

Company Sponsored Research  
Update Note  
12/06/2021

# Chimeric Therapeutics

## (ASX: CHM)

### CORE-NK Platform Transformative for Company

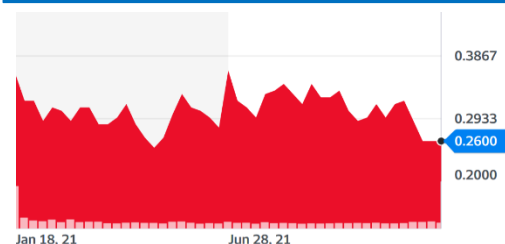
#### Investment Highlights

- Platform Technology is Transformative** - To expand its pipeline and its expansion in emerging immunotherapies, Chimeric has recently acquired an exclusive option to license the clinically validated NK cell platform. Natural Killer (NK) cells have been shown to have potent cytotoxic activity against tumor-infected cells and hold various advantages over T-cells. Licensing the CORE-NK platform reduces the company's dependency on its T-cell-based immunotherapy pipeline and also enhances its current pipeline adding two major oncological conditions - Blood Cancers and Sarcomas. NK cells' broad target cell reactivity and its natural potent toxicity make it a promising alternative and complement to T-cell-based immunotherapies creating synergistic opportunities. The CORE-NK platform not only provides the innate safety features of NK cell therapy but also provides the benefits of being an off-the-shelf therapy.
- Creating a Foundation for CAR NK Cell Therapy** - Chimeric will extend its existing pipeline of antigen receptors (CLTX AND CDH17) based immunotherapies towards NK cells as well. CAR allows the engineering of NK cells providing specificity to target the intended cells. The company is expected to leverage the clinically validated NK cell platform to develop CLTX CAR-NK, CDH17 CAR-NK, CHM 3301 (target undisclosed) and CHM 0301 a next generation CORE-NK platform (targeting blood cancer combination therapies).
- Encouraging Interim Phase 1 Trial Results** - Chimeric recently reported interim phase 1 trial results for its rGBM immunotherapy. The trial results showed promising safety data and a disease control rate of 75% in 3 out of 4 patients treated. There was no dose-limiting toxicity aside from one subject patient who developed cerebral edema. The initial trial results confirm the correlation between the MMP-2 marker and CLTX binding supporting the rationale to explore MMP-2 as a corrective marker. We see this early-stage data as encouraging as the company progresses further with its phase 1 trial using higher dose levels and dual-routes of administration.
- Valuation** - We have increased our valuation from \$1.04 per share to \$1.19 per share incorporating the option to license the CORE-NK platform, contingent on successful execution by the company. The company's expansion into CAR-NK cell therapies more than doubles the company's novel therapies count targeting major oncological conditions. The initial positive data from the CLTX CAR-T trial albeit early stage is promising. We have updated our valuation model to incorporate the CORE-NK platform and the incremental R&D cost associated with the clinical trials.

#### Biotechnology

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#### Price- Volume History



Source: Yahoo Finance

#### Key Statistics

<b>Closing Price (As of 12/03/2021)</b>	A\$0.26
<b>52 Week Range</b>	A\$0.24-\$0.44
<b>Average Volume (10 days)</b>	1.09M
<b>Shares Outstanding (M)</b>	333.44
<b>Market Capitalization (M)</b>	A\$86.69
<b>Number of Analysts Covering</b>	2
<b>Valuation Per Share</b>	A\$1.19
<b>Enterprise Value/Revenue</b>	N/A

#### Revenue(\$ in millions)

Dec. FY	2020A	2021A	2022E
<b>FY</b>	-	-	-

#### EPS(A\$)

Dec. FY	2020A	2021E	2022E
<b>FY</b>	(0.08)	(0.07)	(0.07)

#### 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

## CORE-NK platform – Expansive 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 **Clinically validated, Off the shelf, Robust, Enhanced Natural Killer** 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 immunoncology 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.

*Chimeric therapeutics expands pipeline with a platform technology*

*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 cells 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<sup>1</sup>. Recent clinical trials suggest that high dosages of NK cells (>10<sup>9</sup>/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*

