturally abundant and robust enough to fight cancer as it grows. Chimeric Therapeutics believes that despite its limitations, NK-based cell therapy holds a lot of promise and has thus obtained an exclusive option to license a **C**linically validated, **O**ff the shelf, **R**obust, **E**nhanced **N**atural **K**iller cell platform (CORE-NK platform) developed at Case Western Reserve University (CWRU). The platform is designed and developed by Dr. David Wald, who is a leading expert in immuno-oncology at CWRU, which leverages the natural anti-cancer properties of naked natural killer cells that provides an optimal foundation for the development of next-generation CAR NK therapies.

Natural Killer Cells innate ability to identify and kill and tumor cells

The core NK platform uses membrane-bound IL-21-based NK cell feeder cell lines to activate and expand the healthy donor naked natural killer cells to make them more active and robust to combat cancer as it grows. Interleukins (IL) are a type of cytokine which helps to modulate growth, differentiation, and activation during inflammatory and immune responses. IL-21 is one of the several interleukins, which acts on various immune cells of the innate and the adaptive immune system that helps in enhancing NK cell activity. Using membrane-bound IL-21 ensures robust and sustained proliferation of highly cytotoxic NK cells. The expanded NK cells exhibit increased cytotoxic function against a panel of blood cancer and solid tumor cells compared to IL-2-activated non-expanded NK cells[1]. Recent clinical trials suggest that high dosages of NK cells (>10^9/kg) are safe and efficient. Unlike T-cells, another major potential advantage of NK cell-based therapy is that it can be carried out as off-the-shelf therapy and supports single donor expansion to treat multiple patients.

NK cell-based therapies could have various advantages over T-cell therapies

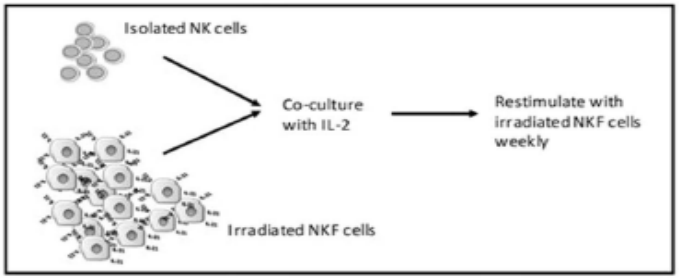

Exhibit 1: Schema of the NKF based NK cell expansion platform[2]

[1]Ojo, E.O., Sharma, A.A., Liu, R. *et al.* Membrane bound IL-21 based NK cell feeder cells drive robust expansion and metabolic activation of NK cells. *Sci Rep* **9,** 14916 (2019). https://doi.org/10.1038/s41598-019-51287-6

[2] Ojo, E.O., Sharma, A.A., Liu, R. *et al.* Membrane bound IL-21 based NK cell feeder cells drive robust expansion and metabolic activation of NK cells. *Sci Rep* **9,** 14916 (2019). https://doi.org/10.1038/s41598-019-51287-6

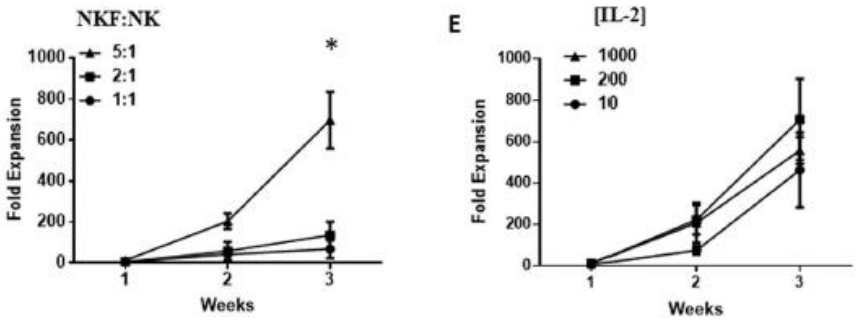

Exhibit 2: Fold expansion of NK cells at the indicated NKF: NK ratios and 200U/ml IL-2 after three weeks, n = 4[3]

