

Kidswell Bio (TYO:4584)

The biosimilar business continues to be profitable. The timing for turning the consolidated operating account into the black has been revised, but efforts have not been slackened to strengthen the company's structure.

◇ 2Q of FY2025/3 Financial Highlights: Progress as expected

The company announced its financial results for the second quarter of FY2025/3 on November 12, 2024. On a cumulative basis, sales were 1.74 billion yen, operating loss was 260 million yen, ordinary loss was 260 million yen, and interim net loss attributable to owner of parent was 240 million yen. This is in line with expectations.

In the company's biosimilar business, the addition of indications for GBS-007 and the approval of GBS-010 in the previous fiscal year have benefited from the steady expansion of demand in the medical field. As a result, despite rising costs at overseas production bases due to inflation and the weak yen, the business has maintained a profit-making trend. Due to factors such as increased R&D costs, the company is operating at a loss on a consolidated basis, but this is a typical example of a research and development-oriented bio-venture.

To deal with the increased working capital needs associated with the sales growth of its biosimilar business, the company is working with its partner pharmaceutical companies to improve the efficiency of its working capital. In a situation where sales are growing, the company has already reduced its working capital by over 1 billion yen, which will reduce its dependence on raising funds through the stock market and is therefore a welcome move from a shareholder perspective.

◇ Revision of the full-year earnings forecast for FY2025/3: The likelihood of achieving the forecast has increased

The company has revised its full-year consolidated earnings forecast for FY2025/3. Previously, it had only given a range for sales of 3.5 billion yen to 4.5 billion yen for sales, but this time, it has given specific figures of 4.0 billion yen for sales, 1.0 billion yen for operating loss, 1.0 billion yen for ordinary loss, and 950 million yen for net loss attributable to owner of parent. The company aims to license its cell therapy business during the current fiscal year, but this revenue has not been factored into these earnings forecasts.

We would like to positively evaluate the fact that the company has finalized its manufacturing and delivery plans with partner pharmaceutical companies and contract manufacturing companies in its biosimilar business, which is one of its core businesses, and that demand for the company's biosimilars in medical settings is strong, resulting in an increase in revenue and a reduction in losses compared to the results for FY2024/3 (on a non-consolidated basis).

However, the company's biosimilar products are affected by overseas inflation and exchange rate trends, so it is still necessary to pay attention to exchange rate trends (particularly a weak yen).

◇ Status of cell therapy business development: Looking forward to the R&D briefing scheduled for December 3

In the second quarter, S-Quatre Corporation concluded a joint research agreement with Dokkyo Medical University and HOYA Technosurgical Corporation to develop new treatments for ischemic bone diseases. However, there was little additional information this time about the clinical research on cerebral palsy led by Nagoya University, which is progressing with the development of autologous SHED, or the corporate clinical trials on allogeneic SHED for cerebral palsy (in the remote period) in Japan. The R&D briefing scheduled for December 3rd is awaited.

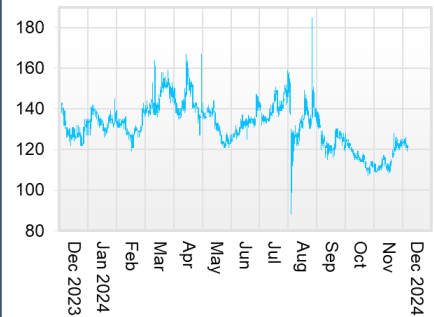
2Q results update

Healthcare

As of December X, 2024

Share price(12/4)	¥121
52 weeks high/low	¥119/122
Avg Vol (3 month)	266 ^{thou} _{shrs}
Market Cap	¥4.9 bn
Enterprise Value	¥5.4 bn
PER (25/3 CE)	- X
PBR (24/3 act)	6.4 X
Dividend Yield (25/3 CE)	- %
ROE (24/3 act)	-166.5 %
Operating margin (24/3 act)	-54.9 %
Beta (5Y Monthly)	N/A
Shares Outstanding	40.657 ^{mn} _{shrs}
Listed market	TSE Growth