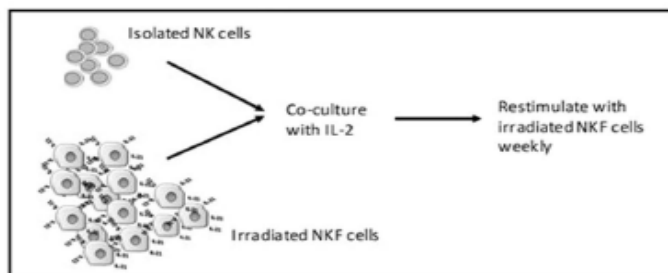


Exhibit 1: Schema of the NKF based NK cell expansion platform<sup>2</sup>

<sup>1</sup>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>

<sup>2</sup> 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>

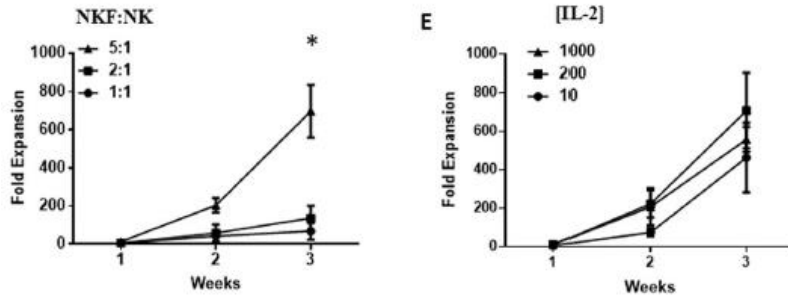


Exhibit 2: Fold expansion of NK cells at the indicated NKF: NK ratios and 200U/ml IL-2 after three weeks, n = 4<sup>3</sup>

## Pre-Clinical Efficacy and Safety Profile

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<sup>4</sup>. 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 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.

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

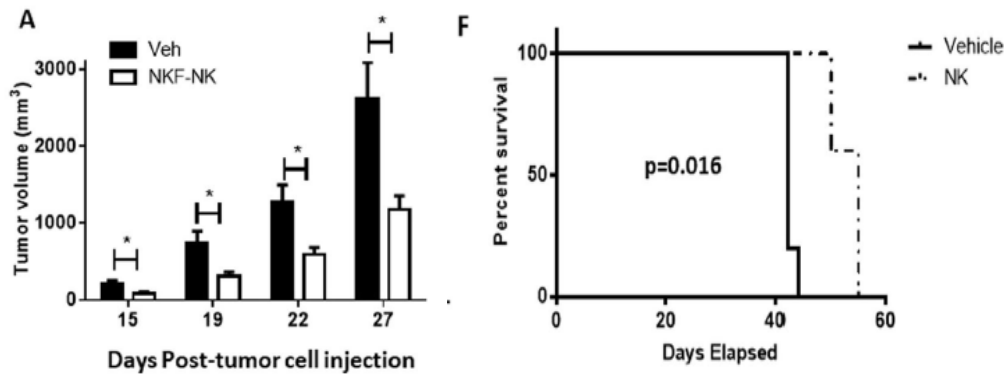


Exhibit 3: NKF-NK cells exhibit efficacy in a mouse sarcoma model<sup>5</sup>

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.

<sup>3</sup> 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>

<sup>4</sup> 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>

<sup>5</sup> 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 Allogeneic (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 hold 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.<sup>6</sup>

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).<sup>7</sup>

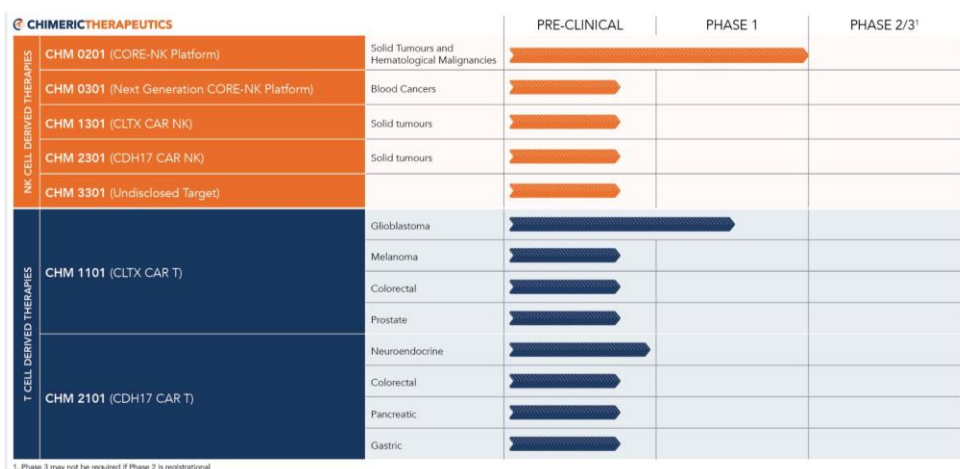


Exhibit 4: Chimeric Therapeutics Investment Presentation

<sup>6</sup> CAR-engineered NK cells; a promising therapeutic option for treatment of hematological malignancies. *Stem Cell Research & Therapy*. 12. 10.1186/s13287-021-02462-y.

<sup>7</sup> 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 Dostralinab, 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  $44 \times 10^6$  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  $44 \times 10^6$  to  $440 \times 10^6$ .

## Valuation

We have raised our valuation from A\$X1.04 per share or A\$346X million to A\$X1.19 per share or A\$396 million, contingent on successful execution by the company. The increase in valuation is largely attributed to the company acquiring the option to license the CORE-NK cell platform targeting various solid tumors and blood cancers. Chimeric is expected to add 3 CAR-NK cell therapies taking its current pipeline to seven novel cell therapies. The lead NK-cell therapy has recently completed its phase 1 trial, with results expected by 2022. Total Incidence of cancer targeted by CHM0201: CORE-NK platform is over 300,000 (includes blood cancers and solid tumors), providing a huge market opportunity. The CORE-NK platform provides the benefit of an allogeneic setting drastically reducing the per-patient per infusion cost compared to currently approved CAR-T cell therapy. While this licensing deal might prove transformational for the company, we have assumed a commercialization success rate of 15%, given that the option is yet to be exercised and the major focus for the company seems to be the CAR-NK therapies with planned phase 1 trial expected by 2023.

