Supplementary Information for Financial Results FY12/24

Feb. 13, 2025

To accelerate drug discovery and development of mAb for therapeutics to overcome current medical unmet-needs

Chiome Bioscience Inc.



- 1. Overview of FY12/24 "Financial results"
- 2. Overview of FY12/24 "Operation highlights"

Appendix.

Corporate information Pipeline information



Overview of FY12/24 "Financial results"

Financial Results: Profit and Loss



(JPY in millions)

	FY2023	FY2024	Increase (decrease)	Main reasons for increase / decrease
Net sales	682	780	98	
Drug Discovery & Development	-	202	202	Revenue from PFKR license agreement
Drug Discovery Support	682	577	△104	Decrease in transactions caused by organizational changes within a client company
COS/SGA	1,887	1,811	△75	
R&D Expense	1,051	936	△115	Decrease in CMC costs, e.g., manufacturing cost of study drugs
Other costs	835	874	39	
Operating Loss	(1,205)	△1,030	174	
Ordinary Loss	(1,217)	△1,019	198	
Net Loss	(1,220)	△1,020	199	

Financial Results: Balance Sheet



(JPY in millions) As of Dec. 31, 2023 As of Dec. 31, 2024 2,337 1,629 Current assets 1,325 2,063 (Cash on hand in banks) 303 274 (Other current assets) 122 131 Non-current assets 1,751 2,468 Total assets 539 493 **Current Liabilities** 54 55 Non-current liabilities 593 548 Total liabilities Total net assets 1,157 1,920 2,468 Total liabilities and net assets 1,751



(JPY in millions)

	FY2023	FY2024
Cash flows from operating activities ^{*1}	(1,069)	(1,000)
Cash flows from investing activities	0	0
Cash flows from financing activities	667	1,738
Net increase (decrease) in cash and cash equivalents	(401)	737
Cash and cash equivalents as of the beginning of the year	1,727	1,325
Cash and cash equivalents as of the end of the year	1,325	2,063

*1 Expenditures, such as R&D expenses mainly on clinical development, and sales, general, and administrative expenses



Overview of FY12/24 "Operation highlights"

Key Topics



Exclusive license agreement with Asahi Kasei Pharma for PFKR Several discussions are underway with pharmaceutical companies to obtain out-licensing contracts for other drug discovery projects.

Decided to add a cohort of melanoma patients expected to respond to CBA-1205, extending the clinical study period. ⇒Aiming for more out-licensing opportunities and maximizing product

⇒Aiming for more out-licensing opportunities and maximizing product value

Extended the clinical study period to confirm the safety and efficacy sisnals of CBA-1535 ⇒Possible out-licensing in early stage

Promoting IDD* to monetize our knowledge and experience (referred to as Intelligence) by expanding business opportunities based on our own antibody-related technologies and expertise in antibody generation ⇒Joint research agreement with Eisai Co., Ltd.

*: Integrated Drug Discovery

Through business alliance agreement with Kidswell Bio Corporation, entered the new biosimilar business

Selection/negotiation of the third partner responsible for development and sales are underway



Drug Discovery and Development – Pipeline

CBA-1205	 ✓ SD (stable disease) assessment with tumor shrinkage in a malignant melanoma patient from the first part of CBA-1205 Phase I study, has been lasting for more than 42 months. Dosing is still ongoing. ✓ Decision was made to set a melanoma cohort. 		
CBA-1535	 ✓ The safety and efficacy are being evaluated with dose escalation for patients with solid tumours—no significant safety concerns at present. ✓ Blood marker changes associated with T-cell activation, which deem the proof of concept for this study drug, have started to show. 		
License candidates	 ✓ Conclusion of out-licensing agreement with Asahi Kasei Pharma for PFKR ✓ Out-licensing activities with several drug discovery projects in preclinical stage are ongoing. ✓ Presented research results of drug discovery and technical development projects in domestic and international conferences. 		
New Business			
IDD	✓ Joint research agreement with Eisai Co., Ltd.		
Biosimilar business	✓ Business alliance agreement with Kidswell Bio Corporation. Aiming for securing new source of revenue, partner company selection/negotiation are underway to establish biosimilar business using our clinical/CMC related functions.		
Drug Discovery	Support Business		
Deals with pharmaceutical companies	 ✓ Net sales of ¥577 million in FY12/2024, lower than last year, mainly due to organizational changes within a client company. ✓ Business alliance agreements with Merk and FUJIFILM Wako Pure Chemical Corp., aiming to expand sales channels for antibody generation services and steady growth of this business through efficiency. 		



