Chiome Bioscience (TYO: 4583)

Despite a decrease in revenue, the deficit has been reduced. It is awaited that the Drug Discovery and Development Business will be licensed out and the company will be profitable in a single year.

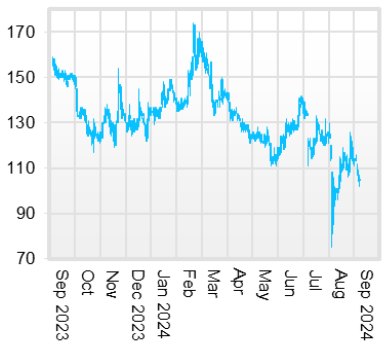
2Q results update

Healthcare

As of September 9, 2024

Share price(9/6)	¥105
52weeks high/low	¥102/106
Avg Vol (3 month)	771.2 thou shrs
Market Cap	¥6.0 bn
Enterprise Value	¥5.1 bn
PER (24/12 CE)	– X
PBR (23/12 act)	5.6 X
Dividend Yield (24/12 CE)	– %
ROE (23/12 act)	-83.6 %
Operating margin (TTM)	-176.6 %
Beta (5Y Monthly)	0.6
Shares Outstanding	57.049 mn shrs
Listed market	TSE Growth

Share price



%	1M%	3M%	12M%
Share price	29.63	-13.93	-33.54
Japan TSE TOPIX	16.63	-5.49	9.23

Points of interest

Can the company successfully out-license its products, such as CBA-1205 and CBA-1535, and achieve its business target of a profit in a single year by FY2025, and can it do so ahead of schedule?

After that, Will there be sufficient resources to maximise corporate value through continued out-licensing, combined with milestone revenues from previously out-licensed products and revenue contributions from Drug Discovery Support Business and Biosimilars Business?

This report (Company note) has been prepared at the request of Chiome Bioscience. For details, please refer to the Disclaimer on the last page.

◇2Q of FY12/2024: Highlights of Financial Results: Despite a decrease in revenue, the deficit has been reduced

In the second quarter results of FY12/2024, announced by Chiome Bioscience (hereafter, the company) on 13 August 2024, the company saw a YoY decrease in revenue, but the deficit narrowed. Net sales were 260 million yen (- 26% YoY), operating loss was 580 million yen (vs. a loss of 650 million yen in the same period of the previous fiscal year), and ordinary loss was 560 million yen (vs. a loss of 660 million yen). Interim net loss was 560 million yen (vs. a loss of 660 million yen).

Looking at the results by division, in the Drug Discovery and Development Business, despite recording R&D expenses of 440 million yen due to progress in clinical development, the amount recorded for expenses such as investigational new drug manufacturing costs decreased YoY, resulting in an segment loss of 440 million yen (an improvement of 150 million yen YoY) (the development status is described later).

In the Drug Discovery Support Business, the company provides antibody generation services and antibody affinity enhancement services utilising its antibody generation technology platform centred on the ADLib® system, the company's proprietary antibody generation method, as well as protein preparation, expression, and purification services, under contract to Ono Pharmaceutical, Chugai Pharmaceutical and others. The company concluded an outsourcing agreement with Takeda Pharmaceutical in the current fiscal year. However, sales were 260 million yen (- 90 million yen YoY) due to a delay in the inspection period for some new projects and a decrease in transactions due to organisational changes on the part of customers. Segment profit was 130 million yen (- 70 million yen YoY) due to factors such as capital investment in anticipation of the expansion of the contract business. The full-year sales forecast for the Drug Discovery Support Business, which was initially expected to be 720 million yen (a forecast increase of 40 million yen YoY), has been left unchanged, with the company anticipating orders will recover in 2H.

In terms of cash flow, the company has made up for the cash decrease associated with the losses mentioned above by issuing new shares in conjunction with the exercise of stock acquisition rights, and the balance of cash and deposits at the end of the period was 1.1 billion yen(- 220 million yen YoY). Short-term borrowings were 290 million yen, a slight decrease YoY.