Pre-Clinical Efficacy and Safety Profile

Preclinical trial results indicated decreased growth of tumor cells and improvement in survival rate

The NKF-NK cells developed through the CORE-NK platform were first tested on mouse models of sarcoma and lymphoid leukemia. The sarcoma model was used as it leads to metastasis to the lungs, the most common site for sarcoma metastasis in humans and a known site for NK-cell trafficking in vivo[4]. The initial results were encouraging pertaining to the sarcoma model as not only reduction in the growth of sarcoma tumor was observed with NKF-NK cell administration but also a reduction in tumor metastasis to the lungs was also observed. In the case of highly aggressive lymphoid leukemia. NSG mice injected with NKF-NK cells showed decreased proliferation of tumor cells and a 13 days median increase in survival over control-treated mice.

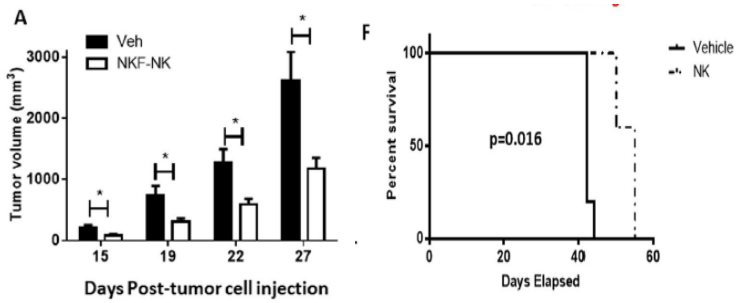

Exhibit 3: NKF-NK cells exhibit efficacy in a mouse sarcoma model[5]

The results from the preclinical trials (mouse models) were encouraging in terms of both efficacy and safety. The NKF-NK cell lines successfully exhibited potent cytotoxicity in blood cancer and solid tumors and reduced tumor burden in both primary and metastatic tumor sites. The university concluded the phase 1 trial in June 2021 involving subjects with both solid tumors and blood cancer. Initial results from the phase 1 trial results are expected in 2022. The trial results will provide early-stage validation for the development of next-generation CAR-NK products where the company's focus lies.

[3] Ojo, E.O., Sharma, A.A., Liu, R. *et al.* Membrane bound IL-21 based NK cell feeder cells drive robust expansion and metabolic activation of NK cells. *Sci Rep* **9,** 14916 (2019). https://doi.org/10.1038/s41598-019-51287-6

[4] Ojo, E.O., Sharma, A.A., Liu, R. *et al.* Membrane bound IL-21 based NK cell feeder cells drive robust expansion and metabolic activation of NK cells. *Sci Rep* **9,** 14916 (2019). https://doi.org/10.1038/s41598-019-51287-6

[5] Ojo, E.O., Sharma, A.A., Liu, R. *et al.* Membrane bound IL-21 based NK cell feeder cells drive robust expansion and metabolic activation of NK cells. *Sci Rep* **9,** 14916 (2019). https://doi.org/10.1038/s41598-019-51287-6

From Autologous to Allogeneic - Creating a Strong Pipeline of NextGen Cell Therapy

