

# Non-Consolidated Financial Results (Japanese GAAP) for the Nine Months Ended September 30, 2023

November 14, 2023

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Scheduled filing date of quarterly financial results: November 14, 2023

Scheduled dividend payment commencement date: -

Supplementary materials prepared for the quarterly financial results: Yes

Holding of the quarterly financial results

explanatory meeting:

(Amounts of less than one million yen are rounded down)

#### 1. Financial Results for the Nine Months Ended September 30, 2023 (January 1, 2023 to September 30, 2023)

(1) Operating Results (Cumulative)

(% figures are the increase / (decrease) compared with the corresponding period of the previous fiscal year)

	Net Sa	les	Operating I	ncome	Ordinary I	ncome	Net Inco	me
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Nine months ended Sep. 30, 2023	524	20.8	(905)	_	(916)	_	(918)	_
Nine months ended Sep. 30, 2022	433	(19.9)	(1,039)	_	(1,029)	_	(1,027)	_

	Net Income per Share	Diluted Net Income per Share
	Yen	Yen
Nine months ended Sep. 30, 2023	(18.82)	_
Nine months ended Sep. 30, 2022	(23.87)	_

Notes: Despite the existence of shares with a dilutive effect, "Diluted Net Income per Share" is not stated because Chiome incurred a loss for each respective period.

#### (2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	Million yen	Million yen	%
As of Sep. 30, 2023	1,753	1,211	67.8
As of Dec. 31, 2022	2,215	1,790	80.2

(Reference) Equity As of Sep. 30, 2023: 1,188 million yen As of Dec. 31, 2022: 1,777 million yen

#### 2. Dividends

2. Dividellus					
	Annual Dividends				
	1Q-End	2Q-End	3Q-End	FY-End	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal Year Ending Dec. 31, 2022	_	0.00	_	0.00	0.00
Fiscal Year Ending Dec. 31, 2023	_	0.00	_		
Fiscal Year Ending				0.00	0.00
Dec. 31, 2023 (Forecast)				0.00	0.00

Note: Revision to the most recently announced dividend forecast: No

# 3. Forecasts of Financial Results for the Fiscal Year Ending December 31, 2023 (January 1, 2023 to December 31, 2023)

As it is difficult to provide reasonable estimates for Drug Discovery and Development Business at present, Chiome discloses only business forecasts for Drug Discovery Support Business; net sales ¥640 million.

#### Notes

- (1) Application of Special Accounting Practices in the Preparation of Quarterly Financial Statements: No
- (2) Changes in Accounting Policies, Changes in Accounting Estimates, and Retrospective Restatements
  - 1) Changes in accounting policies in line with revisions to accounting and other standards: No
  - 2) Changes in accounting policies other than 1) above: No
  - 3) Changes in accounting estimates: No
  - 4) Retrospective restatements: No
- (3) Number of Shares Issued (Common Stock)
  - 1) Number of shares issued as of the end of the period (including treasury stock)
  - 2) Number of treasury stock as of the end of the period
  - 3) Average number of shares for the period (cumulative total for the period)

As of	50,571,400	As of	48,423,500
Sep. 30, 2023	shares	Dec. 31, 2022	shares
As of	6,148	As of	147
Sep. 30, 2023	shares	Dec. 31, 2022	shares
Nine months ended	48,805,777	Nine months ended	43,047,660
Sep. 30, 2023	shares	Sep. 30, 2022	shares

<sup>\*</sup>This summary report on Chiome's quarterly financial statements is not subject to quarterly review procedures.

<sup>\*</sup> Explanation Concerning the Proper Use of Financial Results Forecasts and Other Relevant Specific Items Forward-looking statements including forecasts of financial results contained in this report are based on management's assumptions and beliefs that are determined to be reasonable in light of currently available information. Chiome cautions readers that due to a variety of factors actual results may differ materially from forecasts. For the assumptions that underpin financial results forecasts as well as other related items, please refer to the "1. Qualitative Information Regarding Quarterly Financial Results (3) Explanation of Forward-Looking Statements including Forecasts of Financial Results" on page 4 of this report.

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#### 1. Qualitative Information Regarding Quarterly Financial Results

#### (1) Operating Results

During the nine months of the year under review, the global and domestic economic environment remained uncertain for various reasons, such as a prolonged conflict in Ukraine, soaring costs and prices of resources and raw materials, and further depreciation of the yen.