The above summarises the financial results, which are typical of bio-ventures where drug discovery and development costs come first. Hence, the impact on the share price is thought to be limited.

◇Drug Discovery and Development Business is progressing smoothly

The number of projects in the drug discovery and development business pipeline is three in clinical trials (two in-house developed, one external clinical trial) and seven pre-clinical trials, which is unchanged from the information disclosed in May.

CBA-1205 (In-house developed product) is continuing to progress through the second half of Phase I clinical trials, with administration to patients with hepatocellular carcinoma progressing, and partial response (PR) has been confirmed in one case (unchanged from previous information). In addition, as the melanoma patients who received treatment in the first half of the trial continue to show stable disease (SD) with tumour shrinkage, and treatment has continued for more than 36 months, the company has begun to consider the possibility of developing the drug for melanoma in conjunction with the principal investigator (updated information). At the financial results briefing, it was confirmed that the first half of the project is expected to be presented at a conference within 2024 and that the company intends to conclude a licensing agreement by 2025, when the second half of the project is expected to be completed. Suppose multiple cases of efficacy are confirmed in hepatocellular carcinoma, and the development of melanoma progresses. In that case, the economic value is expected to increase, and the upfront payment will follow suit. This will be important in achieving profitability in a single year by 2025.

CBA-1535 (In-house developed product) is still in Phase I clinical trials, and changes in blood biomarkers that indicate T-cell activation, the concept behind the drug, are beginning to be seen. There have been no safety-related events that would raise concerns about development (as before). At the financial results briefing, it was indicated that from the second half of 2024 to the first half of 2025, the evaluation of T-cell activation and initial clinical efficacy, as well as safety, will progress and that this will be used as a basis for full-scale out-licensing negotiations.

ADCT-701 (the National Cancer Institute is the lead investigator). A phase 1 clinical trial in paediatric neuroendocrine cancer was initiated, and the first subject was administered in July 2024 (updated information).

Out-licensing activities are also continuing for multiple **drug discovery projects** in the pre-clinical stage.

◇ **Entry into the Biosimilar Business**

On 18 June 2024, the company concluded a basic agreement on a business alliance with Kidswell Bio Co. (hereafter, KWB) regarding the development of biosimilar pharmaceuticals. Together with KWB, which has four approved biosimilar products in Japan, the two companies plan to share knowledge, mainly in CMC development of biopharmaceuticals, to operate the business efficiently and share costs and revenues. The biosimilar market is expected to grow as biosimilar spread is promoted as a national policy from the perspective of curbing medical expenses. It is thought to be more difficult to enter than the market for generic small-molecule drugs, so it seems likely that this will lead to the creation of a third source of revenue for the company.

The business can take various forms, including the company and KWB building their own cell lines and then licensing and transferring them to a partner company, licensing and transferring them and then undertaking development on contract from the partner company, or just undertaking development on contract. We await further information.

◇ **Funding allocation progresses**

On 22 July 2024, the acquisition and cancellation of all remaining 18,530 Series 20 warrants was completed. A further 101,700 Series 21 warrants (initial exercise price of 125 yen, with exercise price revision, minimum exercise price of 81 yen, exercise deadline 21 July 2026) and 11,000 Series 22 warrants (initial exercise price of 134 yen, no exercise price revision, exercise deadline 21 July 2026) were issued. The total number of potential shares is11.27 million (approximately 20% of the shares outstanding), and the estimated amount of funds raised is approximately 1.41 billion yen, assuming the initial exercise price. In addition, the first unsecured bond of 250 million yen (with early redemption depending on the progress of the exercise of the 22nd warrant) has also been issued.

Although the impact of dilution is a concern, it is positive that the company has made progress in providing the current funds needed to promote research and development.

