

Kidswell Bio (TYO: 4584)

The biosimilar business has established a solid profitability trend, with the company making fine progress toward its FY2025/3 earnings forecast. Positive expectations are to mount for key upcoming events.

◇ FY2025/3 3Q Financial highlights: Steady profit progress

On February 12, 2025, the company announced its consolidated financial results for the third quarter of FY2025/3. On a cumulative basis, sales totaled 3.03 billion yen, operating loss was 130 million yen, ordinary loss was 160 million yen, and quarterly net loss attributable to owner of parent was 180 million yen. Compared to the non-consolidated figures from the same period of the previous year, sales increased by +194%, gross profit increased by +119%, and operating profit improved by 130 million yen, indicating steady progress.

In the cell therapy business, despite being in a consolidated loss position due to upfront R&D expenses associated with the steady progress of the clinical development for cerebral palsy (in the remote period), as mentioned later, the quality of earnings is improving.

In the biosimilar business, the company successfully supplied APIs as planned for GBS-007 and GBS-010, which continue to see strong demand, leading to significant revenue growth. Despite a decline in the gross profit margin due to the impact of weak yen and inflation, the total gross profit increased. Additionally, cost efficiencies in SG&A expenses have contributed to a reduction in operating losses. In the non-consolidated financial results, where the biosimilar business is the primary driver, an operating profit trend has been established, with profit levels increasing quarter by quarter.

◇ FY2025/3 Full-year earnings forecast maintained: Potential for outperformance

The company has maintained its full-year earnings forecast for FY2025/3, projecting sales of 4.0 billion yen, an operating loss of 1.0 billion yen, an ordinary loss of 1.0 billion yen, and a net loss attributable to owner of parent of 950 million yen. However, given the progress through 3Q, the forecast appears conservative.

Comparing the full-year forecast with the 3Q actual results suggests that 4Q (January–March) would require sales of 960 million yen and an operating loss of 860 million yen. According to the company, it is not anticipating a sudden decline in biosimilar sales or a sharp increase in R&D expenses during 4Q. Furthermore, the company aims to license out its cell therapy business during the rest of the current fiscal year, though this revenue is not included in the forecast.

As long as biosimilar sales remain strong, there is room for upside, particularly in profitability.

◇ Biosimilar business: Building on established profitability, the company lays the groundwork for further growth

The biosimilar business is a key pillar of the company's future stable growth, as it leverages its strengths in an expanding market. Despite headwinds such as a weak yen and overseas inflation, the company has posted operating profit for three consecutive quarters.

By the end of 3Q, several key developments had emerged.

First, to expand its fifth and subsequent biosimilar products, the company has been engaged in discussions with multiple domestic and international pharmaceutical companies. It has set a concrete target of concluding co-development agreements, including those aimed at overseas market expansion, by the end of September 2025.

Second, to address the increasing working capital requirements driven by strong biosimilar demand and rising costs due to the weak yen and global inflation, the company has successfully negotiated and coordinated with partner pharmaceutical companies, reducing over 1 billion yen. This achievement indicates that similar measures could be taken if needed, mitigating concerns about potential working capital shortages.

Third, the company has reaffirmed that the transition to a new manufacturing system, designed to ensure a stable biosimilar supply and reduce production costs, will be postponed to FY2026 due to delays in regulatory approval. In FY2025, the company prioritizes the stable supply of biosimilars to medical institutions, meaning that additional API orders placed with existing contract manufacturers will be shipped first. As a result, the new manufacturing system's cost-reduction benefits will begin materializing in FY2026. However, the company's ability to manage increased working capital has improved in conjunction with the effect of reducing manufacturing working capital, as well as through various measures such as refinancing via the issuance of new stock acquisition rights announced in December 2024 and the utilization of indirect financing. As a result, its risk resilience has strengthened.