Share price



%	1M%	3M%	12M%
Share price	11.01	-8.33	-15.38
Japan TSE TOPIX	3.64	0.27	15.03

Points of interest

Will the probability of achieving the full-year consolidated sales forecast of 4 billion yen will increase?; whether the company will disclose its profit forecast; whether the stable supply and profitability of the already-launched biosimilars will be secured and the optimization of cash flow will continue; whether the development of new biosimilars will progress and the results of the collaboration with Chiome Bioscience will be realized; whether the conclusion of a contract with a development partner in the cell therapy business will be realized. Also, whether the yen's depreciation will stop is essential, as overseas payments are significant.

This report (Company note) has been prepared on behalf of Kidswell Bio. For more information, please refer to the Disclaimer on the last page.

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◇Change in the timing of achieving consolidated operating profit: profitability is expected in FY2027/3

The company had planned to achieve sales of 3.0 billion yen and operating income of 1.0 billion yen in FY2026/3 but has now announced that it will achieve consolidated operating profit in FY2027/3.

As investors are already aware, the company has achieved its sales target as forecast in its consolidated earnings forecast for the year ending March 2025, and demand for the company's biosimilars and the biosimilar market as a whole is expected to continue to grow steadily, contributing to an improvement in the company's gross profit.

Countervailing factors include a decline in the gross profit margin due to inflation, the depreciation of the yen, and an expected increase in development investment for future growth. Furthermore, although the development of manufacturing processes at new contract manufacturers has been completed to reduce costs and significantly boost the gross profit margin, the expected timing for obtaining approval for this has been delayed by around six months compared to initial estimates. These have led to a postponement of the timing for achieving consolidated operating profitability.

Under the original plan, the company was to start receiving deliveries of bulk pharmaceuticals manufactured by the new contract manufacturer in FY2026/3 and to benefit from lower costs (and stable procurement). However, as the approval period was expected to be delayed, the company placed additional orders with the existing contract manufacturer to ensure a stable supply of biosimilars to medical institutions without interruption. From the perspective of providing a stable supply, the additional manufacturing at the existing contract manufacturer will cover the necessary active pharmaceutical ingredients, etc., during the FY2026/3 period, so the delivery of active pharmaceutical ingredients, etc., manufactured at the new contract manufacturer is expected to begin in the FY2027/3 period.

Looking at it this way, it seems reasonable to change the timing of the consolidated operating profit turnaround. As mentioned earlier, taking into account the actual results of the working capital reduction in the biosimilar business, the possibility of a license-out agreement being concluded by S-Quatre Corporation, the subsidiary in charge of the cell therapy business, and the preparations for a flexible capital policy, it is not necessary to view this matter in a particularly negative light.

◇Stock price trends and points to watch going forward

The company's share price has been falling gradually over the last three months, but there have been signs of a rebound since late October. The share price reaction after the announcement of these results was also limited to a slight fall, and the stock market has begun to appreciate the positive factors for the company we have been discussing.

Based on the above, the critical point to watch in the near term will be whether or not the positive signs that have begun to appear in the stock market continue to develop. In other words, the company must ensure that it achieves its full-year consolidated earnings forecasts and continues to provide a stable supply and profitability of its marketed biosimilars. It must also optimize its cash flow over the FY2026/3 and FY2027/3 periods. It must also progress in the development and collaboration of new biosimilars and conclude contracts with development partners in the cell therapy business, which will be concluded as planned in FY2025/3. An agreement will be reached that clarifies the business potential of the cell therapy business. If additional funding from the stock market is needed, it will be suppressed, and of course, the company will achieve consolidated operating profit in FY2027/3. It is also necessary to continue to pay attention to exchange rate trends.

We look forward to the R&D briefing on December 3.

Company profile

Kidswell Bio Inc. (hereafter, the company) is a drug discovery venture company that originated at Hokkaido University. It is a pioneer in the biosimilar business, has obtained approval for, and supplies four products.