◇ **Share price trend and future highlights**

The company's share price is in a gradual downtrend. From a broad perspective, this is due to the long lead time before the new drug is licensed out. During this time, the company had no choice but to raise funds for research and development by issuing new shares, typical of drug discovery bio ventures.

However, according to previous disclosures, the company is approaching a critical point when it should be looking at the possibility of a successful out-licensing of its in-house developed product, as the Phase I clinical trials are now well underway. If the company succeeds in out-licensing its in-house development product and makes a profit in a single year, and if investor expectations rise for subsequent out-licensing, the share price will more actively factor in the value of the Drug Discovery and Development Business pipeline, and the company will be on track to see its corporate value increase, reversing the dilution mentioned earlier.

The immediate focus will therefore be on the chances of successful out-licensing of in-house developed products such as CBA-1205 and CBA-1535, whether the economic conditions are sufficient, and whether the company can achieve its business target of returning to profitability in a single year by 2025, and whether it can do so ahead of schedule.

Company profile

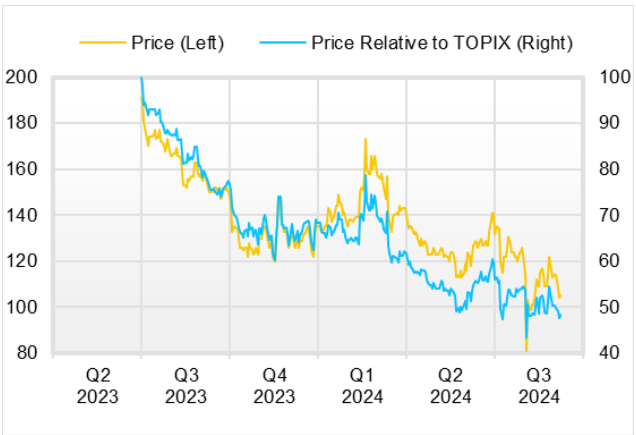
Chiome Bioscience Inc. is a bio venture company that challenges unmet needs through antibody drug discovery and development based on its proprietary ADLib/Tribody technology. The company's Drug Discovery and Development Business (the business of in-house or joint development of antibody drug discovery in disease areas with high unmet needs, licensing the patents and other intellectual property rights relating to the resulting antibodies to pharmaceutical companies and other parties, and earning upfront payments, milestone payments, royalties and other income) is a pillar of its growth. The company has a pipeline of around ten products, three of which are in the clinical stage. In addition, as a complementary business, it has established a track record in the Drug Discovery Support Business (a high-value-added contract research business that mainly provides major domestic pharmaceutical companies with antibody production, antibody engineering and protein preparation services utilising the antibody drug discovery technology platform). The company has also started to expand into the biosimilar business.