With the addition of the CORE-NK platform, Chimeric Therapeutics has the potential to offer a complete range of therapies from Autologous (personalized) to Allogenic (off the shelf). The company's major focus is on integrating Chimeric Antigen Receptors (CAR) with NK cells which enhances the recognition of specific antigens on tumor cells, allowing targeted destruction of cancerous cells. Chimeric Therapeutics, in collaboration with Dr. David Wald at CWRU, will begin the research collaboration to further engineer the CORE-NK platform by using the company's current pipeline of chimeric antigen receptors (CLTX and CDH17). The five new therapies that the company is adding to its pipeline include CLTX CAR-NK, CDH17 CAR-NK, an undisclosed CAR-NK, the CORE-NK platform (phase 1 trial completed), and a next-generation CORE-NK platform targeting combination therapies for Acute Myeloid Leukemia, Multiple Melanoma, and B Cell Malignancies. This takes the company's total to seven novel cell therapies utilizing NK cells and T-cells. Combining the CORE-NK platform with that of Chimeric Antigen Receptors (CARs) enhances the platform leading to the targeted killing of tumor cells. CAR-NK cell therapy holds a lot of promise, due to its large-scale clinical use. Various preclinical research has shown that NK cells can be effectively engineered to express extensive cytotoxic activity against hematological and solid tumors. Chimeric Therapeutics has built an innovative cell therapy pipeline and strengthened its positioning as Australia's leading cell therapy player. The company is expected to completely license the NK platform from CWRU in return for the development milestones and industry-standard royalty rates based on net sales.[6]

Currently, 19 trials investigating CAR-NK cells for the treatment of hematological malignancies and the treatment of solid tumors are underway. Most of the CAR-NK cell trials are conducted in China (15 trials), while three trials are ongoing in the US, and only one trial is performed in Europe (Germany). In addition, a few trials are currently addressing CAR-NK/T cell products (2 trials in the US and one trial in China) as well as CAR-modified cytokine-induced killer cells (1 trial in Italy).[7]

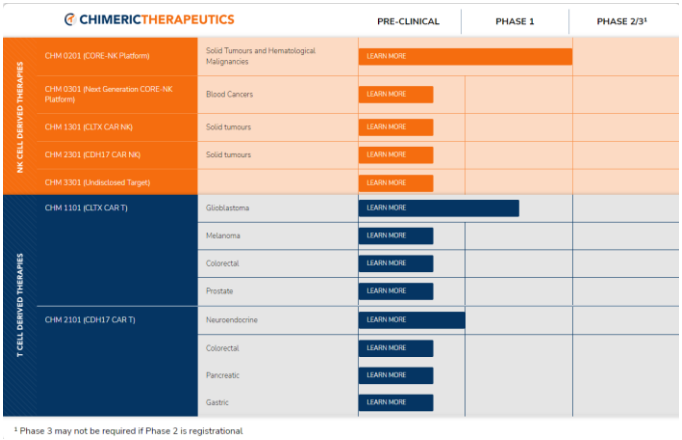

Exhibit 4: Pipeline Overview. Source: Chimeric Therapeutics Investment Presentation

[6] CAR-engineered NK cells; a promising therapeutic option for treatment of hematological malignancies. Stem Cell Research & Therapy. 12. 10.1186/s13287-021-02462-y.
[7] Albinger, N., Hartmann, J. & Ullrich, E. Current status and perspective of CAR-T and CAR-NK cell therapy trials in Germany. *Gene Ther* **28,** 513–527 (2021). https://doi.org/10.1038/s41434-021-00246-w

The Target Market

Chimeric's and CWRU's focus is on treating various solid tumors, including various forms of blood cancers. Blood cancer starts as rapid and out of control growth of abnormal cells in blood-forming tissue, including the bone marrow. There are various kinds of blood cancers, but Acute Lymphocytic Leukemia (ALL), Chronic Lymphocytic Leukemia (CLL), non-Hodgkin lymphoma, and multiple myeloma are the most common forms of blood cancer. An estimated 186,400 cases of blood cancer are expected to be diagnosed in the US. The 5-year survival rate for all types of leukemia is 65%, while it is the 11th leading cause of cancer-related mortality worldwide. The standard of care for leukemia is Chemotherapy and radiation therapy, but in the past decade, various immunotherapies, including CAR-T cell therapies, have been FDA approved to treat some lymphomas, leukemias, and multiple myeloma.