The company is also promoting a cell therapy business (regenerative medicine) that utilizes Stem cells from Human Exfoliated Deciduous teeth (SHED), and clinical research using autologous SHED for cerebral palsy (in the chronic stage) led by Nagoya University has already begun. To begin clinical trials of allogeneic SHED for cerebral palsy (in the chronic phase) in Japan, preparations are underway for the manufacture of the trial product, consultations are being held with the Pharmaceuticals and Medical Devices Agency, and it is planned that a contract will be concluded with the development partner company that will lead this clinical trial during FY2025/3. Preparations for international expansion are also underway.

In FY2025/3, SHED development was transferred to the newly established wholly owned subsidiary S-Quatre Corporation, and the company became a structure that mainly specialized in the biosimilar business, allowing it to visualize the business value of the two businesses and take the most appropriate financial strategy for each business.

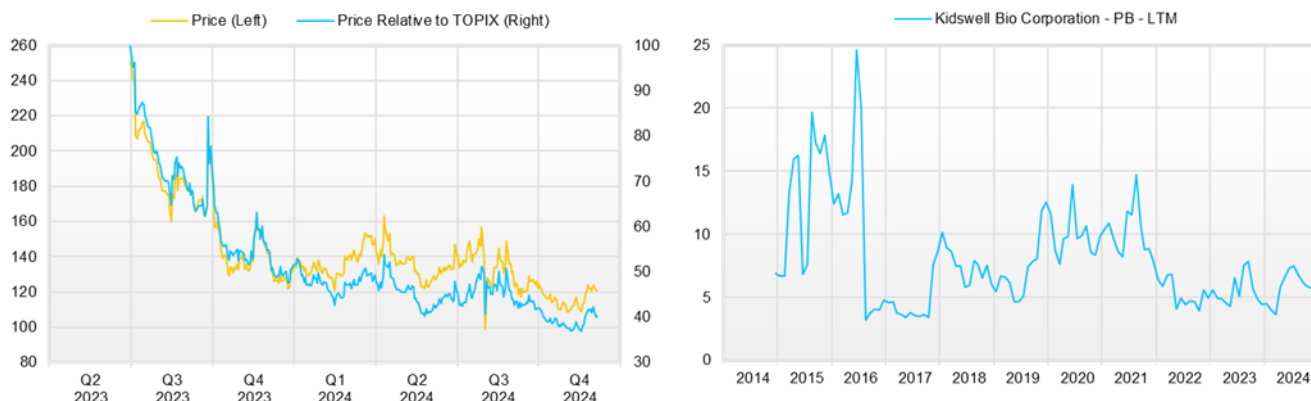
The company aims to achieve consolidated operating income in FY2027/3.

Key financial data

Unit: million yen	2019/3	2020/3	2021/3	2023/3	2024/3	2025/3 CE
Sales	1,078	997	1,569	2,776	2,431	4,000
EBIT (Operating Income)	-1,161	-970	-976	-551	-1,336	-1,000
Pretax Income	-7,314	-1,000	-550	-656	-1,421	
Net Profit Attributable to Owner of Parent	-7,316	-1,001	-551	-657	-1,422	-950
Cash & Short-Term Investments	2,033	1,461	1,161	1,067	2,231	
Total assets	3,592	3,934	3,470	3,895	5,086	
Total Debt	2,575	2,575	2,575	2,575	2,575	
Net Debt	344	344	344	344	344	
Total liabilities	2,105	2,324	1,767	2,661	4,254	
Total Shareholders' Equity	831	831	831	831	831	
Net Operating Cash Flow	-1,325	-1,267	-1,170	-1,421	-454	
Net Investing Cash Flow	-137	-22	527	-29	0	
Net Financing Cash Flow	1,222	718	369	1,356	1,618	
Free Cash Flow	-1,327	-1,267				
ROA (%)	-216.99	-26.61	-14.88	-17.85	-31.67	
ROE (%)	-346.86	-64.66	-33.25	-44.78	-137.73	
EPS (Yen)	-264.7	-34.8	-17.9	-20.8	-40.2	
BPS (Yen)	53.8	54.4	54.2	38.5	21.4	
Dividend per Share (Yen)	0.00	0.00	0.00	0.00	0.00	0.00
Shares Outstanding (Million shares)	27.65	29.06	31.44	31.90	37.31	