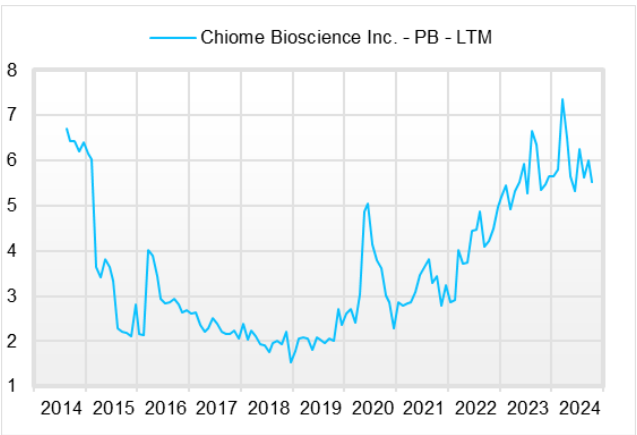
Key financial data

Unit: million yen	2019/12	2020/12	2021/12	2022/12	2023/12	2024/12 CE
Sales	448	481	713	631	682	NA
EBIT (Operating Income)	-1,402	-1,284	-1,334	-1,259	-1,205	NA
Pretax Income	-1,401	-1,291	-1,466	-1,238	-1,215	NA
Net Profit Attributable to Owner of Parent	-1,404	-1,294	-1,480	-1,243	-1,220	NA
Cash & Short-Term Investments	2,106	2,686	1,791	1,727	1,326	
Total assets	2,808	3,495	2,339	2,215	1,751	
Total Debt	291	291	291	291	291	
Net Debt	-1,035	-1,035	-1,035	-1,035	-1,035	
Total liabilities	187	385	446	425	594	
Total Shareholders' Equity	1,158	1,158	1,158	1,158	1,158	
Net Operating Cash Flow	-1,537	-1,360	-1,131	-1,191	-1,069	
Capital Expenditure	0	0	0	0	0	
Net Investing Cash Flow	-26	-4	-35	0	0	
Net Financing Cash Flow	1,341	1,944	271	1,127	667	
ROA (%)	-49.79	-41.06	-50.73	-54.57	-61.51	
ROE (%)	-52.99	-45.15	-59.16	-67.48	-82.76	
EPS (Yen)	-44.6	-36.1	-36.7	-28.3	-24.6	
BPS (Yen)	78.8	78.7	46.4	37.0	22.0	
Dividend per Share (Yen)	0.00	0.00	0.00	0.00	0.00	
Shares Outstanding (Million shares)	58.28	58.28	58.28	58.28	58.28	

Source: Omega Investment from company data, rounded to the nearest whole number.

Share price





Quarterly topics

Key Topics

SD (stable disease) assessment with tumor shrinkage in a Malignant Melanoma patient from the first part of CBA-1205 Phase 1 study, has been lasting for more than 36 months.
⇒ Development possibility for indication expansion of CBA-1205 to melanoma started
*Final analysis results yet to be completed.

In the CBA-1535 Phase I Clinical Study, a change in blood biomarkers indicating the activation of T-cells, which is the concept of this antibody, has begun to show. No development concerns on safety, only minor adverse events observed at present

The first dosing of ADCT-701 in the National Cancer Institute (NCI) Phase I study for neuroendocrine tumor commenced in July, 2024.

In the drug discovery projects, due diligence and negotiation on financial terms are ongoing with pharmaceutical companies to obtain out-licensing contracts in the current financial year

Through business alliance agreement with Kidswell Bio Corporation, we entered the new biosimilar business.
Aiming to create the third source of revenue followed by drug discovery and pharmaceutical company research support.

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Source: Omega Investment from company materials

Operation Highlights

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 36 months. Dosing is still ongoing. ✓ Scientific review with the investigator started on development possibility for indication expansion of this study drug to melanoma
CBA-1535	✓ The safety, T cell activation that is the concept of this study drug, and initial efficacy are evaluated by stepwise dose escalation for patients with solid tumors. ✓ No development concerns on safety, only minor adverse events observed at present.
License candidate	✓ Out-licensing activities with several drug discovery projects in preclinical stage are ongoing. ✓ Under CDAs, discussions, MTA evaluations and negotiations on financial terms are in progress.

Pipeline - Outsourced Clinical Studies

ADCT-701	✓ NCI started a Phase I clinical study for neuroendocrine tumor, and the dose to the first patient started in July 2024.

New Business

Biosimilar business	✓ Business alliance agreement with Kidswell Bio Corporation. Aiming for securing new source of revenue, entered to Biosimilar business using our company's clinical/CMC related functions.

Drug Discovery Support Business

Deals with pharmaceutical companies	✓ Net sales of ¥263 million in 2024 2Q (progress rate 36.7%, sales forecast for the current fiscal year ¥720 million. ✓ Net sales lower than the same period last year mainly due to an organizational changes within a client company. ✓ Entrustment Agreement with Takeda Pharmaceutical Company Limited, drug discovery support services implemented. ✓ Towards steady growth of this business, new negotiations to expand business opportunities are in progress.

