Chimeric Therapeutics – Q3 2023 Cash Flow Update, Expanding Patent Portfolio and Progress in Clinical Trials

Chimeric Therapeutics (ASX: CHM)

Share Price: A$0.04 | Valuation: A$0.70

Key Statistics

52 Week Range	A$0.036 - A$0.15
Avg. Volume (3 months)	504.11K
Shares Outstanding	437.09M
Market Capitalization	A$16.60M
EV/Revenue	N/A
Cash Balance*	A$2.83M
Analyst Coverage	2

***Cash balance as of March 2023**

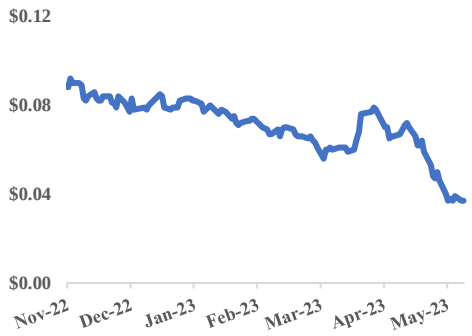
Revenue (in A$mm)

June - FY	2022A	2023E	2024E
1H	0.00	0.00	0.00
2H	0.00	0.00	0.00
FY	0.00	0.00	0.00

EPS (in A$)

June – FY	2022A	2023E	2024E
1H	(0.03)	(0.03)	(0.03)
2H	(0.01)	(0.02)	(0.03)
FY	(0.04)	(0.05)	(0.06)

Stock Price Chart (in A$)



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Investment Highlights

- **Phase 1B Trial of CHM 1101 Approved for Initiation:** The company's first autologous CAR T cell therapy aimed to treat patients with recurrent or progressive glioblastoma is in its final stages of Phase 1A clinical trial. The company has previously reported strong efficacy data from the first two of the four cohorts in the CHM 1101 phase 1A study. Three of the four patients treated in cohort 1 (44 x 10^6 CLTX CAR T cells) exhibited a stable disease, while two of the three evaluable patients in cohort 2 (88 x 10^6 CLTX CAR T cells) reported stable disease. The company has completed the dosing in the third cohort with no dose-limiting toxicities, and the fourth dose cohort (440 x 10^6 CLTX CAR T cells) has been initiated. Furthermore, Chimeric has received ethics approval to initiate a two-part phase 1B multi-center clinical trial in recurrent GBM patients. The multi-site trial will be supported by the participation of the Sarah Cannon Research Institute (SCRI), one of the world's leading oncology research organizations conducting community-based clinical trials. Part A, or the dose confirmation part of the trial, will enroll 3-6 patients and will be a completion of the phase 1 dose-escalation/confirmatory study. *The comprehensive initial Phase 1A data readout at the end of 2023 will be a crucial milestone for CHM 1101*, potentially supporting further development of the drug. Based on safety and efficacy data from the dose escalation/confirmation cohorts and the optimal dosage, part B of the trial, a dose expansion phase will enroll 12-26 patients assessing multiple efficacy endpoints and safety. The successful completion of the part B dose expansion cohort will be followed by a registration trial in a much larger patient population.

- **Moving Another Potential Drug Candidate to Clinical Testing:** Chimeric Therapeutics has made considerable strides in progressing its diversified pipeline of multiple candidates toward clinical trials. Recently the company announced positive feedback from its pre-IND meeting with the U.S. FDA and the successful completion of viral manufacturing and quality release supporting the initiation of Phase 1 clinical trial for CHM 2101. Both milestones signify a third candidate in the clinic that will be evaluated in patients with gastrointestinal and neuroendocrine tumors in the proposed phase 1 clinical trial. CHM2101, or CDH17 CAR T, is a novel CAR T therapy designed to find and kill CDH17-expressing cancer cells. Preclinical evidence has demonstrated strong anti-tumor properties in eight different types of gastrointestinal cancers with no off-target toxicity. The company's pre-IND meeting with the FDA provided a clear clinical development pathway for IND submission for CHM 2101. Furthermore, in early March, the company announced the completion of manufacturing and quality release for the CHM 2101 viral vector amidst a challenging market environment and the current shortage of vector manufacturing capacity. These supply chain challenges have significantly delayed multiple other companies' cell therapy development programs.