3Q results update

Healthcare

As of March 5, 2025

Share price(3/4)	¥134
52 weeks high/low	¥185/88
Avg Vol (3 month)	685 ^{thou} shrs
Market Cap	¥5.5 bn
Enterprise Value	¥6.5 bn
PER (25/3 CE)	- X
PBR (24/12 act)	5.62 X
Dividend Yield (25/3 CE)	- %
ROE (24/3 act)	-166.6 %
Operating margin (24/3 act)	-54.9 %
Beta (5Y Monthly)	N/A
Shares Outstanding	40.771 ^{mn} shrs
Listed market	TSE Growth

Share price



%	1M%	3M%	12M%
Share price	25.23	10.74	-4.29
Japan TSE TOPIX	-0.38	-1.58	0.03

Points of interest

Whether the certainty of achieving operating profitability in FY2027/3 will increase, whether the financial performance and cash flow for FY2026/3, which is expected to incur an operating loss, will remain within expectations, and whether the development agreements for new biosimilars, the signing of contracts with SHED development partners, and the submission of clinical trial plans will progress as planned.

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

◇ **Status of cell therapy business: Steady progress**

Regarding the cell therapy business (regenerative medicine), which is expected to drive a significant increase in future business value, the key developments up to 3Q are as follows.

The first key development is that the clinical research on autologous SHED for cerebral palsy (in the remote period), led by Nagoya University, is progressing smoothly. Since patient registration began in October 2023, all cases have been successfully enrolled. SHED administration and subsequent observation for the first and second patients are currently ongoing. After the planned administration and observation of the third patient, interim analysis results of the clinical research are expected to be announced by Nagoya University around September 2025.

The second key development is the progress in corporate clinical trials for allogeneic SHED targeting cerebral palsy (in the remote period) in Japan, using the company's established master cell bank (MCB). Preparations for manufacturing the investigational product and consultations with the PMDA are moving forward. The company has reaffirmed its commitment to signing agreements with development partners in FY2025/3 and aiming for the submission of clinical trial plans by the respective development partners in FY2026/3.

Additionally, efforts toward clinical development for cerebral palsy (in the remote period) in overseas markets are ongoing. The company has commissioned an overseas contract research organization (CRO) to evaluate the adequacy of its existing preclinical trial data, manufacturing processes, and future trial plans. The evaluation confirmed that the necessary data collection and process development are proceeding smoothly.

The third key development is an update on manufacturing technology. The company has completed pilot production for early-stage clinical trials and has successfully developed a proprietary large-scale culture method for late-stage clinical trials and commercialization. The findings will be presented at the International Society for Cell & Gene Therapy (ISCT) conference in the U.S. in May 2025. Furthermore, the company has signed a joint development agreement with NIPRO Corporation to apply this method to late-stage clinical trials and commercial production. It is advancing the technology transfer from its subsidiary, S-Quatre Corporation.

◇ **Reducing dependence on equity financing**

The company is working toward an early completion of fundraising through stock acquisition rights and is striving to create an environment where its business value is appropriately recognized in the stock market.

As mentioned, the company has successfully controlled the increased working capital requirements for the biosimilar business. In addition, on December 26, 2024, the company resolved to repurchase and cancel its 15th and 18th stock acquisition rights (existing rights) and issue the 23rd and 24th stock acquisition rights (new rights) for refinancing. The payment for issuing the new stock acquisition rights was completed on January 14, 2025. By reducing the number of issued shares by 7.1% and shortening the exercise period, the company aims to complete fundraising quickly while mitigating concerns about stock dilution.

From now on, both the biosimilar and cell therapy businesses will require continued investment in R&D for further expansion. The company will focus on the biosimilar business to address this, while its consolidated subsidiary, S-Quatre, will specialize in the cell therapy business. The company plans to flexibly utilize various funding sources by appropriately prioritizing projects, including development partners, government grants, and indirect financing.

◇ Earnings guidance & key business events toward FY2027/3 profitability

In its 3Q earnings presentation materials, the company provided a range-based earnings forecast for FY2026/3 and FY2027/3. When listed alongside the earnings forecast for the FY2025/3, it is as follows.