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Source: Omega Investment from company materials

Quarterly topics

Drug Discovery and Development - Pipeline

Outsourced Clinical Studies

Code	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Phase 1	Clinical Study Entity
ADCT-701 (LIV-1205 ADC)	DLK-1	Oncology /ADC			(NCT06041516)	National Cancer Institute

In-house developed product

★ First in class ★★ World first drug discovery modality moving into clinical phase

Code	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Phase 1	Status
★ CBA-1205 (ADCC enhanced)	DLK-1	Oncology			(jRCT2080225288)	Phase 1
★★ CBA-1535 (Tribody™)	5T4×CD3×5T4	Oncology			(jRCT2031210708)	Phase 1

License candidate and drug discovery project

Code	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Phase 1	Status
★ PCDC	CDCP1	Oncology/ADC				Licensing opportunity
PTRY	5T4×CD3×PD-L1	Oncology				Data is being obtained to prepare to stage up to clinical stage
BMAA	SEMA3A	Renal and other diseases				Licensing opportunity
LIV-2008 /2008b	TROP-2	Oncology				Licensing opportunity
PFKR	CX3CR1	Autoimmune disease				Licensing opportunity
PXLR	CXCL1/2/3/5	Oncology				Licensing opportunity
Discovery PJ/ Drug discovery research	Undisclosed	Oncology, Ophthalmology, etc.				–

As of Aug. 13, 2024

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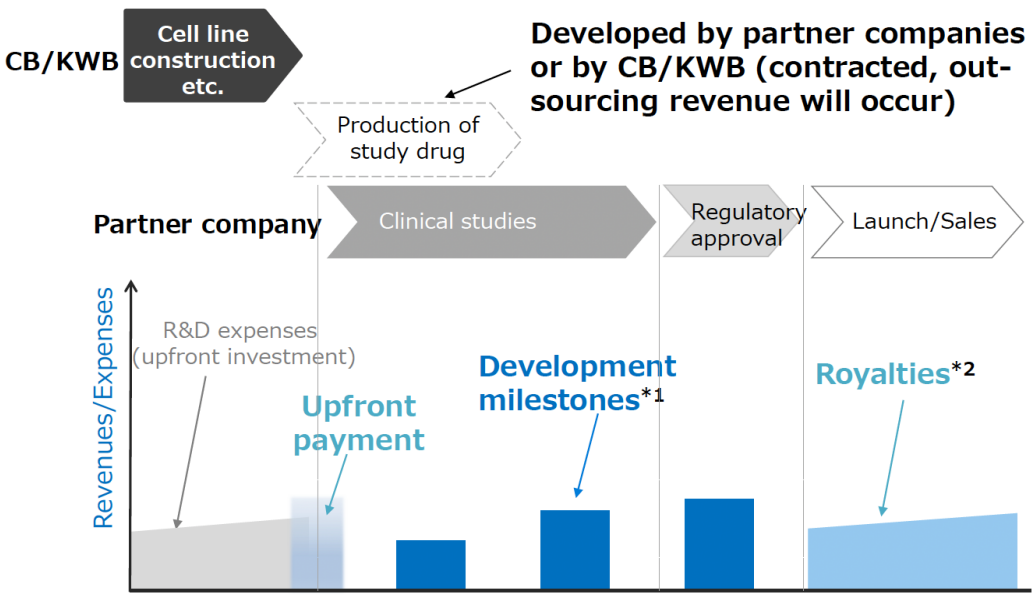
Source: Omega Investment from company materials

Business model for biosimilar drug development



CB: Chiome Bioscience Inc.
KWB: Kidswell Bio Corporation

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

*2 Royalties: Income received as a percentage of the sales amount after a product is launched.