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

Share price



Quarterly topics

2Q earnings results

Income statement



(Unit: thousand yen)

Subject	FY2023	FY2024		2Q Results KWB Non-consolidated (non-consolidated)
	2Q Results (non-consolidated)	2Q Results (consolidated)	Year-on- year ratio	
Gross sales	1,116,111	1,749,911	157%	1,748,698
Cost of goods sold	420,954	1,257,582	299%	1,257,582
Gross profit	695,156	492,329	71%	491,116
Selling, general and administrative expenses	684,018	754,850	110%	438,280
R&D expenses	251,787	340,907	135%	136,600
Other SG&A expenses	432,230	413,942	96%	301,680
Operating income ("-" means operating loss)	11,137	-262,520	--	52,835
Ordinary income ("-" means ordinary loss)	-42,082	-267,993	--	70,907
Net income ("-" means net loss)	-42,687	-241,794	--	97,196

<u>Gross sales/gross profit</u>	<ul style="list-style-type: none"> Deliveries of biosimilar active pharmaceutical ingredients (APIs) is progressing as planned With the addition of a new indication for GBS-007 and the approval of GBS-010 in Sep 2023, revenue saw significant growth, reaching 157% y/y Negotiations with partner pharmaceutical companies are advancing, and we expect margin improvements from 3Q onward although the gross margin in the biosimilars business declined substantially due to ongoing yen depreciation and rising prices
<u>R&D & other SG&A expenses</u>	<ul style="list-style-type: none"> Continuing to control expenditures through prioritization R&D activities and efficiency improvements in other business operations
<u>Net income</u>	<ul style="list-style-type: none"> KWB (biosimilars business) has maintained operating profitability despite the continued impact of yen depreciation and rising prices

Source: Company materials

Outlook for FY2025/3

Outlook for the current fiscal year (ending March 31, 2025)

- Completed adjustments of manufacturing and delivery schedules and supply volumes of biosimilars with partner pharmaceutical companies
- Revenue expected to grow significantly due to strong demand for GBS-007 and GBS-010
- Revenue growth and a R&D expenses revision are expected to reduce operating losses, although gross margin is projected to decline due to yen depreciation and inflation

(Unit: thousand yen), 1 USD = 150 JPY)

(school) subject	FY2023	FY2024	
	4Q Result (Non-consolidated)	Full-year Forecast (consolidated)	Progress rate
Net sales	2,431,236	4,000,000	+64.5%
Research and development expenses*	1,453,349	1,000,000	-31.2%
Operating income (minus is operating loss)	-1,335,597	-1,000,000	-25.1%
Ordinary income (minus is ordinary loss)	-1,389,601	-1,000,000	-28.0%
Net income (minus is net loss)	-1,422,078	-950,000	-33.2%