Income Statement	FY2020 A	FY2021 A	FY2022 E	FY2023 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2028 E	FY2029 E	FY2030 E
Net sales	-	-	-	-	-	-	379,217,788.8	505,229,048.3	856,496,566.8	1,211,711,648.7	1,570,955,310.3
Cost of sales	-	-	-	-	-	-	(56,882,668.3)	(75,784,357.2)	(128,472,985.0)	(145,405,397.8)	(188,514,637.2)
Gross profit	-	-	-	-	-	-	322,335,120.4	429,444,691.1	728,023,581.8	1,066,306,250.9	1,382,440,673.1
<b>Operating expenses</b>											
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)	(202,091,619.3)	(342,594,626.7)	(424,099,077.0)	(549,834,358.6)
Marketing Expense	(748.0)	-	-	-	-	-	-	(37,921,778.9)	(50,522,904.8)	(68,518,525.3)	(96,936,931.9)
Research and Development	-	(3,778,382.0)	(9,823,793.2)	(14,735,689.8)	(16,209,258.8)	(17,830,184.7)	(16,047,166.2)	(17,651,882.8)	(85,648,656.7)	(84,819,815.4)	(78,547,765.5)
Share Based Payments	-	(2,102,327.0)	-	-	-	-	-	-	-	-	-
EBITDA	(64,008.0)	(14,844,057.0)	(16,166,272.2)	(21,395,292.8)	(23,201,841.9)	(24,962,619.4)	261,091,091.9	159,178,284.1	231,251,373.0	460,450,426.5	675,510,783.4
Depreciation and amortization expenses	-	(2,633.0)	(919,344.6)	(919,994.6)	(920,644.6)	(921,294.6)	(1,158,955.7)	(4,010,852.1)	(9,944,297.9)	(17,958,566.0)	(28,741,400.4)
<b>Other income/ (expense)</b>											
License Agreement Payments	-	-	(5,879,628.0)	(208,333.0)	(2,986,110.0)	(1,597,221.0)	(26,839,553.6)	(39,396,578.2)	(72,315,232.1)	(32,762,799.1)	(42,615,427.3)
Other non operating expenses	-	-	-	-	-	-	-	-	-	-	-
EBIT	(64,008.0)	(14,846,690.0)	(22,965,244.8)	(22,523,620.3)	(27,108,596.4)	(27,481,135.0)	233,092,582.7	115,770,853.8	148,991,843.0	409,729,061.5	604,153,955.7
Interest Income	-	2,646.0	4,482.0	163.8	5,877.0	606.3	6,307.4	39,243.3	54,278.1	70,936.4	110,969.0
Interest Expense	-	(5,877.0)	-	-	-	-	-	-	-	-	-
Profit before exceptional items, extraordinary items and tax	(64,008.0)	(14,849,921.0)	(22,960,762.7)	(22,523,456.5)	(27,102,719.4)	(27,480,528.7)	233,098,890.1	115,810,097.0	149,046,121.1	409,799,997.8	604,264,924.7
Exchange loss (net)	-	(263,790.0)	-	-	-	-	-	-	-	-	-
Provision for costs associated with closure of operations and impairment of ir	-	-	-	-	-	-	-	-	-	-	-
Employee seperation cost	-	-	-	-	-	-	-	-	-	-	-
Profit before tax from continuing operations	(64,008.0)	(15,113,711.0)	(22,960,762.7)	(22,523,456.5)	(27,102,719.4)	(27,480,528.7)	233,098,890.1	115,810,097.0	149,046,121.1	409,799,997.8	604,264,924.7
Income tax (expense) benefit	-	-	-	-	-	-	-	(80,605,711.4)	(30,110,625.2)	(38,751,991.5)	(106,547,999.4)
Net earnings including noncontrolling interests	(64,008.0)	(15,113,711.0)	(22,960,762.7)	(22,523,456.5)	(27,102,719.4)	(27,480,528.7)	172,493,178.7	85,699,471.8	110,294,129.6	303,251,998.4	447,156,044.3
Share of profit / (loss) of associates (net)	-	-	-	-	-	-	-	-	-	-	-
Minority interest	-	-	-	-	-	-	-	-	-	-	-
Net earnings attributable to Chimeric Therapeutics	(64,008.0)	(15,113,711.0)	(22,960,762.7)	(22,523,456.5)	(27,102,719.4)	(27,480,528.7)	172,493,178.7	85,699,471.8	110,294,129.6	303,251,998.4	447,156,044.3
Adjusted Net income	(64,008.0)	(14,849,921.0)	(22,960,762.7)	(22,523,456.5)	(27,102,719.4)	(27,480,528.7)	172,493,178.7	85,699,471.8	110,294,129.6	303,251,998.4	447,156,044.3

Exhibit 5: Income Statement Snapshot

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