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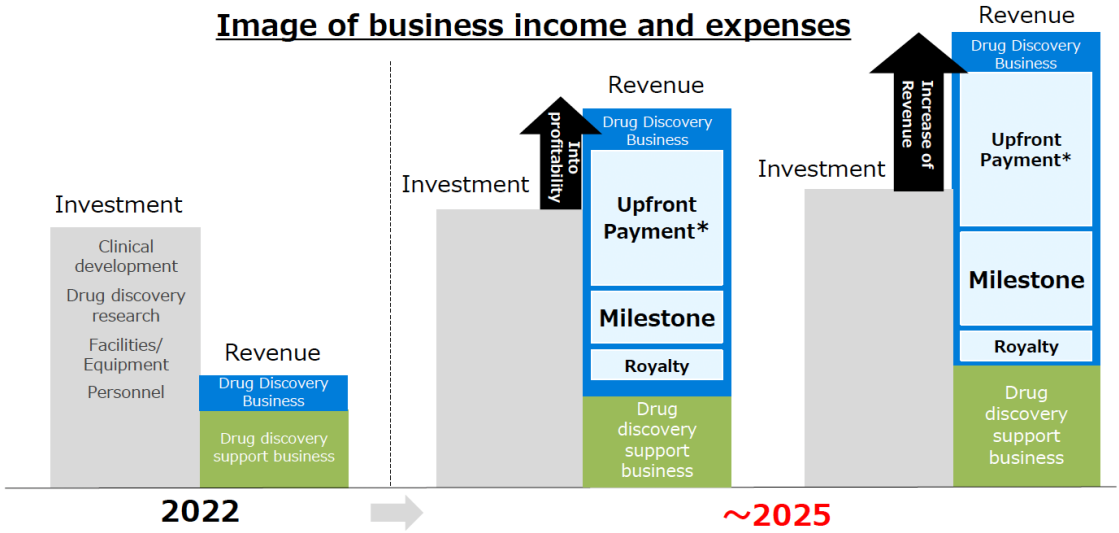
Source: Omega Investment from company materials

Quarterly topics

Image of transitioning to profitability

Transition from **investment phase to revenue phase** by out-licensing in-house products

Image of business income and expenses



*On assumption of out-licensing either CBA-1205, CBA-1535 or PCDC. On assumption of out-licensing agreement with milestone income

At the time of publication of this material, the actual out-licensing agreement terms and conditions, such as licensees and various amounts, have not yet been determined. This material was created to show the profitable image of our company.

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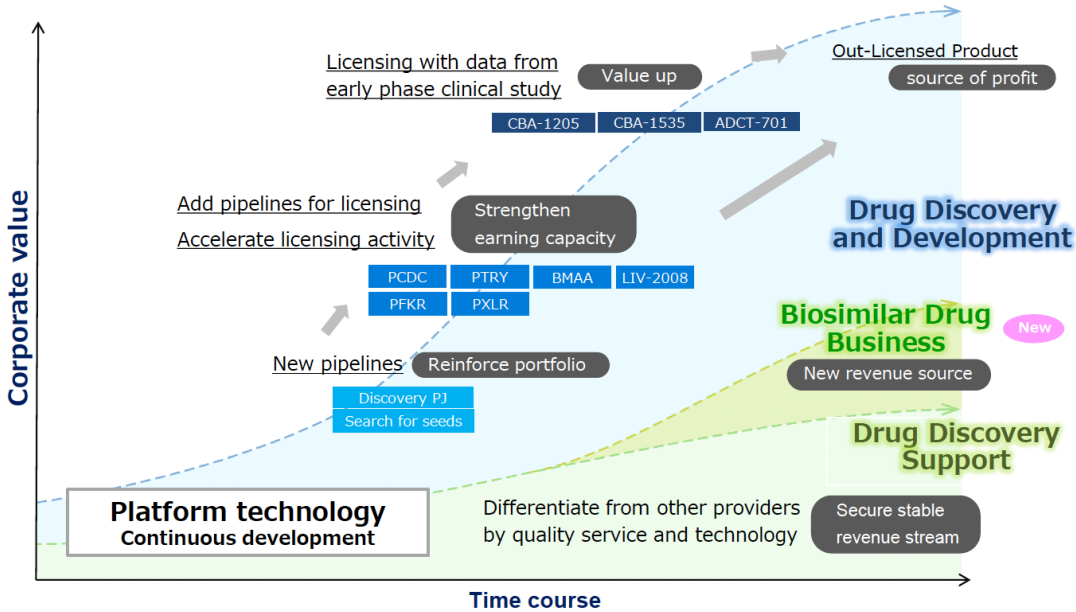
Source: Omega Investment from company materials

Business strategy for the future growth

Create candidate of innovative antibody drugs for unmet medical needs and pay maximum efforts to increase the corporate value by developing and licensing highly valuable antibodies.