★ First in class

World first drug discovery modality moving into clinical phase

	Code	Target	Therapeutic Area	Status		
*	CBA-1205 (ADCC enhanced)	DLK-1	Oncology	Phase 1 (jRCT2080225288) (NCT06636435)		
**	CBA-1535 (Tribody®)	5T4×CD3×5T4	Oncology	Phase 1 (jRCT2031210708)		
*	PCDC (ADC)	CDCP1	Oncology/ADC	Non-clinical studies in progress		
	PTRY	5T4×CD3×PD-L1	Oncology	Non-clinical studies in progress		
	PXLR	CXCL1/2/3/5	Oncology	Non-clinical studies in progress		
	PFKR	CX3CR1	Autoimmune disease	November 2024 Out-licensed to Asahi Kasei Pharma		

As of Dec. 31, 2024

For other pipeline projects, we continue to work towards achieving results and report progress as appropriate.

PFKR: Exclusive License Agreement with Asaki Kasei Pharma



- Exclusive license agreement with Asahi Kasei Pharma for our therapeutic antibody, —humanized anti-CX3CR1 antibody (project code: PFKR)—, on November 20, 2024
- Under the terms of the agreement, we grant Asahi Kasei Pharma worldwide license, with the right to grant sublicenses for the development, manufacturing and commercialization of PFKR

PFKR

Exclusive developement, manufacturing and commercialization rights worldwide with sublicensing



Financial terms

- Upfront payment: ¥200 million
- Receive milestone payments based on future development and sales progress (up to ¥24.8 billion)

After product launch
 Royalties based on product

Royalties based on product net sales

CBA-1205 Phase 1 Study



PR case confirmed with a hepatocellular carcinoma patient Melanoma part was added





The first part of CBA-1535 Phase I study is in progress



Revising Profitability Target & Clinical Development Outlook

- Maximizing out-licensing opportunities and the product value by additional development parts with a view to expanding indications of CBA-1205. Aiming to out-license CBA-1535 with the result of the first part in the middle of development race of T cell engager.
 Extend development period for both study drugs (-2026) and aiming license agreements with meaningful data
- 2) The target of achieving a surplus within the year 2025 depended on an important premise: Acquiring upfront payment by concluding licensing agreements. Since above clinical development plans have been extended, we will revise the target.

=> Confirmation of efficacy is expected in future clinical studies. Continue providing updated development status to candidate companies for out-licensing



Drug Discovery Support Business



- Net sales of FY12/2024 were ¥577 million.
- Net sales lower than the same period last year mainly due to an organizational changes within a client company.
- A business agreement with Takeda Pharmaceutical Company Limited which had been worked on a spot base is developed into a new entrustment agreement.
- New business alliance agreements with Merk and FUJIFILM Wako Pure Chemical Corp. concluded to expand the sales channels of antibody generation service.



Major clients	Contract date
Chugai Pharmaceutical Co., Ltd.	Jun. 2011
Chugai Pharmabody Research Pte. Ltd	Aug. 2012
Mitsubishi Tanabe Pharma Co., Ltd. TANABE RESEARCH Laboratories U.S.A., Inc.	Dec. 2016
Ono Pharmaceutical Co., Ltd.	Oct. 2018
Kyowa Kirin Co., Ltd.	Jul. 2019
Takeda Pharmaceutical Co., Ltd.	Feb. 2024
Sales collaboration	Contract date
Merck Ltd. (Japan)	Sep. 2024
FUJIFILM Wako Pure Chemical Corporation	Dec. 2024



Launch IDD business to strengthen our profitability in the business development and ensure a stable management base from 2025 onwards



Drug Discovery Support

"High-value contract research business" offering antibody generation/engineering and protein preparations using our antibody generation and engineering platform. IDD

NEW

A business offering solutions for various R&D needs from partner companies, including pharmaceutical companies, based on our knowledge, experience and technology, and advancing to collaborative antibody drug discovery to acquire milestone revenue.