- **Valuation:** In the past quarter, the company has made headway on multiple fronts, with material progress visible in its pipeline candidates. With the announcement of the company's cash flow report, we have made changes to our valuation model, reflecting the updated financial numbers and accounting for potential dilution. The diverse pipeline of the company, the advancements seen in various candidates, and the promising early clinical and pre-clinical data have prompted a reassessment of the company's risk profile since our initiation coverage. Consequently, an adjustment has been made to the discount rate to align with this updated assumption. Furthermore, we have updated the comparable company analysis yielding a valuation of $0.70 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

- **Quarterly Cash Flow Update for Q3 2023 and Capital Raise:** The operating cash burn for the third quarter of the financial year 2023 was A$3.8 million, 87% of which was incurred for direct research and development expenditure (A$1.23 million) and staff costs (A$2.06 million). The company also received A$3.1 million as government grants and tax incentives during the quarter. Chimeric reported cash and cash equivalents at A$2.83 million for the quarter ended March 2023. The company has received commitments from its board and management to raise A$1.04 million by issuing 22,663,040 shares at A$0.046 per share. Additionally, the company has also launched a share purchase plan (SPP) to raise an additional A$5.25 million. The combined A$6.29 million raise when completed will add approximately 153 million shares to the total shares outstanding. It should also be noted that the company, in the recent ASX filing relating to its SPP offering, stated that it has reduced operating costs, including reduced employment costs, by A$1.7 million and A$2.5 million for the calendar years 2023 and 2024, respectively, further extending its cash runway.

- **Expanding Patent Portfolio:** Chimeric Therapeutics announced an expansion of its patent portfolio for its CLTX CAR technology and other assets. The Indian Patent Office granted a patent covering certain aspects of its CAR technology using CLTX, and the Israel Patent Office issued a notice of allowance for the same. Additionally, the Indian Patent Office issued a patent covering its pre-clinical stage asset CHM 1301.

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

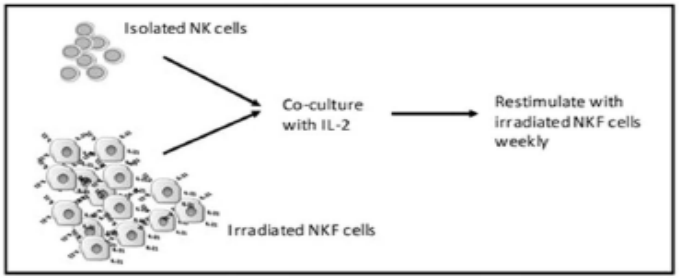

Exhibit 1: Schema of the NKF based NK cell expansion platform[2]

[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

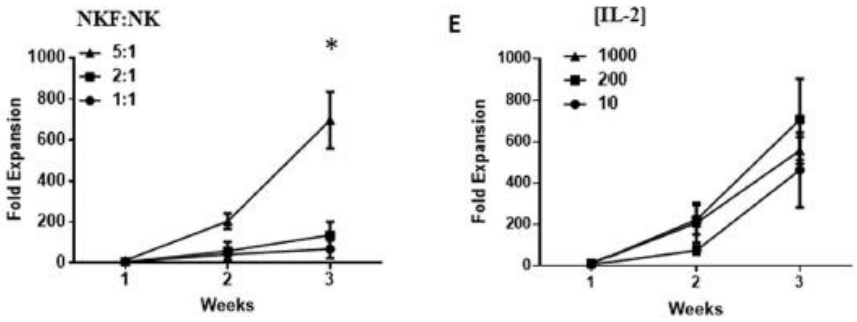

Exhibit 2: Fold expansion of NK cells at the indicated NKF: NK ratios and 200U/ml IL-2 after three weeks, n = 4[3]

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.