Initiatives to improve and expand profitability

Status

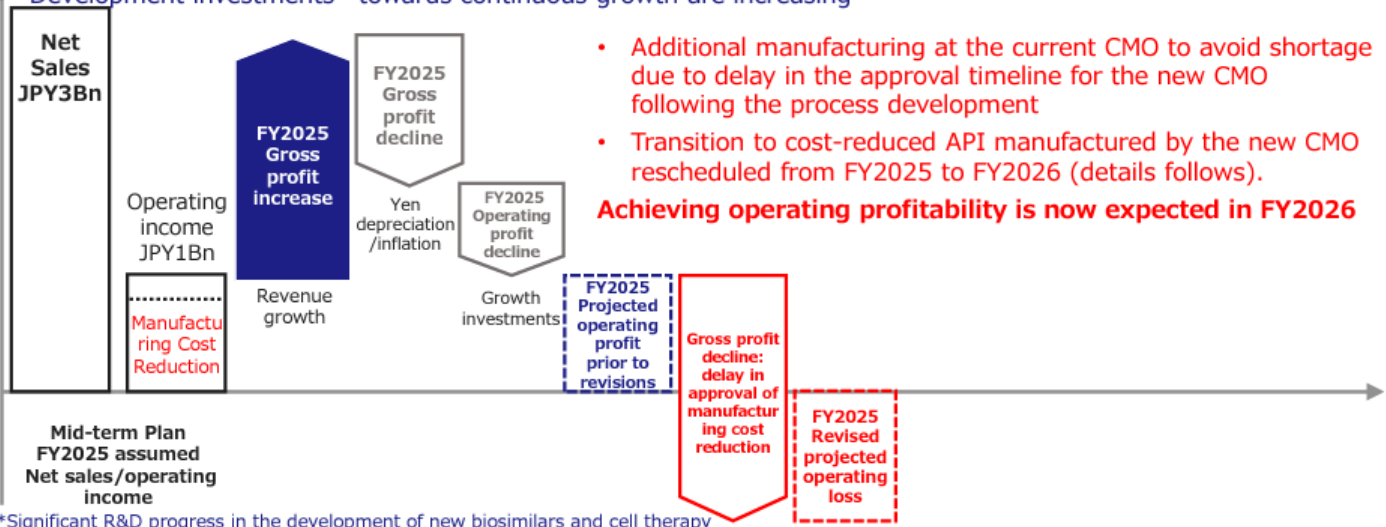
Biosimilars Business	Negotiation of supply prices for biosimilar products to partner pharmaceutical companies in accordance with NHI price revisions	Partially completed
	Response to the rising production price of bulk biosimilars (e.g., impact of yen depreciation, labor and material price hikes, and how to respond to such price hikes)	Partially completed
	Coordination of manufacturing and delivery schedules and supply of biosimilar APIs and formulations	Completed
	Discussions regarding co-development agreements for new biosimilars	In progress
Cell Therapy Business	Discussions with potential development partners	In progress

Source: Company materials

Change in the timing of achieving operating profit

Deviation from the mid-term management plan KWB 2.0

- ✓ Achieved the mid-term management plan's revenue target of JPY3Bn for this fiscal year, with further expansion expected from 2025 onwards.
- ✓ Gross margin expected to improve significantly due to approval of manufacturing cost reduction at the current CMO following the process development improve, though it deteriorated due to yen depreciation and rising prices
- ★ Development investments* towards continuous growth are increasing



*Significant R&D progress in the development of new biosimilars and cell therapy

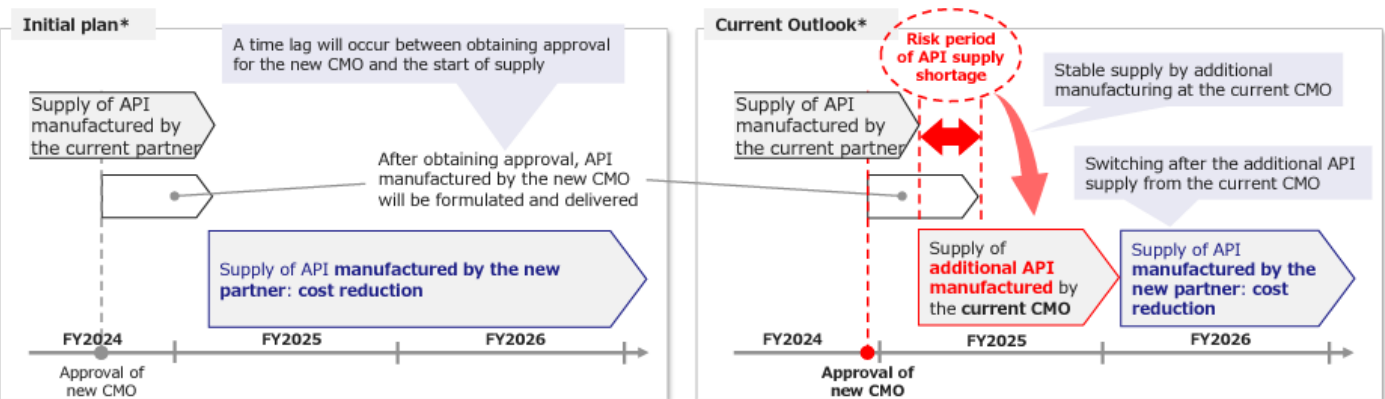
*This chart shows an image of changes in earnings and does not guarantee actual results.