Solid tumors targeted by the CORE-NK platform in initial Case Western Reserve University trials include colorectal cancer, Ewing sarcoma, and soft tissue sarcoma. Sarcoma occurs in bones and other soft tissues of the body, including cartilage, muscle, fibrous tissue, or other connective or supportive tissue. Soft tissue sarcomas are by far the most common form of sarcomas, while malignant bone tumors account for 10% of all sarcomas. Sarcomas as a whole is a rare disease accounting for just 1% of all adult solid malignant tumors. About 13,460 new cases of soft tissue sarcomas and 149,500 cases of colorectal cancer will be diagnosed in the US in 2021. The 5-year relative survival rate of soft tissue sarcoma and colorectal cancer is 65%, while it varies from 15% to 80% for distant stages to localized forms of cancer, respectively. Colorectal cancer that has not spread to distant sites and small-low grade sarcomas may be removed through surgery. In contrast, the high-grade sarcomas and stage 0 and stage I colorectal cancer are treated through a combination of chemotherapy, radiation therapy, and surgery. Aside from the standard therapies, three FDA-approved immunotherapies are used to treat sarcoma, while many more are being investigated in a clinical trial. Immunomodulators, including Dostralimab, Pembrolizumab, and Denosumab as targeted antibodies, are the FDA-approved immunotherapies.

Chimeric Reports Encouraging Interim Phase 1 Trial Data for its rGBM Indication

The CLTX CAR-T cell therapy provided encouraging insights into the safety data in the early stage of the phase 1 trial. The therapy was well tolerated with no dose-limiting toxicities among the four patients enrolled in dose level 1 of the trial. A disease control rate of 75% was observed in three out of four patients exhibiting the best response of stable disease at the lowest dose level of $44x10^6$ CLTX CAR-T cells. The cell dosage was also well-tolerated, and none of the patients experienced dose-limiting toxicity aside from one subject who experienced grade 3 cerebral edema. The bioactivity of the cells was also persistent throughout treatment, indicating that the CLTX CAR T cells are not immunogenic. The company is expected to progress the trial with plans to expand to a multi-site trial in 2021. Dosage is expected to increase from the current $44x10^6$ to $440x10^6$.