Under the external environment, the Company's performance for the nine months under review was as follows. Net sales of \(\frac{\pmathbf{\text{\text{Y}}}}{24,023}\) thousand (an increase of \(\frac{\pmathbf{\text{\text{\text{\text{Y}}}}}{90,328}\) thousand year-on-year), operating loss of \(\frac{\pmathbf{\text{\tex{

Net sales increased in the current period compared to the same quarter last year. This was because of acquiring new clients in the drug discovery support business, including the conclusion of a new entrustment agreement with a domestic pharmaceutical company, as well as stable business with existing clients. In Profit and Loss, the operating loss, ordinary loss and net loss decreased compared to the same quarter last year, mainly because of the decreased CMC-related cost for CBA-1535 and R&D expenses compared to the same quarter last year.

An overview of the Company's business activities for the nine months under review is as follows.

In the drug discovery business, the Phase I studies of CBA-1205 and CBA-1535 are proceeding. For CBA-1205, currently, the second part of the Phase I study is ongoing, where the safety and initial efficacy of the study drug is to be assessed in hepatocellular carcinoma patients. Furthermore, we are actively promoting collaborative research with overseas research institutions to extend indications other than hepatocellular carcinoma, and exploring further drug discovery targeting DLK-1 to increase the value of CBA-1205 for out-licensing. The second clinical development product, CBA-1535, is a multi-specific antibody for cancer treatment. The first part of the study is ongoing, where we continue the dose escalation part to assess the safety in patients with solid tumors. For PCDC, a drug discovery pipeline, discussions are in progress with several overseas pharma companies under Mutual Confidentiality Agreements (and some under Material Transfer Agreement) mainly on the scientific aspects, with a view to execute out-licensing contracts. Our company is developing its business to achieve a surplus in a single year through upfront income from future out-licensing agreements on CBA-1205, CBA-1535 and PCDC.

For PFKR, a therapeutic antibody in central nervous system area, our company has been focusing on as an important project followed by PCDC. Its patent application was completed by the end of the previous fiscal year, and our out-licensing activities have started at major BD conferences in Japan and abroad. We are also promoting to generate further results in drug discovery business. For example, in one of the drug discovery projects in oncology which we already completed the patent application, after the presentation at an international conference last year, discussion is in progress on research direction, etc with an overseas company who were interested in the project. In addition, we continue the R&D work on the generation of lead antibodies against novel targets in order to expand the number and quality of our development pipelines.

#### > Drug Discovery Pipeline (out-licensed products)

Regarding LIV-1205, which was out-licensed to Switzerland-based ADC Therapeutics SA only for ADC (Antibody-Drug Conjugate) with PBD ("ADCT-701"), clinical studies are planned at the National Cancer Institute (NCI) in the USA for neuroendocrine cancer. An IND (Investigational New Drug) application has been submitted to conduct Phase I clinical studies. The Phase I clinical study is expected in 2023 that will be led by NCI.

### > Drug Discovery Pipeline (In-house programs, out-licensing candidates)

For CBA-1205, it is in Phase I clinical study in Japan. The main purpose of the study is to evaluate the safety and tolerability in patients with solid tumors in the first part, and in patients with hepatocellular carcinoma in the second part of the study. The patient enrollment of the first part has completed, and the high safety and tolerability of the antibody have been demonstrated. A Malignant Melanoma (a type of high-risk skin cancer) patient who was reported in the previous statement continues SD (stable disease) assessment for a long time and it has now exceeded more than 27 months with tumor shrinkage by RECIST v1.1. Dosing is still ongoing. In general, patients with solid tumors participating in Phase I study are those who had already received several standard treatments but are nonresponsive or intolerant to those treatments, or patients with unresectable advanced or recurrent solid tumors. The patients who participated in the first part had already received several standard treatments, therefore, we consider the continued SD evaluation with tumor shrinkage to be meaningful. As the continued dosing period is much longer than our initial forecasts in the above case, we are establishing a system in place to accomplish the Phase 1 study, including manufacturing additional study drugs which will be available by the end of the year. At the second part where we evaluate safety and initial efficacy of patients with hepatocellular carcinoma are proceeding, we confirmed one PR (partial response tumor shrinkage of 30% or more). Upon obtaining the PR case, we have decided to modify the eligibility criteria for patients' enrollment so that we should be able to analyze the scientific relationship between the PR case and the dosing of the study drug in order to verify its therapeutic potential. Also, the study period has been extended. There will be no change in the out-licensing schedule to date. We will proceed with our out-licensing activities while providing information on the progress of the study to potential pharma partners as appropriate.

For CBA-1535, we started dosing to the first patient at the end of June 2022, and it has made a steady progress in the clinical study in Japan. Regarding the timing for opening the second part of the study, we changed it to open after confirming the efficacy signals in the first part of the study, expected to be in 2024. This is to efficiently control our investment into the clinical development with considering the possibility of out-licensing CBA-1535. This is the first-in-human study to validate the mechanism of action of Tribody<sup>TM</sup> format as a T cell engager, which binds to both cancer cells and immune cells (T cells), hence activates T cells to kill cancer cells. If this concept is proved in CBA-1535, this will open up the possibility of applying the Tribody<sup>TM</sup> format to many other tumor antigens.