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Source: Company materials

Change in timing of effect of manufacturing cost reduction measures

- We completed process development with a new CMO to reduce manufacturing costs for API production. However, since the approval timeline is delayed from the initial plan, there is a risk of API supply shortages considering the formulation period using API produced by the new CMO.
- We have decided to increase production with the current API manufacturing CMO to prioritize uninterrupted supply to patients
- Even after obtaining approval for the new CMO, delivery of the API manufactured by the current CMO will take precedence. Consequently, the transition to API manufactured by the new CMO is scheduled to begin in FY2026, even with minimum additional manufacturing levels



*Additional project to secure an API manufacturing partner aimed at reducing manufacturing costs

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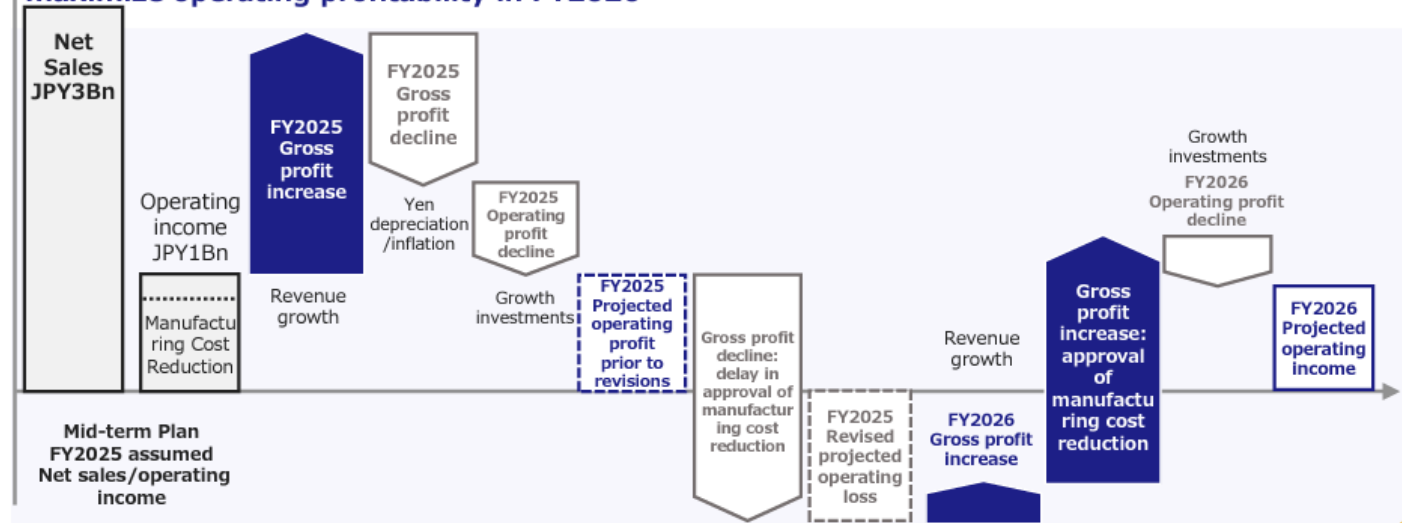
Source: Company materials

Change in the timing of achieving operating profit

Future initiatives to achieve operating profitability and maximize profit margins

We will maintain a stable supply system, secure additional approvals for new API manufacturing partners, advance the formulation of APIs produced by these partners, and ensure effective management of R&D and fixed costs

To balance continued ongoing development investments and achieve sustainable growth and maximize operating profitability in FY2026



*This chart shows an image of changes in earnings and does not guarantee actual results.