FY2025/3: Sales: 4.0 billion yen, Operating Loss: 1.0 billion yen

FY2026/3: Sales: 4.5-5.0 billion yen, Operating Loss: 1.0-2.0 billion yen

FY2027/3: Sales: 5.5-6.0 billion yen, Operating Profit: 1.0-10.0 billion yen
(Achieving operating profitability)

*Assumed Exchange Rate: 150-160 JPY/USD

For FY2026/3, as cost reductions for biosimilars are not expected, the company anticipates revenue growth but also a likely expansion of losses. However, for FY2027/3, the company aims to achieve operating profitability.

However, in addition to financial performance, several key business events are scheduled as follows:

FY2025/3: Signing of agreements with SHED development partners.

FY2026/3: Announcement of interim analysis results from the Nagoya University-led clinical research on SHED (expected around September 2025)

Conclusion of joint commercialization agreements for new biosimilars and other products (by the end of September 2025)

Submission of clinical trial plans by SHED development partners (noted in company materials)

In other words, while FY2026/3 is expected to be financially challenging, these upcoming events will be crucial in shaping the company's future business value. Although exchange rate trends remain uncertain, a shift toward yen appreciation would provide a clear upside to profitability in the biosimilar business. Furthermore, if the company enhances its financial management, diversifies its funding sources, and alleviates concerns over stock dilution through refinancing, investors will likely factor these developments into the stock price accordingly.

◇ Stock price trends & key points to watch

The company's stock had been on a long-term decline but began to rebound in February 2025, continuing to perform steadily after the 3Q earnings announcement. This suggests that the equity market is recognizing the company's efforts to enhance its corporate value, appreciating its business potential, and becoming less concerned about stock dilution.

If the stock price reflects the company's business value properly, key factors to watch in the near term will be the final full-year earnings results for FY2025/3 (whether they exceed expectations) and the outcomes of the aforementioned business events.

Additionally, attention should remain on exchange rate trends, global inflation, and the company's ability to manage its finances effectively.

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.

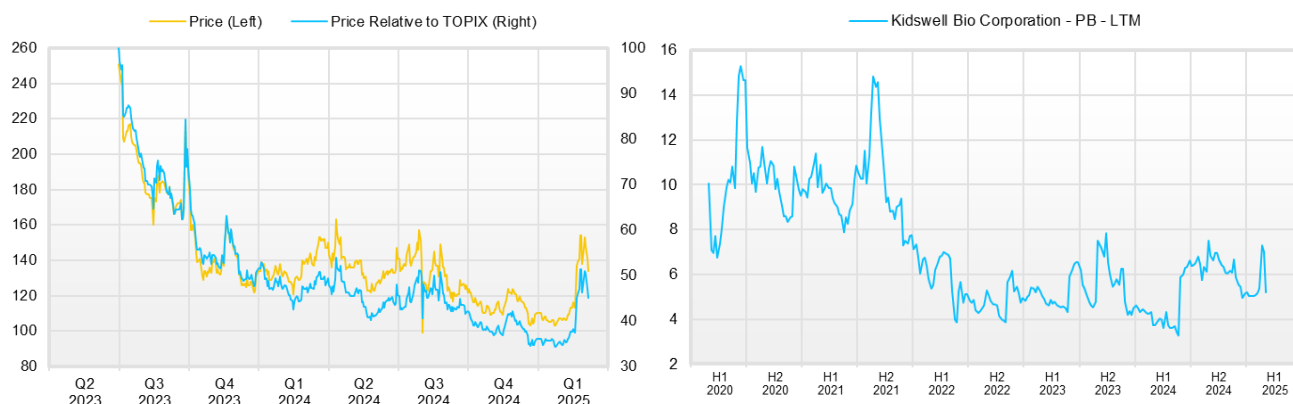
The company aims to achieve consolidated operating income in FY2027/3.