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Source: Omega Investment from company materials

Financial data (quarterly basis)

Unit: million yen	2022/12			2023/12				2024/12	
	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q
(Income Statement)									
Sales	150	155	197	169	189	165	158	130	134
Year-on-year	7.8%	-0.8%	15.1%	31.8%	26.6%	6.2%	-19.6%	-23.5%	-29.2%
Cost of Goods Sold (COGS)	69	72	83	73	77	67	67	73	56
Gross Income	80	84	114	96	113	98	92	57	78
Gross Income Margin	53.7%	53.9%	57.8%	56.6%	59.5%	59.6%	57.8%	44.0%	58.0%
SG&A Expense	373	344	333	322	546	344	391	379	337
EBIT (Operating Income)	-293	-260	-219	-226	-433	-246	-300	-322	-259
Year-on-year	12.5%	-40.3%	-54.6%	-53.5%	48.0%	-5.4%	36.7%	42.6%	-40.2%
Operating Income Margin	-195.6%	-167.3%	-111.3%	-133.4%	-228.6%	-149.0%	-189.3%	-248.5%	-193.1%
EBITDA	-292	-260	-219	-226	-433	-246	-300	-322	-259
Pretax Income	-277	-255	-214	-226	-435	-254	-300	-303	-259
Consolidated Net Income	-279	-257	-215	-228	-436	-255	-302	-304	-260
Minority Interest	0	0	0	0	0	0	0	0	0
Net Income ATOP	-279	-257	-215	-228	-436	-255	-302	-304	-260
Year-on-year	12.3%	-40.9%	-66.2%	-53.8%	56.5%	-0.7%	40.1%	33.5%	-40.4%
Net Income Margin	-186.2%	-165.0%	-109.2%	-134.4%	-230.1%	-154.3%	-190.3%	-234.5%	-193.9%
(Balance Sheet)									
Cash & Short-Term Investments	1,472	1,592	1,727	1,566	1,245	1,342	1,326	1,325	1,104
Total assets	1,920	2,081	2,215	2,086	1,686	1,753	1,751	1,754	1,557
Total Debt	188	188	184	301	298	316	291	314	292
Net Debt	-1,284	-1,404	-1,543	-1,265	-947	-1,026	-1,035	-1,012	-812
Total liabilities	444	431	425	524	541	542	594	506	487
Total Shareholders' Equity	1,476	1,650	1,791	1,562	1,145	1,211	1,158	1,248	1,071
(Profitability %)									
ROA	-70.19	-66.16	-54.57	-46.44	-62.98	-59.13	-61.51	-67.53	-69.09
ROE	-84.99	-81.62	-67.48	-60.83	-86.66	-79.25	-82.76	-92.28	-101.15
(Per-share) Unit: JPY									
EPS	-6.5	-5.8	-4.6	-4.7	-9.0	-5.2	-5.8	-5.6	-4.6
BPS	34.3	35.9	37.0	32.3	23.6	23.9	22.0	22.4	19.0
Dividend per Share	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Shares Outstanding (million shares)	42.74	45.23	48.42	48.42	48.50	50.01	52.19	55.40	56.39

Source: Omega Investment from company materials

Financial data (full-year basis)