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Source: Company materials

Financial data (quarterly basis)

Unit: million yen	2023/3			2024/3				2025/3	
	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q
(Income Statement)									
Sales	505	611	1,049	46	536	985	864	483	1,267
Year-on-year	15.5%	-5.0%	464.2%	-92.5%	6.1%	61.3%	-17.6%	950.4%	136.4%
Cost of Goods Sold (COGS)	128	233	597	1	351	352	688	259	998
Gross Income	377	378	453	45	185	633	176	224	269
Gross Income Margin	74.6%	61.8%	43.2%	98.1%	34.5%	64.3%	20.4%	46.3%	21.2%
SG&A Expense	328	524	868	500	449	580	845	383	372
EBIT (Operating Income)	49	-147	-415	-455	-265	53	-669	-159	-104
Year-on-year	-134.7%	-915.9%	90.4%	1097.7%	-638.6%	-135.9%	60.9%	-65.1%	-60.9%
Operating Income Margin	9.7%	-24.0%	-39.6%	-989.7%	-49.4%	5.3%	-77.3%	-32.9%	-8.2%
EBITDA	49	-146	-415	-455	-264	53	-668	-159	-103
Pretax Income	39	-152	-462	-470	-309	35	-676	-176	-65
Consolidated Net Income	38	-152	-463	-471	-310	33	-675	-177	-65
Minority Interest	0	0	0	0	0	0	0	0	0
Net Income ATOP	38	-152	-463	-471	-310	33	-675	-177	-65
Year-on-year	-125.6%	-141.3%	1.3%	481.4%	-909.1%	-121.6%	45.9%	-62.5%	-79.0%
Net Income Margin	7.6%	-24.9%	-44.1%	-1023.6%	-57.8%	3.3%	-78.0%	-36.6%	-5.1%
(Balance Sheet)									
Cash & Short-Term Investments	1,875	1,500	1,067	625	622	2,187	2,231	1,167	1,695
Total assets	4,260	4,173	3,895	3,044	3,194	5,199	5,086	4,609	4,646
Total Debt	2,175	2,075	1,950	1,850	1,775	2,275	2,575	2,402	2,131
Net Debt	300	575	883	1,225	1,153	88	344	1,235	436
Total liabilities	2,560	2,485	2,661	2,276	2,119	3,755	4,254	3,895	3,789
Total Shareholders' Equity	1,700	1,688	1,234	769	1,075	1,444	831	714	857
(Profitability %)									
ROA	-3.21	-16.14	-17.85	-28.50	-37.43	-25.82	-31.67	-29.48	-22.54
ROE	-7.05	-34.05	-44.78	-86.81	-100.55	-77.27	-137.73	-152.15	-91.46
(Per-share) Unit: JPY									
EPS	1.2	-4.8	-14.4	-14.7	-9.3	0.9	-17.5	-4.5	-1.6
BPS	54.0	52.7	38.5	24.0	30.0	37.6	21.4	18.1	21.1
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)	31.45	31.90	32.06	32.06	37.09	37.31	38.43	39.41	40.66

Source: Omega Investment from company materials

Financial data (full-year basis)