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	1,225	1,100	700	1,950	2,575	
Net Debt	-808	-361	-461	883	344	
Total liabilities	2,105	2,324	1,767	2,661	4,254	
Total Shareholders' Equity	1,487	1,610	1,703	1,234	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	-23.7
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

3Q earnings results

Income Statement



(Unit: thousand yen)

Subject	FY2023	FY2024		FY2024
	3Q Results (non-consolidated)	3Q Results (consolidated)	Year-on- year ratio	3Q Results KWB Non-consolidated (non-consolidated)
Gross sales	1,566,742	3,036,304	194%	3,034,828
Cost of goods sold	703,808	2,005,685	285%	2,005,686
Gross profit	862,934	1,030,619	119%	1,029,142
Selling, general and administrative expenses	1,529,959	1,168,523	76%	752,181
R&D expenses	807,465	541,604	67%	221,786
Other SG&A expenses	722,493	626,918	87%	530,395
Operating income ("-" means operating loss)	△667,025	△137,904	--	276,961
Ordinary income ("-" means ordinary loss)	△712,858	△161,196	--	362,431
Net income ("-" means net loss)	△747,400	△187,773	--	335,989

Gross sales/gross profit	<ul style="list-style-type: none"> Deliveries of biosimilar active pharmaceutical ingredients (APIs) is progressing as planned Demand for GBS-007 and GBS-010 remained strong, and sales grew significantly by 194% year-on-year. Ongoing yen depreciation and rising prices strains the gross profit margin in the biosimilar business significantly, however, due to the substantial expansion of sales accompanying strong market demand, gross profit has increased year-on-year.
R&D & other SG&A expenses	<ul style="list-style-type: none"> Continuing to control expenditures through prioritization R&D activities and efficiency improvements in other business operations
Quarterly Net Income	<ul style="list-style-type: none"> Despite the continuing impact of the weak yen and rising prices, Kidswell Bio (biosimilar business) maintained its operating profit and increased its operating profit margin

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Source: Company materials

Outlook for FY2025/3

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

Keep manufacturing and delivery of biosimilar APIs and formulations according to the schedule agreed with partner pharmaceutical companies.

Improve the gross profit margin of the biosimilar business as a result of efforts to address issues such as rising manufacturing costs.

Continue to monitor the manufacturing and delivery status of biosimilar APIs and formulations, as well as the progress of R&D activities, while revising our business performance forecasts.

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

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 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

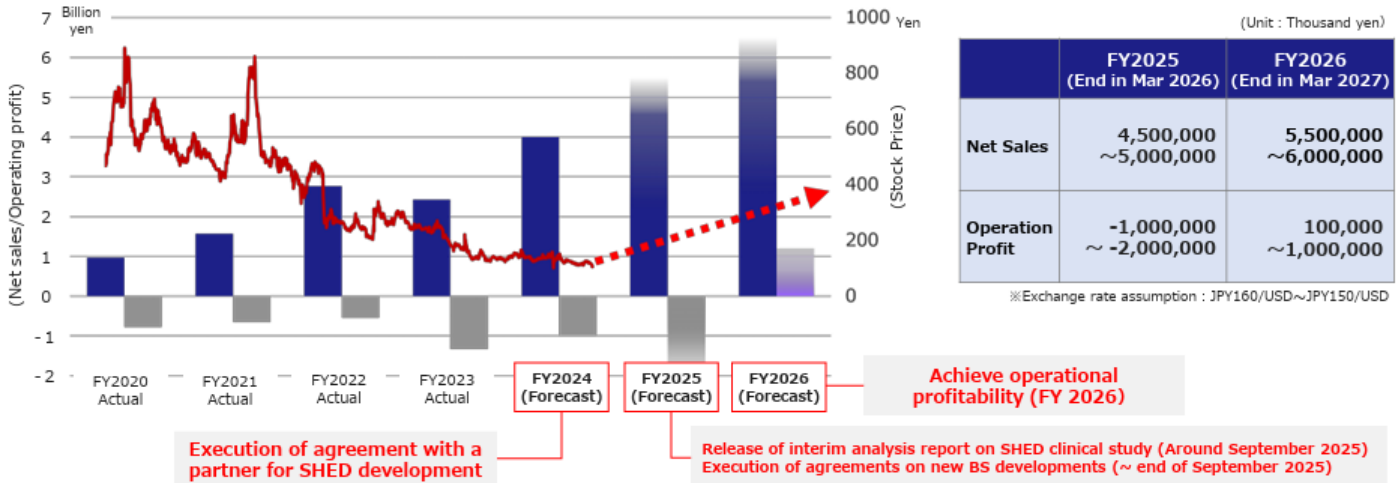
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Source: Company materials