PCDC, as an antibody-drug conjugate of humanized anti-CDCP1 antibody, we are working on out-licensing activities, mainly for the use of ADC. Regarding this antibody, as development needs to combine ADC technology which companies already own with our antibody is high, our out-licensing activities are in progress with companies with ADC technology. Currently discussions are in progress with several pharma companies under Mutual Confidentiality Agreements (and some under Material Transfer Agreement) mainly on the scientific aspects, with a view to execute out-licensing contracts.

PTRY is a Tribody™ antibody and is designed to expect immune checkpoint inhibitory function in addition to the T cell engager function of CBA-1535. Its initial evaluations using animal models have shown strong anti-tumor effects. Currently, we are focusing on preclinical studies as one of our drug discovery pipelines.

For the humanized anti-Semaphorin 3A antibody, BMAA, we have been promoting joint research with Academia and other organizations based on the data we have obtained to date. We will proceed to out-licensing activities after adding recently obtained efficacy data.

For LIV2008/2008b, we will promote licensing activities in conjunction with other drug discovery pipelines.

PFKR is our new pipeline for out-licensing opportunity. This is a therapeutic antibody targeting CX3CR1, a GPCR, for autoimmune disease in CNS area. This is a joint research program with the National Center of Neurology and Psychiatry.

For other drug discovery projects in the exploratory phase, we will continue research activities that will contribute to their commercialization in the future, while considering out-licensing and development plans. The company will expand its new pipeline and seek for out-licensing opportunities by continuously creating new drug seeds and making them into intellectual property. We are also participating in a basic research program in the field of

infectious diseases and technology development in collaboration with academia in Japan, which is supported by a grant from the Japan Agency for Medical Research and Development (AMED). We are developing technology with aim to implement it as a new drug discovery technology for our company in the future.

As a result of the above, in the drug discovery business, R&D expenses for the nine months under review amounted \$\pmu8803,247\$ thousand due to progress in clinical development (a decrease of \$\pmu113,169\$ thousand year-on-year), segment loss was \$\pmu803,247\$ thousand (segment loss of the same period last year was \$\pmu916,417\$ thousand).

Drug discovery support business contributes to the Company's stable earnings. We offer contract services such as antibody discovery and affinity maturation using the ADLib® system, our proprietary antibody generation expertise, protein preparation, expression, and purification to accelerate biopharmaceutical research and development at pharmaceutical companies and research institutions. The number of transactions and projects is steadily increasing, as our technical service capabilities are highly recognized by mainly domestic pharmaceutical companies. We have concluded an entrustment agreement with one of the major pharmaceutical companies in Japan in the nine months under review, as well as starting an entrusted service with one of diagnostic drug companies in Japan. We are developing new clients to strengthen the earning base and will continue to focus on and promote the growth of this business.

The results in the drug discovery support business in the nine months under review were net sales of \(\xi\)524,023 thousand (an increase of \(\xi\)90,328 thousand year on year), segment profit of \(\xi\)307,091 thousand (an increase of \(\xi\)72,100 thousand year-on-year), segment profit margin of 58.6% (target 50%) due to the stable transactions with existing clients, mainly domestic pharmaceutical companies.

#### (2) Financial Position

(Assets)

Total assets at the end of the third quarter of the current fiscal year amounted to \$1,753,201 thousand, a decrease of \$462,268 thousand compared to the end of the previous fiscal year. This was mainly due to a decrease in cash and deposits.

(Liabilities)

The balance of liabilities at the end of the third quarter of the current fiscal year amounted to \$542,179 thousand, an increase of \$117,454 thousand compared to the end of the previous fiscal year. This was mainly due to an increase of the short-term debt by \$132,300 thousand.

(Net assets)

The balance of net assets at the end of the third quarter of the current fiscal year amounted to \(\pm\)1,211,022 thousand, a decrease of \(\pm\)579,723 thousand compared to the end of the previous fiscal year. This was mainly because of a decrease in retained earnings after recording the net loss in the period under review, even though capital stock and capital reserves were increased due to the exercise of subscription rights.

#### (3) Explanation of Forward-Looking Statements including Forecasts of Financial Results

There are no changes to the financial results forecasts for the fiscal year ending December 31, 2023 announced on February 14, 2023.