Unit: million yen	2014/3	2015/3	2016/3	2017/3	2018/3	2019/3	2020/3	2021/3	2022/3	2023/3	2024/3
(Income Statement)											
Sales	301	61	1,161	1,089	1,060	1,022	1,078	997	1,569	2,776	2,431
Year-on-year	397.8%	-79.9%	1817.7%	-6.2%	-2.7%	-3.6%	5.5%	-7.5%	57.5%	76.9%	-12.4%
Cost of Goods Sold	142	15	501	398	423	413	653	120	553	1,251	1,393
Gross Income	159	45	660	692	637	609	425	877	1,017	1,525	1,038
Gross Income Margin	52.8%	74.5%	56.9%	63.5%	60.1%	59.6%	39.4%	88.0%	64.8%	54.9%	42.7%
SG&A Expense	672	403	1,480	1,876	1,551	1,414	1,586	1,847	1,992	2,076	2,374
EBIT (Operating Income)	-512	-358	-820	-1,184	-913	-806	-1,161	-970	-976	-551	-1,336
Year-on-year	43.1%	-30.1%	129.1%	44.4%	-22.9%	-11.8%	44.2%	-16.5%	0.6%	-43.5%	142.4%
Operating Income Margin	-170.0%	-591.6%	-70.7%	-108.7%	-86.2%	-78.8%	-107.8%	-97.3%	-62.2%	-19.8%	-54.9%
EBITDA	-512	-358	-820	-1,184	-913	-805	-1,161	-969	-973	-550	-1,335
Pretax Income	-517	-374	-786	-1,222	-903	-854	-7,314	-1,000	-550	-656	-1,421
Consolidated Net Income	-519	-377	-788	-1,225	-905	-856	-7,316	-1,001	-551	-657	-1,422
Minority Interest	0	0	0	0	0	0	0	0	0	0	0
Net Income ATOP	-519	-377	-788	-1,225	-905	-856	-7,316	-1,001	-551	-657	-1,422
Year-on-year	37.7%	-27.4%	108.9%	55.5%	-26.1%	-5.3%	754.4%	-86.3%	-45.0%	19.3%	116.3%
Net Income Margin	-172.3%	-622.9%	-67.9%	-112.4%	-85.4%	-83.8%	-678.9%	-100.5%	-35.1%	-23.7%	-58.5%
(Balance Sheet)											
Cash & Short-Term Investments	1,610	887	817	2,380	1,891	2,009	2,033	1,461	1,161	1,067	2,231
Total assets	1,887	922	1,694	3,706	3,025	3,151	3,592	3,934	3,470	3,895	5,086
Total Debt	775	0	810	0	0	0	1,225	1,100	700	1,950	2,575
Net Debt	-835	-887	-7	-2,380	-1,891	-2,009	-808	-361	-461	883	344
Total liabilities	834	34	1,291	206	421	420	2,105	2,324	1,767	2,661	4,254
Total Shareholders' Equity	1,053	888	403	3,500	2,604	2,731	1,487	1,610	1,703	1,234	831
(Cash Flow)											
Net Operating Cash Flow	-730	-305	-607	-1,759	-438	-860	-1,325	-1,267	-1,170	-1,421	-454
Capital Expenditure	0	0	2	0	0	0	2	3	0	0	0
Net Investing Cash Flow	-2	-0	-122	-150	-50	-0	-137	-22	527	-29	0
Net Financing Cash Flow	1,454	907	947	3,472	0	978	1,222	718	369	1,356	1,618
(Profitability %)											
ROA	-36.97	-26.84	-60.21	-45.35	-26.88	-27.73	-216.99	-26.61	-14.88	-17.85	-31.67
ROE	-53.51	-38.85	-122.00	-62.74	-29.64	-32.10	-346.86	-64.66	-33.25	-44.78	-137.73
(Per-share) Unit: JPY											
EPS	-60.0	-59.6	-75.7	-68.5	-47.3	-43.8	-264.7	-34.8	-17.9	-20.8	-40.2
BPS	110.4	106.7	34.9	182.9	136.1	134.3	53.8	54.4	54.2	38.5	21.4
Dividend per Share	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Shares Outstanding (million shrs)	8.59	9.54	10.85	18.74	19.14	19.68	27.65	29.06	31.44	31.90	37.31

Source: Omega Investment from company materials



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