FY2026 Business outlook and expected key events

Business forecast and events expected to impact the share price **Kidswell.Bio**

- Improve the profitability of marketed biosimilar products aiming to show positive operating profit in FY2026 as a group and maximize the amount of the profitability
- Increase the values of both Biosimilar business and Cell Therapy business by achieving the business milestones



Source: Company materials

Financial data (quarterly basis)

Unit: million yen	2023/3		2024/3				2025/3		
	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q
(Income Statement)									
Sales	611	1,049	46	536	985	864	483	1,267	1,286
Year-on-year	-5.0%	464.2%	-92.5%	6.1%	61.3%	-17.6%	950.4%	136.4%	30.6%
Cost of Goods Sold (COGS)	233	597	1	351	352	688	259	998	748
Gross Income	378	453	45	185	633	176	224	269	538
Gross Income Margin	61.8%	43.2%	98.1%	34.5%	64.3%	20.4%	46.3%	21.2%	41.8%
SG&A Expense	524	868	500	449	580	845	383	372	414
EBIT (Operating Income)	-147	-415	-455	-265	53	-669	-159	-104	125
Year-on-year	-915.9%	90.4%	1097.7%	-638.6%	-135.9%	60.9%	-65.1%	-60.9%	136.8%
Operating Income Margin	-24.0%	-39.6%	-989.7%	-49.4%	5.3%	-77.3%	-32.9%	-8.2%	9.7%
EBITDA	-146	-415	-455	-264	53	-668	-159	-103	
Pretax Income	-152	-462	-470	-309	35	-676	-176	-65	107
Consolidated Net Income	-152	-463	-471	-310	33	-675	-177	-65	54
Minority Interest	0	0	0	0	0	0	0	0	0
Net Income ATOP	-152	-463	-471	-310	33	-675	-177	-65	54
Year-on-year	-141.3%	1.3%	481.4%	-909.1%	-121.6%	45.9%	-62.5%	-79.0%	64.4%
Net Income Margin	-24.9%	-44.1%	-1023.6%	-57.8%	3.3%	-78.0%	-36.6%	-5.1%	4.2%
(Balance Sheet)									
Cash & Short-Term Investments	1,500	1,067	625	622	2,187	2,231	1,167	1,695	1,318
Total assets	4,173	3,895	3,044	3,194	5,199	5,086	4,609	4,646	4,575
Total Debt	2,075	1,950	1,850	1,775	2,275	2,575	2,402	2,131	2,034
Net Debt	575	883	1,225	1,153	88	344	1,235	436	715
Total liabilities	2,485	2,661	2,276	2,119	3,755	4,254	3,895	3,789	3,523
Total Shareholders' Equity	1,688	1,234	769	1,075	1,444	831	714	857	1,052
(Profitability %)									
ROA	-16.14	-17.85	-28.50	-37.43	-25.82	-31.67	-29.48	-22.54	-17.65
ROE	-34.05	-44.78	-86.81	-100.55	-77.27	-137.73	-152.15	-91.46	-69.11
(Per-share) Unit: JPY									
EPS	-4.8	-14.4	-14.7	-9.3	0.9	-17.5	-4.5	-1.6	1.3
BPS	52.7	38.5	24.0	30.0	37.6	21.4	18.1	21.1	25.9
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)	31.90	32.06	32.06	37.09	37.31	38.43	39.41	40.66	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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