Income Statement	FY2020 A	FY2021 A	FY2022 E	FY2023 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2028 E	FY2029 E
Net sales	-	-	-	-	-	-	-	520,182,504.7	790,409,897.1	1,114,882,800.0
Cost of sales	-	-	-	-	-	-	-	(104,036,500.9)	(158,081,979.4)	(222,976,560.0)
Gross profit	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**416,146,003.8**	**632,327,917.7**	**891,906,240.0**
Operating expenses										
General and Administrative Expenses	(63,260.0)	(8,963,348.0)	(6,342,479.0)	(6,659,603.0)	(6,992,583.1)	(7,132,434.8)	(7,275,083.5)	(208,073,001.9)	(316,163,958.9)	(445,953,120.0)
Marketing Expense	(748.0)	-	-	-	-	-	-	(52,018,250.5)	(79,040,989.7)	(111,488,280.0)
Research and Development	-	(3,778,382.0)	(9,823,793.2)	(11,788,551.8)	(12,967,407.0)	(14,264,147.7)	(15,690,562.5)	(17,259,618.7)	(79,040,989.7)	(78,041,796.0)
Share Based Payments	-	(2,102,327.0)	-	-	-	-	-	-	-	-
EBITDA	**(64,008.0)**	**(14,844,057.0)**	**(16,166,272.2)**	**(18,448,154.8)**	**(19,959,990.1)**	**(21,396,582.5)**	**(22,965,646.0)**	**138,795,132.7**	**158,081,979.4**	**256,423,044.0**
Depreciation and amortization expenses	-	(2,633.0)	(919,344.6)	(919,994.6)	(920,644.6)	(921,294.6)	(921,944.6)	(3,614,214.0)	(9,368,996.8)	(16,752,006.0)
Other income/ (expense)										
License Agreement Payments	-	-	(5,879,628.0)	(208,333.0)	(2,986,110.0)	(1,597,221.0)	(16,874,999.0)	(34,107,490.7)	(61,456,579.7)	(17,762,573.4)
Other non operating expenses	-	-	-	-	-	-	-	-	-	-
EBIT	**(64,008.0)**	**(14,846,690.0)**	**(22,965,244.8)**	**(19,576,482.3)**	**(23,866,744.7)**	**(23,915,098.0)**	**(40,762,589.5)**	**101,073,428.0**	**87,256,402.9**	**221,908,464.6**
Interest Income	-	2,646.0	4,482.0	163.8	6,466.4	1,844.2	8,258.8	14.6	12,559.7	19,742.5
Interest Expense	-	(5,877.0)	-	-	-	-	-	-	-	-
Profit before exceptional items, extraordinary items and tax	**(64,008.0)**	**(14,849,921.0)**	**(22,960,762.7)**	**(19,576,318.5)**	**(23,860,278.2)**	**(23,913,253.8)**	**(40,754,330.7)**	**101,073,442.6**	**87,268,962.6**	**221,928,207.1**
Exchange loss (net)	-	(263,790.0)	-	-	-	-	-	-	-	-
Provision for costs associated with closure of operations and impairment of int	-	-	-	-	-	-	-	-	-	-
Employee seperation cost	-	-	-	-	-	-	-	-	-	-
Profit before tax from continuing operations	**(64,008.0)**	**(15,113,711.0)**	**(22,960,762.7)**	**(19,576,318.5)**	**(23,860,278.2)**	**(23,913,253.8)**	**(40,754,330.7)**	**101,073,442.6**	**87,268,962.6**	**221,928,207.1**
Income tax (expense) benefit	-	-	-	-	-	-	-	(26,279,095.1)	(22,689,930.3)	(57,701,333.8)
Net earnings including noncontrolling interests	**(64,008.0)**	**(15,113,711.0)**	**(22,960,762.7)**	**(19,576,318.5)**	**(23,860,278.2)**	**(23,913,253.8)**	**(40,754,330.7)**	**74,794,347.5**	**64,579,032.3**	**164,226,873.2**

Exhibit 5: Income Statement Snapshot Source: Diamond Equity Research

Risk Factors

- **Dependence upon License Agreements:** Chimeric has entered into a license agreement with City of Hope for its CLTX CAR-T technology, thus its business is in part dictated and dependent on the terms and conditions agreed upon by both parties. Any non-compliance with the terms of this agreement can have an adverse impact on Chimeric's business.

- **Product in Development and not approved for commercial sale:** Chimeric Therapeutics' oncology pipeline is still in its early phases of trials and further even if trials are successful there is no guarantee that the following commercialization will be successful.

- **Arrangement with Third-Party Collaborators:** The company may collaborate with other pharmaceutical and life sciences companies to complete its development and commercialization of products. Currently, it has a license agreement with the City of Hope and similarly, Chimeric has also been granted worldwide exclusive rights to the novel 3rd generation CDH17 CAR-T Cell Therapy from the University of Pennsylvania.

- **Competition from Ongoing Trials:** The number of clinical trials has increased over the years with currently 5 FDA-approved CAR T cell therapies for treating acute lymphoblastic leukemia, B-cell lymphoma, follicular lymphoma, mantle cell lymphoma, multiple myeloma, and 18 ongoing clinical trials that can put Chimeric in direct competition with the companies who have substantially greater resources than the company and may alter Chimeric's contemplated pricing and margins if its drugs are approved.

- **Ability to raise capital:** The company will likely be required to raise additional equity or debt capital in the future. There is no assurance a raise will be successful when required and/or at attractive terms.

These risk factors are not comprehensive. For a full list of risk factors, please read Chimeric Therapeutics' latest prospectus and/or annual filings.

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