Ddrug Discovery Projects

In-house or collaborative antibody drug development, followed by licensing to companies including pharmaceutical companies for intellectual property rights (e.g. patent rights), generating revenue from upfront payments, milestone revenue, and royalties.

IDD Business: Manetizing Chiome's Knowledge and Experience (Intelligence)



Platform business for antibody drug discovery

Developing an end-to-end platform for antibody drug discovery projects from screening, to in vitro/vivo evaluation, CMC, IND and early clinical stages. Based on Chiome's knowledge, experience and technology of drug discovery research and development, offer various solutions to partner companies. Business model that promotes collaboration work with mainly domestic companies that have promising antibodies but lack the expertise or resources to start antibody drug discovery research.



Entering the Biosimilars Business



Through business alliance agreement with Kidswell Bio Corporation who has a proven record in the development of several biosimilar products, our company has entered the new biosimilars business. Aiming for securing new sources of revenue and solve social issues leading a reduction of social security costs.



Business Model for Biosimilar Drug Development





Appendix. Corporate information

Corporate Overview



Biotech company dedicating to satisfy unmet medical needs



Management principle

- Place the highest priority on sound management and credibility and aim to become a corporation that grows with society.
- With creativity and science, develop therapeutic drugs for unmet medical needs, and contribute to the health of patients.
- Achieve successive product pipelines and improvement of corporate value through collaboration with external institutions.

Founded:

February 2005

- Listed on the stock exchange: Dec.2011 (Tokyo Stock Exchange Growth Section)
- President and Chief Executive Officer: Shigeru Kobayashi, M.E.

\blacksquare Location :

- <Head Office and Research Laboratories> 3-12-1Honmachi, Shibuya-ku, Tokyo <Drug Discovery Laboratories>
- 2-13-3 Nogawahonchou, Miyamae-ku, Kawasaki-city, Kanagawa
- Number of Employees : 64 (As of Dec. 31, 2024)
- Business :
 - Chiome Bioscience (4583.T), is a public company leveraging a proprietary monoclonal antibody generating technology, for drug discovery and development, as well as providing drug discovery supports.



Drug Discovery and Development Business

This is business to obtain revenues such as upfront, milestone, and royalty payments relating to out-licensing of patents of pipeline product and drug candidates, and also, income from collaborative research. It drives our future growth.

Drug Discovery Support business

This is business to obtain revenues from antibody generation service by using platform technology that Chiome possesses to support drug discovery research at pharmaceutical companies, or for diagnostic and research purposes at academia or institutes on fee-for-service scheme. It secures constant revenue stream.



Technology Platform (Chiome's mAb Discovery Engine)



Chiome possesses antibody platforms including its proprietary technology, and extensive knowhows and experiences in protein/antibody engineering to streamline the process of drug discovery.

Promoting two businesses by using our technology platform.

Drug Discovery and Development

Drug Discovery Support

Business responsible for growth

Business that earns stable revenue

Core technology that support 2 businesses: ADLib[®] System

<u>Generating method of human antibodies in cultured cells (in vitro) without living</u> <u>organisms (animals)</u>



- Generate human antibodies quicker than conventional methods
- Unlike immunization methods using individual animals, not affected by immune tolerance
- By utilizing the feature of autonomous genetic diversification, a high affinity of antibodies can be achieved in sequence
- Acquire antibodies as early as possible leads to early application for patents

Core Technology: Tribody[®](Multispecific Antibody Production Technology)



Technology that enables the generation of multi-specific antibodies, each molecule has three binding sites.





Drug development process and Chiome's revenue model



As the stage progresses, the amount received in each milestone increases.



The above is the image of earnings to explain the Pharmaceutical Licensing Agreement. The actual agreements may vary in terms of the upfront payment, milestone stages and number/amounts of milestones, and royalty rate for each contract.

*1 Milestone: Income received by the licensee at each milestone after out-licensing through the progress of clinical studies and others.

*2 Royalty: Income received as a percentage of the sales amount after a product is sold (launched)

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Reduce reliance on equity funds and promote the IDD business by leveraging our knowledge and experience (Intelligence) to enhance profitability, stabilize management, and maximize company value.