## 2. Quarterly Financial Statements

## (1) Quarterly Balance Sheets

		Thousand
	As of	As of
	Dec. 31, 2022	Sep 30, 2023
Assets		
Current assets		
Cash on hand and in banks	1,727,270	1,341,811
Accounts receivable	115,218	84,280
Inventories	71,478	58,089
Advance payment-trade	91,477	83,948
Consumption taxes receivable	29,567	12,483
Other current assets	57,154	53,146
Total current assets	2,092,166	1,633,759
Non-current assets		
Property and equipment		
Machinery	254,610	234,713
Accumulated depreciation	(252,173)	(233,253)
Machinery, net	2,437	1,459
Tools and equipment	97,024	90,671
Accumulated depreciation	(97,024)	(90,671)
Tools and equipment, net	0	0
Total property and equipment	2,437	1,459
Investments and other assets		
Long-term prepaid expenses	8,055	5,172
Lease deposits and others	112,811	112,811
Others	0	0
Total investments and other assets	120,866	117,983
Total non-current assets	123,303	119,442
Total assets	2,215,470	1,753,201

		Thousand yer
	As of	As of
	Dec. 31, 2022	Sep. 30, 2023
Liabilities		
Current liabilities		
Accounts payable, trade	31,866	37,336
Short-term borrowings	184,000	316,300
Accounts payable, other	70,800	49,729
Accrued expenses	$26,\!558$	23,994
Income taxes payable	23,943	12,579
Advances received	22,100	31,200
Deposits received	4,835	12,857
Provision for bonuses	6,351	3,596
Total Current liabilities	370,455	487,592
Non-current liabilities		
Asset retirement obligations	54,268	54,586
Total non-current liabilities	54,268	54,586
Total liabilities	424,724	542,179
Net assets		
Shareholders' equity		
Capital stock	2,097,017	2,262,123
Capital reserve	3,696,798	3,861,903
Retained earnings	(4,016,331)	(4,934,796)
Treasury stock	(292)	(292)
Total shareholders' equity	1,777,192	1,188,937
Subscription rights to shares	13,554	22,085
Total net assets	1,790,746	1,211,022
Total liabilities and net assets	2,215,470	1,753,201

		Thousand y
	Nine Months	Nine Months
	Ended Sep. 30, 2022	Ended Sep. 30, 2023
	(Jan.1, 2022	(Jan. 1, 2023
	to Sep. 30, 2022)	to Sep. 30, 2023)
Net sales	433,694	524,023
Cost of sales	198,703	216,931
Gross profit	234,990	307,091
Selling, general and administrative expenses		,
Research and development expenses	916,417	803,247
Other, net	357,902	409,157
Total selling, general and administrative expenses	1,274,320	1,212,405
Operating loss	(1,039,329)	(905,313)
Non-operating income		
Interest income	19	17
Foreign exchange gains	_	251
Subsidy income	16,000	_
Other, net	210	432
Total non-operating income	16,230	702
Non-operating expenses	<u> </u>	
Interest expenses	980	1,481
Share issuance expenses	2,393	1,785
Subscription rights issuance cost	_	7,705
Foreign exchange losses	3,020	_
Other, net	286	655
Total non-operating expenses	6,680	11,627
Ordinary loss	(1,029,779)	(916,239)
Extraordinary income		
Gain on sale of non-current assets	_	119
Gain on reversal of share acquisition rights	5,977	1,426
Total extraordinary income	5,977	1,545
Extraordinary losses		
Loss on sale of non-current assets		14
Total extraordinary losses		14
Loss before income taxes	(1,023,801)	(914,707)
Income taxes-current	3,757	3,757
Total income taxes	3,757	3,757
Net loss	(1,027,559)	(918,465)

#### (3) Notes Concerning Quarterly Financial Statements

(Notes Regarding Going Concern Assumptions)

Not applicable.

(Notes Regarding Substantial Changes in Shareholders' Equity)

• Exercise of the subscription rights to shares.

The balance of capital stock and capital reserve increased separately by \\$165,105 thousand due to exercise of the Subscription Rights to Shares.

As a result, as of September 30, 2023, the balance of capital stock and capital reserve came to \$2,262,123 thousand and \$3,861,903 thousand, respectively.

#### (Important subsequent events)

(Capital increase attributed to the exercise of subscription rights to shares)

During the period from October 1 to October 31, 2023, 19th Stock Acquisition Rights were exercised. The summary of the exercised Stock Acquisition Rights is as follows.

- (1) Type and number of shares issued: Common stock, 874,900 shares
- (2) Increased capital stock: ¥53,027 thousand
- (3) Increased legal capital reserve: ¥53,027 thousand

As a result, as of October 31, 2023, the total number of the common stock issued is 51,446,300 shares. Capital stock and capital reserve are \$2,315,150 thousand and \$3,914,930 thousand respectively.