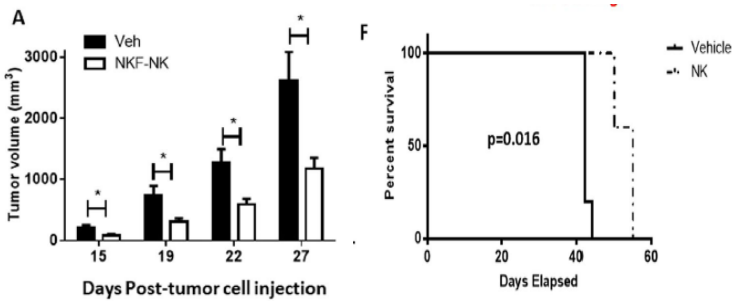

Exhibit 3: NKF-NK cells exhibit efficacy in a mouse sarcoma model[5]

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]

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

[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

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.

Appendix

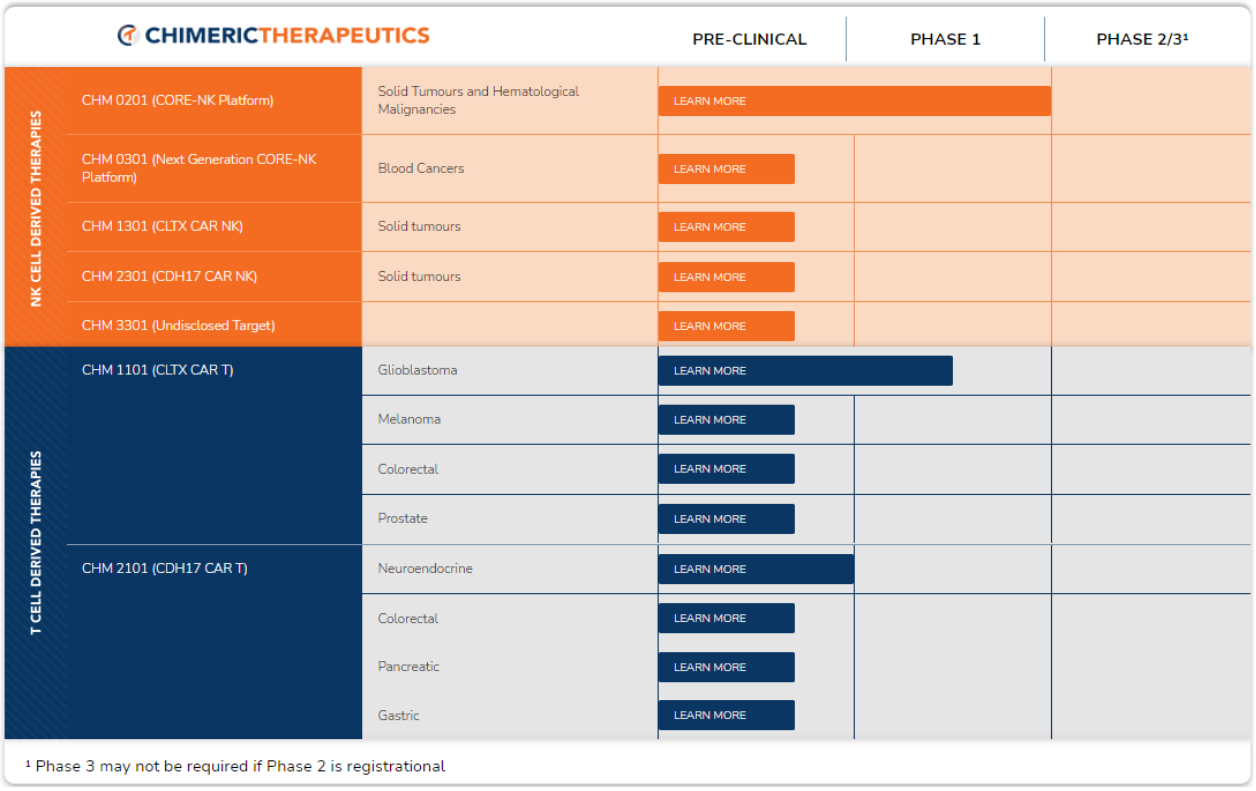

Exhibit 4: Chimeric Therapeutics Pipeline Overview. Source: Chimeric Therapeutics Website

Income Statement

Income Statement	FY2021 A	FY2022 A	FY2023 E	FY2024 E	FY2025 E	FY2026 E
Net sales	-	-	-	-	-	-
Cost of sales	-	-	-	-	-	-
Gross profit	-	-	-	-	-	-
Operating expenses						
General and Administrative Expenses	(8,963,348.0)	(7,896,788.0)	(10,135,273.8)	(11,148,801.2)	(12,263,681.3)	(13,490,049.4)
Marketing Expense	-	-	-	-	-	-
Research and Development	(3,778,382.0)	(5,174,094.0)	(15,535,790.4)	(18,642,948.4)	(23,303,685.5)	(29,129,606.9)
Share Based Payments	(2,102,327.0)	(3,169,055.0)	(4,705,900.8)	(5,958,349.9)	(7,113,473.4)	(8,523,931.3)
EBITDA	**(14,844,057.0)**	**(16,239,937.0)**	**(30,376,965.0)**	**(35,750,099.5)**	**(42,680,840.2)**	**(51,143,587.6)**
Depreciation and amortization expenses	(2,633.0)	(949,762.0)	(975,716.4)	(986,409.8)	(987,059.8)	(987,709.8)
Other income/ (expense)						
License Agreement Payments	-	-	(208,333.0)	(2,986,110.0)	(1,597,221.0)	(16,874,999.0)