Appendix. Pipeline information



First in class

CBA-1205 (Humanized afucosylated anti-DLK1 antibody)

Origin	A humanized antibody generated by hybridoma technology in Livtech which Chiome acquired in 2015.
ADCC	GlymaxX (ProBioGen)
Therapeutic Area	Liver cancer, lung cancer, neuroblastoma etc.
Expectation	First-in-class therapeutic antibody targeting intractable cancers. Providing new therapeutics for highly malignant tumors that are without effective therapeutic drugs including hepatocellular carcinoma.
Patent	Granted in Japan, US, Europe, China etc.

Phase I clinical study

First part: Evaluate the safety in patients

- > No serious adverse reaction reported.
- SD (stable disease) evaluation with tumor shrinkage has been continued in a patient with Melanoma and the continuous dosing period has exceeded more than 42 months. Dosing is still ongoing.

Second part: Evaluate the safety and efficacy of the drug in patients with hepatocellular carcinoma.

- > One PR(Partial Response) case has been confirmed and longer duration of response is expected.
- > Decision to add a development part for melanoma patients



No toxicity of Grade 3 or higher were observed High level of safety was confirmed

CBA-1205 Related Adverse Events

	Dose (mg/kg)							
Adverse Events (AE)	0.1	0.3	1	3	10	20	30	Total (n=22)
	(n=3)	(n=3)	(n=3)	(n=4)	(n=3)	(n=3)	(n=3)	
Patients with CBA-1205 Related AEs	1	0	2	3	1	3	3	13
Grade 1-2	1	0	2	3	1	3	3	13
≧ Grade 3	0	0	0	0	0	0	0	0
Dose Limiting Toxicity	0	0	0	0	0	0	0	0
Serious Adverse Events	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0
Treatment Discontinuation	0	0	0	0	0	0	0	0

(As of Jun. 30, 2024)

Only Grade 1 (mild) or Grade 2 (moderate) study drug related adverse events were reported at each dose. No Grade 3 (severe or medically significant but not immediately life-threatening) or higher serious toxicity findings were reported. No adverse reactions that would have stopped dosing were reported, and the high safety of CBA-1205 was confirmed.



CBA-1535 (Humanized anti 5T4 & CD3 trispecific antibody)			
Origin	CBA-1535 is a T-cell engager, trispecific antibody, directed against the 5T4 tumor antigen, a protein found on various solid tumors and is thought to be involved in metastasis.		
Therapeutic Area	Malignant mesothelioma, small cell lung cancer, non small cell lung cancer, TNBC etc.		
Expectation	First-in-class therapeutic antibody with trispecific format Offer a new treatment option for a disease which has poor prognosis and where there are only a few effective treatments.		
Patent	Granted in Japan, UK, US, EU China etc.		

Phase I study: Dosing for patients has started in the first part for safety and initial drug efficacy evaluation. Study sites: National Cancer Center Hospital

Shizuoka Cancer Center





PCDC (humanized anti-CDCP1 antibody for antibody drug conjugate)

Origin	Humanized anti-CDCP1 antibody discovered by Chiome's proprietary antibody technologies.
Therapeutic Area	Solid tumors (lung, colorectal, pancreatic, breast, ovarian etc.)
Expectation	CDCP1 is a First-in-class therapeutic target highly expressed in broad range of solid tumors, including standard-of-care resistant cases. High efficacy and safety expected from binding and toxicological profiles of the antibody.
Patent	Granted in Japan, China. Pending in US, Europe etc.

- > Promoting out-licensing activities, mainly in the field of ADC
- Progressing in contacting out-licensing candidate companies in Japan and abroad at conferences such as BIO International.

Out-licensing strategy/target

As the development needs for combining the ADC technology and our antibodies are in higher demand in out-licensing candidate companies, we will prioritize our out-licensing activities with companies with ADC technologies who need antibodies for ADC.