Unit: million yen	2014/12	2015/12	2016/12	2017/12	2018/12	2019/12	2020/12	2021/12	2022/12	2023/12
(Income Statement)										
Sales	370	280	252	260	213	448	481	713	631	682
Year-on-year	-	-24.4%	-10.0%	3.0%	-18.1%	110.3%	7.4%	48.3%	-11.5%	8.2%
Cost of Goods Sold	119	225	228	94	107	167	238	292	283	285
Gross Income	252	55	25	166	106	281	243	421	348	398
Gross Income Margin	67.9%	19.8%	9.7%	64.0%	49.6%	62.7%	50.5%	59.0%	55.1%	58.3%
SG&A Expense	1,406	1,325	1,067	1,054	1,645	1,683	1,526	1,755	1,606	1,603
EBIT (Operating Income)	-1,154	-1,270	-1,042	-888	-1,539	-1,402	-1,284	-1,334	-1,259	-1,205
Year-on-year	-	10.0%	-17.9%	-14.8%	73.4%	-8.9%	-8.4%	3.9%	-5.7%	-4.2%
Operating Income Margin	-311.6%	-453.4%	-413.3%	-341.6%	-723.1%	-313.2%	-266.9%	-187.2%	-199.5%	-176.6%
EBITDA	-1,046	-1,168	-929	-877	-1,532	-1,397	-1,280	-1,331	-1,257	-1,204
Pretax Income	-1,180	-1,281	-1,501	-880	-1,531	-1,401	-1,291	-1,466	-1,238	-1,215
Consolidated Net Income	-1,180	-1,283	-1,491	-883	-1,534	-1,404	-1,294	-1,480	-1,243	-1,220
Minority Interest	-30	0	0	0	0	0	0	0	0	0
Net Income ATOP	-1,150	-1,283	-1,491	-883	-1,534	-1,404	-1,294	-1,480	-1,243	-1,220
Year-on-year	-	11.5%	16.3%	-40.8%	73.8%	-8.5%	-7.8%	14.4%	-16.0%	-1.8%
Net Income Margin	-310.6%	-457.9%	-591.2%	-339.6%	-720.5%	-313.6%	-269.1%	-207.6%	-197.0%	-178.8%
(Balance Sheet)										
Cash & Short-Term Investments	5,576	4,100	4,553	4,027	2,329	2,106	2,686	1,791	1,727	1,326
Total assets	6,257	4,919	4,789	4,419	2,831	2,808	3,495	2,339	2,215	1,751
Total Debt	0	100	54	4	0	0	180	183	184	291
Net Debt	-5,576	-4,000	-4,499	-4,023	-2,329	-2,106	-2,506	-1,608	-1,543	-1,035
Total liabilities	418	355	224	202	154	187	385	446	425	594
Total Shareholders' Equity	5,828	4,564	4,565	4,218	2,677	2,622	3,110	1,893	1,791	1,158
(Cash Flow)										
Net Operating Cash Flow	-789	-1,245	-970	-867	-1,689	-1,537	-1,360	-1,131	-1,191	-1,069
Capital Expenditure	119	168	11	5	0	0	0	0	0	0
Net Investing Cash Flow	-619	-1,780	1,989	-137	0	-26	-4	-35	0	0
Net Financing Cash Flow	2,131	124	1,434	479	-10	1,341	1,944	271	1,127	667
(Profitability %)										
ROA	-30.46	-22.95	-30.72	-19.17	-42.30	-49.79	-41.06	-50.73	-54.57	-61.51
ROE	-33.51	-24.69	-32.67	-20.10	-44.49	-52.99	-45.15	-59.16	-67.48	-82.76
(Per-share) Unit: JPY										
EPS	-	-58.3	-65.9	-33.5	-57.3	-44.6	-36.1	-36.7	-28.3	-24.6
BPS	265.6	207.0	179.3	157.5	99.9	78.8	78.7	46.4	37.0	22.0
Dividend per Share	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Shares Outstanding (million shares)	21.93	22.05	25.31	26.78	26.78	33.28	39.51	40.31	48.42	52.19

Source: Omega Investment from company materials

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