Other non operating expenses / income	-	2,082,169.0	6,624,635.0	5,965,743.5	7,457,179.4	8,156,289.9
EBIT	**(14,846,690.0)**	**(15,107,530.0)**	**(24,936,379.4)**	**(33,756,875.8)**	**(37,807,941.6)**	**(60,850,006.5)**
Finance income	2,646.0	12,977.0	17,427.2	3,166.9	2,776.9	7,946.5
Finance expenses	(5,877.0)	(640,127.0)	(10,302.0)	-	-	-
Profit before exceptional items, extraordinary items and tax	**(14,849,921.0)**	**(15,734,680.0)**	**(24,929,254.2)**	**(33,753,709.0)**	**(37,805,164.7)**	**(60,842,060.0)**
Exchange loss (net)	(263,790.0)	-	-	-	-	-
Employee seperation cost	-	-	-	-	-	-
Profit before tax from continuing operations	**(15,113,711.0)**	**(15,734,680.0)**	**(24,929,254.2)**	**(33,753,709.0)**	**(37,805,164.7)**	**(60,842,060.0)**
Income tax (expense) benefit	-	(163,720.0)	(104,361.0)	-	-	-
Net earnings including noncontrolling interests	**(15,113,711.0)**	**(15,898,400.0)**	**(25,033,615.2)**	**(33,753,709.0)**	**(37,805,164.7)**	**(60,842,060.0)**
Share of profit / (loss) of associates (net)	-	-	-	-	-	-
Minority interest	-	-	-	-	-	-
Net earnings attributable to Chimeric Therapeutics Shareholders	**(15,113,711.0)**	**(15,898,400.0)**	**(25,033,615.2)**	**(33,753,709.0)**	**(37,805,164.7)**	**(60,842,060.0)**

Exhibit 5: Income Statement Snapshot (in A$). 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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