PTRY -Licensing-



PTRY (humanized antibody 5T4/CD3/PD-L1 multi-specific antibodies) Target molecules : 5T4×CD3×PD-L1

Origin	Therapeutic antibodies for cancer treatment using Tribody [®] technology consisting of three binding sites. Therapeutic antibodies for cancer treatment targeting antigen-binding sites 1) solid tumor expressing 5T4, 2) T-cell engager CD3, and 3) immune checkpoint inhibitor PD-L1.	
Therapeutic Area	Malignant mesothelioma, small cell lung cancer, non-small cell lung cancer, Triple Negative Breast Cancer (TNBC) etc.	
Expectation	A new study drug for patients who have not responded adequately to standard cancer immunotherapy. It is also expected to be useful in contributing to the healthcare economy by reducing drug prices.	
Patent	Patent application completed	
<u>CB</u> (5T4×	A-1535 5T4×CD3)	



The results of the joint research with Ceinge Biotecnologie Avanzate ("Ceinge") in Italy were published in the Journal of Experimental & Clinical Cancer Research, and Cancers.

Passariello et al. (2022). Novel tri-specific tribodies induce strong T cell activation and anti-tumor effects in vitro and in vivo. *Journal of experimental & clinical cancer research : CR, 41*(1), 269. Manna et al. (2023). A Comparison of the Antitumor Efficacy of Novel Multi-Specific Tribodies with Combinations of Approved Immunomodulatory Antibodies. *Cancers, 15*(22), 5345



PXLR (humanized anti-CXCL1/2/3/5 antibody) Target molecules: CXCL1/2/3/5

Origin	Functional inhibitory antibody for CXCL1/2/3/5, chemoattractant of CXCR2 expressing cell. Cancer therapeutic antibody that improves drug-resistant cancer microenvironment
Therapeutic area	Solid tumors (gastric, breast, ovarian etc.)
Expectation	Cancer cells express CXCL1/2/3/5 and attract immunosuppressor cells that cause the drug- resistant environment. Dosing PXLR antibody will reduce immunosuppressor cells. It is expected to overcome drug-resistance and inhibit the recurrence of cancers.
Patent	Patent application completed.
Joint development partner(s)	Osaka Metropolitan University

Drug resistant environment

Weaking of drug-resistant environment



CXCL1/2/3/5 is a ligand of CXCR2, G-protein-coupled receptor (GPCR), and is involved in various tumorigenesis and formation processes. Cancer cells attract immunosuppressive cells with CXCL1/2/3/5 and create a drug-resistant environment. PXLR weakens drug resistant ability of cancer cells by binding to CXCL1/2/3/5.



PFKR (humanized anti-CX3CR1 antibody) target molecules: CX3CR1

Orgin	Functional inhibitory antibody of Fractalkine (CX3CL1) receptor and a therapeutic antibody that inhibits disease progression of autoimmune neurological diseases, etc.		
Therapeutic area	Secondary Progressive Multiple Sclerosis (SPMS), neurodegenerative disorder etc.		
Expectation	SPMS is an intractable form of multiple sclerosis and is a disease with a need to develop high safety and effective therapeutic agents. By suppressing cytotoxic Eomes-positive CD4+T cells function which are considered directly related to lesions in SPMS (demyelination, neurodegeneration), expected to inhibit the progression of symptoms.		
Patent	Patent application completed		
Joint development partner(s)	National Center of Neurology and Psychiatry		
	·	Exclusive license agreement with Asahi Kasei Pharma	
<u>~~~~~~~~~~~</u> ~~~~~~~~~~~~~~~~~~~~~~~~~	ک ت ت ت ت ت ت ت ت ت ت ت ت ت	ON NOVEMBER 20, 2024 CX3CR1 is a type of G protein-coupled receptor(GPCR), and its ligand, Fractalkine (CX3CL1), causes the migration of CX3CR1-expressing cells to inflammatory sites.	
PFKR Cellular membrane		In cytotoxic Eomes positive CD4+T cells, which are considered directly related to lesions in SPMS (demyelination neurodegeneration), CX3CR1 is expressed in many.	
		A paper suggesting that Eomes positive CD4+T cells are involved in the pathogenesis of ALS and Alzheimer's disease patients was published in March 2024 by the joint research	
CX3CKI U	Cytoplasm	partner.	

Shine light on unmet needs. Bring a brighter future to patients.

To accelerate drug discovery and development of mAb for therapeutics to overcome current medical unmet-needs



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